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SUSTAIN

TRAINING: QA/QC SHORTCOURSE
"Training of Trainers"

AUGUST 3 - 6, 1993

GUATEMALA

S haring
U nited
S tates
T echnology to
A id in the
I mprovement of
N utrition

A U.S. Private Food Industry initiative
in collaboration with the U.S. Agency for International Development
through a Cooperative Agreement with the National Cooperative Business Association

Upgrading the Food Processing Industries in Developing Countries.

Why SUSTAIN?

SUSTAIN represents a successful collaborative effort between the U.S. food industry and the Agency for International Development (A.I.D.) to upgrade food processing in developing countries. It provides an excellent model for similar private-public sector joint ventures in health, agriculture and other areas of concern to developing countries.

Food processing is a major contributor to development. It serves multiple roles. Food processing can increase the available food supply by extending the life of perishable food products. It can improve the nutritional quality of the diet by making nutritious foods available the year round. It can lead to the growth of related enterprises in transportation, storage, distribution and marketing. And, it can produce much needed foreign exchange by creating value added products both for export and for internal substitution of imported processed foods.

The U.S. food industry has embraced the concept that freely sharing its expertise and knowledge is of mutual benefit to recipient and donor - to the recipient by improving current operations - to the donor by contributing to a healthier global future.

How SUSTAIN Works

A.I.D. missions and trade associations in developing countries publicize SUSTAIN's goals and activities. Executives of U.S. food companies with technical expertise and overall knowledge of the food industry serve as the SUSTAIN Steering Committee, providing guidance and overseeing activities.

Food related companies in developing countries submit their requests to SUSTAIN through the A.I.D. mission or a designated organization in their country. SUSTAIN screens all incoming requests and if necessary asks for additional information. Appropriate U.S. companies are then invited to respond.

Some problems can be readily resolved by providing information. Others require that consultants be sent. When a consultant is sent, the usual assignment is for one to three weeks. Upon completion of the assignment, the consultant prepares a report describing findings and making recommendations. Depending on need, some consultants may return for follow-up visits to ensure that recommendations have been appropriately implemented.

SUSTAIN Helps

Requests are diverse. Help may be needed to solve processing problems, to identify equipment needs and sources of new and used equipment, to train personnel in the use of new equipment and new technologies, to find new uses for indigenous commodities, to establish or improve quality assurance procedures, to control insects and rodents in food processing plants and to improve plant layouts and materials handling.

In the past, U.S. food companies, large and small, have provided technical assistance in the form of information, consultants and training to food processors in Africa, Asia, Latin American and the Caribbean.

SUSTAIN PROGRAM

SHORT COURSE ON QUALITY CONTROL/QUALITY ASSURANCE
"Training of Trainers"

Guatemala

August 3 - 6, 1993

by

SUSTAIN Volunteers:

Dr. James V. Chambers, Professor, Purdue University

Dr. Jay Marks, Associate Professor, Purdue University

Dr. Patricia Rayas-Duarte, Assistant Professor, North Dakota State University

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NCBA/SUSTAIN Project 111.022

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SUMMARY OF TRAINING ACTIVITY IN QUALITY ASSURANCE/CONTROL

Purpose:

Short course training was geared towards developing a core group of instructors in Central America who can train food processing workers and managers in food manufacturing practices and basic plant sanitation. Raising the level of food quality and safety is fundamental to preventing and controlling micronutrient deficiencies and communicable and food-borne diseases. Elevating the quality of these foods will make them better able to compete in local, regional, and international markets. By having a group of trainers within Central America, we build a resource capable of dispersing training activities where we can reach rural and village level food processors.

Profile of Trainers:

Training was offered to individuals in Central America who agreed to be part of a core group of instructors that would offer training in good manufacturing practices and basic plant sanitation to local food processors and micro-entrepreneurs. The "training of trainers" was conducted by experts identified through the SUSTAIN Program.

Class size for the initial training was limited to a maximum of 30 trainees. Criteria for the selection of the trainees, as well as their selection, was handled by INCAP and AGTA. Trainees were selected from the following sectors and organizations: INCAP, industry, and universities.

Location:

The training of trainers and the first offering of the short course to local industry was conducted at INCAP.

Schedule:

See Appendix III.

REPORT OF TRAINING THE TRAINERS
AUGUST 1 - 5, 1993
GUATEMALA, CENTRO AMERICA

The course was developed in collaboration with Purdue University and North Dakota State University. The curriculum was developed in March of 1993 during the visit of Dr. James V. Chambers to the Institute of Nutrition of Central America and Panama (INCAP), Guatemala, C.A. Instructors of the course were Dr. James V. Chambers and Dr. Jay S. Marks from Purdue University and Dr. Patricia Rayas-Duarte from North Dakota State University.

The course was offered August 3 - 6, 1993, with sixteen participants from private food industries, Laboratorios Unificados de Control de Alimentos y Medicamentos (LUCAM) and INCAP personnel. A range of topics including food safety, microbiology, chemistry, and processing were presented during the intensive three-day period. Testing covering the material, plus observation and interaction with the US instructors, demonstrated that the attendees gained significant knowledge during the course.

A new short course will be offered October 13 - 15, 1993. This short course will be taught by the participants or trainers of the course reported here. The short course will be directed to small to medium-size industry product and quality assurance managers. The emphasis of the short course will be in Good Manufacturing Practices.

The evaluation of the course by the instructors of this Training the Trainers Course includes that the participants were dedicated and showed professional capacity to deliver the next course. Some areas of improvement include 1) to show more confidence during the presentations of the laboratory demonstrations and 2) to avoid talking among themselves during the presentations.

James V. Chambers, Professor
Food Science, Purdue University

Mauro, Assoc. Professor
Food Science, Purdue Univ.

Patricia Rayas-Duarte
Assistant Professor
Cereal Science and food technology
North Dakota state University

40 40 is perfect score

PARTICIPANTS	TEST 1	TEST 2
Ing. Rolando Galvez B., Nabisco	26	31
Ing. Pablo Suazo, Nabisco	23	34.5
Ing. Luis Reyes Garay, Fecaexca	21	35
Ing. Carlos Rafael Anzueto, Osmosis	27	34
Ing. Henry Gill, B.E.S.T.	16	26
Ing. Steven O'Brien, B.E.S.T.	27	19
Teresa de Miranda, LUCAM	19	19
Lic. Noemí de Tapia, INCAP	15	23
Lic. Floridalma Cano, INCAP	20	22
Lic. Mynor Ordóñez, INCAP	22	28
Ing. Leonardo De León, INCAP	19	24
Ing. Carlos Argueta, INCAP	18	24
Dr. Jorge Zúñiga, INCAP	20	28
Lic. Azucena de Zúñiga, LUCAM	19	19
Lic. Zoraida Morales, LUCAM	21	—
Lic. Ma. Mercedes de Asturias	28	35
NANCY QUAN	—	23

SUSTAIN PROGRAM

The program **Sharing U.S. Technology to Aid in the Improvement of Nutrition (SUSTAIN)** provides access to U.S. expertise in food processing to help improve nutrition in the developing world. Technical assistance is provided by volunteer professionals from U.S. food companies, universities, and other organizations who donate their time and expertise.

SUSTAIN was granted a five-year renewal from the U.S. Agency for International Development (USAID) on September 30, 1991. The program is managed under a cooperative agreement with the National Cooperative Business Association (NCBA) and receives advice from a Steering Committee made up of private sector representatives.

NCBA was founded in 1916 and is a membership association representing America's 45,000 cooperative businesses. Known overseas as CLUSA, NCBA works overseas with its own member co-ops, USAID, World Bank, UNDP, and other donor agencies to promote development and joint ventures in the third world.

Many benefits can accrue to the developing world through improvements in food processing. From the standpoint of alleviating hunger and improving nutrition, food processing has much to offer. It helps meet food and nutritional requirements and reduce post-harvest food losses. From the economic standpoint, food processing provides a means for increasing foreign exchange earnings through exporting value-added processed foods rather than commodities. It helps generate employment and stimulates technological development and the growth of allied industries.

SUSTAIN helps improve food quality, expand production, and lower operating costs of locally grown and processed foods by providing technical assistance in post-harvest food systems, including: (a) food safety, quality, and sanitation (b) food preservation and storage (c) food processing (d) food fortification (e) packaging (f) marketing (g) weaning foods and (h) environmental technologies.

How the Program Works

SUSTAIN receives requests for assistance from individual food companies, research institutions, and USAID. Short-term technical assistance is provided by experienced U.S. professionals who donate their time and expertise to the project. Missions are typically one to three weeks in duration. SUSTAIN covers international travel costs. Companies or host organizations requesting SUSTAIN assistance are asked to contribute towards in-country expenses. Due to budget constraints, priority is given to requests that can demonstrate an ability to improve the nutritional quality, safety, and availability of food in the local community.

SUSTAIN is able to solve many problems by providing information that exists either in technical literature or in the "memory" of a company. If the problem cannot be solved through correspondence, then SUSTAIN volunteers may be sent to provide short-term technical assistance. Workshops and seminars can also be organized to help address food technology issues. The program does not fund product or equipment acquisitions.

The program publishes a quarterly newsletter (*SUSTAIN Notes*) on food technology issues. It is provided gratis to approximately 2300 recipients in more than 50 countries.

For more information, please write to:

SUSTAIN Program
National Cooperative Business Association
1401 New York Avenue, NW, Suite 1100
Washington, DC 20005-2160
Phone: (202) 638-6222
Fax: (202) 628-6726

JAMES CHAMBERS (Ph.D., Food Science & Nutrition, The Ohio State University, 1972) is Professor and Extension Food Scientist at Purdue University's Food Science Department. His extension activities focus on the transfer of technical information on food quality and safety, materials handling, food microbiology, and on energy use and conservation in the food industry. He has expertise in the application of analytical methods for the assessment of food quality factors, with an emphasis on food safety, nutrition, and shelf life performance. He is nationally recognized for his work in wastewater management and sanitation practices in the food industry. Before joining the Purdue faculty in 1973, Dr. Chambers was Corporate Microbiologist at Ross Laboratories, Columbus, Ohio (1961-1969) and Director of the Food, Dairies, and Drug Laboratories for the Ohio Department of Agriculture (1969-1972). In recent years, Dr. Chambers has been active in assisting developing countries with food quality control through assessment and training support. This work has taken him to Taiwan, Indonesia, and Guatemala.

JAY MARKS (Ph.D., Chemical Engineering, University of Kansas, 1965) is Associate Professor of Food Engineering at Purdue University, where he has taught since 1978. His research and publications in process design and development focus on food sterilization, in-line fat analysis, and food product spray dryer design. In addition to teaching and extension work, he consults in process design and plant energy conservation for several companies. Prior to joining the Purdue faculty, Dr. Marks was Manager of Marketing Services in the Polymer Division of Ralston Purina Company (1977-1978) and Plant Manager of Ralston's Ralcon Foods based in Memphis (1973-1977). He also served as Manager of Market Research for the Medicinal Chemicals Division of Mallinckrodt, Inc., St. Louis (1970-1973) and as Manufacturing Superintendent at Mallinckrodt, Inc., St. Louis (1970-1973). Dr. Marks holds patents for sterilization and dehydration processes and for a whey-based animal feed block. In 1991, as a visiting scholar to Indonesia, he helped to present an industry workshop and conference on quality control in food processing; he also visited Russia and Ukraine in that year to develop linkages between Purdue and research institutes, universities, and individual scientists in those countries.

PATRICIA RAYAS-DUARTE (Ph.D., Food Science and Technology, University of Nebraska, 1988) is an Assistant Professor of Cereal Science and Food Technology at North Dakota State University. Her expertise in cereal-legume processing, extrusion, and laboratory technologies, and she is certified by Better Process Control School to supervise thermal and aseptic processing and acidified foods. Dr. Rayas-Duarte teaches starch chemistry and food processing, and conducts research on the utilization of alternative crops for food and non-food uses. Active research projects include studies on the physico-chemical properties of amaranth starch; extrusion of buckwheat flour incorporated into corn and wheat formulations; and screening of squalene (isoprenoid) from plant sources.

TRAINING THE TRAINER COURSE
Guatamala City at INCAP
June 29 - July 2, 1993

Tuesday (June 29)

8:15 am — Introductory Remarks
- Dr. Elisa, INCAP
- Mr. McDonald - AGTA
- Dr. Chambers - Purdue/Sustain

8:35 am — Preliminary Examination - 40 Questions - Multiple Choice

9:15 am — Assessing Quality Control Needs in the Food Delivery System: From Producer to Consumer

1. Production Practices at the Farm
2. Storage and Transportation practices
3. Receiving Assessment for Quality
   a. Product Quality Standards
   b. Sampling and Analyses Procedures Commonly Used
4. The Process Environment
   a. Standard Operating Procedures
   b. Production Quality Standards
   c. Record Keeping and Process Monitoring
   d. Meeting Label Requirements

10:15 am — Refreshment Break

10:30 am — Analyzing for Quality (Laboratory Activities)

Microbiology Laboratory (Group A, am; Group B, pm)

	Analysis	Reason
1.	Standard Plate Count and Coliform Count	Bacteria quantitation
2.	Measuring pH of Foodstuffs a. acid food b. low acid food	Influences type of microbial activity that can occur
3.	Demonstration of Solid Sample Preparation for Microbiological Analysis	Proper Preparation means Validity of the Analysis Performed
4.	Touching Agar Plates	To Demonstrate the Presence of Microorganisms on Hands
5.	Using the Microscope a. Demonstration Slide of Pseudomonas b. Demonstration Slide of Mold Count Cell	Examination of Contaminants
6.	Demonstration of Most Probable Number Method	Used to Evaluate Water Sources for for Potability

7. Stereoscope Set Cereal Sample with winsects present — To asses the degree of insect infestation for grain

Noon - Lunch

1:00 pm Continue Laboratory Activities.
Group A Move to the Chemical Laboratory

Chemistry Laboratory (Group B, am; Group A, pm)

10:30 am Analyzing for Quality

	Analysis	Applicable Commodity	Reason
1.	Titratible Acidity	Dairy	Temperature abuse; bacteria Activity
2.	Freezing Point		Added water
3.	Browning Reaction	Fruit	Temperature abuse; Enzyme Activity
4.	Brix/Refractometer		Sugar Concentration Value
5.	Viscosity		Characterizes Fluid Flow
6.	HPLC		Quantitates and Detects Compositional Characteristics
7.	Water of Activity		Measures available moisture to support Microbial Activity
8.	Atomic Absorption		Quantitates Minute Concentrations of elements

Noon - Lunch

1:00 pm Continue Laboratory Activities
Group B Move to the Microbiology Laboratory
Both Laboratories Repeat Morning Activities

2:30 pm Microbiology and Food Quality

3:00 pm Food Chemistry Affecting Quality
1. Enzymatic Changes
2. Light Activated Changes
3. Oxidative Changes

3:45 pm Good Manufacturing Practices, The Foundation for a Quality Assurance Program
1. Industry Standards of Practice
2. GMPs and HACCP Practices
3. Written Procedures

4. Monitoring and Documentation
5. Equipment Maintenance Programs
6. Government Regulations/Public Relations

5:00 pm Adjourn for the Day

Wednesday (June 30)

8:00 am Understanding Principles of Heat Transfer and Heat Exchange Operations (Combination Lecture and Lab)

1. Factors that influence the transfer of heat
2. Getting the most out of the energy source
3. Kettle/Vat/Batch Processing
4. Scrape Surface Heat Exchanger Applications
5. Tube and Shell Heat Application
6. Plate Surface Heat Applications (Pasteurizer)

10:00 am Refreshment Break

10:15 am Food Handling Practices Leading to Product Contamination Infestation and Abuse

1. Harvesting Methods
2. Bulk Handling and Transporting Methods
3. Storage Conditions
4. Process Handling Equipment and the Sanitary Environment

11:00 am Assessing the Sanitary Environment for Food Processing

1. Housekeeping Practices
2. Frequency for Cleaning Storage and Process Food Handling Systems
3. Chemistry of Soil Removal
4. Using the Appropriate Sanitizer
5. Monitoring the processing environment

Noon - Lunch

1:00 pm Understanding the Operation of Pumps and Pumps Sizing and Product Flow Rates

1. Why important to know
2. Critical applications (e.g. residence time; cleaning)
3. Functional Aspects of Pumps (Centrifugal vs. Positive Displacement)
4. Friction Losses
5. Back Pressures
6. Sizing the pump to the system

3:00 pm Refreshment Break

3:15 pm Quality Control Methods for the Food Processing Environment

1. Defining Critical Control Points within the food processing system
2. Collectin representativew, valid samples for analysis

3. Using statistical methods to monitor process operations
4. Applicable QC chart

4:30 pm Influence of Food Presentation Processes on Nutrient Content

5:15 pm Adjourn for the Day

Thursday (July 1)

8:00 am Principles of Thermal Processing and Lethality

9:00 am Practices in the Dairy Industry to Assure the Quality of Fluid Milk (Combination Lecture and Lab)

10:30 am Refreshment Break

10:45 am Practices in the Cereal and Baking Industries to Ensure Quality

Noon - Lunch

1:00 pm Practices Associated with the Fruit and Vegetable Processing Industries

2:30 pm Protecting Meat and Poultry Products From Contamination for Quality

3:30 pm Refreshment Break

3:45 pm Evaluating Packaging Integrity (Metal, glass, plastic, multimaterial)

5:00 pm Adjourn

Friday (July 2)

8:00 am Examination (40 Questions, Multiple Choice)

8:45 am Evaluating the Course - Turn in Forms

9:15 am Developing the August 3-6 Food Industry Short Course on Food Quality Control

10:15 am Refreshment Break

10:30 am Finalize Industry Short Course with Instructors Commited and topics identified

11:45 am Finalize Arrangements for Industry Short Course and Summary Comments

Chapter 2

MICROORGANISMS AND FOODS

Man is in a constant race with microorganisms for the consumption of foods. The microbes have more voracious appetites and are less "picky" about the foods they eat so they end up consuming most of the total supply. However, man has developed procedures for long term preservation of a high percentage of those food materials which he finds most appetizing. While some of these procedures (e.g., salting, drying, fermenting) were practiced in biblical times, the science of food preservation could only develop after Louis Pasteur and others (mid 1800's) proved that microorganisms were responsible for food spoilage. The procedure called pasteurization was so named in honor of Louis Pasteur.

It was soon discovered that microorganisms were also the causative agents of certain diseases and that food was one way in which these diseases were transmitted to man. Therefore, it became imperative that procedures used for food preservation be devised not only to prevent food spoilage but also to protect the consumer from microorganisms which could cause illness or death. The latter objective is not only the primary concern of our regulatory agencies but must also be foremost in the minds of food processors and distributors.

It is obvious that anyone with significant responsibilities in commercial food processing should be informed about microorganisms and their importance in food preservation. The following is intended to introduce you to this important invisible world. Remember that you really do not have to see a cow to know that her milk is good or to see a cobra to know that the venom may be fatal. It is hoped that similar mental images will emerge from this discussion of microorganisms.

General Microbiology

What are microorganisms? Micro = very small; so we are talking about very small organisms. All the microbes of primary concern to food processors are much too small to be seen as individuals with the unaided eye. However, included in the biological definition are certain seaweeds which are over 100 feet long. What is different? Microorganisms do not have specialized tissues such as leaves, stems, roots, hearts, lungs, kidneys, etc. Bacteria, algae, fungi, and protozoa are all microorganisms. Fortunately, food processors are primarily concerned with only a few groups of bacteria and of fungi (yeasts and molds).

The bacteria vary greatly in their shape and organization. However, the common ones are single cells which are either spheres (cocci; singular, coccus) or rodlets (bacilli; singular, bacillus). The cocci may occur either singly, in pairs, tetrads, short to long chains, or clusters (Fig. 2.1).

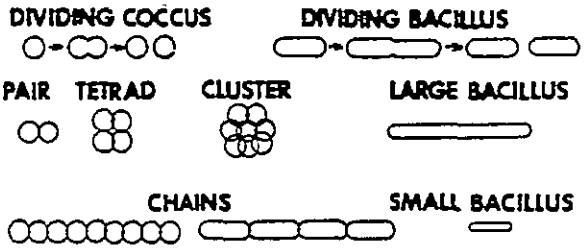

Fig. 2.1. Shapes and organization of common bacteria.

The bacilli vary primarily in the size of the cells. Most all reproduce by fission; i.e., one cell divides into two equal cells. These are the smallest organisms we will discuss. The common cocci may vary from about 0.5 to 1.5 μm (1 μm = 1/1,000,000 meters = 1/25,400 inches) in diameter, and the bacilli from 1 to 3 μm long. It takes about 500 thousand billion cells of an average bacterium to weigh 1 pound. When bacteria grow in a clear liquid such as brine they have to reach a population of about 10 million per ml (1 ml = 1/1000 liter = 1/946 qt.) or about 5 billion cells per pint before the liquid shows any visible turbidity.

While bacteria have to reach large populations before they become visible, it does not take very long for them to do this under favorable conditions. They divide by fission so the population increases exponentially (Figure 2.2). The rate of cell division depends not only on the

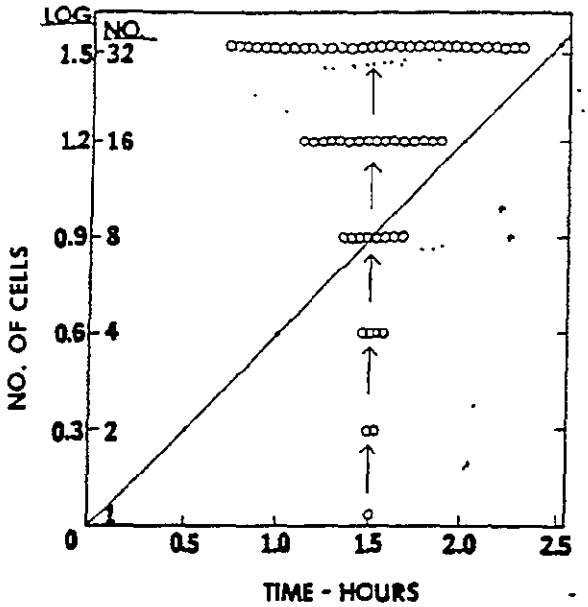

Fig. 2.2. Rate of multiplication of bacteria. The circles (o) represent individual bacterial cells. Starting with a single coccus dividing every ½ hour, there would be 32 cells in 2½ hours and 1 million cells in 10 hours.

organism but on the environment, and the actual time per division may vary from 20 minutes to several hours. Starting with only 1 cell in a pint jar dividing every 20 minutes, a clear medium would start to become turbid within 1/2 day (over 50 billion cells). If the cells could continue dividing at this rate, the cell mass at the end of 2 days would be greater than that of the earth. We hope this never happens.

Some bacteria form resting bodies called endospores or more commonly spores. These might be considered analogous to plant seeds but spores are quite different. The sporulation cycle is illustrated in Fig. 2.3 As indicated in the figure, in some bacteria the cell in which the spore is formed (the sporangium) is swollen while in others this is not true.

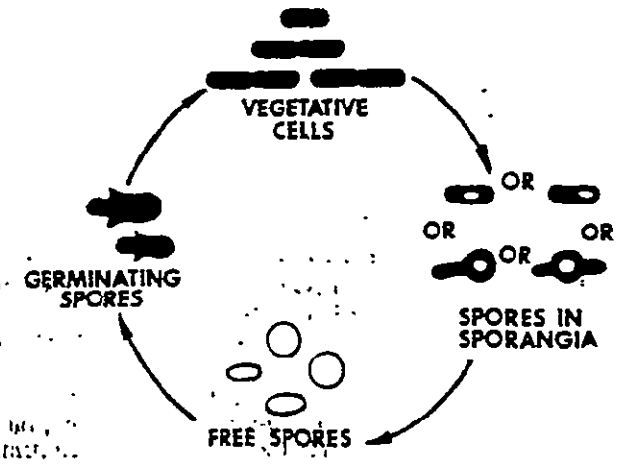

Fig. 2.3. The sporulation cycle of bacteria. The spores are very refractile as compared to cells, and the spores will not stain with simple stains.

The spore is very different from the cell not only in shape, but also in other characteristics. Spores have no detectable metabolic activity, and they are extremely resistant to heat, irradiation, dehydration, chemical treatments, and other unfavorable environments. Heating some spores at boiling temperatures (212°F., 100°C.) only encourages them to germinate as soon as the temperature is reduced to a favorable level. Therefore, low-acid canned foods (pH greater than 4.6) in which spore-forming organisms can grow must be heated at temperatures above boiling; i.e., they must be heated in a retort. Alternatively, low-acid foods may be acidified to a finished equilibrium pH of 4.6 or below, or they may be refrigerated.

The fungi of importance to the food processor are commonly referred to as yeasts and molds. Representative types are illustrated in Fig. 2.4. There is no sharp

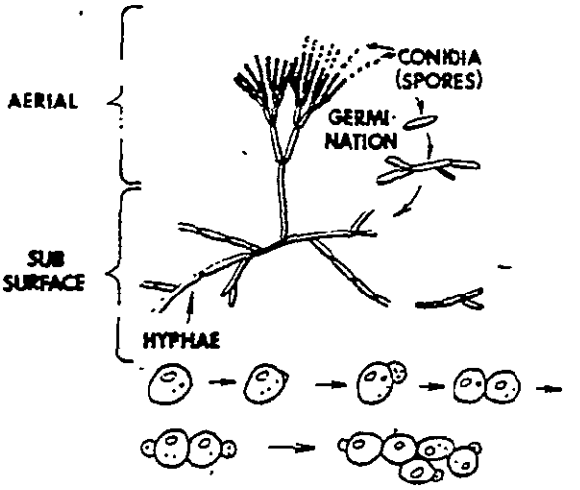

Fig. 2.4. Typical shapes and modes of reproduction of molds (top) and yeasts (bottom). Most molds reproduce both by fragmentation of hyphae and by spores produced on fruiting structures. Yeasts characteristically reproduce by budding.

line of demarcation between the two groups. However, yeasts commonly reproduce by budding and are referred to as "budding fungi". The most common molds grow by elongation of threads called hypae and reproduce by fragmentation of the threads and by production of specialized seed-like spores. They produce masses of hypae which are called mycelia (singular, mycelium). However, some filamentous yeasts also produce hypae and specialized spores in addition to reproduction by budding. While the cells of most of the yeasts and molds are somewhat larger than most bacteria, they are still much too small to be seen as individuals. There can be millions of these on or in a food without any visible evidence.

Where are microorganisms found? Microorganisms may be found practically everywhere in nature except inside of intact, healthy living tissues and there may be exceptions to this. The soil is teeming with all types of bacteria, bacterial spores, yeasts, and molds and they are also present in the air we breathe. The intestinal tract of man and animals and the rumen of cows contain very high populations of bacteria. It is possible to wash one's hands or the surfaces of fruits or vegetables many times and still find high populations of bacteria in the washings.

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While the yeasts and molds are both widely distributed, there are certain places where they are most troublesome. The yeasts are a constant threat in sugar and organic acid[1] solutions, and the molds grow well on moist surfaces of walls and equipment. A number of molds also grow on walls of refrigerators and on the surfaces of refrigerated food.

What do microorganisms do? They make it possible for us to continue to live on the earth. Without microbes to mineralize all of the plant and animal residues so the elements can be used again by plants, our world would soon become uninhabitable to man. There is no known naturally occurring organic compound that cannot be attacked by one or more microorganism. This versatility and the ability of these organisms to multiply rapidly and of representatives to grow in essentially every natural environment uniquely equips them for their primary role.

Unfortunately, the microbe not only attacks unwanted materials but competes with man for his food supply. In addition, some microorganisms invade and cause disease of man, animals, and plants. Others produce poisons (toxins) when they grow in foods which result in illness and sometimes death if consumed.

In a number of instances, man has harnessed the microbe to produce useful products. A number of bacteria and molds are used to produce antibiotics to help fight other microbes, yeasts are used to produce alcohol and alcoholic beverages, bacteria convert alcohol to vinegar, lactic acid bacteria are used to ferment cucumbers, cabbage, milk, etc. Still other systems have been developed to encourage microorganisms to digest sewage and industrial wastes. It is quite probable that many more uses will be found for microorganisms in the future. They have great potential for the production of food, fodder, and fertilizer and for the conversion of waste organic matter to natural gas.

TABLE 2.1

FACTORS INFLUENCING GROWTH, ACTIVITY, AND SURVIVAL OF MICROORGANISMS

Nutrients available
Oxygen availability
Moisture - Water activity and salt concentration
Temperature
pH and acidity
Chemicals
Light

[1]Organic acids are carbon-containing acids such as acetic, lactic and citric acids. The acids normally in food are organic acids.

Factors influencing microorganisms. The same factors which influence all living things influence the growth, activity, and survival of microorganisms (Table 2.1). However, the microorganisms vary more widely in their responses to individual factors than do plants and animals. As noted previously there are microorganisms adapted to the extremes of all natural environments.

Some bacteria such as the lactic-acid bacteria require sugar to grow. Many yeasts require sugar in the absence of oxygen but will use acids such as acetic or lactic acid when oxygen is present. Practically all molds require oxygen and will grow on sugars and a variety of acids, alcohols, and other organic compounds. Those organisms which require oxygen for growth are called *aerobes* (aero = air), those which cannot develop in the presence of oxygen are called *anaerobes* (prefix an- = no) and those which are able to multiply either in the presence or absence of oxygen are called *facultative anaerobes*. The ever-dangerous *Clostridium botulinum* and it's relatives such as *Clostridium perfringens* are anaerobes which cannot tolerate oxygen. Other common food poisoning bacteria *(Staphylococcus* and *Salmonella)* are facultative. The lactic acid bacteria *(Lactobacillus, Pediococcus,* and *Streptococcus)* are aerotolerant bacteria in that they metabolize sugar like anaerobes but they will tolerate the presence of oxygen. In fact, they are termed *microaerophilic* because they grow better in the presence of small amounts of oxygen.

All living things have a high water content and require moisture for growth. Dehydration is an excellent way to preserve some foods. As a group, the molds are capable of growth at lower moisture levels than other microorganisms. They grow on surfaces on which only very thin layers of condensate accumulate. For example, molds grow on leather boots stored in a damp closet or basement. These microbes are the most troublesome in dehydrated foods.

Microbial growth and activity are influenced not only by the total water content, but by the types of materials dissolved in the water (solutes) and their concentration. These solutes influence the availability of water for microorganisms, and explain why some foods have to be dryed to much lower moisture levels than others in order to preserve them. The availability of water is measured by determining the *water activity*, abbreviated a_ω. The a_ω is directly related to the vapor pressure of the water in the solution and is determined by measuring the equilibrium relative humidity of the air over the solution in a closed container (Fig. 2.5). Relative humid-

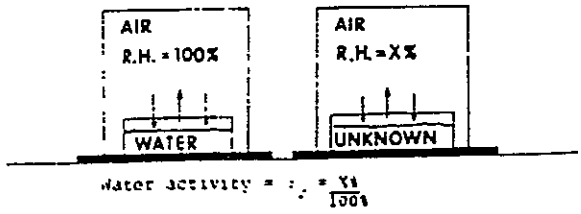

Fig. 2.5 Measurement of water activity (a_ω). The relative humidity (R.H.) (percent saturation) of the air over the solution in a closed container is measured after allowing time for equilibration.

ity divided by 100 equals a_ω. Air over water in a closed container becomes saturated and the relative humidity is 100% which is equal to an a_ω of 1.0. Any solution which results in a lower relative humidity has a lower a_ω.

The effects of salt and sugar on the a_ω is shown in Table 2.2. Most common bacteria, including all of those

TABLE 2.2

APPROXIMATE WATER ACTIVITY (a_ω) VALUES OF VARIOUS SALT AND SUGAR SOLUTIONS AT 25°C

a_ω	Percent salt	Percent sucrose
1.0	0	0
0.99	1.7	15.4
0.98	3.4	26.1
0.96	6.5	39.6
0.94	9.3	48.2
0.92	11.8	54.3
0.85	18.9	67.2
0.80	23.0	--

of public health significance will not grow when the water activity is 0.85 or less. However, many yeasts and molds have been found to grow below this level and some will grow down to an a_ω level of 0.60. Salt solutions affect some microorganisms at concentrations much lower than necessary to reduce the a_ω to an inhibitory level. A number of molds that can grow in other environments with very low water activity values, cannot grow in salt solutions with an a_ω level of 0.96.

There are bacteria which will grow at freezing temperatures and others which will grow at 149°F (65°C). Those that prefer low temperatures are called *psychrophiles* (cold loving) and those that grow at high temperatures are called *thermophiles*. However, most bacteria prefer intermediate temperatures *(mesophiles)* of 80-100°F (25-40°C). The yeasts and the molds prefer lower temperatures for growth. Their optimum temperatures are usually near 70-85°F (20-30°C). However, a number of molds can grow well at refrigerator temperatures.

Most molds and yeasts are very sensitive to temperatures of 160°F (71°C) or higher and are killed within a very few minutes. One exception is a species of mold called *Byssochlamys fulva* which is heat resistant and has caused spoilage of pasteurized fruit. Most bacterial cells are reasonably sensitive to this pasteurization temperature, but some of them are quite resistant. These are known as *themoduric* bacteria. Bacterial spores are completely insensitive to heat at 160°F.

The pH and the acidity have both independent and combined effects on the growth, activity, and survival of microorganisms. Since these factors are of prime importance in the preservation of acid foods, they will be discussed in detail in the following chapters. The chemicals used as food preservatives are organic acids and the effects of these will also be discussed later.

Most microorganisms are sensitive to some degree to ultra violet light. Even the relatively low amounts of ultra violet in sunlight prevents the growth of filamentous yeasts on the surface of cucumber brine tanks. However, ultra violet has no penetrating power and will only affect microbes on surfaces directly exposed to it. Bacterial spores are relatively insensitive to ultra violet light.

Food Fermentations

The natural fermentation of fruit juices for wine, the lactic fermentation of milk to produce cheeses, and the leavening ("rising") of bread by microorganisms were practiced centuries before we had any knowledge of microorganisms. They were partially successful because of natural selection for desirable microorganisms which occurs in certain foods. These fermentations are now conducted by industry under carefully controlled conditions using pure cultures of the most desirable organisms for each type of product. However, pickle, sauerkraut, and olive fermentations are still mostly dependent on natural selection of lactic acid bacteria. Nevertheless, these processes have been studied in detail and many practices developed to insure a more consistent quality product.

Cucumber fermentations. When cucumbers are placed in salt brine at reasonable temperatures, nutrients, including sugars, are rapidly extracted from the tissue and a natural fermentation by lactic acid bacteria develops quickly. How rapidly this develops is very dependent on the initial salt concentration and the temperature. If the salt concentration is too high or the temperature too low the fermentation will be very slow in starting. However, under normal conditions, the lactic acid bacteria consistently predominate and reach high populations in the brine within 24 to 48 hours. This is a critical period in the fermentation and should be carefully controlled and monitored to insure that the production of lactic acid is initiated quickly and that the pH decreases rapidly to pH 4.0 and below.

Most cucumbers which are fermented are fermented for "salt stock" pickles. There are 3 species of lactic acid bacteria which consistently predominate in these brines; viz., *Pediococcus cerevisiae, Lactobacillus plantarum*, and *Lactobacillus brevis* (Fig. 2.6). The first two species are the most desirable because they produce primarily lactic acid from sugar (homofermentative) while the latter species produces considerable amounts of carbon dioxide and alcohol in addition to lactic acid.

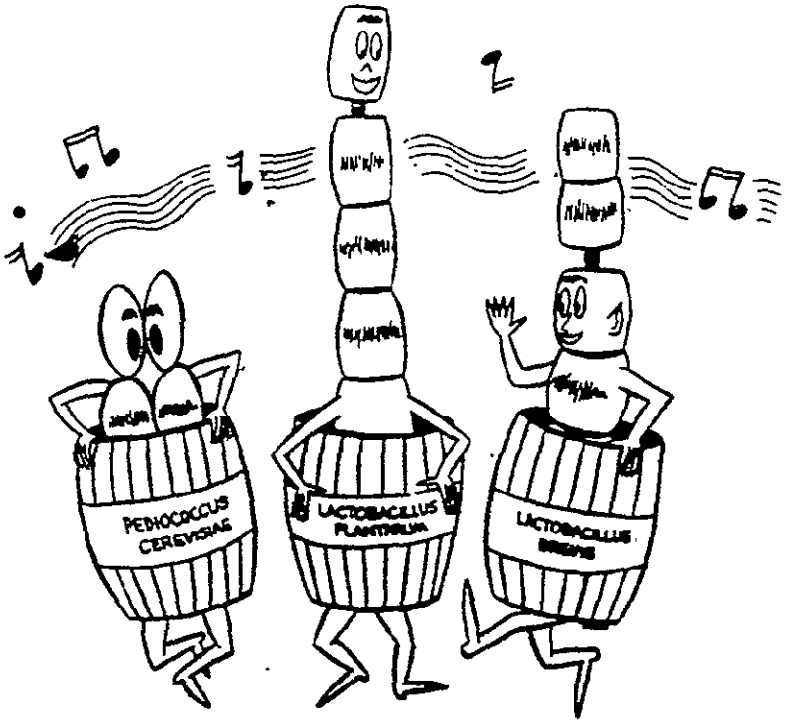

Fig. 2.6. Species of lactic acid bacteria which predominate in salt stock pickle fermentations. The *Pediococcus* characteristically occur in tetrads (⊞), while the rod-shaped lactobacilli occur singly, in pairs and short chains.

The accumulation of large amounts of carbon dioxide in brines frequently causes serious losses due to hollow pickles (bloaters). Special purging procedures to remove this gas must be used in either natural or controlled (see below) fermentations to prevent bloaters when large diameter cucumbers are fermented.

A detailed process has been developed for the controlled fermentation of cucumbers for salt stock. This procedure basically involves killing most of the microorganisms on the cucumbers and inoculation of the brine with a pure culture of *Lactobacillus plantarum*. Key elements of this process are the initial acidification of the brine to insure that undesirable and possibly dangerous bacteria have no opportunity to grow, and the use of a buffer to allow the homofermentative lactic acid bacterium to ferment most of the sugar present.

In natural salt stock fermentations, sugar not utilized by lactic acid bacteria is fermented by yeasts which produce large amounts of carbon dioxide. There are a number of species of these yeasts involved and they are all more resistant to both salt and acid than are the bacteria. However, none of these have been found to cause defects of the pickles if the carbon dioxide is purged from the brines properly.

Since salt stock brines are normally anaerobic except at the surface, molds and filamentous oxidative yeasts can only develop on the surface. Most fermentation tanks are not covered and the surfaces are directly exposed to sunlight which prevents the growth of these organisms. Brine surfaces protected from sunlight quickly become covered with filamentous yeasts. Many of these yeasts are extremely salt tolerant, and they will oxidize the lactic acid in the brines. They should be skimmed from brine surfaces regularly, or procedures used to prevent their development.

Most molds are not nearly as salt tolerant as the yeasts and have not been a problem in cucumber fermentations. However, they can result in serious losses if allowed to grow on brine surfaces because many molds produce softening enzymes (pectinases and cellulases). They are strictly aerobic and can only grow on brine surfaces. The same procedures used to control filamentous yeasts will control the molds.

Sauerkraut fermentations. The natural fermentation of salted shredded cabbage involves all the lactic acid bacteria found in cucumber fermentations and a few additional species. These bacteria not only produce the acid necessary for preservation, but produce the characteristic flavor of sauerkraut.

It is essential that the surface of the sauerkraut brines be protected from air. The salt concentration is relatively low in these brines as compared to salt stock pickle brines and a variety of oxidative molds and yeasts can grow on the brine surfaces if oxygen is available. These organisms can produce serious defects in color, odor, taste, and texture.

Microbial Spoilage

Fresh foods. It is impossible to produce a high quality product from poor quality raw materials. As soon as a fruit or vegetable is harvested or an animal killed,

microorganisms attack. The organisms involved and the type of spoilage that occurs are very dependent on the type of food and on the way the food is handled. However, the procedures to control microbial spoilage of fresh foods are similar. These are:

1. Prompt handling. Process as soon after harvest as *possible*.
2. TLC - Tender loving care. The surfaces of fruits and vegetables provide a natural barrier from microbial attack. Prevent mechanical damage to tissues.
3. Low temperatures. Cool fresh foods immediately after harvest and store at low temperatures.

Spoilage during manufacture. Foods must be moved rapidly through the manufacturing operation; and the manufacturing facilities and equipment must be clean and sanitary. Foods to be acidified should not be held for prolonged periods in water or brine without sufficient acid to prevent the development of food poisoning organisms. Spoilage microorganisms will build up rapidly when provided an opportunity, and those most adapted to the environment will predominate. For example, molds grow nicely on the surfaces of equipment in a moist environment. Food coming into contact with such surfaces will receive a large inoculum which will develop rapidly if given an opportunity. Since molds oxidize acids, the pH of an acid food can be increased to an unsafe level by heavy mold growth.

Spoilage of finished products. It is easy to recognize gross microbial spoilage of food packaged in glass containers. As noted earlier, when microbes grow to high populations, in clear liquid the liquid becomes turbid. In time the microbes will settle on the surfaces of the food and the bottom of the container as a whitish deposit. Cans must be opened to detect this type of spoilage. If the spoilage organism produces much gas, it will result in swelling of a jar cap or the ends of a can. Gross spoilage is also frequently detectable by odor or chemical analysis. It is always unwise to taste any food suspected to have undergone spoilage.

Warning! *Clostridium botulinum* may grow and produce toxin in a food with a pH slightly about pH 4.6 without producing obvious changes in the food. Do not trust any pasteurized canned food with a pH greater than 4.6.

Microbial spoilage resulting from underprocessing of acid foods is usually due to either homo- or heterofermentative lactic acid bacteria or to yeasts since these are both acid tolerant organisms which can grow anaerobically. If the canned food has been pasteurized, spoilage is usually due to lactic acid bacteria as the yeasts are more sensitive to heat. In contrast, where preservation is dependent on sugar and acid concentrations, yeasts are more commonly the cause of spoilage.

If a jar or can of acid food spoils as a result of leaking, molds and/or filamentous yeasts usually grow on the surface. These will use the acid in the food, increase the pH, and then a variety of microorganisms may initiate growth including *Clostridium botulinum*.

Food Infections and Poisonings

Classical food poisoning (gastroenteritidis) is characterized by a rapid onset of symptoms, vomiting, diarrhea, and varying degrees of prostration. In some instances such illnesses are the result of poisons (toxins) produced by a bacterium growing in the food prior to it's being eaten, while in other instances the same symptoms result from the growth of the bacterium in the intestinal tract (infections). These illnesses are sometimes called ptomaine poisoning. This is inaccurate. Compounds known as ptomaines are not poisons when eaten and smell so bad that no one would eat food containing them. There are still other diseases which may be transmitted by food which have symptoms quite different from classical food poisoning. Table 2.3 summarizes the kinds of illnesses which may result from eating food. The food handler needs to be aware of all these possibilities and utilize all practical safeguards to prevent their occurrence.

TABLE 2.3

ILLNESSES WHICH MAY RESULT FROM EATING FOOD

FOOD POISONINGS
Naturally poisonous foods
Chemical poisons introduced by accident
Bacterial poisons produced in food
Staphylococcus aureus
Clostridium botulinum
INFECTIONS
Classical symptoms of food poisoning type
Salmonella
Vibrio parahaemolyticus
Clostridium perfringens
Other diseases transmitted by food
Typhoid fever
Bacterial and amoebic dysenteries
Cholera
Poliomyelitis
HYPERSENSITIVITY (Individual Allergies)

Food poisonings: When either *Staphylococcus aureus* or *Clostridium botulinum* are allowed to grow in a food, they produce poisons (toxins) which they release into the food. The organism then may die and the toxin remain in the food to cause the characteristic illness.

Staphylococcal food poisoning is very common in the United States. The illness is characterized by severe diarrhea, vomiting, and stomach cramps, which usually start 3 to 6 hours after eating the food. The patient recovers in 1 or 2 days. The illness is practically never fatal but the patient may wish he/she was dead. The foods involved are frequently custards, salads, gravies and dressings. Such foods are easily contaminated by human carriers and are frequently held at room

temperature for long periods allowing the organism to grow and produce toxin. Normal cooking may kill the organism but will not destroy the toxin. While staphylococci are able to grow anaerobically, they are neither heat resistant or acid tolerant. They will grow in the presence of 7 to 8 percent salt, but not at low pH.

Botulism is the only type of food poisoning which is usually associated with canned foods. Unfortunately, the toxin produced by *Clostridium botulinum* is the most lethal poison known. It is much more potent than cyanide or cobra venom. It has been calculated that ½ pound of pure botulinum toxin would be enough to kill all of the humans in the world. Survival or death depends greatly on the amount of toxin eaten (dosage) and on how quickly the illness is diagnosed and treatment initiated. The mortality frequency has been reduced from about 80% to 20% during the last 25 years.

There are 7 different types of botulinum toxin separated on the basis of the antitoxins which neutralize them. However, all are similar in that they are extremely poisonous, cause the same symptoms, and are inactivated by boiling. Symptoms appear within a few hours or up to several days after eating the food. Characteristic symptoms are vertigo (dizziness), double vision, difficulty in swallowing and breathing, vomiting and constipation. When death occurs it is usually the result of respiratory failure.

Clostridium botulinum is a spore forming anaerobic bacterium (Fig. 2.7). It is widely distributed in soil so essentially all raw foods must be considered to have spores present. The spores of most types are quite heat resistant, and boiling water temperatures cannot be relied on to destroy them. Fortunately, this bacterium cannot grow at pH 4.6 or below. This makes it possible to pasteurize foods safely at temperatures of 212°F. (100°C.) or below. *However, one must be absolutely sure that the final pH of all water phases (water in liquids and solids) inside the container are at this pH or below!*

With respect to botulism, some of the most potentially dangerous canned foods are those with relatively low pH values (pH 4.7-5.5). *Clostridium botulinum* may grow poorly in such foods and produce no obvious changes in appearance, odor or flavor. However, it may produce considerable amounts of toxin. Also, such canned foods are frequently not cooked before eating. Thus, any toxin formed would not be destroyed.

While some strains of *Clostridium botulinum* have been found to grow in food with salt concentrations of 7%, no toxin was found. No growth of these organisms has been observed in the presence of 10% salt. Also, foods having a water activity of 0.85 or below will not allow the growth of this organism.

Fig. 2.7. Photographs of *Clostridium botulinum*, type A, cells (A), spores in sporangia (B), free spores (C), and germinating spores (D). All preparations were stained with a simple stain and photographed through a microscope with a magnification of 1100X.

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Food infections. Classical symptoms of food poisoning are produced during the growth of some species of *Salmonella, Vibrio parahaemolyticus* and some strains of *Clostridium perfringens* in the intestinal tract. Some symptoms characteristically appear 12-36 hours after eating a food containing large numbers of living cells (the organism must be able to grow in the food) of one of these organisms. Characteristically, the illnesses run their course within 1-3 days and the patient recovers.

Contamination of foods with *Salmonella* may be by a human carrier or by rats and mice which commonly harbor these bacteria. Fortunately these bacteria are not acid tolerant nor heat resistant. Therefore, they should not constitute a public health hazard in foods with a pH below 4.6. *Vibrio parahaemolyticus* requires salt for growth and is associated with raw sea food. It will not grow below pH 5.0.

Clostridium perfringens is an anaerobic spore-forming bacterium that is commonly found in soil. Therefore, almost any fresh food may be contaminated with spores, and it is necessary to handle the food so that the germination and growth of these spores is prevented. While the spores will survive normal pasteurizing temperatures and may remain dormant for long periods in an acid food, the organism is unable to grow at low pH. This same organism is frequently the cause of gas gangrene.

Food as a disease vector. We have all heard the story of Typhoid Mary. Like Mary, many people who have had typhoid fever continue for many years as carriers of the causative bacterium, *Salmonella typhosa*. Procedures are now available for identifying such carriers and they are not allowed to work as food handlers. However, there are other diseases which may be transmitted by food. Two of these, dysentery and cholera, are caused by bacteria. Amoebic dysentery is caused by a protozoan, and poliomyelitis by a virus. In all of these instances, the causative organism is found in the feces of infected persons and is usually transmitted to the food by way of the hands. However, they may also reach the food by way of insects. It is very apparent that good sanitation practices must be enforced where food is handled for public consumption.

None of these pathogens (patho = disease, genic = producing) are heat resistant and would be destroyed by most pasteurization procedures. However, both the polio virus and the protozoan might well withstand high acid conditions for prolonged periods. Fortunately neither of these diseases is prevalent in the United States at this time.

Summary

General microbiology:

1. Man and microbes are in a constant race for food and man must use all his talents to win.
2. The first priority for food processors is to ensure that all foods are safe to eat, the second priority is to prevent food spoilage, and the third priority is to make sure that the food is of the highest possible quality.
3. Billions of bacteria must be present in a jar of brine before turbidity is seen, but some divide so quickly that many billion cells can be produced from 1 cell in less than ½ day.
4. Spores of bacteria are the most resistant forms of life known. They survive for years in unfavorable environments and initiate growth when conditions become favorable. Some spores are completely insensitive to boiling temperatures.
5. Yeasts and molds are usually somewhat larger than bacteria, but there can be millions of these on a food without any visible evidence.
6. Microorganisms are everywhere in nature. One has to assume that all fresh foods are either contaminated or susceptible to contamination by all kinds of microbes.
7. Like all living things, microbes are influenced by the nutrients available, the oxygen supply, moisture levels and activity (a_ω), temperature, pH and acidity, and light. However, there are microbes which prefer or are able to survive in the extremes of environments.
8. Some bacteria require oxygen (aerobes), some can grow either with or without oxygen (facultative anaerobes), and others cannot survive in the presence of oxygen (anaerobes). The yeasts are mostly either aerobic or facultative while practically all molds are aerobic.
9. Water activity is a measure of the availability of water. Microorganisms of public health significance will not grow when the water activity is 0.85 or less.
10. Some microbes grow and prefer temperatures near freezing (psychrophiles), other prefer temperatures very near those used for pasteurization (thermophiles), but the majority prefer intermediate temperatures (mesophiles).

Food Fermentations:

1. Both cucumber and sauerkraut fermentations should be closely monitored during the first 2 days to insure that the lactic acid fermentation is initiated promptly and that the pH is depressed rapidly.
2. Both salt concentration and temperature will affect the time required for the initiation of a lactic acid fermentation.
3. Acidification and buffering of the brine are essential steps in conducting controlled cucumber fermentations with pure cultures.
4. The surfaces of salt-stock brine tanks which are protected from the sun must be skimmed regularly to prevent development of filamentous yeasts which will use the lactic acid.
5. Surfaces of sauerkraut tanks must be protected to prevent yeast and mold growth. These organisms will use the lactic acid, raise the pH, and allow other organisms to grow.

Microbial Spoilage:

1. Fresh foods must be handled promptly and with tender loving care (TLC) to prevent mechanical damage. When practical, they should be cooled and stored at low temperatures.
2. Foods should be processed rapidly in a clean and sanitary manner. Partially processed foods should not be held in water or brine for prolonged periods without sufficient acid to prevent the growth of food poisoning bacteria.
3. Molds are capable of using sufficient acid to increase the pH of a food above the safety point.
4. Gross spoilage of canned foods is easy to recognize, but *Clostridium botulinum* may grow

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and produce toxin in a food with a pH above 4.6 without producing obvious changes in the food.

5. If a jar or can of acid food leaks, aerobic yeasts and molds may grow on the surface and use enough acid to raise the pH above 4.6. This could allow spores of *Clostridium botulinum* to germinate and grow.

Food Infections and Poisonings:

1. Some cases of "food poisoning" result from eating foods containing poisons (toxins) produced during the growth of a bacterium in the food. Others result from eating food containing high number of living bacteria which infect the intestinal tract.
2. *Clostridium botulinum* is a spore forming anaerobic bacterium which produces the most lethal poison known during growth in a food.
3. Spores of *Clostridium botulinum* are common in soil, and these spores are not destroyed by pasteurization.
4. *Clostridium botulinum* will not grow or produce toxin at pH 4.6 or below, when the water activity is 0.85 or below, or in 10% salt brine.
5. The botulinum toxin is destroyed by boiling 15 minutes.
6. Pasteurized foods with a pH slightly above pH 4.6 are potentially very dangerous. The organism may grow poorly and fail to cause any apparent changes in the food, but will still produce toxin. Also, some of these foods are routinely served without heating.
7. It is absolutely essential that the final pH of all water phases inside a container of pickled, fermented or acidified food is at pH 4.6 or below.
8. Some infectious diseases may be transmitted through foods. All foods should be protected in so far as possible from contamination by such organisms. Maintaining a pH of 4.6 or below will prevent the growth of such organisms in the food.

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Chapter 3

ACIDITY, pH, AND BUFFERS

Manufacturers of acidified and fermented foods rely heavily on the presence of edible acids in the finished product to preserve the product and to reduce the pH sufficiently (pH 4.6 or below) to ensure public health. In addition, the quality of the product depends on the types and amounts of acid present. Therefore, it is necessary that personnel involved in the manufacture of acid foods have a good understanding of acidity and pH, and of buffers which have pronounced effects on the pH which results from addition of a given amount of acid.

Acidity

Definition: Acids are compounds which release one or more hydrogen ions (H^+) to some extent in solution. This can be illustrated as follows:

$$\boxed{H}-\boxed{A} \Rightarrow \boxed{H^+} + \boxed{A^-}$$

The undissociated acid is not charged. It dissociates into a positively charged hydrogen ion (H^+) and a negatively charged anion (A^-). Acidity refers to the total amount of acid present in solution. This is routinely measured by titration of all of the available H^+ with a compound known as a base and will be discussed in the next chapter. The titratable acidity is expressed in terms of percent of some specific acid. The acidity of foods packed in liquids should be expressed as grams of some acid per 100 ml of the packing medium. This is quantitatively equal: grams acid/volume of sample x 100. For solid or semi-solid foods, the percent of some acid is equal: grams acid/grams of sample x 100. Vinegar contains acetic acid and the strength of vinegar is frequently expressed in terms of grains. This refers to the percentage of acetic acid times 10. For example, 100 grains vinegar contains 10% acetic acid.

Types of acids: Acids are frequently classed as either mineral or organic. Mineral acids such as hydrochloric and sulfuric acids are comprised of inorganic elements and are strong acids. Organic acids such as acetic, lactic, and citric acids are carbon-containing compounds and are weak acids. The strength of an acid depends on how readily it gives up H^+. This will be discussed in context with pH. In dilute solutions, mineral acids dissociate completely. For example, when hydrochloric acid (HCl) is added to water it separates completely into H^+ and chloride (Cl^-) ions. In contrast, the extent to which organic acids dissociate varies widely with individual acids, and with other components of the system.

Acetic acid in the form of vinegar is the most common acid used to acidify foods, and it is relatively weak. Lactic acid, the predominant acid in fermented foods, is considerably stronger than acetic; and citric acid which is found in citrus fruits is stronger yet.

pH

Definition: pH is defined as a measure of hydrogen ion activity. For simplicity, we will define it as a *measure* of hydrogen ion concentration, $[H^+]$[1], in a solution. Hydrogen ion concentration is different from the total acid concentration as determined by titration. This difference will become very apparent during this discussion.

The pH scale: There are two very important characteristics of the pH scale which must be understood. (1) The scale is inverse; that is, the higher the pH the lower the concentration of H^+ in solution. (2) The scale ranges from 0 to 14 and it is not linear; that is, a change by 1 pH unit does not reflect a change of 1/14 in the H^+ concentration. Instead, a change in 1 pH unit reflects a 10-fold change in $[H^+]$. One of the

[1] $[H^+]$ means the concentration of H^+ in mole/liter. Since the weight of H^+ is equal to about 1.0, it means gram H^+ liter of solution.

reasons for devising such a scale is because the scale must cover such a wide range of very low H^+ concentrations. As evident in the left column of Fig. 3.1, H^+

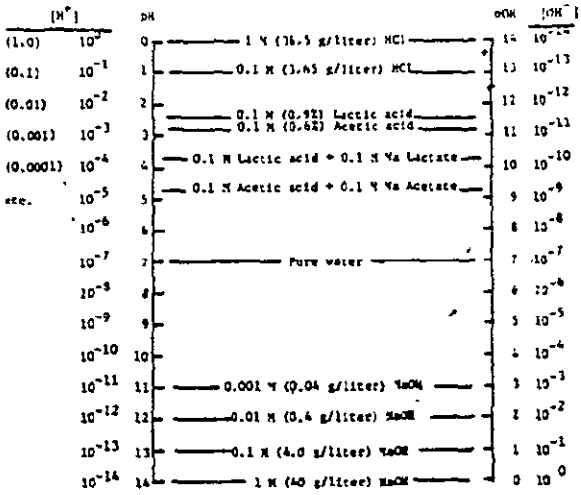


Fig. 3.1. The pH scale. $[H^+]$ = concentration of hydrogen ions (H^+) in moles per liter = gram H^+ per liter. $[OH^-]$ = concentration of hydroxyl ions (OH^-) in moles per liter = gram OH^- per liter divided by 17. The concentrations of acids indicated are for solutions in pure water.

concentration varies from 1 gram/liter to 1,/100,000,000,000,000 (10^{-14}) gram/liter. These are difficult figures with which to work but their logarithms (0 to −14) are quite simple. Since these are negative numbers and it is much easier to refer to positive whole numbers, pH was arbitrarily defined as equal to the negative logarithm of the hydrogen ion concentration (−log $[H^+]$. Converting negative numbers to positive ones results in the scale being inverse. Since it is a logarithmic scale, a change of 1 unit represents a 10X change in concentration.

The logarithm (log) to the base 10 of a number is the exponent of the power to which 10 has to be raised to produce a number. Following are a few examples:

Number	Log
$1{,}000{,}000 = 10^6$	6
$100 = 10^2$	2
$1 = 10^0$	0
$0.1 = 10^{-1}$	−1
$.001 = 10^{-3}$	−3
$.000{,}001 = 10^{-6}$	−6

Therefore, if the H^+ concentration is .001 gram/liter it is equal 10^{-3} gram/liter. The log of 10^{-3} is −3. Since the pH is equal the −log $[H^+]$, it is equal − (−3). A minus times a minus is a plus, so the pH is 3.0. See Fig. 3.1 for further examples.

While the concentration of H^+ in grams per liter is very low even at low pH, the numbers of hydrogen ions per liter are very high. (Table 3.1). One mole of a

TABLE 3.1

NUMBERS OF INDIVIDUAL HYDROGEN IONS (H^+) PER LITER OF SOLUTION AT VARIOUS pH LEVELS

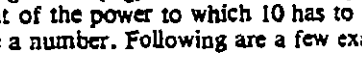
pH	Mole* H^+/liter	Billons of H^+/liter
0	10^{-0}(1)	602,000,000,000,000
2	10^{-2}(.01)	6,020,000,000,000
4	10^{-4}(.0001)	60,200,000,000
6	10^{-6}(.000001)	602,000,000
8	10^{-8}(etc.)	6,020,000
10	10^{-10}	60,200
12	10^{-12}	602
14	10^{-14}	6.02

*One mole of a compound is made up of six hundred and two thousand billion billions (6.02×10^{23}) molecules. Since a hydrogen ion (H^+) has a molecular (atomic) weight of 1, one mole weighs 1 gram.

compound (1 gram of H^+) consists of 6.02×10^{23} (602 thousand billion billions) molecules or ions, so even at pH 14 there are still over 6 billion H^+ per liter of solution.

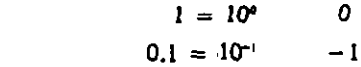
The pH scale goes from 0 to 14, and pure water has a pH of 7.0 which is right in the middle of the scale (Fig. 3.1). Pure water has a neutral pH. When an acid is added to water that solution becomes more acidic and the pH value decreases. When a base such as sodium hydroxide (NaOH or caustic soda) is added to water the solution becomes more basic and the pH value increases. Solutions with pH values above 7.0 are said to be basic or alkaline while solutions with pH values below 7.0 are said to be acidic.

Why choose a pH scale from 0 to 14? Why not 0 to 10? The reason is that the scale is based upon an important property of water. Pure water dissociates *very* slightly as follows:



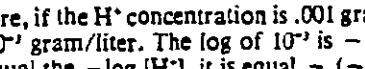
$$H_2O \rightleftharpoons H^+ + OH^-$$

At room temperature (22°C., 71.6°F.), the equilibrium is such that the concentration of H^+ is 10^{-7} molar (moles/liter) (10^{-7} gram H^+/liter) and the concentration of hydroxyl (OH^-) ions is also 10^{-7} molar (17×10^{-7} gram OH^-/liter).[2] Thus, the pH (−log $[H^+]$) is equal to 7.0 (neutrality). Similarly, the pOH (−log $[OH^-]$) is equal to 7.0. If we add a strong acid such as hydrochloric acid (HCl) to pure water, it dissociates as follows:



$$HCl \rightarrow H^+ + Cl^-$$

Thus, the pH decreases. Conversely, if we add a strong base such as sodium hydroxide (NaOH) to pure water, it dissociates as follows:



$$NaOH \rightarrow Na^+ + OH^-$$

[2]The weight of OH^- is 17 as compared to 1 for H^+.

Here, the OH^- concentration increases and the pOH decreases. An important property of water is that the concentration of either H^+ or OH^- depends on the concentration of the other; an increase in one results in a corresponding decrease in the other. The sum of the pH and pOH is always equal to 14 at any pH (see left and right columns of Fig. 3.1). Thus:

$$pH + pOH = 14$$

On the addition of an acid, the pH decreases and the pOH increases; and, conversely, on addition of a base the pOH decreases and the pH increases. Since the sum of pH and pOH is always equal 14, the only pH scale possible is 0 to 14.

Effects of different acids on pH: *A decrease of 1 pH unit means that the hydrogen ion concentration, [H⁺], has increased 10 fold* (Fig. 3.1) For example, a decrease in the pH from 6.0 to 5.0 means that the H^+ concentration has increased 10 times, and a decrease from pH 6.0 to 4.0 means that the H^+ concentration has increased 100 times. Decreasing the pH from pH 4.5 to pH 4.0 results in an increase in the H^+ concentration of over 3 fold. The rate of increase in H^+ concentrations goes up rapidly as the pH increments decrease (Fig. 3.2). If the

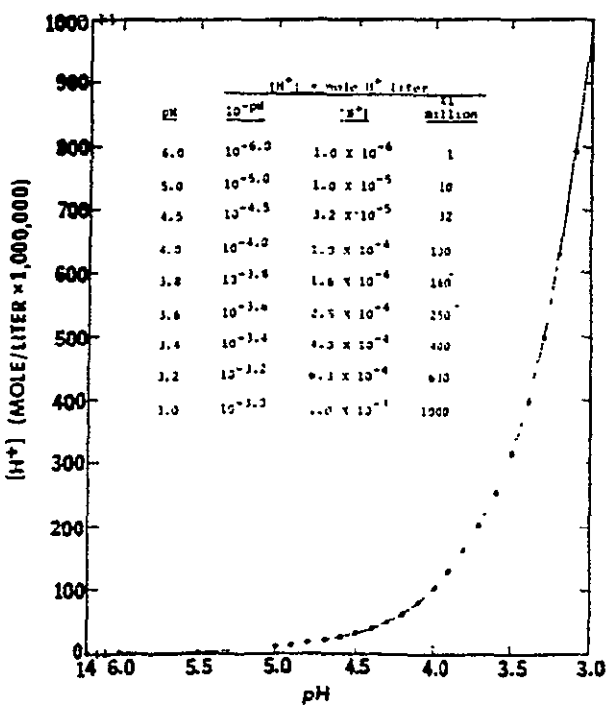


Fig. 3.2. Rate of change in hydrogen ion (H^+) concentration with change in pH.

H^+ concentrations in this figure were plotted on a logarithmic scale, a straight line plot would be obtained. pH is an exponential (logarithmic) scale.

The pH attained by adding different amounts of different acids to water is quite variable. Thus, the addition of 3.65 grams/liter (0.365%) hydrochloric acid (HCl) yields a pH of 1.0 while 0.9% lactic acid and 0.6% acetic acid only reduces the pH to about 2.5 and 2.8 respectively. There are two reasons for this: (1) the amount of a given acid required to supply 1 gram of H^+ varies with the size (molecular weight) of the acid, and (2) different acids vary in their tendency to give up H^+ in solution. These phenomena are illustrated in Fig. 3.3.

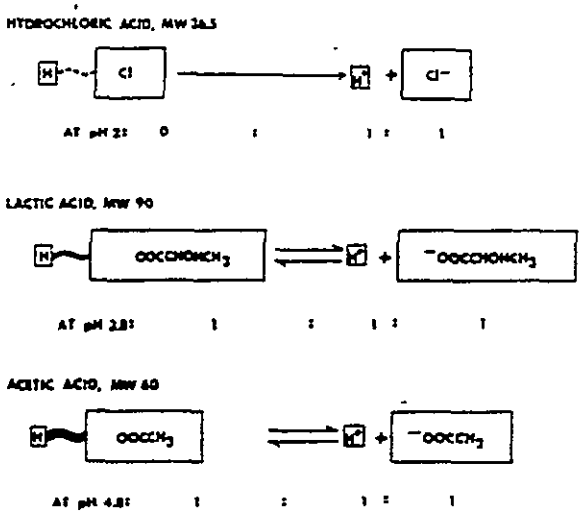


Fig. 3.3. Relative size and affinity for hydrogen ions of a mineral acid (HCl) compared to two organic acids (lactic and acetic acids).

The differences in size are readily apparent. Thus, 36.5 grams of HCl contains 1 gram of H^+, while 90 grams of lactic acid and 60 grams of acetic acid are required for each gram of H^+. Differences in tendencies to give up H^+ are represented in this figure by the width of the bonds in the undissociated molecules. Hydrochloric acid is a strong acid and has a weak attraction for the H^+. Only a very weak bond is found between the H^+ and chloride (Cl^-) ion. Thus, at relatively low concentrations in water, it completely dissociates. In contrast, both lactic and acetic acids are "weak" acids and have a relatively high affinity for the H^+. They form relatively strong bonds with H^+. Thus, when these acids are added to water, they only partially dissociate. Note in the figure that lactic acid forms a weaker bond with H^+ than does acetic acid; thus, lactic acid is a stronger acid than acetic.

The amounts of hydrochloric, acetic, and lactic acids necessary to add to *pure* water to attain various pH levels is given in Table 3.2. Note that at the higher pH

TABLE 3.2

AMOUNTS (GRAMS/LITER) OF HYDROCHLORIC, ACETIC, AND LACTIC ACIDS NECESSARY TO ACHIEVE A GIVEN pH WHEN ADDED TO PURE WATER

pH	HCl	Acetic	Lactic
6.0	.000036	.000063	.000091
5.5	.00013	.00023	.00029
5.0	.00036	.00093	.00098
4.5	.0013	.0054	.0035
4.0	.0036	.041*	.015
3.5	.013	.36	.086
3.0	.036	3.52	.66

*Note: Fresh pack pickles must have about 5 grams/liter (0.5% or 5 grains) of acetic acid to achieve pH 4.0.

levels, the differences in amounts required are due almost entirely to the differences in molecular weights of the acids. However, as the pH decreases, the required amounts of both acetic and lactic acids increase dramatically compared to HCl. This is because weak acids supply less and less H^+ as the pH decreases. It must be remembered that the values in Table 3.1 are valid only for pure water. As indicated in the footnote, the amount of acetic acid required to give a pH of 4.0 in fresh pack pickles is over 100 times that required in pure water.

The ratio of the amounts of acetic to lactic acids necessary to attain a given pH changes as the pH decreases (Table 3.2). At pH 6.0, more lactic acid is needed than acetic; but, at pH 3.0, one must add 5X more acetic than lactic acid. This is because lactic acid is a stronger acid (has less affinity for a H^+) than acetic acid.

Weak acids in solution dissociate and attain an equilibrium which is a constant for any given acid at a given temperature. This may be represented as follows:

Undissociated *Dissociated*

$$HA \rightleftharpoons H^+ + A^-$$

$$\text{Equilibrium constant } (K_{eq}) = \frac{H^+ \times A^-}{HA}$$

On examination of this simple equation, it is obvious that an increase in either H^+ or A^- or both must result in an increase in HA to maintain the equilibrium constant. If a constant fraction of an added acid dissociated, the product of $H^+ \times A^-$ would increase more rapidly than HA. To maintain the equilibrium constant, the relative amount of undissociated acid increases as increasing amounts of a weak acid are added to solution. The relation of the extent of dissociation of acetic and lactic acids and of hydrochloric acid in water solutions at various pH levels is shown in Fig. 3.4. Note that a

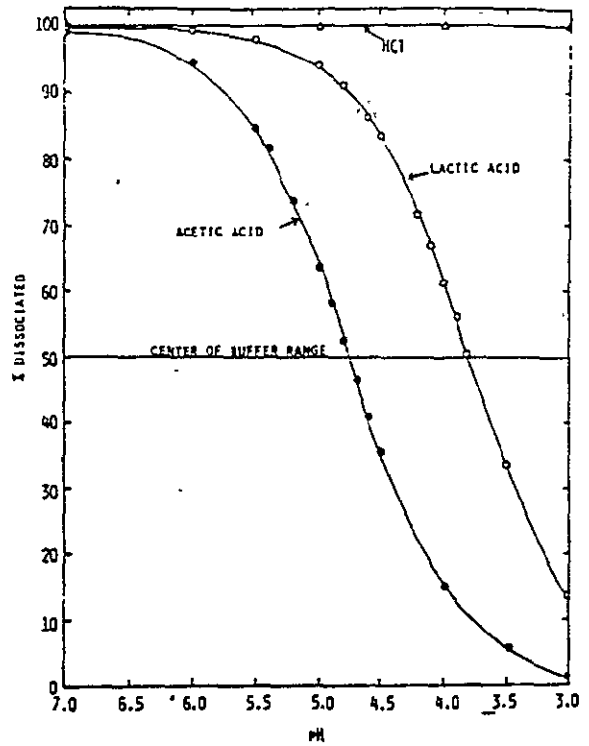


Fig. 3.4. The extent to which a mineral acid (HCl) and two organic acids dissociate (release H^+) at various pH levels.

strong acid (HCl) dissociates completely even at low pH levels, while the extent of dissociation of acetic and lactic acids decreases rapidly as the pH decreases. Also, note that lactic acid is a stronger acid than acetic acid, since it is still about 90% dissociated at the pH where acetic acid is only 50% dissociated.

Buffers

Definition: Webster's dictionary defines buffers as anything "serving to deaden a shock or bear the brunt of a collison." Thus, a front bumper on a car bears the shock of someone hitting your car and resists a change in the radiator. In exactly the same way, a pH buffer bears the shock of adding either an acid or a base to a solution and resists a change in pH. Chemically, buffers are solutions of weak acids or weak bases and their salts.

How buffers act: Fig. 3.1 shows that a 0.1 molar solution of either acetic or lactic acids in water results in lower pH values than solutions containing the same amounts of each acid along with an equal molar amount of the corresponding salts. The reason for this can best be understood by examination of the following two equations:

$$(1)\ HA \rightleftharpoons H^+ + A^-$$

$$(2)\ NaA \rightarrow Na^+ + A^-$$

As noted above, the value of $H^+ \times A^-/HA$ is a constant for a weak acid. Salts, in general, completely ionize (dissociate) when dissolved in water, equation (2). Thus, when the sodium salt (NaA) of an acid is added to a solution it increases the value of A^- in the solution and

shifts the reaction in equation (1) to the left increasing the level of HA and resulting in the removal of H^+ from solution. This explains why the acid alone yields a lower pH than when it is combined with its salt. If a base such as NaOH is added to a solution of the acid, it dissociates into Na^+ and OH^-. The OH^- reacts with some of the H^+ to form water and the result is a shift of the reaction in equation (1) to the right, releasing more H^+. Addition of HCl would shift reaction (1) to the left, as a result of an increase in H^+ concentration, and absorb some H^+. In this way, the buffer resists a change in pH on addition of either an acid or a base.

Buffering activities of different salts: Different weak acids and their salts buffer at different pH levels. The stronger the acid, the lower the pH level at which it buffers. The buffering actions of salts of phosphoric acid ($H_2PO_4^-/HPO_4^=$), acetic acid (CH_3COOH / CH_3COO^-) and lactic acid ($CH_3CHOHCOOH/CH_3CHOHCOO^-$) are illustrated in Fig. 3.5. As indicated, each acid

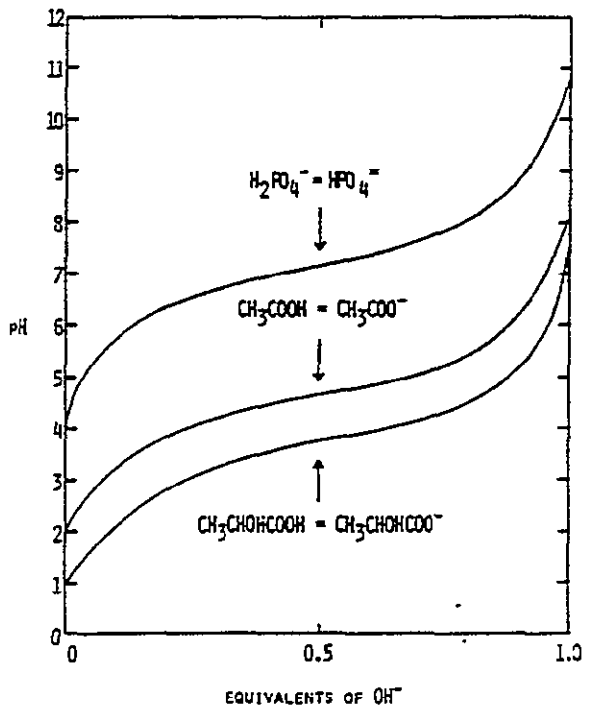


Fig. 3.5. Titration curves of different buffers. The arrows indicate the points where the acids were 50% titrated. This represents the center of the buffer range for each acid. The concentrations of salt and acid are equal at this point.

buffers in a characteristic range which extends over about 2 pH units and each is most effective in the center of the range. Thus, the phosphate buffer is most effective at pH 7.2 and has a buffer range from about 6.2 to 8.2; acetate is most effective at pH 4.76 and lactate at about 3.8. The center of the buffer range corresponds to the point where the acids are 50% dissociated (see Fig. 3.3).

An example of the buffering action of lactic acid is illustrated in Fig. 3.6. In this experiment, 11 liters of "spent" salt-stock brine were titrated with 2N NaOH, and the pH recorded after addition of various amounts of the base. The brine was strongly buffered up to about pH 4.7; 200 ml of 2N NaOH were required to increase the pH by 1.2 units. This was due to the lactic acid in the brine (see Fig. 3.5). After leaving the buffer range for lactic acid, the pH incresed much more rapidly indicating relatively little buffer capacity.

Buffer strength: Buffer strength can be measured in terms of the amount of acid or base necessary to bring about a 1 unit change in pH. The strength is largely determined by the concentration of the buffer. If the concentration of lactic acid in the brine titration, Fig. 3.6, had been doubled, it would have required about

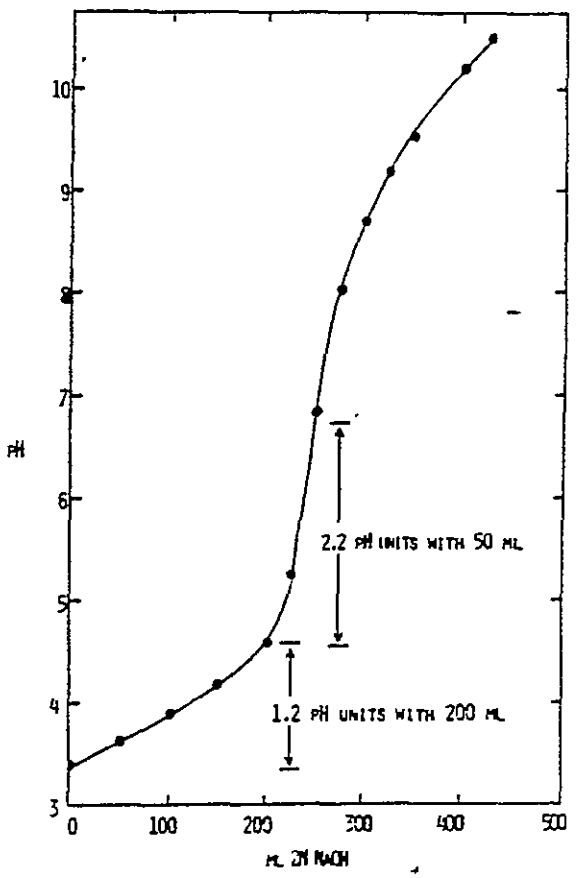


Fig. 3.6. Typical titration curve of "salt stock" pickle brine. Eleven liters of brine were titrated using a pH meter.

two times the amount of base to titrate it to pH 4.7. The base required to titrate from pH 4.7 to 7.0 would have been about the same.

All living tissues are highly buffered, and therefore much more acid is needed to attain a given pH when added to such tissue than when added to water. As indicated in Table 3.2, *approximately 100X more acetic acid is needed to obtain a pH of 4.0 in a jar of fresh pack pickles than in the same amount of pure water.* This is the effect of buffers. The more pickles present in a jar, the more buffer present, and the more acid required to attain a given pH.

Variability of pH and Acidity

The final equilibrated pH and acidity of pickled, fermented and acidified foods are influenced by a variety of factors. The primary variables are as follows:

1. The kind and amount of acid used.
2. The kind of raw material.
3. The size and shape of raw material and how tightly it is packed.
4. Other ingredients added.
5. Residues from pretreatment such as from caustic peeling.

Because of the differences in sizes (molecular weights), ⅓ more lactic acid than acetic acid is required to provide the same titratable acidity. However, since lactic acid is a stronger acid when the pH is below 4.5, the final pH achieved at a given titratable acidity may be lower with lactic than with acetic acid (Table 3.2). This table also shows that the amount of acetic or lactic acid required to result in a unit change in pH increases dramatically as the pH decreases.

Different fruits and vegetables vary in their initial pH and in their buffering range and capacity. The size and stage of maturity of the raw product also affect these variables. Small cucumbers have a higher buffering capacity than larger ones.

The ratio of product to liquor has a pronounced effect on the final acidity and pH of many products. This is of particular importance when the product is being acidified in the container. With a constant amount of acid in the cover brine or syrup, a tight pack may result in low acidities and high pH levels. This variable becomes very critical with a product being acidified to pH levels approaching 4.6. It is unsafe to have even an occasional jar above pH 4.6.

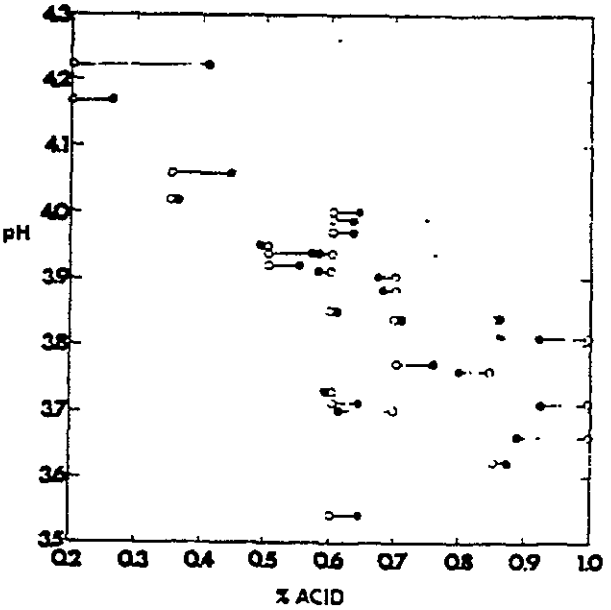


Fig. 3.7. Equilibrated pH and titratable acidity (% acid) in pasteurized cucumber pickles. Individual values plotted represent the averages of measurements made on 3 jars of non-spoiled pickles after 6 months storage. The closed circles are the measured values of both pH and titratable acidity. The open circles are the percent acid levels which were desired plotted against the final pH levels. Corresponding desired and equilibrated acidity levels are connected by horizontal lines.

The variation in pH and acidity which may occur in pasteurized fresh-pack dill pickles is illustrated in Fig. 3.7.[1] These jars (32 oz.) were carefully hand packed with a measured amount of brine containing the vinegar necessary to equilibrate at the desired acidity levels. The data presented are the mean pH and acidity levels from 3 non-spoiled jars after 6 months storage. Individual jar variation would still be greater than indicated. The cucumbers used in these experiments were not blanched which may have accounted for some of the variation. However, these data illustrate the basic problem of pH variation even at constant acidity in this type of product. The pH varied from 3.54 to 4.0 with final titratable acidities of 0.6 to 0.64 percent. Attempting to add just enough acid to individual containers to equilibrate at pH 4.5 would be impractical and dangerous. When a final pH approaching 4.6 is desired, the acidification and equilibration should be accomplished prior to packaging.

The addition of salt or alum to foods tends to decrease the pH. However, the amounts added to finished products are too low to have pronounced effects. They cannot be relied on to reduce the pH to a safe range.

Summary

1. Acids are compounds which have one or more H^+ which are released to some extent in solution. Bases are compounds which release hydroxyl ions (OH^-).

2. The titratable acidity is a measure of all the available H^+ in solution and is expressed as percent (weight/100 ml volume) of the acid in solution or as grains of acid (% X 10).

3. Mineral acids are strong acids and dissociate completely in solution, while organic acids are weak acids and only partly dissociate in solution.

4. pH is a *measure* of hydrogen ion activity. For practical use, it is a measure of the hydrogen ion concentration, $[H^+]$. Numerically it is equal to the negative logarithm of the H^+ concentration ($-\log [H^+]$). It is quite different from the total acidity as determined by titration.

5. The pH scale covers the range from 0 to 14. A pH of 7.0 is neutral and the H^+ and hydroxyl (OH^-) ion concentrations are equal.

6. As the H^+ concentration increases the pH decreases; as the OH^- increases the pH increases (the H^+ concentration decreases). pH is an inverse scale.

7. Solutions with a pH below 7.0 are said to be acidic while solutions with a pH over 7.0 are said to be basic or alkaline.

8. A change of 1 unit on the pH scale represents a 10 fold change in the H^+ concentration. For example, a change from pH 6.0 to 5.0 represents a 10X increase in the H^+ while a change from 6.0 to 4.0 represents a 100X increase in H^+ concentration.

9. Strong acids dissociate completely in dilute solutions, which makes it simple to calculate the amount of acid required to supply a given concentration of H^+ in pure water.

[1]Data from Monroe, R.J., J.L. Etchells, J.C. Pacilio, A.F. Borg, D.H. Wallace, M.P. Rogers, L.J. Turney, and E.S. Schoene, 1969. Influence of various acidities and pasteurizing temperatures on the keeping quality of freshpack dill pickles. Food Technol. 23:71-77

10. Weak acids such as acetic and lactic acids, have a high affinity for H^+, and only partially dissociate. The lower the pH of a solution, the lower the extent of dissociation of weak acids.

11. The amount (%) of an acid which must be added to a solution to achieve a given pH depends on (a) the size (molecular weight) of the acid, (b) the degree to which the acid dissociates (releases H^+) at various H^+ concentrations, and (c) the type and amount of buffer which is present.

12. With weak acids such as acetic and lactic acids, the lower the pH of a solution, the more acid required to depress the pH of a given amount.

13. A pH buffer is a compound which resists a change in the pH on addition of either an acid or a base to the solution.

14. Common buffers are solutions of weak acids or bases and their salts.

15. Different buffers are effective at different pH levels and buffer over a range of about 2 pH units.

16. All living tissues including fruits and vegetables are highly buffered. The more tissue present in a jar, the greater the buffering action.

17. About 100X more acetic acid is needed to attain a pH of 4.0 in fresh pack pickles than in the same amount of pure water.

18. The equilibrated pH of a food will be influenced by:

a. The kind and amount of acid used.
b. The kind of raw material.
c. The size and shape of raw material and how tightly it is packed.
d. Other ingredients added.
e. Residues from pretreatment such as from caustic peeling.

19. A great amount of variation in the equilibrated pH of individual containers may occur when the product is acidified in the jar.

20. Foods having an equilibrated pH approaching 4.6 should be acidified and equilibrated before final packaging.

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Chapter 4
MEASUREMENT OF pH AND ACIDITY

Methods for determinations of pH and acidity of acidified foods are described in Section 114.90 of the Food and Drug Administrations Good Manufacturing Practices. These should be studied carefully. Principles of some of these methods will be discussed in more detail below.

Preparation of Samples

Sampling procedures used for foods are of primary importance. Except for juices, most foods are mixtures of solids and liquids and therefore non-homogeneous. It is imperative that all aqueous phases of acidified foods have a pH of 4.6 or below. Therefore, in some instances it is necessary to sample separately solid and liquid phases. Where equilibration readily occurs as in cucumber pickles, the contents of an entire container can be blended to measure the equilibrated pH and acidity. Oil in marinated products may interfere with acidity and pH determinations, and it should be separated from samples.

Potentiometric Method for Determining pH

Components and principles of operation: The most accurate method of measuring pH is with a pH meter. There are many instruments in use that appear different, but all have basically the same components and operate in a similar manner. The meter measures an electrical signal (potential) from the electrodes as a result of changing pH. It is a simple millivolt meter with a readout in pH units from 0 to 14. This readout may be either digital (numbers) or analog (needle pointer and scale). The basic components of the entire system are illustrated in Fig. 4.1.

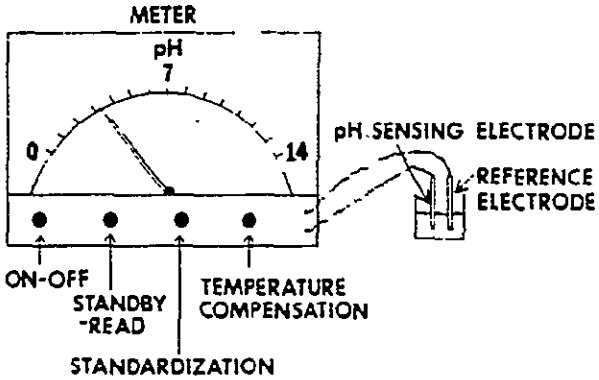

Fig. 4.1. Basic components of the pH meter.

The millivolt signal measured by the meter is generated at the glass electrode as a response to differences in pH is described by the Nernst equation as:

$$E = E_e + KT \log H^+$$

where E = millivolts (mv) measured

E_e = constant potential corrected for by the reference electrode

K = a constant

T = temperature (degrees Kelvin)

H^+ = hydrogen ion activity.

The importance of temperature is obvious from this equation. At 25 °C (77 °F) there is a potential change of 59 mv per pH unit while at 0 °C (32 °F) and 100 °C (212 °F) the changes are 54 and 74 mv/pH unit respectively. As evident in Fig. 4.2, the further away the solution is from neutral pH (pH 7.0), the greater effect temperature has on the potential generated.

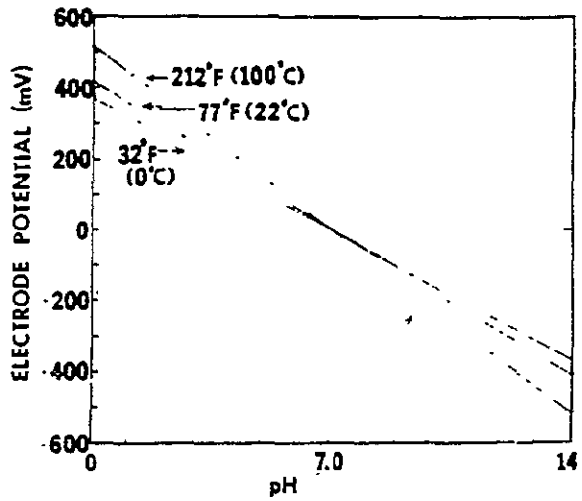

Fig. 4.2. Effect of temperature on the pH electrode potential at various pH levels.

The pH sensing electrode is called the glass electrode. The tip of this electrode is made of very thin pH-responsive glass. The electrode is filled with a buffer in which a silver wire coated with silver-chloride is immersed. This electrode is completely sealed.

The other electrode is the reference electrode. It produces a reference potential against which the potential from the glass electrode is compared. There are two types in common usage. The calomel electrode consists of a mixture of mercury and mercuric chloride sealed in a glass tube. The other type is simply a silver wire coated with silver chloride. Both types are encased in a glass tube with a porous junction. The glass tube is filled with a saturated solution of potassium chloride (KCl) or 4M KCl saturated with silver chloride and must be refilled on occasion (follow the manufacturers instructions). It is critical that the porous junction remains open to allow a small amount of the KCl solution to flow into the sample. This is necessary to create the reference potential. When problems occur with an electrode system, in most instances they can be traced to the porous liquid junction of the reference electrode.

There are a number of combination pH electrodes in use which have both the glass and reference electrodes in one unit. Some of these are highly satisfactory, but are somewhat more expensive.

Care of instrument and electrodes: Most pH meters are rugged instruments. The manufacturers instructions should be followed carefully. If possible, the instrument should be stored in a room with a relatively low relative humidity. High humidity can create problems with almost all electrical systems.

Electrodes should be handled with care. New reference electrodes should be filled and new glass electrodes soaked according to manufacturers recommendations. When not in use, they should be immersed in a solution. Some manufacturers suggest storing electrodes in pH 7.0 buffer and others recommend dilute HCl or buffer at about pH 4.0. Follow the instructions provided.

Wash electrodes between samples with distilled water from a wash bottle and blot, not wipe, the excess water from them. Alternatively, if you have large samples, rinse the electrodes with the next sample.

If the time required for the instrument to stabilize at a given pH is greater than 20-30 seconds, the glass electrode may need cleaning. Gently wipe the tip of the glass electrode with tissue paper saturated with a 75% solution of methanol. Immerse the electrode in 0.1M HCl for 5 minutes, rinse with distilled water and soak in buffer overnight. Whenever organic solvents such as ethyl ether are used to clean oil or grease from an electrode, the electrode should be soaked in buffer several hours before use.

Standardization and measurements: It is absolutely necessary that a pH meter be standardized for accurate pH measurement. How frequently this is required will vary with the use and with the particular meter. An instrument should be standardized at least one time each day, and more often when indicated. When samples contain oil or grease which coat the electrodes, the meter should be standardized after every 2 or 3 determinations. When the pH level of an acid food is near the critical pH of 4.6, it would be advisable to standardize the meter before and after each sample. When working buffers are used for frequent standardization checks, they should be checked at least once each day against National Bureau of Standards reference buffers.

At least two buffers at very different pH levels should be used for standardization. After the meter is standardized at pH 4.0, it should read within ± 0.3 pH unit in [illegible] 9.18 Th[illegible] [illegible] ru[illegible]ment is responding properly. If it is not, the instrument should be adjusted according to the manufacturers directions.

The temperature of the buffers used for standardization and of the sample must be the same. If the instrument is standardized at room temperature, attempts to measure the pH of a sample at a much higher temperature by merely resetting the temperature control on the meter will be inaccurate. The hydrogen ion activity (pH) changes with temperature. Therefore, the pH will not be the same at a high temperature as at room temperature. When possible, the pH meter, electrodes, standard buffers, and unknown samples should be at the same temperature.

Other factors which may have some effects on pH determinations are the use of stirrers and the ionic strength (salt concentration) of the sample. If a magnetic stirrer or other device is used while measuring the pH of a sample, it should also be used during standardization. High salt concentrations influence pH measurements but usually not to any great extent. For the greatest accuracy, the ionic strength of the standardizing buffers should be about the same as that of the samples.

Colorimetric Estimation of pH

Section 114.90(b) of the GMP states that a colorimetric method may be used for pH determination if the pH is below 4.0. These procedures are exceedingly simple, rapid, and inexpensive, and should be applicable to a large number of acidified foods. Samples to be used for these determinations must be prepared in the same manner as those for the potentiometric method.

Indicator solutions: Different indicator dyes change color over different pH ranges. Since this method of pH estimation can only be used with foods having a pH below 4.0, the most useful dyes are those that change color most rapidly between pH 3 and 4.5. Brom phenol blue is recommended since it has a useful pH range from 3.0 to 4.6, and color standards are commercially available at intervals of 0.2 pH unit.

As indicated in the GMP, estimates of pH may be made by comparing colors of samples mixed with dye in tubes or on spot plates with appropriate standards. However, comparator blocks are more accurate and they are inexpensive and readily available. These would be particularly appropriate for use with samples in which the pH approaches 4.0. Highly colored samples may interfere with this method.

Indicator paper: Rolls of pH paper of the appropriate range, pH 3.0-5.0, are available and are reasonably accurate. A piece of paper is torn off, dipped into the sample, and the color, which develops immediately, is compared to color standards accompanying the paper. This is the most rapid of all the methods and is quite appropriate for samples with pH values which are known to be low (≤4.0).

Titratable Acidity

Although pH cannot be measured by determining the total acid content, it is the acidity which produces the low pH. A given level of total acidity can be relied on to reduce the pH of a specific product to at least some maximal value. This relationship can be readily [illegible] [illegible] f[illegible] [illegible]vid[illegible] product. For products

below pH 4.0, titratable acidity may be used for process control and for certification of final maximal pH. The total acidity is critical not only for controlling pH, but for preserving the product and producing flavor. For these reasons, accurate determination of the acid levels must be made at all stages of manufacturing as well as on the finished product.

Principle: Titratable acidity is a measure of essentially all of the available hydrogen ions (H^+) in a solution. This includes not only the free H^+ present at the start of the titration, but also those which dissociate as the titration proceeds. As pointed out in Chapter 3, food acids such as acetic and lactic acids are largely undissociated at low pH, but become completely dissociated as the pH approaches neutrality. When a base such as sodium hydroxide (NaOH) is added to an acid solution, it dissociates into Na^+ and OH^- ions and the OH^- combines with the H^+ to form water resulting in an increase in pH. By using a solution of a base with a known amount of OH^- in a given volume (a standard solution), one can determine the number of H^+ present (both dissociated and undissociated) in excess of those in pure water. A pH indicator (phenolphthalein) is used during the titration and becomes pink in color when the pH exceeds 8.2. This is known as the phenolphthalein end point.

Standard solutions: A standard solution of a base used for titration is expressed in terms of normality (N). The normality of a solution is equal to the number of gram equivalents of H^+ it will supply or react with per liter of solution. In the case of sodium hydroxide (NaOH), each molecule will supply one OH^- which will react with one H^+. The modecular weight of NaOH is 40 and the atomic weight of H^+ is essentially 1. Therefore, a water solution containing exactly 40 grams of NaOH in exactly 1 liter total volume has a normality of 1. Therefore, for NaOH:

$$N = \frac{\text{grams/liter total volume}}{40}$$

The problem with preparing standard solutions of NaOH is that the crystalline compound is not pure. NaOH pellets and solutions absorb carbon dioxide and moisture from the air. This results in the formation of carbonates. Therefore, special procedures must be used for preparing and standardizing solutions. These procedures are detailed in the 12th edition of Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) 1975, sections 50.032-50.035, page 946. They will not be reproduced here. Standard solutions are also available from commercial sources.

Titrations: Samples prepared in the same manner outlined for pH determinations should be used for titrations. Liquid samples should be measured accurately with appropriate pipettes, while slurries of blended samples should be weighed.

It is frequently useful to add a measured volume of distilled water to colored samples and to samples containing considerable solid material. This will make no difference in the titration, but will make it easier to observe the color change of the pH indicator. In instances where the pH change cannot be observed with ease, the titration should be conducted with a pH meter. It is convenient to stir the sample with a magnetic stirrer and titrate the sample with the pH electrodes immersed in it. Titration should proceed to a pH of 8.2, the point at which phenolphthalein becomes faintly pink.

Detailed procedures for titration are outlined in the 12th edition of AOAC, 1975, sections 22.060-22.061, page 401.

Calculations: The total titratable acidity is commonly expressed in terms of the predominating acid known to be present. The basic equation used for this calculation is as follows:

$$\% = (\text{weight of acid/volume of solution}) \times 100 = \frac{N_{NaOH} \times \text{ml NaOH} \times \text{equivalent weight of acid}}{\text{ml sample} \times 10}$$

where the equivalent weight of the acid is equal to the molecular weight divided by the number of H^+ which it can supply per molecule (= grams acid/gram H^+). This equation is a combined version of the following relationships:

N_{NaOH} = grams H^+ that 1 liter of NaOH solution will react with

$N_{NaOH}/1000$ = grams H^+ that 1 ml of NaOH solution will react with

$\frac{N_{NaOH}}{1000} \times$ ml NaOH used in titration = grams H^+ titrated

$\frac{\text{grams } H^+ \text{ titrated}}{\text{ml sample titrated}} \times 100$ = grams H^+/100 ml

grams H^+/100 ml X equivalent weight of acid = grams acid/100 ml = %

In the case of acetic and lactic acid the equivalent weight equals the molecular weight, while the equivalent weight of citric acid is ⅓ of the molecular weight. Since the molecular weight of acetic acid is 60 and that of lactic acid is 90, the ml of a standard base used to titrate a given volume of a solution of 0.6% acetic acid would be the same as for a solution of 0.9% lactic acid. The calculations can be further simplified by selection of the normality of the NaOH used. If 0.1667 N NaOH is used to titrate samples containing acetic acid, the ml NaOH used divided by the ml of sample equals % acetic acid. If a 10 ml or 10 g sample is used, the ml NaOH used equals grains of acetic acid. The same relationships exist for lactic acid if 0.1111 N NaOH is used in the titration.

Summary

1. Procedures for preparing samples and measuring pH and acidity are specified in Section 114.90 of Good Manufacturing Practices, and these should be followed carefully.

2. All aqueous phases of acidified foods should be at pH 4.6 or below. Therefore, solid and liquid phases must be sampled separately for pH determinations.

3. The pH meter is a millivolt meter which measures an electrical signal from the electrodes resulting from a change in pH.

4. Temperature directly affects the change in voltage per pH unit. The further away from neutral pH (pH 7.0) that the solution is, the greater effect temperature has on the voltage generated and, thus, on the pH measurement itself.

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5. The pH-sensing electrode is the glass electrode. The tip of this electrode is made of very thin pH responsive glass.

6. The other electrode is a reference electrode and is filled with a saturated solution of potassium chloride (KCl) or with 4M KCl saturated with silver chloride. It has a small porous junction which must remain open to allow a small amount of the KCl solution to flow into the sample. This electrode must be refilled occasionally.

7. Combination electrodes have both types of electrodes in a single unit.

8. Electrodes should be treated according to manufacturers recommendations.

9. Electrodes should be handled with care, kept immersed in buffer when not in use, washed between samples with distilled water and blotted dry.

10. When necessary, glass electrodes should be cleaned by wiping carefully with tissue paper saturated with methanol (methyl alcohol), immersed 5 minutes in 0.1M HCl, rinsed with water, and soaked in buffer overnight.

11. The pH meter should be standardized frequently using two buffers. Whenever there is any doubt about the meter accuracy, it should be standardized.

12. The temperature of the buffers used for standardization and that of the sample must be the same.

13. If a stirrer is to be used while measuring the pH of the sample, a stirrer should also be used in the buffers for standardization.

14. The pH of foods with a pH below 4.0 may be estimated by use of a pH responsive dye or by pH paper. Titratable acidities may be used to control maximal pH's when they are below 4.0. In case of doubt, a pH meter should be used.

15. Standard solutions of sodium hydroxide used for acid titrations should either be purchased commercially or prepared by official procedures. Solutions should be protected from constant exposure to the air.

16. A pH meter should be used for titrations of samples when color changes are difficult to see.

Chapter 5

EFFECTS OF pH, ACIDS, FOOD PRESERVATIVES, SALT AND SUGAR ON MICROORGANISMS

Some acidified and fermented foods are preserved without exposure to any heat processing. Others are heated but at temperatures much too low to preserve non-acid foods. The primary factors responsible for the protection of these foods from spoilage by microorganisms are low pH, high acidities, presence of food preservatives, and/or high salt or sugar concentrations. No single one of these factors can be relied on alone since there are microorganisms which are adapted to all natural extreme environments. However, they can be extremely effective when used together in an appropriate manner. To do this, it is necessary to understand how each of these factors affect microorganisms alone, and how the different factors influence the effectivensss of each other.

pH

Responses of microorganisms to pH: Each microorganism has an optimum pH range for growth and most organisms can grow only over a rather narrow pH range (3 to 4 units). Most organisms grow best at pH values near neutrality (pH 7.0), but there are species which will grow at pH 1.0 and others which grow at pH 13. Fortunately, organisms growing at the extremes are not of major concern to food processors. In fact, there are relatively few groups of bacteria which will grow at pH values below 4.6, and none of these are of public health significance. The lactic acid producing bacteria are the most common ones which will grow at low pH, and the pH is depressed still further during their growth.

However, most yeasts and fungi actually grow best in an acid environment (pH 4.5 - 6.0), and many will grow well at pH levels down to 3.0. If oxygen is present in the food, many yeasts and molds will use the acid for growth and increase the pH. Therefore, acid foods should not be exposed to air for extended periods unless other precautions are taken to prevent yeast and mold growth. Fermentative yeasts will grow well at low pH in the absence of air if sugar is present. Other procedures must be used to prevent their growth.

Low pH not only prevents the growth of many microorganisms, but will also kill many cells. High H^+ concentrations are effective in denaturing proteins as [illegible] by [illegible] w [illegible] it so[illegible]s. Similarily, many of the proteins of cells, including the cell machinery (enzymes), are strongly inhibited or denatured (inactivated) at low pH levels.

This pH effect on cells is greatly enhanced as the temperature increases. Microorganisms are much easier to kill with heat at low pH than at high. This effect is very dramatic (Fig. 5.1). Pasteurization temperatures

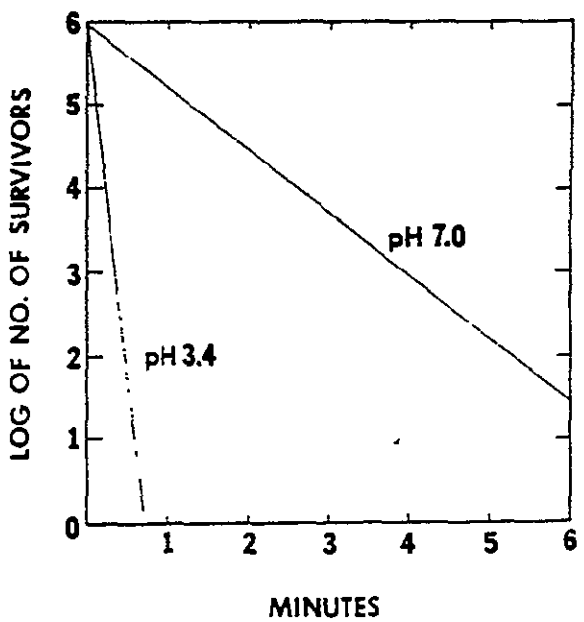

Fig. 5.1. Effect of pH on the rate of death of cells of a *Lactobacillus* at a temperature of 160°F.

and heating times must be adjusted dramatically even with relatively small changes in pH. This holds true for bacterial cells, yeasts and molds. Bacterial spores also become less heat resistant as the pH is decreased. However, pasteurization temperatures cannot be relied on to kill them. Fortunately, most bacteria which form spores cannot grow at pH 4.6 or below.

pH classes of foods: Table 5.1 gives a classification of

TABLE 5.1

pH CLASSES OF FOODS, SPOILAGE ORGANISMS, AND RELATIVE HEAT RESISTANCES OF ORGANISMS

Food class	pH range	Spoilage organisms	Minutes to kill at various temperatures		
			250°F	212°F	160°F
Low acid and semi-acid	Above 4.6	Thermophilic spores	5	Infinite	Infinite
		Mesophilic spores including *C. botulinum*	0.1	300	Infinite
Acid	4.0–4.6	Thermophilic spores	0.05	20	Infinite
		Mesophilic spores (Butyric anaerobes)	–	0.5	500
		Lactic acid bacteria	0	<0.1	1-5
High acid	Below 4.0	Lactic acid bacteria, yeasts, and molds	0	<0.1	1-5

foods based on pH and the relative heat resistance of the more heat resistant microorganisms which can grow in them. In low-acid foods above pH 4.6, the destruction of even those spores which can grow at ordinary storage temperatures, including *Clostridium botulinum*, requires heating at temperatures well above boiling. Boiling has little or no effect on these spores. Fortunately, at pH 4.6 and below *Clostridium botulinum* cannot grow and produce toxin even if the spores survive the heating process. However, there are some spore forming bacteria which can grow and cause great difficulty in some acid foods (pH 4.0 to 4.6). The butyric anaerobes can produce some vile-smelling pickles. With the advent of low acid pickles (acid foods, pH 4.0 to 4.6) it is probable that these organisms will become a problem. The pasteurization process used for pickles isn't high enough to destroy these spores, and they can grow in pickles if the acid is too low. Pickles have been treated as high-acid foods for years and preservation methods have developed accordingly. If they move up into the lower acid range, the temperature of pasteurization should be greatly increased. As an example, a relative heat resistance of 0.5 at 212°F would be equivalent to about 500 at 160°F. Bacterial spores are activated at 160°F, not killed.

Acids

Acids may inhibit or kill microorganisms by virtue of (a) the increase in hydrogen ion (H^+) concentration (decrease in pH), (b) the concentration of undissociated acid, and/or (c) the concentration of some characteristic anion (negatively charged ion). Inorganic acids inhibit microbes by supplying hydrogen ions (low pH). The pH necessary to effectively inhibit microorganisms with inorganic acids is quite low compared to that required to inhibit with organic acids. The relative effectiveness of acids will vary from one organism to another and, also, with the conditions under which they are tested. A comparison of the effectiveness of organic acids (acetic and lactic) with an inorganic acid (HCl) at various pH levels in inhibiting and killing one bacterial species is given in Table 5.2. These data show that the organic acids

TABLE 5.2

COMPARATIVE EFFECTS OF ORGANIC AND INORGANIC ACIDS ON *STAPHYLOCOCCUS AUREUS*[a]

Acid	pH Inhibiting	pH Killing
Acetic	4.6(1)[b]	4.4(1)[b]
Lactic	4.3(2.5)	3.8(2.6)
HCl	2.9(50)	2.4(66)

[a]Data from Nunheimer and Fabian, Michigan State University, M.S. Thesis, 1938.

[b]Numbers in parentheses indicate relative H^+ concentrations.

exerted a great effect on this organism at H^+ concentrations 1/20th to 1/60th that necessary with an inorganic acid. Therefore, the H^+ level is not the only factor involved.

The differences between organic and inorganic acids are primarily (a) the difference in the anion (negatively charged ion) and (b) the degree to which the ions dissociate. These differences are illustrated in Table 5.3.

TABLE 5.3

INORGANIC VS ORGANIC ACIDS

Type of acid	Undissociated acid	Hydrogen ion	Anion	% Dissociated
INORGANIC:				
Generalized	$HA \rightarrow$	$H^+ + A^-$		[a]>95, pH 2.0
Hydrochloric	$HCl \rightarrow$	$H^+ + Cl^-$		>95, pH 2.0
Sulfuric	$H_2SO_4 \rightarrow$	$2H^+ + SO_4^{=}$		>95, pH 2.0
ORGANIC:				
Generalized	$HA \rightleftharpoons$	$H^+ + A^-$		[a]<50, pH 3.0
Acetic	$CH_3COOH \rightleftharpoons$	$H^+ + CH_3COO^-$		50, pH 4.76
Lactic	$CH_3CHOHCOOH \rightleftharpoons$	$H^+ + CH_3CHOHCOO^-$		50, pH 3.86

[a]> = greater than; < = less than

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Note that the inorganic acids dissociate to essentially 100% at even very low pH values, while the extent of dissociation of organic acids depends on the pH of the medium and the particular acid in question. At pH's near neutrality, most common organic acids are almost completely dissociated. Conversely, at low pH's they are almost completely undissociated. Each acid has a characteristic pH at which it is 50% dissociated (see Table 5.3). When the pH is increased by 1 unit above the point where the acid is 50% dissociated, the acid will be about 90% dissociated. At 1 pH unit below the 50% point, the acid will be only about 9% dissociated. For further discussion, see Chapter 3.

Cells of microorganisms are adept at protecting their machinery inside the cells. Only certain kinds of compounds can get in and out. The cell surface is negatively charged, and this repels negatively charged molecules. Still more complex mechanisms are used by the cell to keep out positively charged molecules like H^+ ions. The internal pH of healthy bacterial cells is maintained at about neutrality (pH 7.0) and that of yeasts and filamentous fungi at about pH 6.0. Cells are normally impermeable to dissociated acids (the acids cannot diffuse into the cells), but they are permeable to undissociated acids. In fact, cells may concentrate organic acids inside the cell. Once the undissociated acid enters a cell it may become mostly dissociated in the internal environment at high pH, and then cannot get back out of the cell. This may be the mechanism by which common food acids such as acetic and lactic acids kill cells—they may be concentrated sufficiently to overcome the buffering capacity of the cell and alter the pH to the extent the cell cannot metabolize. It is not known for sure how these acids work, but it is known that the effectiveness of any one organic acid is directly related to the amount of the acid in the undissociated form, which is directly dependent on the pH.

There are differences in the effectiveness of the various organic acids, and the effectiveness of each acid may be quite different with different microorganisms. For example, Nunheimer and Fabian found that the decreasing order of germicidal activity on staphylococci of the acids tested was as follows: acetic > citric > lactic > malic > tartaric > hydrochloric. In contrast, Wadsworth and Fabian found that the decreasing order of some of these acids to inhibit yeast respiration was, acetic > hydrochloric > lactic > malic > tartaric. Thus, the results obtained may vary widely with the test organism and the conditions under which they are tested.

Food Preservatives

Types permitted: The chemicals approved for use as food preservatives and the concentrations allowed are listed in Table 5.4. Some of these have highly restricted use. Nitrates and nitrites are used only in cured meats; sulfur dioxide and sulfites in dehydrated fruits, wines, fruit juices, and sauerkraut; and calcium propionate in baked goods and cheese items. Use of ethylene oxide is restricted to walnut meats, copra, and whole spices. Sodium benzoate and potassium sorbate are used most widely in acid foods. Methyl and propylparaben are similar to benzoate in effectiveness when added to acid foods, and have the advantage of retaining their antimicrobial activity at higher pH levels than benzoate.

TABLE 5.4

FOOD PRESERVATIVES AND MAXIMUM CONCENTRATIONS ALLOWED

Preservative	Concentration
Sodium benzoate	0.1%
Methylparaben	0.1%
Propylparaben	0.1%
Potassium sorbate	0.1%
Calcium propionate	0.1%
Sodium nitrate	500 ppm
Sodium nitrite	200 ppm
Sulfur dioxide	variable
Ethylene oxide	50 ppm residue

Effects of pH on antimicrobial activity: The antimicrobial activities of sodium benzoate, potassium sorbate, and calcium propionate are very dependent on pH. These are all salts of organic acids. The salts dissociate completely in solution and the anions are in equilibrium with the undissociated acids. As shown in Table 5.5, the relative amount of the undissociated form is very dependent on pH. The lower the pH, the more undissociated acid present. Since the inhibition of microorganisms is directly related to the concentration of undissociated acid, it can be seen that benzoic and sorbic acids have little activity at pH 6.0 and above, and approach maximal effectiveness at pH 3.5. Benzoate is less than one-half and sorbate only about two-thirds as effective at pH 4.5 as at pH 3.5. As noted above, methyl- and propylparabens, while chemically related to benzoate, are not directly affected by pH because they are not acids.

Sulfur dioxide and sulfites form sulfurous acid in solution, and this is the active antimicrobial form. This acid acts very much like an organic acid, so the effectiveness of these compounds is very dependent upon pH.

Microorganisms affected: All food preservatives other than ethylene oxide function primarily by inhibition of microorganisms rather than by killing them. In every case there are certain microbes which are very sensitive and others completely insensitive to the chemical. The number of individual microbes studied with each preservative is very limited. It is known that benzoate, the parabens, and sorbate inhibit some but not all bacteria, yeasts, and molds. In general, potassium sorbate is more effective than sodium benzoate in protecting acid foods from yeasts and molds, while the opposite is true when bacteria are the major problem. Lactic acid bacteria are almost completely insensitive to sorbate, and some anaerobic bacteria, including *Clostridium botulinum*, can actually utilize this compound. In general, it must be realized that the addition of food preservatives cannot be relied on alone to

TABLE 5.5

EFFECT OF pH ON THE FORMS OF BENZOIC AND SORBIC ACIDS IN SOLUTION

Sodium benzoate:

$$COO^- + Na^+ + H^+ \rightleftharpoons COOH + Na^+$$

50% at pH 4.2

Potassium sorbate:

$$CH_3CH=CHCH=CHCOO^-K^+ + H^+ \rightleftharpoons CH_3CH=CHCH=CHCOOH + K^+$$

50% at pH 4.75

pH	% Active Form (HA)	
	Benzoate	Sorbate
6.0	1.6	5.3
5.0	14	36
4.5	35	64
4.0	62	85
3.5	83	95

preserve a food. Preservatives act in concert with low pH, presence of other organic acids, and other factors to enhance keeping quality.

Ethylene oxide is a very toxic gas and will kill all kinds of cells. It is used to sterilize plastics and other heat sensitive items. Thus, it has to be used under carefully controlled conditions, and its use in foods is very limited.

Salt

Salting is one of the oldest means of preserving foods. However, salt alone will not prevent the growth of all microorganisms. There are a number of bacteria and fungi which will grow in saturated salt solutions, and some bacteria called halophiles which require high concentrations of salt to grow. However, most salt tolerant organisms cannot grow at pH 4.6 and below.

Salt concentrations of 10% by weight (38° salometer[1]) and higher will inhibit practically all bacteria growing at pH 4.6 and below including all those of public health significance. However, there are a number of both fermentative and oxidative (film) yeasts which will grow at considerably higher salt levels than this. The fermentative yeasts will not grow when the sugar supply is exhausted, and the oxidative type may be controlled by maintaining anaerobic (oxygen free) conditions or exposing surfaces to direct sunlight or ultraviolet light. For example, in salt-stock pickle fermentations, sub-surface yeasts ferment all sugar not utilized by lactic acid bacteria and then stop growing. Tanks exposed directly to the sunlight do not develop scum on their surfaces, but if they are under cover or shaded most of the day, they quickly become covered with a film of surface yeasts even at high salt concentrations.

[1]Salometer equals percent saturation of a water solution of salt at 25°C (77°F). Salometer = 26.4 × % salt by weight in water.

It was pointed out in Chapter 2 that one of the ways salt inhibits microorganisms is by reducing the available water as indicated by the reduction of water activity (a_ω). The higher the salt concentration, the lower the a_ω level. However, many microorganisms will not grow at salt concentrations much lower than those necessary to reduce the water activity to an inhibitory point. For example, many molds which can grow at very low a_ω levels are completely inhibited by salt concentrations between 5 and 10 percent.

It is probable that salt solutions are inhibitory to many microorganisms because of high osmotic pressures. This results in the dehydration of the cell. Also, the chloride ion is toxic to some cells.

Sugar

Sugar inhibits microorganisms primarily by reducing the water activity. Thus, much higher concentrations of sugar are necessary to inhibit most microbes compared to salt (see Chapter 2, Table 2.2). Bacteria are the most sensitive to sugar and the fungi most tolerant. Some yeasts will grow in saturated sugar solutions but none have been found to grow in saturated solutions at pH 4.6 and below. Molds and other filamentous fungi will grow on the surface of saturated sugar solutions unless the solutions are protected from the air. These organisms will reduce the sugar concentration at the surface and make it possible for other organisms to grow.

Preservation prediction charts have been developed for sweet pickles for different levels of sugar and acetic acid with and without added preservatives, and these are available from Pickle Packers' International. These charts show clearly that the amount of sugar necessary to preserve sweet pickles decreases dramatically as the acetic acid concentration increases and vice versa. Also, the required amounts of both sugar and acid decrease

potassium sorbate instead of benzoate reduces the levels of sugar and acid required still further.

Summary

1. Most microorganisms prefer to grow at pH values near neutrality, but some exist which grow at extreme pH levels.

2. Yeasts and molds grow well at pH levels down to 3.0.

3. In the presence of air, some yeasts and molds will use acid and increase the pH.

4. Microorganisms are easier to kill with heat in solutions at low pH than at a pH near neutrality.

5. Heating at boiling temperature (212°F., 100°C.) or below cannot be relied on to kill spores of *Clostridium botulinum*, but this organism will not grow and produce toxin at pH 4.6 and below.

6. Problems may occur with spoilage due to spore-forming bacteria in pasteurized, acidified, and fermented foods having a pH of 4.0-4.6.

7. Microorganisms are inhibited and killed by inorganic acids as a result of low pH, while organic acids inhibit at much higher pH levels.

8. Inhibition of microorganisms by organic acids is directly related to the concentration of the undissociated form in solution, and this is controlled by pH. The lower the pH, the higher the percentage of the undissociated form.

9. Most common food preservatives are salts of organic acids and their effectiveness is also controlled by pH.

10. Even at low pH, food preservatives will not prevent the growth of all microorganisms.

11. Salt alone will not prevent the growth of all microorganisms, but salt concentrations of 10% and higher in solutions with a pH of 4.6 and below will inhibit all organisms of public health significance.

12. Growth of surface yeasts and molds on the surface of acid, salt or sugar solutions can be prevented by protecting the surface from air or by exposure to ultraviolet light.

13. Both salt and sugar solutions may inhibit organisms by lowering the water activity (a_w) of foods, and salt may inhibit by other mechanisms also.

14. Sugar, acid, and food preservatives all interact in preserving food. An increase in the concentration of one may allow a decrease in the amount of the other required to preserve the food.

Chapter 6
PASTEURIZATION

Pasteurization refers to a process of heating at mild temperatures (212°F, 100°C, or less) to increase the keeping quality of foods. This process was first used by Louis Pasteur to preserve beer, and then the term was applied to the process used to destroy pathogens (disease producing) organisms in milk. Pasteurization does not imply sterilization, and cannot be used for processing of low-acid foods (pH greater than 4.6) packaged in hermetically sealed containers. As applied to acidified and fermented foods, pasteurization can be defined as the heating process designed to destroy all organisms capable of growing in the product under the conditions of storage.

Heat Resistance of Microorganisms

Bacterial Cells: Bacterial cells vary widely in their heat resistances. Some very sensitive species die rapidly at a temperature of 120°F (49°C) while some thermophilic bacteria grow well at this temperature. Several minutes at temperatures of 175°-200°F (80-93°C) are required to kill a population of the latter bacteria. However, vegetative cells of all bacteria can be destroyed by heating at boiling temperature or less.

The lactic acid bacteria which most often spoil pasteurized foods having a pH of 4.0 or below are not very heat resistant. They are readily destroyed in a few minutes at 160°F (71°C) when the pH is low. There are thermophilic lactic acid bacteria which potentially could spoil such foods and considerably more heat than commonly used today is required to destroy them. However, they have not been a problem. The normal storage temperature for foods is below the minimum levels required for many thermophilic bacteria to grow.

Bacterial endospores: The spores of bacteria are extremely heat resistant compared to vegetative cells. Most of them are insensitive to temperatures used for pasteurization. However, the spores of different species of bacteria also vary considerably in terms of heat resistance. Those formed by thermophilic species are usually more heat resistant than those of mesophilic bacteria. *Clostridium botulinum* is a mesophilic organism but it would be necessary to boil food for over 6 hours to destroy the spores it produces. The spores of some thermophiles are only activated by boiling.

There are relatively few spore-forming bacteria which can grow at pH 4.6 and below. However, there are a few which can grow in foods between pH 4.0 and 4.6 (see Chapter 5, Table 5.1). These will not be destroyed by heating at temperatures of 160 to 180°F (71 to 82°C) and may cause spoilage unless inhibited from growth. However, none of these organisms are of public health significance.

Yeasts and Molds: Most yeasts and molds are heat sensitive and easily destroyed by pasteurization at temperatures of 140-160°F (60-71°C). This includes both the vegetative and spore stages.

Most molds are not only heat sensitive but require oxygen to grow. An exception to both of these generalizations is a mold named *Byssochlamys fulva*. This organism has been responsible for the spoilage of pasteurized canned fruits. It is quite heat resistant, requiring about 1 minute at boiling temperature. Therefore, it is not likely to be destroyed by normal pasteurization procedures used for most acidified and fermented foods. Fortunately, this mold has not been reported to be a problem in such foods.

Factors Influencing Heat Resistance of Microbes

Not only do different species of microorganisms vary widely in heat resistance, but the time of heating necessary to destroy a single species is also variable. The more important variables are as follows.

Number of cells present: Individual cells are not all killed by heat at the same time. With most bacteria, a given percentage of the cells present at any given time are killed in a given time increment; thus, the destruction rate is exponential (logarithmic). For example, if there were 1 million cells present initially and 90% of them were killed by heating at 160°F (71°C) for 1 minute, the numbers of viable (living) cells expected at different periods would be as follows:

Time of heating (min).	Viable Cells No.	Log.
0	1,000,000	6
1	100,000	5
2	10,000	4
3	1,000	3
4	100	2
5	10	1
6	1	0
7	0.1	−1

Therefore, a straight line results when the log of the number of viable cells is plotted versus time (Fig. 6.1).

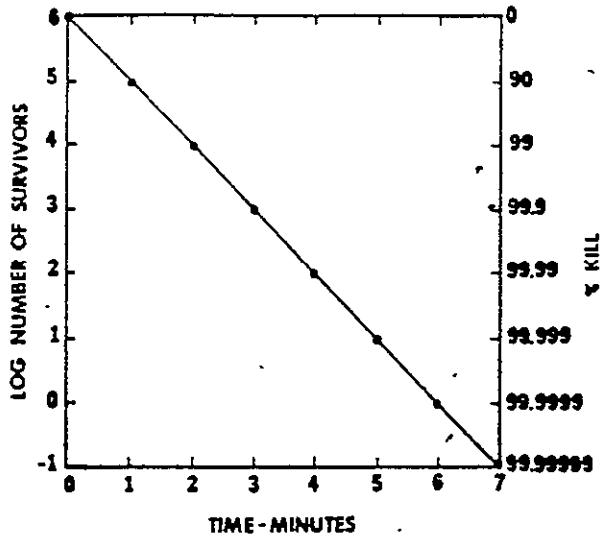

Fig. 6.1. Example of rate of killing of bacteria by heat. A given percentage of the living cells present are killed in each increment of time; 1 minute increments in this example. The rate of destruction is logarithmic; i.e., a plot of the log of survivors versus time is a straight line.

It is obvious from these data that the time required at a given temperature to reduce the viable cell population to less than 1 is dependent on the number of cells present initially. It is very important that manufacturers of acid foods understand this. If acid resistant organisms are allowed to contaminate and grow in the food prior to pasteurizing, more heat will be required to preserve the product. Therefore, equipment should be cleaned on a regular schedule and the food moved through the manufacturing operation rapidly. This is why sanitation is so important in food processing plants.

Relationship of time and temperature: The time required to kill microorganisms with heat changes dramatically with temperature. With most bacteria, it has been observed that a change in temperature of about 18°F (10°C) will result in a 10x change in the time required for pasteurization. This varies considerably however with the organism and the conditions. Some relationships between time and temperature for 3 species of lactic acid bacteria are given in Table 6.1 (Robbins and Costilow, unpublished data).

TABLE 6.1

EFFECT OF TEMPERATURE ON TIME REQUIRED TO KILL LACTIC ACID BACTERIA

Organisms	Minutes* 140°F (60°C)	Minutes* 160°F (71°C)	°F/10x Change**
Lactobacillus brevis	11.8	1.2	20.5
Lactobacillus fermenti	12.5	2.5	27.5
Lactobacillus plantarum	8.8	1.1	21.0

*Time required to kill 99.999% of cells present at pH 7.0.

**The number of °F the temperature had to be increased from 140°F to decrease the required heating time (min.) by a factor of 10

Physiological condition of the microbe: Even a single species of bacteria will vary considerably in its resistance to heat under a given set of conditions. Important factors known to influence this are (a) the culture medium in which the organism is grown, (b) the temperature of growth, and (c) the phase of growth or age of the culture. These factors are not controllable in commercial pasteurization of foods. Therefore, it is necessary to test organisms experimentally and develop pasteurization procedures which will kill them when the cells are the *most* resistant.

Moisture: Moist heat is much more effective than dry heat in killing microbes. Cells killed almost instantly in boiling water may survive for hours on dry surfaces in an oven at much higher temperatures. Cells suspended in oil respond very much like cells on dry surfaces. This is an important consideration in developing pasteurization procedures for marinated acid foods.

pH and acidity: Most cells are most heat resistant at pH levels near neutrality but some yeasts and molds are more resistant at somewhat lower levels. The time required to kill cells of lactic acid bacteria is dramatically reduced by addition of acetic acid (Table 6.2). This effect is primarily due to the reduction in pH. Doubling the acetic acid concentration had little effect.

The resistance of bacterial endospores to heat is also reduced at low pH. However, some spores usually survive pasteurization in acid foods, and the low pH and high acidities must be relied on to prevent their growth.

Sugar and salt: Many bacteria and yeasts are protected from heat by the presence of sugar in solution. The concentration of sugar which is protective varies with the organism. As evident in Table 6.2, *Lactobacillus fermenti* is protected by sugar solutions of 15

TABLE 6.2

EFFECT OF SUCROSE, ACETIC ACID, AND SALT ON HEAT RESISTANCE OF *LACTOBACILLUS FERMENTI**

Heating medium	*pH*	*Minutes at 160°F***
Buffer	7.0	2.5
Sucrose, 15%	7.0	4.9
25%	7.0	6.6
Sucrose, 25%		
+0.5% Acetic acid	3.4	0.6
+1.0% Acetic acid	3.3	0.4
+3% Salt	3.3	0.4

*Robbins and Costilow, unpublished data.
**Time to kill 99.999% of cells present

and 25%. However, cells of this organism died off rapidly in 30% sugar solution held at room temperature. In contrast, osmophilic yeasts which grow best in high concentrations of sugar are most heat resistant in sugar solutions near saturation. It is probable that sugar protects organisms from heat by reducing the water activity (a_w) and offers maximum protection

when a_w levels are near the minimum levels for a given organism.

Salt at concentrations normally present in pasteurized foods has little or no effect on heat resistance. Addition of 3% salt to the heating medium had no effect on the heat resistance of *Lactobacillus fermenti* (Table 6.2).

Other food ingredients: Food constituents such as oils and fats protect organisms from heat to varying degrees. As noted above, cells suspended in oils may be very heat resistant due to the lack of moisture.

Heat Penetration into Foods

It must be assumed that microorganisms are distributed uniformly in a can or jar of food. Therefore, every part of the food must receive an adequate amount of heat to ensure that all spoilage organisms are killed. Pasteurization processes must be based on temperatures achieved at that point in the container which heats most slowly. While this point is usually near the center of the container, its actual position depends on the type of food and the modes of heat penetration.

Modes of heat penetration: The three general modes of heat penetration into cans of food are illustrated in Fig. 6.2. Heat moves through a solid or semi-solid

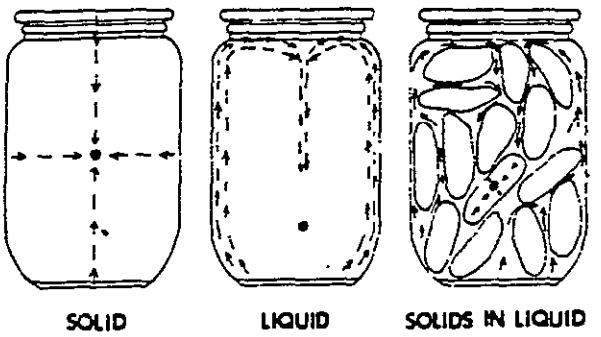

Fig. 6.2. Modes of heat penetration into jars containing different types of foods. Arrows indicate directions of heat penetration. The black dot (●) represents the location of the slowest heating point in each container.

substance by a "bucket brigade"; i.e., it is passed on from molecule to molecule. Different substances conduct heat more rapidly than others. In general, metals conduct more rapidly than glass which conducts more rapidly than plastics. Solid or semi-solid foods will also vary in the rate of conduction of heat. With such foods the slowest heating point in the container is the geometric center.

In liquids, heat is rapidly distributed by movement of the liquid. The density of a liquid decreases as the temperature increases. Therefore, as liquid adjacent to the surface of a container is heated, it moves toward the top creating a convection current. Jars or cans containing liquid foods heat more rapidly than those with any other type of food. The slowest heating point in containers heating by convection is about 3/4 inch from the bottom in the center of the container (see Fig. 6.2).

Foods such as pickles which are solids suspended in liquid heat by a combination of convection and conduction. The coldest point in the container is the center of a [illegible] located below the center of the con-

Factors influencing time required to raise temperature to pasteurization levels: The container used affects heating rates. Metal cans conduct heat more rapidly than glass, the coldest point in small containers will reach a given temperature more quickly than in large containers, and a long cylindrical container will heat through quicker than one with a diameter about equal to its height when both contain the same volume of food.

As noted above, the type of food strongly influences heating rates. Watery liquids heat faster than heavy syrups. Foods with a high water content will conduct heat more rapidly than starchy foods.

The smaller the particles of a food suspended in liquid, the more rapidly heat will be conducted to the center of the particles. However, this may be negated by packing small particles more tightly than large particles resulting in slowing down or eliminating convection in the liquid phase. For example, pickle relish heats almost entirely by conduction heating. The tightness of packing of solid particles (solid: liquid ratio) has pronounced effects on required heating time.

The higher the initial temperature of the food the quicker it will arrive at a temperature which will kill microorganisms. Also, the high the temperature in the pasteurizer, the quicker this temperature will be attained. However, care must be taken that the pasteurizer temperature is not so high that the food is damaged (overcooked) near the surfaces of the containers.

Containers packed closely together in the pasteurizer will not receive as much heat as widely spaced containers. Heat penetration rates should be checked in containers packed as tightly as possible in the pasteurizer. Some pasteurizers have been designed to rotate and agitate containers during pasteurization. This provides some mechanical movement of foods with a liquid phase and increases the rate of heat transfer.

Measurements: Detailed procedures for measurements of heat penetration into food containers are beyond the scope of this manual. These should be accomplished in each type of food in all different sizes and types of containers used, and at a variety of positions in the pasteurizer. Thermocouples are positioned at the predetermined coldest point in each container, and the temperature recorded during both the heating and cooling operation. The Continental White Cap Company has a special remote temperature-pressure recorder under development for this purpose. Pasteurizers should be checked with such an instrument frequently.

Hourly heat penetration checks should be conducted by removing containers from the pasteurizer at different periods during the process and inserting a dial thermometer to the coldest point in the container. The container contents must not be mixed before measuring temperature. To determine the maximum temperature attained during pasteurization, a maximum reading thermometer is inserted into the coldest point of a clearly labelled container.

Establishment of Heat Processes

Every manufacturer of acidified and fermented foods should have a standard pasteurization procedure for each product requiring heat processing. These pro- [illegible] for the individual operation

and should be developed by competent technical personnel. Scientific methods for doing this are too complex to be presented here. However, it is important that supervisors of food manufacturing operations have a general understanding of how heat processes are established. Following are summaries of scientific procedures used in determining pasteurization temperature and time requirements.

Mathematical method: To mathematically determine a pasteurization procedure, it is necessary to know two things: (1) details of the heat resistance in the particular food of the most heat resistant microorganism which might be present and cause spoilage, and (2) details of the rate of heat penetration to the coldest point in the slowest heating container under the actual conditions of pasteurization. Using these data, the scientist can calculate with a high degree of accuracy the time required at various temperatures to destroy a given population of organisms. Then he must estimate the maximum potential population of cells of the heat resistant microbe which might be present, and recommend a heat treatment which would result in an extremely low probability of a single cell surviving even in a large number of containers.

Experimental packs: It is always advisable to test a calculated pasteurization procedure by the use of experimental packs. A number of containers of the specific food are inoculated with a large number of cells of the most heat resistant organisms. These are clearly identified and pasteurized under commercial conditions and then incubated at the optimum temperature for the growth of the organism.

Most heat processing procedures for acidified and fermented foods were developed through the use of experimental packs. The widely accepted procedures of heating a great variety of pickle products to 165 °F (center of jar) and holding at that temperature for 15 minutes was recommended by Etchells and Jones (Fruit Products J. 21, 330-332, 1942) as a result of examinations of great numbers of experimental packs. This procedure and modifications thereof have stood the test of time. However, this does not mean that this pasteurization process would be adequate for *all* acidified and fermented foods. In fact, it is quite likely that if large numbers of pickles having a pH between 4.0 and 4.6 were pasteurized by this same procedure, a significant amount of spoilage would occur. This is because the pickles used in the development of the process all had an equilibrated pH less than pH 4.0.

Operation of Pasteurizers

Scheduled heat processes: The specific pasteurization procedure for each food product in each size and type of container should be carefully detailed, and made readily available to the supervisor in charge of the operation of the pasteurizer. It is his responsibility to insure that each item receives the appropriate heat treatment and that this is completely documented in the records. To do this he must make sure that the pasteurizer is in good operating condition; that the food is properly packed, sealed, and at the correct temperature on entering the pasteurizer; and that the correct temperatures are achieved during the pasteurization process.

Operation of the steam pasteurizer: The White Cap Company, Chicago, IL has prepared a list of Packers International, Inc. These are as follows:

A. Inspection of pasteurizer
   1. Inspect incoming steam line controls.
      a) Are pressure gauges functional?
      b) Have pressure gauges been checked for accuracy within the last year?
      c) Is the reducer valve set properly to supply correct pressure and steam flow to the pasteurizer?
   2. Measure conveying belt speed.
      a) Many times belt speeds do not correspond to Q.C. specifications.
      b) If belt speeds are faster or slower than specifications then it is likely the cook will differ from what is anticipated.
   3. Inspect steam line controls for individual zones.
      a) Check to see if automatic control valves are operating. Many times valves are not sequencing for various reasons.
         1) Valves stuck due to corrosion problems.
         2) Controls have been damaged and not repaired.
         3) Valves are not sequencing due to over heating resulting from adjacent zones. This is a clue to look for problems in the adjacent zones.
      b) Check to see that the automatic controller is set at the desired temperature level.
      c) Check to see if dial thermometers are indicating the temperatures set on the control valve.
         1) There should be two dial thermometers; one above the conveyor and one below. Large differences between these readings will indicate poor control of steam distribution.
         2) Some times bottom dial thermometers are not used and in some cases there is no hole for one.
      d) Check to see that thermocouple for automatic controller is not submerged in water.
         1) If drains are blocked water will fill individual zones.
         2) If thermocouple is submerged it will record water temperature, not zone temperature, resulting in improper controller response.
   4. Inspect cooling sections.
      a) Make sure fresh water valve is open.
      b) Check to determine if tempering section water temperatures are correct.
      c) Inspect cooling water pumps.
      d) Inspect drains to ensure that cooling water is not backing up inside the cooler.
      e) Inspect cooling water spray nozzles. Clean all nozzles that are plugged.
         1) Plugged nozzles will result in improper cooling.
   5. Periodically inspect curtains between zones.

b) Damaged or missing curtains can result in excessive heating or cooling of adjacent zones, improper heat distributions make control valves work harder trying to compensate.

6. Make sure jars are evenly distributed across full width of pasteurizer belt to insure best quality as related to cook time.

a) Adjust conveyor speed to line speed to ensure equal pack of jars across conveyor belt.

b) Of course pasteurizer must be set to correspond to this belt speed. Once set for given belt speed, efforts should be made to keep line speed constant.

c) Unequal loading of product onto conveyor will cause control problems.

d) Unequal distribution across the conveyor will cause control problems.

1) Many times jars will be loaded uniformly across only half the width of the conveyor. This causes unbalanced heat requirements which result in poor control of temperature distribution.

B. Package checks

1. Check brine temperatures at the briner or brine temperature inside jar after capper.

a) Variations in initial brine temperatures will effect heat penetration results.

b) Hotter initial brine temperatures could result in overcooking. Lower initial temperatures could result in undercooking and possible spoilage problems.

c) Once given brine temperature and pasteurizer control relationship is established, maintain it.

2. Check vacuum in package immediately after capper.

3. Measure head space level.

4. Check 4 or 5 jars to establish if brine volume is correct.

a) This is checked between capper and pasteurizer.

5. Count the number of whole pickles.

C. Heat penetration checks

1. Have pasteurizer heat penetration checked once a year.

a) Use standard thermocouple procedures such as White Cap's new remote temperature-pressure recorder or the established 100 foot wire method.

b) Best time for such a check is immediately before or at the beginning of fresh pack.

c) All inspections of the pasteurizer operations as listed above should have been completed and corrections made before attempting heat penetration studies.

2. Day to day heat penetration checks.

a) Select side access windows that will provide correct timing for the desired cook and hold temperatures that are specified by Q.C.

b) Carefully remove jar from the window.

1) Select jars from a mass to ensure a proper representation. Lonely single jars will undoubtedly be hotter.

2) When removing jar do not shake or turn it upside down. Any rapid motion will redistribute brine thus equalizing temperatures between outside and center brine.

c) Insert dial thermometer into center of center pickle.

1) Center pickle is usually considered to be located between one third and one half the distance from the bottom of the jar.

2) Displace or remove several top pickles and plunge thermometer probe into the center pickle approximately one to one and a half inches (depending upon pickle size).

3) If step no. 1 is omitted then the insertion of the dial thermometer down into the center of the jar will probably give you center brine temperatures. This result can be misleading and could result in improper pasteurization.

d) Insert second dial thermometer to measure outside wall brine temperature.

e) Measure brine volume and count pickles.

1) Temperatures and heat penetration vary with variation on brine volume.

2) Maintain accurate record of pickle and brine temperatures, brine volume and pickle count so that a reliable history of results can be used for accurate quality control.

f) Run max. thermometer checks.

1) Clearly mark jar so that it can easily be identified for removal at the end of the cooler.

2) Remove and record max. thermometer reading. You are in the business of selling pickles, not thermometers.

D) Maintain accurate records

1. Make sure that all temperature and package data are recorded properly for future reference.

2. When an excellent pack is achieved, it is useful to review the records. These records should be used as guidelines for the following year.

Records: While there are no specific requirements for records of pasteurization, such records are absolutely essential for quality assurance. Failure to adequately pasteurize many fermented or acidified foods may result in very serious economic losses due to microbial spoilage. Detailed, accurate records of pasteurizer and food temperatures should be made on each coded lot on at least an hourly schedule. Records should also include data on other factors affecting pasteurization such as head space, liquid/solid ratios, etc. An example of a form for a pasteurizer record is appended to this chapter.

Summary

1. Pasteurization processes for acidified and fermented foods are designed to destroy all

organisms capable of growing in the product under the conditions of storage. Many organisms survive these processes but are unable to grow.

2. Bacterial cells, yeasts, and molds are killed quickly at boiling water temperature, but many spores of bacteria are only activated by this temperature. It would be necessary to boil food for over 6 hours to kill the spores of *Clostridium botulinum*.
3. At a given temperature, the time required to kill all bacterial cells increases as the number of cells present increases. Thus, it is important to prevent gross contamination and growth of bacteria in food prior to pasteurization.
4. Microbes are protected from heat by high sugar concentrations and by the absence of moisture.
5. Low pH levels greatly reduce the heat resistance of bacteria. However, many bacterial spores will survive pasteurization at low pH.
6. In uniform liquids, heat reaches the center of a container by convection currents in the liquid. Such foods heat most rapidly.
7. In solids, heat must be conducted to the center of the container. This is analogous to a "bucket brigade" in which the heat is transferred from molecule to molecule. This is the slowest form of heat penetration into foods, and will vary widely according to the nature of the food.
8. A combination of convection and conduction heating occurs in foods such as pickles in which solids are suspended in liquid. The solids: liquid ratio has a pronounced effect on the rate of heat penetration.
9. The temperature of the food at the time it enters the pasteurizer is very important. The higher the initial temperature, the more quickly all of the food reaches a temperature which becomes effective in killing microorganisms.
10. The rate of heat penetration into a food is determined by measuring the temperature increase at the coldest point in the container. In liquids, this is about ¾ inch from the bottom center of the container; in solids it is the geometric center of the container; and in solids suspended in liquids, it is at the center of a large solid particle located just below the center of the container.
11. The heat process necessary for each product is dependent on (a) the heat resistance of the most resistant microorganism which might be present and grow in the product and (b) the rate of heat penetration into the coldest point in the container. The actual processes may be calculated mathematically or determined by the use of experimental packs.
12. The pasteurization procedure should be included as a part of the overall "scheduled process" for each food product, and should be carefully adhered to.
13. Pasteurizers must be checked on a regular basis to ensure that they are operating efficiently and heating uniformly.
14. Heat penetration rates into food products under regular operating conditions should be checked frequently.
15. Careful records of the pasteurization process for each coded lot of each product must be maintained.

COMPANY — PASTEURIZER RECORD

Plant_____ Pasteurizer No.:_____ Line:_____ Shift:_____ Date:_____

Product:_____ Size container:_____ Code:_____ Operator:_____

Time	Prepasteurizer					Past. belt speed	Pasteurizer temperatures in sections							Product, °F			°F cool prod
	Closure	# Vac.	Head sp.	°F Prod.	Oz. brine			1	2	3	4	5	6	Sect No.	Cold spot	Brine Top / Cen.	
Specs:			in.			in/min	Chart Set									/	
							Pen										
							Check Top									/	
							Bot.										
							Chart Set									/	
							Pen										
							Check Top									/	
							Bot.										

IMPORTANT: *Record any problems with conveyer, drive, filters, head exchanger, pumps, Taylor controls, spray nozzles, etc.*
Record each time pasteurizer is stopped, how long it was stopped, and the reason for stopping.

Chapter 7
SCHEDULED PROCESSES

Paragraph (c) (2) of section 108.25 of the Emergency Permit Control Regulation states that all commercial processors of acidified foods must file information on scheduled processes with the Food and Drug Administration. Scheduled processes is defined in paragraph (e) of section 114.3 of the GMP as "the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a product that will not permit the growth of microorganisms having public health significance. It includes: control of pH and other critical factors equivalent to the process established by a competent processing authority." Every different food must be identified under a scheduled process. This information is filed on Form FD-2541C (Food canning establishment and process filing for other than still retort and agitating processes). A copy is appended.

Scheduled processes must be established by qualified personnel with the appropriate background of training and experience. However, all supervisory personnel must be thoroughly familiar with them and be prepared to recognize and respond quickly to any deviations from them. While there are no GMP's established for fermented foods per se and scheduled processes do not have to be filed, these foods should also be manufactured in accordance with procedures developed by competent authorities. Therefore, a discussion of basic principles of processes for fermented foods is included herein.

Fermented Foods

Fermented foods are foods that have undergone a lactic acid fermentation and should have an equilibrium pH value of 4.6 or lower. There are a variety of such foods but the major ones are pickles, sauerkraut, and green olives. The fermentations of all these products are conducted in different ways and the scheduled processes are quite different. However, they are all dependent on growth and acid production by lactic acid bacteria.

The development of these bacteria and the rate and extent of acid production is strongly influenced by the following factors:

- Raw products
- Product/brine ratios
- Temperature
- Salt concentration
- Acidity and pH

Therefore, scheduled processes should be developed which provide due consideration to each of these variables. Records relating to each of them should be maintained for each fermentation vessel.

The rapid initiation of a lactic acid fermentation is essential to decrease the pH quickly to safe levels. Therefore, scheduled processes should provide for procedures to ensure that this occurs in every fermentation. In the case of salt stock pickles, the scheduled process should include the salt concentration, acidity, and pH levels to be maintained during storage.

Manufacturing of Finished Products

Preparation for packaging: All primary operations in preparing different types of products for packaging should be outlined in the scheduled processes. These will vary widely from product to product but all will include:

- Inspection of raw products
- Washing
- Handling

In addition, pickles prepared from salt-stock must be desalted, sauerkraut may be drained, and fresh fruit or vegetable material will be blanched. Some products will involve a cutting operation. Procedures, specifications, and schedules for these operations should be written for each type of product. It is of critical importance that the foods not be held for extended periods at a pH above 4.6.

Acidification and pH control: All acidified foods must have an equilibrium pH of 4.6 or below. Therefore, it is absolutely essential that all scheduled processes specify procedures for acidification, and schedules and methods of pH measurement. Paragraph (a) (3) (i)-(v) of section 114.80 of the GMP states that any of the following acidification methods are acceptable: "(i) Blanching of the food ingredients in acidified aqueous solutions. (ii) Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care must be taken to ensure that the acid concentration is properly maintained. (iii) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification. (iv) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solids or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container. (v) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations."

Frequent measurements of acidity and pH on each lot of food by methods outlined in section 114.90 of the

GMP and discussed in Chapter 3 must be accomplished to be sure that the final equilibrated pH is at pH 4.6 or below. From a practical standpoint, the final pH of most acidified foods should be 0.3 to 0.4 unit below 4.6 to provide a safety factor. This is particularly true when the food is being acidified in individual containers. Special precautions must be taken in instances where a food has come into contact with a strong base such as lime and there may actually be undissolved particles present. These particles can result in an occasional final jar or can having a pH above the minimum. When this might occur, the individual lots of the food should be acidified and equilibrated prior to final packing.

Final processing: Major factors to be considered in scheduled processes in the final packaging operations are:

- pH
- Coding of containers
- Freedom from extraneous materials
- Integrity of containers and closures
- Solid/liquid ratios (drained weights)
- Amount of acid per container when acidification achieved in this manner
- Vacuum
- Pasteurization

Procedures and control measures for meeting minimum standards for each of these must be developed. The importance and roles of most of these factors are discussed elsewhere in this manual. The solid/liquid ratios and the amount of acid per container are of particular importance in many acidified and fermented foods. When a cover liquid with a given percent acid or grains vinegar is used for final acidification, a high solid/liquid ratio in some containers may result in a final pH above the maximum tolerance. This must be carefully controlled. Both the titratable acidity and volume of cover liquid going into each container must be measured and recorded frequently, and related to the equilibrium pH of the finished product. When sufficient data are available to relate titratable acidity to maximal pH of a product, the measurement of the equilibrated acidity is adequate for pH control of products with a pH below 4.0. The equilibrated pH of products having a final pH of 4.0-4.6 must be measured with a pH meter.

Pasteurization and its' control were discussed in Chapter 6. Conditions of pasteurization are an important part of the scheduled process for each type of food, and records of the pasteurization process for each coded lot must be maintained.

Final sampling and analysis of finished containers from every coded lot is critical. Sufficient numbers of containers from each lot should be analyzed to be sure that all finished products have an equilibrium pH of 4.6 or below and meet the other specifications established in the scheduled processes.

Deviations from Scheduled Processes

In all instances, when one or more containers of a given lot of acidified food is found to have an equilibrium pH above 4.6, it must be concluded that there has been a deviation from the scheduled process for the entire lot. Such a lot must either be (a) fully reprocessed by a process developed by a competent authority as adequate to ensure a safe product, (b) thermally processed as a low-acid food, or (c) set aside for careful expert evaluation of its public health safety (Section 114.89 of GMP). Usually the first alternative is the only logical one when the equilibrium pH is found to be above 4.6. Whenever the pH of any single container of a given lot of food approaches pH 4.6, a large number of containers should be sampled to assure that none of them exceeds this critical value.

Even if the pH is uniformly at pH 4.6 and below, whenever other deviations from scheduled processes occur, the reworking of the entire lot should be quickly and carefully considered. While in most cases such deviations will not result in any public health hazard, they may have pronounced effect on the quality of the product. For example, if records indicate that there was a malfunction in a pasteurizer during a given period, all product which may have been pasteurized during that period should be immediately reworked. Marked departures from the scheduled total acidity, salt and sugar concentrations, or drained weights of the finished products should be considered deviations and the product affected set aside for evaluation. Products with low vacuum or improper seals should be treated similarly.

Detailed records of all departures from scheduled processes must be maintained. These will be discussed in Chapter 10.

Summary

1. "Scheduled processes" must include methods for controlling pH and other procedures necessary to ensure that no microorganisms of public health significance will grow in the food.
2. In practice, manufacturers should detail procedures, specifications, and programs covering every phase of the process for each food product.
3. Fermented foods are foods that have been fermented to an equilibrium pH value of 4.6 or lower.
4. Fermented foods are dependent on the growth and acid production by lactic acid bacteria.
5. The rapid initiation of lactic acid fermentation is critical in fermented foods to ensure that the pH decreases quickly to below pH 4.6.
6. Low-acid ingredients of acid foods must not be held for extended periods under conditions which allow the growth of organisms of public health significance (see Chapter 2).
7. Scheduled processes must specify procedures for acidification, and schedules and methods of pH measurements to guarantee that the equilibrium pH of the finished product is at 4.6 or below.
8. Solid/liquid ratios (drained weights) and the amount of acid per container are critical variables in pH control in many acidified foods.
9. Any time that the equilibrium pH of an acidified or fermented food is above 4.6, that lot of food must be considered to have deviated from the scheduled process, and should be reworked immediately.
10. Even when the pH is in an acceptable range, foods that have deviated from the scheduled processes should be set aside and carefully evaluated for both public health safety and product quality.
11. Detailed records must be maintained in all instances of deviations from scheduled processes.

Form Approved
OMB No. [illegible]

FOOD CANNING ESTABLISHMENT AND PROCESS FILING FOR OTHER THAN STILL RETORT AND AGITATING PROCESSES *(Please type or print all information requested. If item does not apply enter "NA".)*

THIS IS AN ☐ ORIGINAL SUBMISSION ☐ AMENDED SUBMISSION

FDA USE ONLY
FCE NO

A	ESTABLISHMENT NAME		FDA USE ONLY	000	D	PARENT COMPANY NAME		PARENT COMPANY AF NO	
B	ADDRESS *(No. and Street)*			000	E	ADDRESS *(No. and street)*		DATE RECEIVED BY FDA	
C	CITY	STATE	ZIP CODE	COUNTRY 000	F	CITY	STATE	ZIP CODE	COUNTRY

A. FOOD PRODUCT NAME AND FORM

B. PROCESSING METHOD *(Check one)*
1 ☐ HYDROSTATIC RETORT
2 ☐ ASEPTIC PACKAGING SYSTEM
3 ☐ FLAME STERILIZER
4 ☐ OTHER *(Specify)*

NAME OF STERILIZER

PROCESS ORIGIN
SOURCE
MONTH AND YEAR

CONTAINER TYPE *(Check one)*
1 ☐ TINPLATE OR STEEL CAN
2 ☐ ALUMINUM CAN
3 ☐ GLASS
4 ☐ OTHER *(Specify)*

C.

MAXIMUM WATER ACTIVITY[1]	pH NORMAL	pH MAXIMUM[2]	MAXIMUM CONSISTENCY OR VISCOSITY IN CENTIPOISES OR APPROPRIATE UNITS[3] VALUE AT 77 ± 2°F	VALUE AT OTHER TEMP	OTHER TEMP (°F)	UNITS	METHOD NAME	MINIMUM CONTAINER VACUUM AT CLOSING MACHINE (in of Hg at 77 ± 2°F)[4]	SPECIFIC GRAVITY AT 77 ± 2°F[5]	INSIDE DIAMETER OF HOLDING TUBE (inches)[6]	HOLDING TUBE LENGTH (inches)[6]
0.											

OTHER CRITICAL CONTROL FACTORS *(Check all that apply)*
61 ☐ PERCENT SOLIDS
62 ☐ RATIO OF SOLIDS TO LIQUIDS
63 ☐ SIRUP STRENGTH
64 ☐ ARRANGEMENT OF PIECES IN CONTAINER
65 ☐ GROWING CONDITIONS
66 ☐ CONTAINER POSITION IN RETORT
67 ☐ TENDENCY TO MAT
68 ☐ METHOD OF PREPARATION
69 ☐ MATURITY
70 ☐ FORMULA CHANGES
71 ☐ OTHER *(Specify)*

		CONTAINER DIMENSIONS (CAN SIZE)			MINIMUM NET HEAD SPACE (Decimal inches)[7]	MINIMUM INITIAL TEMP (°F)	SCHEDULED PROCESS TIME (min)	TEMP (°F)	LEAST STERILIZING VALUE (F) OF THE SCHEDULED PROCESS[8]	MAXIMUM FOOD FLOW RATE (gal/min)[9]	CHAIN OR CONVEYOR SPEED (ft/min)	THRUPUT (cans/min)	MAXIMUM DRAINED WEIGHT (oz)[3]	MINIMUM NET WEIGHT (oz)[3]
D	01													
D	02													
D	03													
D	04													
D	05													
D	06													
D	07													
D	08													

AUTHORIZED COMPANY REPRESENTATIVE

NAME	TITLE	SIGNATURE	DATE

[1] Indicated water activity is used as an adjunct to the process, specify the maximum water activity.
[2] When acidification is followed for normally low-acid foods, vegetables or vegetable products for the purpose of thermal processing, specify the maximum finished product equilibrium pH
[3] If a critical factor in the process.
[4] For vacuum processes only.
[5] Or equivalent scientific basis of process adequacy
[6] For aseptic packaging systems only.

Form 4041C (3-74)

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Chapter 8

PRINCIPLES OF FOOD HANDLING, PLANT SANITATION AND PERSONAL HYGIENE

Section 402(s) of the Food, Drug and Cosmetic Act states that "A food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." This is the basis for the umbrella GMP (21 CFR Part 110) regulations which outline general conditions applicable to the entire food industry and for the more specific GMP's for acidified foods. It must be understood that it is not necessary to establish that a food *is* contaminated or *is* injurious to health to declare it adulterated. This means that it is absolutely necessary that food is prepared, packaged and stored under sanitary conditions by personnel who are knowledgeable about good sanitation procedures and who practice good personal hygiene.

The National Pickle Packers Association (now Pickle Packers International, Inc.) recognized the importance of sanitation many years ago and prepared and published a "New Revised Code of Sanitation." This has gained wide acceptance in the industry and has been of great value in upgrading sanitation programs. With the permission of Pickle Packers International, Inc. some parts of this Code are copied directly herein. Many of the regulations concerned with sanitation and personal hygiene are in the umbrella GMP entitled "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food." This must be studied in conjunction with this chapter.

Sanitation is basically GOOD HOUSEKEEPING which is a matter of orderliness. It must be practiced in every aspect of good production, storage, and distribution to guard against possible contamination. A sanitation program should be organized in every food factory with a specific clean-up crew assigned to the task. The crew should be thoroughly familiar with their clean-up jobs and should be under constant direction of a supervisor. It is advisable that the supervisor should be responsible to top management for the condition of the plant.

Grounds and Buildings

Development of a sanitation program starts with the selection of the building site and the design of the buildings for a good manufacturing operation. It is impossible to develop an effective program for insect and rodent control if the plant is located adjacent to a swamp, or to provide good drainage unless the terrain provides that opportunity. Similarily, unless the plant is properly designed, it is not possible to separate adequately the various operations, protect against invasion by insects and rodents, avoid accumulation of soil and waste on floors etc., and organize efficient clean-up programs.

Tank yards: Sites for tank yard construction for use in fermenting foods must be carefully chosen to provide for good drainage. Accumulated water and brine in the tank yard is an excellent place for breeding insects and insect larvae. This will not occur with an adequate drainage system.

The tanks must be arranged to allow easy access for clean-up around each one. No rubbish, junk or other waste should be permitted to accumulate anywhere in the tank yard to provide food and shelter for insects, rodents, and birds. Lights should not be placed directly over the tanks to attract insects. If lights are over tanks, the lights should be protected to prevent killing insects which will fall into the tanks.

A tank yard must also provide facilities for inspection of the product and separation of unsound raw material, and for salt-storage and handling. Waste raw material must be moved from the area promptly. Salt should be stored in a covered area of rodent-proof construction.

Manufacturing department: All final manufacturing operations should be in totally enclosed buildings. Special attention should be given to the fit of doors and windows, soundness of the foundations and walls, and screening on windows and doors to minimize insofar as practical, the entry of insects, birds, rodents, and other animals.

Floors must be smooth, water tight and sloped to adequate drains and the drains properly trapped. Walls and ceiling shall be smooth and free of cracks and ledges. Overhead pipes, fixtures, etc. must be located so that no dust or condensate from them can fall into food or on food contact surfaces. The building materials must be carefully selected for corrosion resistance. Acids and salt water are very corrosive to most building materials. Proper installation and operation of ventilation system is very important in many plants to maintain low concentrations of acetic acid vapors and to reduce the

relative humidities. Without adequate ventilation, molds will grow on walls and ceilings of the plant.

It is also imperative that the plant be designed to provide for separation of waste and unsound raw products promptly, and to prevent contamination of the raw product, any ingredients, or packaging material. This can usually best be achieved by physical separation of the various steps in the manufacturing operations.

Storage rooms: Storage rooms and warehouses should be totally enclosed with floors, walls, and ceilings of smooth construction to permit easy cleaning. Ingredients such as sugar, salt and spices should be stored in rodent-proof containers or rooms. Use of special screening and self closing doors to prevent entrance of insects and rodents is recommended.

Warehouses for finished foods should be protected from manufacturing operations by physical separation or by appropriate self-closing doors and screens. These areas must also be constructed to deter entrance of insects, animals, and birds, and to allow for easy inspection and utilization of pest control measures. While such pests cannot directly contaminate food in sealed glass or metal containers, they may contaminate the containers with harmful microorganisms. The food may be contaminated on opening the container.

Facilities for personnel: Toilets, washrooms, dressing rooms, and lunch rooms should be totally enclosed and well lighted. They should be totally screened, have self-closing doors, and be well ventilated with openings to the outside or away from manufacturing operations. It is suggested that double doors be used in toilets located in or adjoining manufacturing areas. All these facilities must comply with local building codes, and be constructed to permit easy cleaning.

Handwashing facilities must be readily available to all personnel. These facilities must have running water of the appropriate temperature and the water should be controlled by valves designed to prevent recontamination of cleaned hands. Suitable soap or detergents, and sanitary towels or suitable drying devises must also be provided for. Permanent and prominent signs should be installed instructing everyone to wash their hands before commencing work after each visit to the toilet rooms, and any other time when their hands have been soiled or contaminated. Such signs should be conspicuously posted in toilets, dressing rooms, and in processing rooms.

Drinking fountains of a sanitary design and with adequate water pressure must be provided and cleaned on a regular schedule.

Lighting: Adequate lighting must be provided throughout the manufacturing plant and warehouse not only to perform the various operations but to permit inspections. Clean up jobs frequently require additional lighting. Lights should be installed and protected in a manner which will prevent accidental breakage and contamination of food or food-contact surfaces.

Equipment

Equipment used in the manufacturing of any food must be designed so that all food contact surfaces are smooth and readily accessible for cleaning and sanitizing. Even non-contact surfaces must be properly designed to prevent the build-up of extraneous material and microorganisms which may contaminate the food. Equipment used for handling acidified and fermented foods must be corrosion resistant. Pitted surfaces are very difficult to clean and the pits are excellent places for the growth of microorganisms.

All equipment should be conveniently located near hot and cold water supplies and should be spaced far enough apart to provide easy access for cleaning. Unless the design is adequate to provide for in-place cleaning and sanitizing, equipment should be disassembled for cleaning.

Pest Control

The first line of defense against pests is the elimination of food, water and shelter for them. Measures for doing this are mentioned above, and must be applied both inside and outside the plant. The second line of defense is to physically keep them out of the plant and out of the food. Proper screening of all openings to the plant and the use of self-closing doors and air currents are all useful in this regard. Prompt filling of all holes, cracks and crevices is also necessary to protect against insects and rodents. Prompt cleaning of barrels, tanks, vats and other containers after each use is necessary to prevent them from attracting insects. Containers holding pickle-stock or brine should be tightly covered or otherwise protected from insects.

A particular effort must be made to protect sweet and acid brines from vinegar flies (Drosophila). Sweetening tanks in pickle plants are a prime target of these insects. They lay eggs on tank and pickle surfaces above the brine. On hatching, the brine becomes contaminated with pupae and maggots. This constitutes an adulteration. Special inspections should be made constantly for any signs of Drosophila, and special efforts made to prevent their invasion.

Since personnel and materials must move in and out of the plant, insects and rodents will find their way into the most well protected buildings. Therefore, it almost always is necessary to finally resort to extermination of such pests. Mechanical and chemical means of pest control are available. Because of the potential for contamination of food, pesticides should be used only under the guidance of a licensed pest control operator, or by specifically trained personnel.

Regular scheduled inspections of all facilities for pests are necessary. Careful inspection should be made for paper or wood gnawings, excerta pellets, urine stains and nests of rodents. Darkened rooms should be entered at night when the plant is not operating to listen for scurrying of rodents or the chirping of crickets. Then the light should be turned on to check for roaches. Anytime pests are detected in the plant, all three lines of defense should be checked, i.e., (a) elimination of food and shelter, (b) physical barriers, and (c) extermination.

Handling of Raw Products, Food Ingredients, and Packaging Materials

Inspection of raw products: Food is lawfully defined as adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." (Federal Food, Drug and Cosmetic Act of 1938) Therefore, it is mandatory that the raw products are carefully inspected. Any products showing signs of disease, decay, or insect infestation must be separated as waste. Dirt and foreign material

must be removed from all acidified and fermented food before final packaging.

Tank yard management: Only sound fruits or vegetables should be fermented. Therefore, the raw product should be inspected before brining and unsound product and extraneous material removed. Cucumbers brined for salt stock are thoroughly washed after fermentation. However, if fresh cucumbers are excessively dirty or covered with undesirable foreign material they should be washed before brining. Sauerkraut is not usually washed after fermentation, therefore it is necessary to remove all unsound cabbage, dirt, and foreign material prior to fermentation. All waste should be disposed of promptly to avoid attracting pests.

Before filling, all tanks and covers must be thoroughly washed with lime, chlorine, or other suitable cleaning agent and then rinsed sufficiently to remove the agent. After filling, the area around each tank should be inspected to make sure there is no raw product or other material which would provide food and/or shelter to insects, birds, or animals. Also, drains must be inspected to see that they are open and operative.

Tanks containing fermenting materials should be inspected frequently for insect infestation and contamination with foreign material. The tanks should be skimmed promptly whenever these are detected. Whenever scum is detected on the tank surface, it should be skimmed off and disposed of with other wastes. Scum or other debris should never be dumped over the side of the tank.

Many tanks are made of wood and are stored full of water when not in use. This is an excellent breeding place for various insects. Also, these surfaces are frequently covered with mats of algae. Control measures must be used to prevent this. The addition of 10 lbs. of lime per tank or of a quaternary ammonium compound (200 ppm) will usually keep the water in good condition. If chemicals are used for control of insects and microbes, the tanks must be rinsed thoroughly before use to ensure that the chemicals do not contaminate the fermented food.

Storage: Raw fruits and vegetables to be processed into acidified and fermented foods should be used as soon as possible after harvesting because quality decreases rapidly. During shipment and storage, raw products should be maintained at the lowest possible reasonable temperatures. They must be protected against contamination.

Solid food ingredients such as salt, sugar, and spices must be stored in rodent-proof rooms with low relative humidities. They should be in closed containers well off the floor, and arranged for easy inspection from every side. Liquid ingredients such as sugar syrups and vinegar are stored in tightly covered containers.

Waste disposal: All solid waste should be physically separated promptly from the food manufacturing operations and from the plant area at least once each day. The waste should be prominently labeled and covered during any holding period in the plant area. Liquid wastes must be moved continuously into a waste treatment facility as rapidly as they are generated.

and sanitizing of food processing equipment and facilities are absolutely essential to prevent adulteration of the food. When food is available for them, microorganisms grow exponentially, and unless removed at frequent intervals they will reach fantastic populations (Fig. 8.1). The food will be contaminated not only

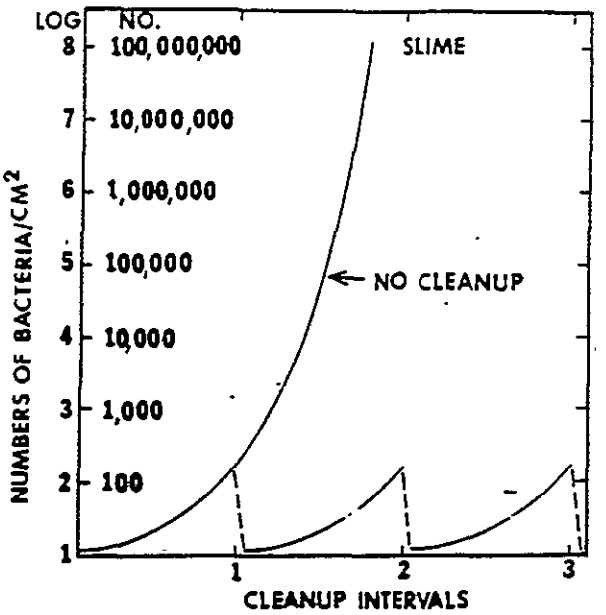

Fig. 8.1. Effect of cleaning and sanitizing on the buildup of microbes on food-contact surfaces. The microbes must adapt after every cleanup before starting exponential growth.

with large numbers of microbial cells but also with products produced by the cells, including spoiled food material. In addition to adulterating the food, such contamination may lead to microbial spoilage. The higher the numbers of microbes present, the more difficult it is to destroy them or to inhibit their growth.

Washing is the key process not only in the removal of accumulated waste and soil, but also in removing and controlling microorganisms. Most of the microbes are found in and on the solids and liquids which accumulate on food contact surfaces because they grow on this food material. By removing all of the food residues with a good wash, most of the microorganisms are also removed. The organisms that remain have no source of food and cannot grow. Even after processing has started again, the microbes must go through a period of adaptation before initiating rapid growth (Fig. 8.1). Also, all sanitizers (agents which kill a large percentage of microorganisms present) are much more effective in the absence of organic matter than in the presence of it. Not only does organic matter provide physical protection for the microorganisms, it also rapidly inactivates some sanitizers, particularly those with a chlorine base.

Sanitizers are defined as substances used on inanimate surfaces to reduce the numbers of microorganisms to a safe level or at least to reduce the total numbers significantly. They do not sterilize. Their efficiency depends on concentration, temperature, pH, time of exposure, and the amount of organic material

sanitizers is similar to killing by heat (see Chapter 6, Fig. 6.1) A given percentage of all living cells present are destroyed in a given time period, and the higher the population of cells, the longer the time required to reach a given level of survivors.

Heat in the form of steam or hot water may be used as a sanitizer. If so, care must be taken that the surfaces being sanitized get hot enough and stay hot long enough to kill most of the microorganisms. High pressure steam looks and sounds scary, but it is not possible to blow or frighten microbes from surfaces.

Establishment of programs and schedules: Every food plant should have some individual in charge of the sanitation program who is directly responsible to top management. This individual should formulate in writing specific schedules for cleaning and sanitizing of facilities and equipment. Procedures should be written for cleaning each piece of equipment and type of surface. Specific employees should be assigned to cleanup crews and trained for their specific tasks.

However, maintaining a clean plant and clean equipment must involve all personnel. All employees should be educated to practice routinely good housekeeping procedures. Everyone should:

1. Be tidy. Accomplish tasks in an orderly manner. When a job is completed, pick up and return everything to its' proper place.
2. Rinse utensils and equipment after each use to prevent materials drying on surfaces which become difficult to wash off.
3. Handle all food and ingredients carefully to reduce spillage to a minimum.

Everyone will be happier working in an orderly plant and the regular cleanup operation will be made much easier if everyone follows these simple procedures.

Washing: It is beyond the scope of this manual to discuss all the specific washing procedures in use. There are a number of excellent detergents available and a number of different procedures recommended for their use. The selection of which to use will be influenced by the following variables:

1. Type of soil to be removed. For example, different washing methods are more efficient for removing greases and fats than for removing other types of organic soils.
2. Types of surfaces and equipment to be cleaned. In-place cleaning frequently requires different procedures than does cleaning of disassembled items.
3. Composition of items to be cleaned. Some metals are easily eroded by strong detergents, and must be washed with mild alkaline detergents.

The choice of detergents and procedures should be made in consultation with an expert in the area.

It is absolutely necessary to take every precaution that food is not contaminated with a cleaning agent. All equipment must be thoroughly rinsed with potable water after washing. Detergent should not be used in areas where food is being processed if there is any chance of contamination. When not in use, all detergents should be stored in closed containers physically separated from food processing operations.

Chemical sanitizers: Sanitizers are used to reduce microbial populations. All chemicals sold for this purpose must be registered and approved by Federal regulatory agencies. All of them must be able to kill a high percentage (99.9999%) of the cells of a test bacterium within 30 seconds at 70 to 75 °F. (21 to 24 °C.). This would reduce a population 10 million (10^7) cells to 10 (10^1) cells. This does not mean that a sanitizer will be this effective in actual use. Many microorganisms may be more resistant than the test organism. Also, the presence of residual organic material may greatly reduce the effectiveness of the sanitizer.

There are basically three different types of chemical sanitizers in common use today; viz., (a) chlorine compounds, (b) iodine complexes (iodophors) and (c) quaternary ammonium compounds (quats). All have certain advantages and disadvantages. Some of the more important considerations are listed in Table 8.1.

TABLE 8.1

ADVANTAGES AND DISADVANTAGES OF THREE MAIN CLASSES OF CHEMICAL SANITIZERS

Type of sanitizer	Principal advantages	Principal disadvantages
Chlorine compounds	Kills widest variety of microorganisms Non-film forming Concentration measured easily Non-organic chlorine compounds leave no residues to adulterate food Inexpensive	Activity eliminated rapidly by organic matter Solutions lose activity rapidly Corrosive to many metals Offensive odors and irritating to skin Relatively ineffective at high pH
Iodophors	More stable than chlorine in presence of organic matter Non-corrosive, non-irritating Non-film forming Concentration measured easily	Less effective than chlorine against some microbes Will stain plastic surfaces Unstable in hot water above 120 °F (49 °C) Ineffective at high pH
Quats	Stable in hot water and more stable than chlorine to organic matter Odorless, colorless, non-irritating, non-corrosive Is surface active, has cleaning properties Active over a wide pH range	Film forming Produces foams Cannot be used with some detergents Concentration not easily measured

All three types have a sufficiently wide spectrum of activity and are sufficiently effective if used on clean surfaces. No sanitizer can kill microorganisms unless it comes into direct contact with them and remains active and in contact for a reasonable period of time.

Technical data are available from manufacturers specifying where and how sanitizers should be used. These directions should be followed carefully. For example, it is unnecessary to rinse equipment after treatment with some sanitizers while a rinse is required with others. However, any time that a sanitizers is used in

conjunction with a detergent, the surfac nust be rinsed with potable water.

Personal Hygiene

Hygiene is defined as "the science of the preservation of health." Personal hygiene refers to the practice of these principles by the individual. Cleanliness is one of these practices. Cleanliness of the individual handling food is imperative. Food may easily be adulterated from clothing or from the skin. In addition, the hair must be kept clean and must be covered at all times during food handling operations.

No one who is unhealthy should be allowed to work in a food manufacturing operation. Man is one of the most common carriers of infections and food poisoning organisms such as *Salmonella* and *Staphylococcus*. Any person known to be a carrier of *Salmonella* or anyone with boils or other lesions (sources of *Staphylococcus*) should not be allowed to handle food. All food handlers should be educated to report promptly any illness or injury and be relieved until they are well. As mentioned earlier, all personnel should be trained to wash their hands thoroughly after each visit to the restroom.

Practicing good personal hygiene is a way of life. It is reflected not only in the individuals appearance but also in his work habits. Selection of employees who have already developed such habits will be of great benefit to the total sanitation program in a food plant.

Inspections

Regularly scheduled inspections of the buildings, grounds, and equipment must be made by the plant sanitarian directly responsible to management. Check lists should be developed for these inspections to ensure that all areas and possible problems are checked. Inspections must include observations for evidence of insect and rodent invasions, integrity of screens and doors, separation and control of wastes, cleanliness and tidiness of all areas in and around the plant, toilet facilities, lunchroom facilities, and the appearance and activities of personnel. The efficiency and completeness of the clean-up operation should be carefully monitored daily. Also, frequent checks should be made on the concentrations of sanitizers and how they are used. In some instances, it may be desirable to check the efficiency of the sanitizer being used on equipment. This involves microbiological techniques and should be conducted by a qualified technician.

Summary

1. Anytime food has been prepared, packed, or held under conditions where it *may* have become contaminated with filth or where it *may* have been rendered injurious to health the food may be declared to be adulterated.
2. Sanitation is basically good housekeeping.
3. Top management must be responsible for sanitation in food plants.
4. Food plants must be located, constructed, and maintained so as to:
   a. Avoid providing food or shelter to insects, rodents, or birds.
   b. Prevent entrance of insects, rodents or birds into buildings.
   c. Provide for physical separation of various storage and food manufacturing operations.
   d. Provide for good drainage and easy cleanup of waste.
   e. Provide for easy cleaning of both facilities and equipment.
   f. Provide adequate lighting and ventilation.
   g. Provide adequate facilities for personnel.
5. The three lines of defense against pests are (a) elimination of food and shelter, (b) physical barriers, and (c) extermination.
6. Raw products must be carefully inspected and any portions showing signs of disease, decay, or insect infestation separated as waste.
7. Dirt and foreign material must be removed from all acidified and fermented food before final packaging.
8. Fermentation tanks and covers must be washed and rinsed before use, and kept free from accumulation of foreign material.
9. Good sanitation practices must be used in tank yards as well as inside food manufacturing buildings.
10. Solid waste must be removed from the plant area at least once each day.
11. Washing and sanitizing of equipment, utensils and facilities must be performed frequently by a cleanup crew trained to do the job properly.
12. All plant personnel should be selected and trained to practice good housekeeping.
13. Specific procedures and schedules should be written for washing and sanitizing each piece of equipment.
14. Frequent adequate washing is essential for control of microorganisms on food contact surfaces.
15. Anytime detergents are used, they must be followed with an adequate rinse.
16. Chemical sanitizers are used to reduce significantly the number of microorganisms on surfaces.
17. For maximum effectiveness, equipment must be cleaned before chemical sanitizers are applied.
18. Every precaution must be taken to ensure that food is not contaminated with detergents, sanitizers or their residues.
19. Only healthy individuals who practice good personal hygiene should be allowed in food plants.
20. Regular inspections of all facilities and activities should be made by the plant sanitarian using a check list.

Chapter 9
CONTAINERS AND CLOSURES

Most acidified foods are packaged in air-tight (hermetically sealed) containers. This ensures against leakage and against contamination by microorganisms. Also, the exclusion of oxygen from the container is frequently necessary to prevent the growth of molds and oxidative yeasts which will utilize the acid and increase the pH. These organisms will rapidly spoil acid foods. Therefore, container integrity is very important.

An organized container integrity program must be a part of every food manufacturing operation. Personnel should be specifically trained and assigned responsibility for quality control and maintenance of records in this area.

Metal Containers

Containers: Selection of appropriate cans and closures with the proper sealing compound or gasket should be based on the advice of experts in the field. Each shipment or lot of cans and closures should be inspected for metal quality and uniformity, integrity of seams, uniformity and quality of sealing compound or gasket, deformations and scratches, and presence of foreign materials. The containers and closures must be stored and handled in such a way as to prevent contamination and/or mechanical damage.

Closures: Cans used for low acid foods processed in retorts at high temperatures are stressed much more than cans which are subjected only to pasteurization temperatures. At high temperatures, seams may develop small leaks which reseal on cooling. Contamination of canned low-acid food represents a serious public health hazard. Therefore, very stringent requirements for inspections of can closures are included in the GMP for such food. While the regulations are not as stringent for acidified foods, some of the mandatory inspections of closures of cans of low-acid foods are appropriate for any canned food.

Most cans have a double seam closure which is formed in two operations. The results of the two operations and common terminology used for double seams are shown in Fig. 9.1. The sealing compound must fill all

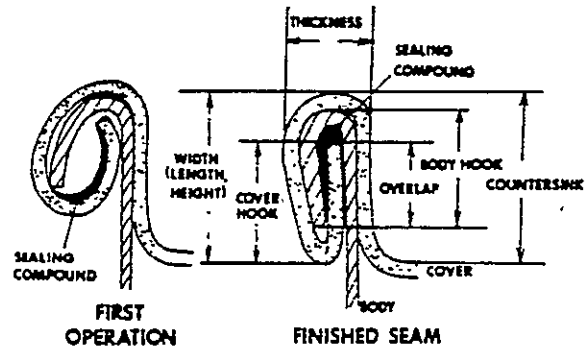

Fig. 9.1. Configuration of the top double seam of cans after first and second operations.

the voids in the finished seam. Any major departure from the configuration illustrated for the finished seam may result in leaky containers.

A number of major defects in double seams can be detected by inspection of the intact seams. Running a finger around the inside of the countersink wall will detect any roughness or unevenness resulting from a broken chuck in the seamer. Also, a sharp or cut-over seam (Fig. 9.2,A) is most easily detected in this manner. Such a defect is usually found at the lap of the can body where the seam has 6 thicknesses of metal rather than 4. False seams (Fig. 9.2,B) can usually be detected by careful examination of the lower edge of the seam. A false seam may not be visible if the lower edge of the cover hook is folded below the body hook. However, such a major defect would result in a very leaky container which would be readily detected. Skidding or dead-heading (Fig. 9.2,C) results in an incomplete loose

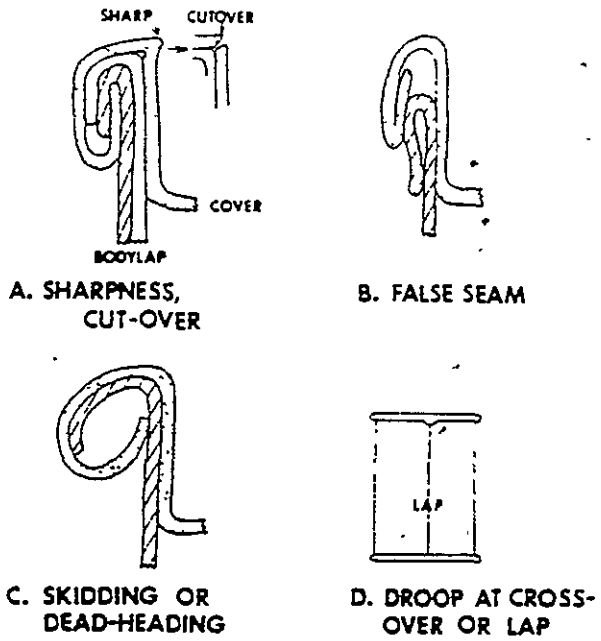

Fig. 9.2. Defects in double seams of cans.

seam and the cover will appear to be cocked-up on one side and the lower edge of the loose seam will protrude outward from the body. A small droop (smooth projection) of the double seam at the lap (Fig. 9.2,D) is common because of the two extra thicknesses of metal in the seam at that point. A slight droop at the lap is normal, but if excessive the closure is defective. Visual inspection will also reveal any buckling of the can walls resulting from the seamer. This occurs most frequently at the lap in the can body.

Three measurements which can be made quickly on intact seams are thickness, width, and countersink depth (see Fig. 9.1). Specifications for these measurements are supplied by the can manufacturers. Measurements should be made with a seam micrometer and a countersink gauge at 3 points around the seam away from the body lap. These measurements combined with visual inspection, and tests for leakage and retention of vacuum should provide adequate closure assurance for most acidified or fermented foods. However, should problems occur it may be necessary to perform teardown examinations of double seam cans. These should be performed by trained personnel. Following is a list of some excellent well illustrated references on double seams.

Double Seam Inspection and Evaluation of Sanitary Cans
Booklet No. 4800-S
American Can Company
Sainte Claire Plaza
1121 Boyce Road
Pittsburgh, PA 15241

Top Double Seaming Manual—(booklet)
Continental Can Company, Inc.
633 Third Avenue
New York, NY 10017

Canned Foods. Principles of Thermal Process Control and Container Closure Evaluation
2nd Ed., 1975. **The Food Processors Institute,**
1950 Sixth Street
Berkeley, CA 94710

Evaluating a Double Seam. W.R. Grace Co.,
Dewey and Almy Chemical Division,
Cambridge, MA

Double Seam Instruction
National Can Corporation
5959 S. Cicero Avenue
Chicago, IL 60638

The Formation and Evaluation of Double Seams
The Metal Box Company Ltd.
Research Department
Technical Communication No. 15,
Third Edition, November, 1965

Laboratory Manual for Food Canners and Processors. **National Canners Association**
Volume 2
AVI Publishing Company
P.O. Box 670
Westport, CT 06880

Bacteriological Analysis Manual, Assoc. of Official Analytical Chemists, 5th Ed., 1978.
Chapter XXI Examination of Canned Foods, D.A. Kautter et. al.;
and Chapter XXII Examination of Metal Container Integrity, R.C. Lin, P.H. King, and M.R. Johnston.

Glass Containers

Containers: The three basic parts to a glass container are the finish, body, and bottom. The finish is a very critical area because it includes the sealing surface and the lugs which hold on the cap. Unless the finish is properly constructed the jar will leak. There are a number of different standardized types of finishes for different types of closure. Each type has a number, and uniform specifications and tolerances have been established for each. These are available from glass manufacturers.

Each lot or shipment of glass should be carefully inspected for defects, freedom from foreign material, and conformity to size and volume specifications. Defects in glass range from critical to minor. Any defects must be considered to be serious if they might result in (a) contamination of food with glass or other foreign material, (b) an incomplete seal, or (c) development of cracks or fractures. Following is a list of critical and major defects. Critical defects are those likely to result in hazardous or unsafe conditions to the consumer. Major defects may significantly effect the functional performance of the jar and closure and/or impair the filling line or closure application.

A. Critical defects:

1. Birdswing — A thin string of glass connected from inner wall to inner wall.
2. Spikes — A sharp pointed projection of glass occurring on the inner wall or on the inside of the bottom of the jar.

3. Filaments — Thread-like or glass appendages usually attached to the inner body of the jar which may easily become loose in the filling process.
4. Internal Soft Blister — Any bubble inside the jar which is > 1/8th inch in the longest dimension, and which could easily break.
5. Sharp Projection — Any sharp projection occurring anywhere on the outside of the bottle which could result in an injury to the consumer.
6. Tramp Glass — Any loose glass particles in a bottle, when there are no broken bottles in case.

B. Major defects:

1. Split Finish — A crack or split running from the top of the finish downward toward the neck.
2. Chipped Finish — Chipped glass on top edge of finish resulting in an interruption of the sealing surface.
3. Checks — Any crack or fracture found in the glass wall, frequently found in the finish area.
4. Split Bottom or Check Bottom — Any vertical split or crack running upward from the rim of the bottom toward the body of the jar.
5. Uneven Warp or Dip Finish — An uneven or rough finish which will result in discontinuity of seating of closure.
6. Overpress or Flange Finish — A fin of glass protruding upward from the inside of the finish. Classified as a major defect only if over and above the top of the finish and subject to spoiling or chipping in sealing, shipping or use of the package.
7. Blow-out — A circular area in the container in which the glass has noticeably blown away creating a thin spot.
8. Lugs-unfilled, checked and chipped — Lugs which are not blown to full size, a check under a lug, or a chip out of a lug or thread.
9. Stones — Any small pieces (> .080 inch) of stone embedded in the glass.
10. Soft Blister (other than internal) — Any air bubble on the outside of jar which is > ¼ inch, the longest dimension and which could break.
11. Stuck or Protruding Glass — Any stuck or protruding glass around the shoulders.
12. Blister over Finish — Any air bubbles (> 1/16th inch) across the top finish or on the outer or inner top edge.
13. Rocker Bottom or Drop Bottom — A condition in which the center of the bottom is lower than the outside rim of the bottom or it also may be caused by one place on the rim being lower than the rest of the bottom rim.
14. Out of Shape — A bottle that has settled to one side, frequently called a "Leaner".
15. Poor Distribution — A condition in which the glass did not properly distribute throughout the bottle, where glass sides are thick in some areas, thin in others which could cause line breakage. A swung baffle is an indicator of a potential poor distribution problem.
16. Foreign Material — Any inside spot of rust, oil, graphite carbon, furnace dripping, dirt or any other similar material.
17. Knock Out Ring — A small fit or droplet of glass on the inside of the finish protruding upward. A defect only if above the top of the finish and interferes with sealing.

Closures: There are three general types of closures used for glass containers; viz., the "side seal", "snap reseal", and "twist-off". The side seal or press-on closure is made of tinplate coated on both sides to prevent corrosion. The gasket material is usually synthetic rubber which provides for a vacuum seal. It is known as a side seal because the seal results from the gasket pressing tightly against the side wall of the glass finish (Fig. 9.3). The glass finish may have a straight wall or a bead

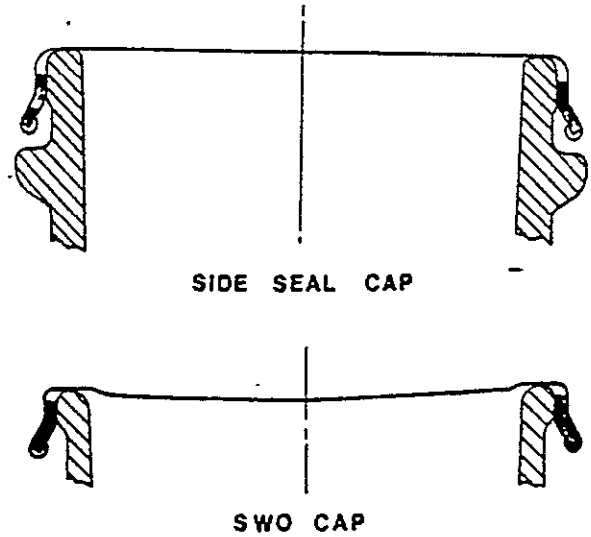

Fig. 9.3. Cross-sections of side-seal finishes and closures. The SWO cap is used with the beaded finish. The shaded areas represent the gasket.

to provide for a better mechanical hold on the gasket. Beaded side seals do not require as much vacuum and offer a better reseal than straight wall finishes. Straight wall finishes cannot be used for acidified or fermented foods which require pasteurization. Such products require a specific beaded finish under which the gasket locks to prevent the cap coming off during pressure build up.

The deep snap reseal (DSR) closure has a plastisol liner for a gasket which seals against the top of the container's finish (Fig. 9.4, top). The cap's shell has several lugs which snap over a beaded glass finish holding the cap in place with minimum vacuum.

All of the closures discussed above require a tool to open. They have been largely replaced by the twist-off closure. The cap has a plastisol gasket and lugs which engage glass threads on the jar finish (Fig. 9.4, bottom). It is applied in a vapor vacuum machine. The top of the glass finish makes an impression in the steam softened plastisol gasket, providing the seal. The number of lugs on the cap and corresponding threads on the glass finish depends on the diameter of the jar mouth. They vary from three to eight. There are two basic types of glass finishes for the twist-off cap. One has continuously

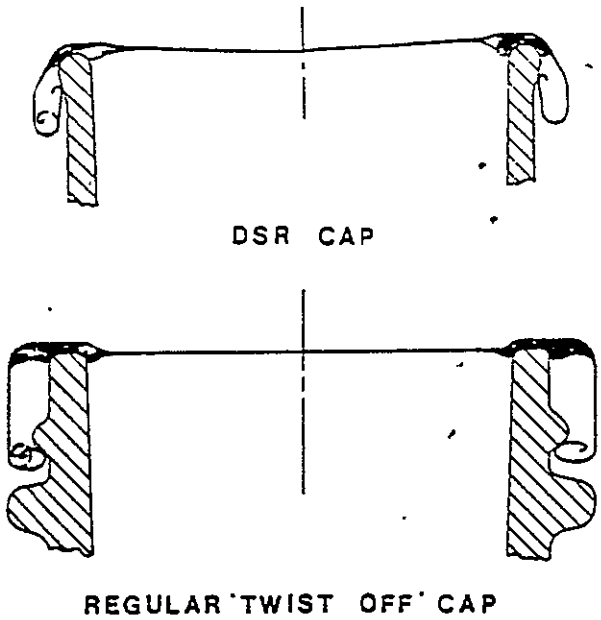

Fig. 9.4. Cross sections of the deep snap reseal (DSR) and "twist-off" caps and glass finishes. The shaded areas represent the plastisol seal.

helical glass threads (helix finish), and the other has a helical lead-in and a final flat portion (angle-flat finish) (Fig. 9.5). The latter finish often has a stop to prevent

Fig. 9.5. Continuously helical or helix (left) and angle-flat (right) glass finishes used with twist-off caps.

turning the lugs past the flat portion. Each glass finish corresponding to a specific closure design has been designated a Glass Packaging Institute (GPI) number and is manufactured according to standard specifications. Specifications are given in Table 9.1 for closures

TABLE 9.1
WHITE CAP "TWIST-OFF" CLOSURES*

Closure size, mm	No. of lugs	Glass finish Style	Glass finish GPI No.
27-38 DTO**	3	Angle-flat	2060
27-38 RTO**	3	Angle-flat	2000
43,48	4	Angle-flat	2010
53,58	4	Helix	2020
63,66,70,77	4	Helix	2030
82	6	Helix	2040
89	6	Helix	2050
110	8	Helix	2070

*Additional specifications include type of sealing compound and variations in design of cap panel and skirt.
**DTO refers to a deep profile and RTO to a regular profile of the glass finish.

sold by Continental White Cap for use with acidified and fermented foods.

Each new shipment or lot of closures should be inspected for defects. Following is a list of critical and major defects (see definition under glass containers).

A. Critical Defects

Plastisol Gasket

1. Absence of Plastisol Gasket — Such a cap will be held on by cap lugs but will inevitably fail.
2. Partial Gasket — A closure manufactured with gasket material not properly covering 360° of sealing area.

B. Major or Functional Defects

Plastisol Gasket

1. Blisters — Blister or pimple on the sealing surface of the plastisol gasket in such proportions as to reduce efficiency of the seal.
2. Dips — Indentations or dips on the sealing surface of the plastisol gasket in such proportion as to reduce efficiency of the seal.
3. Foreign Material in Gasket — Material baked into the plastisol gasket which will affect seal.
4. Air Holes or Voids — Voids or air holes in plastisol gasket which will affect final seal.
5. High and Low Compound — Variation in plastisol quantity to the extent that it affects seal.
6. Improper plastisol placement to the extent that it affects seal.
7. Compound Splashes — Plastisol splashes that are or will easily become loose in use.
8. Improperly Cured Gasket — This is to be determined by a line test of a sample of caps.

Inside Enamel

1. Absence of, or voids on the inside enamel will result in excessive corrosion.
2. Scratches — scratches on the inside surface which are exposed to the product and penetrate to the metal surface. These will cause corrosion, discoloration and off flavor. This is to be verified by testing with $CuSO_4$ solution.
3. Foreign Material in Enamel — Grease, oven condensate, ash, dirt, or other foreign material not baked into the enamel.
4. Openings in Reverse or Inside Enamel — Enamel voids that discolor or otherwise affect product.

Outside Coatings

1. Absence of, or voids in the outside coating may result in severe corrosion any time the cap is exposed to moisture.
2. Compound on Face of Cap — To the degree that cap hoppering and feeding is affected or sealing or capping line efficiency is affected.

Finished Cap

1. Cuts or Perforations — Holes in the closure, which will not allow the package to hold vacuum.
2. Misformed Caps
   a. Bends — overall bending of closure, which will not allow passage of cap through cap chute or will result in a mis-applied closure.
   b. Dents — concave on face at the glass contact area "If It Would Cause A Sealing Failure"

—convex on the face, which will not allow cap to pass through cap chute.

3. Smashed Cap — A cap which is almost totally deformed.
4. Misformed Lug — An abnormal distortion of lug in which the cap will not pull down properly or will jam in the cap chute.
5. Bent Sidewall — Where the sidewall is buckled to such an extent that the distorted portion of the cap will interfere with the glass lugs or cause cap to stick in the cap chute.
6. Dimensions — Any cap or plastisol gasket dimension that does not satisfy production efficiency or that causes container failure will be considered Functional.
7. Upside Down Cap — Cap formed from upside down blank. Functional if seal or line efficiency is affected.
8. Scrap in Die — As it causes any deformation that will interfere with the design function of the cap.

Vacuum: Of the different styles of glass closures, the twist-off cap has the greatest ability to take the pasteurization process. It will tolerate a certain amount of pressure build up during pasteurization, and allows venting when excessive pressures develop. Venting does not normally jeopardize jar security but is not desirable. To prevent venting, the cap must be properly applied and the proper vacuum obtained. Proper cap application and evaluation is discussed below.

Vacuum in jars from vapor-vacuum (steam-flow) capping machines (capper) results from steam driving out the air followed by condensation of the steam in the headspace of the jar and from the contraction of the product after cooling. Therefore, the total amount of vacuum achieved will be influenced by:

1. The efficiency of the capper in terms of replacing all of the air in the headspace with steam.
2. The amount of headspace in the jar. The greater the headspace, the more vacuum achieved at a given capper efficiency. Also, the greater the headspace, the more room for expansion and the less pressure build up during pasteurization. This helps to reduce venting.
3. The temperature of the product when the jar is sealed (initial temperature). The higher the temperature, the more vacuum is achieved when the jar is cooled to room temperature. Also, the higher the initial product temperature, the less the temperature rise during pasteurization, and the less pressure build up.
4. The amount of gas in the product. Blanching of fresh foods is necessary to remove air and carbon dioxide. The higher the initial temperature of the product, the lower the solubility of gas, and the greater the vacuum obtained.

Jars coming from vapor-vacuum capping machines will have a vacuum immediately after closing. Visual observation of the failure of caps to flex downward and measurements of the vacuum in jars coming from the cappers are useful in detecting an improperly operating capper. When setting the capping machine, a "cold water vacuum check" is very useful. Jars are filled to the proper headspace with cold water. These are run through the warmed-up capper to deaerate the water. Then the jars are opened, recapped, and the vacuum measured.

Jars of a given coded lot of food which do not vent should contain a uniform vacuum. Jars which vent may have a higher or lower vacuum depending on the temperature at which they reseal. If they reseal at a higher temperature than the product temperature at the time of capping, they will have a higher vacuum than non-venting cans, and vice-versa. Vented jars can frequently be detected by inspection of the plastisol gasket in the closure. This is particularly true of products containing colored materials which stain the gaskets when passing under it.

Determinations of proper closure application: Inspections should be made both at the capper and after pasteurizing and cooling. Side seal and deep snap reseal caps should be examined as follows:

A. Cap tilt: Caps should be level. Tilt is measured in relation to the shoulder on the glass finish, and no cap should vary more than 3/32 inch from horizontal.
B. Vacuum: The center of the caps will be concave inward (dished in) if there is significant vacuum and many jars can be visually examined by observation. However, vacuum should be measured at frequent intervals on every coded lot of products. Both the headspace and temperature of the product should be measured on the jars used for vacuum measurements.
C. Gasket: The gasket should be inspected at the capper for uniformity and freedom from defects. After processing and cooling, the gasket should have a uniform 360° impression in it resulting from contact with the glass finish.

Continental White Cap[1] has published the following procedures for inspections and measurements to determine proper closure application.

1. Large mouth "Twist-off" with helix glass finishes:
   1.1 Physical measurements taken at capper & after cooling:
      1.1.1 Pull-up (lug distance from a fixed point on glass finish)
      This is a visual inspection noting the location of the lug in relation to one of the two vertical parting lines (mold match) on the glass finish. Usually the leading edge of a cap lug will be ¼" from the parting line on the glass finish. However, this distance can vary ¼" in either direction on the helix. The difference is due to the dimensional variations and design of the finish. Closures should not be *overapplied*. Overapplication is defined as having the closures applied to the extent that the lugs pass the parting line of the glass finish. Pull-up measurements clockwise from the parting line are negative (−), counterclockwise from the parting line are positive (+).

      Caution: We do *not* recommend that this inspection replace the security check (see Section 1.1.2). It is intended as a *secondary*, external examination once the

[1]This slightly modified version of these inspection procedures are reproduced with the permission of the White Cap Division of Continental Can Company.

pull-up/security relationship of a specific lot of glass and closures has been established.

1.1.2 Security value (lug tension of an applied closure). This measurement should be taken by authorized personnel at periodic intervals during every production period. Security values are most important for judging "good" or "bad" cap application.

The "security" measurements are made as follows and are taken right after capping as well as after cooling.

a. With a marking pen or pencil make a vertical line on the cap and a corresponding line on the container, as shown in Fig. 9.6 (left).

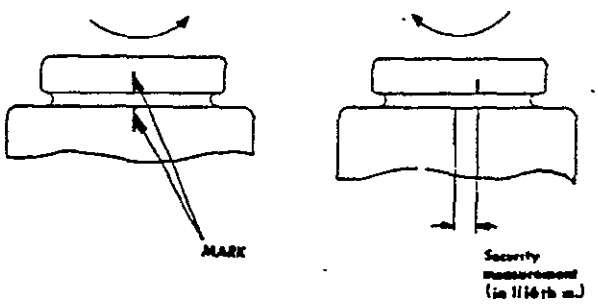

Fig. 9.6. Measurement of security value of large mouth twist-off caps used on helix glass finishes.

b. Turn closure counterclockwise until vacuum is broken. No need to completely remove the cap.

c. Reapply closure to container just until the gasket material touches the glass surface and the closure lug touches the glass thread or until the closure is just "finger tight". Do not use force.

d. Measure the distance between the vertical line in 1/16" increments. See Fig. 9.6 (right). This number is "security".

e. "Security" is considered positive if the line on the cap is to the right of the line on the container and negative if the line on the cap is to the left of the line on the container during the measurement, Step d.

Recommended security values*

	At the Capper	After Cooling
4 lug caps	3-5	2-5
6 and 8 lug caps	2-4	1-3

*expressed in increments of 1/16".

It is suggested that security checks be made and recorded at the start of a shift and at periodic intervals thereafter, the frequency of which will be dictated by practical considerations such as line speed, etc. Security should be rechecked every time a packaging component (caps, glass) changes, or when a product change takes place. Three consecutive packages out of the capper should be checked by this procedure.

To insure proper cap application after cooling, security checks should be made there as well as at the capper, and with equal frequency.

Special Note:

While the method of obtaining security readings always applies, the "security numbers" given above are general in nature and intended only as suggestions. From time to time conditions may vary to the extent that a deviation from the suggested security numbers is necessary.

Variations may be coexistent with the type of plate or the compound used in the caps and/or glass lubricant used by the glass maker.

One or a combination of these conditions may dictate a shift of the proper security range in either direction for the specific operation. In some cases lower security values may be entirely acceptable as long as some positive security is on packages going into the warehouse. Conversely, higher security values may be necessary if the user feels that the recommended range produces a percentage of unsatisfactory packages, and higher securities reduce them.

1.1.3 Remaining compound thickness (related to sealing area impression).

The actual measured thickness is an optional check; however, a complete 360° impression in the sealing area must be observed at the time of capping. Remaining compound thickness usually ranges from .008-.022" (gauge reads zero on plate in center panel) at the time of capping and .005-.19" after cooling. Most of sealing materials used in "Twist-off" closures require heat obtained from the steam supply to the capper to form the desired impression in the sealing area.

Steam temperatures for proper operating conditions will vary with specific vacuum requirements for any particular product being capped. Ideally, capper temperatures for these closures are as follows:

Steam Distributor Ledge (capper head)	215° - 240°F.
Cap Chute	190° - 210°F.
Cap Pick-up Area	212° - 230°F.

Slow line speeds with large jar spacing may require less cap chute heat, providing the steam in the steam distributor is supplying sufficient heat for the desired impression.

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On fast continuous runs, a somewhat higher ledge temperature may be used.

1.1.4 Removal Torque

This is an optional check that may be performed for Quality Control records, but it is not recommended to be used as a control for cap application. Adjusting the capper to specific torque limits may promote loose cap problems. Removal torques vary significantly with glass lubricant or treatment, filling conditions, sealing conditions, package vacuum level and how tightly the cap is applied. Torque reading differences under identical conditions can also be noted between personnel operating the torque meter. For this reason, we have not prescribed any specific torque limits.

A general rule of thumb to be used only as a guideline is that the *minimum* torque at the time of capping should be 1/6 the millimeter size in inch-pounds at the minimum security level.

Special Note:

For reasons outlined in the "Security" section, a deviation from the "rule of thumb" mentioned above may be necessary. Removal torques immediately after capping may be quite low and should not be used as a criterion for establishing quality control limits. Removal torques will be higher after processing or cooling of the product and will increase some in a relatively short time. It is because of this known increase that attempts to raise torques immediately after capping are discouraged.

We very definitely discourage the practice of checking the "tightness" of caps immediately after sealing by having the Quality Control operator try to spin the cap off. This practice can only lead to loosening of closures.

2. Small mouth "Twist-off" used on angle-flat glass finishes:

2.1 Pull-up (position of lug with respect to fillet)

This inspection is recommended at the time of capping and after cooling. Periodic checks should be made and recorded as frequently as possible. Lug position should be directly over the "locating dot" on the transfer bead of the glass finish for best cap application (Fig. 9.7).

Occasionally closures may be found with the lug not up against the primary fillet or stop. However, it is imperative that the full lug be completely on the flat or horizontal portion of the thread to be acceptable. Closure lugs not completely on the flat portion of the thread indicate that the closures are not sufficiently applied. Overapplication of the closure is identified by the lug position being significantly over the primary stop. Dimensional characteristics of the closure, glass or sealing conditions may require different capper settings to properly apply the closures.

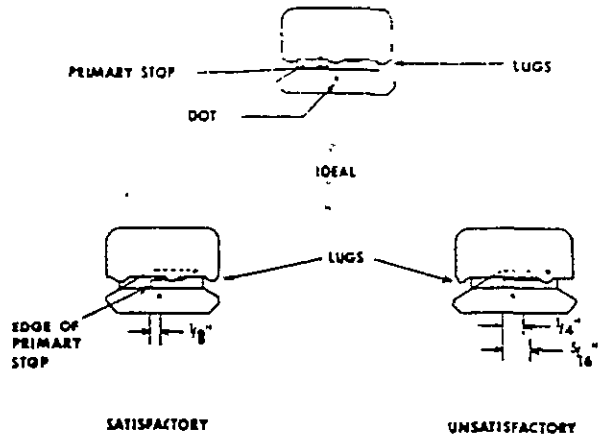

Fig. 9.7. Inspection of position of cap lug with respect to primary stop or fillet on angle-flat glass finishes.

The larger (43 and 48 mm) angle-flat glass finishes do not have the locating dot, because the position of the lug on the finish is easy to see. The relative positions of the lugs on the finish is as outlined above.

2.2 Remaining compound thickness (related to sealing area impression)

The actual measured thickness is optional; however, a complete (360°) impression in the sealing area must be observed at the time of capping and after cooling.

The remaining compound thickness usually ranges from .004-.020" (not including tinplate thickness) at the time of capping, and .003-.018" after cooling. For the 43 and 48 mm caps the thickness ranges from 0.010"-0.022" at the capper and 0.008"-.018" after cooling. The sealing material used in "Twist-off" closures requires heat obtained from the steam supply to the capper to form the desired impression in the sealing area.

Steam temperatures for proper operating conditions will vary with specific vacuum requirements for any particular product being capped. Ideally, the capper temperatures for these closures are as follows:

Steam Distributor Ledge (Capper Head)	212° - 230°F.
Cap Chute	190° - 212°F.

High volume steam conditions for maximum package vacuum may require less cap chute heat. Low volume steam conditions for lowest package vacuum may require maximum cap chute heat to obtain the desired sealing area impression.

2.3 Removal torque

This is an optional check that may be performed for Quality Control records, but it is not recommended to be used as a control for cap application.

Removal torque can vary significantly with sealing conditions, filling techniques, glass finish lubricant or treatment, package vacuum levels, and dimensional relations between the closure and glass finish.

Differences in removal torque readings taken under identical sealing conditions can also be noted between personnel operating the torque meter on packages sealed under identical conditions. For this reason, we have not prescribed any specific torque limits.

A general rule of thumb to be used only as a guideline is that at the time of capping the minimum removal torque is approximately 1/7th (1/6th for 32 and 48 mm caps) of the millimeter size measured in inch-pounds of torque, and reseal torque is approximately 1/2 of the original removal torque value. On fast continuous runs, a somewhat higher ledge temperature may be used.

In addition to the above, vacuum measurements should be made routinely. Also, the plastisol gasket should be inspected for evidence of venting.

Inspections and Records

The quality control division should develop schedules, procedures, and record forms for inspections of all new shipments of containers and closures, and for final closure security. Security checks for closures of either cans or jars always should be made at the seamer or capper and after cooling of the product at the following times:

1. Every change of work shift or extended break.
2. Change of the container size.
3. Change of product or coded lot.
4. Breakdown or jam-up of closing machine.
5. Any major discrepancy noted in vacuum or condition of closures during routine inspections.
6. At regularly scheduled intervals during normal operations.

Record forms should be complete enough to ensure that any major defect will be noted. There should be completed and filed for each coded lot of product, and the corrective action taken for any defects should be described.

Summary

1. Hermetically sealed (air-tight) containers are used for acidified and fermented foods to (a) prevent leakage and contamination of food, and (b) prevent growth of molds and yeasts which may increase the pH.
2. Every shipment of metal cans and closures should be inspected for overall quality and freedom from foreign material.
3. Most common defects of double seam closures used on cans can be detected by inspection and measurements of the finished seam. Common defects to look for are:
   (a) Roughness or unevenness of countersink wall due to broken chuck of seamer.
   (b) Sharp seam (sharp edge at top of inside rim) or cut-over seam (metal crack at top of inside rim).
   (c) False seam (hooks not interlocked).
   (d) Skidding or dead-heading (incomplete loose seam).
   (e) Severe droop (smooth projection downward of the side of the seam at the body lap).
4. Measurement should be made of the width and thickness of the seam and of the countersink depth.
5. Teardown inspections of faulty seams may be necessary and personnel should be specifically trained to conduct them.
6. Glass containers are made of three basic parts—the bottom, body, and finish. The finish includes the sealing surface and the lugs which hold the cap.
7. A standardized finish has been developed for each type of closure. Each has been assigned a number by the Glass Packaging Institute (GPI), and must conform to uniform specifications and tolerances.
8. Glass containers should be inspected for any defects which might result in:
   (a) Contamination of food with glass or other foreign material.
   (b) An incomplete seal.
   (c) Development of cracks or fractures.
9. Major defects in caps for glass containers are (a) defects in the gasket, (b) defects in the enamel coating, and (c) bent or misformed cap or lugs.
10. The twist-off cap is applied in a vapor machine and the seal obtained by the top of the glass finish making an impression on the steam softened plastisol gasket. It is held firmly in place by lugs.
11. There are two basic types of glass finishes for twist-off caps:
    (a) Continuously helical glass threads.
    (b) Helical lead-in threads and a final flat portion. This frequently has a stop at the end of the flat portion.
12. Vacuum in jars results from:
    (a) Condensation of steam from capper in headspace of jar. This is immediate.
    (b) Contraction of product after cooling.
13. The total amount of vacuum in the jar will be influenced by:
    (a) Efficiency of the capper in replacing all air in the headspace with steam.
    (b) Amount of headspace in jar.
    (c) Temperature of the product when the jar is sealed.
    (d) Amount of gas (air or carbon dioxide) in product.
14. Venting of jars with twist-off caps may occur if pressure build-up is too great during pasteurization. Factors controlling vacuum should be checked to correct for this.
15. Closure assurance checks of twist-off caps should include:
    (a) Pull-up (position of lug relative to specified points of glass finish).
    (b) Security measurements on continuously helical finishes.
    (c) Continuous (360°) uniform impression in plastisol gasket.
    (d) Vacuum.
16. Inspections of closures of either cans or jars must be made both at the closing machine and after cooling of the finished product. These must be made often enough to ensure that every coded lot is uniformly protected, and records must be maintained to reflect this.

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Chapter 10
RECORDS

Records are essential in every aspect of modern life. Their complexity ranges from the simple personal checkbook to the accounting systems required for the multi-billion dollar defense department budget. Each individual organization must develop records systems most suited for their situation or operation.

In the food industry, records must be maintained to (a) comply with governmental regulations, (b) assure product quality, (c) identify individual lots of foods in instances where questions arise as to its quality, and (d) aid management in planning, scheduling, and decision making. Management must decide what records are necessary to provide the information needed for each of these functions, and then develop the necessary forms and procedures to be used. In general, the simpler the forms and procedures, the more successful the system will be. Records for records sake only take up filing space. Inaccurate records are worse than none. Personnel must be trained specifically in this area.

Required Records

Food and Drug Administration document 21 CFR Section 108.25, Emergency Permit Control. Acidified foods: This document requires that all commercial processors of acidified foods accomplish the following:

1. The registration and filing of processes with FDA on Form FD-2541(c). The critical element in all scheduled processes for high acid foods is pH and its control.
2. That commercial processors have process and pH information which they will provide in writing when requested by the FDA. Again, pH control is of prime importance, but much more process information may be required.
3. That processors promptly report to the FDA "any instance of spoilage, process deviation or contamination with microorganisms" which might be of public health significance, providing that the food has entered distribution in commerce. Any lot of food in which one or more containers contain food with a pH greater than 4.6 would represent a deviation from a scheduled process which would be of public health significance.
4. Processors must have written procedures for recalling products that may be injurious to health. Chapter I, subchapter A, part 7, of FDA regulations (Title 21) establishes guidelines on recall policy, procedures to be used, and industry responsibilities. This document became effective July 17, 1978. Plans appropriate to each processor's individual situation must be developed in accordance with the provisions of this document. Plans must include procedures for "identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls, for notifying the Food and Drug Administration of any recalls; and for implementing recall programs."

   These same plans and procedures can be of considerable value to a processor in the "Market Withdrawal" or "Correction" of a product which may be defective but would not be subject to legal action by the FDA.
5. Required records must be maintained for at least 3 years from the date of processing.

Good Manufacturing Practices, Acidified Foods, 21 CFR Section 114.00: The following specific records are required under the provisions of this document:

1. Section 114.100 requires the following records be maintained for 3 years:
   a. Examinations of raw materials.
   b. Examinations of packaging materials.
   c. Examinations of finished products.
   d. Records of suppliers' guarantees or certifications.

e. Processing and production records showing adherence to scheduled processes including records of pH measurements and other critical factors. These records must include product code, date, container size and product.
f. Departures from scheduled processes which might be of public health significance. These records must include the departures which occur, the action taken on them, and the disposition of the product involved. Records of departures from scheduled processes must be filed separately.
g. Initial distribution of finished products.

Most of the records required are normally a part of a good quality control program. Forms used should be carefully reviewed to reflect these mandatory records. Entries on mandatory record forms should not be erased. A mistaken entry should be lined through and initialed.

Product Coding

All containers of food must bear a permanent identifying code which is clearly visible (Section 114.80(b)). When possible the code should be embossed or inked on the container. Alternatively, the label may be perforated or marked with the code. The need for identifying individual batches or runs of a product is obvious in instances of recalls or withdrawals of products. Without such identification, the total production of a given item would have to be recalled. Coding is also important in the analysis and correction of quality control problems.

Information: The regulation specifies that the code identify the plant, product, and the year, day, and period in which it was packed. Any system which will accomplish this is satisfactory. Following is an example of a very complete code:

KD3168B212
KD = Kosher dills
316 = Day of year (November 12)
8 = year (1978)
B = Plant B
2 = Line
1 = Shift (1st)
2 = Batch (2nd of day)

Simpler codes are frequently possible. For example, where a processor has only a single plant or single line this part of the code is unnecessary.

Frequency of code changes: Codes must be changed on one of the following bases: "intervals of 4 to 5 hours; personnel shift changes; or batches, providing the containers comprising such batch do not represent those processed during more than one personnel shift." From a control standpoint, it is suggested that the code be changed for each batch of a given product and at each personnel shift.

Record Forms

Since pH is the critical factor with respect to the safety of acidified foods, all food processing records should reflect it. When titratable acidity is used to control processes of foods with a pH below 4.0, it is [illegible] to have r[illegible] w[illegible] the re[illegible] ip[illegible]ween the acidity values and the final equilibrated pH of the product. As shown in Fig. 3.7, Chapter 3, in certain instances, this can be quite variable for even one type of product. It may vary even more for different products containing different acids. Therefore, a large number of measurements of both titratable acidity and pH must be made with each product and container size. These can be used to relate maximal pH levels with given levels of titratable acid. Colorimetric estimates of pH are permissible for foods with a pH below 4.0, and should be employed on all equilibrated samples until a large amount of data has been accumulated. These data may be graphed as illustrated in Fig. 3.7, Chapter 3, so that the relationship can be readily seen.

When the pH is 4.0 or higher, the records must show the equilibrated pH of the product as determined by the potentiometric method. These same records should reflect frequent standardization and checking of the pH meter. A meter standardized with pH 4.0 buffer at room temperature (25 °C) should read between 8.88 and 9.48 when checked in borax buffer at pH 9.18. Readings obtained in the borax buffer should be included in records to reflect the times at which the instrument was standardized.

Fermentation records: Initially, measurements of pH and/or titratable acidity with a known relationship to pH should be recorded daily until an active fermentation is initiated and the pH is below 4.0. After this, recordings should be made frequently enough to ensure that the fermentation is not interrupted and that a low pH is maintained throughout the storage period. Because of the importance of salt concentration in the development of fermentations and the subsequent storage of fermented foods, records should include estimates of salt levels. A record form for salt-stock pickle fermentations available from Pickle Packers International, Inc. is appended.

Daily process records: A detailed record must be maintained of the final equilibrated pH of every coded lot of product. This should reflect the total number and frequencies of measurements. A chart such as illustrated in Fig. 10.1 is an excellent way to record such critical data. Points are made on the chart each time the product is checked. Points falling out of the acceptable limits are obvious immediately so that appropriate corrective measures may be initiated. With a product below pH 4.0 such as the one illustrated, measurements of pH need only be made when the titratable acidities are below some minimal level.

For the purposes of quality control, a number of other records are also essential. A slightly revised version of a form in use by the pickle industry for recording analysis of pickles is shown in Fig. 10.2. Other daily records which should be maintained for quality control purposes include:

(a) Inspections of can seamers or jar cappers.
(b) Temperature recording charts of pasteurizers.
(c) Measurements of in-jar temperatures during pasteurization.
(d) Detailed inspections of closures (cans or jars).

In addition to the above, records should be maintained of inspections of raw ingredients, and of each lot or shipment of jars or cans and closures for them. Also, each manufacturer will have unique needs for other ty[illegible] r[illegible]ds

Company: _____ Date _____

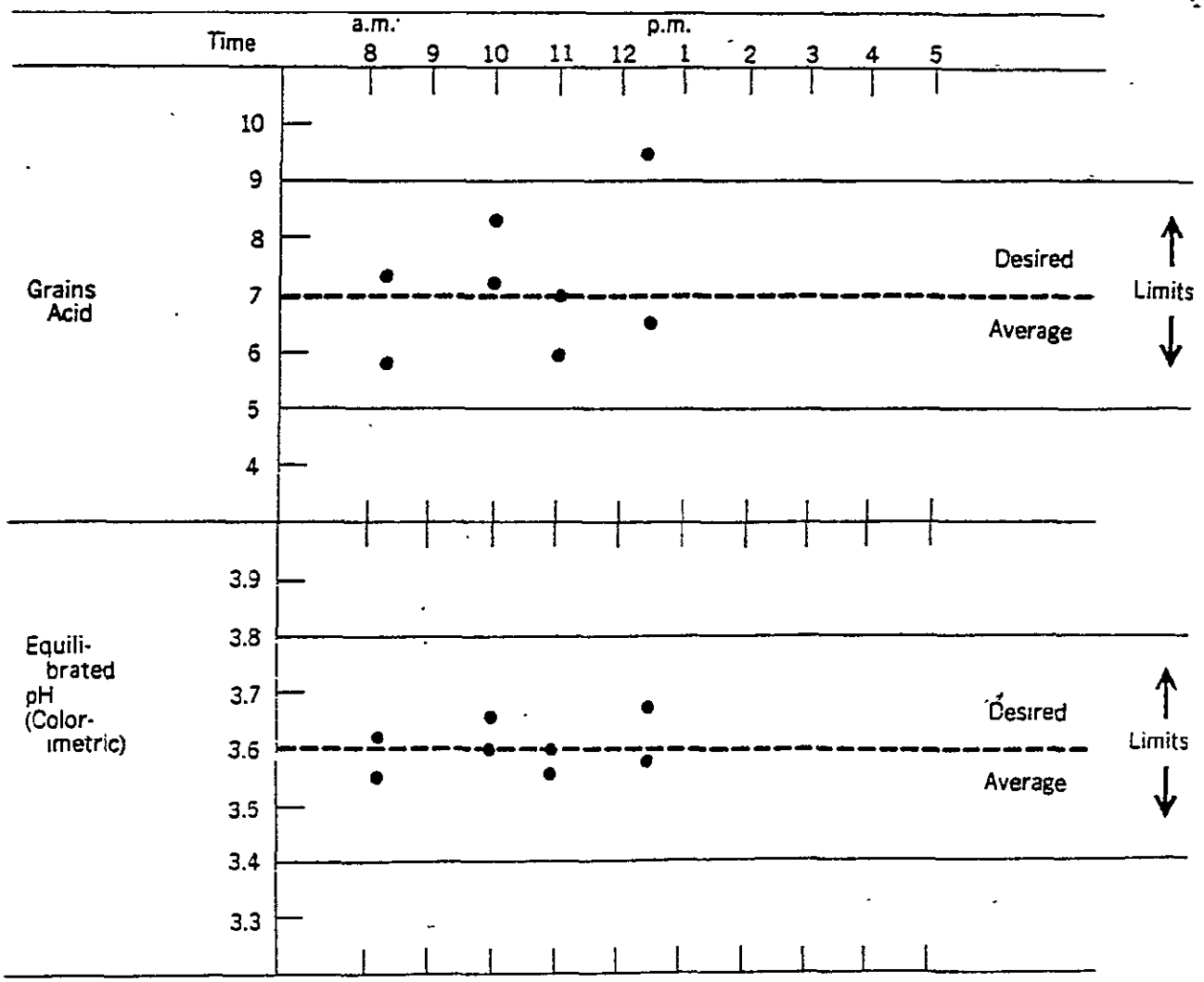
Plant _____

Product _____ Code _____

Container Size and Type _____ No. Cases: _____

Brine of Syrup: Lot # _____ % Acid _____ pH _____

°Brix _____ % Salt _____



Signed: _____

Reviewed: _____

10.1 T ... y ... rd of ir ... lots of product

PRODUCT ANALYSIS FORM

Date of Analysis: ...

Product _____ Container Size: _____ Code: _____ No Cases Packed: _____

Desired Analysis Net Weight: _____ oz. *Brix _____ Acidity _____ % (Acetic) (Lactic)

Liquor: _____ oz. % Salt _____ Maximal pH _____

Time of Sample	Vacuum	Seal Security	Head Space	Net Wt. Oz.	Liquor Oz.	Count Per Jar	*BRIX	% Salt	% Acid	pH*	Texture	Color	Flavor	Defects	Comments

*pH determined by:
pH meter checks pH in borax buffer

Signed:

Reviewed:

Fig. 10.2. Form for recording complete analysis of samples of each coded lot of product

Summary

1. Records must be maintained to:
   a. Comply with regulations
   b. Assure product quality
   c. Identify individual lots of food
   d. Aid management.
2. FDA 21 CFR Section 108.25 requires:
   a. Registration and filing of scheduled processes.
   b. Process and pH records available to FDA
   c. Reporting of spoilage, processes deviation, or microbial contamination which might constitute a public health hazard.
   d. Written recall procedures.
   e. Maintenance of required records for 3 years.
3. FDA, GMP 21 CFR Section 114.100 requires the following records:
   a. Examinations of raw materials, packaging materials, and finished products.
   b. Suppliers guarantees.
   c. Processing and production.
   d. Departures from scheduled processes.
   e. Initial distribution of products.
4. No entries on required records should be erased. Mistaken entries should be lined through and initialed.
5. Every food container must bear a code which identifies the plant, product, and the packing date and period of day.
6. Codes must be changed at least as often as personnel shifts are changed.
7. Processing records of acidified and fermented foods should include pH data. If the pH is below 4.0, titratable acidity may be used if records are maintained that relate titratable acidity to maximal pH levels of each specific product.
8. When the final pH is above 4.0, pH must be measured by the potentiometric method. These records should also reflect the standardization of the pH meter.
9. Initially, food fermentations should be checked for pH or titratable acidity on a daily schedule until the pH is below 4.0. Checks must be made often enough thereafter to ensure that the pH remains below pH 4.0.
10. A daily process chart of titratable acidities and equilibrated pH of each coded lot of product is an excellent way to detect variations beyond acceptable limits.
11. A product analysis record must be maintained for quality control purposes and should contain the pH levels of the samples tested.
12. Each processor should make a complete listing of the records needed and devise the necessary forms and procedures for their maintenance.

Section 7

Principles Of Thermal Processing

INTRODUCTION

In 1874, A.K. Shriver, a canner in Baltimore, Maryland, invented the closed-kettle, the first retort system, using steam under pressure for processing foods at high temperatures. This event signaled the beginning of the commercial processing of canned foods.

Before Shriver's invention, boiling water baths were used to apply heat to canned foods. The length of time in the boiling water required to prevent spoilage depended on the food product and on the canner's previous experience with food spoilage. Not only did spoilage frequently occur, but it was dealt with by an arbitrary increase in the time of the boiling water process. The result of this unscientific method of processing canned foods was well expressed by a canner who said, "Sometimes they kept and sometimes they didn't."

This chapter discusses the theoretical considerations that form the basis for the scientific application of thermal processes to canned foods. The principal purpose of this discussion is to identify and review some of the major factors affecting thermal processing.

BASIS OF THERMAL PROCESSES

The basis for establishment of thermal processes for canned foods is a sound knowledge of food microbiology. Food spoilage microorganisms are present on virtually all raw food ingredients. Since they are living organisms, they cannot grow under adverse environmental conditions, and they die if their surroundings become unfit. The most easily regulated feature of their environment is temperature although other sterilization agents may be used such as chemicals or high energy radiation. Food contaminated with microorganisms and placed in a sealed container can be prevented from spoiling when subjected to a high temperature for a sufficient time. The high temperature kills the microorganisms already present and the sealed container prevents recontamination of the food.

Determining the proper temperature and length of time needed to sterilize a container of food has been the subject of earnest study in the development of the canning industry. The procedure for process determination is not simple. It depends upon the knowledge of a number of factors, including the nature of the product, the dimensions of the container in which it is to be packed, and the details of the thermal processing procedures used. Of equal significance is knowledge of the growth and survival characteristics and thermal resistance of the contaminating microorganisms. Once this information has been obtained, the process must be based on the answer to the following question. How long and at what temperature should a particular product in a particular container be processed in order to destroy the spoilage organisms?

The regulatory agencies require that scheduled processes be established by a processing authority. A processing authority is a person or organization having expert knowledge of thermal processing requirements for foods

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packed in hermetically sealed containers and having adequate facilities to make process determinations.

PROCESS SCHEDULE

The scheduled process or process schedule is designed by a processing authority to provide a commercially sterile or shelf-stable product. Commercial sterility (FDA) or shelf stability (USDA) means the condition achieved in a product by the application of heat to render the product free of microorganisms capable of reproducing in the product at normal nonrefrigerated conditions of storage and distribution.

The scheduled process includes thermal process parameters such as product initial temperature, process temperature and process time, and critical factors that may affect the attainment of commercial sterility. Critical factors may include any characteristic, condition or aspect of a product, container, preparation procedure, or processing system which affects the scheduled process.

ESTABLISHMENT OF THE THERMAL PROCESS

The establishment of a thermal process is based on two factors. First, the heat resistance of microorganisms (the amount of heat required for their destruction) must be known in each specific product. Second, the heating rate of a specific product must be determined. These two factors are used to calculate the scheduled process (*Figure 1*).

Once a process has been established for a particular food, it is specific for that one food, its formulation, its method of preparation, the container size in which it is processed, and the kind of retort system used. A process must not be altered unless specific instructions for change are obtained from a processing authority.

THERMAL RESISTANCE OF MICROORGANISMS

The thermal resistance of microorganisms is dependent upon a number of factors that can be divided into three broad categories. They include the growth characteristics of microorganisms, the nature of the food in which the microorganisms are heated, and the kind of food in which the heated microorganisms are allowed to grow. Thermobacteriology is a complex science, and variations in any of these factors can affect the heat resistance of microorganisms.

The amount of heat required to destroy microorganisms in a product can be obtained through thermal death time (TDT) tests which involve the TDT tube, TDT can, and/or three-neck flask methods. (See *Figures 2, 3,* and *4.*) The TDT tubes are useful with liquid suspensions while TDT cans are most useful with thick purees or solid materials that must be heated to a temperature above that of boiling water. The three-neck flask is useful for acid or acidified products heated at temperatures less than that of boiling water. The choice of method depends upon a variety of factors, including the type of food and the processing system to be used.

PRODUCT HEATING DATA DETERMINATIONS

The rate at which a product heats can be measured using devices that monitor the change in temperature as food is being heated. The determinations are accomplished with a temperature sensor located in the product at the slowest heating region of the container. The time/temperature data are monitored on a temperature recording device. These data are necessary to calculate the scheduled process.

CALCULATED PROCESSES

The processing authority will calculate a process using the product heating data and the thermal resistance data

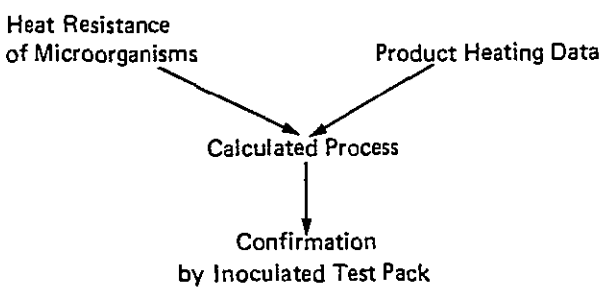

Figure 1—Diagram of steps employed in determining a process.

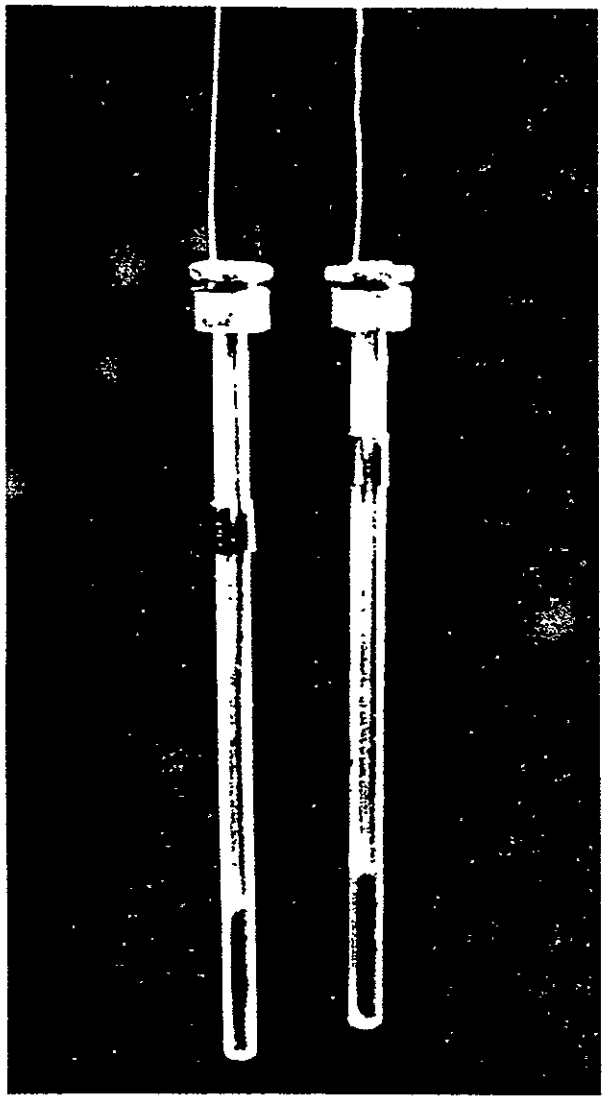

Figure 2—TDT tubes with thermocouples inserted.

Figure 3—TDT cans with thermocouples inserted.

for the significant spoilage organisms expected to be present in the product. There are a number of ways to calculate the process. Since it is not within the scope of this discussion to go into these calculation methods, it need only be indicated that it is mathematically possible to utilize the data described to arrive at a process adequate to sterilize the product.

INOCULATED TEST PACK

It is possible, and sometimes desirable, to check the calculated process by means of inoculated test packs. In this procedure, the test product is prepared under commercial plant operating conditions. Appropriate microorganisms are added to the product. The product, inoculated with a known number and kind of bacteria, is then subjected to various time periods at one or a number of different processing temperatures. The product is then incubated at an appropriate temperature. Product that received a process inadequate to destroy the added microorganisms will show evidence of spoilage. A satisfactory process is demonstrated by absence of spoilage. Substantial agreement between calculated processes and those determined by inoculated packs furnish the strongest possible assurance of the adequacy and safety of a particular process.

Occasionally, due to peculiarities in the processing procedure or in the product, reliable heating data cannot be obtained. Under these circumstances, consideration may be given to utilizing an inoculated pack alone to establish a safe thermal process.

THERMAL PROCESSING METHODS

There are many methods for processing products packed in hermetically sealed containers. Most products are filled into containers, which are sealed and then processed in some type of retort (pressure vessel). This type of processing system has become known as conventional thermal processing. A different and newer thermal processing method is aseptic processing. The number of systems and the variety of products being aseptically processed are rapidly expanding. This method involves the sterilization of the product and package separately and bringing them together in a sterile environment. Both conventional and aseptic processing methods are discussed thoroughly in later sections.

Retorts and aseptic systems must be constructed and operated in such a manner that the finished product will be commercially sterile. The operating procedures shall be developed by a processing authority or the equipment manufacturer.

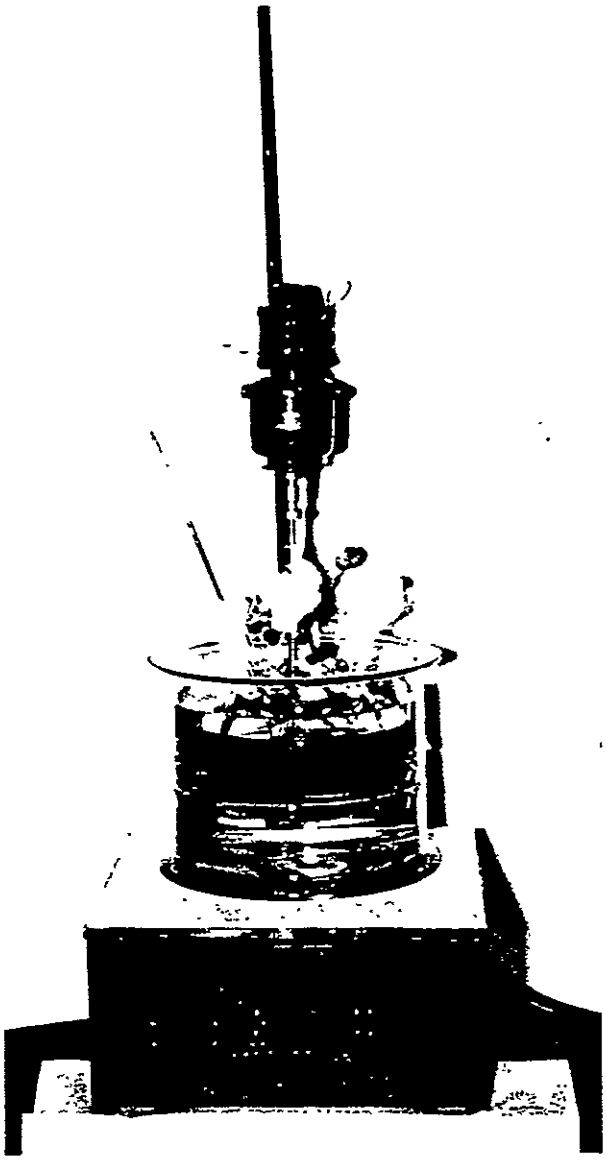

Figure 4—Three neck flask for thermal death time determinations. A thermometer is inserted through one of the side necks, a stirrer through the center neck. The sample is withdrawn through the third (side) neck at selected time intervals. The flask is immersed in the heating medium, usually water.

DETERMINATION OF RETORT OPERATING PROCEDURES

Processing authorities use heat distribution tests to assist in establishing operating procedures for most retort types. Temperature sensors are located between containers throughout a retort load. The temperatures are monitored during the process to ensure that the temperature indicating device for the retort (mercury-in-glass thermometer—MIG) is representative of the temperature throughout the retort.

Retort operating procedures shall be designed to provide uniform temperature distribution in the heating medium throughout the retort. Regardless of the heating medium, process timing shall not start until the temperature indicating device reaches processing temperature and uniform temperature distribution has been attained within the retort. *(Figure 5)* The specific operating steps depend upon whether steam, water, or a steam/air mixture is the heating medium. In all cases, however, proper temperature uniformity should be accomplished during the come-up-time, which is defined as the elapsed time between the start of heating ("steam on") and the start of process timing. Process timing ordinarily begins when the retort reaches the prescribed processing temperature as indicated by the temperature indicating device (MIG).

For retorts using steam as the processing medium, it is important that air be removed from the retort prior to the beginning of process timing because it is a much less efficient heating medium than steam. This procedure is often referred to as venting. Steam carries considerable heat or "stored energy" that results from conversion of water to vapor. When steam condenses, such as occurs in the retort, this heat is given up. In other words, the steam has been able to carry an "extra load" of heat from the boiler to the retort, which hot air would not have accomplished. This fact can be demonstrated by comparing the effect of placing one's hand in a dry heat oven at 250°F (121°C) and live steam at 212°F (100°C).

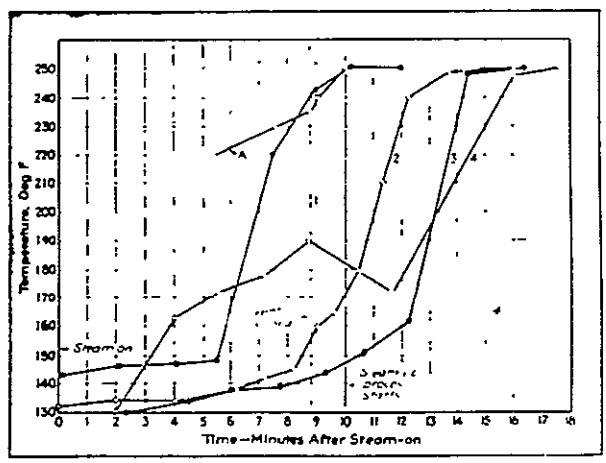

Figure 5—Heat distribution test example. Points 1, 2, 3, and 4 represent temperature at intervals at four places. 1 was in a well-vented area, while 2, 3, and 4 were in "air pockets." "A" represents the mercury thermometer during come-up. Timing of the process was started when the mercury thermometer indicated 250°F/121°C (vertical line at 10 min.) Containers in the air pockets (points 2, 3 and 4) would not receive the full specified process.

SUMMARY

1. A process is the application of heat to food for a scientifically-determined specified time and temperature.

2. A process which has been scientifically determined is specific for the given product, its formulation, method of preparation, container size and type of retort system.

3. The determination of a process depends upon reliable heating information and the heat resistance of microorganisms in the product.

4. The heat resistance of microorganisms depends upon the microorganism used, the food in which it is heated, and the food in which the organism grows.

5. The determination of heating data (time/temperature) should be conducted on a product which simulates commercial preparation.

6. The data obtained from thermal resistance and heat penetration tests are used to calculate a process.

7. It is sometimes desirable to check the calculated process by means of an inoculated test pack.

8. Standard operating procedures for thermal processing systems should be available to authorized plant personnel.

Process Room Instrumentation, Equipment and Operation

It is of vital importance that thermal processing systems are properly installed and operated by trained personnel and that adequate records are maintained.

The regulations require certain instrumentation on all retort systems. The information in this section provides an overview of those regulations and serves as a guide to the selection and maintenance of equipment and proper retort operation. It is important to prevent processing deviations, and through proper equipment and instrument maintenance, as well as proper operating practices, this goal may be achieved.

INSTRUMENTATION

TEMPERATURE INDICATING DEVICE

The mercury-in-glass thermometer serves as the official temperature indicating device for all retorting systems. This type of thermometer is the most widely used temperature measuring device in the canned food industry. The relative simplicity of this type of device makes its use desirable in thermal processing operations. The FDA and USDA regulations require that each retort system be equipped with at least one mercury-in-glass thermometer. The USDA and FDA require that a mercury-in-glass thermometer have easily readable divisions to 1°F and temperature range that does not exceed 17°F per inch of graduated scale. USDA regulations allow processors to propose other types of temperature indicating devices.

Thermometers shall be installed where they can easily be read and protected from mechanical damage. A metal guard should be installed to protect the thermometers. Thermometers should not be installed in the retort doors or lids or anywhere they would be subject to jolts or jars. The bulbs of mercury thermometers shall be installed within the retort shell or in external wells attached to the retort. The external wells shall be connected to the retort through at least ¾" diameter opening and equipped with a 1/16" or larger bleeder opening. The specific installation locations will vary depending on the specific retort and will be discussed in each of the following sections. Thermometers shall be tested for accuracy against a known accurate standard upon installation, at least once a year thereafter, and at any time the accuracy of the thermometer is questionable, such as when the mercury column is divided. A thermometer with a divided mercury column or defect shall be replaced before further use of the retort system. The records of thermometer accuracy checks shall be maintained and shall specify the date, standard used, methodology, results and person(s) performing the tests. Each thermometer should have a tag, seal, or other means to identify the thermometer with the standardization records.

PROCEDURE FOR CHECKING THE ACCURACY OF RETORT THERMOMETERS

The mercury-in-glass thermometer is not a foolproof instrument. It must be calibrated and maintained in good operating condition.

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One system that is suitable for the purpose of checking the accuracy of retort thermometers is illustrated in *Figure 1*.

This system employs the following equipment:

1. A mercury-in-glass thermometer of known accuracy that has been standardized against a certified thermometer at the appropriate retort temperatures;

2. A cross of ¾ inch pipe fittings for holding thermometers, with 1/16 inch holes for bleeders drilled in the couplings holding the thermometers.

Install the testing equipment in any convenient ¾ inch hole in a retort or in steam manifold. Remove the cover glasses from the thermometers to be tested and check for loose stems by gently attempting to move the stem up and down. Thermometers with loose stems should not be used; they should be repaired or replaced. Place the thermometers in the test equipment with the known accurate standard thermometer between them.

Bring the retort or steam manifold to the required appropriate retort temperature, making certain that it is vented sufficiently to eliminate all air.

Open the steam valve on the test equipment and allow the thermometers to come to equilibrium, which will require 10 to 15 minutes. If adjustment is required, loosen the screws on the temperature scale and adjust it up or down so that it reads the same as the standard thermometer.

Tighten the scale adjustment screws and take another reading to make certain the thermometers are properly standardized. Mark each thermometer for future identification, and keep a record of the date on which each thermometer was standardized. Mark broken thermometers in such a way that they will not be used. Clean the cover glasses and replace them on the thermometers.

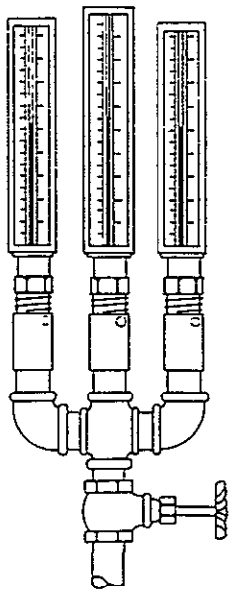

Figure 1—Pipe fittings for holding 3 thermometers.

TEMPERATURE/TIME RECORDING DEVICE

In addition to a temperature indicating device, each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperature and time during processing. This recording device may be combined with the steam controller to form a temperature recorder-controller. The temperature recorder shall be adjusted to agree as closely as possible with, but in no event higher than, the temperature indicating device. USDA regulations require that the temperature recorder be accurate to within 1°F at the processing temperature. A means of preventing unauthorized changes in adjustment shall be provided. A lock or a notice from management posted at or near the recording device as a warning that only authorized persons are permitted to make adjustments is satisfactory means for preventing unauthorized changes.

The temperature/time recorder should be used only with the appropriate chart paper for that particular instrument. However, some of the more sophisticated recorders are capable of printing their own time-temperature scales. The temperature chart graduations shall not exceed 2°F, within a range of 10°F of the processing temperature. Each chart shall have a working scale of not more than 55°F per inch within a range of 20°F of the processing temperature. Most instruments produce a continuous line which represents the recorded temperature. Multipoint recorders can be used and, as the USDA regulations indicate, must print at intervals that will assure that the parameters of process time and process temperature have been met. The frequency of recordings should not exceed 1-minute intervals.

The location of the temperature recording bulb will vary depending on the type of retort system. The bulbs may be installed within a well attached to the retort or located directly within the retort shell. In general, the recorder bulbs are installed adjacent to the temperature indicating device. The specific regulations governing the location of the recorder-controller bulbs will vary and are discussed in the following sections.

TEMPERATURE CONTROL SYSTEM

Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. Most steam controllers are either air operated or electrically operated. Self-activating controllers responding only to pressure may be found on older installations and are not recommended for general use.

The steam controller may be combined with the temperature recorder to form a recorder-controller. The steam control valves in these systems can be either electrically or air operated. *Figures 2* and *3* illustrate the principle

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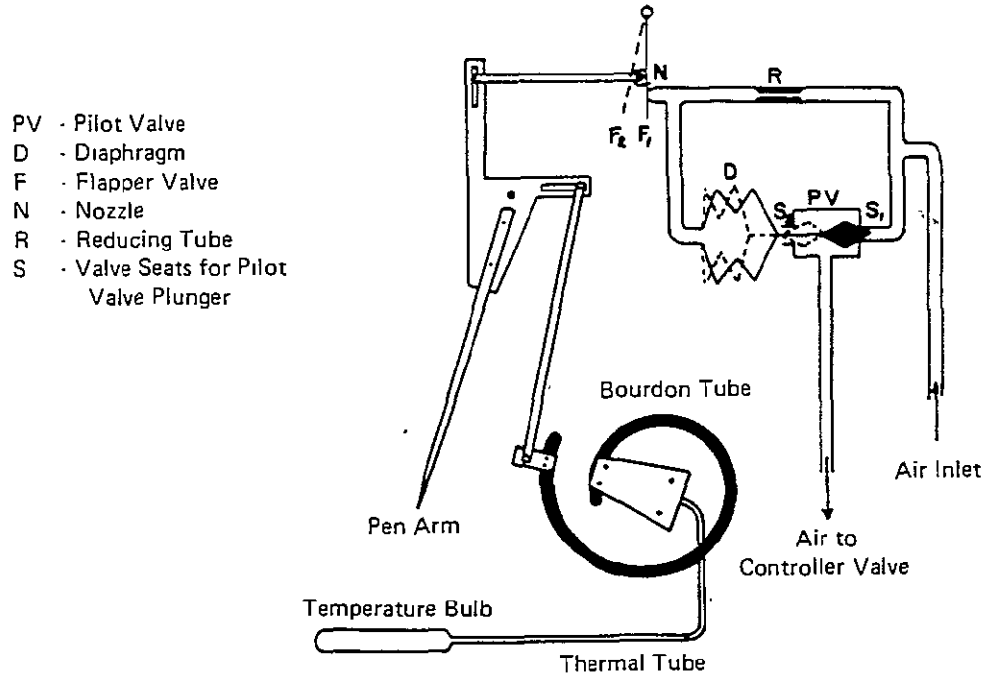

Figure 2—Diagram of simple temperature control system.

simple air operated temperature control system, which is the system most commonly used.

The temperature bulb is located in the retort and attached to the Bourdon Tube by means of the thermal tube. As the temperature rises, the Bourdon Tube expands and closes the flapper valve at N, preventing the escape of air. The air pressure expands the diaphragm D, which closes valve S in the pilot valve PV, shutting off the main supply of air to the controller valve. The spring in the air-to-open controller valve then closes the main steam valve.

The degree of opening or closing of the valve is determined by balancing the air pressure above the diaphragm against the opposing force of the valve spring.

The temperature to be controlled is set by adjusting the tension on the thermal system. The position of the recording pen arm is synchronized with the temperature indicating device reading by means of an adjusting screw.

The diaphragm-operated control valve installed in the retort should be the air-to-open type because it is fail-safe. If there is a failure in the air supply these valves automatically close, thus preventing excessive temperature and pressure in the retort.

A compressible packing material is used to prevent leaking of steam or air along the stem of the push rod. These elements must be properly adjusted to always permit free movement of the push rod.

Air operated temperature control systems are most often used for thermal processing. When these systems are installed, the thermal tube should be protected from damage with sharp bends or kinks avoided. Damage to

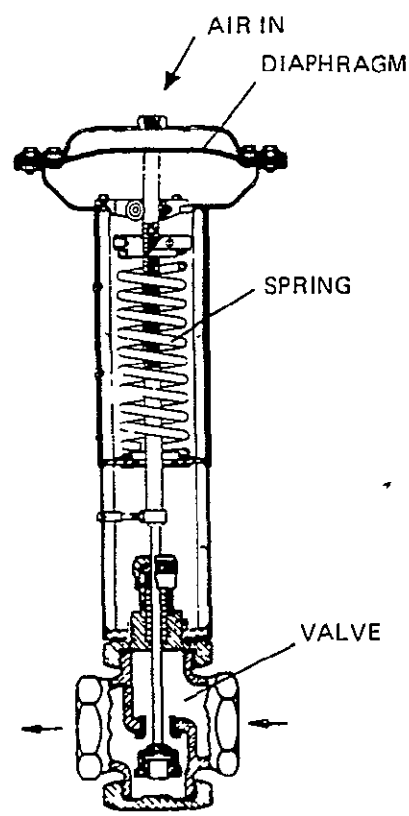

Figure 3—Controller valve and diaphragm motor.

the thermal tube could cause erroneous temperatures to be recorded. If an electrical control system is used, it should be installed in a manner which permits accurate operation.

INSTRUMENT AIR SUPPLY

Air operated control systems should be equipped with adequate filter systems to supply clean, dry air at the proper pressure. Moisture, oil, corrosive liquids, or particulates in the air supply will eventually adversely affect the operation of the instrument. Such contaminants are frequently the cause of instrument failure or unreliable operation. A properly maintained system supplied with clean, dry air will operate most effectively.

The air supply system should be designed to supply air at the proper rate and pressure. A dedicated air supply system should be used to supply air to the instruments. A typical air supply system is indicated in *Figure 4*.

PRESSURE GAUGES

Each retort should be equipped with a pressure gauge or other suitable device to monitor pressure within the retort. If a gauge is used, it should be graduated with divisions not to exceed 2 pounds per square inch. (Some types of packages require a retort pressure greater than the steam pressure during the thermal process or a specific pressure during cooling.) In addition, a pressure gauge can provide the retort operator with useful information during operation and can serve as a safety device by alerting the retort operator to abnormal pressures within the retort.

TIMING DEVICES

The use of pocket or wrist watches is not permitted for timing purposes. Analog or digital clocks are permitted and should be accurate to assure that specific times are satisfied. The clock should be located so that it can be easily and accurately read by the operator. If the clock does not indicate seconds, a one minute safety factor shall be added to each timed function.

MAINTENANCE

It is a good practice and a USDA requirement that, upon installation and at any time proper functioning or accuracy is questioned, all instrumentation be checked. Proper instrument maintenance is essential to provide adequate control and documentation of thermal processing operations.

EQUIPMENT

STEAM SUPPLY

Steam is the most common heating medium for retort systems. The steam supply to the thermal processing area shall be adequate to bring the retorts to processing temperature and maintain that temperature under normal operating conditions.

VALVE TYPES AND USES

There are basically two types of valves used in thermal processing operations: globe valve, which is a better

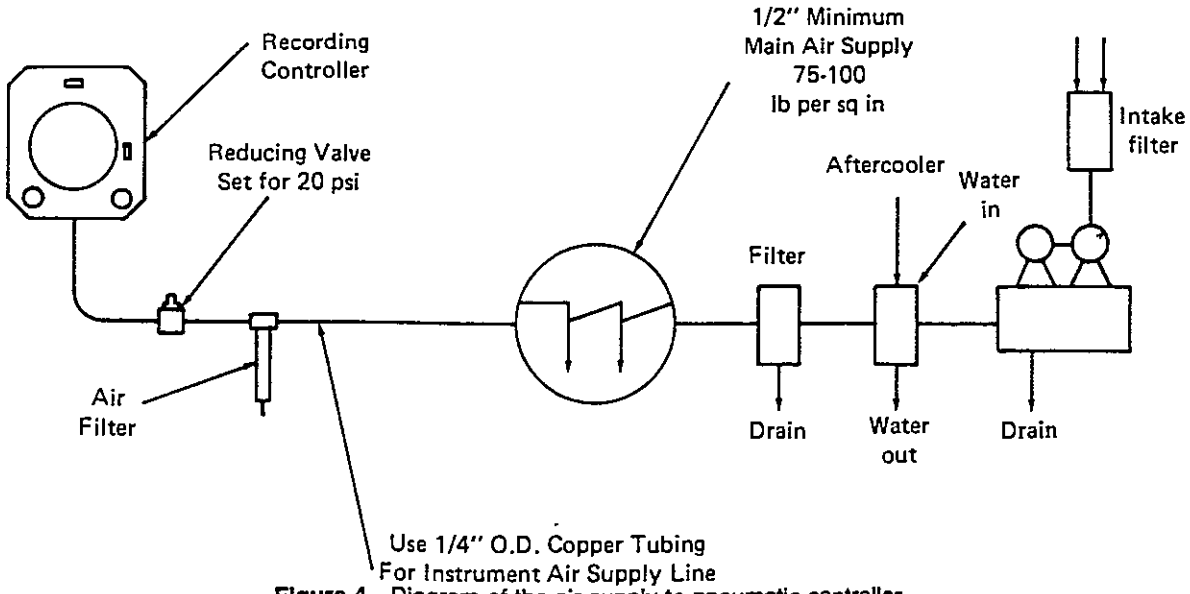

Figure 4—Diagram of the air supply to pneumatic controller.

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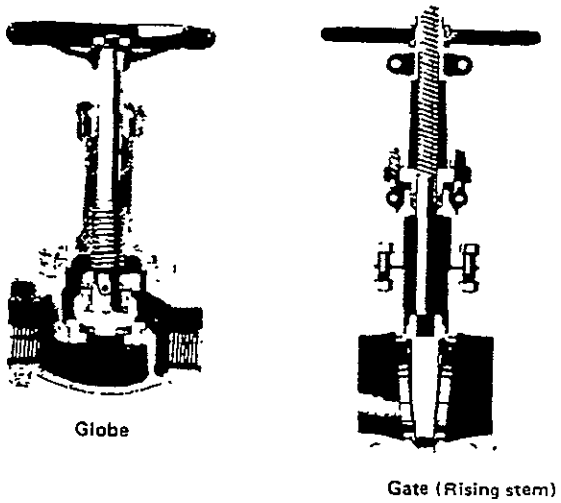

Figure 5—Cross section of a typical globe and gate valve.

sealing valve, and gate valve, which is a full flow type valve (*Figure 5*).

Vents are large valve-controlled openings in retorts that are used to remove air prior to processing in a steam atmosphere. Globe valves are not recommended for use in vent lines because they reduce flow through the valve. Vents shall be controlled by a gate, plug cock, or other adequate type valve that permits a rapid discharge of air and steam from the retort. (Additional information is included in the following sections.)

All air lines and water lines connected to a retort shall be equipped with globe valves or other suitable valves to prevent air or water from leaking into the retort. The USDA requires that a globe valve or other equivalent type valve be used on all air lines connected to retorts using steam as the processing medium and/or water lines that are intended to be closed during the processing cycle.

BLEEDERS

Bleeders are small openings in the retort used to provide circulation of a steam heating medium, to remove any air entering the retort with the steam, to provide a full flow of a heating medium past a thermometer bulb, or to remove condensate from the bottom of a retort. Bleeders can range from 1/16" openings or larger for a thermometer pocket to 1/4" openings on larger processing vessels. All bleeders shall be arranged in such a way that the operator can verify that they are functioning properly.

(See sections on specific processing systems for further information.)

SPREADERS

Spreaders are continuations of a steam or water line inside the retort that are used to provide a uniform distribution of steam or water through the retort. Spreaders may also be used for other purposes, such as venting when connected to both vent and water lines. (See sections on specific processing systems for further information.)

MUFFLERS

Mufflers may be used on bleeders or vents to reduce the noise level of the escaping steam and air. If mufflers are used, evidence that they do not impede the removal of air or steam, so as to interfere with the temperature uniformity within the retort, shall be maintained by the processor. This information may be in the form of heat distribution data.

EQUIPMENT MAINTENANCE

It is good practice and a USDA requirement that at least once a year each thermal processing system be examined by an individual not directly involved in daily operations to ensure that the system is functioning properly. In addition, each processing system should be examined thoroughly after a prolonged shutdown. The examination shall include, but is not limited to, an examination of air and water valves for leakage, vent and bleeder mufflers for restrictions that could reduce efficiency and water spreaders that are used for venting to assure the holes are of the intended size. Records shall be kept on file of all maintenance items that could affect the adequacy of the scheduled process. The records shall include the date and type of maintenance performed and the person conducting the maintenance.

RETORT OPERATION

Company management should perform careful analysis of processing room operations to assure that measures are taken to maintain efficiency and protect product safety. The operators should be thoroughly trained and have a working understanding of the equipment and various steps associated with a thermal processing operation.

POSTING OF THERMAL PROCESSES

Operating processes, along with such operating procedures as venting schedules, if applicable, shall be posted in a conspicuous place near the thermal processing equipment or made readily available to the retort operator or duly authorized government inspector. This procedure will help to eliminate errors and provide for a reliable operation.

PREVENTION OF RETORT BYPASS

A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process. All retort baskets, trucks, cars, or crates containing unretorted product shall be plainly and conspicuously marked by a heat-sensitive

indicator or by other effective means. As an alternative, some of the containers on top of each basket shall be marked.

Several marking systems, such as indicator paints, tags, or tapes, are available for this purpose. However, a change in the color merely indicates that the steam has been turned on. These indicators must not be relied upon to measure process time or the adequacy of a process. The use of a heat indicator, with the proper temperature recorder charts and production records, provides added assurance that each basket was processed at the correct temperature and time.

A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator to ensure that each unit of product has been retorted. A written record of the check should be made. This requirement is intended to prevent an unretorted lot of containers from bypassing the retort and going directly from the closing machine to the warehouse.

Retorts should not be closed temporarily during loading. They should be closed only when the retort operator is ready to start the process. When several products requiring different processes are being packed at the same time, they should be identified so that each is given the proper process.

Any cans of doubtful status that are found in the cook room or in the bottom of a retort shall be destroyed.

CODING OF CONTAINERS

Each hermetically sealed container of product shall be marked with an identifying code that will be permanently visible. Codes are most commonly embossed or imprinted directly on the container. When these methods are not possible, the label may be legibly perforated or otherwise marked, providing the label is securely affixed to the product container. The FDA requires that the code identify the establishment where packed, the product contained within, and the year, day, and period when packed. The period code shall be changed with sufficient frequency to enable ready identification of lots during sale or distribution. Codes may be changed on the basis of every 4-5 hours, personnel shift changes or batches provided that a batch does not exceed a personnel shift.

The USDA requires that the code identify, at a minimum, the product (unless the name is lithographed or printed elsewhere on the container) and the day and year packed. Reasonable manufacturing practice suggests that codes be changed along the lines described above.

The importance of coding is described in a detailed discussion found in the section on "Records for Product Protection." Container coding provides a means to isolate and/or retrieve questionable product. The more information provided in the product code, the more it will assist in accurately locating that product and linking that product with the appropriate production records. The more frequently the code is changed the better the chance of minimizing the amount of product involved in a product recall.

TEMPERATURE/TIME RECORDING SYSTEMS

The temperature recording system shall be adjusted to agree as closely as possible with, but in no event be higher than, the known accurate temperature indicating device. Most recorders are equipped with a screw or dial permitting easy adjustment. If a circular chart is used, the pen arc should match the pen arc on the chart paper during rapid changes in temperature. If the arc does not match, the pen arc should be adjusted or the proper chart paper installed in the recorder.

At the start of the day's operations, the recorder clock should be turned on and set at the proper time of day. The USDA requires that the temperature/time recorder correspond to within 15 minutes of the time of day on the written records. It is advisable to verify the accuracy of the recording device by checking the time on the recorder and comparing it with the actual time of day.

INITIAL TEMPERATURE

Though often confused with the temperature at which the product is filled into the container, the initial temperature designates the average temperature of the contents of the coldest container to be processed at the time the sterilization cycle begins. The initial temperature is determined by selecting a container representing the coldest container in the retort load. Just prior to the start of the process, the contents of the container are thoroughly mixed, and the temperature determined. For those operations that involve processing in water, provisions shall be made to ensure that the initial temperature is representative of the coldest container or the water in the retort, whichever is colder. The thermal process used must be the process designated for the intial temperature of the retort load. The initial temperature is a critical factor as important as process time, retort temperature, and any other critical factor.

PROCESS DEVIATIONS

A process deviation is defined as a thermal process for which one or more of the critical factors (initial temperature, process time, retort temperature, etc.) specified in the scheduled process have not been satisfied. Deviations involving USDA regulated products may be handled in accordance with USDA approved quality control programs. In the absence of such a program the following procedures shall be used:

If deviations are identified during processing, the product may be immediately given a complete reprocess, an appropriate alternate process established in accordance with USDA regulations, or may be held for later evaluation by a processing authority. Process deviations identified through records review shall be evaluated by a processing authority. When an evaluation is conducted

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by a processing authority, a complete description of the deviation, along with a copy of the evaluation report and product disposition, shall be provided to the USDA program inspector. The inspector will submit this information to the FSIS Canning Procedure Branch in Washington for review. No product may be shipped until the USDA has reviewed the submitted information and approved the product disposition actions. If product involved in a deviation shall be destroyed, destruction shall be conducted in accordance with USDA regulations.

FDA regulated process deviations shall be handled in accordance with the following requirements: The product may be given a complete scheduled process, an appropriate alternate process established in accordance with FDA regulations, held for evaluation by a processing authority, or destroyed. Specific regulatory requirements for continuous rotary retort may be found in the section on "Agitating Retorts—Continuous Container Handling."

The processor shall maintain full records for both the USDA and FDA products regarding the handling of each processing deviation regardless of the degree of seriousness of the deviation. The records should include, at a minimum, the appropriate processing and production records, a full description of the corrective actions, evaluation procedures and results, and disposition of the product. These records shall be maintained in a separate file or in a log detailing the appropriate information. The deviation file shall be made available to USDA or FDA inspectors as requested. Additional information on deviations may be found in Section 6, "Records for Product Protection" and in the specific processing systems sections which follow.

SUMMARY

1. The reference instrument for retort temperature during thermal processing operations is the mercury-in-glass thermometer. The USDA allows alternate temperature indicating devices with approval.

2. An accurate temperature/time recording device is required.

3. Each retort should be equipped with a pressure gauge.

4. Pocket or wrist watches shall not be considered satisfactory for timing purposes.

5. Bleeders shall be arranged so the operator can verify functioning.

6. Operating processes shall be posted or be readily available to the operator.

7. All retort crates containing unretorted material shall be marked to indicate visually to thermal processing personnel whether or not each unit has been retorted.

8. Each container shall be coded.

9. All critical factors, including initial temperature, must be adequately determined and recorded for each retort cycle.

10. Process deviations must be handled according to appropriate regulations.

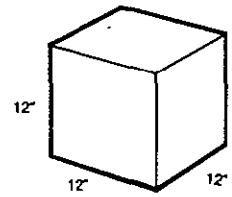
FLUID FUNDAMENTALS

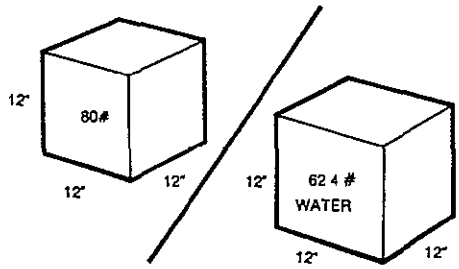
Fluids include liquids, gases, and mixtures of liquids, solids, and gases. For the purposes of this manual, the terms **fluid** and **liquid** are used interchangeably to mean pure liquids, or liquids mixed with gases or solids which act essentially as a liquid in a pumping application.

DENSITY, OR SPECIFIC WEIGHT of a fluid is its weight per unit volume, often expressed in units of pounds per cubic foot, or grams per cubic centimeter.

EXAMPLE: If weight is 80#; density is 80#/cu. ft.

The density of a fluid changes with temperature.





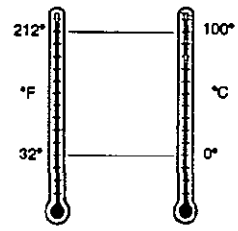
SPECIFIC GRAVITY of a fluid is the ratio of its density to the density of water. As a ratio, it has no units associated with it.

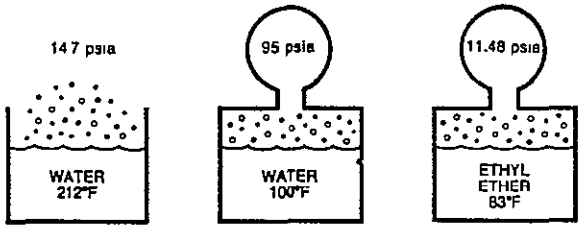
EXAMPLE: Specific gravity is $\frac{80\#}{62.4\#}$

or S.G. = 1.282

TEMPERATURE is a measure of the internal energy level in a fluid. It is usually measured in units of degrees fahrenheit (°F) or degrees centigrade (°C). The temperature of a fluid at the pump inlet is usually of greatest concern.

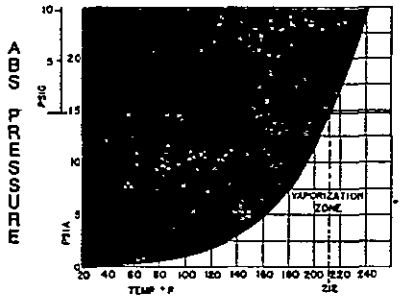
See °F - °C conversion chart on Page 116

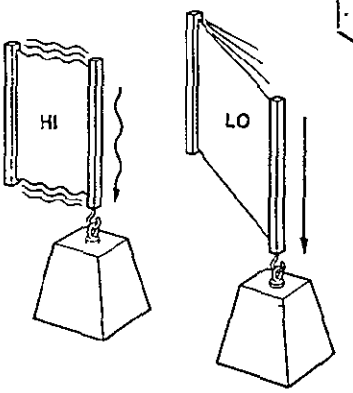




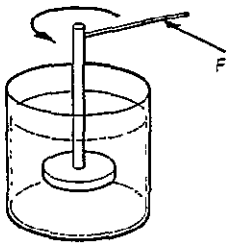
For example: If 100° water is exposed to this reduced absolute pressure of .95 psia, it will boil, even at 100°F.

VAPOR PRESSURE of a liquid is the absolute pressure (at a given temperature) at which a liquid will change to a vapor. Vapor pressure is best expressed in units of psi absolute (psia). Each liquid has its own vapor pressure-temperature relationship.



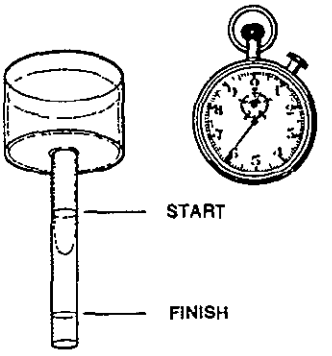


VISCOSITY—The viscosity of a fluid is a measure of its tendency to resist a shearing force. High viscosity fluids require a greater force to shear at a given rate than low viscosity fluids.



The **CENTIPOISE** (cps) is the most convenient unit of viscosity measurement. A measure of **absolute** viscosity, it can be obtained directly from an instrument such as a Brookfield viscometer which measures the force needed to rotate a spindle in the fluid.

Other units of viscosity measurement such as the centistoke (cks) or Saybolt Second Universal (SSU) are measures of **Kinematic** viscosity where the specific gravity of the fluid influences the viscosity measured. Kinematic viscometers usually use the force of gravity to cause the fluid to flow down a calibrated tube, while timing its flow.



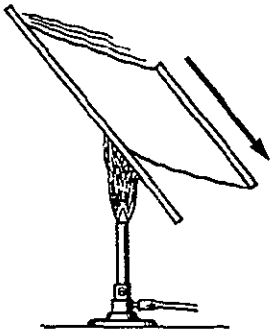
The **absolute viscosity**, measured in units of **centipoise** ($^1/_{100}$ of a poise) is used throughout this manual as it is a convenient and consistent unit for calculation.

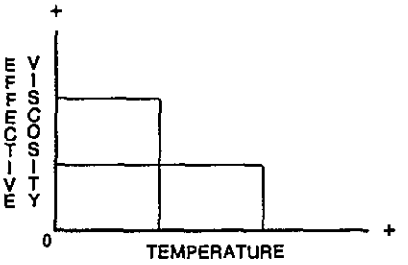
Other units of viscosity can easily be converted to **centipoise.**

Kinematic viscosity	X	Specific Gravity	= Absolute Viscosity
Centistokes	X	S.G.	= Centipoise
SSU X .216	X	S.G.	= Centipoise

A conversion chart for viscosity is on page 114

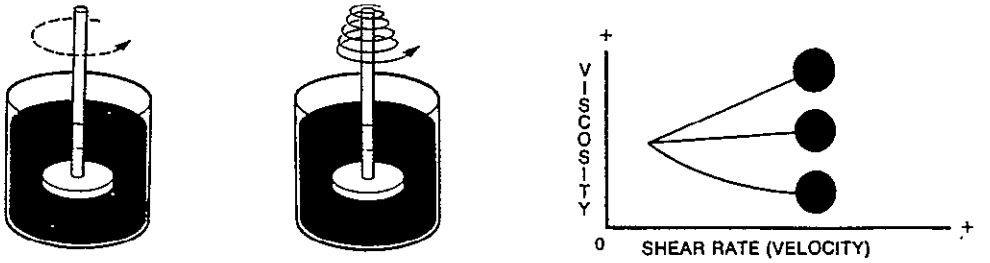
Viscosity unfortunately is not a constant, fixed property of a fluid, but is a property which varies with the conditions of the fluid and the system.





In a pumping system, the most important factors are the normal decrease in viscosity with **temperature** increase.

And the **viscous behavior** properties of the fluid in which the viscosity can change as shear rate or flow velocity changes.



EFFECTIVE VISCOSITY is a term describing the real effect of the viscosity of the **ACTUAL** fluid, at the **SHEAR RATES** which exist in the pump and pumping system at the design conditions.

VISCOUS FLUID BEHAVIOR

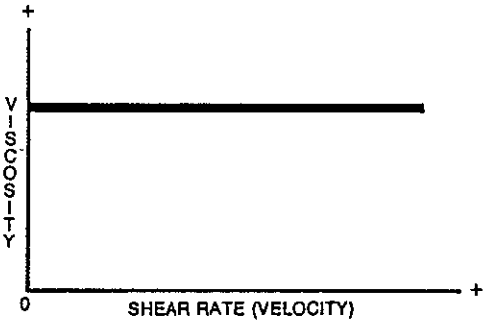
EFFECTIVE VISCOSITY can be understood better by looking at the behavior of viscous fluids at different shear rates. There are a number of types of viscous behavior.

1. NEWTONIAN FLUIDS

Viscosity is **constant** with change in **Shear Rate** or Agitation.

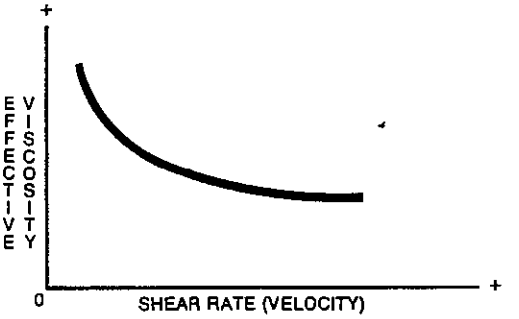
Forces to cause motion increase proportionately as speed increases.

Fluids showing Newtonian behavior include water, mineral oils, syrups, hydrocarbons, resins.



2. THIXOTROPIC FLUIDS

Viscosity **decreases** as shear rate or agitation increases. The forces to cause motion are relatively lower as speed increases.



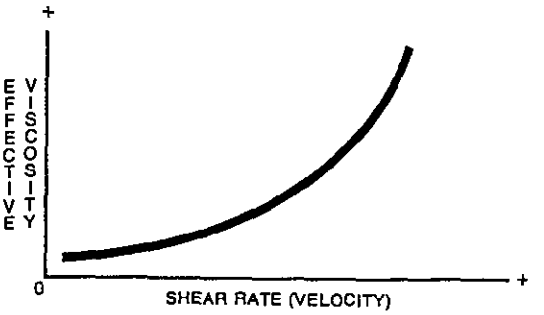
Examples of thixotropic fluids are: greases, soap, starches, tars, asphalts, vegetable oils, shortening, hard wax, glue, inks, vegetable gums, resins, varnishes, peanut butter, and some slurries.

3. DILATENT FLUIDS

Viscosity **increases** as shear rate increases.

Forces to cause motion may greatly increase as speed increases.

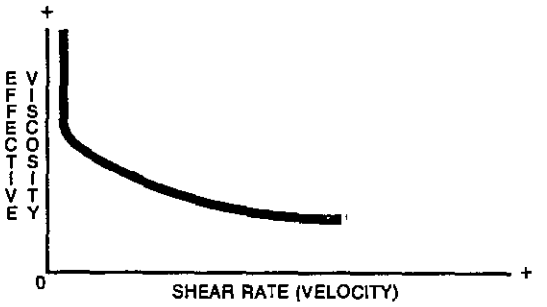
Some fluids showing dilatent behavior are: slurries, clay, and candy compounds.



4. PLASTIC AND PSEUDO-PLASTIC FLUIDS

Viscosity decreases as shear rate increases, **but** initial viscosity may be so high so as to prevent start of flow in a normal pumping system.

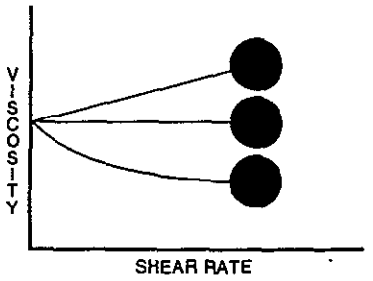
Typical fluids are: Gels, latex paints, lotions, and shortening.

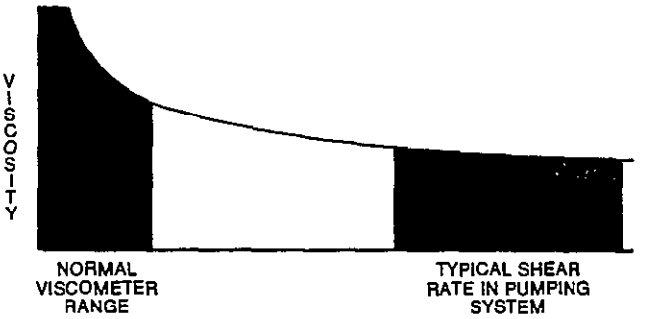


There are other classifications of fluid behavior, and mixtures of characteristics which are found commonly. These properties are best determined by laboratory tests.

Most empirical and test data for pumps and piping systems have been developed using **Newtonian** fluids in a wide range of viscosities. When working with **non-Newtonian** fluids, we use **"EFFECTIVE VISCOSITY"** to represent the viscous characteristics of the fluid as though it **were Newtonian** at that given set of conditions (shear rate, temperature). We can then use this **"EFFECTIVE VISCOSITY"** in calculations, and in using charts, graphs, and "handbook" information.

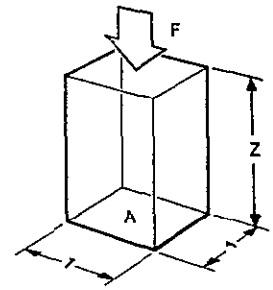
It is not always obvious which type of viscous behavior a fluid will exhibit. The important thing to consider is the shear rate which will exist in the pump and pumping system at the design conditions. It is not unusual to find the **EFFECTIVE VISCOSITY** $^1/_{20}$ to $^1/_{50}$ as much as the viscosity measured by standard instruments.



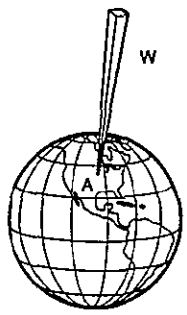


BASIC DEFINITIONS AND HYDRAULIC FUNDAMENTALS

PRESSURE The basic definition of pressure is force per unit area. As commonly used in hydraulics and in this manual, it is expressed in pounds per square inch (psi).



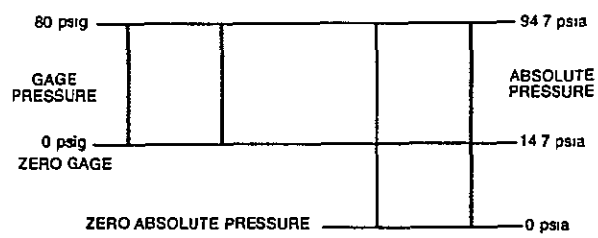
$$P = \frac{F}{A}$$



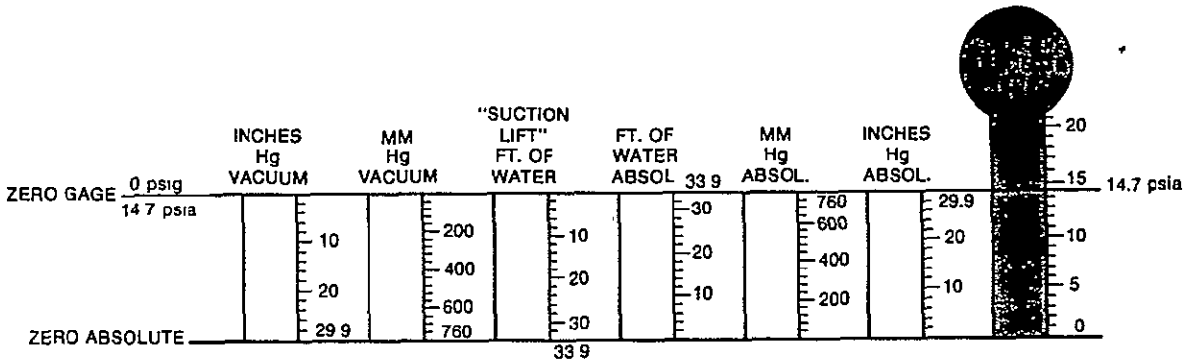
ATMOSPHERIC PRESSURE is the force exerted on a unit area by the weight of the atmosphere. At sea level, the atmospheric standard pressure is 14.7 pounds per square inch.

GAGE PRESSURE Using atmospheric pressure as a **zero reference**, gage pressure is a measure of the force per unit area exerted by a fluid. Units are psig.

ABSOLUTE PRESSURE is the total force per unit area exerted by a fluid. It equals atmospheric pressure plus gage pressure. Units are expressed in psia.



VACUUM OR SUCTION are terms in common usage to indicate pressures in a pumping system below normal atmospheric pressure, and are often measured as the difference between the measured pressure and atmospheric pressure in units of inches of mercury vacuum, etc. **It is more convenient to discuss these in *absolute* terms; that is from a reference of absolute zero pressure, in units of psia.**

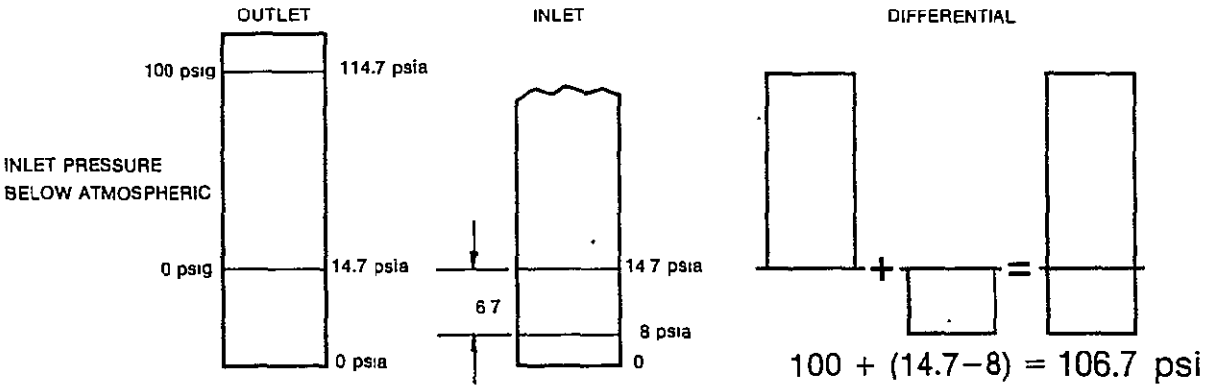


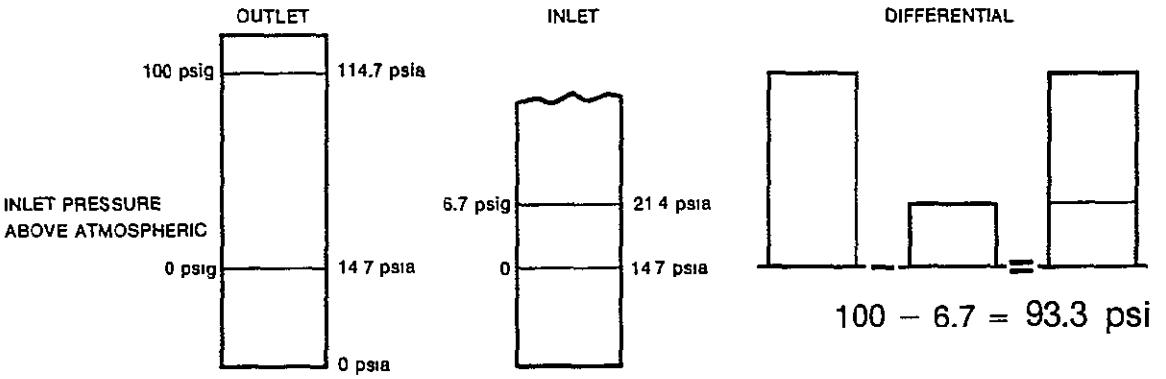
OUTLET PRESSURE or discharge pressure is the average pressure at the outlet of a pump during operation, usually expressed as gage pressure (psig).

INLET PRESSURE is the average pressure measured near the inlet port of a pump during operation. It is expressed either in units of absolute pressure (psia) preferably, or gage pressure (psig).

DIFFERENTIAL PRESSURE is the total absolute pressure difference across the pump during operation.

EXAMPLES:

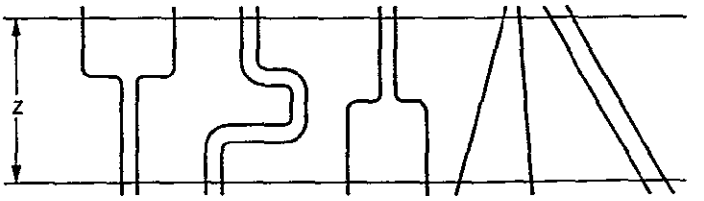




RELATION OF PRESSURE TO ELEVATION

In a static liquid (a body of liquid at rest) the pressure difference between any two points is in direct proportion **only** to the **vertical** distance between the points.

This pressure difference is due to the weight of the liquid and can be calculated by multiplying the vertical distance by the density (or vertical distance x density of water x specific gravity of the fluid). In commonly used units:



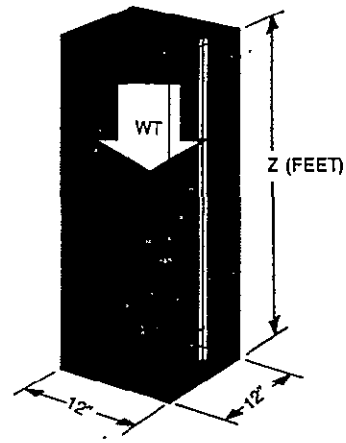
$$P \text{ static (in psi)} = Z \text{ (in feet)} \times \frac{62.4 \text{ lbs./cu. ft.} \times \text{S.G.}}{144 \text{ sq. in./sq. ft.}}$$

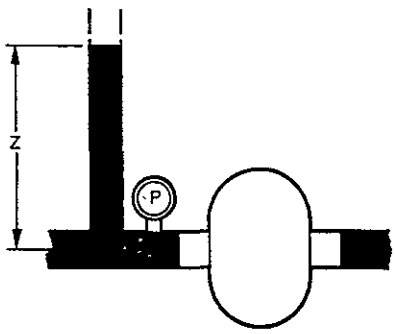
EXAMPLE: Calculate pressure difference between 2 points—vertical distance 18′ specific gravity 1 23

$$P = Z \times \frac{62.4}{144} \times S.G.$$

$$P = 18 \times .433 \times 1\ 23$$

$$P = 9.59 \text{ psi}$$





To obtain pressure in elevation units the equation is rearranged:

$$z \text{ (feet)} = \frac{P \text{ static (psi)}}{62.4 \text{ lbs./cu.ft.} \times S.G.} \times 144 \text{ sq.in./sq.ft.}$$

EXAMPLE: A pressure gage reads 85 psi. The fluid has a specific gravity of .95. What is the height of the equivalent column of fluid that would produce that same pressure.

$$Z = \frac{P}{62.4 \times SG} \times 144$$

$$Z = \frac{85 \times 144}{62.4 \times .95} = 206.5 \text{ FT.}$$

This relationship, the elevation equivalent of pressure, is commonly called head and is still frequently used. Although this manual uses pressure units, it may be helpful to explain certain terms in head units: That is, pressure converted to the equivalent height of fluid that would produce that pressure.

Static Head—The hydraulic pressure at a point in a fluid when the liquid is at rest.

Friction Head—The loss in pressure or energy due to frictional losses in flow.

Velocity Head—The energy in a fluid due to its velocity, expressed as a head unit.

Pressure Head—A pressure measured in equivalent head units.

Discharge Head—The outlet pressure of a pump in operation.

Total Head—The total pressure difference between the inlet and outlet of a pump in operation.

Suction Head—The inlet pressure of a pump when above atmospheric.

Suction Lift—The inlet pressure of a pump when below atmospheric.

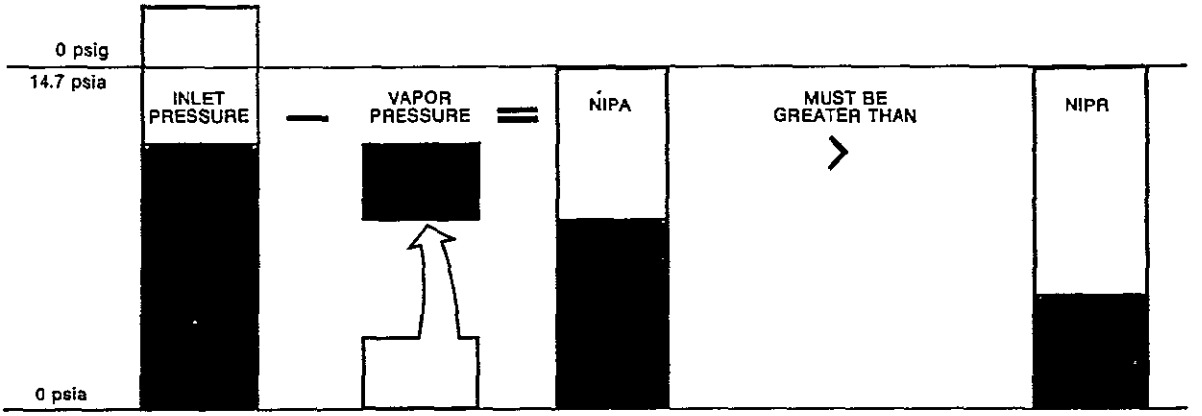
These terms are sometimes used to express different conditions in a pumping system, and can be given dimensions of either pressure units (psi) or head units (feet).

In rotary pump usage, and throughout this manual, *pressure units,* and the terms such as inlet pressure and outlet pressure, will be used, as they represent a consistent, simple way of describing pumping conditions.

A common term used to describe pump inlet conditions is Net Positive Suction Head (NPSH). Although still used in centrifugal pump terminology, two new terms are now used for rotary pump inlets.

Net inlet pressure available (NIPA) is the average pressure (in psia) measured near the inlet port during operation, **minus** the vapor pressure. It indicates the amount of useful pressure energy available to fill the pump cavities.

Net inlet pressure required (NIPR) is an individual pump characteristic, determined by test, of what pressure energy (in psia) is needed to fill the pump inlet. It is a characteristic which varies primarily with the pump speed and the viscosity of the fluid. For satisfactory operation under any set of conditions, the NIP available must be greater than the NIP required.



FLOW OF FLUID IN A PUMPING SYSTEM

Fluids at rest, or in motion, must conform to the principle of "conservation of energy."

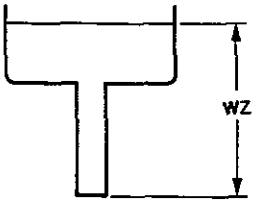
In the following:

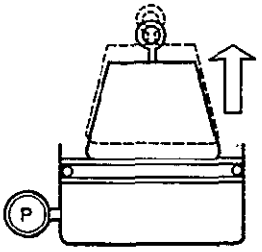
W = Weight of fluid	P = Pressure
V = Velocity	w = Weight per unit volume
g = Acceleration of gravity	Z = Height

The types of fluid energy in a pumping system are:

POTENTIAL ENERGY

Energy due to the elevation of the fluid above some reference level.



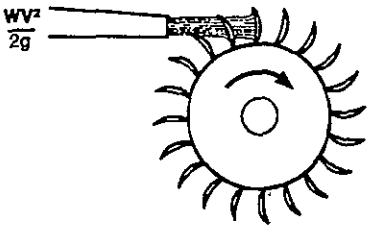


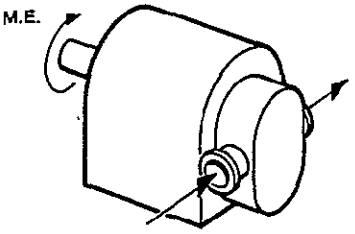
PRESSURE ENERGY

The internal energy of the fluid which could do work.

KINETIC ENERGY

Energy due to the motion of the fluid.



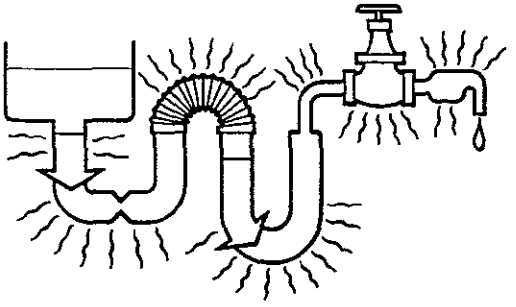


MECHANICAL ENERGY

Energy put into the fluid by a pump, or taken out by a motor, or other device.

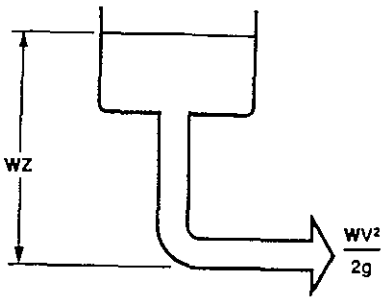
FRICTIONAL LOSSES

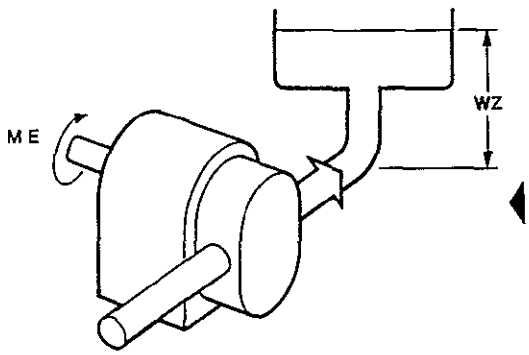
Represents the energy loss due to friction when a fluid flows through the parts of a system.



These forms of energy can be changed from one form to another within the system. For Example:

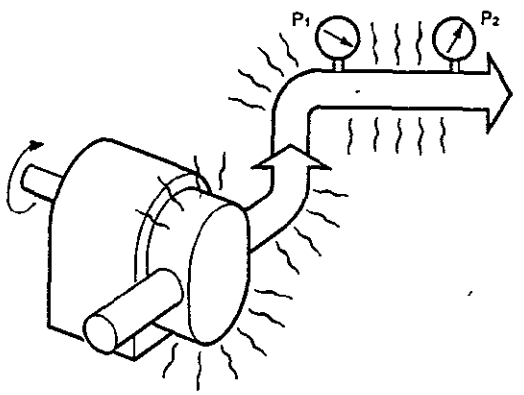
The **potential energy** of fluid in an elevated tank is changed to **kinetic energy** as it flows down through a piping system.





Mechanical Energy—added by a pump can be changed to **potential energy** by pumping fluid to a higher elevation.

Potential, Pressure, Mechanical or Kinetic energy can be changed to **heat energy** through frictional losses. This energy loss is often seen as a change in pressure energy.



So the energy in a system is "conserved," that is, not created or destroyed but merely changed in form.

For a part of a pumping system where energy is not added or removed, the total energy (E) is constant and equal to:

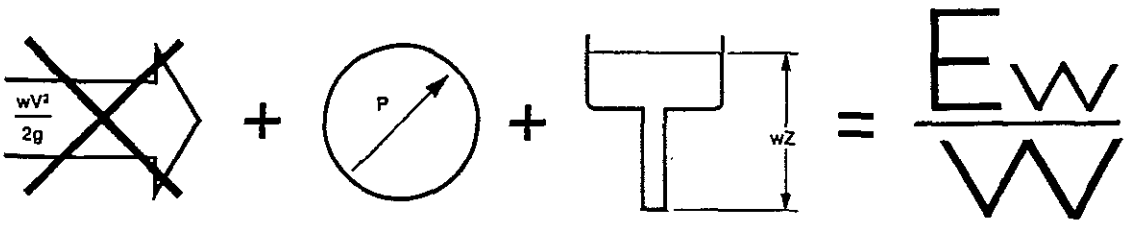
$$\frac{WV^2}{2g}\ \text{(Kinetic Energy)} + \frac{WP}{w}\ \text{(Pressure Energy)} + WZ\ \text{(Potential Energy)} = E$$

If the equation is divided by W (weight) and multiplied by w (weight per unit volume) it becomes:

$$\frac{wV^2}{2g} + P + wZ = \frac{Ew}{W}\ \text{(Constant)}$$

in which each term represents energy per unit volume and each has the dimension of pressure.

In a rotary pump system, the kinetic energy of the fluid is usually small in relation to other forms and is often left out.



It is then very handy to consider these energy levels in terms of **PRESSURE**, as most measurements can easily be made with pressure gages.

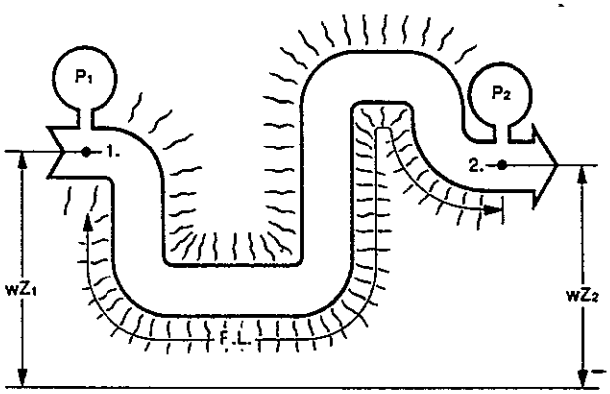
For the simple steady-state system, the energy relationship is.

$$P + wZ = \frac{Ew}{W}$$

When we consider the frictional losses in flow from one point to another, the relationship takes the form:

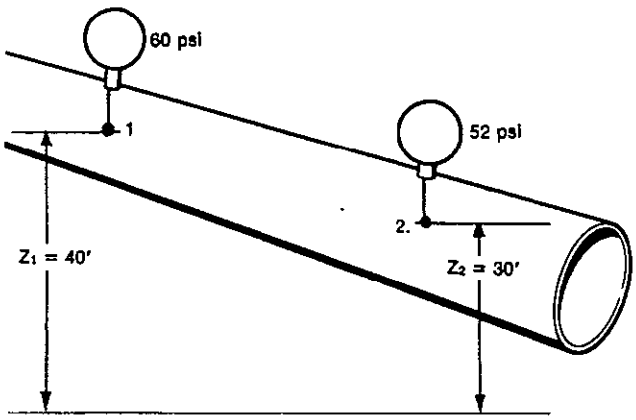
$P_1 + wZ_1 = P_2 + wZ_2 + FL$

Where FL is the pressure loss due to friction of the fluid flowing from point 1 to point 2. This is the form that pressure calculations will take in this manual.



As shown before, the units are made consistent by using P in units of psi, and by converting wZ to psi by:

$Z \text{ (feet)} \times \frac{62.4}{144} \times \text{S.G. or: } Z \times .433 \times \text{S.G.}$



Example: What is the pipe friction loss or pressure loss from 1 to 2 ?

Specific Gravity = 1.2

P_1 = 60 psig

P_2 = 52 psig

$P_1 + wZ_1 = P_2 + wZ_2 + FL$

$60 + (.433 \times SG)(Z_1) = 52 + (.433 \times S.G.)(Z_2) + FL$

$60 + (.433 \times 1.2)(40') = 52 + (.433 \times 1.2)(30') + FL$

$60 + 20.78 = 52 + 15.59 + FL$

$FL = (60 + 20.78) - (52 + 15.59)$

$FL = 80.78 - 67.59$

$FL = 13.19$ psi

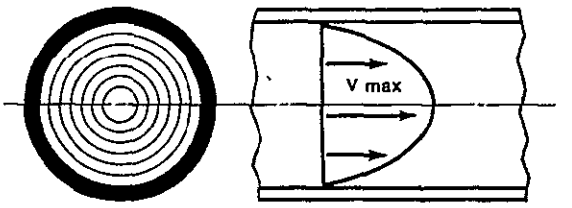
FRICTIONAL LOSSES

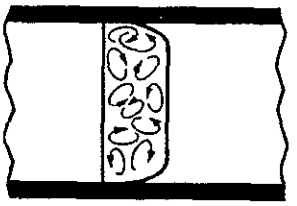
The nature of frictional losses in a pumping system can be very complex. Losses in the pump itself are determined by actual test, and are allowed for in the manufacturers curves and data. Similarily, manufacturers of processing equipment, heat exchangers, static mixers etc. usually have data available for friction losses.

Frictional losses due to flow in pipes are commonly considered to occur in two principle modes: Losses under laminar flow and turbulent flow.

In laminar flow, sometimes called viscous flow, the fluid moves thru the pipe in concentric layers with maximum velocity in the center of the pipe, decreasing towards the walls where the fluid particle is essentially standing still. A cross section of velocity would appear as shown. There is very little mixing of fluid across the pipe cross section. Friction loss is directly proportional to

- the length of pipe
- the flow rate
- $1/d^4$ (d is pipe diameter)
- the viscosity (centipoise)





In turbulent flow, considerable mixing takes place across the pipe cross section and the velocity is nearly the same across this section as shown.

Turbulent flow is more likely to occur in thin liquids, and is often characterized by higher friction losses than would be expected.

The friction loss is proportional to

- the length of pipe
- the flow rate squared (Q^2)
- $1/d^5$
- viscosity (to $^1/_4$ to $^1/_{10}$ power)

There is a range between laminar and turbulent flow sometimes called mixed flow where conditions are unstable, and have a blend of each characteristic.

A convenient number, called the Reynolds number, can be used for estimating the transition between laminar and turbulent flow. The Reynolds number, a ratio of flow rate to viscosity, can be computed by the relation

$$R = \frac{Q}{d \times \mu/S.G.}$$

where

R = Reynolds Number
Q = Flow in GPM
d = Pipe diameter in inches
μ = Viscosity in poises
S.G. = Specific gravity

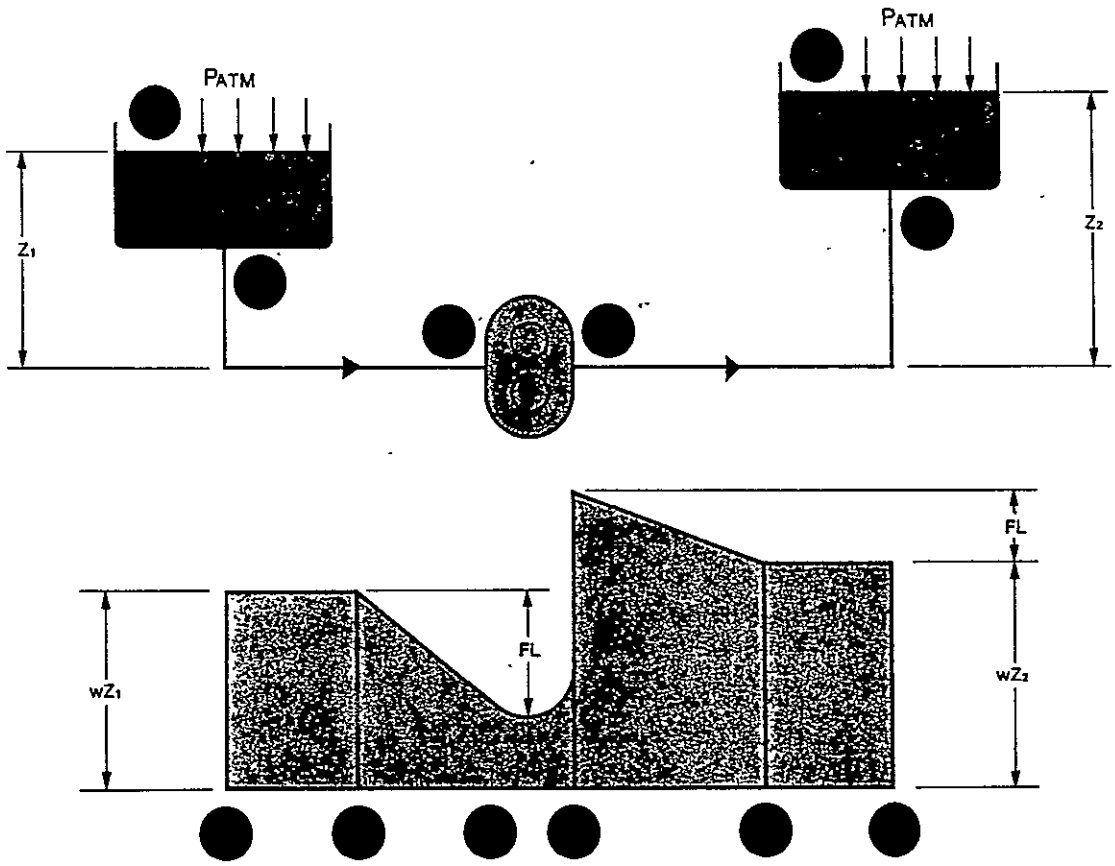
Normally we can expect

Laminar flow - If R is less than 63
Turbulent flow - If R is more than 63

ENERGY LEVELS IN A PUMPING SYSTEM

Using the fact that energy can change form in a system, we can look at several simple pumping systems, and at a useful type of energy level graph. The energy level graph can be used to help understand system calculations, and to help identify potential problems in a pumping system.

In the system below, we identify points 1 thru 6 in a system and below it show the "energy gradient" line as the fluid flows thru the system.



1 - 2 Potential energy (wZ_1) changes to pressure energy: Very small frictional loss because tank area is large.

2 - 3 Potential energy changing to pressure energy but with loss of pressure energy due to frictional losses (FL).

3 - 4 Internal pump frictional losses—then rise in pressure energy as mechanical energy is added by pump.

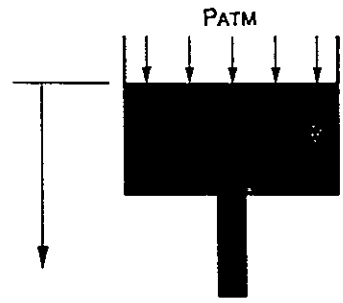
4 - 5 Pressure energy changing to potential energy but with loss of pressure energy due to frictional losses (FL).

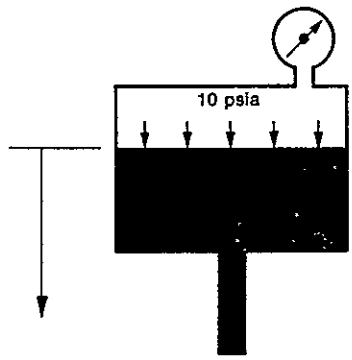
5 - 6 Pressure energy changing to potential energy (wZ_2)—very small frictional loss.

It should be realized here that **THE PUMP ADDS ONLY ENOUGH ENERGY TO FULFILL THE SYSTEM REQUIREMENTS;** that is: Take the fluid at its inlet, increase its pressure sufficiently to raise it to the higher elevation and to overcome the pipe friction losses.

In this last example, the system can be called an "open system," where at one or more points the fluid is "open" to atmospheric pressure.

It is usually easiest to use a "free surface" (that is: the liquid level exposed to the atmosphere) as a beginning point in calculations, because the pressure there is known and constant.



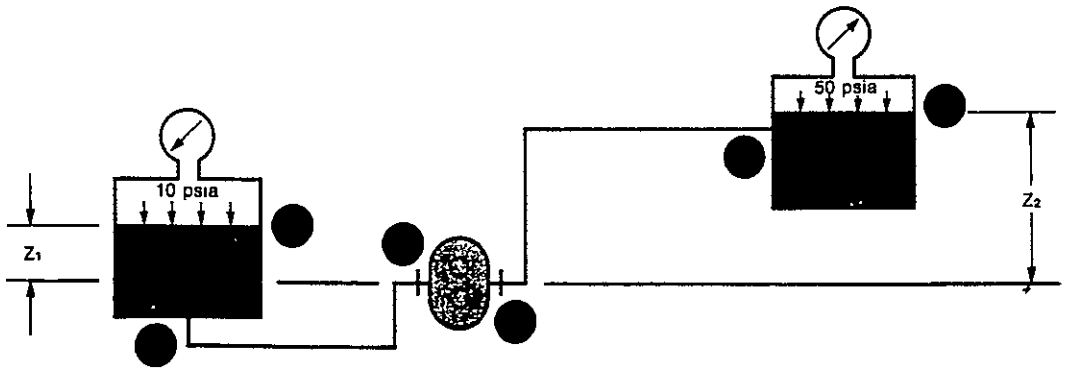


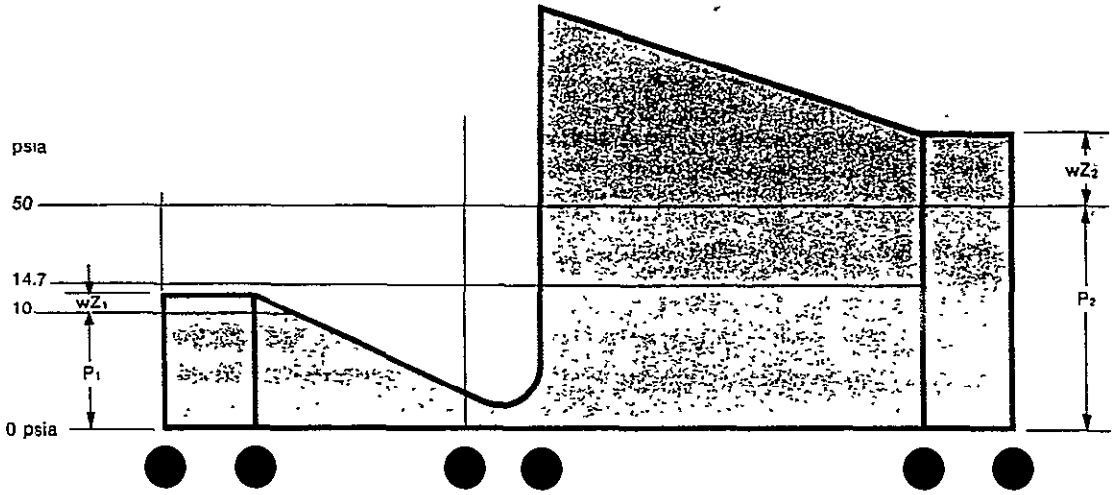
In a "closed system," a free surface can be used as a reference, if the pressure is known.

The method of analyzing energy levels in a closed system is similar.

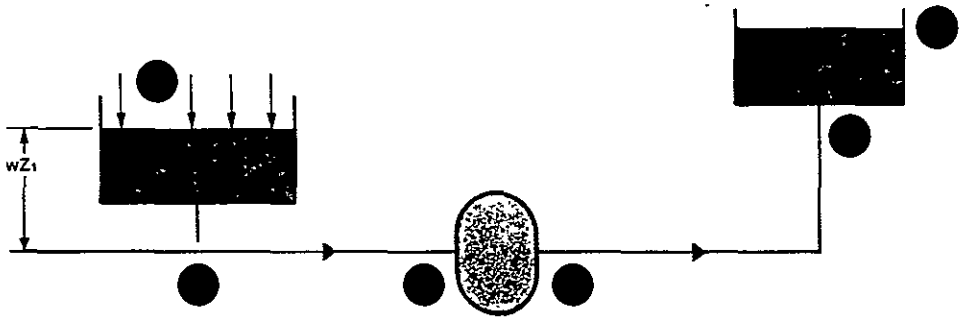
In the following example we assume that tank A has a pressure on the free surface less than atmospheric, $P_1 = 10$ psia, and the fluid in tank B has a free surface pressure of 50 psia. These are conditions that often can be found in processing equipment.

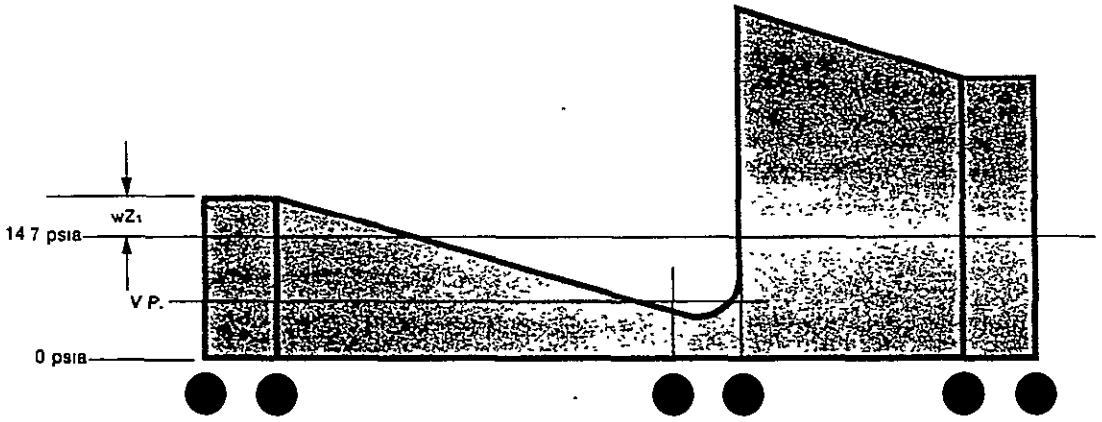
The energy gradient principles are the same, as are calculations. The inlet portion of the system is analyzed starting with the free surface pressure: The outlet portion calculated ending with the free surface pressure. The pump input must provide the difference required from its inlet to its outlet.





Below we show a pumping system with a low potential energy level (wZ_1) at the inlet. With high frictional losses to the pump inlet, the energy available to fill the pump may become critically low.





At point 1 or 2, it can be seen that atmospheric pressure plus the potential energy due to elevation provide the only energy available to get the fluid into the pump: if the friction loss is great in the inlet line, the pressure at the inlet (3) may fall below the liquid vapor pressure. Reduced flow or no flow will occur as the liquid flashes into vapor.

The term "flooded suction" was sometimes used to describe the condition where a fluid level was above the pump inlet.

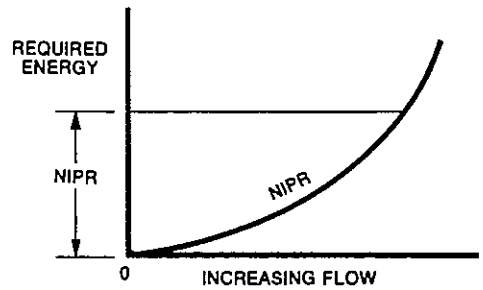
The fluid level **does not** insure flow into the pump; the **energy available** at the inlet port must be high enough.

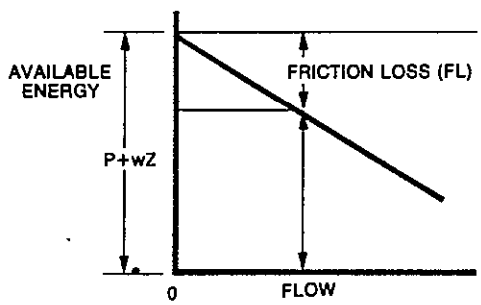
THE INLET SIDE

The energy **available** to push a fluid into the pump inlet is usually very limited, often less than the 14.7 psia atmospheric pressure on the free surface of the fluid. This fact makes the inlet side in a pump installation the critical part of pump selection.

The energy **required** by a pump, called Net Inlet Pressure Required (NIPR), is a characteristic of the pump, and varies primarily with the pump speed and the fluid viscosity.

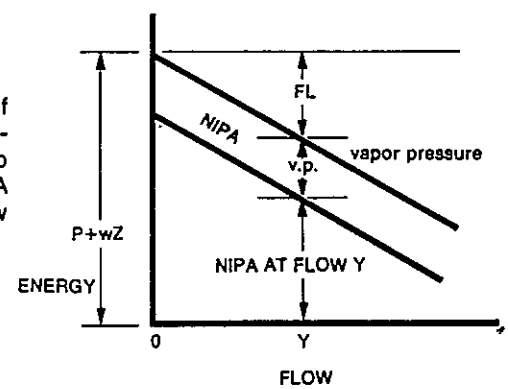
With a given fluid viscosity, the energy graph of a pump would appear as below, with the NIPR increasing as flow increases.

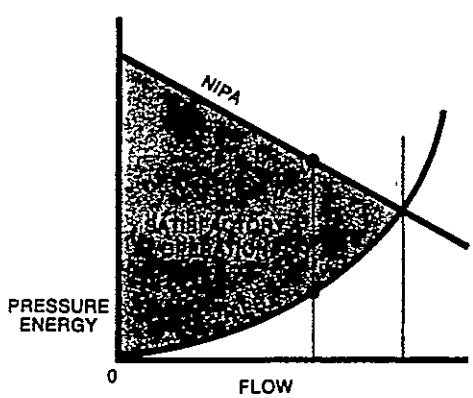




In a typical pumping system, the graph for energy **available** at the pump inlet would appear as shown. As flow increases, the friction loss increases—thus **reducing** the energy available.

From the energy graph above, the **vapor pressure** of the fluid must be subtracted—because the vapor pressure represents the pressure energy needed to keep the fluid as a fluid—the energy level left is NIPA. A graph of energy available to fill the pump at any flow rate can be plotted as shown.





Combining the graph of NIPA and NIPR, we have the result as shown.

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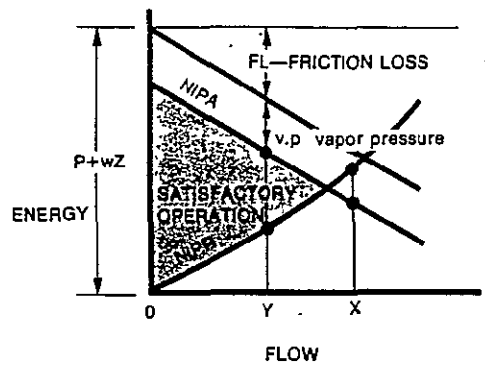
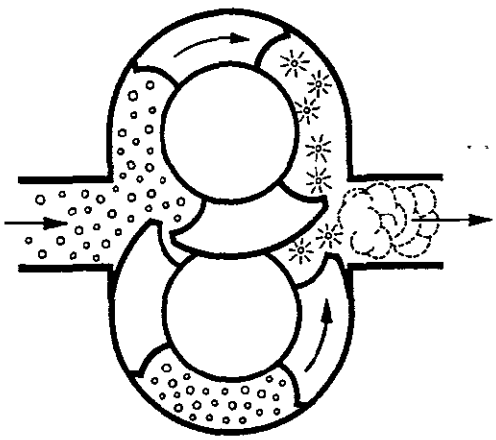
WHENEVER THE NIPA IS GREATER THAN NIPR, SATISFACTORY OPERATION WILL RESULT.

The total graph of system energy and losses would appear as shown—plotted against increasing flow.

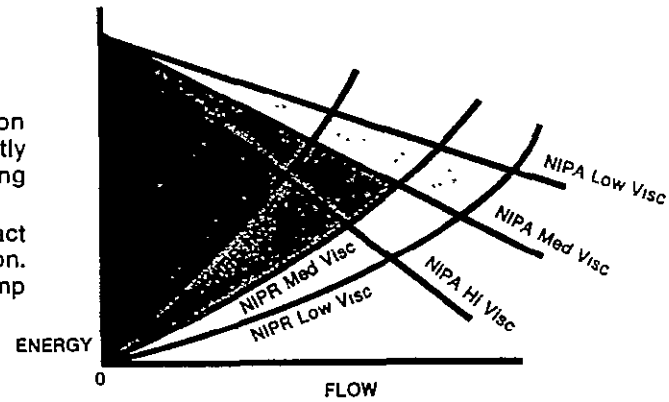




If the NIPA is too low for a specific pumping condition, as at Point X, the pressure at a point in the pump, or near its inlet, will become lower than the vapor pressure of the fluid. The fluid will vaporize, or change to a gas, which will fill the pump cavities instead of fluid. This will reduce the pumping capacity of the pump. The collapse of this vapor in the pump or outlet line is called cavitation and is the cause of noisy, inefficient operation, often resulting in pump damage.

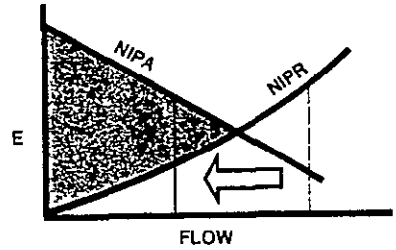
As fluid viscosity increases the effect can be seen on both NIPA and NIPR. Friction losses increase directly proportional to absolute viscosity—thus lowering NIPA.

The NIPR of the pump also increases, and they both act to rapidly decrease the zone of satisfactory operation. It is usually necessary to reduce pump speeds to pump viscous liquids.

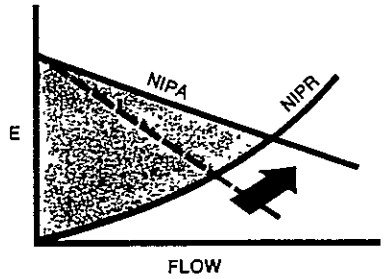


The system characteristics can be changed to assure operation in the satisfactory zone. By these physical changes, the NIPA or NIPR lines can be shifted to expand the zone of operation—to avoid cavitation or pump "starvation" and assure that NIPA is greater than NIPR.

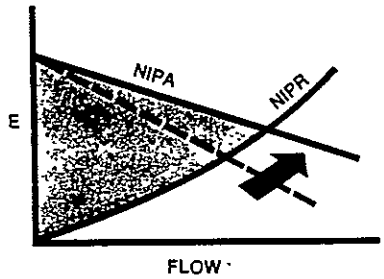
SLOWING DOWN THE SPEED OF THE PUMP (Decrease Flow)



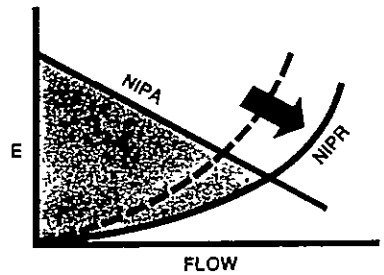
INCREASE INLET LINE SIZE



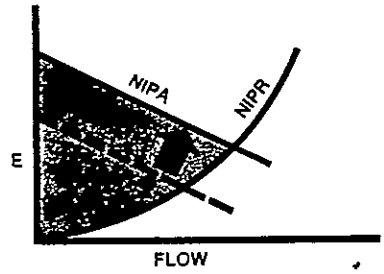
SHORTEN INLET LINE LENGTH. MINIMIZE DIRECTION & SIZE CHANGES. REDUCE NUMBER OF FITTINGS



INCREASE PUMP SIZE FOR GIVEN FLOW, THIS LOWERS NIPR



ELEVATE LIQUID SOURCE—OR—LOWER PUMP—OR —PRESSURIZE SOURCE TANK

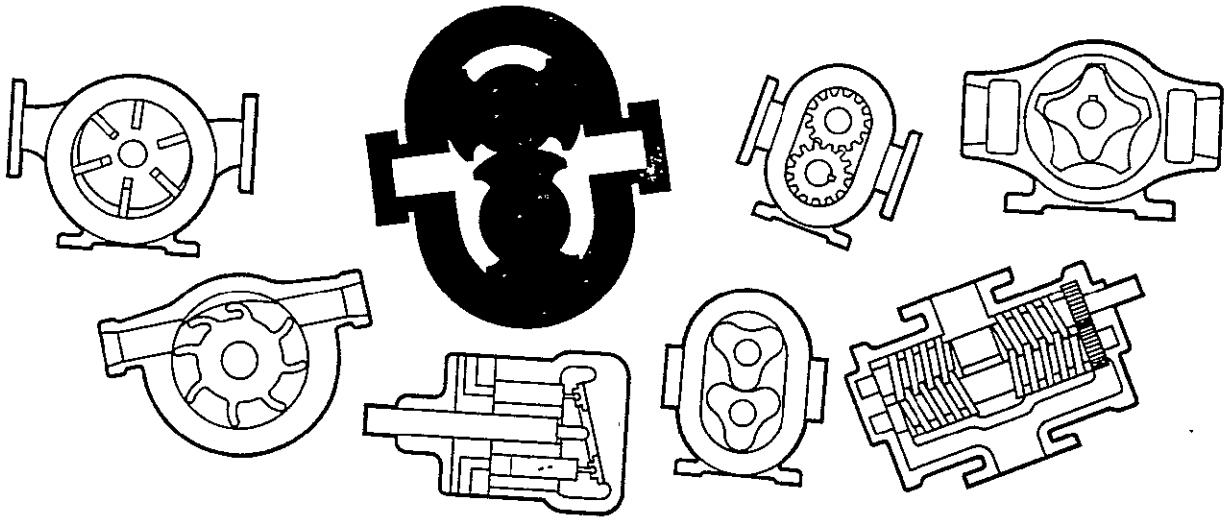


By any of these changes, or combinations of them, the system and pump characteristics can be selected to allow operation at satisfactory flow rates and system conditions.

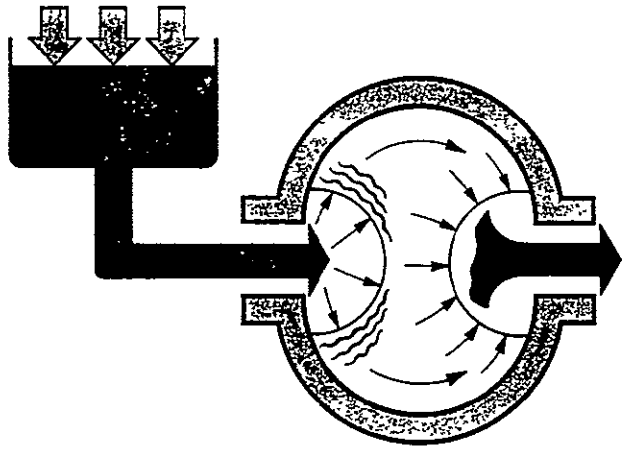
Rotary pumps, such as the Waukesha, have better inlet characteristics (low NIPR) than most other types of pumps, and are often selected for their ability to operate under low net available inlet pressures, to self prime, to lift the liquid on the inlet side, or to pump fluids from vacuum equipment. They are particularly suited for pumping viscous liquids and are often the only pumps which can be used in this service.

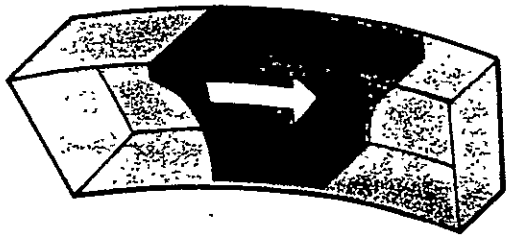
ROTARY PUMP FUNDAMENTALS

A rotary pump is a positive displacement pump which moves fluids by means of the motion of rotors, cams, pistons, screws, vanes, or similar elements in a fixed casing, usually without the need of inlet or outlet valves.



The motion of the rotary parts causes specific volumes to be "created" near the pump inlet, allowing atmospheric or external pressures to force liquid into the pump: Near the outlet these volumes are collapsed or "destroyed" forcing the liquid out of the pump.

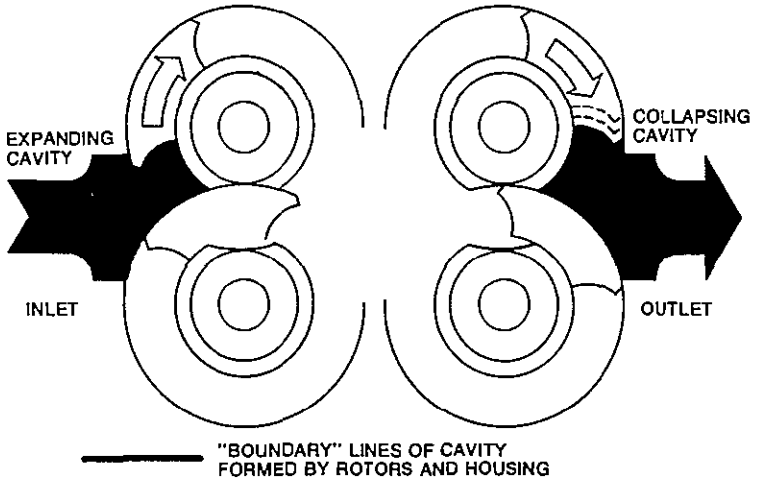


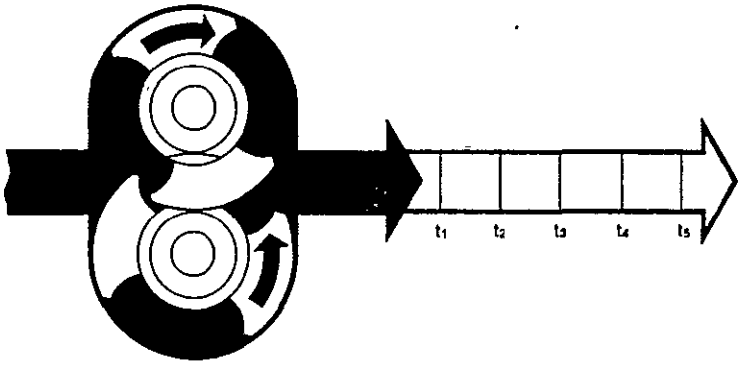


The Waukesha Rotary Pump is classified as an "external circumferential piston" pump. What this means is that arc shaped "pistons" travel in annularly shaped "cylinders" as shown.

Each rotor has two "pistons"; two rotors are used in the pump—driven by external timing gears to rotate in opposite directions.

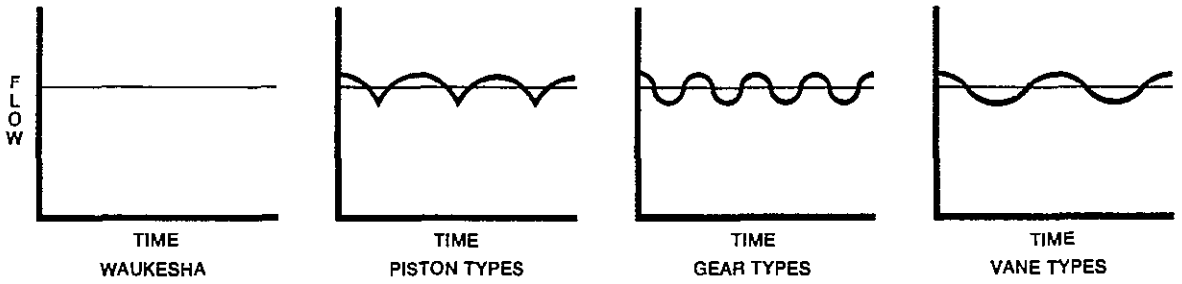
The motion of the rotors "creates" an expanding cavity on the inlet side allowing fluid to flow into the pump chamber. The rotors then carry the fluid around the cylinder to the outlet side, where it is forced out of the pump as the cavity contracts.



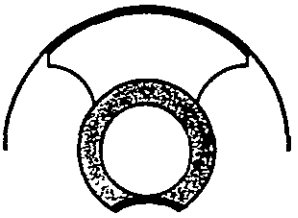


The rotors turn at constant velocity, and the shape of the rotors and cavities allow the Waukesha pump to deliver a constant volume per unit of time for any rotor position.

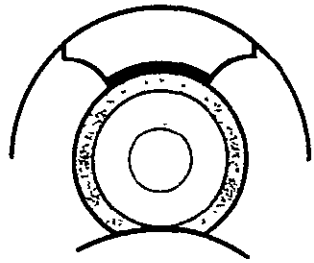
This means a Waukesha pump delivers a smooth, non-pulsating flow. Many other pump types have a variation in flow per unit of time, resulting in pulsations.

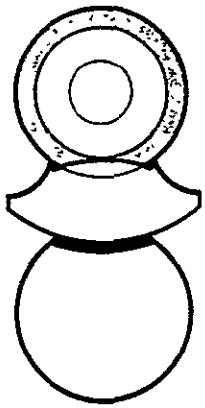


Each rotor forms a long "seal" path between its outer diameter and the housing:



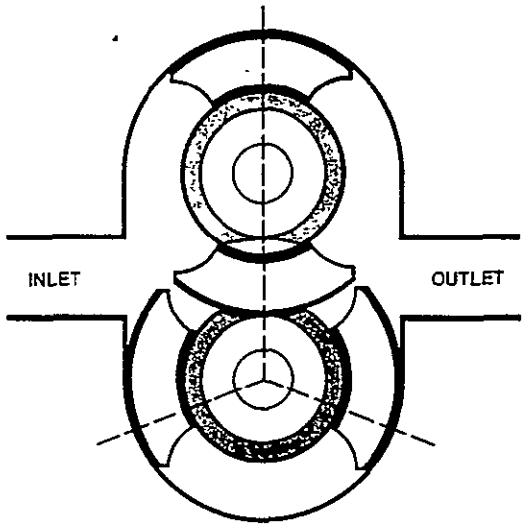
Between its inner diameter and the Body Hub:



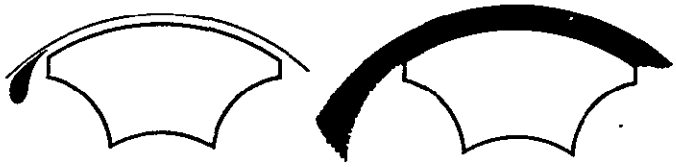


Or, between the outer diameter and the "scallop" in the opposite Hub.

So, at any position in the rotation of the two rotors, there is a long and continuous "sealing" path between the inlet and outlet.



These long sealing paths limit the backflow or **slip** from the high pressure pump outlet to the low pressure inlet.



The clearance between rotating and stationary parts is even more important in limiting slip. Slip increases rapidly with increasing clearances (proportional to clearance to the 3rd power—C^3).

Using alloy combinations that minimize galling, Waukesha pumps can be machined to very close clearances, making it a low slip pump.
The combination of the basic style, the materials of construction, and close clearances makes the Waukesha pump one of the most efficient rotary pumps available.

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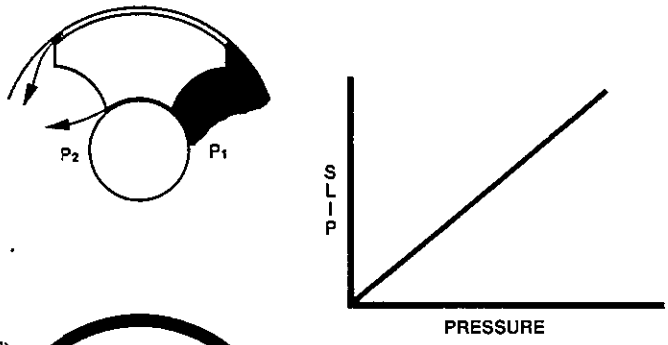
SLIP AND EFFICIENCY

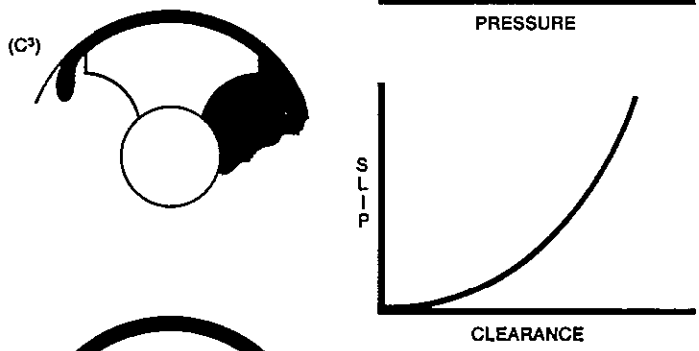
Pump performance in many cases is dependent on the slip (slip flow), which occurs in a pump.

Stated again: slip increases:

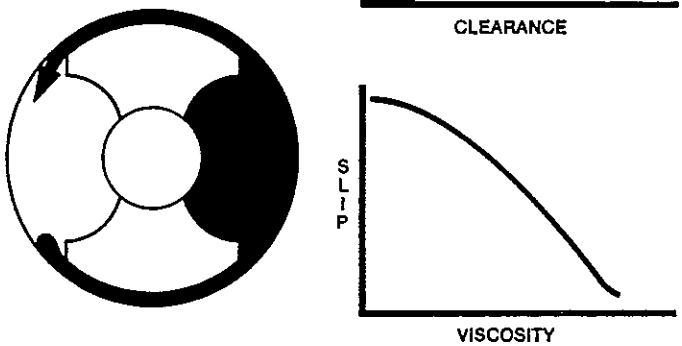
Directly with pressure.



Directly with clearance.

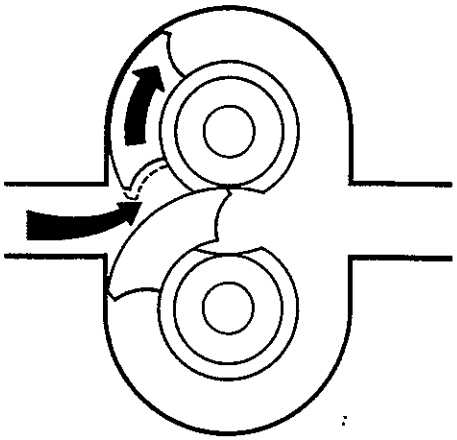


Inversely with viscosity.



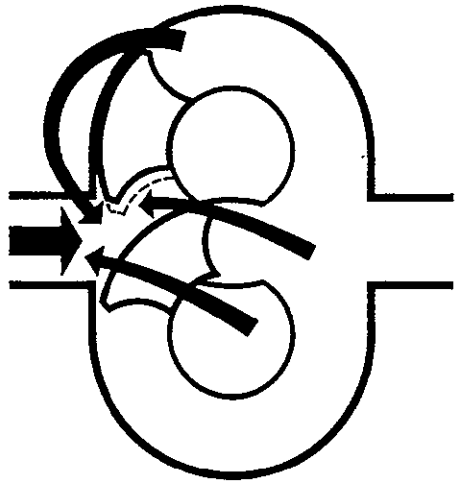
The major effect of slip on pump performance is the loss in flow capacity.

Let us illustrate it this way.



The expanding cavity on the inlet side creates a low pressure area that "asks" to be filled with fluid. This cavity can be filled with fluid from the inlet line in normal performance.

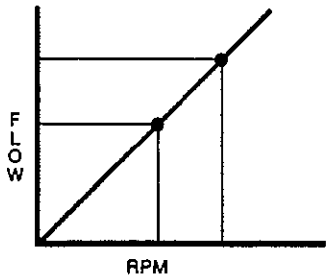
However, if the slip is high, the cavity can be partly filled with fluid flowing back through the pump from the outlet side.



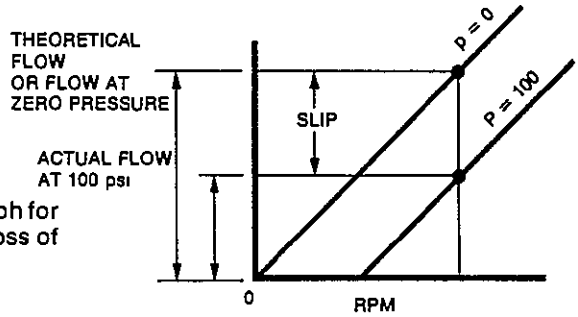
If this occurs, the pump loses the ability to deliver the volume of fluid it is theoretically capable of pumping.
This phenomena is sometimes defined by the term **volumetric efficiency**, or:

$$V.E. = \frac{\text{Actual flow}}{\text{Theoretical flow}}$$

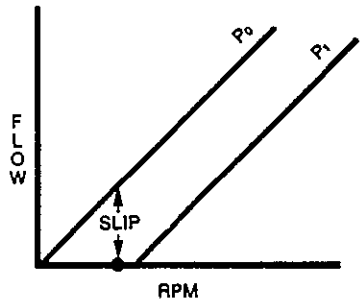
Although often used by pump manufacturers, this term is less useful than really understanding slip.



For a **given pump** and fluid, the slip is proportional to the pressure differential from outlet to inlet. If the pump had no slip, the volume pumped would be directly proportional to speed or rpm.

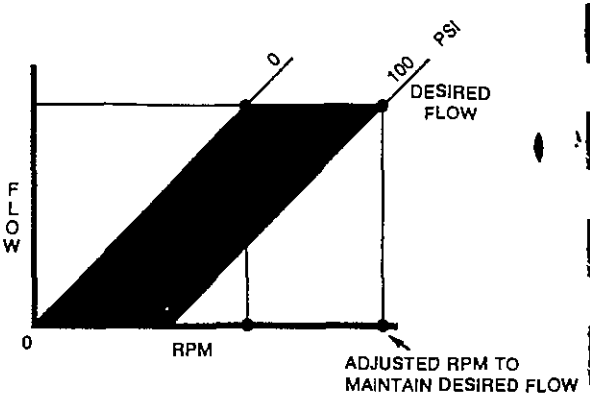


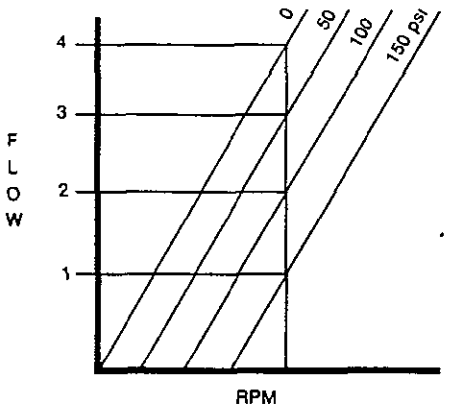
When the slip flow is superimposed on this graph for a given pressure differential, we can see the loss of flow which is due to slip.



With this illustration a number of things can be seen.
If the slip is high enough at a certain speed, **no flow at all could occur.**

If a certain flow is needed at a given pressure, the speed must be increased.

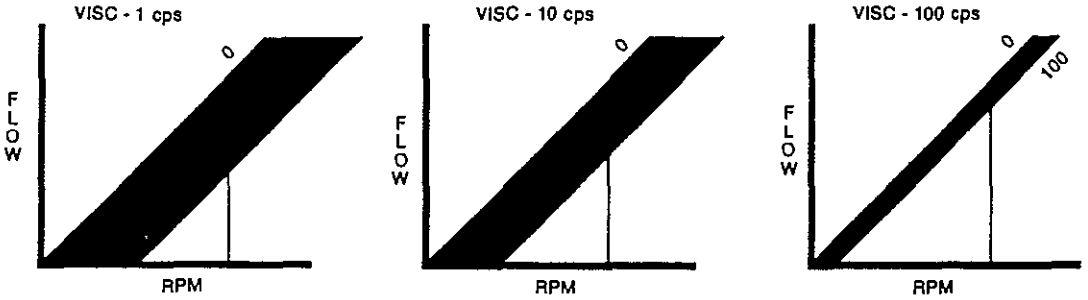




If the pressure is increased, the slip will increase, and therefore, the actual flow will decrease.

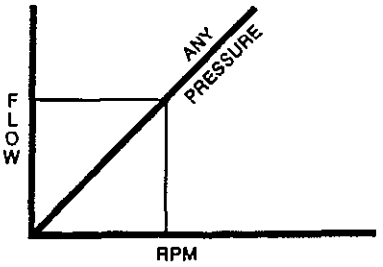
This type of chart is commonly used to show pump performance.
It should be remembered that this type of chart shows the performance for only one fluid viscosity.

If the viscosity increases, the slip will decrease (for a given pressure differential and pump).



So a series of charts would actually be needed to cover a full range of viscosities.
In a close clearance Waukesha Pump the slip is essentially zero when the viscosity is above 160 centipoise. Therefore, the pump will deliver its theoretical displacement **at any pressure** in its working range.

The flow performance can then be shown as one line for all viscosities above 160 cps, and the theoretical or zero pressure line can be used to find flow and rpm.

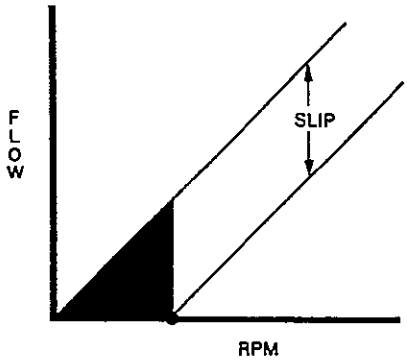


Later we will develop a type of chart which can be used for all viscosities, even between 1 and 160 cps.

THE EFFECT OF SLIP ON PUMP PERFORMANCE

When the internal slip of a pump is low, as in the Waukesha, the pump can be used effectively to:

1. Pump low viscosity-fluid in low NIPA Systems.
2. Pump from "vacuum" vessels.
3. Self prime. (And, lift fluids from lower levels.)
4. Meter fluids.

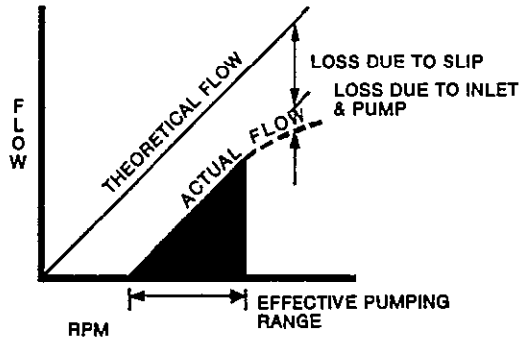


1. LOW NIPA SYSTEMS

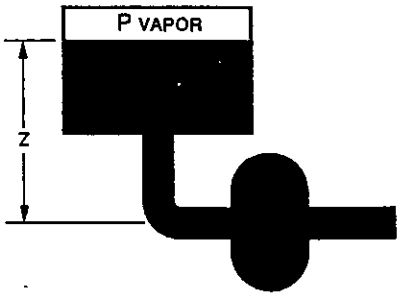
When pumping low viscosity fluids in low NIPA systems, the effect of slip in reducing capacity, along with the energy requirements in entry to the pump (NIPR) must be considered. A careful balance must be made in selecting pump size and speed.

At low pump speeds, the inlet losses are low, but if the pressure differential across the pump causes excessive slip, little or no flow may result.

At higher speeds, the inlet and internal pump losses may be high enough to limit flow. At these higher speeds a "point of no return" can be reached where high velocities within the pump chamber create localized low pressure zones. Vapor formation can take place in these zones, and the vapor can fill the pump cavities, destroying its ability to sustain uniform flow of fluid.

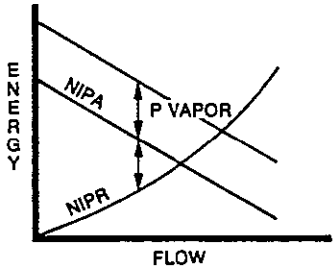


The selection of pump size to get the required flow and acceptable speeds may also be cost dependent, with smaller pumps generally costing less.



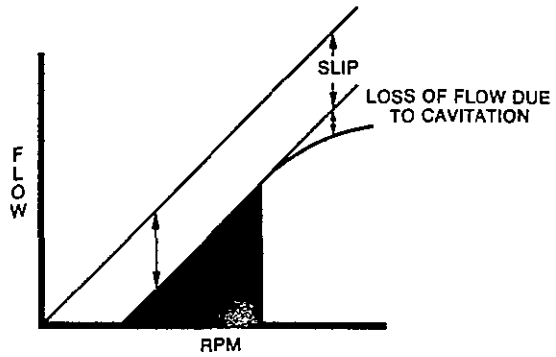
2. VACUUM VESSELS

Pumping from vacuum vessels is an extreme example of low NIPA operation which is possible with a low slip pump. Typically the vacuum chamber is used to evaporate fluids or to process at low temperatures. This causes an additional problem, in that operation is taking place at the vapor pressure of the fluid. In these cases, the maximum energy available to push fluid into the pump is that of the "liquid leg" or elevation.

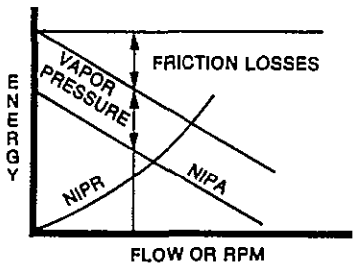


If this liquid leg is low, and NIPA is barely higher than the NIPR, cavitation in the lines or pump can easily occur. In the design of these systems, it is typical to elevate the tanks, often to 30 ft. or more, to obtain the leg needed.

If the viscosity is low, the additional factor of slip flow must be overcome. We have again the limits on speed range—where at low speeds the slip may be a high percentage of theoretical flow, resulting in little net flow, and at higher speeds, the flow can be limited by cavitation or vaporization of fluid.

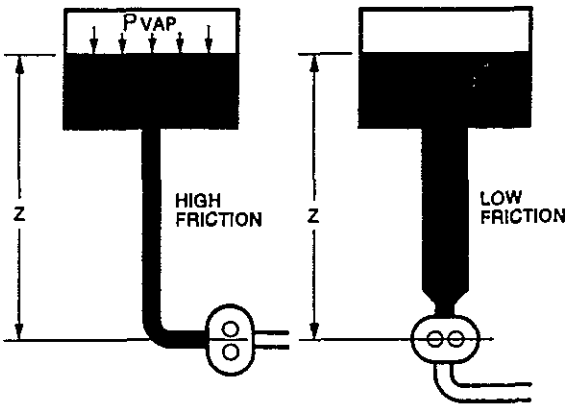


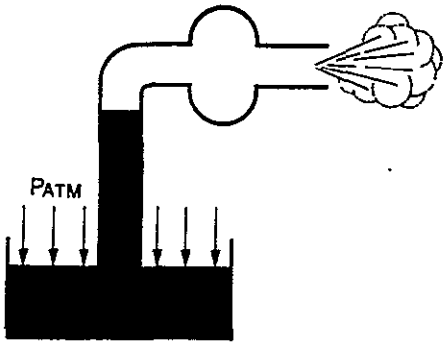
Pumping low viscosity fluids from a vacuum is nearly impossible with a high slip pump. The low slip Waukesha can do this job when the system and pump conditions are carefully selected.



In pumping viscous fluids from vacuum vessels, slip is not a factor, and the NIPA and NIPR values determine the operating range, with both subject to the increased frictional losses due to higher viscosities.

Care in systems design must be taken, because raising the liquid level to obtain more energy to fill the pump, also means that the inlet lines are longer and the increased frictional losses may offset the higher elevation. A typical solution to this problem is a large diameter standpipe, (to reduce frictional loss) tapering down to the pump port size just at the inlet, with a minimum of elbows and fittings.





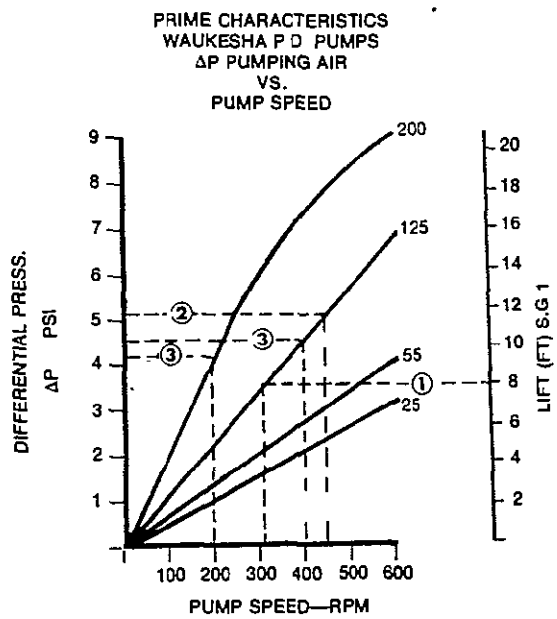
3. PRIMING ABILITY

The Waukesha pump clearances are small enough, that at higher speeds, the pump can even move air. What this means is that the pump can be used to "dry prime," or actually evacuate the air in the inlet line, reducing the pressure and allowing the liquid to move up in line, fill the pump chamber and begin normal pumping.

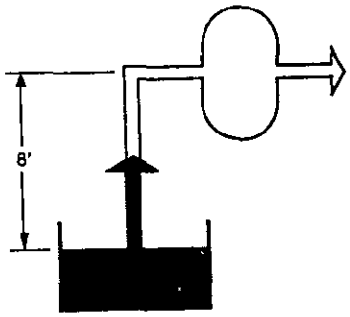
This ability can be very important and useful, as the Waukesha is one of the few pumps which can be used to empty barrels, tanks, and tank cars, etc. . . in this way, without priming with liquid.

When pumping low viscosity fluids this "dry priming" action happens rapidly. Higher viscosity fluids move up the inlet piping more slowly, but they **will move** and the priming **will** take place. The Waukesha pump can run **dry** without damage, long enough for these viscous fluids to reach the pump inlet.

CHART—Shows the dry priming ability of different size pumps at various speeds. The pressure differential shown is expressed in psia, but can easily be converted to vertical lifts. The second scale shows the lift possible for water, assuming 14.7 psia atmospheric pressure, and negligible line losses.



DETERMINING SPEED FOR LIQUID LIFT



Example 1:

Given '125' size pump handling water, what minimum speed must pump run to lift water (self prime) from a tank with liquid surface 8 ft. below pump?

On chart, for 8 ft. lift for liquid of S.G.=1, curve for '125' size pump indicates minimum speed of 305 RPM.

Note: $8' \times \frac{62.4\ ft^3}{144\ ft^2} \times S.G. = PSI$

$8' \times .433 \times 1 = 3.46\ PSI$

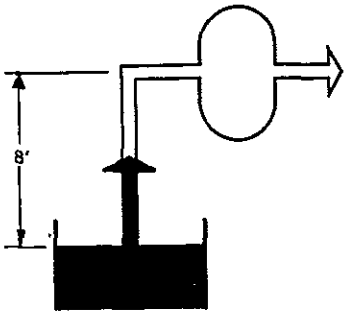
Example 2:

Effect of specific gravity on priming ability. For the pump above, a '125' size, with a lift requirement of 8 ft., what speed must the pump run to lift Trichloroethylene of S.G. = 1.47?

$8' \times .433 \times S.G. = PSI$

$8' \times .433 \times 1.47 = 5.09\ PSI$

On chart for 5.09 PSI '125' size pump requires minimum speed of 445 RPM.



When a pump must be selected for its priming ability, it can be seen on the graph that a smaller pump, running faster, often must be used to develop more "dry prime" differential pressure.

Example 3:

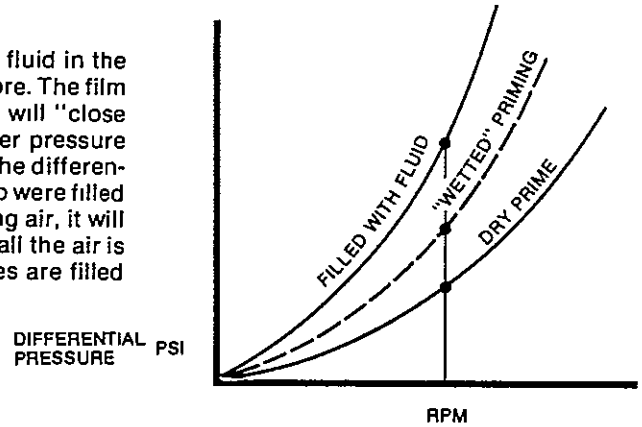
For a 100 GPM flow rate, a '200' size pump at 200 RPM could be used, or a smaller '125' size pump at 400 RPM. (See typical flow vs. RPM cruves.)

For 100 GPM flow rate, on water (S G. = 1):

'200' size pump at 200 RPM can develop 4.2 PSI differential or lift 9.7 feet.

'125' size pump at 400 RPM can develop 6.3 PSI differential or lift 14.5 feet.

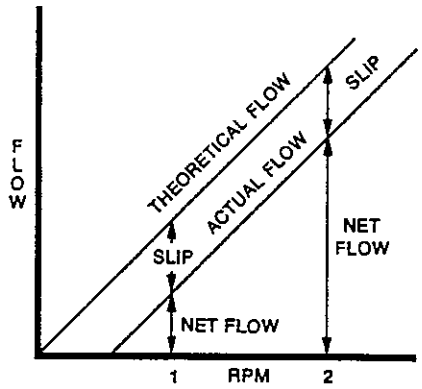
Of course, if it is possible to have some fluid in the pump, priming will be improved even more. The film of liquid in the clearances of the pump will "close up" those clearances, and allow a higher pressure differential to be created, approaching the differential which could be developed if the pump were filled with fluid. Because it will still be pumping air, it will not reach full pumping conditions until all the air is expelled and the lines and pump cavities are filled with fluid.



4. METERING FLUIDS

A low slip pump can be used effectively to meter fluids. If the slip is low, a pump will deliver nearly its theoretical displacement in each revolution. By electrically counting and controlling revolutions of the pump, or its revolutions per minute, we can get a measure of the **amount** of liquid displaced, or the **rate** (GPM) of flow.

Let's see how this can be done with a low slip pump.

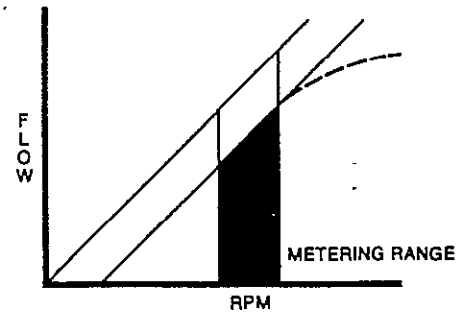


We saw before that slip is proportional to pressure. In a metering application, to reduce slip as much as possible, the pressure differential should be kept low. This can be aided with short, large diameter lines with few fittings or bends. With this low pressure differential, slip will be low and constant.

Looking then at a FLOW-RPM chart, we can see that at a low pump speed, the slip might be still a sizeable **percentage** of theoretical flow (1). If the pump speed is increased, the slip becomes a small percentage of theoretical flow (2), and by counting shaft revolutions only a small constant error exists, which can be compensated for in several ways.

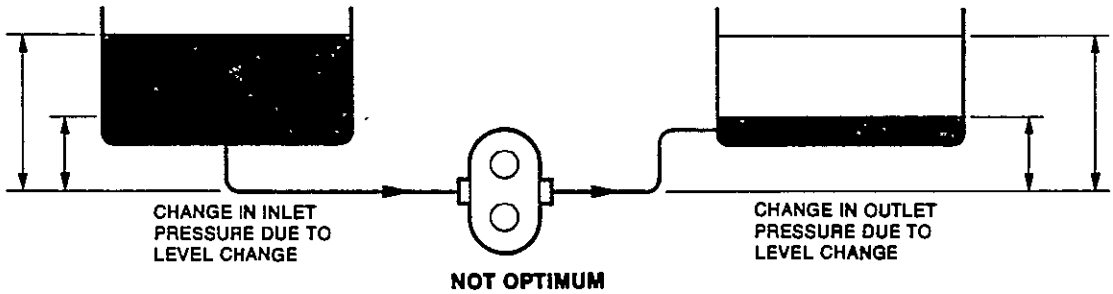
In any case, **repeatability** is usually obtained and is often what is really needed.

Then for metering **low** viscosity fluids the pump size should be selected so it will run at high speed, but avoiding loss of flow due to cavitation.

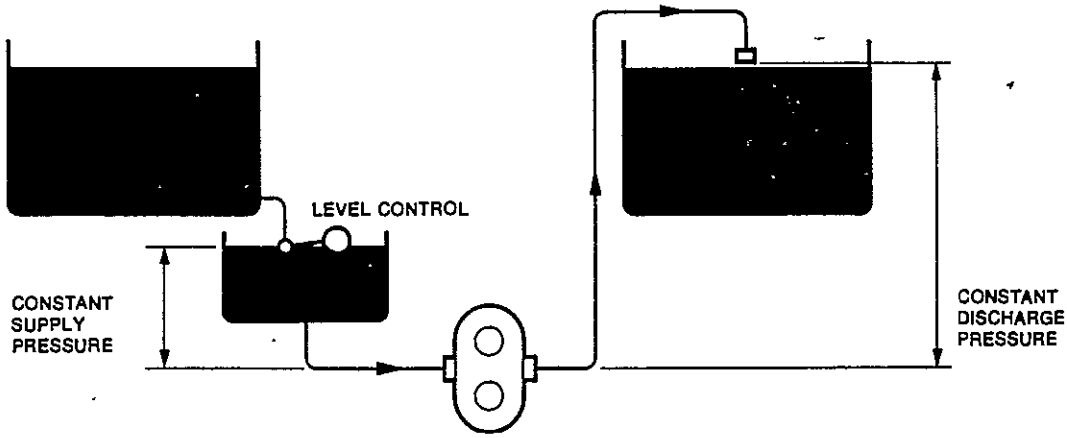


To obtain best metering performance when using a standard Waukesha pump on low viscosity fluids, the system should be designed to operate under a constant pressure differential if possible. On the inlet side, changes in pressure due to liquid level changes in a supply tank can be minimized by using a small balance tank with a level control.

In the outlet side, pressure can often be kept constant by discharging at the top of the delivery container.



NOT OPTIMUM



PREFERRED

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At fluid viscosities of 160 cps and over, metering is very effective in a standard Waukesha pump. The slip is essentially zero, and the pump will deliver its theoretical displacement. This is true at **all** speeds, allowing an easy, optimal choice of pump to do the metering job. Every Waukesha pump is available with electrical pulse generating devices, which feed pulses proportional to the pump flow to standard counters and controllers. By pre-setting the desired **flow rate** (GPM) on Model 1,101 controllers, or the batch size (gallons) on Model 1,001 controllers, the Waukesha DIGI/FLOW systems can be used for effective, low cost pumping control.

Bulletin SS-365 describes these standard systems in detail.

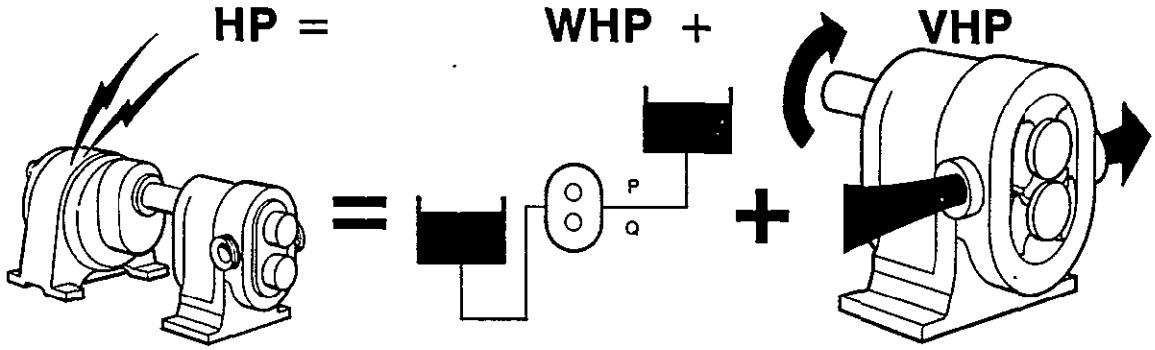
POWER REQUIREMENTS IN A PUMPING SYSTEM

All the system energy requirements, and the energy losses in the pump must be supplied by the pump drive in the form of mechanical energy. The rate of energy input needed is defined as power, commonly dimensioned as horsepower, where 1 HP = 33,000 ft. lbs./min.

In a pump and system, we find it convenient to consider separately:

- Power required due to external system conditions—WHP—sometimes called fluid horsepower, hydraulic horsepower or water horsepower.
- Power required due to internal conditions in the pump—VHP—which includes viscous power losses and mechanical friction.

Therefore—total horsepower needed at the pump shaft:



WHP is defined as $\frac{QP}{1714}$ where: Q = GPM
P = Pressure in psi
1714 is a conversion constant

VHP—viscous horsepower is the power loss due to viscous fluid friction in the pump. We have also included the mechanical losses due to bearing, seal, and gear drag. VHP is determined by test of each pump.

Many manufacturers use the term efficiency defined as

$$EFF = \frac{WHP}{BHP}$$

and often use it in a horsepower formula as follows:

$$HP = \frac{QP}{1714 \times EFF}$$

which is equivalent to

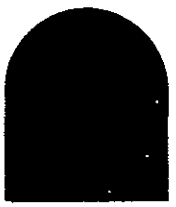
$$HP = \frac{WHP}{EFF}$$

Although a useful concept it means that a vast number of efficiency values must be determined by test for many combinations of flow, pressure and viscosity.

W

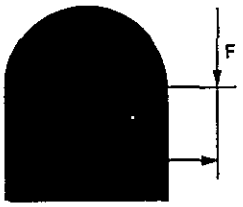
By identifying VHP and WHP separately, Waukesha has developed a very simple and effective form of horsepower chart for calculation of all conditions of viscosity, flow and pressure. This is discussed later in the section entitled "Calculating Power Requirements."

TORQUE—
The power requirements for mechanical devices such as pumps and pump drives are best expressed in terms of Torque and Speed where—



TORQUE—is the moment of the forces required to cause motion

—is usually expressed in units of inch-lbs. or ft.-lbs.



—can sometimes be identified as F x r.

In rotary motion—HP (the rate of doing work) can be expressed in terms of Torque and RPM—

$$HP = \frac{T\ (\text{Ft.-lbs.})\ X\ N\ (\text{rpm})}{5250} \text{ or } \frac{T\ (\text{In.-Lbs.})\ x\ N\ (\text{rpm})}{63025}$$

Since power requirements were calculated as HP = WHP + VHP, the horsepower will generally be known, and it may be necessary to calculate Torque. Rearranging the equation—

$$T\ (\text{Ft.-Lbs.}) = \frac{HP\ x\ 5250}{N\ (\text{rpm})} \text{ or } T\ (\text{In.-Lbs.}) = \frac{HP\ x\ 63025}{N\ (\text{rpm})}$$

Later, in selecting drives for pumps, it can be seen that not only must a drive have sufficient horsepower to drive the pump, but in the useful range of the drive, the **Torque** must be adequate to drive the pump. In addition, drive components such as V-Belts, couplings, and clutches must have enough Torque capacity to do the job.

Still Retorts — Pressure Processing In Steam

DESCRIPTION OF THE RETORT

A still retort is a batch-type, nonagitating, vertical or horizontal pressure vessel used for processing foods packaged in hermetically sealed containers. Generally, containers are stacked or jumble loaded into racks, crates, cars, baskets, or trays for loading and unloading the retort. However, crateless retorts operate without the use of container support systems.

Since retorts are pressure vessels, they are made of ¼ inch or thicker boiler plate formed into shape and riveted or welded together. The doors or lids are made of either cast iron or heavy plate. Various lugs and locks are used to secure the doors. These devices are important for worker safety and should always be in satisfactory working condition to prevent the lid or door from blowing off during the operation. The pressure inside the retort is tremendous. At 250°F (121°C) with 15 lbs/sq. in. pressure, about 10 tons of force pushes against the lid or door of a retort.

INSTALLATION AND OPERATION OF RETORTS

Proper installation and operation of the retort is essential to achieve satisfactory processing results. The steam supply should be adequate to bring the retort to processing temperature in a reasonable time. If containers are cooled in the retort, the water supply should be sufficient to permit an adequate and uniform cooling in a reasonable period of time. The vents shall be designed, installed, and operated so that air is removed from the retort before timing of the process begins. Some typical installations are shown in *Figures 6, 7* and *8*.

INSTRUMENTATION

Bulb sheaths or probes of the temperature indicating device (mercury-in-glass thermometer) and the temperature/time recording device shall be installed within the retort or in an external well attached to the retort. An external well shall be connected to the retort through at least a ¾ inch diameter opening and shall have a 1/16 inch or larger bleeder opening located to provide a constant flow of steam past the length of the bulb or probe. The external well bleeder shall emit steam continuously during the entire processing period. The bulb of the time/temperature device should be located adjacent to the temperature indicating device except in still vertical retort installations, which may use steam or water as the processing medium. (Further information may be found in the instrumentation section of "Retorts Processing with Overpressure".)

STEAM HEADER AND SUPPLY

Steam should be supplied to the processing room through a header large enough to provide adequate steam to all the retorts in use. Insufficient steam supply is indicated by the inability to meet vent requirements, longer

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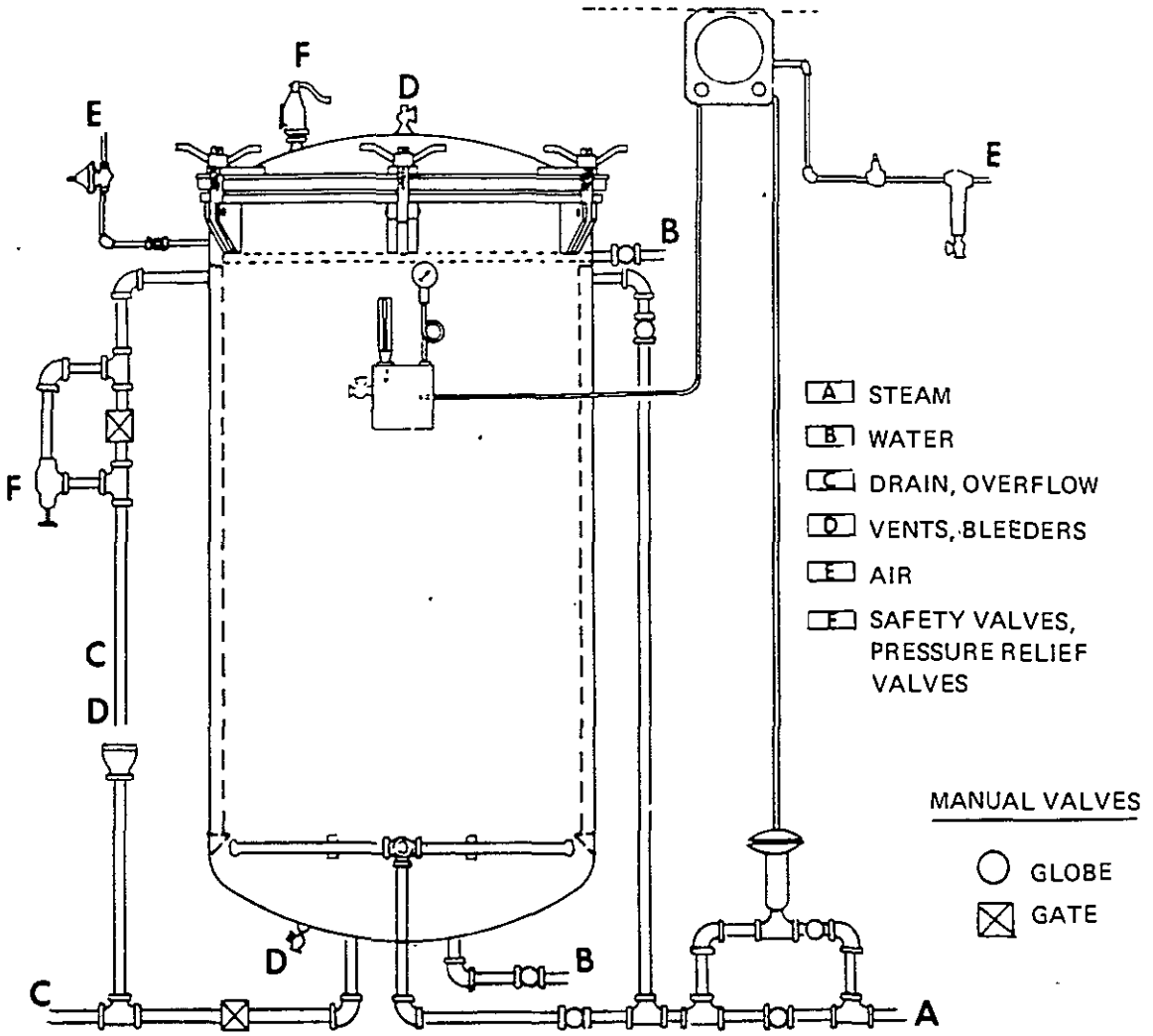

Figure 6—Vertical retort.

times to reach process temperature, and temperature fluctuations on retorts in use when additional retorts are being vented.

STEAM INLET

The steam inlet to each still retort shall be large enough to provide sufficient steam for proper operation of the retort and it shall enter at a point to facilitate air removal during venting. Although steam may enter the top portion or the bottom of the retort, the FDA and USDA require that the steam inlet be located opposite the vent.

STEAM CONTROLLER AND BYPASS

Still retorts shall be equipped with an automatic steam controller to maintain the retort temperature. This device may be recording-controlling instrument when combined with a temperature/time recording device. The details of the control system are described in the section on "Process Room Instrumentation, Equipment and Operation."

The use of a smaller sized control valve than the steam inlet pipe may have the advantage of controlling the process temperature with less fluctuation than occurs when a larger sized valve is used. However, a control valve that is the same size as the inlet pipe is a desirable safety feature when one operator has several retorts to watch, because the retort can be brought up rapidly without using a steam controller bypass.

When a bypass is used, the operator should stay with the retort during the come-up period to prevent excessive build up of pressure in the retort. As the retort reaches the processing temperature, the bypass valve should be closed slowly to avoid a sudden drop in temperature. Retorts equipped with a bypass can be operated manually in the event of a controller failure. The operator should know how to operate the retort manually.

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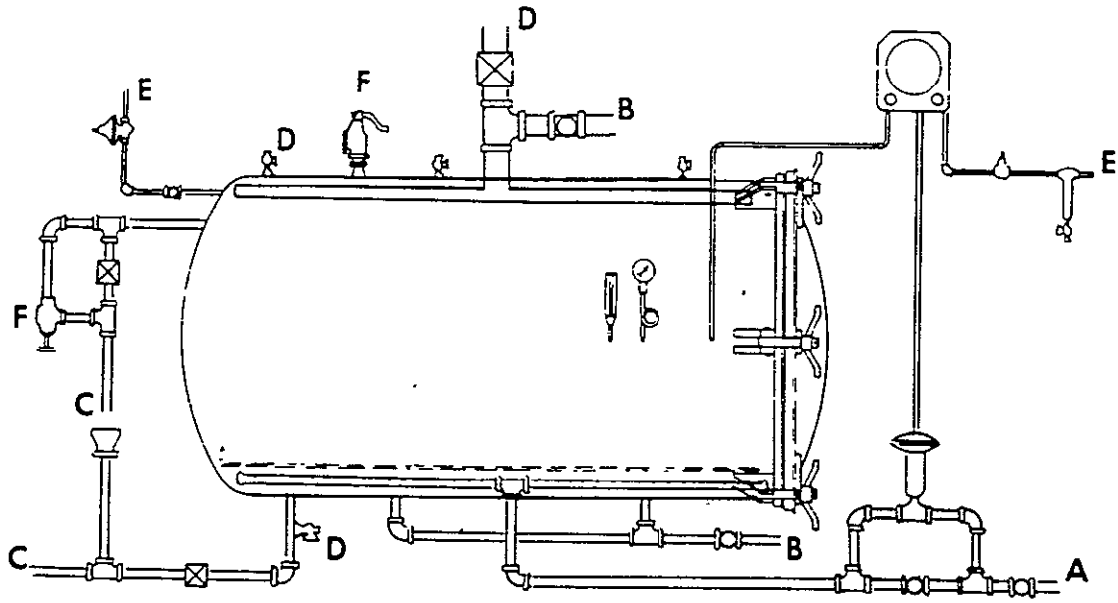

A STEAM
B WATER
C DRAIN, OVERFLOW
D VENTS, BLEEDERS
E AIR
F SAFETY VALVES, PRESSURE RELIEF VALVES

MANUAL VALVES
GLOBE
GATE

Figure 7—Horizontal retort.

STEAM SPREADERS

Steam spreaders are continuations of the steam line inside the retort that promote steam circulation. Perforated spreaders that extend the full length of the retort are required in horizontal still retort installations. For still retorts over 30 feet long, it is desirable to have two inlets connected to the spreader, as shown in *Figure 9*.

Perforations in the spreader for horizontal still retorts should be along the top 90° of this pipe. They should not be directed down against the retort shell because the steam would tend to follow around the shell and exit through the vents without driving out the air. In addition, when the steam is jetted against the shell, it will gradually erode a hole through the shell.

Spreaders are not required in vertical retort installations, but they may be used if desired. In vertical still retorts, the spreaders, if used, should preferably be in the form of a cross with perforations along the top or sides of the pipe. A vertical retort can be vented satisfactorily without a spreader when the steam enters through a single opening at either end of the retort.

The number of perforations in the spreader should be such that the total cross-sectional area of the perforations is equal to 1 ½ to 2 times the cross-sectional area of the smallest part of the steam inlet line. *Table 1* may be used as a guide.

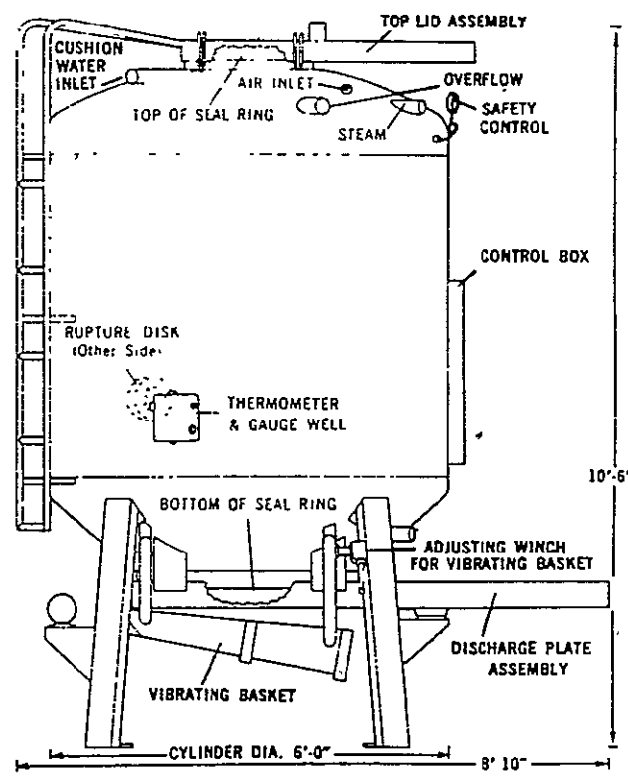

Figure 8—Crateless retort.

VENTS

Vents are large valve controlled openings in retorts used for elimination of air during the venting period. They shall be located in that portion of the retort opposite from the steam inlet and designed, installed, and operated in such a way that air is adequately removed from the retort before timing of the process is started. Vents shall be controlled by gate, ball, or other full flow valves which shall fully open to permit rapid discharge of air from the retort during the venting period. Globe valves of the same size as the vent pipe are not recommended because they reduce the efficiency of the venting due to the resistance of steam and air flow through the valves.

Vents shall not be connected directly to a closed drain system without an atmospheric break in the line. Exceptions are made for other systems provided adequate documentation is provided by a processing authority. In crateless retorts with top steam entry, the drains are connected to a manifold header and used as vents after the cushion water has been drained from the retort. Operating procedures for venting these retorts or other retorts with unusual piping arrangements should be obtained from a processing authority.

Where a retort vent manifold connects several vent pipes from a single still retort, it shall be controlled by a gate, ball, or other full flow valve. The retort manifold shall be of such a size that the cross-sectional area of the pipe is larger than the total cross-sectional area of all connecting vents. The manifold shall not be connected directly to a closed drain system without an atmospheric break in the line.

A vent manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The vent manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes or vents from all retorts venting simultaneously.

BLEEDERS

Bleeders are small openings in the retort used to remove air entering the retort with the steam and to provide circulation of steam in the retort. Bleeders shall be wide open and continuously emitting steam during the entire process, including the come-up time. A 1/16" or larger bleeder shall be used on thermometer wells and a 1/8" or larger bleeder shall be used on the retort.

All bleeder openings shall be arranged in such a way that the operator can observe that steam is escaping during the process. In retorts having a steam inlet at the top or above the level of the lowest container, a 1/8" or larger bleeder opening shall be installed in the bottom of the retort to completely remove condensate. All bleeders, including the condensate bleeder, shall be arranged so that the operator can observe that they function properly. They shall be checked with sufficient frequency to ensure that they are functioning or that condensate is adequately removed. Visual checks with recorded results are suggested at 15 minute intervals. USDA requires that intermittent condensate removal systems be equipped with an alarm system to serve as a continuous monitor of condensate bleeder functioning. The alarm system shall be tested for proper operation at the beginning of each shift and the results recorded.

Horizontal still retorts shall have at least one bleeder located within approximately 1 foot of the outermost location of containers at each end along the top of the retort and additional bleeders not more than 8 feet apart along the top. Vertical still retorts shall have at least one bleeder at a location opposite steam entry. Bleeders may be installed at positions other than these, as long as there are heat distribution data or other adequate documentation indicating that they accomplish adequate removal of air and circulation of steam within the retort. This

Table 1—Number of holes in steam spreaders for steam inlet pipe sizes.

Size Holes (inches)	1 inch pipe	1-¼ inch pipe	1-½ inch pipe	2 inch pipe	2-½ inch pipe
3/16	47-62	81-108	111-148	183-244	260-346
1/4	27-36	45-60	62-84	102-137	147-196
3/8	—	21-28	28-37	45-60	66-88
1/2	—	11-15	15-20	26-36	36-48

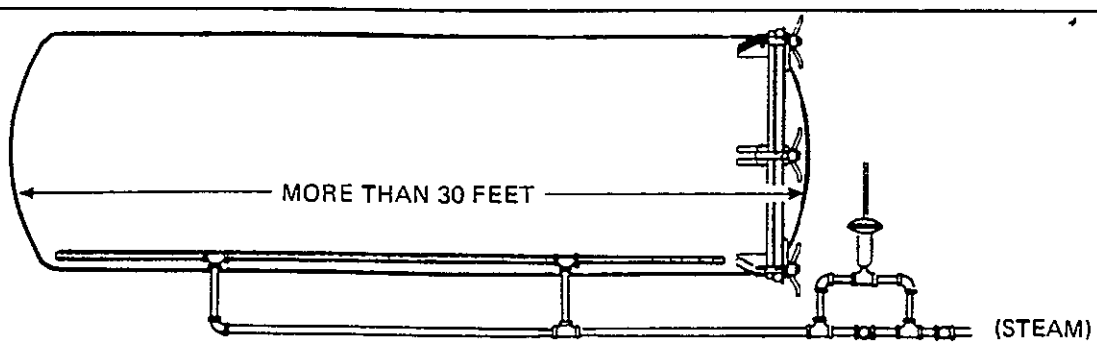

Figure 9—Steam spreader recommended for long retorts.

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information shall be maintained on file by the processor and must be made available to USDA and FDA personnel as required.

MUFFLERS

Mufflers are often used on bleeders and vents to reduce the noise created by escaping steam. If mufflers are used, evidence that they do not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or a letter from the manufacturer, the designer, or a processing authority.

AIR SUPPLY

Retorts may need a compressed air supply for two reasons:

1. Most retorts are equipped with air-operated, automatic steam controllers.

2. The use of air for pressure cooling of containers in the retort is preferable to the use of steam due to the noncondensable properties of air. This attribute eliminates the possibility of accidentally condensing the steam in the retort, thus reducing the retort pressure and increasing the possibility of buckling the containers.

Retorts using air for pressure cooling shall be equipped with a suitable valve (globe valve or the equivalent) on the air line to prevent air leakage into the retort during processing.

WATER SUPPLY

Most retorts are piped to supply water to cool the containers partially or completely after processing. The regulations require that retorts using water for cooling be equipped with a suitable valve (globe valve or equivalent) to prevent leakage of water into the retort during processing.

If cooling water enters the top of the retort, care should be taken to prevent condensing the steam remaining in the retort after the process is completed. This condensation can create a partial vacuum in the retort and cause buckling or straining of the can ends. A vacuum breaker may prevent this situation.

CONSTRUCTION OF CRATES, CARS AND DIVIDERS

Crates, cars, gondolas, and trays for holding containers are made of strap iron, perforated sheet metal, or other suitable material. When perforated sheet metal is used for the bottoms, the perforations shall (USDA) be one-inch holes on two-inch centers or their equivalent. Other arrangements may be used if adequate heat distribution is documented by a processing authority. This documentation shall be maintained on file by the processor and made available to FDA or USDA personnel as required. If dividers between layers of containers are used, they should be perforated as above. USDA requires that the establishment have on file documentation of venting adequacy whenever divider plates are utilized between layers of cans.

PROCESSING CONSIDERATIONS

Venting Considerations

No single venting method applies to all still retorts, and therefore all venting schedules must be designed by a processing authority. To assure adequate air removal during the venting period, time, temperature, and other requirements specified in the venting schedule for a particular retort installation shall be met. Timing of the process shall not begin until the retort has been properly vented and the processing temperature is reached and maintained.

Before the retort cycle begins, there is a large amount of air in the retort. A horizontal retort fully loaded with cans still has 70 to 80 percent of its space occupied by air. A fully loaded vertical retort has more than 60 percent of its space occupied by air. It is essential that the air be removed before a steam process begins.

Venting procedures have been established for vertical, horizontal, and crateless retorts with specific piping arrangements. For retorts with unusual piping, loading, or operating procedures, heat distribution tests should be conducted to establish adequate venting procedures. For retorts with unusual piping, loading, or operating procedures, heat distribution tests should be conducted to establish adequate venting procedures. For any system using steam as the heating medium, heat distribution tests or other suitable tests are used to establish adequate venting schedules. This information should remain on file and be made available to FDA or USDA as necessary.

EFFECT OF DIVIDER PLATES ON VENTING

When divider plates are used between layers of cans, an increased vent schedule above that used for conventional loading systems may be required for adequate removal of air. Dividers may inhibit the flow of steam among the cans. The venting adequacy should be documented by the processing authority, kept on file and made available to FDA or USDA personnel as necessary.

INITIAL TEMPERATURE

The initial temperature of the coldest container in the retort at the time the sterilizing cycle begins must be determined. The details for determining initial temperature are discussed in "Process Room Instrumentation, Equipment and Operation."

PROCESS TIMING

The timing of a process shall not start until the scheduled venting cycle is completed and the scheduled retort temperature is observed on the temperature indicating device (mercury-in-glass thermometer). Accurate timing devices shall be used to determine process and vent times. Additional information on timing devices can be found in the section on "Process Room Instrumentation, Equipment and Operation."

CONTAINER COOLING

Containers may be partially or completely cooled in the retort. In pressure cooling, pressure is maintained in the retort while containers are cooled sufficiently to reduce their internal pressure to a safe level. Then the containers may be exposed to atmospheric pressure without danger of buckling the containers or straining the seals.

No specific times for pressure cooling can be listed because they are affected by a number of factors such as product, container size, process temperature, cooling water temperature, and the amount of water used. As a general rule, cans of 401 diameter or larger require pressure cooling when processed at 240°F (116°C) or higher. In some instances where low retort temperatures are used, the smaller can sizes may be processed without pressure cooling. On the other hand, cans smaller than 401 diameter may require pressure cooling, especially when processed at higher than 250°F (121°C).

Containers are completely cooled when the temperature of their contents is reduced to approximately 100°F (38°C). A complete flooding of containers in the retort is suggested since spray-cooling may not produce uniform cooling.

COOLING WATER TREATMENT

FDA requires that container cooling water be chlorinated or otherwise sanitized as necessary for cooling canals and for recirculated water supplies. In addition, there should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler. USDA regulations contain the same basic requirements. However, for systems that reuse or recirculate water supplies, USDA requires that systems be designed to prevent organic build up and be easily cleaned. In addition, information about the recirculation system shall be made available to a USDA representative for review. Also note that only approved chemicals may be added to cooling water in USDA regulated establishments. For further information on cooling water sanitizers, see the section on "Food Plant Chlorination."

RECORD REQUIREMENTS

All critical factors specified in the scheduled process shall be measured and recorded at intervals of sufficient frequency to insure that the critical factors remain within the limits specified in the scheduled process. These intervals should not exceed 15 minutes. In addition to the generic record requirements outlined in Section 6, "Records for Product Protection", the written records for still retorts shall include time steam on, venting time, temperature to which vented, time the process begins mercury-in-glass thermometer/recorder readings and time steam off.

SUMMARY

1. Vents shall be installed and operated in such a way that air is removed from the retort before timing of the process begins.

2. The steam inlet in each still retort shall be large enough to provide enough steam for proper operation of the retort.

3. Every retort shall be equipped with a mercury-in-glass thermometer.

4. There shall be an accurate temperature recording device on each retort.

5. Divider plates should have perforations at least equivalent to one-inch holes on two-inch centers.

6. Steam spreaders are required in all horizontal retorts.

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Still Retorts—Processing With Overpressure

INTRODUCTION

The term "overpressure" refers to the pressure supplied to a retort in excess of that exerted by the heating medium at a given process temperature. In a steam retort the pressure at 250°F is 15 psig; any pressure supplied to the retort in excess of that 15 psig is referred to as overpressure. For example, the retort systems described in this chapter may operate at a pressure of 25-35 psig with a 250°F retort temperature. Contrary to the operation of still retorts using pure stream, the retorts utilizing water or steam/air mixtures as the heating medium can now have air introduced during the processing cycle.

Overpressure during processing is required to maintain the integrity of containers that, due to package construction and/or type of closure, have a limited resistance to internal pressure (*Figure 10*). The internal pressure in these containers will be greater than pressure of pure steam at the process temperature. Some examples of containers processed with overpressure are semi-rigid plastic containers with heat sealed lids, flexible pouches, metal trays, and glass jars.

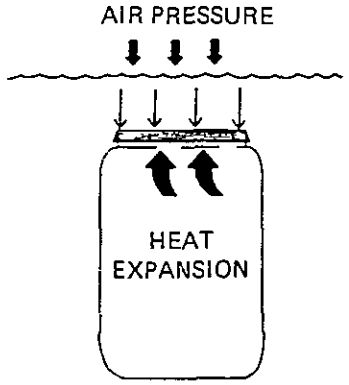

Figure 10—Overriding air pressure prevents container damage or loss of seal during the process.

DESCRIPTION OF RETORTS

There are a variety of retort types that are designed to provide overpressure during still processing. The retort may use either steam or air as the source of overpressure. The processing medium used will vary from water that is cascaded over the containers, to water in which the containers are totally immersed, to a steam/air mixture. The container handling system will vary between batch type or continuous container handling systems.

INSTALLATION AND OPERATION OF RETORTS

The installation considerations for these retort systems vary depending on the type of heating medium and the source of overpressure. These retorts are equipped with various controls and alarms necessary to monitor the critical factors.

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INSTRUMENTATION

At least one temperature indicating device (mercury-in-glass thermometer) and a temperature recording device are required for each retort. The general specifications for these instruments and information on pressure gauges, timing, and mufflers may be found in "Process Room Instrumentation, Equipment and Operation."

When water is the processing medium, the bulb or probe of the temperature indicating device (mercury-in-glass thermometer) shall be located beneath the water throughout the process. For vertical retorts that immerse the containers in water, the bulb may be installed in a thermometer pocket. The pocket should be designed to permit good circulation of water around the bulb. A hemispherical thermometer pocket is suggested; however, a rectangular pocket of at least 8×8×4 inches may be used. On horizontal retorts the bulb or probe shall be inserted directly into the retort shell. In both horizontal and vertical retorts, the bulb or probe shall extend a minimum of 2 inches into the processing water without a separable well or sleeve.

When a steam/air mixture is the processing medium, the USDA requires that the bulb or probe of the temperature indicating device (mercury-in-glass thermometer) be inserted directly into the retort shell and be located so that steam does not strike it directly.

The bulb or probe of the temperature/time recording device should be located adjacent to the temperature indicating device (mercury-in-glass thermometer), except in vertical retorts equipped with a combination recorder-controller. In vertical retorts where containers are immersed in water, the recorder-controller bulb shall be located below the lowest crate support in such a position that steam does not strike it directly. In horizontal retorts the bulb of the temperature recorder-controller shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam contact with the bulb or probe of the recorder-controller.

For retorts that use a steam/air mixture as the heating medium, USDA specifies that the bulb of the temperature recorder-controller shall be inserted directly into the retort shell in such a position that steam does not strike it directly.

STEAM CONTROLLER

Regardless of the processing medium, each retort shall be equipped with an automatic steam controller to maintain retort temperature. This may be a recording-controlling instrument when combined with a temperature/time recording device. The automatic steam controller must be responsive to temperature only.

PRESSURE CONTROL

Overriding pressure may be supplied in the form of air or steam. The USDA specifies that the required overpressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. Each retort shall have an automatic pressure control unit to introduce compressed air or steam into the retort at the proper rate. There are several ways this can be accomplished. One design involves introducing air or steam at a constant rate and relieving the pressure when it rises above a certain level. Another design involves the introduction of steam at the top of the retort above the water level. Automatic control valves control the air or steam entering or leaving the retort. In those retorts using a steam/air mixture as the processing medium, the USDA requires that the retort be equipped with a recording pressure controller to control the air inlet and steam/air mixture outlet.

If compressed air is used to provide overpressure, then a nonreturn (check) valve shall be provided in the air supply line to prevent moisture from entering the system. If steam is used to provide overpressure, then an independently controlled steam source is needed for maintenance of the proper overpressure. This system should be separate from the steam source used to maintain retort temperature.

The USDA requires that each retort system shall be equipped with a pressure recording device, which may be combined with a pressure controller. In addition, each retort should be equipped with a pressure gauge which can be easily read by the operator.

PROCESSING MEDIUM CIRCULATION

No matter which processing medium is utilized, a means shall be provided to assure uniform heat distribution within the retort during processing. This uniformity shall be documented by heat distribution tests or other documentation from a processing authority. There are basically two ways in which adequate circulation can be provided. In vertical retort systems, compressed air may be used to promote water circulation and heat distribution. For both vertical or horizontal retort systems, water may be mechanically circulated within the retort to provide adequate heat distribution (*Figure 11*).

When air is used to promote circulation, the air shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. Air moves into the retort with the steam and usually passes through a spreader at the bottom of the retort. The air provides agitation of the heated water as it rises upward through the crates. Two spreader designs are illustrated in *Figure 12*. It is recommended that crate centering guides be used to provide a 1½" clearance between the side wall of the crate and the retort shell. This clearance allows space for ample water circulation along the retort wall. Bottom crate supports are required in vertical retorts. Baffle plates are not permitted in the bottom of the retort.

In addition to promoting circulation of the water, air introduced into the steam line also serves to reduce undue vibration (steam knock or hammer) resulting when

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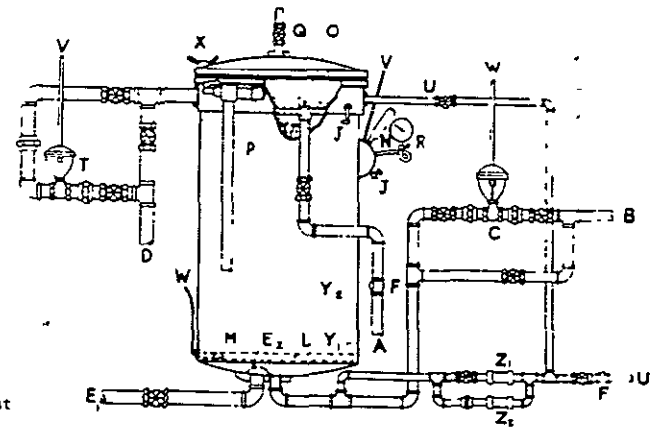
VERTICAL RETORTS

A Water line
B Steam line
C Temperature control
D Overflow line
E_1 Drain line
E_2 Screens
F Check Valves
G Line from hot water storage
H Suction line and manifold
I Circulating pump
J Petcocks
K Recirculating line
L Steam distributor
M Temperature controller bulb
N Thermometer
O Water spreader
P Safety valve
Q Vent valve for steam processing
R Pressure gauge
S Inlet air control
T Pressure control
U Air line
V To pressure control instrument
W To temperature control instrument
X Wing nuts—8 required
Y_1 Crate support
Y_2 Crate guides
Z_1 Constant flow orifice valve used during come-up
Z_2 Constant flow orifice valve used during cook



HORIZONTAL RETORTS

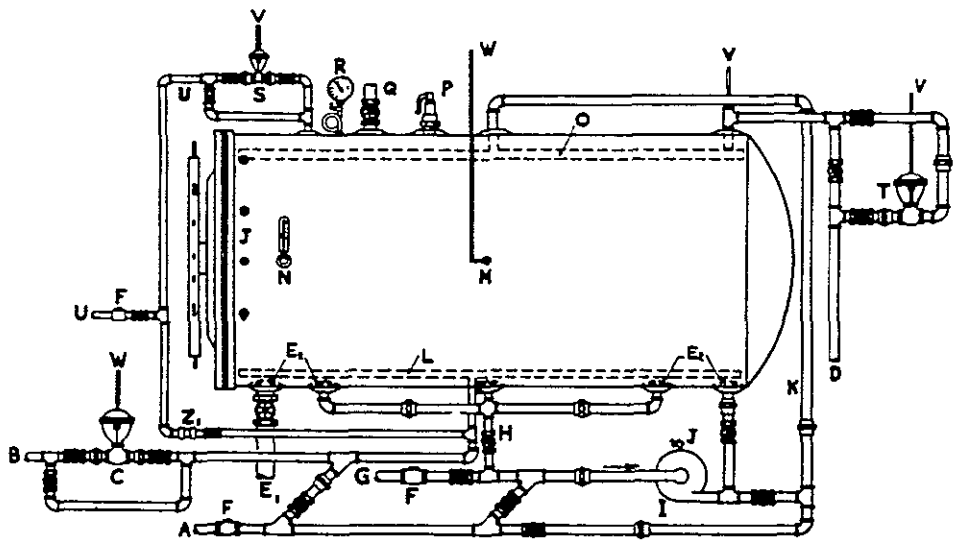


Figure 11—Basic piping and instrumentation requirements for still retorts used for pressure processing in water.

steam is introduced into cold water. During the come-up-time a greater volume of air is needed to reduce vibration. After the come-up-time is completed, the volume of air may be reduced to that necessary to maintain adequate heat distribution. Normally, the air supply line is designed to allow air to flow through two constant flow orifices: one for the come-up-time air and a smaller one for air during processing. The air introduced into the steam line will also serve to maintain overpressure.

In many retorts designed to use water as a processing medium, such as horizontal retorts, the use of air alone

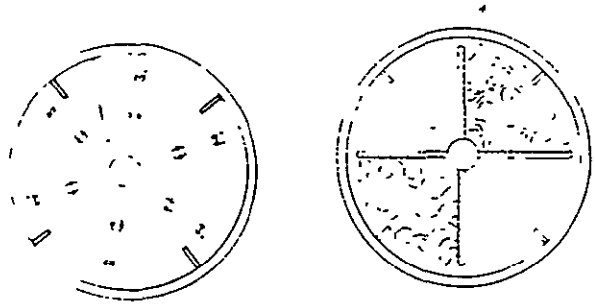


Figure 12—Top view of two types of steam spreaders used in vertical retorts for pressure processing in water.

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Aseptic Processing and Packaging Systems

INTRODUCTION

The processing systems which have been described in the last five sections of this text operate by thermally processing product within a container to achieve commercial sterility. This procedure is commonly called conventional canning. Aseptic processing, the subject of this section, achieves the same result but by a different method.

In aseptic processing, packages and food product are sterilized in separate systems. The sterile package is then filled with sterile product, closed and sealed in a sterile chamber. Since aseptic processing is a continuous operation, the behavior of one part of the system can affect the overall performance of the entire system. As a result, there are numerous critical factors associated with aseptic processing and packaging often requiring automated control systems. Process establishment for aseptic systems must consider not only the sterilization of the product, the processing equipment, and downstream piping, but also the sterilization of the packaging material and the packaging equipment and the maintenance of sterile conditions throughout the aseptic system.

DEFINITIONS

To assist in the discussion of aseptic processing and packaging systems, some definitions are presented below. You should be familiar with these terms and their particular significance to aseptic systems.

Aseptic describes a condition in which there is an absence of microorganisms, including viable spores. In the food industry, the terms aseptic, sterile, and commercially sterile are often used interchangeably.

Aseptic system refers to the entire system necessary to produce a commercially sterile product contained in a hermetically sealed container. This term includes the product processing system and the packaging system.

Aseptic processing system refers only to the system that processes the product and delivers it to a packaging system.

Aseptic packaging system refers to any piece of equipment that fills a sterile package or container with sterile product and hermetically seals it under aseptic conditions. These units or systems may also form and sterilize the package.

BASIC ASEPTIC SYSTEM

Figure 28 is a diagram of a simplified aseptic system. Raw or unprocessed product is heated, sterilized by holding at high temperature for a predetermined amount of time, then cooled and delivered to a packaging unit for packaging. Commercial sterility is maintained throughout the system, from the moment of product heating to the discharge of hermetically sealed containers.

Achieving successful aseptic processing of foods requires as a minimum the following conditions:

1. equipment that can be brought to a condition of commercial sterility;
2. commercially sterile product;
3. commercially sterile packages;

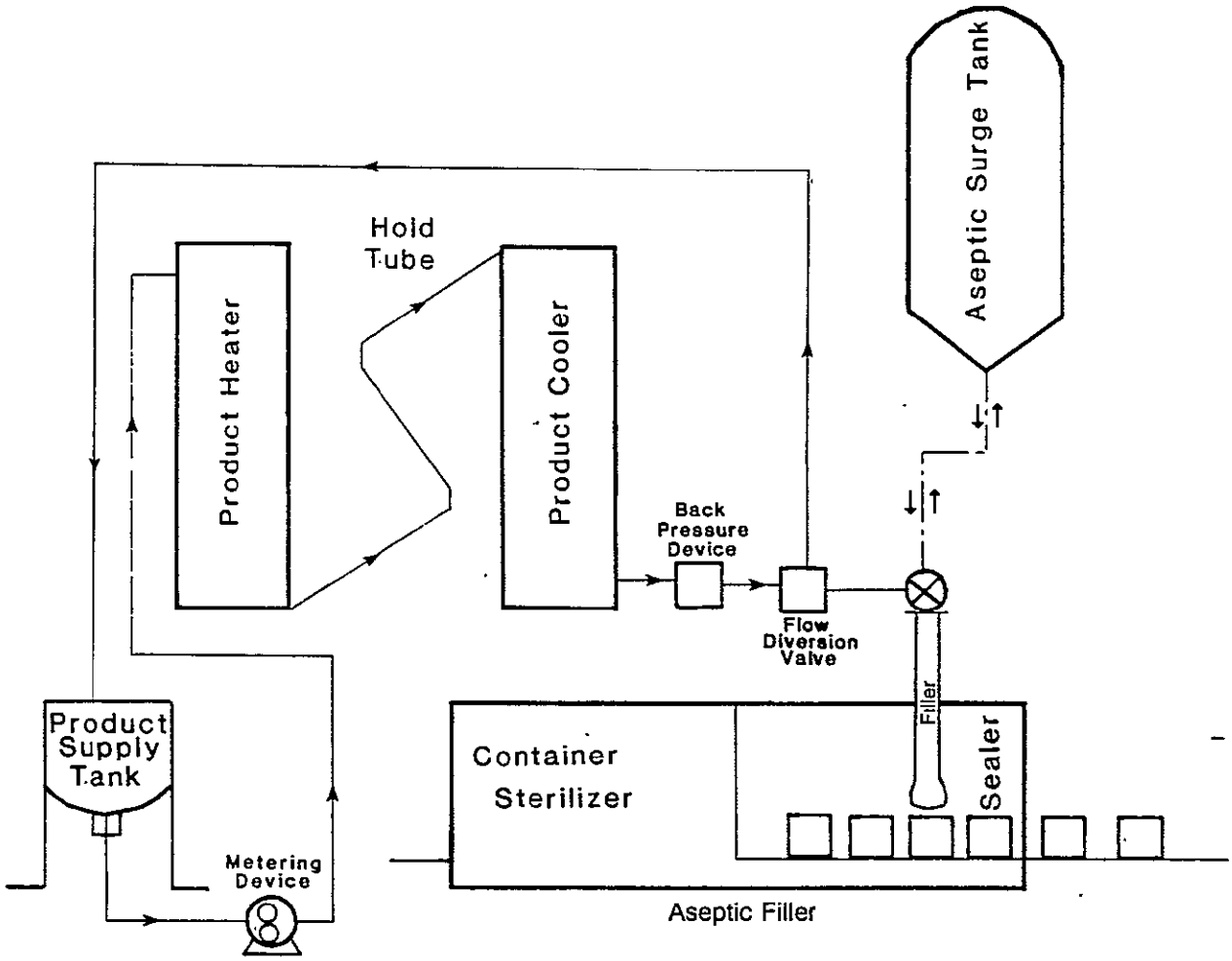

Figure 28—Simplified diagram of an aseptic processing system.

4. a commercially sterile environment within the packaging machine in which to bring sterile product and packages together and hermetically seal the packages;

5. monitoring, recording, and control of critical factors; and

6. proper handling of finished packages to ensure container integrity.

DESCRIPTION OF THE ASEPTIC PROCESSING SYSTEM

Although the equipment for aseptic processing systems varies, all systems have certain common features:

1. a pumpable product;

2. a means to control and document the flow rate of product through the system;

3. a method of heating the product to sterilizing temperatures;

4. a method of holding product at an elevated temperature for a time sufficient for sterilization;

5. a method of cooling product to filling temperature;

6. a means to sterilize the system prior to production and to maintain sterility during production; and

7. adequate safeguards to protect sterility and prevent nonsterile product from reaching the packaging equipment.

PRE-PRODUCTION STERILIZATION

Producing a commercially sterile product cannot be assured unless the processing system and filler have been adequately sterilized before starting production. It is important that the system be thoroughly cleaned before sterilization; otherwise the process may not be effective.

Some systems, or portions thereof, utilize saturated steam for sterilization. However, for most systems, equipment sterilization is accomplished by circulation of hot water through the system for a sufficient length of

time to render it commercially sterile. When water is used, it is heated in the product heater and then pumped through all downstream piping and equipment up to (and generally past) the filler valve on the packaging unit. All product contact surfaces "downstream" from the product heater must be maintained at or above a specified temperature by continuously circulating the hot water for a required period of time.

Surge tanks are generally sterilized with saturated steam rather than hot water due to their large capacity. Although sterilization of surge tanks may occur separately, it is usually conducted simultaneously with hot water sterilization of the other equipment.

In order to control aseptic system sterilization properly, it is necessary that a thermometer or thermocouple be located at the coldest point(s) in the system to ensure that the proper temperature is maintained throughout. Thus, the temperature measuring device is generally located at the most distant point from the heat exchangers. Timing of the sterilization cycle begins when the proper temperature is obtained at this remote location. If this temperature should fall below the minimum, the cycle should be restarted after the sterilization temperature is reestablished. Recording devices are recommended to provide a permanent continuous record to show that the equipment is adequately sterilized before each production run.

FLOW CONTROL

Sterilization time or residence time, as indicated in the scheduled process, is directly related to the rate of flow of the fastest moving particle through the system. The fastest moving particle is a function of the flow characteristics of the food. Consequently, a process must be designed to ensure that product flows through the system at a uniform and constant rate so that the fastest moving particle of food receives at least the minimum amount of heat for the minimum time specified by the scheduled process. This constant flow rate is generally achieved with a pump, called a timing or metering pump.

Timing pumps may be variable speed or fixed rate. The pumping rate of the fixed rate pump cannot be changed without dismantling the pump. Variable speed pumps are designed to provide flexibility and allow for easy rate changes. When a variable speed pump is used, it shall be protected against unauthorized changes in the pump speed which could affect the rate of product flow through the system. A lock or a notice from management posted at or near the speed adjusting device warning that only authorized persons are permitted to make adjustments is a satisfactory way to prevent unauthorized adjustments.

PRODUCT HEATING

A product heater brings the product to sterilizing temperature. There are two major categories of product heaters in aseptic food processing: direct and indirect.

Direct heating, as the same implies, involves direct contact between the heating medium (steam) and the product. Direct heating systems can be one of two types: steam injection or steam infusion.

Steam injection introduces steam into the product in an injection chamber as product is pumped through the chamber (*Figure 29*), while the process of steam infusion introduces product through a steam-filled infusion chamber (*Figure 30.*) These systems are currently limited to homogeneous, low viscosity products.

Direct heating has the advantage of very rapid heating, which minimizes organoleptic changes in the product. The problems of fouling or "burn on" of product in the system may also be reduced in direct heating systems compared to indirect systems.

There are also some disadvantages. The addition of water (from the condensation of steam in the product) increases product volume. Since this change in volume increases product flow rate through the hold tube it must be accounted for when establishing the scheduled process.

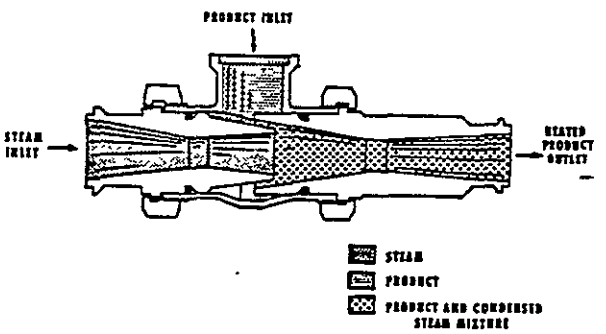

Figure 29—Steam injection.

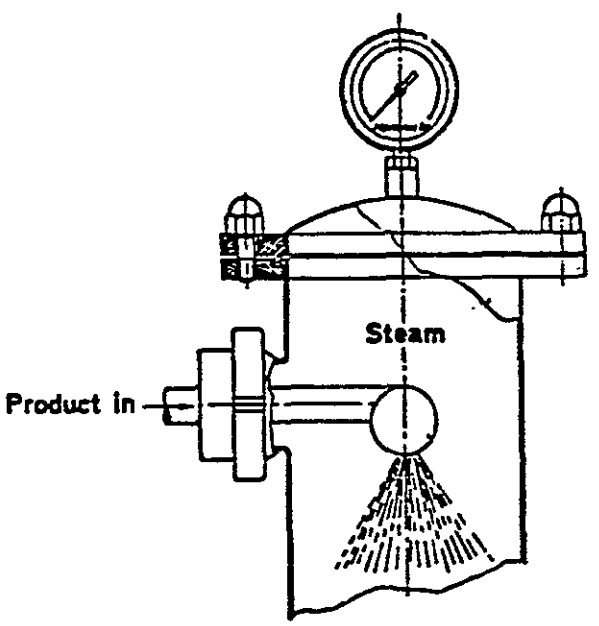

Figure 30—Steam infusion.

Depending on the product being produced, water that was added as steam may need to be removed. Water removal is discussed under product cooling. Steam used for direct heating must be of culinary quality and must be free of non-condensable gases. Thus, strict controls on boiler feed water additives must be followed.

The other major category of product heaters is **indirect heating** units. Indirect heating units have a physical separation between the product and the heating medium. There are three major types of indirect heating units: plate, tubular, and swept-surface heat exchangers.

Plate heat exchangers (*Figure 31*) are used for homogeneous liquids of relatively low viscosity. The plates serve both as a barrier and a heat transfer surface with product on one side and the heating medium on the other. Each plate is gasketed and a series of plates are held together in a press. The number of plates can be adjusted to meet specific needs.

Tubular heat exchangers (*Figure 32*) employ either two or three concentric tubes instead of plates as heat transfer surfaces. Product flows through the inner tube of the double tube style and through the middle tube of the triple tube style, with the heating medium in the other tube(s) flowing in the opposite direction to the product. In a shell and tube heat exchanger (considered a type of tubular exchanger), the tube is coiled inside a shell (*Figure 33*). Product flows through the tube while the heating medium flows in the opposite direction through the shell. As with plate heat exchangers, tubular heat exchangers are used for homogeneous products of low viscosity.

Scraped-surface heat exchangers are normally used for processing more viscous products (*Figure 34*). The scraped surface heat exchanger consists of a mutator shaft with scraper blades concentrically located within a jacketed, insulated, heat exchange tube. The rotating blades continuously "scrape" the product off the wall. This scraping reduces buildup of product and "burn on." The heating medium flowing on the opposite side of the wall is circulating water or steam.

Some systems incorporate the use of product-to-product regenerators. These devices are either plate or tubular heat exchangers with product flowing on both sides of the plates or through both sets of tubes. This process allows the heat from the hot sterile product to be transferred to the cool, incoming, non-sterile product. Energy and cost savings can be significant by "recycling" the heat from sterile product.

When a product-to-product regenerator is used, the regenerator shall be designed, operated, and controlled so that the pressure of the sterilized product in the regenerator is at least 1 psi greater than the pressure of any non-sterilized product in the regenerator. This differential helps ensure that any leakage in the regenerator will be from sterilized product into nonsterilized product. In addition, an accurate differential pressure recorder shall be installed on the regenerator. One pressure sensor has to be installed at the hot sterilized product outlet and another at the cooler nonsterilized product inlet. Upon installation, the recorder shall be tested against

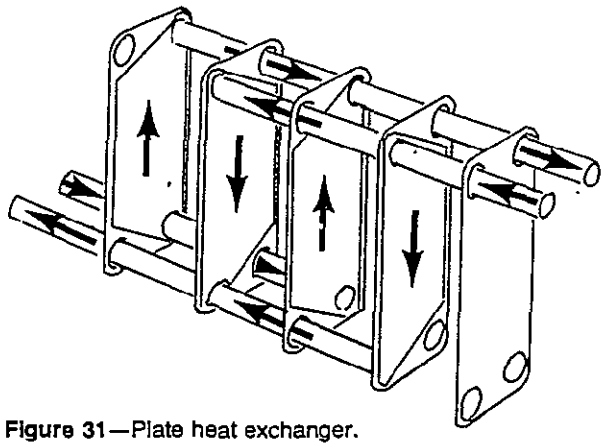

Figure 31—Plate heat exchanger.

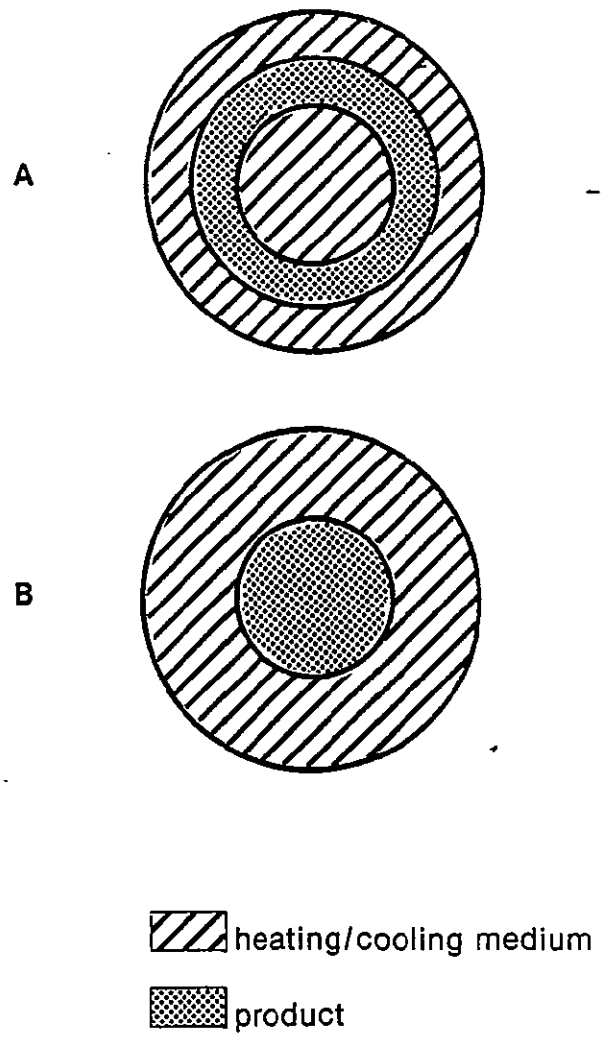

Figure 32—Tubular heat exchanger (A = triple tube, B = double tube).

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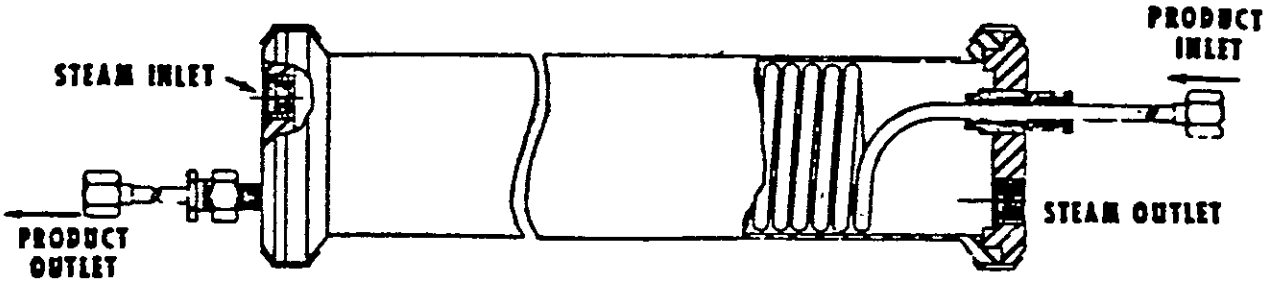

Figure 33—Shell and tube heat exchanger.

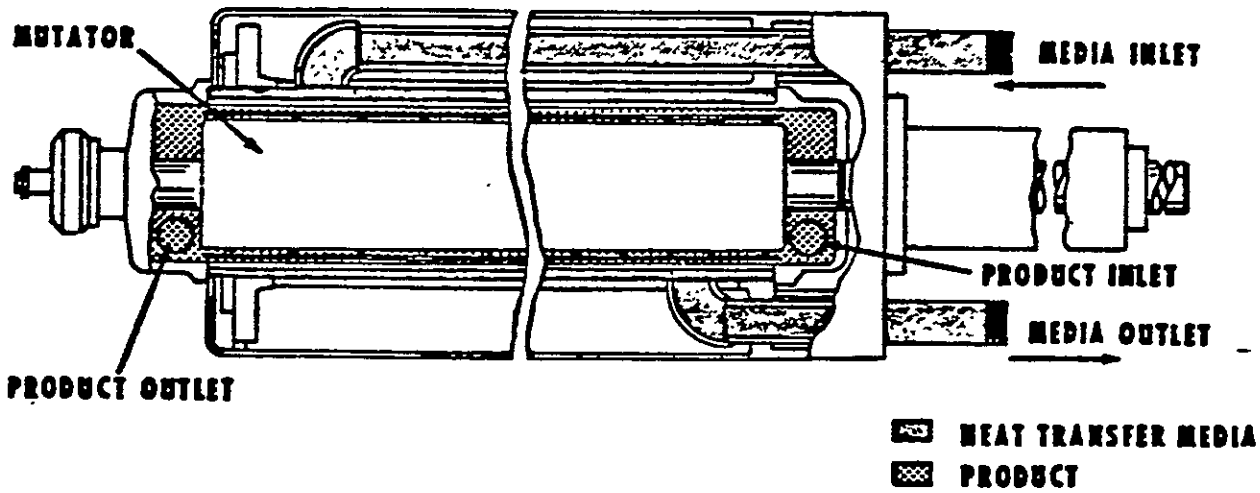

Figure 34—Scraped surface heat exchanger.

a known accurate standard pressure indicator and shall be retested at least once every three months, or as often as necessary to ensure proper functioning. Pressure differential maintenance and recording is also recommended for heat exchangers employing product-to-water regeneration and may be a requirement in certain instances.

HOLD TUBE

Once the product has been brought to sterilizing temperature in the heater, it flows to a hold tube. The time required for the fastest product particle to flow through the hold tube is referred to as the residence time. The residence time must be equivalent to or greater than the time necessary at a specific temperature to sterilize the product and is specified in the scheduled process. Hold tube volume, which is determined by hold tube diameter and length, combined with the flow rate and flow characteristics of the product, determines the actual residence time of the product in the hold tube. Since the hold tube is essential for ensuring that the product is held at sterilization temperatures for the proper time, certain precautions must be followed:

1. The holding tube shall have an upward slope in the direction of product flow at least 0.25 inch per foot to assist in eliminating air pockets and prevent self-draining.

2. If the holding tube can be taken apart, care should be taken that all parts are replaced and that no parts are removed or interchanged to make the tube shorter or different in diameter. Such accidental alterations could shorten the time the product remains in the tube.

3. If the holding tube can be taken apart, care should be exercised when reassembling to ensure that the gaskets do not protrude into the inner surface. The tube interior should be smooth and easily cleanable.

4. There must be no condensate drip on the tube, and the tube should not be subjected to drafts or cold air, which could affect the product temperature in the holding tube.

5. External heat shall not be applied at any point along the hold tube.

6. The product in the hold tube must be maintained under a pressure sufficiently above the vapor pressure of the product at the process temperature to prevent "flashing" or boiling because flashing can decrease the

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product residence time in the hold tube. The prevention of flashing is usually accomplished by use of a back pressure device.

The temperature of the food in the holding tube shall be monitored at the inlet and outlet of the tube. The temperature at the inlet of the tube is monitored with a temperature recorder-controller, sensor which shall be located at the final heater outlet and shall be capable of maintaining process temperature in the hold tube. A mercury-in-glass thermometer, or other acceptable temperature-measuring device (such as an accurate thermocouple-recorder), shall be installed in the product sterilizer holding tube outlet between the holding tube and the cooler inlet. An automatic recording thermometer sensor shall also be located in the product at the holding tube outlet between the holding tube and cooler to indicate the product temperature. The temperature-sensing device chart graduations shall not exceed 2°F (1°C) within a range of 10°F (6°C) of the required product sterilization temperature.

PRODUCT COOLING

Product flows from the hold tube into a product cooler which reduces product temperature prior to filling. In those systems which utilize indirect heating, the cooler will be a heat exchanger which may be heating raw product while cooling sterile product. Those systems that utilize direct heating will typically include a flash chamber or vacuum chamber. The hot product is exposed to a reduced pressure atmosphere within the chamber resulting in product boiling or "flashing." The product temperature is lowered, and a portion or all of the water that was added to the product during heating is removed by evaporation. Upon discharge from the flash chamber, product may be further cooled in some type of heat exchanger.

MAINTAINING STERILITY

After the product leaves the hold tube, it is sterile and subject to contamination if microorganisms are permitted to enter the system. One of the simplest and best ways to prevent contamination is to keep the sterile product flowing and pressurized. A back pressure device is used to prevent product from boiling or flashing and maintains the entire product system under elevated pressure.

Effective barriers against microorganisms must be provided at all potential contamination points, such as rotating or reciprocating shafts and the stems of aseptic valves. Steam seals at these locations can provide an effective barrier, but they must be monitored visually to ensure proper functioning. If other types of barriers are used, there must be a means provided to permit the operator to monitor the proper functioning of the barrier.

ASEPTIC SURGE TANKS

Aseptic surge tanks have been used in aseptic systems to allow the packer to hold sterile product prior to packaging. These vessels, which range in capacity from about one hundred gallons to several thousand gallons, provide flexibility, especially for systems in which the flow rate of a product sterilization system is not compatible with the filling rate of a given packaging unit. If the valving that connects a surge tank to the rest of the system is designed to allow maximum flexibility, the packaging and processing functions can be carried out independently with the surge tank acting as a buffer between the two systems. A disadvantage of the surge tank is that all sterile product is held together and if there is a contamination problem, all product is lost. A sterile air or other sterile gas supply system is needed in order to maintain a protective positive pressure within the tank and to displace the contents. This positive pressure must be monitored and controlled to protect the tank from contamination.

AUTOMATIC FLOW DIVERSION

An automatic flow diversion device may be utilized in an aseptic processing system to prevent the possibility of potentially unsterile product from reaching the sterile packaging equipment. The flow diversion device must be designed so that it can be sterilized and operated reliably. Past experience has shown that flow diversion valves of the gravity drain type should *not* be used in aseptic systems due to the possibility of recontamination of sterile product. Since the design and operation of a flow diversion system in critical, it should be done in accordance with recommendations of an aseptic processing authority.

The flow diversion valve should divert product automatically if a deviation occurs. A few examples of situations which may cause a diversion are temperature at the hold tube dropping below the scheduled minimum, inadequate pressure differential in the regenerators, or the packaging unit dropping below minimum operating specifications.

ASEPTIC PACKAGING SYSTEMS

BASIC REQUIREMENTS

Aseptic packaging units are designed to combine sterile product with a sterile package resulting in a hermetically sealed shelf-stable product. As with aseptic processing systems, there are certain features common to all aseptic packaging systems. The packaging units must:

1. create and maintain a sterile environment in which the package and product can be brought together;
2. sterilize the product contact surface of the package;
3. aseptically fill the sterile product into the sterilized package;
4. produce hermetically sealed containers; and
5. monitor and control critical factors.

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There are a wide variety of packaging systems that satisfy these requirements in many different ways. The following discussion will concentrate on those requirements common to all aseptic packaging systems, using the features mentioned above as a basis for discussion.

STERILIZATION AGENTS

Sterilization agents are used in aseptic packaging units to sterilize the packaging material and the internal equipment surfaces to create a sterile packaging environment. In general, these agents involve either heat, chemicals, high-energy radiation, or a combination of these. For aseptic packaging equipment the sterilization agents used must effectively provide the same degree of protection in terms of microbiological safety that traditional sterilization systems provide for canned foods. This requirement applies to both the food contact surface of the packaging material and the internal machine surfaces that constitute the aseptic or sterile zone within the machine. The safety and effectiveness of these agents must be proven and accepted or approved by regulatory agencies for packaging commercially sterile low-acid or acidified foods in hermetically sealed containers. Food processors considering use of an aseptic packaging unit should request written assurances that the equipment has passed such testing and that the equipment and sterilizing agents are acceptable to the regulatory agencies for their intended use.

Heat is the most widely used method of sterilization. Steam or hot water is commonly used and referred to as "moist" heat. Superheated steam or hot air may also be used in certain situations and is refered to as "dry" heat. Dry heat is a much less effective sterilization agent than moist heat at the same temperature. Systems that use moist heat operate at elevated pressures compared to dry heat systems, which operate at atmospheric pressures. Other methods may be used to generate heat, such as microwave radiation or infrared light. As new methods are developed, they will have to be evaluated by aseptic processing authorities.

Chemical agents such as hydrogen peroxide are often used in combination with heat as sterilization agents. The FDA regulations specify that a maximum concentration of 35% hydrogen peroxide may be used for food contact surfaces. If hydrogen peroxide is used as a sterilant, the packaging equipment must be capable of producing finished packages that also meet FDA requirements for residuals. Not more than 0.5 ppm hydrogen peroxide may be present in tests done with distilled water packaged under production conditions. These requirements apply also to USDA regulated products.

Other sterilants, such as high energy radiation (UV light, gamma or electron beam radiation), could be used alone or in combination with existing methods. Completely new alternative sterilants may be developed in the future. Whatever methods are developed, they will have to be proven effective in order to protect the public health and will be compared with existing methods.

ASEPTIC ZONES

The aseptic zone is the area within the aseptic packaging machine which is sterilized and maintained sterile during production. This is the area in which the sterile product is filled and sealed in the sterile container. The aseptic zone begins at the point where the package material is sterilized or where presterilized package material is introduced into the machine. The area ends after the seal is placed on the package and the finished package leaves the sterile area. All areas between these two points are considered as part of the aseptic zone.

Prior to production, the aseptic zone must be brought to a condition of commercial sterility analogous to that achieved on the packaging material or other sterile product contact surfaces. This area may contain a variety of surfaces, including moving parts composed of different materials. The sterilant(s) must be uniformly effective and their application controllable throughout the entire aseptic zone.

Once the aseptic zone has been sterilized, sterility must be maintained during production. The area should be constructed in a manner which provides sterilizable physical barriers between sterile and nonsterile areas. Mechanisms must be provided to allow sterile packaging materials and hermetically sealed finished packages to enter and leave the aseptic zone without compromising the sterility of the zone.

The sterility of the aseptic zone can be protected from contamination by maintaining the aseptic zone under positive pressure of sterile air or other gas. As finished containers leave the sterile area, sterile air flows outward, preventing contaminants from entering the aseptic area. The sterile air pressure within the aseptic zone must be kept at a level proven to maintain sterility of the zone. Air or gases can be sterilized using various sterilization agents, but the most common methods are incineration (dry heat) and/or ultrafiltration.

PRODUCTION OF ASEPTIC PACKAGES

A wide variety of aseptic packaging systems are in use today. These are easily categorized by package type as follows:

1. preformed rigid and semirigid containers, including;
   a. metal cans
   b. composite cans
   c. plastic cups
   d. glass containers
   e. drums
2. webfed paperboard laminates and plastic containers;
3. partially formed laminated paper containers;
4. thermoform-fill-seal containers;
5. preformed bags or pouches; and
6. blow molded containers.

There are a number of different packaging systems represented in these categories. Not all of these systems, however, are being used in the U.S. for aseptic applications.

Containers in these categories may be sterilized by a variety of means. For example, one system utilizing metal cans uses superheated steam to sterilize the containers. In other systems, preformed plastic cups may be sterilized by hydrogen peroxide and heat or by saturated steam. Systems using containers formed from paperboard laminates also utilize hydrogen peroxide and heat or hydrogen peroxide and ultraviolet irradiation to sterilize packages. Thermoform-fill-seal containers may be sterilized by the heat of extrusion (dry heat) or by hydrogen peroxide and heat. Plastic pouches or bags may be sterilized by gamma irradiation, by the heat of extrusion, or by chemical means such as hydrogen peroxide.

Research is now being conducted to explore alternative sterilization methods for most categories of packaging. Thus, it can be said with some certainty that currently familiar equipment may not be "state of the art" tomorrow. Nevertheless, whatever equipment or sterilant or packaging material is used, the monitoring and control of critical factors will be vital to successful operation.

INCUBATION

Incubation is defined as the holding of a sample at a specified temperature for a period of time for the purpose of permitting or stimulating the growth of microorganisms that may be present. Routine product incubation programs are recommended as a check on the overall quality and sterility of aseptic products. If the packer is producing an item that is covered by the inspectional authority of the USDA (see section on regulations, below), routine incubation of samples is mandatory, and the exact program should be established in cooperation with the regulatory representative. Incubation tests should be conducted on a representative sample of containers of product from each packaging code. Records of the incubation tests should be kept.

RECORD REQUIREMENTS

Accurate record keeping is essential to successful operation of aseptic systems. Automatic recording and monitoring systems are relied upon more heavily than in traditional processing because of the inherent complexity and numerous critical factors associated with aseptic systems.

The kind of recording or monitoring system used is determined by the variability of individual factors during operation. For example, machine packaging rate is often a pre-set function with relatively little variability. When machine packaging rate is a critical factor, operator monitoring may be sufficient to ensure that the rate stays within critical factor limits. On the other hand, critical factors such as temperature, which could be affected by a variety of other machine functions, can exhibit greater variability. Thus, the need for automatic recording or monitoring of temperature would be greater.

Production records for an aseptic system consist of production logs and recording charts from both the aseptic processing system and the aseptic packaging system. Recording charts are a continuous record of the aseptic system's performance. It is necessary that operators mark the charts clearly, in ink, to indicate the time that sterilization and production begin and end. If production is stopped for any reason, such as a drop in process temperature, loss of sterile air pressure, or packaging problems, the time of day that production is stopped and restarted should be noted on the chart.

The production log is a written record of the aseptic system's operation. The operator shall note in the log the time of day that events occur, along with any problems and related corrective action. In addition, the appropriate regulations must be consulted to ensure that all required information is included in the log.

Examples of production log entries may include the following information (*Figure 35*):

1. Temperatures at the hold tube outlet taken from the recorder chart and from the temperature indicating device;
2. Maintenance of a proper pressure differential if a product-to-product regenerator is used;
3. Adequate operation of steam seals;
4. Information relating to additional critical factors.

Although entries for the aseptic packaging system would change according to the type of equipment, the following information could be included (*Figure 36*):

1. Temperature in container sterilizer tunnels (metal containers);
2. Container rate through the packaging unit;
3. Temperature and pressure in the air sterilizer;
4. Temperature of heated air or hydrogen peroxide;
5. Hydrogen peroxide concentration at start and end of production;
6. Any additional critical factors.

For aseptic surge tanks, a record shall be kept to show that the tank has been sterilized and that the sterile air within the tank is maintained at the proper pressure. If the air is sterilized by heat, a record of the incinerator temperature is necessary. If the air filter is sterilized, a record shall show that the filter and sterile air supply system was sterilized at the required temperature and time at the beginning of the operation and that the filter cartridge was changed at proper intervals.

CONTAINER INTEGRITY

The integrity of aseptic containers must be ascertained by inspection and testing in order to assure that the containers will maintain a hermetic seal during handling, distribution, and storage. The concept of maintaining

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Container Size _____
Filler Used _____
Production Process
(Time/Temp.) _____

Chart No. _____ Page ____ of ____
Date _____
Lot. No. _____

Product/ Code	Production Start	Production Stop	Production Time	CPM/ GPM	HOMO PSI	Holding Tube Inlet °F	Holding Tube Outlet T/C °F	Holding Tube Outlet Hg °F	Pre-Heat °F	Regen. PSIG Diff.	Visual Steam Seal Check

Sterilization of	°F	Time	°F	Time
Processing System				

COMMENTS: _____

Figure 35—Processing log—product processing system.

container integrity is part of good manufacturing practice and an important function of every good quality control and assurance program.

Because there is such a wide variety of containers, the test methodology may be designed for a particular type of package. Both the FDA and USDA require that container integrity be determined through regular inspection procedures.

GOVERNMENT REGULATION OF ASEPTIC PROCESSING AND PACKAGING

There are three sets of regulatory requirements for food safety applicable to aseptic food processing and packaging operations. Aseptic systems can fall under the regulatory jurisdiction of either FDA or USDA, and the processor will need to determine which requirements are pertinent. When milk or a milk product, as defined in the Grade A Pasteurized Milk Ordinance (PMO), is involved, the aseptic operation must comply with the provisions of the PMO in addition to the FDA regulations.

The specific FDA regulations for aseptic processing and packaging systems are covered under 21CFR113.40 (g). FSIS elected to omit aseptic operations when they promulgated their canning regulations in 1986; thus there is no specific reference to aseptic processing in 318.300 or 381.300. Information on FSIS requirements for aseptic systems are found in "Guidelines for Aseptic Processing and Packaging Systems in Meat and Poultry Plants," which is available from:

Aseptic Processing and Packaging
Systems, Committee, Chairman
MPITS/FSIS/USDA
Room 2168-S
Washington, DC 20250

These documents are supplemental to the Meat and Poultry Inspection Regulations. In order for a federally inspected meat or poultry establishment to aseptically process and package food products for entry into commerce, the establishment personnel must first submit (1)

Chart No. _____ Page___of___
_____ Date _____
Lot No. _____

Product/Code	Production Start	Production Stop	Production Time	Sterile Air Temp. °F	Sterile Air Pressure		H_2O_2 System Level	H_2O_2 System Low cons.	H_2O_2 System Wet Guard	H_2O_2 System PSM	Heating Element °F

Sterilization of Filler	Sterile Air Temp. °F	Heater Draw	Time

H_2O_2 Concentration: _____
Start of Production: _____
End of Production: _____

COMMENTS:
_____
_____
_____

Figure 36—Processing log—aseptic filler.

an "acceptable" proposal to FSIS and (2) an "acceptable" Partial Quality Control (PQC) program for the operation and maintenance of the accepted system.

SUMMARY

1. "Aseptic" is a term which describes the absence of microorganisms and may be used interchangeably with commercial sterility.

2. An aseptic processing system consists of a timing pump, a means to heat the product, a hold tube, and a means to cool the product.

3. The processing system from the hold tube past the fillers is brought to a condition of commercial sterility prior to the introduction of product into the system.

4. The thermal process occurs in the hold tube where flow rate, or residence time, *and* temperatures are critical factors.

5. In the event of a process deviation, flow diversion devices are used to prevent potentially inadequately processed product from reaching the filler.

6. Aseptic packaging machines create and maintain an aseptic zone (sterile environment) in which sterilized containers are filled and sealed.

7. Sterilization agents such as heat, chemicals, high-energy radiation, or a combination of these, can be used to sterilize packages or machine surfaces.

8. Accurate record keeping is essential to successful operation of aseptic processing and packaging operations.

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Closures For Metal Containers

The metal container is responsible for the success of food canning and its role in providing a year-round supply of high quality and nutritious foods within the reach of all the nation's people regardless of location or income. Thus, the can plays a vital role in our way of life. We enjoy a high standard of living and increased leisure in great part through the convenience and reliability of the metal food can.

HOLE AND CAP CAN

Tin cans, or as they were originally known, tin canisters, were invented in 1810 to preserve perishable foods. These containers were constructed with a cylindrical body, a top (ring), and a bottom (disc). The edges of the top and bottom were flanged 90° and then snapped over the openings at each end of the cylinder. The body was rolled, while tilted, through a solder bath to seal and bond one end. Then, it was tilted so that the other end could roll through the solder bath, immersed just enough to let the solder contact this lap seam and flow into it (*Figure 1*).

An opening in the ring, which was the top end, was used as a filling hole for the product. Then a small disc, with a tiny hole in the center, was placed over the filling hole and soldered. After exhausting the headspace by preheating the can and contents, the small hole in the center of the disc was solder-tipped to close the container completely. Then it was heat processed.

OPEN TOP CAN

The turn of the century brought with it a new style of can known as the open top can. The side seam was still soldered, but the ends were fastened to the body by crimping (or as it is known today, by double seaming). By 1920 the open top can had replaced the hole and cap can. This technological breakthrough meant that:

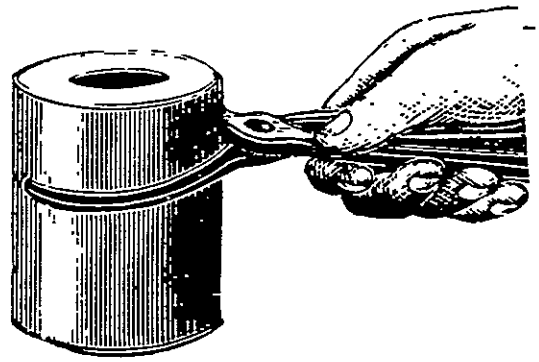

Figure 1—Hole and cap can used until 1900.

1. Cans could be made faster.
2. Cans could be filled faster.
3. Cans could be closed faster.
4. The hermetic seal was more reliable.

In recent years still further innovations have been made in the open top can. New technologies have evolved, including the welded side seam three-piece steel can and the seamless two-piece can where the body and bottom are formed as a single unit. These technological advancements have been accompanied by further developments in materials and designs such as the all-aluminum can, the half steam table tray, and the plastic can.

CAN MANUFACTURING PLATE

The "tin" can was originally manufactured from steel sheets that had been dipped in molten tin. This "hot dipped" method, as it was known, was gradually replaced by electroplating the tin coating onto the base steel. This new method allowed for the disposition of lower and more uniform weights of tin as well as differential coating (different weights of tin on each side of the sheet). Also, electrolyte coated plate is produced in a continuous coil form rather than individual sheets.

Today, tin-free steel or steel sheet that has a light chromium surface treatment but no tin coating is used extensively for applications where tin is not required to protect against corrosion or to facilitate the side seam welding process. For instance, tin-free steel is used widely for ends and for the manufacture of drawn two-piece cans.

Certain characteristics of the plate used in can manufacture affect the characteristics of the finished double seams. Depending on the can's size and strength requirements, different thicknesses of metal can be used. For steel containers, the thickness of the metal is indicated by specifying the theoretical weight in pounds per base box instead of actual thickness or gauge. A base box is a unit of area amounting to 31,360 square inches, or 217.78 square feet. It corresponds to the area covered by 112 sheets, each 14 × 20 inches. The relationship of base weight to plate thickness is shown by the following formula:

$$\text{Base Weight} = \frac{\text{Plate Thickness (inch)}}{.00011}$$

When dealing with materials other than steel, such as aluminum or plastic, thickness is specified directly in inches or millimeters.

The temper of tinplate, usually designated by a number such as T1, T2, T3. . .etc, indicates the forming properties or hardness of tinplate (T1 = dead-soft; T5 = very hard). In recent years, double cold-reduced or double-reduced plate was made available to the can manufacturing industry. This plate is a steel-tin mill product which is given a partial cold reduction to near final guage and then given another cold reduction to final gauge. The resultant tinplate is stiffer, harder, and stronger than conventional tinplate and enables the use, wherever applicable, of lighter base weights for container components.

Neither base weights nor tempers can be attained in tinplate without some variation. They can only be controlled within a range and the nominal value is somewhere in the middle of this range. Obviously, with such variability in the basic material used in can manufacture, double seam characteristics can also reflect similar degrees of variability.

SEALING COMPOUND

To make a hermetic seal, a rubber-based gasket or sealing material, called sealing compound, is jet or nozzle applied into the annular groove around the end unit that contacts the body flange (*Figure 2*). The amount of compound used depends upon the can diameter, the type of sterilization method used, and the style of the container. The type of compound depends upon the product and also the method of sterilization. Lack of compatibility between compound and product can cause softening, smearing, and oozing, resulting in reduced sealing efficiency. Although the application of sealing compound to the end unit is a relatively precise operation, equipment capability can provide a range of compound application with respect to placement and amount. As in the case of tinplate variability, the amount of sealing compound in the end units must also fall within a range of acceptability.

THE DOUBLE SEAM

A double seam is that part of the can formed by joining the body of the can and the end. The body flange and the curl of the end interlock during the double seaming operation to form a strong mechanical structure. Each double seam consists of three thicknesses of the lid component and two thicknesses of body component with an appropriate sealing compound trapped in the folded double seam to form a hermetic seal (*Figure 3*).

The can double seam is generally formed in two operations referred to as "first operation" and "second operation," hence the name double seam. Each station of the closing machine has a base plate, a seaming chuck, at least one first operation roll, and one second operation roll. The base plate, or can holding chuck, of the machine supports the can body. The snug fitting seaming chuck holds the can cover in place on the can body and

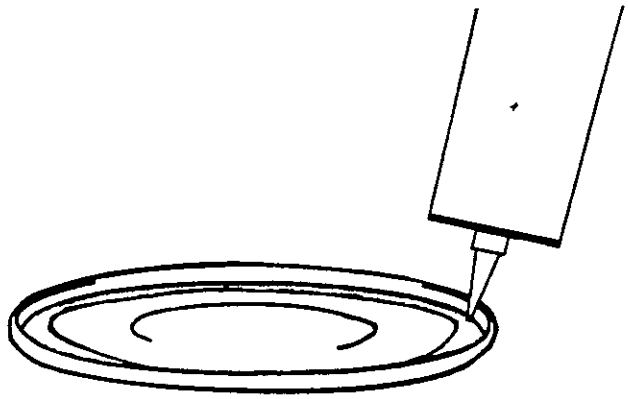

Figure 2—Application of sealing compound to can end.

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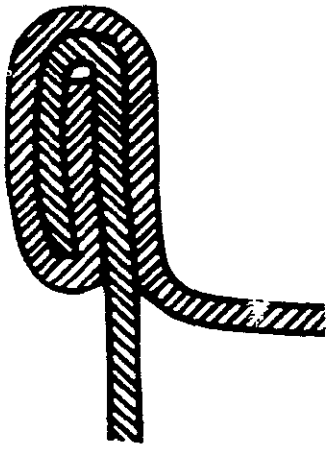

Figure 3—Cross section of a can double seam.

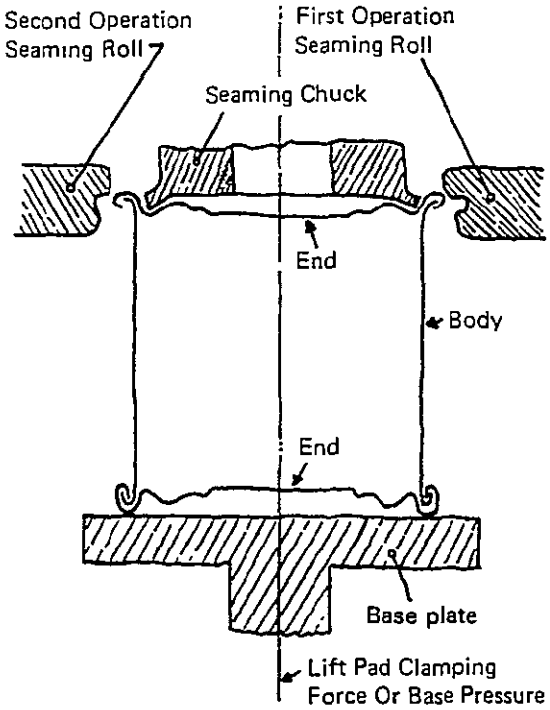

Figure 4—Diagram of seamer head chuck and rolls.

acts as a back-up for the double seaming roll pressure (*Figure 4*).

FIRST OPERATION

In the first operation, the curl of the end is interlocked (sometimes referred to as engaged) with the flange of the can body. The actual interlocking is performed with a roll or roller having a specially contoured groove. The first operation seam should not be too loose or too tight. There is no way to correct a faulty first operation seam during the remaining seaming steps. A good quality first operation seam has the body hook approximately parallel to the cover hook, the edge of the flange of the body (which becomes the body hook) well tucked down in the cover hook radius, and the curl of the cover adjacent to, if not actually touching, the body wall of the can (*Figure 5*). The first operation seam will usually be made properly if the following conditions are met:

1. Correct pin gauge height, which is the distance between the bottom of the seaming chuck lip and the top surface of the base plate.
2. Correct base plate pressure.
3. Correct alignment of seaming rolls to seaming chuck.
4. Correct tightness of the first operation roll.

When the first operation seam is completed, the first operation roll is retracted and no longer contacts the can cover (can end).

SECOND OPERATION

The second operation roll has a different groove profile from that of the first operation roll. This groove is flatter than the first operation groove and is designed to press the preformed hooks together, to iron out wrinkles in the cover hook, to distribute sealing compound in the seam, and, specifically, to develop double seam tightness (*Figure 6*). The tightness or compactness of the finished double seam is a function of the adjustment of the second operation roll, its profile, and its condition. The second operation roll can be adjusted to tighten the finished double seam. If the correct roll profiles are not used, or the rolls are worn excessively, the desired seam structure and tightness cannot be achieved.

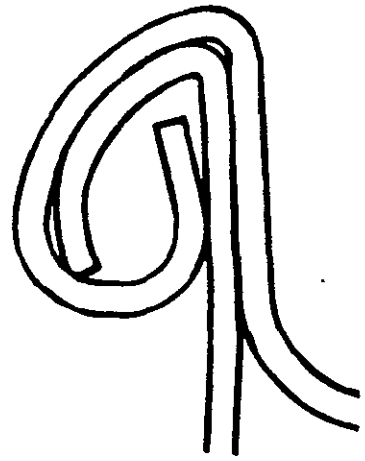

Figure 5—Normal first operation seam.

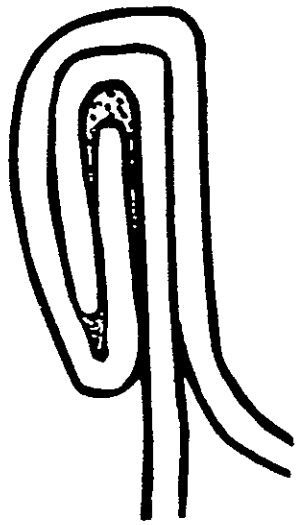

Figure 6—Normal second operation. (Note the compound fills the voids.)

During the double seaming operation, considerable pressure is exerted on the can end, the can body, and the sealing compound. The compound should be enclosed by the double seam. The compression by the seaming rolls will cause the sealing compound to flow and fill voids in the seam, thereby blocking potential leakage paths.

THE HERMETIC SEAL

The sealing compound and the mechanically interlocked can body and can end work together to make the double seam a hermetic seal (see *Figure 6*). Neither the sealing compound nor the interlocked can body and end, by themselves, are able to seal a container hermetically. They must complement each other. The double seam must be correctly formed. The compound, notwithstanding its resilience and ability to fill voids in the double seam, cannot compensate for a defectively formed seam.

CONTAINER STRUCTURE

The container structures that help form and become a part of the finished double seam are the body flange and the end curl.

FLANGE

The flange is the edge of the body cylinder that is flared outward resulting in a rim or ledge. The flange is formed into the body hook during double seaming and becomes interlocked with the cover hook. The width and radius of the flange are determined by requirements of the double seaming operations to form a proper body hook (*Figure 7*).

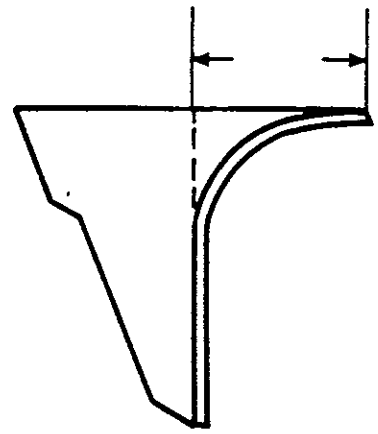

Figure 7—The outward flare of the body cylinder is called a "flange."

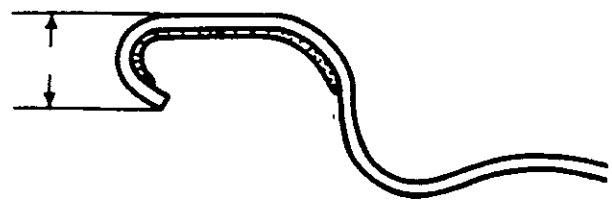

Figure 8—The end curl forms the cover hook and is the area where the sealing compound is placed.

END CURL

The end curl is designed to provide sufficient metal, proper contour, easy feeding of end units into the closing machine, and a structure to form a good cover hook (*Figure 8*).

DOUBLE SEAM STRUCTURE

The quality of a finished first operation or second operation double seam may be judged by measurement and evaluation of specific structures comprising the seam.

Seam specifications are normally furnished by the supplier of the container and end being used. Two sets of dimensions may be provided for each attribute measured. The aim is an ideal starting dimension used for set up. The adjustment tolerance or operating limits set the range for good practice. When the adjustment limits are exceeded for critical measurements, corrective action must be taken.

It is extremely important to understand that seam measurements by themselves cannot be used for determining the quality of a double seam. The seam specifications are provided as guides to be used in setting up the double seam initially and to assist in maintaining acceptable seams during production. The final judgment of the dou-

ble seam can only be made by a visual inspection of the torn down seam in conjunction with the measurements.

Some of the measurements that are provided in the seam specifications are determined by the plate weight, or thickness. For instance, the thickness of either the first operation or second operation seam will depend, to a great extent, on the thickness of the can body and end being used. Body hook and cover hook lengths, on the other hand, are not affected by plate thickness unless extreme variations are encountered.

Seam measurements that are suggested for given can sizes take into account the fact that the body plate and end (cover) plate are subject to inherent variations in thickness and hardness (temper). Consequently, the suggested seam measurements reflect the optimum thickness and tightness necessary for maximum seam integrity.

SEAM MEASUREMENTS

COUNTERSINK

The countersink is the distance measured from the top of the double seam to the end panel adjacent to the inside wall of the double seam. This distance is known as the countersink depth (*Figure 9*).

SEAM THICKNESS

Seam thickness is the maximum dimension measured across or perpendicular to the layers of material in the seam. As previously mentioned, there are three layers of the end and two of the body at locations other than the side seam. This measurement is one indication of the tightness of the double seam. It should be emphasized, however, that it is only one indication of seam tightness (*Figure 10*).

SEAM WIDTH (LENGTH OR HEIGHT)

Seam width, also referred to as seam length or height, is the dimension measured parallel to the hooks of the seam (*Figure 11*).

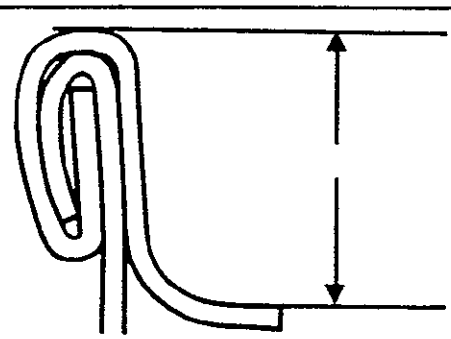

Figure 9—Countersink depth.

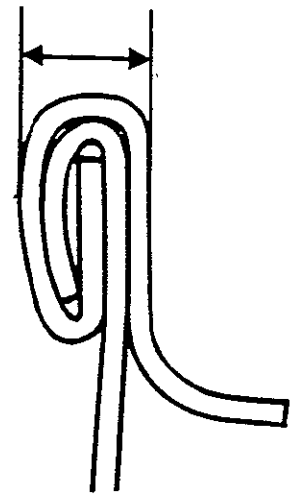

Figure 10—Seam thickness

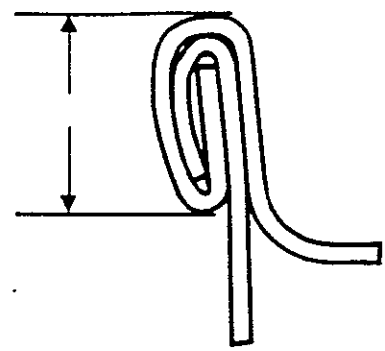

Figure 11—The seam width, length, height.

BODY AND COVER HOOK

The next group of structures and characteristics reflect the internal aspects of the double seam. First, there is the body hook, whose origin was the body flange, as indicated previously. There is also the cover hook, which was formed during the double seaming operation from the end curl. These two structures observed in a cross-section appear in an interlocking relationship to each other (*Figure 12*).

OVERLAP

The degree of interlock between the body hook and cover hook is known as overlap (*Figure 13*).

TIGHTNESS

Seam tightness is judged by the degree of wrinkling of the cover hook. During the first operation, the cover curl is guided around and up under the body flange. This process crowds the cut edge of the curl into a smaller

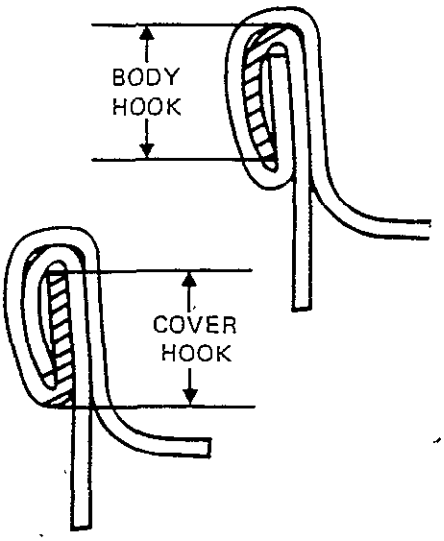

Figure 12—The body hook and cover hook.

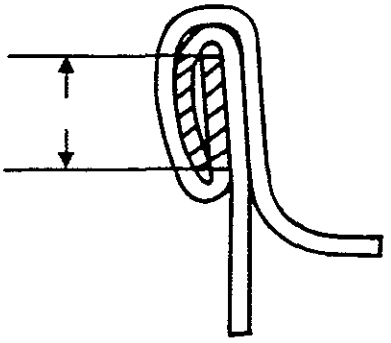

Figure 13—Overlap

Figure 14—Cover hook wrinkles.

circumference, resulting in a wavy cut edge with accompanying wrinkles around the seam. The function of the second operation roll is to press the preformed first operation hooks together to such a degree that the wrinkles may be ironed out sufficiently to ensure a hermetic seal (*Figure 14*).

In a completed double seam, any remaining wrinkles help to indicate double seam tightness. Tightness rating is a numerical designation which indicates the relative freedom from wrinkles, % smoothness of the cover hook (*Figure 49*) For additional information, see Teardown Examinations on p. 134 of this section.

JUNCTURE AREA

The juncture is where the double seam meets and crosses over the side seam area of the can body on a three-piece can. This is the most critical point in soldered side seam cans. There are seven layers of metal folded into the double seam at this area as compared to five thicknesses of metal away from the juncture. The extra thicknesses of metal usually prohibit the cover hook from being completely tucked or "butted" up into the body hook radius (*Figure 15*). This condition can result in a droop at the juncture that is frequently visible on the outside of the can. On can tear down, an impression in the cover hook is visible from which the juncture rating or degree of droop can be evaluated. The minimum cover hook metal remaining minus the droop is examined to provide the side seam juncture rating (see *Figure 50*).

With welded side seam cans, the thickness of the weld is only slightly greater than the thickness of the body metal. While a slight impression of the weld is apparent on the face of the cover hook, droop generally is not evident. Two-piece containerss, of course, have no side seam; therefore they have no side seam juncture.

CRITICAL EVALUATION OF THE DOUBLE SEAM

The variability of can making materials, closing machine adjustments, and/or wear can cause significant variations in the double seam. The shape and conformation of the finished double seam are determined by the contour of the seaming rolls and the taper of the chuck. Roll contours may be changed to accommodate different plate thicknesses. The roll profiles and the adjustments of the pressure of the rolls and the base plate on the closing machine are the factors that finally determine the shape and integrity of the double seam and its dimensions. Along with visual appearance, the measurements of seam thickness, seam width, and countersink depth are quick and easy signals to indicate proper double seam formation.

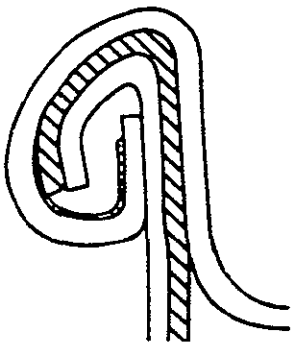

Figure 15—Butting at juncture (first operation).

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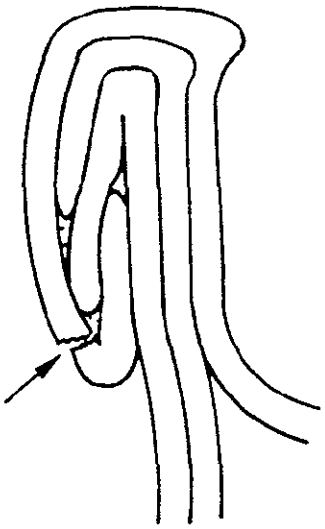

Figure 36—Cut seam at juncture.

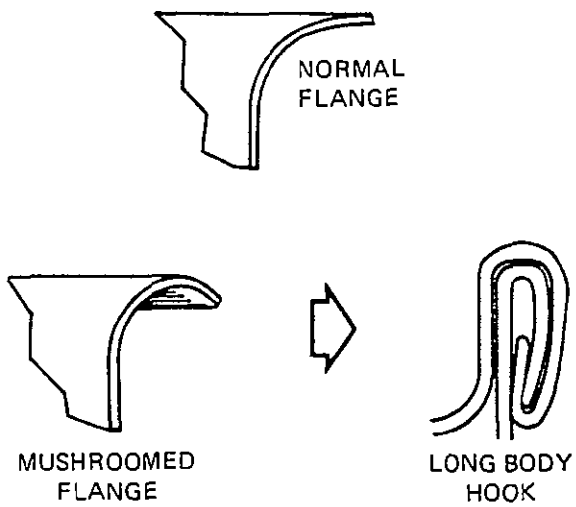

Figure 37—Mushroomed flange.

MUSHROOMED FLANGE

A "mushroomed flange" is a can flange that is over-formed, resulting in a long body hook. It may not be possible to see this condition until a cross-section of the seam is cut and examined (*Figure 37*).

Possible causes are:

1. Poor can handling practices.
2. Over-flanging.
3. Damage by can filler.

FRACTURED EMBOSSED CODES

"Fractured embossed codes" result when the metal of the end has been cut through at the code mark.

Possible causes are:

1. Mis-alignment of male and female type characters
2. Mis-alignment of type holders.
3. Intermixing of new and old type.
4. Improper matching of male and female type.
5. Too deep a code mark.

BROKEN CHUCK

"Broken chuck" defects occur when a portion of the chuck lip has broken away, resulting in what amounts to an excessively loose seam at this point due to a lack of backup support for the seaming rolls.

Possible causes are:

1. Severe jam in the closing machine.
2. Seaming rolls binding on chuck.
3. Metal fatigue in chuck lip.
4. Prying against chuck to clear a jam.

EVALUATION OF DOUBLE SEAM INTEGRITY

It is mandatory that double seams be inspected, by a trained closure technician at regular intervals to ensure that satisfactory double seams are being formed throughout daily production. These inspections shall include both visual and teardown examinations. A regular program of seam inspection will minimize the possibility of inferior double seamed containers reaching the consumer. Personnel performing closure examinations shall be under the supervision of a person who has successfully completed a school recognized as adequate for training supervisors of canning operations.

VISUAL EXAMINATIONS

A visual examination of double seams formed by each closing machine head is required. The external features of the double seam of each container shall be examined for gross closure defects such as the following:

1. cutover or sharpness;
2. knock down flanges, false seams or droops;
3. damage to the countersink wall indicating a broken seaming chuck.

The USDA regulations require and good manufacturing practice suggests that these examinations not be limited to double seam defects; rather they shall include examination of the entire container for product leakage or other obvious defects. When any defects are observed, the observation along with any corrective action(s) taken shall be recorded. These examinations shall be con-

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ducted as often as necessary to ensure proper closure, but under any conditions, the interval between visual inspections should not exceed 30 minutes of continuous closing machine operation. Additional visual examinations shall be made at the beginning of production, immediately following a jam in the closing machine, machine adjustment or a prolonged shut down. It is also recommended that visual examinations follow changes in can or lid supply source and changes in container type or container code.

TEARDOWN EXAMINATIONS

Tools

The results of seam examinations are only as reliable as the accuracy of the tools and the care with which the tools are used. All measurements are made and recorded in thousandths of an inch, thus precision tools and measurements are necessary. Micrometers, given reasonable care, do not easily get out of adjustment. However, they should be checked periodically to avoid the possibility of inaccurate measurements. It is important that care be exercised in making the measurements to avoid excessive pressure being exerted on the barrel of the micrometer. The person who is given the responsibility of tearing down seams should be thoroughly schooled in the proper use of the micrometer and any dial-type depth gauge, such as the countersink gauge. An inaccurate tool and/or measurement may result in containers with poor seams or an unnecessary shut-down and adjustment of closing machines.

Seam Micrometer—The seam micrometer has a standard micrometer barrel incorporated onto a suitable stem which has been designed specifically for measurement of double seam dimensions (*Figure 38*). A standard micrometer with a round anvil also can be used. The micrometer is placed over the surface to be measured by balancing the micrometer with the index finger at a 90 degree angle to the surface. The micrometer is lowered onto the surface until the anvil touches the surface. The adjustment barrel of the micrometer should then be used to bring the stem in contact with the other side of the surface without exerting excess pressure.

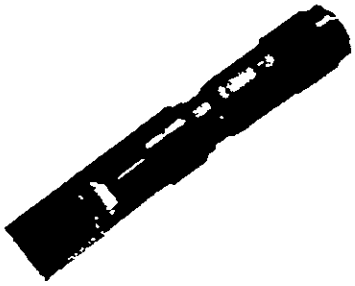

Figure 38—Seam micrometer.

Countersink Gauge—The dial indicator type countersink gauge is probably the best (*Figure 39*). However, there are less expensive instruments available. All are used to measure the countersink depth from the top of the seam to the lowest point adjacent to the countersink wall.

Can Opener—The special manual can opener is a heavy duty unit commercially available from most container suppliers (*Figure 40*). It is adjustable to the can diameter and removes the center panel of the cover without damaging the seams or the body. The use of a conventional household can opener should be discouraged because it leaves a double seam which is not only difficult to tear down, but may be distorted (by such an opener).

Nippers—The nippers are standard No. 5 nippers and are available in most hardware stores (*Figure 41*). Other sizes can, of course, be used. However, experience in-

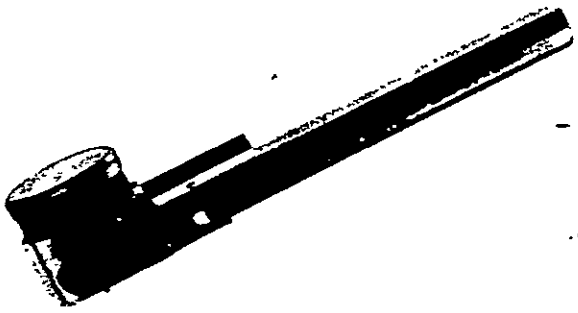

Figure 39—Countersink gauge.

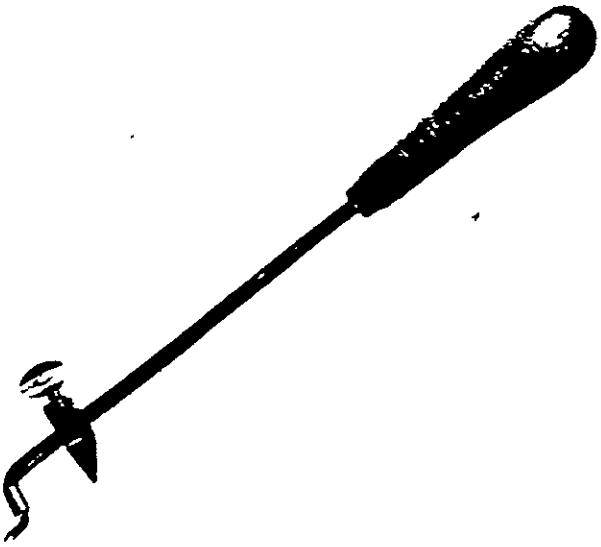

Figure 40—Special can opener.

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Figure 41—Nippers.

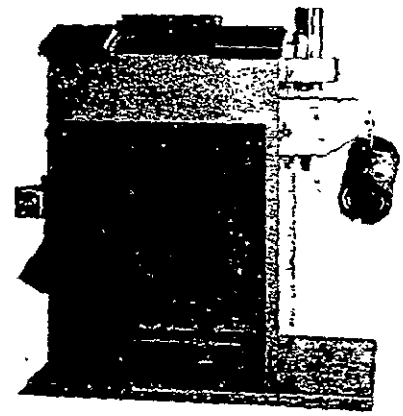


Figure 43—A seam projector.

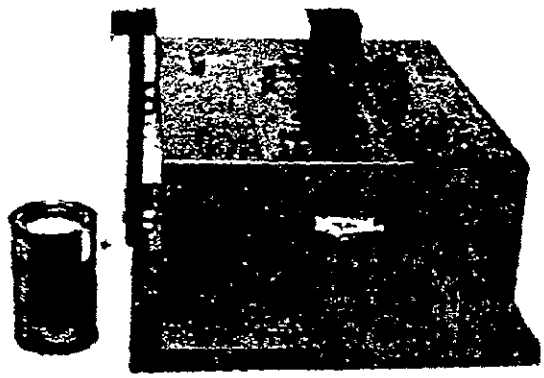


Figure 42—A power-driven seam saw.

Figure 44—Seam scope.

dicates this size to be the most desirable. Nippers are used to tear off the strip of cover left by the can opener.

Seam Saw (Optional)—A cross-section of the double seam can be cut with a fine metal saw. However, a power-driven seam saw is a convenience when many seams are to be inspected (*Figure 42*).

Seam Projector (Optional)—A seam projector is very effective for direct measurement of the seam overlap (*Figure 43*). A small cross-section is first removed from the double seam area of the can. It is then clamped into position and calipers in the base of the projector permit direct measurement on the projected image of the overlap, cover hook, and body hook. The projector allows inspection of the total configuration of the seam at the same time. It should be understood that this unit is limited to observing a cross-section of the seam. It does not eliminate the need for seam tear-down to make a full and complete evaluation.

Seam Scope (Optional)—The seam scope is a pencil-like magnifier with an attached light source (*Figure 44*). It contains a visible scale by which the length of the body hook, cover hook, and overlap can be read directly in thousandths of an inch on the exposed cross-section of the double seam. Its uses and limitations are similar to that of the seam projector.

Teardown Procedures

Teardown examinations shall be performed by a trained closure technician at intervals of sufficient frequency to ensure proper closure. These examinations shall be made on the packer's end double seams using at least one can from each seaming head to ensure maintenance of seam integrity. Tear down examinations should be made at intervals not to exceed four operating hours. The results of teardown examinations along with any corrective actions taken shall be promptly recorded. The USDA and good manufacturing practice suggests that these examinations be performed at the beginning of production, immediately following a severe jam or after adjustments or changes to the seaming machine.

In addition to these requirements, the USDA requires that teardown examinations be performed on the can manufacturer's end of at least one container per closing machine at each seam inspection interval except when teardown examinations are conducted on incoming containers or when the containers are made nearby and the teardown records from the can manufacturer are available to a USDA representative. The USDA also requires that the processor maintain specific guidelines for double seam integrity on file and make them available for review to USDA representatives.

The regulations allow for two methods of double seam teardown examination commonly referred to as the "micrometer" system and the "optical" system. If a micrometer system is used three measurements are made at points approximately 120 degrees apart around the double seam, excluding and at least one-half inch from the side seam juncture. The following measurements/observations are required (see *Figure 45*.)

Cover hook length
Body hook length
Width (length or height)
Tightness (observations for wrinkle)
Thickness
Side seam juncture rating (USDA only)

The following determinations are optional.

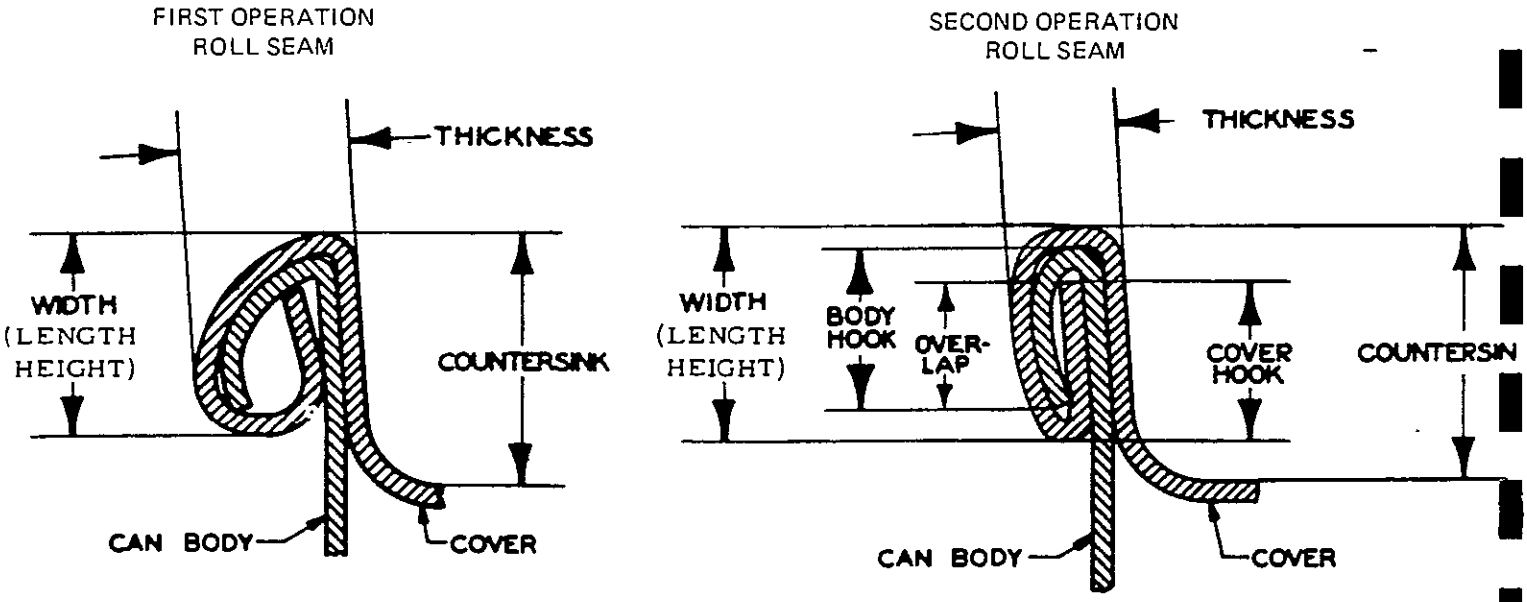
Overlap (by formula)
Countersink

The formula used to calculate overlap when micrometer measurements are employed is:

theoretical overlap length = CH + BH + T − W

where
CH = cover hook
BH = body hook
T = cover thickness*
W = seam width (height, length)
(*For convenience the cover thickness can be assumed to be .010 in.)

The USDA requires that at least the maximum and minimum values for each measurement shall be recorded by the closure technicians.



Minimum Measurements

Width* (not essential if overlap is measured optically)
Thickness (by micrometer)
Countersink (desirable but not essential)
Body hook*
Cover hook* (required if micrometer is used)
Overlap* (essential if optical system used)
Tightness* or wrinkle
Side seam juncture rating* (USDA required)

Calculation of Overlap Length

Overlap length = CH+BH+T−W
Where CH = cover hook
BH = body hook
T** = cover thickness, and
W = seam width

**In general practice 0.010 may be used for the tin plate thickness

*Requirements

Figure 45—Required measurements for evaluating the double seam quality.

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If a seam scope or can seam projector (optical system) is used to make the seam measurements, cuts should be made at at least two different locations, excluding the side seam juncture. The following observations are required:

Body hook
Overlap
Tightness (observations for wrinkle)
Thickness (by micrometer)
Side seam juncture rating (USDA only)

The following are optional but should be made:

Width (length, height)
Cover hook
Countersink

The countersink dimensions should be taken and recorded by using a suitable depth gauge. Care must be exercised in taking these readings to ensure that the point of the depth gauge pin is positioned so that the reading is taken at the base of the countersink radius with the bar of the gauge positioned across the diameter of the end.

In order to make the internal inspection of the seam, the body and end must be separated in a special manner that will properly expose the body hook and cover hook so that they can be accurately measured and rated for tightness and juncture rating. This procedure is commonly referred to as "stripping" or "tear-down" (*Figure 46*).

PROCEDURE—After the cover hook section has been removed from the can, it shall be closely examined for the following (*Figure 47*):

Wave or wrinkle condition
Fractures
Condition of cross-over area

If the micrometer system is used, the required cover hook measurements shall be taken around the seam and recorded. The lowest and the highest readings are recorded.

The body hook (*Figure 47*) which remains on the can after removing the cover hook shall be examined and measured. These dimensions shall also be recorded. As in the case of the cover hook, the required points shall be measured and the maximum and minimum entered on the data sheet. Average dimensions derived by calculation from all of the individual measurements should not be used.

After the body hook has been measured, the cross-over or juncture area should be carefully examined. Also, the pressure ridge area (*Figure 48*) on the inside wall of the can just opposite the body hook should be examined. The pressure ridge is an impression on the body wall as the result of the pressure applied by the second operation roll in creating seam tightness.

TIGHTNESS AND JUNCTURE RATING

When all of the cans in the sample set have been examined and stripped or torn down and the pertinent measurements have been recorded, the condition of the cover hook should be examined for tightness rating. In a completed double seam, any remaining wrinkles help to indicate double seam tightness. Tightness rating is a numerical designation which indicates the relative freedom from wrinkles or smoothness of the cover hook. Several numerical systems are used as indicated in *Figure 49*. The most commonly used system involves rating tightness from 0 to 100% tightness based upon the percent freedom from wrinkle.

Tightness should be judged not by the number of wrinkles but by the amplitude of the largest wrinkle.

The most critical portion of the double seam with the three piece soldered can is at the juncture often referred

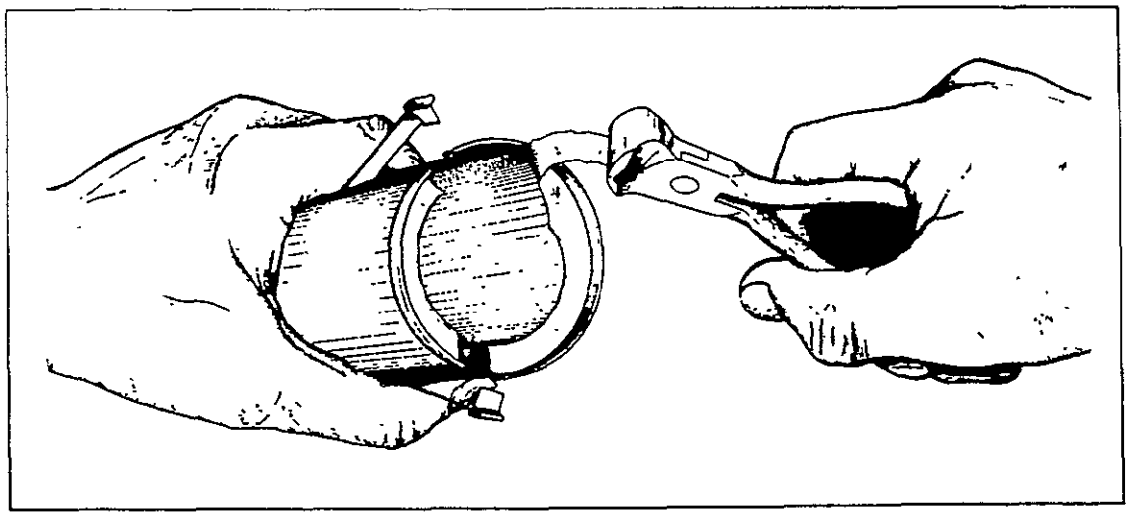

Figure 46—Tearing down the double seam.

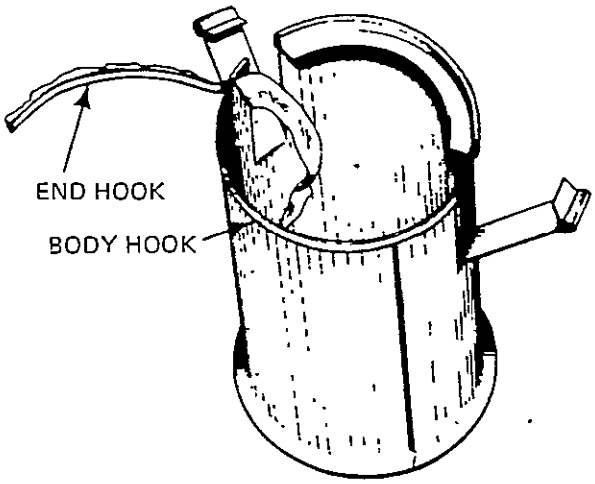

Figure 47—Disengaged cover hook.

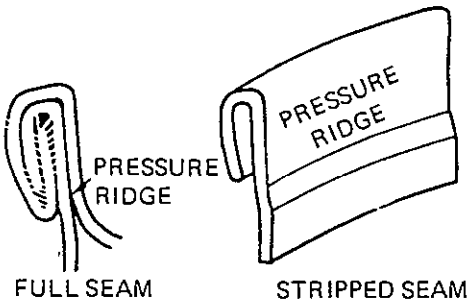

Figure 48—Pressure ridge on inside wall.

to as the cross-over. This is the most frequent site of leakage. The importance of careful visual examination of the cover hook and body hook at this point cannot be over-emphasized. The juncture rating indicates the percent of the cover hook metal available for overlap when it is interlocked with a body hook (*Figure 50*).

In addition to the juncture rating, the seam should be carefully examined for any sign of a looseness wrinkle adjacent to the crossover. This has been previously referred to as a "jumped seam" or "jump-over." Nothing can replace experience and the good judgment of the inspector in this part of the double seam evaluation.

INTERPRETATION OF INSPECTION RESULTS

If either the measurements or visual observations are found to be unsatisfactory for one or more of the cans examined, a repeat sampling from the questionable seaming station should be made before any machine adjustments are attempted. If it is found that the repeat sampling produces the same unsatisfactory condition, one must then decide whether the nature of the defect is of

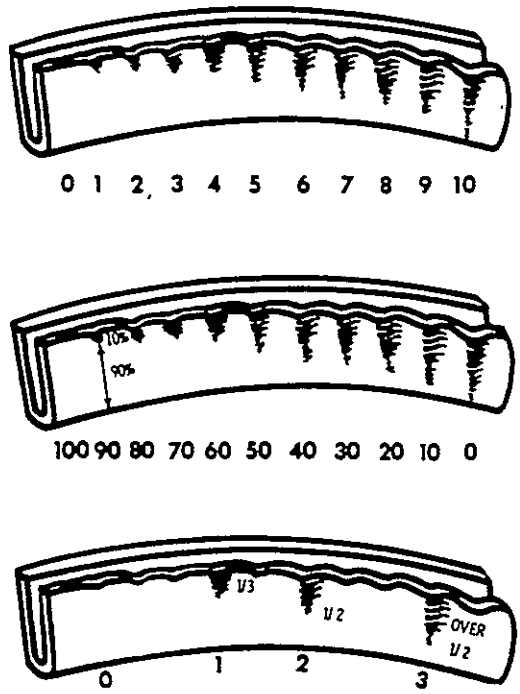

Figure 49—Tightness (cover wrinkle) ratings. Several numerical systems are used.

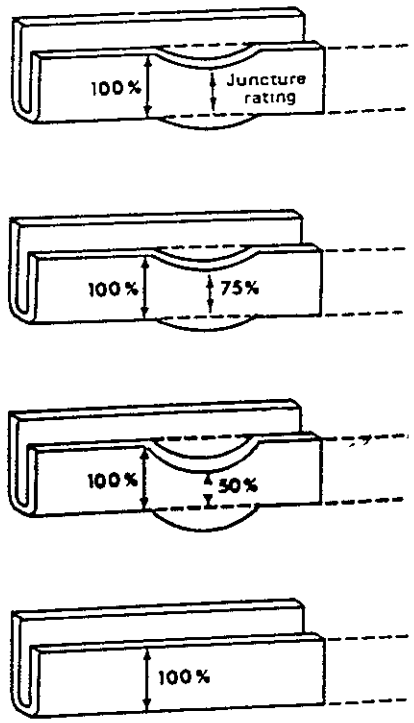

Figure 50—Juncture rating indicates the % of cover hook metal at the juncture available for an overlap when it is interlocked with a body hook.

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sufficient magnitude to warrant shutting down production immediately, or to continue operating until the end of the production period or next normal down-time. Too frequent or over-adjusting of closing machines can be troublesome and produce defective double seams.

The following examples may be cited as conditions under which production might be continued at little risk until a down-time provides opportunity for adjustment without loss of production:

1. If visual inspection indicates slight sharpness, especially in the cross-over area.

2. If the body hook minimum set up range is .075" for the particular can being run and the adjustment tolerance minimum is .072", and inspection reveals that the hooks are running on the low side in the range of .073 to .076", adjustment may be made when convenient.

3. When the thickness adjustment tolerances are .046 to .052" and measurements show thickness on the high side up to .053", but the cover hook displays a 100% tightness, no immediate adjustment is necessary.

There may at times be pressure on the closing machine operator to continue production until a normal down-time comes, even if abnormal seam conditions are observed. This practice should not be tolerated because it will lead to the production of inferior containers.

If unsatisfactory or questionable double seams are being made, the equipment must be shut down and corrections made. If conditions approximating the following examples are found on visual inspection, the equipment must be shut down and corrections made:

1. Sharp cut-over around periphery of inside of seam or fractures.

2. Heavy cut-over at cross-over.

3. Severe droop at cross-over.

4. Vees or lips protruding below bottom of double seam.

5. False seam.

6. Distorted or obviously poorly-formed seams either in the countersink wall or on the outside of the seam which would indicate a probable broken chuck or seaming roll.

7. Skidding or deadheading evidence.

If, after tear-down, measurements on critical factors beyond the adjustment tolerance limits are found, correction must be made immediately.

Good seam formation cannot be judged by purely mechanical means or measurements. The evaluation of good double seams requires experience and skill which cannot be quickly imparted. This section has attempted, however, to highlight those factors involved in double seam evaluation which are most essential to good seam formation and to give the supervisor an insight and appreciation of these factors.

CAN SEAM EVALUATION RECORDS

All double seam visual examinations and measurements shall be recorded. The exact nature of any serious defects observed shall be recorded as well as the steps taken for correction. Any marginal or unusual conditions observed should also be recorded. Complete and accurate records are required by the regulations. The details and examples of forms are contained in Section 6, "Records for Product Protection."

Closures For Glass Containers

THE BASIC PARTS OF A GLASS CONTAINER

From a manufacturing standpoint, the three basic parts to a glass container, based on the three parts of glass-container molds in which they are made, are the finish, the body, and the bottom (*Figure 51*).

FINISH — The finish is the part of the jar that holds the cap or closure, the glass surrounding the opening in the container. In the manufacturing process, it is made in the neck ring or the finish ring. It is so named because in early hand glass manufacturing it was the last part of the glass container to be fabricated, hence the "finish."

BODY — The body of the container is that portion which is made in the "body-mold" in manufacturing. It is the largest part of the container and lies between the finish and the bottom.

BOTTOM — The bottom of the container is made in the "bottom plate" part of the glass-container mold.

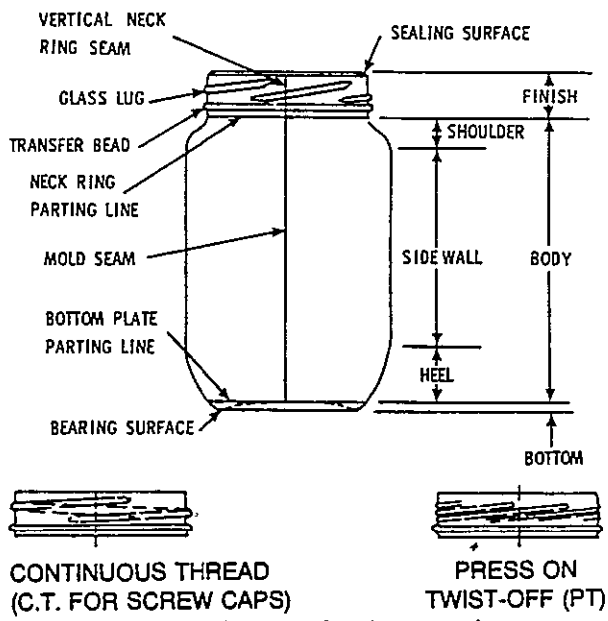

Figure 51—The basic parts of a glass container.

THE FINISH

The finish of glass containers has several specific areas, as follows (*Figure 51*):

SEALING SURFACE — That portion of the finish which makes contact with the sealing gasket or liner. The sealing surface is usually on the top of the finish, but may be a combination of both top and side seal.

GLASS LUG — One of several horizontal, tapering, and protruding ridges of glass around the periphery of the finish that permit specially-designed edges or lugs on the closure to slide between these protrusions and fasten the closure securely with a partial turn. The num-

ber of lugs on the closure and their precise configuration is established by the closure manufacturer.

CONTINUOUS THREAD — A continuous spiral projecting glass ridge on the finish of a container intended to mesh with the thread of a screw-type closure.

TRANSFER BEAD — A continuous horizontal ridge of glass near the bottom of the finish used in transferring the container from one part of the manufacturing operation to another.

Note: Not all glass containers have transfer beads. Some achieve the transfer in manufacturing through different means.

VERTICAL NECK RING SEAM ("Mold Match or Parting Line") — A mark on the glass finish resulting from the joint of matching the two parts of the neck ring.

Note: Some finishes are made in a one-piece ring and do not have this seam.

NECK RING PARTING LINE — A horizontal mark on the glass surface at the bottom of the neck ring or finish ring resulting from the matching of the neck ring parts with the body-mold parts.

THE BODY

The characteristic parts of the body of a glass container are (*Figure 51*):

SHOULDER — That portion of a glass container in which the maximum cross-section of the body area decreases to join the neck or finish area. The neck area is not shown in *Figure 51* because most glass containers for processed goods have very little neck. Actually, the neck would be any straight area between the shoulder and the bottom of the bead or, with beadless finishes, the neck ring parting line.

HEEL — The heel is the curved portion between the bottom and the beginning of the straight area of the side wall.

SIDE WALL — The remainder of the body area between the shoulder and the heel.

MOLD SEAM — A vertical mark on the glass surface in the body area resulting from matching the two parts of the body mold. The body mold seam may or may not align with the vertical neck ring seam.

THE BOTTOM

The designated parts of the bottom area are normally those shown in *Figure 51*:

BOTTOM PLATE PARTING LINE — A horizontal mark on the glass surface resulting from the matching of the body-mold parts with the bottom plate.

BEARING SURFACE — That portion of the container on which it rests. The bearing surface may have a special configuration known as the "stacking feature." which is designed to provide some interlocking of the bottom of the jar with the closure of another jar on which it might be stacked for display purposes.

DISCUSSION OF THE FINISH

Literally hundreds of different finishes are used on glass containers. The diagram (*Figure 51*) shows only three general types. Within these three general types a considerable number of specific finishes are designed for use with specific closures.

Every type of closure for glass-container sealing has a specific glass finish or finishes with which the closure has been designed to function. No attempt would be made to put a lug cap on a jar with a PT finish, but there are several different types of lug closures, each of which has been designed to work best with a specific glass finish.

Fortunately, glass finishes are standardized. For every finish designation, a specific set of dimensions or specifications and tolerances has been established by the Glass Packaging Institute working with the closure industry. Each finish has a specific number and may be purchased from literally any glass container manufacturer.

LUBRICANTS OR GLASS SURFACE TREATMENTS

Surface treatments, or lubricants on glass containers, serve the beneficial purpose of facilitating the smooth flow of containers through conveying systems. They also protect the outside surface of the container from abrasion. Many different treatments are used. If surface treatment or a change in the treatment being used is planned by a canner, the question should be fully discussed with both the glass container and closure suppliers before the change is made in order to prevent problems.

DEFINITIONS OF TERMS FOR GLASS CLOSURES

Among the terms commonly used for describing parts of metal vacuum closures are the following (*Figure 52*):

PANEL — The flat center area in the top of the cap.

RADIUS OR SHOULDER — The rounded area at the outer edge of the panel connecting the panel and skirt.

SKIRT — The flat, nearly vertical portion on the side of the cap. The skirt may be smooth, knurled, or fluted and serves as the gripping surface.

CURL — The rounded or rolled portion at the bottom of the skirt that adds rigidity to the cap and serves to protect the cut edge of the metal.

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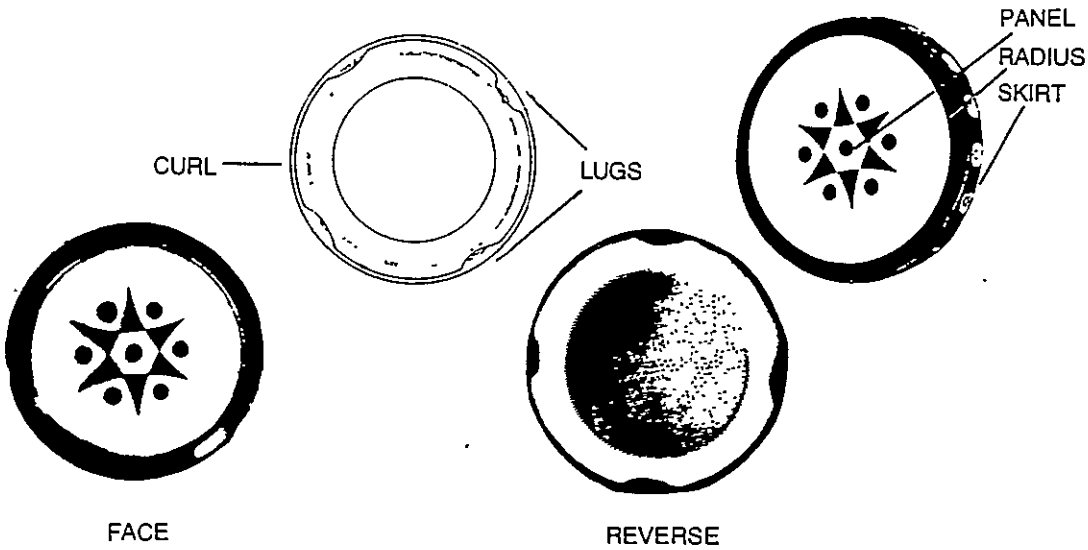

Figure 52—Parts of metal vacuum closures.

LUG — A horizontal inward protrusion from the curl that seats under the thread or lug on the finish of the glass container and holds the cap in position.

FACE — The outside of the cap.

REVERSE — The inside of the cap.

COATINGS AND LITHOGRAPHY — Coatings and inks that are used on the inner and outer surfaces of the cap to protect the metal from attack, adhere gasket materials, and decorate the closure.

GASKET — The actual sealing member of the cap, which must make intimate contact with the glass finish at the proper point to form an effective seal. Gaskets are made from the following materials:

PLASTISOLS — Suspensions of finely divided resin in a plasticizer, which are usually of two types — (a) flowed-in: used in the standard lug or twist-off cap, and (b) molded: used in the PT type cap. Plastisols are tailored to the product and process. For example, a closure intended for sealing a pasteurized product may not be suitable on a retorted product.

SAFETY BUTTON OR FLIP PANEL — A raised, circular area in the center of the panel which is used only for vacuum packed products and serves two principal purposes:

1. **Dud detection** — In the packaging plant it aids in automatic on-line detection of low vacuum or no vacuum packages.
2. **Consumer indicator** — It is an indicator to the consumer that the package is properly sealed when opened in the home. In addition to visual evidence of a disrupted seal, there is also an audible signal.

ROLE OF VACUUM IN OBTAINING GOOD SEALS

Almost all low-acid foods packed in glass containers are sealed with vacuum-type closures. This discussion deals exclusively with this type of cap. The vacuum within the package and the resultant positive pressure on the outside of the cap play an important role in forming and maintaining a good seal. It is important to know how vacuum is formed, what may affect the vacuum level, and how, when, and where it should be measured.

VACUUM CAPPERS FOR GLASS CONTAINERS

The two basic types of cappers which apply caps while forming a vacuum in the container are the mechanical vacuum capper and the steam-flow capper. The first applies the cap to the jar in an evacuated chamber, primarily on dry products, and is rarely used on low-acid processed foods. In steam-flow type cappers, either straight line or rotary, the container is subjected to a controlled steam atmosphere that displaces the headspace gases from the jar by a flushing action. The steam is trapped in the headspace as the cap is applied, then condenses to form a vacuum which helps hold the closure in place. As an aid to good sealing, the gasket in plastisol lined caps is softened by steam.

FACTORS AFFECTING VACUUM FORMATION

There are four primary factors affecting vacuum formation:

1. **Headspace** is an important factor in efficient sealing, particularly in steam-flow cappers. There must be sufficient void or headspace at the top of the container to allow adequate steam to be trapped in the container for forming a vacuum and to accommodate product expansion during retorting. The correct amount of headspace varies with products, processes, and package design, but a rule-of thumb indicator is that it should be not less than 6% of the container volume when measured at the capping temperature. Inadequate headspace can result in displacement or deformation of the closure during retorting.

2. **Product sealing temperature** affects the final vacuum obtained due to the effect of product contraction upon cooling. Other factors being constant, the higher the product temperature at time of sealing, the higher the final package vacuum. Product temperature may also affect the final vacuum by its interaction with the amount of air in the product. Usually, higher filling temperatures result in less air being entrained in the product.

3. **Air in the product,** as mentioned above, can have a direct effect on the final package vacuum and should be kept at a minimum for good sealing, product quality, and product appearance. The more air that is trapped in the product, the lower the vacuum.

4. **Capper vacuum efficiency** refers to the ability of the capper to produce vacuum in sealed containers. The most convenient, routine check on the vacuum efficiency of a steam-flow capper is the "cold-water vacuum check." It is simple and quick. The measurements are made with a vacuum gauge. The cold-water vacuum check shall be made prior to the start-up of actual filling operations or after extended break periods, at change-over from one container size to another, after a major jam, or whenever there is an unexplained significant change in vacuum level in regular line samples. This check can serve the dual purpose of checking capper vacuum efficiency and cap application with the same jars.

METHOD OF COLD-WATER VACUUM CHECK

A series of jars is filled with cold tap water to the approximate headspace that will be maintained with the product to be run. These are then sealed in the capper after the capper has been allowed to warm up to operating temperature and the normal steam setting attained. The jars are then opened and re-run through the capper and then checked for vacuum. The first run through the capper serves to deaerate the water and provide a truer vacuum reading. The vacuum obtained in the jars is then measured by use of a standard vacuum gauge. In most instances, the vacuum reading obtained (closed gauge) should be 22 inches or more or as recommended by the closure supplier.

The number of jars used to perform the cold-water vacuum check should be as follows:

1. Straight-line capper: Four to six containers.
2. Rotary capper: One container for each capping head.

THE PRINCIPAL VACUUM CLOSURE TYPES

Currently, two types of vacuum closures are widely used on low-acid food products.

LUG-TYPE TWIST CAP

The lug or twist cap (*Figure 53*) has gained steadily in popularity to become the predominant vacuum-cap type. It is referred to as a "convenience" or "utility" closure because it can be removed without a tool and forms a good reseal for storage.

1. **Structural components**

The lug cap consists of a steel shell and may have from 4, 6 or 8 lugs, depending on its diameter; it normally contains a flowed-in plastisol gasket.

2. **Application and seal formation**

The headspace is swept by steam the same as the other closure styles. Lug caps are secured to the glass finish by turning or twisting the cap onto the finish to seat the lugs of the cap under the threads on the glass finish. It is desirable, in most instances, that the gasket be softened by heat in the capper to facilitate sealing. Both the lugs and vacuum hold the cap in place on the glass finish but vacuum is the most important.

PT (PRESS-ON TWIST-OFF) CAP

This cap is in widespread use on baby foods as well as on other products (*Figure 54*). It combines the simple application requirements of a press-on closure with the convenience of a lug cap:

1. **Structural components**

The cap consists of a steel shell that has no lugs. The gasket is molded plastisol that covers a sealing area extending from the outer edge of the top panel to the curl

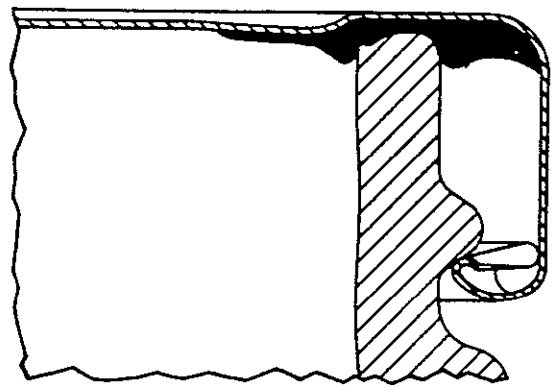

Figure 53—Regular lug-type or twist cap.

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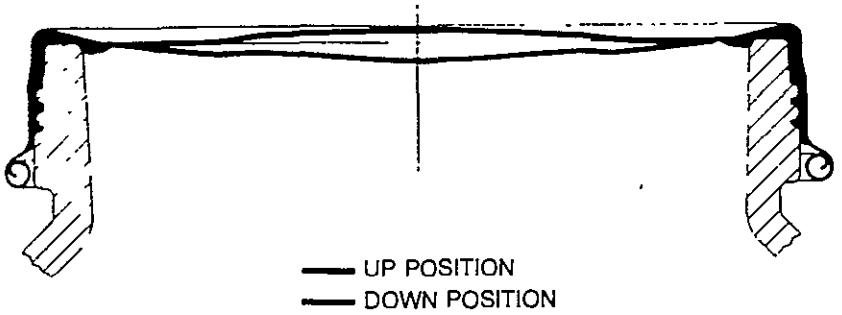

Figure 54—PT (Press-on Twist-off) cap.

of the cap, forming the primary top seal and a secondary long side seal. The standard baby food design contains a safety button or flip panel, as do most other PT caps.

2. Application and seal formation

Application requirements call for simply pressing the cap down on the glass finish after steam sweeping the headspace. The Press-on Twist-off closure gasket must be properly heated prior to application. The glass threads form impressions in the skirt of the cap gasket that allow the cap to be cammed-off when twisted to open. The PT closure is held in place on the finish primarily by vacuum with some assistance from the thread impressions in the gasket wall when the cap is cooled.

CLOSURE EVALUATION

There are two general types of closure inspections: (1) visual, non-destructive, external observations or measurements made at frequent intervals; and (2) cap removal or destructive tests made at less frequent intervals because the integrity of the seal is destroyed. Both of these tests and observations shall be made at the capper and after processing and cooling. The appropriate tests and observations for each type of closure being considered are listed in *Table 1*.

Table 1—Tests and observations of vacuum closures for glass containers.

	Type of Closure	
	PT (Press-on Twist-off)	Lug or Twist
AT CAPPER		
Non-Destructive External Inspection		
Cap tilt	X	–
Vacuum (cap panel concavity)	X	X
Pull-up (or lug position)	–	X
Cocked Cap	–	X
Crushed Lug	–	X
Destructive Removal Inspection		
Cap tilt	X	–
Vacuum (gauge)	X	X
Temperature	X	X
Headspace	X	X
Gasket	–	–
Security	–	X
Compound Impression	–	X
AFTER PROCESSING AND COOLING		
Non-Destructive External Inspection		
Cap tilt	X	–
Vacuum (cap panel concavity)	X	X
Pull-up (or lug position)	–	X
Cocked Caps	–	X
Crushed lugs	–	X
Button down position	X	X
Destructive Removal Inspection		
Cap tilt	X	–
Vacuum (gauge)	X	X
Temperature	X	X
Headspace	X	X
Security	–	X
Compound Impression	X	X
Cam-off, removal torque (opt.)	X	X
Button return to up position	X	X

TESTS AND OBSERVATIONS FOR CLOSURE APPLICATION AND DEFECTS

Cap Tilt — On PT caps, the cap should be essentially level, not cocked or tilted, and seated well down on the finish. This is judged in relation to the transfer bead or shoulder on the glass container and should not exceed 3/32".

Cocked Cap (*Figure 55*) — The term "cocked cap" refers to the lug cap type and is caused by a lug failing to seat under the glass thread. It is readily apparent as it usually results in an unlevel or tilted cap.

Crushed Lug (*Figure 56*) — A crushed lug on a lug type cap may be visible on external examination but may not be readily apparent since it does not necessarily result in a titled cap. It is caused by a lug being forced down over the glass thread by the sealing mechanism of the capper.

Stripped Cap (*Figure 56*) — A stripped cap is a lug cap that has been over-applied to the extent that the lugs have been "stripped" off the glass threads on the finish. On visual examination it appears that the lugs are pulled outwardly.

Vacuum — In most cases, there will be vacuum in the package when it comes out of the capper and the panel of the cap will show a concavity or dished-in ap-

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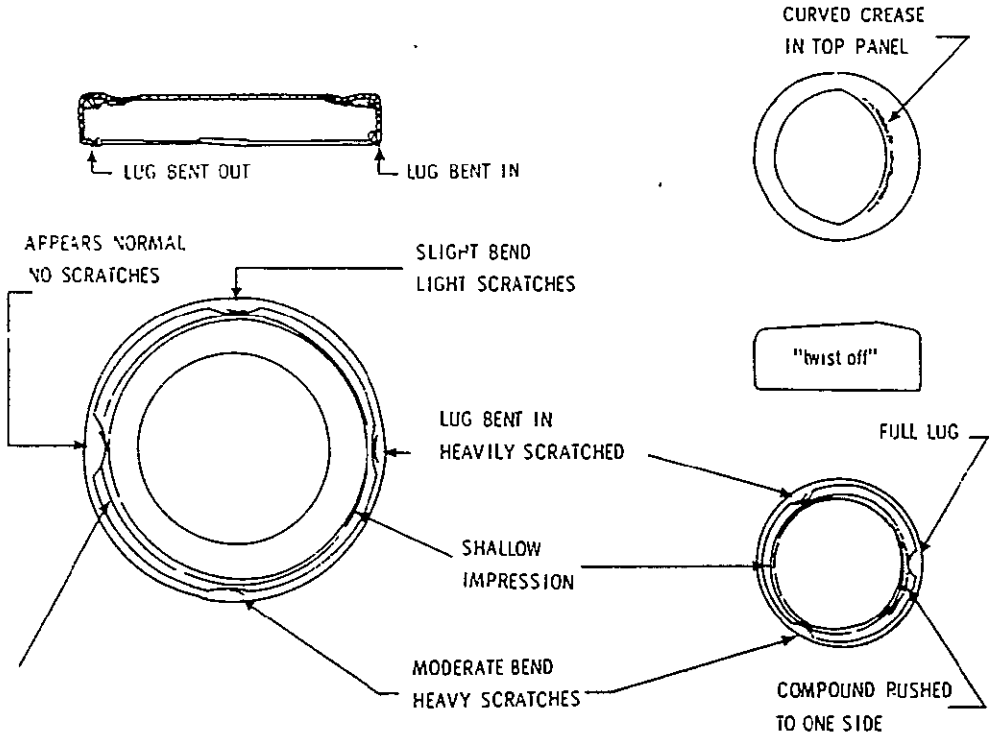

Figure 55—Typical cocked caps.

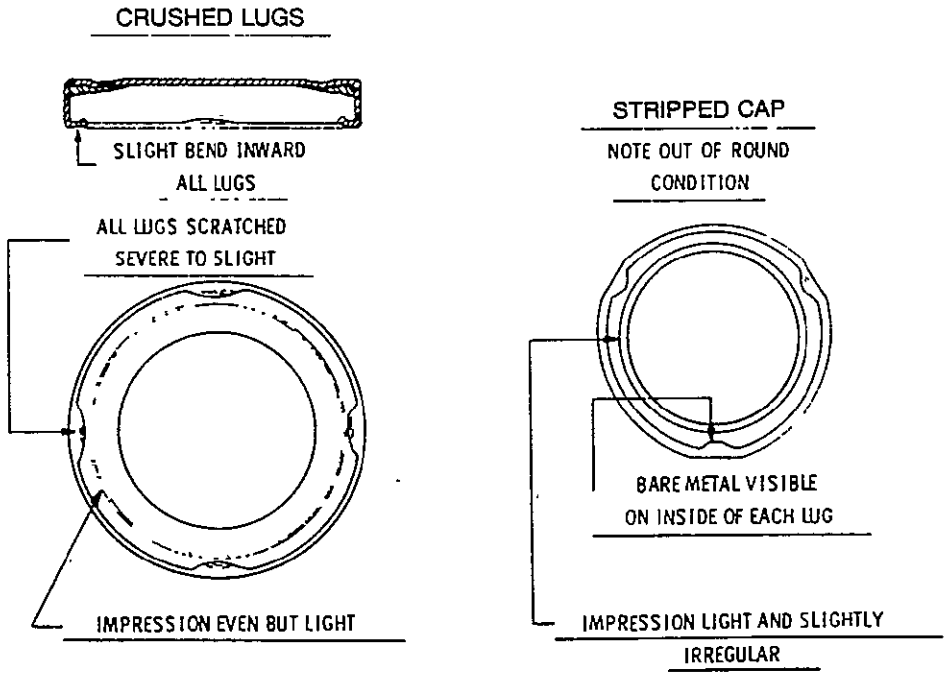

Figure 56—Crushed lugs and stripped caps.

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pearance indicating the presence of a vacuum.

On PT caps there must be at least 3" vacuum out of the capper to avoid loose caps. However, a vacuum button, if present, may not be down at this point. After processing and cooling, the button must be down and return to the up position when the cap is removed.

The exact amount of vacuum present is determined with a vacuum gauge and the amount should read within the range for the product being run. This procedure is a destructive test that results in loss of the package integrity.

Temperature — The product temperature should be within the normal range for the product being run and should be recorded in conjunction with vacuum.

Headspace — In most cases, headspace should be not less than 6% of the container volume at the sealing temperature. Once the relationship of headspace volume for a specific product is established for a given container, the headspace may be measured with a depth or headspace gauge rather than by volume.

Gasket — After cap removal there should be a visible, even impression in the gasket 360° around the circumference made by tight contact with the glass finish.

Cut-Thru — Cut-thru occurs when the top of the glass finish has pushed completely through the compound to the coating on the metal. This problem results in a leaky seal and requires immediate remedial action.

Removal Torque — Removal torque is the force required to remove a cap; it can be measured on a standard torque meter. This test may be valuable for the quality control record but is not recommended as a control for cap application. Cap application may be correlated, through experience, with removal torque after specified storage periods and, as such, may be of value as quality-control check.

Pull-Up — Pull-up, also known as lug position, is a nondestructive method of measuring the engagement of the closure lug on the threads of the glass finish.

This pull-up or lug position is defined as the distance between the leading edge of the cap lug and the vertical neck ring seam on the glass finish. It is measured in 1/16 inch increments. To measure this position, first find the vertical neck ring seam on the glass finish. There are two vertical seams on the glass finish 180° apart. Remember that the vertical neck ring seams are not always aligned with the body seams. Then simply measure the distance from this vertical line to the leading edge of the cap lug positioned nearest it.

Lug position measurements made on the right side of the parting line as you look at the package are referred to as positive (+), and those to the left side of the parting line as negative (−). The normal range specified is on the positive side (*Figure 57*).

Negative lug positions could indicate over-application of the cap, which may, in extreme cases, result in a stripped cap.

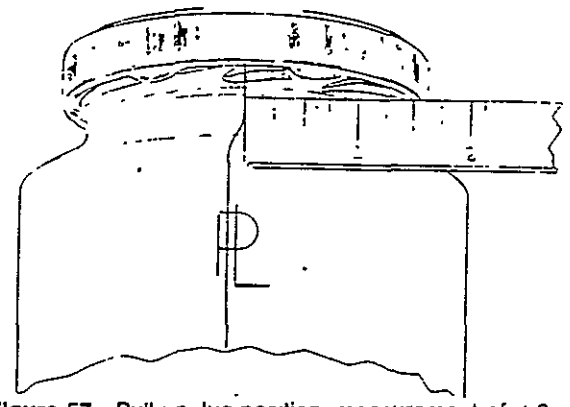

Figure 57—Pull-up, lug position, measurement of +6.

It is not recommended that lug position or pull-up measurements replace the "security" measurements described below, but they are very useful once the relationship between lug position or pull-up and security has been established for a given lot of glass and caps.

In most cases of proper application, the leading edge of the cap lug will be approximately 1/4 inch to the right of the parting line (or + 4 pull-up or lug position); however, the distance can vary 1/4 inch in either direction (*i.e.*, 0 to 8) and still result in good security values within the specified range due to dimensional variations in the glass finish and the cap

Security — Security values (lug tension of an applied closure) are the most reliable measurement of proper lug cap application. Security value ranges at the capper are specified by the closure manufacturer for good application of 4-lug, 6-lug and 8-lug caps. If values are higher than the range specified, it indicates a secure package with some degree of over-application and should be brought back into the range for best overall cap performance. Values that are consistently below the minimums usually indicate under-application, and the condition should be corrected immediately. From time to time, conditions may vary to the extent that a deviation from the suggested security numbers is necessary. Variations may be coexistent with the type of plate or the compound used in the caps and/or glass surface treatment used by the glass maker. One or a combination of these conditions may dictate a shift of the proper security range in either direction for the specific operation. In some cases, lower security values may be acceptable as long as there is some positive security on packages going into the warehouse.

Security measurements are a destructive test, so there are practical limits to the number of packages that can be tested. The security test on a lug type closure is made as follows:

a. With a marking pen or pencil make a vertical line on the cap and a corresponding line on the container

(*Figure 58*). (This line has no relationship to the vertical neck ring seam.)

b. Turn closure counter-clockwise only until vacuum is broken.

c. Reapply closure to container just until the gasket compound touches the glass finish and the closure lug touches the glass thread, or until the closure is just finger-tight (*Figure 58*).

d. Measure the distance between the vertical lines that were made before opening, in 1/16 inch increments (*Figure 58*).

e. Security is considered positive if the line on the cap is to the right of the line on the container and negative if the line on the cap is to the left of the line on the container. Negative securities, unless caused by a misapplied closure, should be investigated and corrected immediately.

Security is measured after processing and cooling in the same manner as at the capper, but the range of measurement for normal application will change to a lower value due to compound sink during processing. With heat and pressure, the cap will be pushed further down on the glass finish, changing the lug tension on the glass thread.

FREQUENCY OF INSPECTION

It is mandatory that your closures be inspected by a trained closure technician at regular intervals to ensure that satisfactory closures are being formed throughout daily production. These inspections shall include both regular visual (nondestructive) and physical (destructive) inspections. A regular program of capper inspection will minimize the possibility of inferior closures reaching the consumer.

VISUAL EXAMINATIONS (NON-DESTRUCTIVE)

The external visual examination includes at least one container from each capper head. The closure shall be examined for gross closure defects such as the following:

1. loose or cocked caps;
2. crushed lugs or stripped caps;
3. low-vacuum (visual examination of vacuum closure).

The USDA regulations require and good manufacturing practice suggests that examinations shall not be limited to specific closure defects and shall include an examination of the entire container for obvious defects such as fractured or cracked containers. When any defects are observed, the defects along with any corrective action taken shall be recorded. These examinations shall be conducted as often as necessary to ensure proper closure and should not exceed 30 minutes of continuous closing machine operation. Additional visual examinations shall be made at the beginning of production immediately following a container jam, machine adjustments or a prolonged shut down. It is also recommended that visual examinations follow changes in jar or lid supply or jar type. Due to varying line speeds and line conditions it is not possible to recommend specific sampling frequencies. The following minimum recommendations should be modified by the processor based on specific operating requirements. It is suggested that visual closure inspections on straight line cappers involve a minimum of six samples taken at random at least once every 30 minutes and on rotary cappers a minimum of one sample for each capper head at least once every 30 minutes. Inspections should be conducted with sample jars taken from the capper and after processing and cooling.

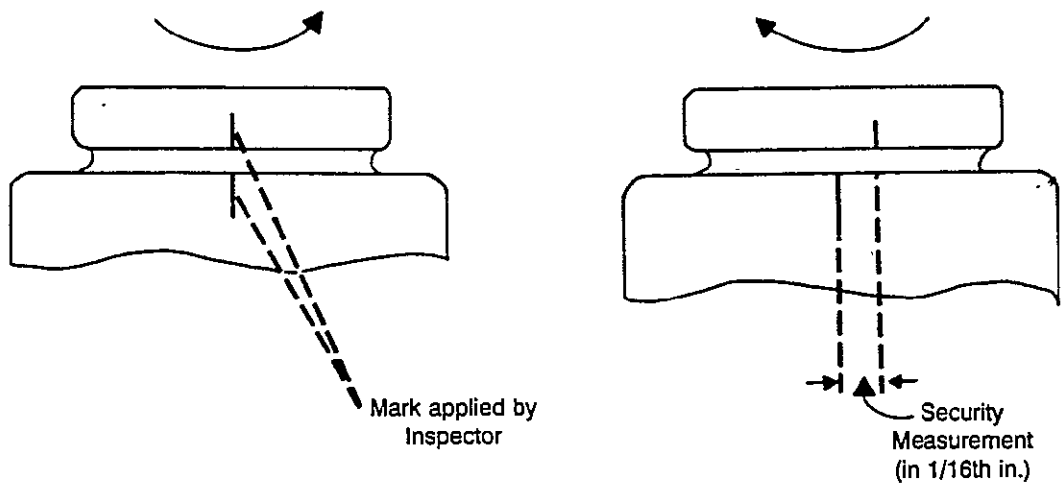

Figure 58—Illustration of security measurement.

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PHYSICAL EXAMINATION (DESTRUCTIVE)

Physical examinations or tests shall be performed by a trained closure technician at intervals of sufficient frequency to ensure proper closure. These examinations should be made at intervals not to exceed four hours of continuous closing machine operation. Any defects shall be recorded along with the corrective action taken. When vacuum closures are used the FDA requires that capper efficiency shall be checked by measuring cold water vacuum. This shall be done before actual filling operations and the results shall be recorded.

The USDA requires that at least one container from each closing machine be examined during each regular examination period. Additional closure examinations should be made at the beginning of production, immediately following a jam and after closing machine adjustment. In addition, specification guidelines for closure integrity shall be maintained on file by the processor and made available to USDA representatives upon request.

Due to operating differences it is not possible to recommend specific sample numbers or frequencies. The following recommendations should be modified by the processors based on specific operating requirements. It is suggested that physical testing for straight line cappers involve a minimum of six samples taken at random at least once every four hours and on rotary cappers at least one sample for each capper head at least once every four hours. These inspections should be done with jars which have just been capped and jars after processing and cooling.

AUXILIARY EQUIPMENT

The role of auxiliary equipment—headspacers, cocked-cap detectors and ejectors, and dud detectors—which may directly or indirectly affect the sealing of the container should be considered and reviewed by the closure inspection supervisor whether or not these operations fall under his/her direct control and responsibility.

HEADSPACERS

As discussed earlier, headspace is of critical importance in obtaining good seals with certain cap types and is of significant importance with all vacuum caps. Consequently, if a headspacer is incorporated in the line, the closure inspection supervisor should be sure that it is set properly. Also, product over the finish, which can sometimes result from headspacer operation, may be detrimental to good sealing.

COCKED-CAP DETECTORS AND EJECTORS

These devices, usually installed on the capper, can serve to eliminate problem packages before they become mixed with the flow of normal packages and can also serve to signal both the capper operator and quality auditing personnel that a problem exists or is developing.

DUD DETECTORS

These units, if properly maintained and checked, can monitor the quality of the seals being formed on all packages and, as a consequence, can serve as an extremely useful tool to the closure inspection supervisor in checking for defective seals and analyzing sealing problems. It should be part of the closure inspection supervisor's duties to see that these units are checked regularly and maintained in the proper operating condition.

SUMMARY

In evaluating proper sealing of glass containers for low-acid foods, the following factors play an important role in obtaining good seals:

1. Factors which affect vacuum formation (all cap types):
   a. Headspace;
   b. Product temperature;
   c. Air in the product;
   d. Capper vacuum efficiency.
2. Main factors for checking application of all cap types:
   a. Cap is level and seated well down on finish;
   b. Vacuum is adequate;
   c. Impression in gasket is even (particularly after processing).
3. Main factors for checking application of lug-type caps:
   a. Cap is level and not cocked;
   b. Pull-up is satisfactory;
   c. Security is within specified range;
   d. Vacuum is adequate;
   e. Impression in gasket is good.
4. Main factors for checking application of PT-type caps:
   a. Cap is level;
   b. Vacuum is adequate;
   c. Proper cam-off exists;
   d. Impression in gasket (after processing) is good.
5. When to act on readings outside desired operating range:
   a. When they persist;
   b. When they are out of operating control limits;
   c. When caps are loose.

BACTERIOLOGICAL EVALUATION FOR THERMAL PROCESS DESIGN

E.S. YAWGER

□ THE ESTABLISHMENT of a thermal process almost always involves two phases. First, to size a cooker to a customer's requirements, heat penetration measurements are made in a laboratory Steritort which simulates a commercial continuous sterilizer. Then a follow-up test, employing bacteriological methods, is made whenever possible on the completed cooker installed in the canner's plant. We feel this test is essential, particularly where products heating by induced convection are involved.

TWO BACTERIOLOGICAL PROCEDURES

There are two main methods of bacteriological process evaluation:

• **The Inoculated Pack System,** described in detail by NCA (1968), is basically a system for controlling the initial spore population and counting the number of survivors. An inoculated pack consists of a series of containers, usually 100, inoculated with a definite number of spores, usually 10,000, per can. The final requirement is that the spore resistance be known. The cans are processed at standard cooks and incubated to permit spoilage by surviving spores.

The advantage of an inoculated pack is that by inoculating the cans with a large number of spoilage organisms, the tal population of 100 cans may become equivalent to that 10,000 cans at normal contamination levels. Thus, the spoilage in 100 cans may approximate commercial operation. Disadvantages are the cost, labor, and time of incubation.

• **The Count Reduction System** was developed in the FMC laboratories in 1952 (Yawger, 1967) and has been used almost exclusively for bacteriological process evaluation since that time. The procedure employed is as follows:

(1) Each test can is inoculated with 30-50 million spores of a heat-resistant organism, usually a thermophilic flat sour organism. Generally ten or more cans are inoculated per variable.

(2) A series of test processes, varying time or temperature, are employed.

(3) The initial count is determined from an unprocessed, inoculated can.

(4) The survivor counts are determined on each processed can.

(5) Standard bacteriological techniques are employed in counting—we employ dextrose tryptone agar spin tubes incubated at 55°C for 48 hr.

(6) The D value of the organism is determined in the product being tested. A survivor curve for a series of timed exposures is employed to determine the D value.

CONCEPT OF INTEGRATED VALUES

The evaluation of process lethality by bacteriological systems is based on a simple equation:

$$I.S. = D(\log I - \log S)$$

where I.S. = integrated sterilizing value
D = 90% spore destruction time
I = initial count
S = survivor count

veral aspects of this equation should be examined:

1. I.S. is the equivalence in minutes at 250°F for the entire product volume, whereas F_o is the equivalence in minutes at 250°F for a single point in the container.

2. The equation demonstrates that at constant I.S. and D, the number of survivors is directly proportional to the initial contamination.

3. Product contamination levels influence the I.S. required for commercial sterility. For example, pet food ingredients are frequently significantly contaminated. To control this contamination, pet food is normally processed to $F_o = 8$ and I.S. > 9.5. By contrast, evaporated milk is produced under strict sanitation, and the resulting low contamination level permits a safe process at $F_o = 3.5$ and I.S. = 3.5. A second consideration is container volume. Since a No. 10 can contains 10 times the volume and contamination of a 10-oz container, the increase in log I − log S is 1, and the process lethality must be increased by one D unit for No. 10 cans.

4. The equation demonstrates that the lethality required for a constant survival level is influenced by organism resistance and the I.S. is directly proportional to the D value of the organism.

5. One of the greatest deficiencies in process lethality selection is lack of accurate estimates of the initial contamination of heat-resistant organisms in commercial canning operations. Until this information is available, the I.S. required for commercial sterility with a realistic probability of spoilage must be based on an estimate of the initial contamination and the resistance of the organisms.

6. Accurate I.S. values require accurate counting of initial and survivor populations. On the basis of two experiments made some years back, I am convinced that additional research on counting techniques is desirable and rigid standardization is essential. The first experiment involved a suspension of *Bacillus stearothermophilus* FS 1518 containing approximately 15 spores/ml. One hundred replicate plates and 100 spin tubes were prepared using dextrose tryptone agar incubated for 48 hr at 55°F. The colonies were counted and statistically analyzed. Plotting counts on a probability scale (Fig. 1) demonstrated that plate counts ranged from 1 to 21, with a mean of 8.98 and a standard deviation of 4.6. The spin tube counts ranged from 4 to 28, with a mean of 17.85 and a standard deviation of 4.9. Thus, spin tubes doubled the count over plates with the same medium and incubation conditions.

The second experiment determined the influence of geometric dilutions (i.e., 1, 2, 4, 8, etc.); the results are presented in Figure 2. Both flat sour thermophils and mesophilic Clostridia were studied. The counts of flat sours ranged from 3.5×10^6 to 12.5×10^6 per ml, while the counts of putrefactive anaerobes ranged from 200×10^6 to 400×10^6 per ml. Low projected counts resulted at low dilutions, where counts per tube approximated 200. At the high dilutions, counts of 1 to 5 projected high total counts. It is obvious that crowding of colonies decreased the projected count by mutual inhibition.

The implications of these tests are: (1) individual counts may introduce significant error—we attempt to minimize this error by employing the maximum practical number of replicates; (2) crowding can significantly decrease counting

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accuracy—we attempt to control the count per tube to a narrow range; (3) all techniques must be standardized; and (4) we wonder what the count truly was.

RELATIONSHIP BETWEEN I.S. AND F_o

I pointed out that both I.S. and F_o are expressed as the equivalent number of minutes at 250°F (121°C). How may these be related?

By definition, F_o is the equivalence in minutes at 250°F (121°C) at the slowest heating point in the container. Thus, F_o presents the minimum lethality in the container, while the remainder of the contents is subjected to a higher but undefined lethality. By contrast, I.S. relates to the lethality of the entire container contents. Thus, we must change our thinking from a single point to the entire volume of a container

Convection-heating and induced-convection-heating products present the simplest example because the product heating is frequently nearly isothermal. Thus, the process results in I.S. values that are practically identical to F_o values because the entire product volume is heated virtually at the same rate.

Conduction-heating products present a different picture, as illustrated in Figure 3, which presents the calculated isothermal heating lag (iso-j) zones in a 303 × 406 can. Since an iso-j zone is isothermal, all points on the curve have the same temperature at any given time. The process lethality of any iso-j zone may be determined, since temperatures in the zone may be calculated at any time.

The iso-j zones are planes of rotation, and the rotation around the can's vertical axis results in a series of concentric shells. These shells enclose definite product volumes and thus a predictable percentage of the total microbial population in the can. Obviously, the highest percentage of organisms is in the outer, fastest heating zones, with smaller and smaller percentages in slower heating zoles as we approach the geometric center. An approach to process lethality calculation involves calculation of number of survivors vs time in the various zones. A summation of survivors in all zones permits calculation of the I.S. value of the container.

In Figure 3, the center j value is designated as 1. To obtain the true j of the specific zone, each j zone must be multiplied by the center j.

About 1960, we were studying a small hydrostatic sterilizer employed to sterilize fruit and tomatoes. This was a deep-tank hydrostatic sterilizer with temperature gradients to 232°F (110°C). We were interested in calculating the lethality of this cooker and decided to evaluate this lethality in terms of 232°F (110°C) units. For comparison, a straight 240°F (115.5°C) process was also evaluated.

Figure 4 presents the calculated F_{212} and $I.S._{212}$ vs time of this 240°F (115.5°C) still process. It can be observed that the F_{212} is virtually zero for about 11 min, at which time the $I.S._{212}$ is about 1.1. After 11 min, the two curves are approximately parallel, although I.S. increases to about 3 units above the F value at the end of the process. A curve defining the most probable survival location is also included. This curve predicts the zone that has the highest probability of survival with time, starting with the outer zones with the highest initial population at the start of heating and moving with time to the center.

Two points are pertinent: First, it appears that our normal processes for canned foods result in the most probable survival location close to the slowest heating point; and second, it can be observed that a shortened process moves the location of most probable spoilage from the center to a zone of greater volume and thus a higher population level. It is conceivable, therefore, that a mild underprocess could quite drastically increase spoilage potential.

EXPERIMENTAL VERIFICATION

Figure 5 presents an experimental verification of I.S. values, showing some fundamental differences from the calculated curves in Figure 4. In this test, twelve 303 cans of commercial cream-style corn were uniformly inoculated

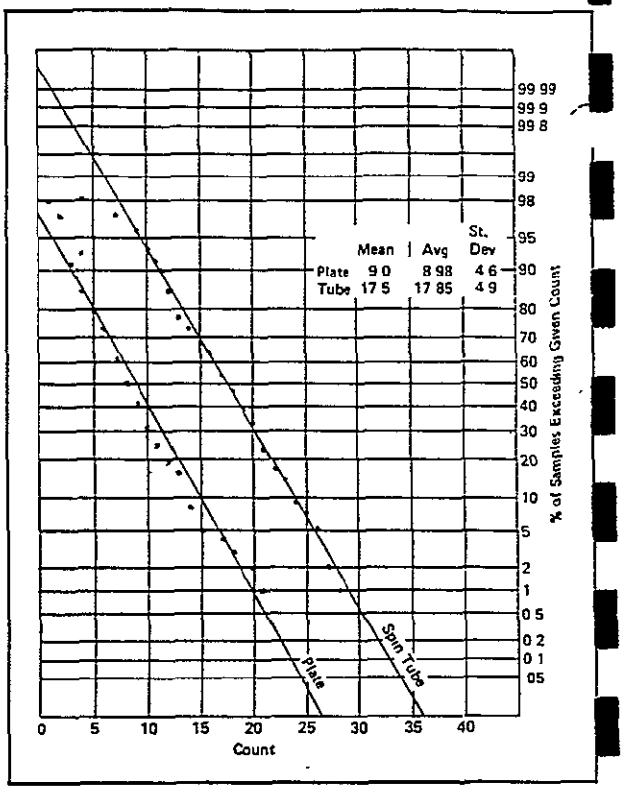

Fig. 1—**STATISTICAL ANALYSIS** *of plate counts vs spin tube counts (100 replicates each) for* Bacillus stearothermophilus *FS 1518 on dextrose tryptone agar*

with 2.7 × 10^6 spores of *B. stearothermophilus* FS 1518. The initial temperature was 70°F, and the individual cans were processed for 10-120 min at 240°F (115.5°C). Survivor counts were made using dextrose tryptone agar and corn agar spin tubes. The I.S. value of each process was calculated from survivor counts, and the D_{212} was determined to be 1.95.

Several points pertain:

1. Higher counts and therefore lower I.S. values were obtained on corn agar than on dextrose tryptone agar.
2. Results for both media indicate that I.S. is a straight-line function of time, whereas the calculated values in Figure 5 indicate an increasing I.S. rate with time.
3. The curve for F_o, based on accepted but not determined heat penetration parameters, shows negligible lethality for 65 min, and thus an initially large spread between I.S. and F_o that gradually decreases with time.
4. The curves appear to come together at 120 min, at which time the survivor counts were too low for accurate I.S. evaluation.

Table 1 presents an analysis of I.S. values for a commercial corn canning operation. Each reported I.S. value was derived from count reduction tests on 20-25 cans commercially canned. Heat penetration tests were not made; F_o values were calculated from accepted parameters. The table demonstrates that:

- Cream-style corn in 211 × 304 to 307 × 409 cans shows calculated F_o values of 5.5-5.8 and average I.S. values of 9.7-10.9.
- Cream-style corn in 603 × 700 cans shows a calculat F_o of 2.3 and an average I.S. value of 10.7.
- Whole-kernel corn in 303 and No. 10 cans shows F, and I.S. values of 9.3-10.4. This confirms that F_o and I.S. values

—Text continued on page 62

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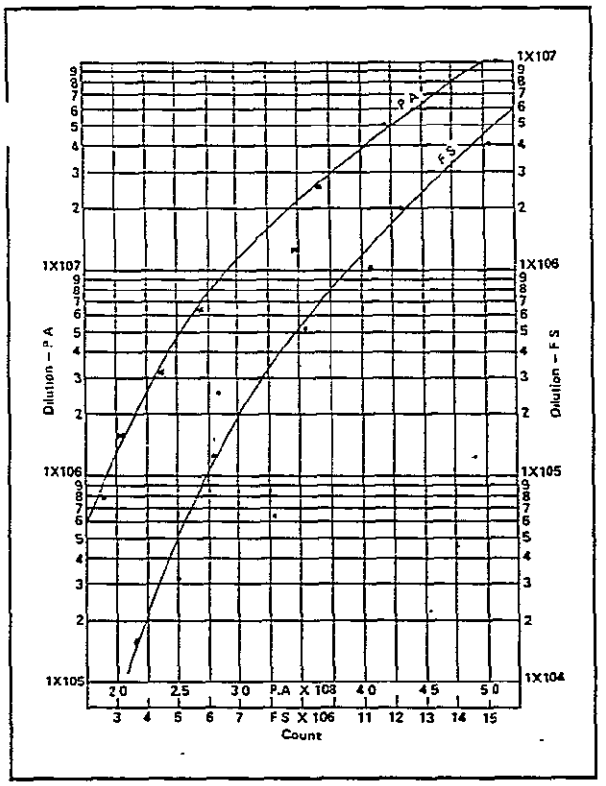

Fig. 2—**EFFECT OF DILUTION** *on counts of putrefactive anaerobes and flat sours*

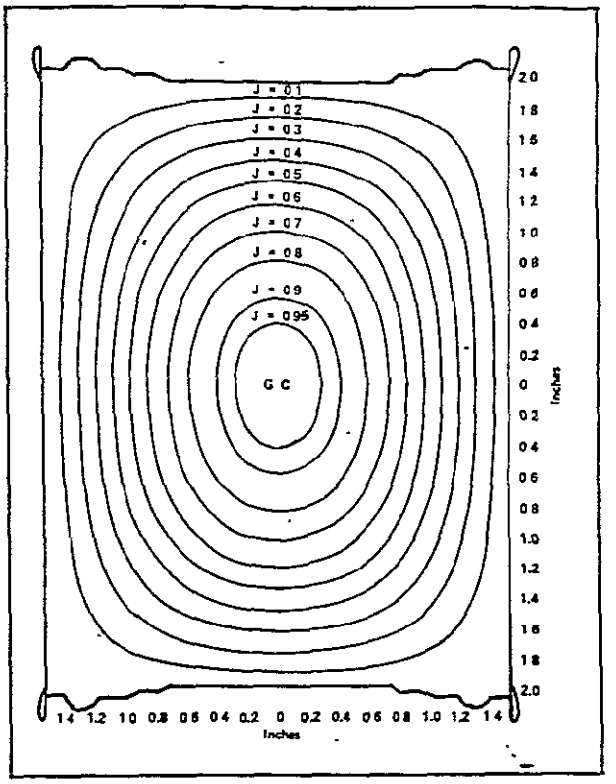

Fig 3—**CALCULATED ISO-J (ISOTHERMAL HEATING LAG) ZONES** *in a 303 × 406 can All points on a particular line have the same temperature at the same time. GC = geometric center*

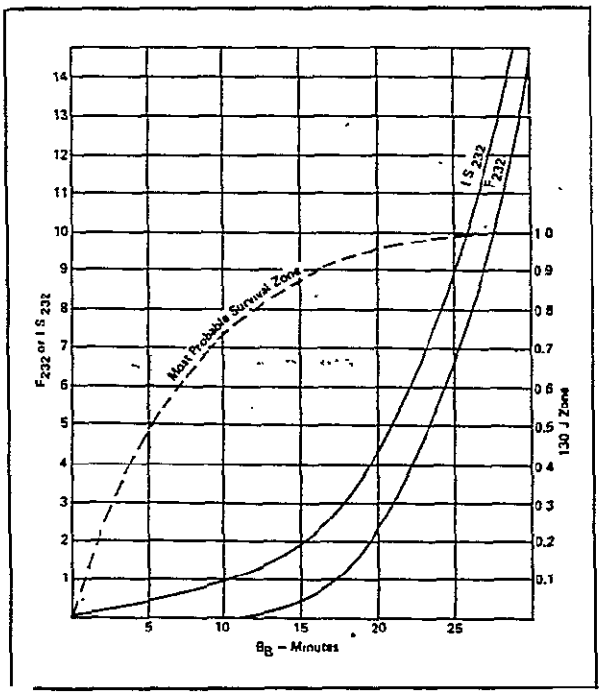

Fig. 4—**COMPARISON OF F AND I.S. VALUES** *at 232°F for a small hydrostatic sterilizer for fruits and tomatoes A curve predicting the zone that has the highest probability of survival with time is also shown. B_B = processing time at a given retort temperature*

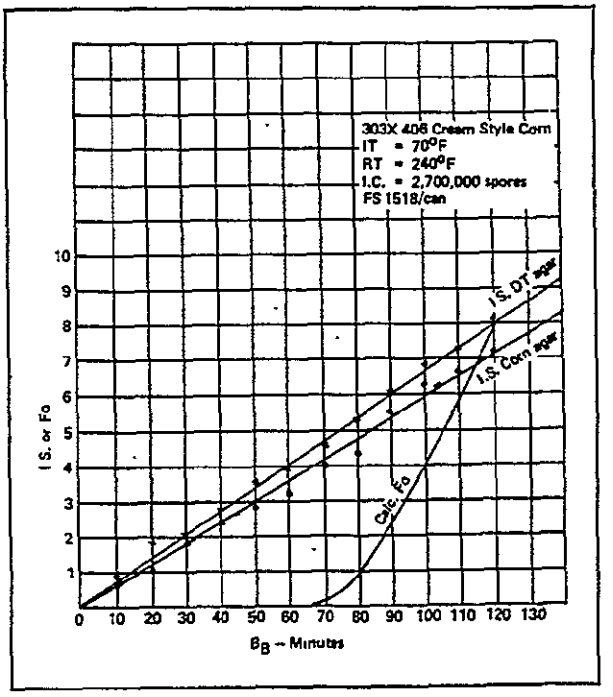

Fig. 5—**EVALUATION OF CORN-CANNING PROCESS LETHALITY** *(I S. and F_J) by count reduction, using corn agar and dextrose tryptone agar*

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are virtually identical for convection-heating products.

- It is obvious that I.S. values are constant for a particular product and more significant than F_o values.
- The relationship between F_o and I.S. is complicated and needs additional study. The complicating factors are: (1) the geometry of the container—large containers show greater spread; (2) the stage of the process—large spreads between F_o and I.S. values appear in early stages and decrease toward the end of the process; and (3) the temperature difference between retort temperature and initial product temperature—a large temperature difference increases the spread between I.S. and F_o.

Figure 6 presents a statistical analysis of I.S. values determined by count reduction of two continuous processes for an infant formula. The curves demonstrate that:

1. Process lethality is related to both time and cooker agitation rate. The higher cooker speed shortens the process, so the lethalities for the two processes are not significantly different.
2. An infant formula presents nearly optimum agitation potential, yet the results indicate that process lethality may vary by two I.S. units, with a mean of 6.5, depending on agitation rate.
3. Some products have viscosities that may result in borderline agitation. The count reduction system presents the optimum detector of poorly agitated cans, since low lethalities and high survivors result.
4. The statistical analysis of I.S. values permits dividing a pack by percentage into lethality groups. A summation of these values permits a probability-of-spoilage analysis that can be very valuable.

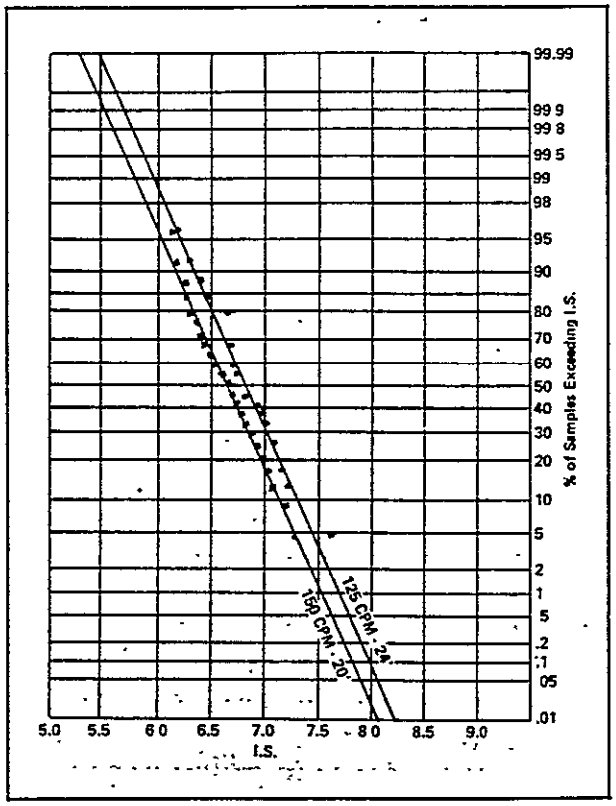

Fig. 6—**EVALUATION OF INFANT FORMULA PROCESS LETHALITY** *(I.S.) for two continuous processes using different agitation rates*

Table 1—**COMPARISON OF I.S. AND F_o VALUES** *for commercial corn-canning processes*

Product	Can size	Process time at 240°F (min)	Calculated F_o	I S value determined		
				Low	High	Averag
Cream-style corn	211 × 304	70	5 8	9 1	11 2	10 0
	303 × 406	85	5 7	9 0	10 9	9 7
	307 × 409	100	5 5	9 9	13 0	10 9
	603 × 700	180	2 3	8 9	12.6	10 7
Whole-kernel corn in brine	303 × 406	50	9 3	8 8	14 0	9 6
	603 × 700	90	10 4	9 3	10 9	10 1

CONCEPT WILL BE USED MORE

I believe the probability-of-spoilage concept will be increasingly employed to optimize processes in the future. To make this possible, we need accurate initial counts and estimates of spore resistance.

Great benefits will accrue from increased sanitation and the resultant decreased initial spore population. This has been clearly demonstrated in the evaporated milk industry.

Finally, we need increasingly accurate process evaluation systems. We have good basic tools, and I am sure that continued research will refine our methods and help to meet our goals of increased quality with increased process safety.

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NCA. 1968. "Laboratory Manual for Food Canners and Processors." Nat'l Canners Assn., Avi Pub Co, Westport, Conn.

Yawger, E S 1967. The count reduction system of process lethality evaluation. Apartes de Información Conservera (Spain), No. 58, Feb.

Based on a paper presented during the symposium, "Thermal Processing of Canned Foods," at the 37th Annual Meeting of the Institute of Food Technologists, Philadelphia, Pa., June 5-8, 1977.

Introductory Remarks (From page 55)...

SYMPOSIUM DOCUMENTS ADVANCES

In 1976, the National Canners Association—now the National Food Processors Association—published the 11th edition of its Bulletin 26-L, "Processes for Low-Acid Canned Foods in Metal Containers," which states, as does Appert's book, all the fundamental principles of thermal processing in still retorts and gives the specific initial temperature, time, and retort temperature for many food products and can sizes. This symposium will document and explore the great accumulation of knowledge and experience in thermal processing technology that has developed between the publication of Appert's works and the publication of the 11th edition of Bulletin 26-L. Specifically, the symposium will discuss the steps involved in establishing scheduled thermal processes. These steps are shown in Figure 1 on page 55.

Based on a paper presented during the symposium, "Thermal Processing of Canned Foods," at the 37th Annual Meeting of the Institute of Food Technologists, Philadelphia, Pa, June 5-8, 1977.

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A REVIEW OF z AND F VALUES USED TO ENSURE THE SAFETY OF LOW-ACID CANNED FOOD

IRVING J. PFLUG and THERON E. ODLAUG

□ THE OBJECTIVE of the canned food industry is to produce safe, high-quality, wholesome food at a price that the consumer is able and willing to pay. However, heat preservation requirements for safety can affect quality, so that in general, manufactured foods cannot be at the same time infinitely safe, high in quality, and low in cost. The more severe the sterilization process, the greater will be the degradation of food quality, both in consumer appeal (color, flavor, texture) and in nutritional factors.

Unfortunately, there is no thermal death point for microorganisms; microorganisms die in a geometric progression, and survival of the microorganism is probabilistic and based on many factors. The sterilization process for low-acid canned foods, therefore, is a compromise that will produce an adequately safe product on the one hand but have minimum quality changes on the other.

PROCESSING TO AVOID BOTULISM

The scientific basis for the design of the heat preservation process used by the low-acid canned food industry is the Bigelow (1921) model. The general equation for the model is:

$$\log F_T = (T_{ref} - T)/z + \log F_{T_{ref}}$$

To use this model, the z value, the reference temperature (T_{ref}), and the sterilizing value (F) must be known.

The chief public health hazard of canned foods is *Clostridium botulinum*, and it is a goal of the food industry to have zero botulism outbreaks. The z and F values have a basic role in process determination, but they are not the only factors involved in controlling the botulism hazard of low-acid canned foods.

There are three general ways in which a botulism hazard can occur: (1) failure in the design of the scheduled sterilization process; (2) failure to deliver the scheduled process; and (3) post-process contamination. In Figure 1, the three ways a botulism hazard can occur are shown, with each cause further broken down into the specific failures that lead to the botulism hazard. Note that the z and F values enter only in the design failure mode and then are only one of three possible causes for a failure in the design of the sterilization process.

The incidence of botulism outbreaks from canned foods from 1899 to 1976 is shown in Table 1. Included are both home-canned and commercially canned foods. Table 2 lists the six botulism outbreaks from commercially canned food that occurred between 1960 and 1976, and those cases in which toxin was found in cans but no outbreak occurred; the causes for the failures, as far as known, are also listed.

The cause of actual botulism outbreaks from commercially canned foods appears to have been either failure to deliver the scheduled process, or post-process contamination. Outbreaks of botulism from home-canned foods, which continue to occur at an unabated rate, appear to be due to the homemakers' failure to deliver recommended adequate processes.

Table 1 shows that the total number of botulism outbreaks from commercially canned foods in the United States from 1899 to 1919 was 17; from 1920 to 1939, 30; from 1940 to 1959, 3; and from 1960 to 1976, 5. The use of a sterilizing $F_{250°F}$ value of about 2.5-3.0 min with a z value of 18°F was generally adopted in the 1930s and appears to coincide with the drop from 30 botulism outbreaks during 1920-39 to three outbreaks during 1940-59. During the latter period, the great majority of low-acid canned food was processed at low temperatures and in a "still-cook" mode. This article will present evidence to support our belief that

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Failure mode	Specific failures	Reasons
Process design or specification	Wrong F	The product pH assumed is wrong Resistance of *C botulinum* is greater than assumed Number of *C botulinum* spores is greater than assumed
	Wrong f_h and/or j	f_h is too small j is too large
	Wrong process calculation	Wrong T_r or T_s used Wrong z value used Mathematical error
Process delivery	Product f_h and j different from design	Change in product recipe Heats by conduction and not convection
	Equipment error in process delivery	Error in thermometer or recording chart Inadequate steam supply Inaccurate timing devices No steam controller Faulty retort piping
	Human error in process delivery	Time of cook is shortened T_r or T_s is changed Wrong process is used Inadequate vent Wrong can size Product not retorted
Post-process contamination	Poor can seam	Dead head, droop, false seam, etc. Side-seam poor Manufactured and made poorly
	Cooling water	Inadequate chlorination Water source highly contaminated Temperature, pH, chemicals interfere with chlorination
	Can handling damage	Damaged when removed from retort Damaged during warehousing Damaged in travel or when stocked

Fig. 1—**THE THREE AREAS** *in which a botulism hazard can occur in low-acid foods and the specific failure modes for each area*

Table 1—**INCIDENCE OF BOTULISM OUTBREAKS** *from home-canned and commercially canned foods, 1899-1976*[a]

	No. of outbreaks							
	From home-canned foods[b]				From commercially canned foods[c]			
Food	1899-1919	1920-39	1940-59	1960-75	1899-1919	1920-39	1940-59	1960-75
Beans	16	72	25	14	3	—	—	—
Corn	6	31	20	3	1	—	—	—
Beets	1	16	25	7	1	1	—	—
Asparagus	4	8	12	—	—	—	—	—
Peppers	—	8	7	12	—	—	—	—
Spinach/chard	2	8	9	—	—	9	—	—
Olives	1	3	3	1	4	7	—	—
Mushrooms	—	3	5	6	—	—	1	—
Peas	—	7	5	—	—	—	—	—
Figs	—	5	8	2	—	—	—	—
Meat products	4	9	7	1	2	1	1	2
Fish	—	12	6	5	1	6	—	1
Other low-acid foods	3	15	23	9	4	6	1	2
Tomato products	—	7	6	4	1	—	—	—
Other acid foods	5	3	6	3	—	—	—	—
Total, all foods	42	207	165	67	17	30	3	5

[a]Data from Meyer and Eddie (1965), Center for Disease Control (1974) and HEW (1975, 1976)

[b]Total incidence of botulism outbreaks from home-processed food (canned food plus other foods such as chicken pot pies) was 519 for 1899-1975

[c]Total incidence of botulism outbreaks from commercially-processed food (canned food plus other foods such as smoked fish) was 65 for 1899-1975

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Table 2—**INCIDENCE OF CONTAMINATION** *of commercially canned foods with botulinum toxin, 1960-76*

No. of outbreaks or isolations	Year	No of cases of botulism	No of deaths	Toxin type	Vehicle	Type of processing equipment	Probable cause of failure
Outbreaks[a,b]							
1	1963	3	2	E	Tuna fish	Still retort	Post process contaminatio
2	1963	2	0	A	Liver paste	Still retort	Delivery
3	1971	2	1	A	Vichyssoise soup	Still retort	Delivery
4	1973	7	0	B	Peppers	Water bath	Delivery
5	1973	1	0	B	Marinated mushrooms	Water bath	Delivery
6	1974	2	1	A	Beef stew	Still retort	Delivery
Isolation of toxin, no outbreak[b]							
1	1970	0	0	B	Mushrooms	Still retort	Delivery
2	1971	0	0	A B	Chicken vegetable soup	Continuous agitating retort	Delivery or design error in heat penetration
3	1973[d]	0	0	A,B	Mushrooms	Still retort	Delivery or design error in heat penetration[e] Delivery
4	1974	0	0	C	Tuna fish	Still retort	Post-process contaminatio

[a]Meyer and Eddie (1965), Center for Disease Control (1974), and HEW (1975, 1976)
[b]Lynt et al (1975)
[c]Outbreak involving a Canadian citizen in Canada
[d]Toxin-containing cans from seven U S producers and two foreign plants
[e]Of the nine incidences three were caused by errors in delivery, and six were caused by errors in delivery or heat penetration design

a process using an $F_{250°F}$ value of 3.0 min with a z value of 18°F is a realistic minimum botulinum cook for low-acid foods that will produce canned foods that are safe from a public health standpoint.

DESIGNING THE PROCESS

As indicated in Figure 2, the sterilization process engineer must take the microbiological inputs (MI), the heat penetration data (HP), and the processing conditions (PC), and establish the sterilization process for the product. Designing or establishing the sterilization process would be direct and simple if the values of MI, HP, and PC were firmly known. In reality, they are known only to a greater or lesser degree depending upon the processing situation. The processing conditions are specified, and the microbiological input can usually be established from historical considerations; however, the heat penetration input must be established experimentally.

The overall design of the sterilization process for low-acid food in containers can be considered in two parts: (1) the selection of the sterilization level or F value that is to be used—this will be based on the numbers and resistance levels of the microorganisms expected to be present in the product to be sterilized—and (2) factors that determine or influence the quantity of heat that flows into the container and how long this heat remains in the product during the sterilization cycle.

1. Determining the F Value. An important and vital part of the F value determination is the design level of microbial survival. The objective of the heat sterilization process is to reduce the number of surviving microorganisms

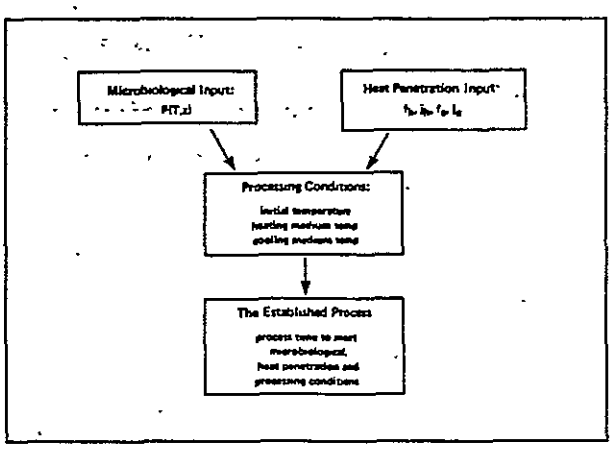

Fig 2—**DATA FLOW** *in sterilization process design*

Table 3—**RATIO** *of new F value to old F value (F_o) as a function of temperature change with z = 18°F*

T_r-T (°F)	F/F_o
0 1	1 013
0 5	1 066
1 0	1.136
1 5	1 212
2 0	1 292

to a low number. A practical way of expressing this is to give the relative number of non-sterile cans. To say that a product is sterile, fewer than one can in one million cans should contain viable non-pathogenic organisms after processing. This is a probability of 10^{-6}.

Stumbo (1973) and Stumbo et al. (1950) have suggested a level of 10^{-4} for non-pathogenic organisms, i.e., commercial sterility. Perhaps either 10^{-5} or 10^{-6} is an acceptable number. However, if we are talking about producing a sterile product, it would seem that 10^{-6} might be a more realistic and defensible value.

For *C. botulinum*, a level of 10^{-9} seems reasonable. This is, in general, compatible with the 12D terminology, since if the initial number of spores in the product is 10^3 per unit and the probability of a non-sterile unit is 10^{-9}, the spore log reduction would be 12, i.e., a 12D process would be required.

The suggested value of 10^{-9} is considerably lower than the value of 10^{-12} suggested by Stumbo et al. (1975). Using a probability of 10^{-12} is not compatible with the 12D terminology and will in general mean a 13- to 15D process depending on the initial *C. botulinum* spore load. The history of the U.S. canned food industry does not appear to warrant increasing the basic public health processing standard.

Sterility cannot be tested *into* a lot of product. Once the product is in the warehouse, sterility of the product can be verified only by testing every container. Since the sterility-testing false-positive rate is 0.5-1.0 per thousand, this is the upper limit as to how far one can verify sterility by testing the product in the container.

2. Adding Safety Factors. There is no specific place in the process calculation procedure to add a safety factor. That being the case, where and how does one compensate for the unknown? The food canning industry must deal with a biological product which contains microorganisms Product and processing conditions vary widely. Allowanc must be made for unknown conditions; there must be a wa to compensate to realistic extremes.

There are only two places to include a safety factor in the design of a heat sterilization process—the F value or the

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Table 4—z VALUES *for* Clostridium botulinum *in phosphate buffer and in food substrates, calculated from F value data*

Experimenter	Test substrate	Spore type	Initial No. of spores[a]	Heating system[b]	Method of calculating F-value[c]	z-value calculated by experimenter (°F)	Recalculated data[e] z-value (°F)	Recalculated data[e] 95% confidence interval
...y and Meyer (1922)	M/15 PO_4 buffer pH 7 0	19A 23A, 97A	6 × 10^8	a	e	17 6[d]	18 63	17 19-20 32
Townsend et al (1938)	M/15 PO_4 buffer pH 7 0	62A	1 × 10^7	b	e	13 6	—	—
			2 × 10^7	b	e	18 0	—	—
			7 5 × 10^7	b	e	27 0	—	—
			7 5 × 10^7	b	e	19 0	—	—
			7 5 × 10^7	b	e	16 5	—	—
	Peas	62A	1 × 10^7	b	e	13 6	—	—
			2 × 10^7	b	e	13 5	—	—
	Spinach	62A	1 × 10^7	b	e	15 1	—	—
			2 × 10^7	b	e	18 0	—	—
	Asparagus	62A	1 × 10^7	b	e	14 3	—	—
			2 × 10^7	b	e	15 8	—	—
	M/15 PO_4 buffer, pH 7 0	213B	2 × 10^8	b	e	16 3	—	—
			2 5 × 10^7	b	e	20 4	—	—
			2 5 × 10^7	b	e	17 5	—	—
			2 5 × 10^7	b	e	13 8	—	—
	Peas	213B	1 2 × 10^7	b	e	13 4	—	—
			2 × 10^8	b	e	18 2	—	—
	Asparagus	213B	1 2 × 10^7	b	e	14 2	—	—
			2 × 10^8	b	e	17.5	—	—
	Spinach	213B	2 × 10^8	b	e	15 5	—	—
Reed et al (1951)	M/15 PO_4 buffer, pH 7 0	213B		c	d	17 9	18 29	—
				c	f	17 9	—	—
				c	g	17 9	—	—
	Green beans	213B		c	d	21 7	22.43	17 97-29 82
				c	f	21 7	—	—
				c	h	21.7	—	—
	Peas, frozen	213B		c	f	17 2	—	—
				c	h	13 8	—	—
	M/15 PO_4 buffer, pH 7 0	62A		c	d	20 9	21 3	16 1-31 5
				c	f	20.9	—	—
				c	g	20 9	—	—
	M/15 PO_4 buffer plus 0 2% $NaNO_3$	62A		c	d	29 3	29 4	16 05-174 36
				c	g	29 3	—	—
	Green beans	62A		c	d	20 3	20 45	14 75-33 24
				c	f	15 5	—	—
				c	h	14 2	—	—
	Corn, frozen	62A		c	d	17 7	17.93	15 4-21.45
				c	f	17.7	—	—
				c	h	14 2	—	—
	Peas, frozen	62A		c	f	15 5	—	—
				c	h	15 5	—	—
	Pea puree	62A		c	f	14 0	—	—
				c	h	19 8	—	—
	Spinach	62A		c	d	19 4	19 73	14 49-30 90
				c	f	19 4	—	—
				c	h	14 4	—	—

[a]Initial number varied from about 1 × 10^4 to 5 5 × 10^6/ml for each test temperature in Reed et al s (1951) tests
[b]Heating system
a = Sealed glass tubes in an oil bath
b = Sealed glass tubes heated in a miniature retort
c = Thermal death time tank (TDTT)
[c]Determining the F-value
d = Time to effect a 5-log reduction in the initial number of spores
e = Thermal death time method where the tube contents were subcultured in a beef heart medium
f = Thermal death time method where a sample was removed from the TDTT and subcultured in pork agar shake tubes
g = Thermal death time method where a sample was removed from the TDTT and subcultured in pork broth tubes
h = Thermal death time method where a sample was removed from the TDTT and the food directly incubated
[d]Calculated by Townsend et al (1938)
[e]Where adequate data were available, z values were recalculated using a linear regression procedure

heating condition represented by the temperature response parameter f_h and the lag factor j. We believe that in the past, a factor of safety has been incorporated in the F_o value. When carrying out heat penetration tests, the sterilization process engineer may add safety factors by using the slowest-heating can in the design and may overfill or make other manipulations to compensate for unknown conditions. It has been stated as a rule of thumb that the F_o value for a continuous-processed product should be about double the F_o value used in the design of a still cook. It appears that Perkins (1969) incorporated a similar safety factor in recommendations for the sterilization of hospital supplies, based on his wide experience with sterilizers and sterilization conditions in hospitals. Lenz and Lund (1977) and Lund (1978) suggest that safety factors for canned food he evaluated using statistical methods. However, they indicate that at this time there is not enough background data ailable to implement those methods.

EFFECT OF TEMPERATURE MEASUREMENT

The Food and Drug Administration (FDA, 1973) has specified that "each retort shall be equipped with at least one mercury-in-glass thermometer which will have divisions which are easily readable to 1°F and whose temperature range shall not exceed 17°F per inch of graduated scale. Thermometers shall be tested for accuracy against a known accurate standard thermometer upon installation and at least once a year thereafter or more frequently if necessary to insure their accuracy."

Taking into account not only the basic accuracy of the thermometer but the combination of thermometer reading and recording errors, temperature variation in equipment, temperature cycling of controls, and the effect on the control point of capacity changes, it is probable that the temperature in a food canning operation will only be accurate to perhaps ±1°F. What level of F value delivery is associated with different levels of temperature accuracy? The ratio F/F_1 as a function of $T_1 - T$ can be calculated using the equation:

$$\frac{F}{F_1} = 10^{\frac{T_1 - T}{z}}$$

—*Continued on next page*

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Values of F/F_r have been tabulated in Table 3 for a range of $T_r - T$ values and a z of 18°F.

If the accuracy of field temperature measurement is considered to be ±1°F, then the potential error in the F_o value due to temperature variation is about ±12%. Reporting or indicating an F value to the nearest 0.01 or even 0.1 min is unrealistic. For low-acid canned foods, we suggest that F values of 2 to 6 be listed to the 0.5 min, 6 to 10 by 1 min, 10 to 20 by 2 min, and over 20 by 5 min.

THE z VALUE

The z value is a basic parameter in the heat process evaluation scheme that originated with the work of Bigelow et al. (1920) and Bigelow (1921).

It seems to have first appeared in Ball (1923), who used it to define the thermal death time curve for use in the development of the mathematical method of process evaluation. Ball stated that "z represents the slope of the curve, its value being the number of degrees passed over by the curve in traversing one logarithmic cycle."

The system of process calculation in use today was developed over a period of time to satisfy a need. Now, some 50 years later, questions are being asked regarding the design of sterilization processes that are to be safe from a public health standpoint—what should the basic design sterilization value be for protecting against *C. botulinum*, and what z value should be used?

The z value problem is not simple, and it is not an easily isolated problem. A discussion of the z value seems in many ways similar to the description of the elephant by the six blind men of Indostan. What one concludes about the z value depends upon how one views the z value. We concluded early on that perhaps there have been too many simple looks at z, F, and D values and that it was time to try to describe the z value rather completely. The results of our studies have led to the singular conclusion that use of a single z value of 18°F—which has been in general use for 30-50 years—is still the best recommendation for calculating low-acid canned food sterilization processes that are to be safe from a public health standpoint. It is possible that this choice was fortuitous; on the other hand, it may have been the purposeful result of research by the canning industry pioneers of the 1920s and '30s.

The role of the z value in calculating heat processes is relatively simple as long as one uses a single z value. However, when the process calculation involves two z values, the situation becomes very complex. We suggest that when two z values are involved—e.g., in comparing the effects of using different z-values, or in converting data from physical, chemical, or biological monitoring systems operating at one z value to another using a different z value—the problem be divided into two parts: (P1) evaluating the effect of the z value on the sterilizing value U of the product in the container calculated at heating-medium temperature, and (P2) moving from one point to another point on the z value curve. It is important to keep these two areas separate because they have differing effects on the process calculation result. For example, when sterilizing processes are specified on the basis of a reference temperature such as 250°F, a z value larger than the true value gives safety at temperatures above the reference temperature, while a z value smaller than the true value gives safety at lower temperatures. This relationship is a P2 effect.

DETERMINING THE z VALUE

We have attempted to collect the published data on the heat resistance of *C. botulinum* spores. Table 4 shows the results of studies in which the thermal death time or other endpoint method was used to determine the F and z values. Table 5 lists the results of studies in which the z value was calculated from D value data. The 95% confidence intervals for the z values are included in these tables to indicate that there is some variability associated with the z value.

We have not made any attempt to summarize these results or to apply weighting factors, since some data appear to be more reliable than others. In some of the studies, the experimental methods were described rather thoroughly and the resulting data are amenable to further evaluation. In other studies, only sketchy information was provided regarding the experimental methods and the treatment of data.

Examination of the experimentally determined D values and F values for *C. botulinum* spores suggests that these spores may behave in a somewhat unique manner regarding destruction values at 212°F compared to other temperatures. There appears to be a relationship where large destruction values at 250°F are associated with large z values and small destruction values at 250°F with small z values. To verify this relationship, the D and F values for *C. botulinum* shown in Tables 4 and 5 were examined for relationships with z values.

A graph of $F_{250°F}$ values vs z values for data reported by Townsend et al. (1938) is shown in Figure 3. These data show a strong trend for the z value to increase with increasing $F_{250°F}$ values. The D value data in Table 5 has been treated using a linear regression analysis to yield $D_{250°F}$

Table 5—D and z VALUES *for* C. botulinum *in*

Experimenter	Test substrate	Spore type	Heating system[a]	Method of calculating D-value[b]
Alderton et al (1974)	Asparagus puree	62A	?	f
	M/15 PO_4, pH 7.1	62A	?	f
Xezones and Hutchings (1965)	Spaghetti sauce, etc., pH 7.0	62A	a	h
	Macaroni creole, pH 7.0	62A	a	h
	Spanish rice pH 7.0	62A	a	h
Schmidt (1964)	M/15 PO_4, pH 7.0	62A	?	?
Stumbo et al (1950)	M/15 PO_4, pH 7.0	62A	a	h
	Distilled water	62A	a	h
	Pea puree	62A	a	h
	Strained squash	62A	a	h
Tsuji and Perkins (1962)	0.03M PO_4, pH 7.0	62A	a	h
Perkins et al (1975)	M/15 PO_4, pH 7.0	213B	b	h
	Meat and vegetables, pH 6.1	213B	c	h
	Poultry sample, pH 6.1	213B	c	h
	Seafood sample, pH 5.9	213B	c	h
Odlaug and Pflug (1978a)	M/15 PO_4, pH 7.0	B-SKDF	b	j
		B-SKAF	b	j
		B-SKBF	b	j
	Mushroom puree, pH 6.3-6.5	B-SKDF	b	j
		B-SKAF	b	j
		B-SKBF	b	j
Knock and Lambrechts (1956)	PO_4 buffer, pH 6.8	B	d	f
	Rock lobster, pH 6.6	B	d	f
Kaplan et al. (1954)	M/15 PO_4, pH 7.0	213B	b	i
			b	g
	Beans, snap	213B	c	i
			c	g
	Beets	213B	c	i
			c	g
	Carrots	213B	c	i
			c	g
	Corn	213B	c	i
			c	g
	Spinach	213B	c	i
			c	g
Grecz and Tang (1970)	M/15 PO_4, pH 7.0	33A	e	f
		36A	e	f
		36A	e	f
		41B	e	f
		51B	e	f

[a]Heating system
- a = Metal cups heated in a thermoresistometer
- b = Screw-cap tubes heated in a miniature retort or a boiling water bath
- c = TDT cans heated in a miniature retort or a boiling water bath
- d = Sealed-glass tubes heated in an oil bath
- e = "Hot-pack" water bath

[b]Methods of calculating D value
- f = Calculated from the slope of the semi-log survivor curve graph
- g = Fraction-negative method of Stumbo (1948a)
- h = Fraction-negative method of Stumbo et al. (1950)
- i = Fraction-negative method of Schmidt (1954)
- j = Fraction-negative method using modified Spearman-Karber (Pflug and Schmidt 1968)

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values and z values. In Figure 4 are shown the z values as a function of $D_{250°F}$ values. The data show a strong trend for the larger $D_{250°F}$ values to have z values of 18 to 21°F and for small $D_{250°F}$ values to have z values of 13 to 15°F.

The F value data of Townsend et al. (1938) in Figure 3, the D value data of Kaplan et al. (1954) and Perkins et al. (1975) in Figure 4, and the line below all data points in Figure 4 were analyzed using linear regression, and the slope and intercept of the regression line of z vs F or D were determined. The z values calculated from two points on the regression line are presented in Table 6, which shows larger z values for $F_{250°F}$ = 3 min or $D_{250°F}$ = 0.25 min than when F or D is small.

These observations have several implications in the overall area of process design and evaluation:

1. A certain amount of order is brought to the problem of varying z values for *C. botulinum*. In heat-resistance testing, the z value as well as the individual D_T values vary among replicated tests. However, at or above 240°F, tests that produce larger D values also have larger z values.

2. In certain instances, *C. botulinum* spores appear to have a reduced resistance at higher temperatures; this results in lower z values.

If low $D_{250°F}$ values and accompanying small z values occur reproducibly for products or processing conditions, this indicates that under these conditions there will be an additional safety factor at higher temperatures for an overall design specification of $F_{250°F}$ of 3.0 min and a z value of 18°F.

PUBLIC HEALTH REQUIREMENTS

Figure 5 shows public health sterilization recommendations that have been used in the production of the thermal death time curve for *C. botulinum* spores by Townsend et al. (1938), who corrected the original data of Esty and Meyer (1922) for heating and cooling lags. Townsend et al. reported an $F_{250°F}$ value of 2.45 min with a z value of 17.6°F. The uncorrected maximum resistance values of Esty and Meyer, on the basis of observations of a number of spore suspensions at 212, 221, 230, and 239°F, are also shown in Figure 5, along with the sterilizing value line with an $F_{250°F}$

phosphate buffer and in food substrates

D value (min)													z value calculated by experimenter (°F)	Recalculated data[a]	
212	220	221	223	225	225 5	230	235	239	240	245	250	260		z value (°F)	95% confidence interval
—	—	—	—	—	—	—	1 9	—	—	0 2	—	—	[b]	10 23	—
—	—	—	—	—	—	—	3.5	—	—	0 8	—	—	—	15 60	—
—	—	—	—	—	—	—	1.9, 3 4	—	—	—	—	—	—	—	—
—	—	—	—	—	—	2 43	1 13	—	0 515	0 233	—	—	15 0	14 72	14 37-15 09
—	—	—	—	—	—	2.48	1 20	—	0 568	0 262	—	—	16 0	15 37	14 73-16 07
—	—	—	—	—	—	2 37	1 21	—	0 550	0 249	—	—	15 5	15 25	13 65-17.28
—	8 8	—	—	—	—	2 8	1 5	—	0 74	0 38	—	—	18 0	18 05	16 32-20 19
—	10 0	—	—	—	—	2 01	—	—	0 530	—	0 133	0.0325	16 3	18 25	15 38-17 22
—	5 49	—	—	—	—	1 01	—	—	0 228	—	0 051	0 0131	15 3	15 29	14 27-16 47
—	10 2	—	—	—	—	1 98	—	—	0 435	—	0 089	0 0203	15 0	14 82	14 38-15 26
	6 92	—	—	—	—	1.79	—	—	0 393	—	0 060	0 0178	14 7	15 03	13 49-16 97
	—	—	—	—	—	—	—	—	0 77	—	—	—	[b]	—	—
21 9	—	—	5 51	—	—	—	1 17	—	—	—	—	—	18 2	18 07	16 35-20 21
41 2	—	—	9 26	—	—	—	1 21	—	—	—	—	—	14 7	14 99	8 29-77 67
42 84	—	—	6 25	—	—	—	0 76	—	—	—	—	—	13 3	13 13	12 97-13 30
38 32	—	—	6 33	—	—	—	0 69	—	—	—	—	—	13 3	13 17	9 15-23 5
—	—	—	—	—	—	1 28, 1.23	—	—	0 24, 0 22	—	—	—	—	—	—
—	—	—	—	—	—	1 13, 1 08	—	—	0 22, 0 22	—	—	—	—	—	—
—	—	—	—	—	—	1 10, 1 02	—	—	0.19, 0.22	—	—	—	—	—	—
—	—	—	—	—	—	0 99	—	—	0.18, 0 11	—	—	—	—	—	—
—	—	—	—	—	—	1 13, 1.08	—	—	0 15 0 18	—	—	—	—	—	—
—	—	—	—	—	—	0 87	—	—	0 18, 0 19	—	—	—	—	—	—
—	11 0	—	—	—	—	2 93	—	—	1 07	—	—	—	19 5	19 76	9 91-∞
—	13 04, 12 32[a]	—	—	—	—	2.98, 3 45[a]	—	—	1 14[a]	—	—	—	—	18.73[a]	15 67-23 28
—	11 6	—	—	—	—	3 27	—	—	1 03	—	—	—	19.5	19 02	14 23-26 65
—	11 37 12 01[a]	—	—	—	—	3 60[a]	—	—	1 00, 1.05[a]	—	—	—	—	18 92[a]	18 06-19 86
23 49	—	4 62	—	—	1.79	1 60	—	0 38	—	—	—	—	15 0	15 43	11.95-21 76
20 70	—	4 36	—	—	1 62	1 39	—	0 30	—	—	—	—	15 0	14 97	11.98-19 94
—	4 07	—	—	1 96	—	0 88	0 51	—	0 28	—	—	—	17.5	17.18	14 90-20 29
—	3 58	—	—	1.82	—	1 01	0 53	—	—	—	—	—	17 5	18 56	14 37-26 19
—	5 65	—	—	2.57	—	1 17	1.00	—	0 57	—	—	—	20 0	20 81	14 95-34 25
—	5 01	—	—	2 53	—	1 09	0 93	—	0 48	—	—	—	19 5	20 23	15 14-30 46
—	3 96	—	—	2 46	—	0 94	0 40	—	0 28	—	—	—	17 0	15 85	12 83-20 73
—	4 24	—	—	2 46	—	—	0 49	—	0.30	—	—	—	17 0	16[a]66	13 25-22 44
—	8 46	—	—	3 51	—	1.03	0 75	—	0 73	—	—	—	16 0	17 87	10 6-56 90
—	8 30	—	—	—	—	1.53	—	—	0 68	—	—	—	18 0	18 41	5.14-∞
—	6 68	—	—	2 91	—	1 75	0 83	—	0 55	—	—	—	18 5	18 43	15 41-22 90
—	—	—	—	2 91	—	1 48	—	—	—	—	—	—	—	17 03	—
10 0	—	—	—	—	—	—	—	—	—	—	—	—	[b]	—	—
3 0	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
20 0	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
27 0	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2 5	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—

[a]z values were recalculated by a linear regression analysis of the experimenter's D values
[b]Recalculated from the raw data of Knock and Lambrechts (1956)
[c]Indicates experimenters did not determine a z value from their data

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value of 3.0 min and a z value of 18°F.

Stumbo et al. (1975) suggested that low-acid canned food processes be designed on the basis of the following assumptions:

1. Maximum 250°F resistance of *C botulinum* spores would be based on $D_{250°F}$ = 0 20 min.
2. All low-acid foods, prior to heat processing, would be assumed to have a population of most-resistant *C. botulinum* spores of one spore per gram (cubic centimeter) of product.
3. The volume of any given can size will be that computed from inside container dimensions, with no correction being made for headspace.
4. The value of z, in characterizing the relative resistance of the most-resistant *C. botulinum* spores, should be taken as 14°F.
5. The probability of a *C. botulinum* spore surviving in any one heat-processed container of low-acid food should be no greater than 10^{-12}.

In addition, they recommended that processes be calculated using integrated sterilizing value procedures and certain other specifications which will not be discussed in this article.

We will now compare F values calculated using Stumbo et al.'s recommendations with some minor modifications, to the historical data presented in Figure 5.

Assumption 2 of Stumbo et al. specifies that there will be one maximum-heat-resistant spore of *C. botulinum* per gram of food product. In this evaluation, we will consider as examples two sizes of container with contents of 10 and 5,000 g which will contain 10 and 5,000 spores of *C. botulinum,* respectively. Sterilization values at 250°F ($S_{250°F}$) can be calculated using the equation:

$$S = D(\log N_o - \log N_s)$$

where D = time to reduce spore population by 90%; N_o = initial number of spores; and N_s = number of surviving spores.

Combining Assumption 1 that the $D_{250°F}$ value is 0.20 min and Assumption 5 that the final probability should be no greater than 10^{-12}, the above equation reduces to:

$$S = 0\ 2(\log N_o + 12)$$

When the container volume is 10 g, N_o = 10 and $S_{250°F}$ = 2.[illegible] min; when the container volume is 5,000 g, N_o = 5,000 and $S_{250°F}$ = 3.14 min.

Assumption 4 requires that a z value of 14°F be used. The cross-hatched area in Figure 5 is the sterilization value area bounded by $S_{250°F}$ values of 2 6 and 3.4 min with a z value of 14°F.

The use of a z value of 14°F increases the processing requirement at low temperatures, specifically all temperatures below 250°F, and decreases the sterilization requirement above 250°F. We believe that if processing hazards exist, they are greater at higher temperatures than at lower temperatures, which suggests that larger rather than smaller z values should be used.

If we establish F value lines for the rather complex assumptions of Stumbo et al. (1975) using a z value of 18°F they fall between $F_{250°F}$ values of 2.6 and 3.4 min. The area is, for all practical purposes, identical to the area of the curves in Figure 5 with an F_o = 2.45 min and F_o = 3.0 min.

Perkins et al. (1975) stated that "a more realistic estimate of the hazard potential in cans of product underprocessed

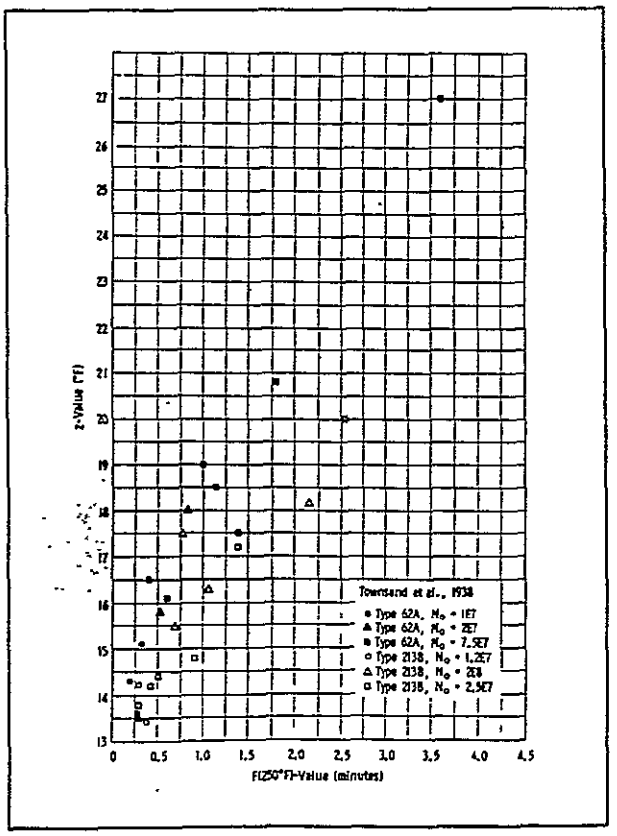

Fig 3—A PLOT OF $F_{250°F}$ VALUES *and z values from the data of Townsend et al (1938)*

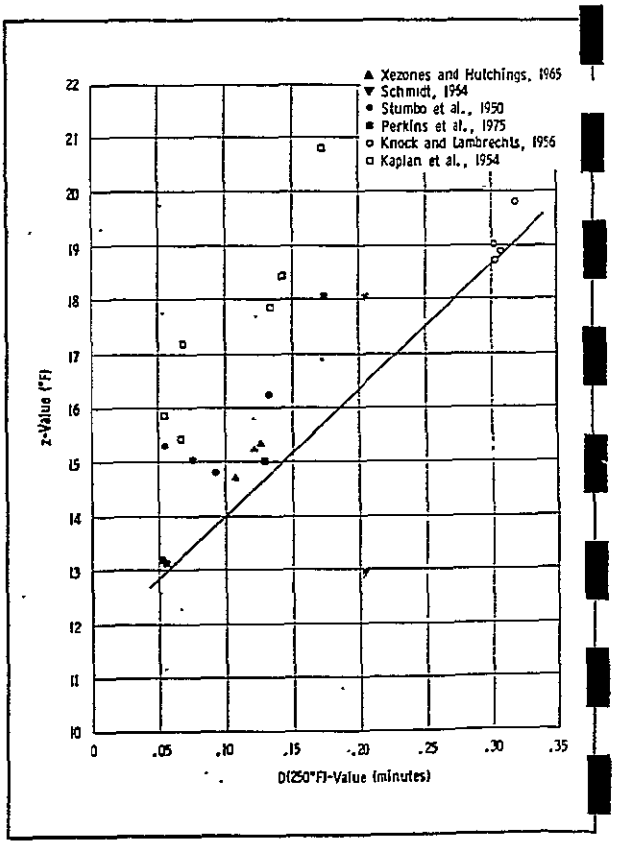

Fig 4—A PLOT OF $D_{250°F}$ VALUES *and z values from publis experimental data*

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by a few degrees or minutes will also be possible if the assumption is made that any contaminating anaerobes may have a z-value of 14°F." Their experimental data support the use of a z value of 14°F in evaluating underprocessed l or food processed at low temperatures. Their . ılts—$D_{250°F}$ values of 0.11 min for formulated meat and vegetables and 0.05 min for formulated poultry and formulated seafood—have been converted into $F_{250°F}$ values using the Stumbo et al. (1975) assumptions of a final sterilization probability level of 10^{-12} and one *C. botulinum* spore per gram. The resulting design $F_{250°F}$ values for 10 and 5,000 g of product were 1.43 and 1.73 min, respectively, for the formulated meat and vegetables and 0.65 and 0.78 min, respectively, for the formulated poultry and formulated seafood. Sterilization value areas were constructed using Perkins et al.'s (1975) z values of 14.7°F for formulated meat and vegetables and 13.3°F for formulated poultry and formulated seafood. These areas are shown in Figure 6 with the data from Figure 5. The transformation of Perkins et al.'s D value data into F values with Stumbo et al.'s (1975) assumptions suggests that sterilization values below 230°F need to be greater than the sterilization values represented by the line with an $F_{250°F}$ of 3.0 and a z of 18°F.

To take care of any possible risk at lower temperatures and at the same time retain safety at higher temperatures, a more practical approach would probably be to increase the $F_{250°F}$ value to 5.0 min and use a z value of 18°F; this sterilization line is also shown in Figure 6. However, there is no epidemiological evidence to show that an $F_{250°F}$ value of 3 min using a z value of 18°F has failed.

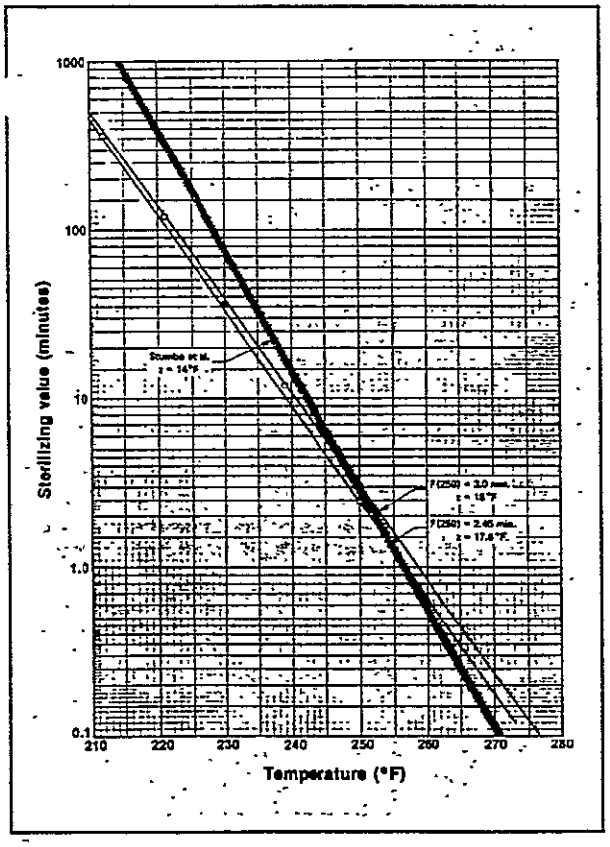
We do not think it wise to try to operate in the thermal processing area with two z values. Considering the field accuracy of sterilization value discussed above, we believe that possible F_o values for a public health sterilization process for low-acid food could be 2.5, 3.0, 4.0, or 5.0 min. We believe that the historical evidence indicates that an F_o of 3.0 min is adequate.

Increasing the design F value will, of course, produce a smaller probability of survival of *C. botulinum* for all those containers that receive the recommended process. We believe that the probability that a canned food fails to receive the design process is roughly 10^{-6} to 10^{-8} and that the probability of post-processing contamination with *C. botulinum* is between 10^{-7} and 10^{-10} (Odlaug and Pflug, 1978 b). It seems to us that a probability of survival of 10^{-9} calculated on the basis of the actual loading of *C. botulinum* spores with maximum heat resistance is in itself more than adequate when compared with other potential points of failure in the processing system.

In this article, we have been considering sterilizing values

Table 6—**z VALUES** *calculated from the linear regression line fitted to the z vs D or F data of specific investigators and for the line below all data in Figure 4*

Source of data	z value (°F)	
	At Y intercept	When $D_{250°F}$ = 0.25 min or $F_{250°F}$ = 3.0 min
Line below all data points in Figure 4	11.8	17.4°F
Perkins et al. (1975)	11.0	20.4°F
Kaplan et al. (1954)	13.7	22.9°F
Townsend et al. (1938)	13.5	23.8°F



5—**STERILIZATION VALUE CURVES** *for producing low-acid canned foods that are safe from a public health standpoint, data from Esty and Meyer (1922), Townsend et al. (1938), and Stumbo et al. (1975)*

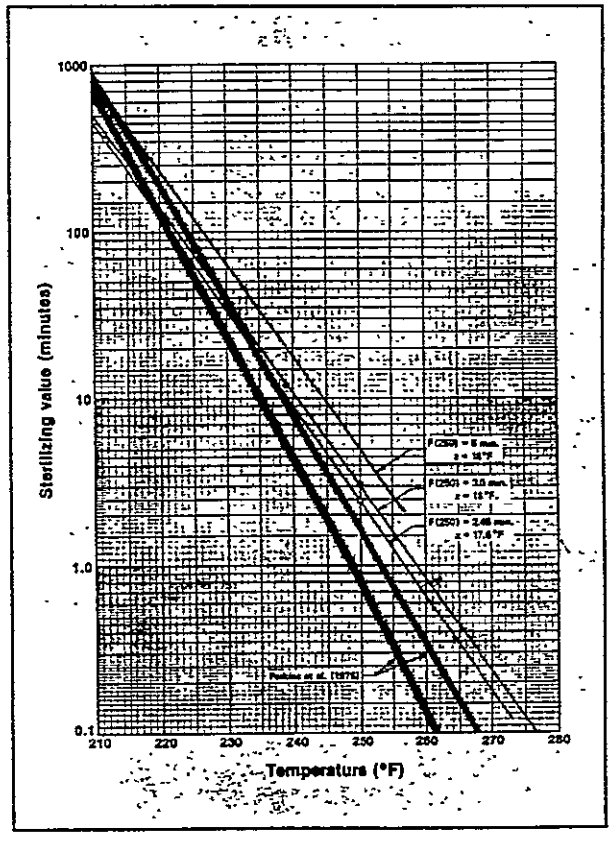


Fig. 6—**STERILIZATION VALUE CURVES CALCULATED** *using the $D_{250°F}$ and z value results of Perkins et al. (1975) superimposed on the sterilization value graph of Esty and Meyer (1922) and Townsend et al. (1938) in Figure 5. An F_o = 5 min sterilization value curve is also shown*

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measured at the slowest heating zone in the container. It is recognized that the use of integrated sterilizing values as proposed by Stumbo (1948b; 1973), Gillespy (1951), and others is essential when relating F_o values determined physically to F_o values determined chemically or biologically (Hayakawa, 1978); however, there is a question as to the benefit of these methods to the sterilization process engineer.

In discussing the F value for public health safety, we have been directing our attention to low-acid canned food in which *C. botulinum* will grow and produce toxin. There are, however, food products that appear to inhibit or at least not promote the growth of *C. botulinum*. The food-phosphate factor (Townsend et al., 1938) has been used to obtain a minimum public health botulinum process for these products. *C. botulinum* will not grow in acid foods (pH <4.6), and there appears to be a gradual decrease in the heat resistance of *C. botulinum* starting at about pH 6 (Xezones and Hutchings, 1965). In this article, space is not available for a full treatment of the food-phosphate factor or the effect of pH.

Since the public health sterilizing value requirement must include adequate safety, not only for microbiological variation, but also for process delivery variation, these factors must be considered in selecting both F and z values. Process delivery variation and the potential accompanying hazard is a function of the product, the container, and the processing system. In general, a greater factor of safety is required as we go from metal to glass to other exotic packaging systems. The overall factor of safety must be increased as we go from a conduction-heating product or a pure convection-heating product to those products that heat by both conduction and convection and may exhibit broken heating curves. The factor of safety must increase as we go from long-time processes at low temperatures to short-time processes at higher temperatures, and as we go from still cooks to agitating cooks.

DELIVERY OF PROCESS IMPORTANT

The record of the commercial canned food industry suggests that use of the wrong process for the product, failure to deliver the scheduled process, and post-process contamination are the chief causes of botulism from commercially canned foods. The problem does not appear to be in the process engineering area, but primarily in the manufacturing or production area. The importance of proper procedures and competent personnel in the canning plant cannot be overemphasized. The continuing problem of botulism from home-canned foods shouts out the message that untrained personnel often fail to deliver recommended sterilization processes.

An $F_{250°F}$ value of 3.0 min using a z value of 18°F has been the minimum botulinum cook standard for more than 40 years. We conclude that there is no epidemiological evidence to show that this standard has failed. A commercial canned food product that has received an F_o of 3.0 min and has been cooled in adequately chlorinated cooling water is safe from a public health standpoint.

The attention given and the discussions carried out regarding the F and z values for a minimum public health process are almost academic and may in fact be counterproductive because they take attention away from the primary problems of the industry, which are in the delivery area. These problems include measuring and controlling the f_h and j of complex heating foods and ensuring that the designed F_o value was actually delivered to every container of product!

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EFFECT OF pH ON GROWTH OF *CLOSTRIDIUM BOTULINUM* IN FOODS

K.A. ITO and J.K. CHEN

□ IT IS a generally accepted fact that a pH of 4.6 or less will inhibit the growth of *Clostridium botulinum* spores in food. The data supporting this view are provided by the published work of several investigators.

MANY STUDIES CONDUCTED

Dozier (1924), working with double-strength veal infusion, 2% peptone-phosphate-buffered medium, investigated the limiting pH for the growth of 37 strains using a vegetative cell inoculum and 19 strains using a spore inoculum. A 0.1-ml inoculum of a stock suspension was added to the medium adjusted to the proper pH. The pH was measured using a pH meter. The average of 52 tests was used to plot a growth curve for vegetative cell inocula. The results showed an optimum pH of 5.91-8.2 with a range of 4.87-8.89. The average of 23 tests was used to plot the growth curve for the spore inoculum. The results showed an optimum pH of 6.17-7.08 with a range on 5.01-8.89. The number of replicate samples, the inoculum size, the types and strains utilized for inoculation, and the incubation temperature were not stated.

Ingram and Robinson (1951) used a buffered bread broth medium inoculated with three type A and two type B strains. Several tubes were inoculated with 10^3-10^4 spores/ml and were incubated anaerobically at 37°C. Growth from ›res did not occur in bread broth below pH 5.0. In ten ies of inocula, this observation held with one exception, a type B strain which grew at pH 4.77-4.91. Growth was based on determining the increase in the number of viable organisms present by plating aliquots on Fildes digest agar after a specific incubation period.

Townsend et al. (1954) inoculated 14 different food products with a type A and a type B spore suspension. When required, the food was blended to ensure homogeneity. Duplicate tubes were inoculated with 20-25 million spores. Incubation was at 30°C for at least a year. Growth was determined by gas formation in the tubes, with confirmation of toxin production. The highest pH level tubes at which no gas formation was observed also were examined for the presence of toxin. The pH at time of growth was determined by examination of an uninoculated control tube. The results of the study show a food-to-food variation in the minimum pH required to inhibit the growth of *C. botulinum*. The lowest pH at which growth was obtained was in pineapple rice pudding, where growth occurred at pH 4.80 but was inhibited at pH 4.59. The highest pH in which growth was inhibited in a food occurred in banana puree, where growth occurred at pH 6.02 but inhibition occurred at pH 5.72. In the other products, the lowest pH at which growth occurred ranged from 4.93 to 5.44. The tendency was for growth in vegetable items to occur at a lower pH value—4.86-5.20, with the majority in the pH 4.9-5.0 area—than in the fruit items (pH 5.2-5.44) with the exception of the pineapple rice pudding. This exception may be due to the nutritive quality of the rice pudding.

Townsend et al. (1954) also conducted a screening study using seven type A and seven type B strains inoculated into culture media. The media were inoculated, incubated, and tested in a manner similar to the food products. Growth in the culture media did not optimize the pH inhibition level over that in the food products, although the inhibition level was comparable to most of the food products tested—with a minimum growth pH in the culture media of 4.98-5.02.

Ohye and Christian (1966) used a trypticase, yeast extract, glucose medium adjusted to various pH levels. They inoculated 10^3 spores/ml into test tubes containing 10 ml of medium. They studied two type A, two type B, and two type E strains. Growth was indicated by turbidity and gas formation. Toxicity tests were performed on the positive samples. Their results showed that no growth occurred at pH 5.0 or 9.0.

Baird-Parker and Freame (1967), using single strains of type A, type B, and type E spores, inoculated a modified reinforced clostridial medium at various pH and water activity levels. They inoculated 10^7-10^8 spores/ml into test tubes containing 2.5 ml of media. Suspensions were incubated at various temperatures and examined for germination, outgrowth, and vegetative cell growth. They found that the type A spores were unable to germinate at pH 5.0 but germinated and grew at pH 5.3. Type B spores germinated at pH 5.0, 20°C, but had no vegetative cell growth. However, at pH 5.0, 30°C, the type B spores were able to germinate and multiply.

Hauschild et al. (1975) directly inoculated type B spores into marinated mushrooms at a level of 10^5 spores/jar. Twelve replicate jars were inoculated and incubated at 30°C and checked for butyric odor for a period up to 10 weeks. The mushrooms from the jars exhibiting the butyric odor were homogenized and the homogenate used for toxicity determinations. Growth and toxin formation occurred at pH 4.77 ± 0.06, but no growth or toxicity was observed at pH 4.62 ± 0.04. At the same time, uninoculated mushrooms were prepared in the same manner; growth occurred in these jars at pH 5.04 ± 0.05, but no growth occured at pH 4.77 ± 0.06. The number of spores present in the naturally contaminated fresh mushrooms ranged from 10 to 214 *C. botulinum* spores per 100 g of mushroom. This indicates that the naturally contaminated jars were inoculated with only 20-400 spores.

Huhtanen et al. (1976) inoculated 4 × 10^3 spores into 4 ml of tomato juice. They individually tested 6 type A and 4 type B strains for growth. The lowest pH at which growth was observed was 5.24 with a type B spore suspension.

RESULTS AFFECTED BY MANY FACTORS

The studies outlined above demonstrate that pH 4.6 is a good general rule which can be utilized to ensure inhibition of *C. botulinum* spores. However, they emphasize that individual foods will have their own minimum pH levels at which growth can be inhibited. The testing procedures utilized to make these determinations have not been uniform. For example, inoculum size has varied from large to small; replicate samples have ranged from one to 12; and studies have been conducted in product, bacteriological media, and product combined with bacteriological media. It would appear that some uniformity would be helpful in comparing results and in assessing the experimental results. The following areas appear to have an effect on the results:

- **The Inoculum Size** affects the minimum pH at which growth in a food product will occur. The larger the inoculum size, the lower the pH limit for growth. This is evidenced in the studies of Hauschild et al. (1975), in which

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an inoculum of 10^3 spores/jar enabled growth to occur at pH 4.77 in mushrooms, whereas a natural inoculum of 20-400 spores/jar enabled growth at pH 5.04 but not at pH 4.77. Ito et al. (1976) inoculated cucumber puree with 10^6 spores/tube and obtained growth at pH 5.0 but not at pH 4.8. With an inoculum of 10^2 spores/tube, growth occurred at pH 5.15 but not at pH 5.0. Segner et al. (1966), using adjusted trypticase-peptone-glucose medium, were able to get growth at pH 5.2 with an inoculum of 2×10^6 spores/tube of type E; but with a 10-fold higher inoculum level, the same strain outgrew at pH 5.03.

- **The Number of Strains Utilized** affects the minimum pH at which outgrowth in a food product will occur. Ingram and Robinson (1951) showed that out of two type B strains tested, one grew in bread broth at pH 4.77-4.91 but was inhibited at pH 4.49, whereas the other grew at pH 5.01-5.19 but was inhibited at pH 4.81-4.90. Of three type A strains, one strain grew at pH 5.8 but was inhibited at 5.5, another grew at pH 5.4 but was inhibited at 4.9, and the last grew at pH 5.5 but was inhibited at 5.19. Thus, unless a strain has been identified as being particularly acid-tolerant, working with only one strain and one type might not provide adequate information regarding the minimum pH at which growth in a food product will occur.

- **The Medium Utilized** affects the results. Experiments have been conducted utilizing product, bacteriological media, and product combined with bacteriological media. Townsend et al. (1954) showed that the minimum pH at which growth will occur in a bacteriological medium is dependent upon the medium utilized. Using a composite of seven type B strains, they got growth and toxin formation at pH 4.98 in Yesair's pork infusion broth, whereas they got growth at pH 5.22 in Wheaton's beef heart-casein broth. Using a composite of seven type A strains, they got growth and toxin formation at pH 4.98 in Yesair's pork infusion broth but got the same results at only pH 5.09 in Wheaton's beef heart-casein broth. Additionally, their work shows that the minimum pH for growth is product dependent and varies from product to product.

- **The Number of Replicate Samples Utilized** varies. With large inoculum sizes, the number of replicate samples utilized may have little importance because the probability of finding the spore which will grow at a low pH is higher. However, with small or moderate inoculum levels, the number of replicate samples may play a role in obtaining growth at the lowest pH. This may be due to exposing more spores to a given environment, providing more opportunity for creating a favorable environment for growth, and providing an opportunity to better determine the potential for the product to support growth at a low pH by observing the number of positive replicates at a given pH level.

- **The Incubation Temperature** affects the ability of the spores to germinate and outgrow. Baird-Parker and Freame (1967) worked with type A and B strains and were able to get outgrowth at 30°C at a lower pH value than when incubation occurred at 20°C. They also concurred with the results of Segner et al. (1966) that type E organisms outgrew at lower pH values when incubated at 30°C than when incubated at lower temperatures. Incubation temperature in the experiments cited have ranged from 20 to 37°C.

- **Criteria for Growth** at the minimum pH have varied from actual subculture to determine the number of organisms present, to determination of gas formation with subsequent verification of the presence of toxin. Since most of the work is accomplished utilizing known inoculated product, verification may not need to be exacting. However, Kautter (1976) indicated that at the minimum growth pH level, very little gas may be found in pimientos. Therefore, if only gas formation is utilized as a criterion, errors may occur.

UNIFORM TESTING PROCEDURE SUGGESTED

To optimize the probability of determining the minimum pH at which *C. botulinum* spores will grow in a food, we suggest that the following protocol be considered:

1. The size of the inoculum should represent a natural contamination level with sufficient excess to allow fo unusual situations. An inoculum of 10^4 spores/containe would appear appropriate.
2. A reasonable number of types and strains should utilized. For most products, this will be types A and Because of strain sensitivity to pH, we suggest the utiliza tion of 3-5 different strains of each type.
3. The product utilized should be the food to be tested rather than a bacteriological medium, or it should be the food product supplemented with a bacteriological me dium.
4. Product should be placed in 5-10 replicate tubes o other appropriate containers at a given pH level.
5. Product should be incubated anaerobically at 30°C. If thioglycolate is utilized, care should be taken, as it ma delay or prevent growth at the minimum pH level if used a too high a concentration (Segner et al., 1966).
6. The presence of toxin should be determined at the minimum pH level at which growth is observed either microscopically or through the production of gas. In addi tion, at least the next lower pH level should be examined fo presence of growth and toxin. Trypsin treatment may b beneficial for optimum toxin detection.

EXPLAINING BOTULISM IN ACID FOODS

Despite these studies which indicate that a pH of 4.6 wi inhibit the growth of *C. botulinum*, periodic occurrences o botulism in home-canned acidic foods occur. The Center for Disease Control (CDC, 1973) reported that two cases of botulism occurred in Kentucky in 1973. Investigation indicated that home-canned blackberries were consume shortly before the illness. *C. botulinum* type B was found in the berries, but no toxin was detected in the berries. The pH of the berries was 3.5. The sera and feces from one patient were examined, and toxin was found. The possibility o "in-vivo" toxin production by vegetative cells of *C. botulin um* was discussed.

In 1974, one case of botulism occurred in Alabama (CD 1974a). Investigations indicated consumption of hor canned tomatoes before the illness. Stools and sera from th patient were positive for *C. botulinum* type B. The suspec jar of tomatoes had been discarded, and other jars of the same lot were negative for *C. botulinum* and for botulinal toxin. The pH of the product in these jars was 4.5.

Also in 1974, one case of botulism occurred in Idah (CDC, 1974). Investigations indicated consumption o home-canned tomato juice before the onset of illness. *C. botulinum* type A toxin was detected in the patient's sera, and type A organisms were isolated from the stool. In addition, the incriminated juice contained type A toxin, and *C. botulinum* type A and with other organisms were isolated from the juice. The pH of the juice was 4.2.

Prokhorovich et al. (1976), in laboratory studies utilizing one type A and one type B strain at a level of 3.5×10 spores/ml in apricot juice and compote, indicated that us of a pH limit of 4.5 combined with their present sterilizing technique does not ensure inhibition of spore germination and toxin formation.

These reports would suggest that the ability of pH 4.6 t inhibit the growth of *C. botulinum* might be in doubt However, the data of Baird-Parker and Freame (1967) indicate that growth and toxin formation at pH 4.6 or less would be highly improbable. Their results indicate tha although spore germination could occur at pH 5.0 wit types A and E, spore outgrowth would not occur. They di find that their type B spores did germinate and outgrow at pH 5.0 when incubated at 30°C but not when incubated at 20°C. No lower pH values were studied. Rowley an Feeherry (1970) determined conditions affecting the germi nation of *C. botulinum* 62A. Using an inoculum level of 10 spores/ml, they found that in the L-cysteine germination system they were using, maximum germination occurred pH 6.5-7.5 and no germination occurred below pH Wynne et al. (1954) studied the germination of one type and one type B strain in buffered glucose medium Using a

—Continued on page 76

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REGULATORY REVIEW OF SCHEDULED THERMAL PROCESSES

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□ SEVERAL INCIDENTS in the past few years have resulted in life-threatening hazards from improperly processed low-acid foods packaged in hermetically sealed containers. Regulatory and health officials have been concerned with the potential public health hazards associated with thermally processed low-acid foods, and these incidents prompted the Food and Drug Administration to issue two regulations directed toward the low-acid canned food industry.

TWO REGULATIONS ISSUED

The first regulation, entitled "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" (21 CFR Part 113, formerly Part 128b), sets forth the criteria to ascertain whether the facilities, methods, practices, and controls used by commercial processors in the manufacture, processing, or packing of low-acid foods are operated and administered in a manner adequate to protect the public health. The major portion of this regulation became effective in March 1973.

Included among the mandatory provisions of Part 113 is the requirement that scheduled processes for low-acid foods be established by a person having expert knowledge in the heat sterilization of low-acid canned foods. The facilities, instrumentation, and equipment must be adequate to determine the heat processing requirements of the food product. The type, range, and combination of conditions encountered in commercial production must be adequately provided for when the scheduled process is established. Acceptable scientific methods of establishing heat sterilization processes shall include the use of appropriate F and z values and/or the development of bacterial spore thermal-death-time data. The established process may be determined by process calculations based on product heat penetration data or the results of inoculated pack or bacterial spore count reduction tests. These requirements are delineated in Section 113.83 (formerly 128b.4), which also includes other requirements and recommendations regarding process establishment.

The second regulation, entitled "Emergency Permit Control" (21 CFR Part 108, formerly Part 90), establishes the procedures for determining the need for a permit, its issuance, and the revocation of the need for a permit. Section 108.35 (formerly 90.20) specifically covers the thermal processing of low-acid canned foods and includes the requirement that commercial processors of low-acid canned foods register their establishments with the FDA and file their scheduled processes with the FDA's Bureau of Foods. The major portion of this regulation became effective in April 1974.

REGISTRATION AND FILING REQUIREMENTS

Section 108.35(c)(1) requires that all commercial processors engaged in the manufacturing, processing, or packing of thermally processed low-acid foods in hermetically sealed containers register with the FDA on Form FD-2541. Since registration has been in effect, almost 1,100 domestic and 2,000 foreign establishments have registered.

After registering, processors are required to file with the FDA information concerning their scheduled processes for each low-acid food in each container size. The required information includes:

1. Processing method.
2. Type of retort or other thermal processing equipment employed.
3. Minimum initial temperature.
4. Process time and temperature.
5. Sterilization value (F_o), or other equivalent scientific evidence of process adequacy.
6. Critical factors associated with the scheduled process.
7. The source and date of the establishment of the process.

It should be noted that the filing of such information does not consititute approval of the information by the FDA, and that the filed information and data are regarded as trade secrets.

Registered processors must file this information not later than 60 days after registration and before packing a new product. The information filed must be submitted on the appropriate forms: FD-2541a for still retort processes; FD-2541b for agitating processes; and FD-2541c for other than still or agitating processes.

The regulation provides for amending previously filed scheduled processes when a packer intentionally makes a change by reducing the minimum initial temperature (IT) or the retort temperature (RT); reducing the time of processing; or changing the product formulation, the container, or any other condition basic to the adequacy of a process. Before such a changed process is used, its adequacy must be substantiated by a processing authority. Within 30 days after first use, the packer must submit to the FDA a complete description of the modifications along with evidence showing prior substantiation by a processing authority. If a change consists solely of a higher IT, a higher RT, or a longer processing time, such information need not be filed unless the modification is to be regularly scheduled.

Process filing requirements became effective on April 30, 1974. Nearly 22,000 filing forms have been received by the Bureau of Foods, representing an estimated 80,000 filed processes.

HOW INFORMATION IS HANDLED

The overall responsibility for processing these forms rests with the Industry Guidance Branch of the Office of Compliance, Bureau of Foods. Forms received by the Bureau of Foods are forwarded to the Industry Guidance Branch for logging and related handling, and are then sent to the Division of Food Technology for editing. This task involves identification of obvious or gross errors made by the processor in completing the form and editing to facilitate computerization of the data. This often includes, for example, the separation of different products which have been incorrectly filed on one form, usually because the other information, including the scheduling process, is the same for the several products.

Next, the forms are returned to the Industry Guidance Branch, where each form is assigned an item number. After all information pertaining to establishment identification

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has been deleted, the forms are sent to a contractor who enters the data onto a computer tape. The tapes are forwarded to the Bureau's Technical Operations Staff, where the information is placed into computer storage.

A printout is obtained which lists, by food canning establishment number, each item number and the associated manufacturer's product name. Each manufacturer's product name is assigned a product code, which provides a means of systematically classifying all food products.

One of the major problems to date regarding process filing has been the significant number of forms with missing information. Attempts are underway to rectify this problem. First, for forms already received and identified as being incomplete, the firms involved are being contacted and requested to provide the missing information. Second, future filings submitted to the Bureau of Foods will not be accepted if an initial review (which is now feasible with the current rate of receipts) reveals that essential information is missing. These forms will be returned to the processor for completion.

A computer program has been developed which allows the data to be selectively retrieved in practically any manner desired. It is possible to obtain a printout of scheduled processes by product, by processing method, by process source, etc. In addition, the computer program allows us to be as selective as necessary to retrieve information and data. For example, it would a simple task to obtain, if required, a complete list of sterilizing values filed for beans in sauce in a specific-size can processed in a hydrostatic retort.

HOW PROCESSES ARE REVIEWED

Since in-depth inspections of low-acid canned food establishments began in 1973, the FDA has documented a number of instances in which processors were using scheduled processes that were not established by a qualified thermal processing authority or whose adequacy to provide commercial sterility was questionable.

The FDA has therefore undertaken a review of filed scheduled processes for the purpose of further identifying inadequate processes and preventing their use. To accomplish this task, an internal FDA committee, chaired by the Bureau of Foods' Associate Director for Technology, has been formed. Members of the "Low-Acid Canned Food Process Review Committee" include individuals with thermal processing expertise in the Bureau of Foods' Divisions of Food Technology and Microbiology, along with a representative from the headquarters office concerned with regulatory functions and the headquarters office concerned with field investigational functions.

During the period of the committee's formation, it became apparent that the anticipated number of filed processes could not be adequately reviewed in an expeditious manner without the use of resources outside the FDA. Therefore, contracts have been negotiated with experts from outside the agency to perform a number of tasks associated with process review and related research.

The work of the contractors is being accomplished through the following organizational, operational, and reporting activities of the contractors and the Process Review Committee:

1. The committee is responsible for identifying potential public health risks and for determining process evaluation priorities.
2. The committee establishes and directs general procedures for process evaluation.
3. The contractors evaluate the filed processes to determine process lethality, and therefore the adequacy of the processes in terms of protection of the public health.
4. The contractors report the results of the process evaluations to the FDA. The committee, when required, participates in the analysis and interpretation of the evaluation results, as well as in the development of recommended follow-up action.
5. A summary of the findings and recommendations is reported for FDA implementation or follow-up as required.

A review of the filed information represents a very sizable undertaking, and considerable planning has gone into developing procedures to accomplish the task. With a recognition of resource constraints, a systematic approach to process review has been developed and initiated.

The first step is the establishment of review priorities. Obviously, priorities must be assigned on the basis of potential public health risks, and high-risk areas are being identified by the Process Review Committee. This determination begins with a review of the filed information and is conducted chiefly by product group, but other factors (e.g., processing system) are also considered. In addition, a knowledge of past problems and the experience of the agency's thermal processing experts are of value in making judgments in this area.

After a category of filed processes has been selected for review, the essential filed process information is submitted to a contractor for an initial classification as to the adequacy of each process within the category. (All information and data provided to a contractor are treated as trade secrets.) The contractor classifies each process as adequate, questionable, possibly inadequate, or lacking sufficient information to determine adequacy.

Follow-up action is contingent upon agency analysis and interpretation of the contract review and initial classification findings. Experience to date has shown that for those processes which are considered possibly inadequate or questionable with respect to providing commercial sterility and/or assuring the safety of a processed product, requests for supplemental information have been the course of action most often recommended.

REQUESTS FOR SUPPLEMENTAL INFORMATION

Authority for the FDA to request supplemental information is provided in 21 CFR 108, Subpart B, which states that when requested in writing, a commercial processor must provide the information deemed necessary to determine the adequacy of a process (108.35(c)(3)(ii)).

These written requests include, in outline form, the type of information a processor is expected to provide if any the more commonly recognized scientific procedures were used in process establishment. We acknowledge that other scientific methods may have been used by a process authority, and if this is the case, we request that a detailed description of the method used and data obtained be provided.

The types of information and data needed for the FDA to evaluate the adequacy of a filed process for the three most common scientific methods used in establishing processes—heat penetration tests, count reduction tests, and inoculated pack tests—are outlined below:

- **The Product and Process.** Regardless of the scientific method employed, a thorough evaluation of the results requires that detailed information on the product and process delivery conditions be provided. For example, a detailed description of the product, including critical factors, must be provided. Was it a commercial product, a laboratory-prepared product, a simulated product, etc.? If the test product was different from the commercial product, a justification for its use should be provided. Also, information on container filling and closing equipment and procedures should be submitted, along with any critical factors such as fill weight, solids-to-liquid ratio, etc.

- **Heating Equipment and Conditions.** Regarding heating equipment and conditions, we expect the following to be submitted:

1. A description (including manufacturer) of the test apparatus.
2. Conditions during heating and cooling; e.g., type of heating and cooling media, heating-medium temperature, cooling-medium temperature, and pressure conditions.
3. Number of test containers and container dimensions.
4. Location and orientation of the containers in the processing apparatus, and the number of containers in the apparatus during a test, compared to the capacity of the processing apparatus.

5. Venting and come-up times (where applicable) and process time.

6. If an agitation process, the type of agitation and related information such as reel diameter and speed.

7. Information demonstrating the adequacy of heat distribution within the test apparatus.

• **Spore Performance Data.** For those process design methods which utilize calibrated bacterial spores, a complete description of the test program used to establish spore performance is essential. In addition to species name and/or collection, the following information is needed:

1. Source of the spore suspension.
2. Heat-resistance test employed.
3. Temperatures at which tests were carried out and the number of replicate tests at each temperature.
4. Number of heating times at each temperature and number of replicates per heating time.
5. Initial number of spores per test unit.
6. Substrate (including concentration) in which spores were suspended during heating.
7. Description of the treatment of survivors.

Furthermore, a description of the treatment of the raw test data used to arrive at calibration results and a copy of all results (e.g., the D value, the thermal resistance curve, and the indicated z value) that were used in determining sterilizing values should be submitted.

• **Heat Penetration Tests.** For heat penetration tests, it is necessary to have information about the equipment used. This should include a brief description of:

1. The thermocouples or other temperature-sensing elements.
2. The temperature-measuring unit.
3. The location of the sensing element in the test container, and the basis for selecting the location.
4. The relative location of the test containers in the heating apparatus.
5. The location of the sensing element used for measuring the heating-medium temperature.

The raw time-temperature data should be furnished for each test container from the time steam is turned on until the end of cooling. If the data were analyzed by the "Ball" method, the resultant heating factors for each test container should be delineated.

Regardless of the calculation procedure used (for example, Ball, Stumbo, General Method), it is necessary to provide a description of the procedure and a copy of the calculations (or the data used) leading to the filed process.

If heat penetration tests were conducted using a heating apparatus other than the equipment used to commercially process a product, a justification of the applicability of the test data to commercial conditions should be provided.

• **Count Reduction Tests.** For filed processes which were established on the basis of count reduction tests, a processor should supply, in addition to spore performance data, the following:

1. Number of spores and volume of spore suspension per container.
2. With direct product inoculation, a description of how the spores were inoculated into the product.
3. With spores in an impermeable carrier unit, a description of the location of the unit in the container.
4. Procedures used for recovering the spores from the product and for sample assay.
5. Treatment of controls; i.e., inoculated but non-heated containers.
6. Method used to determine sterilizing values, and the calculated sterilizing value for each test container. This information should include a sample analysis showing how the spore calibration data and the data from controls and heated containers are combined to yield each sterilizing value.

• **Inoculated Pack Tests.** Where filed processes are based on the results of inoculated pack tests, the information and data that are requested include:

1. A description of the test program. This includes such information as the number of conditions evaluated, the number of replicate containers per test condition, and the number of unheated controls.
2. The background microbial load of the test product.
3. Incubation conditions.
4. The method and criteria used to confirm growth. For example, if swelled containers were used to determine growth, what constitutes a positive container? If subculturing was used, a complete description including procedures used to identify the inoculated organism is needed.
5. Test results for each experimental condition, including the results of non-inoculated control containers, number of containers with confirmed growth, and the estimated sterilizing value.
6. A summary of the interpretation of the results in support of the filed process.

The preceding discussion should provide an appreciation not only of the kinds of information and data that the FDA is requesting, but also of the degree of detail expected. For the three most common process establishment methods, this amount of information is necessary to properly evaluate filed processes that are of questionable adequacy. Furthermore, for processes where other scientific process establishment methods are used, information and data in similar detail are necessary.

In addition to requesting supplemental information on process design, it is anticipated that in certain instances the FDA will be requesting information on the microbiological basis for a process. Of possible concern are processes based on F values that are less than an F_o of 3. In these instances, a processor must submit data on the heat resistance of *Clostridium botulinum* spores in the product. Since this is a spore calibration study, the previously discussed kinds of information and data on the performance characteristics of spores should be provided. Furthermore, it would be worthwhile to obtain data on the microbial spore load of the unprocessed product.

When supplemental information requested by the FDA is submitted by a processor, it is forwarded to a contractor for review and evaluation. It is expected that in certain instances the FDA will direct a contractor to conduct microbial heat resistance studies, heat penetration tests, or inoculated pack tests to confirm the processor's data and/or their interpretation. In addition to the research capabilities of the contractors, the FDA itself now has the expertise and facilities to conduct the required research.

Where there are unquestioned deficiencies in a filed process or a chosen sterilization level, it is expected that a processor will make the revisions needed to assure the adequacy of the process. Where unresolved differences exist, the FDA could initiate regulatory action to obtain compliance.

GOAL TO ASSURE PUBLIC HEALTH

We have briefly discussed those portions of the low-acid canned food regulations pertaining to process establishment and process filing and the resultant activities involved in a review of the processes by the FDA. We hope, however, that this discussion has provided an understanding and appreciation of both the nature and the scope of the task—a task for which most of the work lies ahead.

The goal of this FDA effort is simply to provide increased assurance of protection of the public health. We believe that this goal can be attained with the continued support and cooperation of all concerned.

Based on a paper presented during the symposium, "Thermal Processing of Canned Foods," at the 37th Annual Meeting of the Institute of Food Technologists, Philadelphia, Pa., June 5-8, 1977.

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inoculum level of 10^3-10^4 spores/ml, they found germination occurring at pH 7 but not at pH 4.8. If germination does not occur, then outgrowth and subsequent cell multiplication and toxin formation cannot occur. Even if germination occurs, there is no guarantee that subsequent outgrowth will occur.

A likely explanation for the growth of *C. botulinum* in acid foods is found in the work of Huhtanen et al. (1976). They inoculated mold along with *C. botulinum* spores into tomato juice. They found that the minimum pH for outgrowth of spores with only a *C. botulinum* inoculum was pH 5.24. However, upon inoculation with mold and *C. botulinum* spores, tomato juice with an initial pH as low as 4.2 became toxic. Upon taking the pH of the inoculated medium, they found a pH gradient ranging from the starting pH to as high as 8.2. The highest pH values were recorded directly under the mold mat. This indicates that competitive microorganisms not normally present in properly prepared acid products could initially grow and change the environment to enhance conditions which will support the growth of *C. botulinum* spores.

Thus, growth in these acid foods is not due to the ability of *C. botulinum* to grow under the acidic conditions of the food, pH 4.6 or less, but is due rather to the raising of the pH above the inhibition level by other causes such as the action of other microorganisms.

INHIBITORY pH VARIES WITH FOOD

A review of the literature concerning the effect of pH on growth of *C. botulinum* in foods thus indicates that although a pH of 4.6 will inhibit the growth of *C. botulinum* from spores, the actual minimum pH at which growth is inhibited in a given food will be specific for that food and may be higher than pH 4.6. It also indicates that a uniform testing procedure, such as the one we suggest in this article, would be helpful in evaluating the results of future studies.

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Based on a paper presented during the symposium, "Thermal Processing Canned Foods," at the 37th Annual Meeting of the Institute of Fo Technologists, Philadelphia, Pa., June 5-8, 1977.

39th Annual Meeting

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CHAPTER 2

THE SYSTEM AND ITS ELEMENTS

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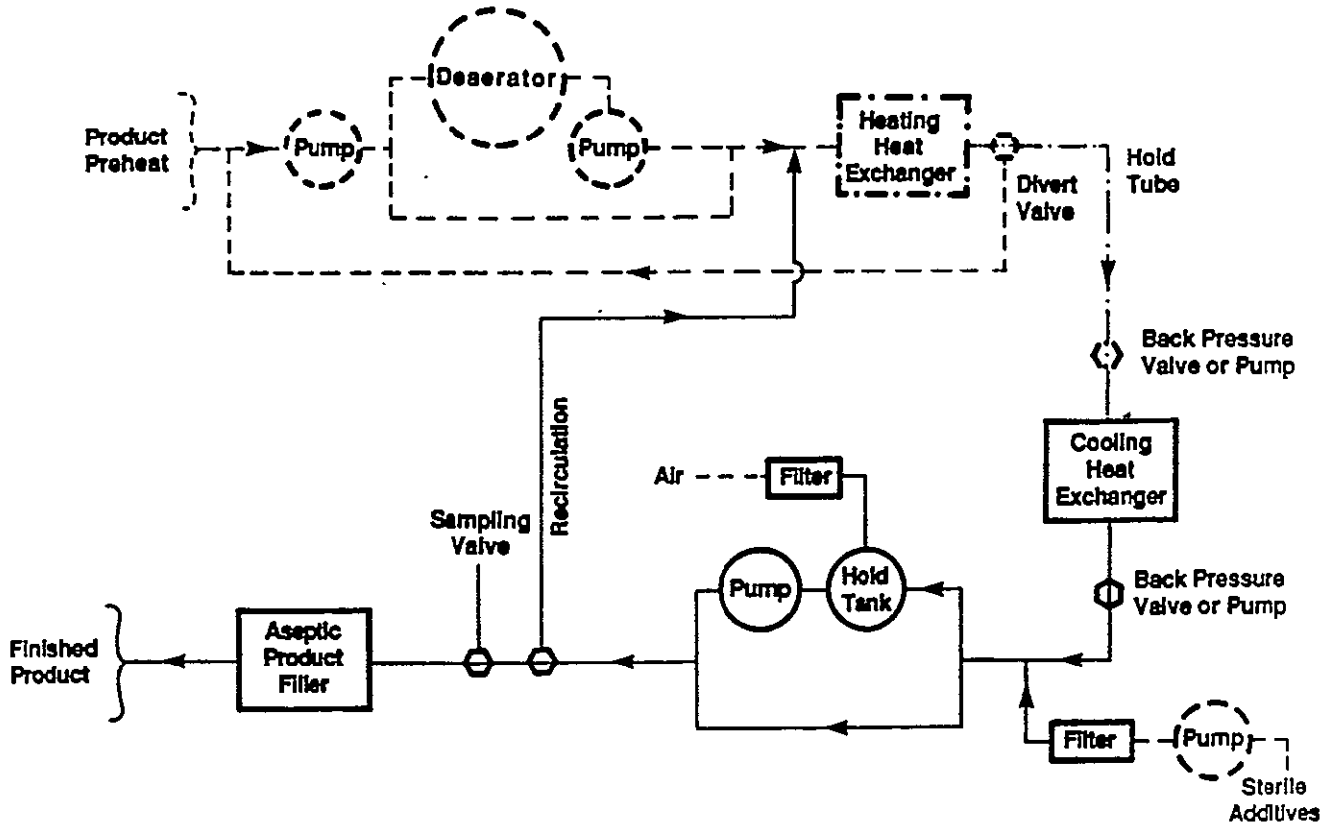
INTRODUCTION

The aseptic processing system can be conveniently divided into several elements: (1) the product; (2) flow control; (3) product heating; (4) hold tube; (5) product cooling; and (6) packaging *(Figure 1)*. Properties of the product dictate the possible options in designing an aseptic processing system. Product considerations include: (1) liquid or liquid plus particulates; (2) size of particulates; (3) product viscosity; (4) thermal sensitivity of product color and flavor; (5) volatility of product flavor; and (6) fouling characteristics of the product. As these characteristics are identified in a systematic manner, an aseptic processing system will emerge which results in acceptable product quality at an acceptable product cost.

The system for aseptically processing foods is extremely complex mechanically and requires meticulous attention to detail if it is to operate successfully. The program for establishing and monitoring the system to ensure optimum performance will be covered in subsequent chapters. In this chapter, the principles of thermobacteriology for design of the heat transfer system will be presented, followed by a description of the actual elements which can be used to accomplish the objective(s) of the process.

Figure 1. Diagram of an aseptic processing system.



BASIC PRINCIPLES

Thermobacteriology

The use of high temperatures to inactivate microorganisms or their spores to prolong the shelf life of foods is a very old process. Since the 1920s the process has been designed based on parameters characterizing the thermal destruction of microorganisms and data on the time/temperature history of the product. Traditionally the process has been applied to products in containers, and equipment has been developed and used extensively since the 1950s for continuous commercial sterilization.

In the 1940s aseptic processing was developed. It differed markedly from in-container processing. In conventional processing the nonsterile product is hermetically sealed in nonsterile containers and then subjected to a thermal process which renders the product commercially sterile. In aseptic processing, the product and package are independently given a heat treatment or chemical treatment resulting in commercial sterility and the product is then packaged and sealed "aseptically." This process is particularly suited to liquids or liquids with small particles, and as a consequence it has been subsequently adopted for continuous processing of liquid foods such as puddings, juices, and purees.

One advantage of aseptic processing is the continuous process. However, a second advantage is the fact that the process could be done at very high temperatures (*e.g.* 300°F/150°C) resulting in very short process times and, in some cases, improvement in product quality. Using these very high temperatures has resulted in the acronym UHT (ultra high temperature) processing.

The design of aseptic thermal processes utilizes the same principles as those used in the design of in-container processing. These include knowledge of thermal inactivation parameters for microorganisms or spores and time/temperature data for the product. However, for aseptic processing it is also necessary to account for a residence time distribution which occurs because of fluid flow.

Destruction of microorganisms and their spores generally obeys first-order reaction kinetics. In the thermal processing industry, this is expressed mathematically as

$$\frac{dc}{dt} = \frac{-2.303\,c}{D} \qquad (1)$$

where $\frac{dc}{dt}$ = rate of destruction

D = decimal reduction time (time for population to decrease by a factor of 10 at a given temperature).

c = instantaneous number of viable cells or spores.

The D-value is the time-constant base 10 for the process and is characteristic of the microorganism and the medium (*e.g.*, pH, composition of the medium, presence of oxygen, etc.).

Equation 1 can be rearranged and integrated as follows:

$$\int_{c_i}^{c_f} \frac{dc}{c} = \int_0^t \frac{-2.303}{D}\,dt \qquad (2)$$

where $c = c_i$ @ $t = 0$ (*i.e.* the initial number of spores)

$c = c_f$ @ t (*i.e.* the final number of spores)

Integration of the left hand side results in $\ln (c_f/c_i)$. The time integral, however, cannot be integrated in its present form because the D-value is not constant. The D-value is dependent on temperature and the temperature is dependent on time. For thermal process calculations, the temperature dependence of the D-value is given by the thermal-death-time model, expressed mathematically as:

$$\log \frac{D}{D_R} = \frac{T_R - T}{z} \qquad (3)$$

where D_R = the D-value at T_R

z = temperature change (°F) necessary for the D-value to change by a factor of 10.

Solving Equation 3 for D and substituting into Equation 2 results in

$$D_R \log \left(\frac{c_i}{c_f}\right) = \int_0^t \frac{1}{10^{(T_R - T)/z}}\,dt \qquad (4)$$

The $\log (c_i/c_f)$ is the number of log cycles the concentration (or number of viable cells) must go through. For *Clostridium botulinum* spores in non-acid foods, it is 12. For most cases T_R is taken as 250°F (121.1°C) and $D_R \log (c_i/c_f)$ is the thermal death time (called F_o). Thus to design a thermal process, a time/temperature treatment must be applied which results in an integrated effect of F minutes at 250°F.

The right hand side of the time-integral still cannot be integrated, however, since the temperature is dependent on time. The term $1/10^{(250-T)/z}$ is called the lethal rate. In the Improved General Method for thermal process calculations, values of lethal rate are calculated for each time/temperature value determined from heat penetration experiments. Lethal rate is then integrated over process time either by graphical integration or by the use of a numerical integration procedure (*e.g.*, Simpson's Rule, Trapezoid Rule, etc.).

An improvement on this method of thermal process design was made when Ball (1923) developed an equation which adequately described the time/temperature profile of foods undergoing a thermal process. The equation became the basis for the Formula Method of thermal process calculations. The time/temperature relationship is shown in *Figure 2* and can be described by

$$\log (RT - T) = \log (j_h I_h) - \frac{t}{f_h} \qquad (5)$$

where RT = heating medium temperature

$I_h = RT - T_{ih}$

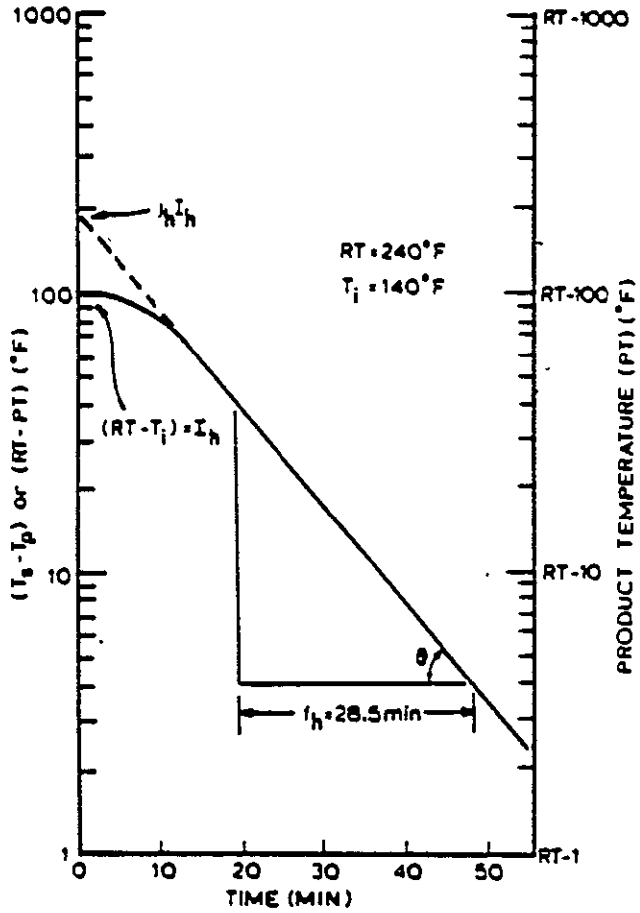
$j_h = (RT - T_{pih})/(RT - T_{ih})$

f_h = time in minutes for (RT − T) to change by a factor of 10

T_{ih} = initial temperature of the product

T_{pih} = pseudo initial temperature of the product (obtained by extrapolating the linear portion of the semi-log heating curve to corrected zero time)

Figure 2. Time/temperature relationship for semilog heating.



The factors j_h and f_h are determined from heat penetration experiments. Ball (1923) differentiated Equation 5, substituted the resulting expression for dt into Equation 4, and, with some simplifying assumptions, developed a rapid method called the Formula Method for calculating the total accumulated lethality of a process.

Although these procedures were developed for in-container thermal processing, the method is adaptable to any thermal process. Equation 4 is universal and requires only that the z-value be independent of temperature. This assumption, however, is currently subject to discussion, particularly as it applies to aseptic processing. The z-value is constant over relatively narrow temperature ranges of about 70°F (for example 210–280°F). However, for ultra-high temperature (UHT) processes which are applied over temperature ranges of more than 100°F, the z-value exhibits temperature dependence. This temperature dependence is an area being actively researched, and the consequences of temperature dependent z-value are still being discussed.

Heat Transfer

The effect of time and temperature on survival of microorganisms is independent of whether the product is in a container or in a continuous flow system. However, the time/temperature profile is specific to the process. Thus a major difference between in-container and aseptic processing is the time/temperature profile which the product experiences. This difference is used to advantage in aseptically processed products because, generally, a higher temperature shorter time process can be used, resulting in increased retention of product quality factors.

Time/temperature profiles in aseptic heating systems have been described by heat transfer models for three systems: (1) steam injection; (2) flow in tubular and plate heat exchangers; and (3) flow in scraped-surface heat exchangers. The complication which arises in fluid flow systems and has significant importance in thermal process evaluation is the residence time distribution of the liquid (and particles, if present) in the system. Unlike in-container processing, which has a positive first-in first-out control, a flowing fluid exhibits a velocity distribution resulting in a distribution of time/temperature treatments.

For indirect heat exchangers (tubular and plate heat exchangers and scraped-surface heat exchangers), the time/temperature profile can be described by Equation 5. The only limitation is that the temperature is the mass-average temperature of the product. Thus if there is a velocity distribution in the heat exchanger (such as in a tube with laminar flow), Equation 5 would give the mass-average temperature. For flow with heat transfer, j_h = 1.0 and Equation 5 reduces to

$$\log (RT - T) = \log (RT - T_{ih}) - \frac{t}{f_h} \qquad (6)$$

There are two conditions of interest in aseptic processing: (1) the heating medium is a constant temperature and (2) the heating medium decreases in temperature as the product temperature increases. The first condition occurs when heating with condensing steam or when the flow rate of the heating medium is much greater than the flow rate of the product. Under these conditions,

$$f_h = \frac{W\,C_p}{UA\ 2.303} \qquad (7)$$

where W = mass of the product in contact with area A [=] lb
C_p = product heat capacity [=] BTU/lb °F
A = area for heat transfer [=] ft²
U = overall heat transfer coefficient [=] BTU/hr ft² °F

The overall heat transfer coefficient is usually estimated by using the following equation to consider the resistance to heat transfer on the product side, the heating medium side, and through the wall:

$$\frac{1}{U} = \frac{1}{h_o} + \left(\frac{x}{k}\right)_w + \frac{1}{h_i} \qquad (8)$$

where U = overall heat transfer coefficient [=] BTU/hr ft² °F
h_o = heating medium heat transfer coefficient [=] BTU/hr ft² °F
h_i = product heat transfer coefficient [=] BTU/hr ft² °F
$(x/k)_w$ = thickness of the wall (x) divided by thermal conductivity of the wall [=] h ft² °F/BTU

In aseptic processing with viscous liquid, the product side heat transfer coefficient (h_i) will control the rate of heat transfer and Equation 7 reduces to

$$f_h = \frac{W\,C_p}{h_i\,A\,2.303} \qquad (9)$$

Typical U values for tubular heat exchangers range from 300–500 BTU/hr ft²°F for plate exchangers from 500–1,000 and for scraped-surface heat exchangers from 50–300. U-values are dependent on type of flow (laminar or turbulent), induced turbulence (including rpm of scraper), viscosity and density of product, and velocity of fluid.

If the temperature of the heating medium decreases as the product heats, then f_h is

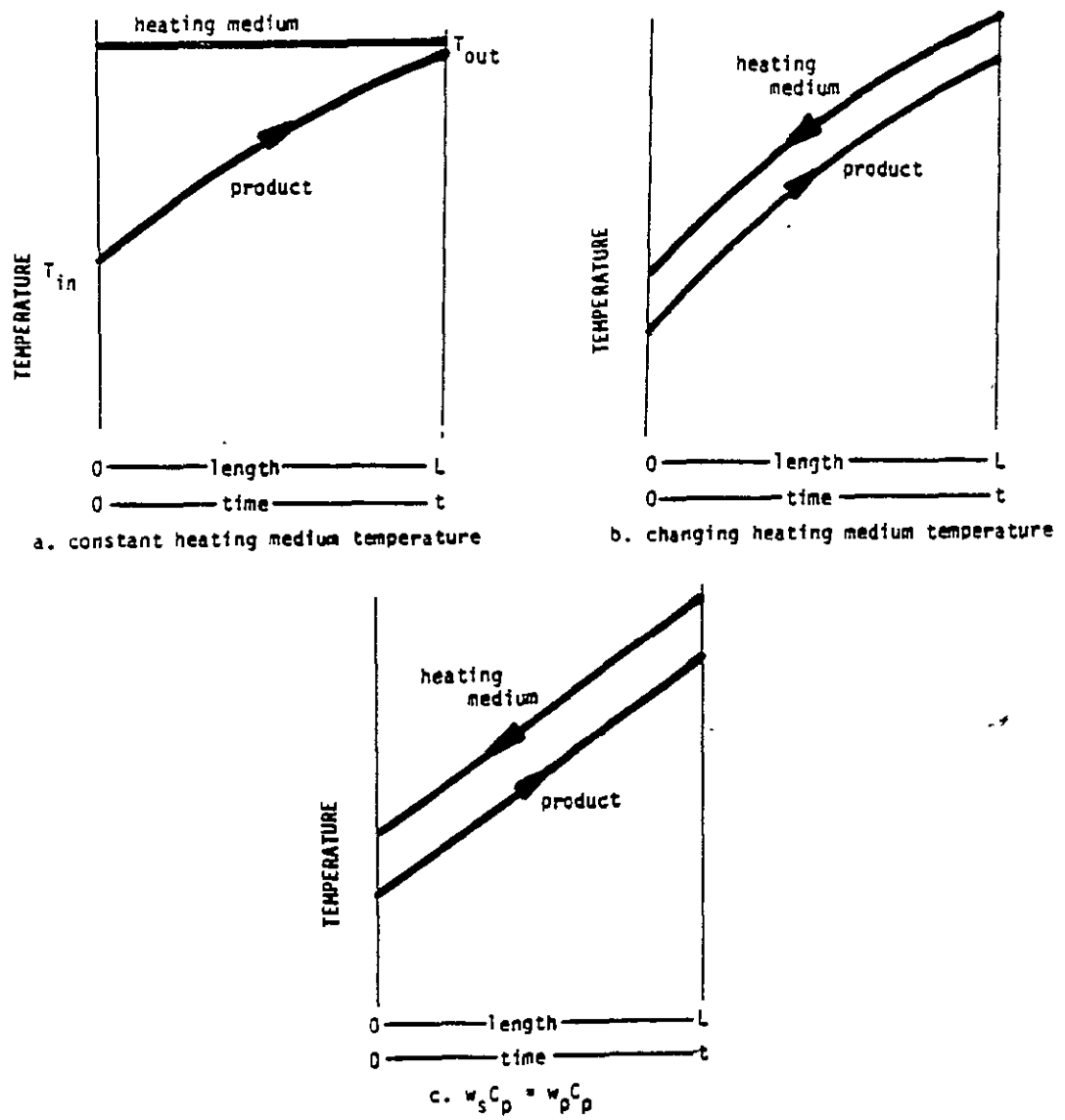
$$f_h = \frac{W\,C_p}{2.303\,UA}\left[\frac{w_s\,C_{p_s}}{w_s\,C_{p_s} - w\,C_p}\right] \qquad (10)$$

where w_s = mass flow rate of the heating medium [=] lb hr
w = mass flow rate of product

If the heating medium and product are countercurrent and of equal flow rate and heat capacity, then the heating and cooling curves are straight lines. Some illustrations of temperature profiles are given in *Figure 3*.

There are two methods for direct heat exchange. (1) steam injection (steam added to product); and (2) steam infusion (product added to steam). Both are used commercially for aseptic (UHT) processing. For direct heat exchange, the U value is very large and extremely rapid heating occurs. Time for the product to attain final temperature is usually on the order of one second or less; consequently, this method is usually considered instantaneous heating.

Figure 3. Time-temperature profiles in heat exchangers.



Typical time/temperature profiles for direct and indirect heating systems are shown in *Figure 4* (Hallstrom, 1977). The total lethality that occurs during the process is the integrated effect of the time/temperature profile on destruction of spores. For all practical purposes, the lethality at temperatures less than 100°C (212°F) is negligible and is thus not counted in total lethality. On this basis of all the lethality in the direct system occurs at the desired process temperature. In the situation described in *Figure 4(b)*, the lethal rate of 140°C for *Clostridium botulinum* spores (z = 10°C = 18°F) is

$$\frac{1}{10^{\frac{(121.1-140)}{10}}} = 77.6 \text{ minutes}$$

and total lethality is

$$F = \text{lethal rate} \times \text{holding time} = 77.6 \times \frac{5.1}{60} \text{ min} = 6.6 \text{ min.}$$

For the indirect system, illustrated in *Figure 4(a)*, the total lethality (F) is 8.40 min.

Velocity Distribution

The preceding discussion for heat transfer and lethality applies only when there is adequate radial mixing in the flow channel so that axial velocity appears uniform in the cross-section. This condition is called plug flow and occurs when there is adequate fluid turbulence. The Reynolds number is used to characterize fluid flow as laminar or turbulent:

$$Re = \frac{\text{kinetic forces}}{\text{viscous forces}} = \frac{\rho D V}{\mu} \qquad (11)$$

where ρ = density of the liquid [=] lb_m/ft^3
D = tube diameter [=] ft
v = velocity of the liquid [=] ft/sec
μ = viscosity of the liquid [=] $lb_m/ft/sec$

For Newtonian fluids (viscosity is independent of velocity), if Re > 4,000, flow is usually turbulent and there is minimum velocity distribution. For fully developed turbulent flow, $\bar{v}/v_{max} = 0.82$ where $\bar{v}$ = mean velocity and v_{max} = maximum velocity. If Re < 2,100, flow is laminar (or streamline) and the velocity profile is parabolic, with maximum velocity in the center of the tube and zero velocity at the wall. In this case, it can be shown that $\bar{v}/v_{max} = 0.5$ where $\bar{v}$ = mean velocity and v_{max} = maximum velocity. The velocity of the liquid is obviously important in aseptic processing since the residence time depends on velocity and tube length. The tube length must be based on the minimum residence time which, in turn, depends on maximum velocity.

$$v_{max} = \frac{L}{t_{min}} \qquad (12)$$

where: L = tube length
t_{min} = minimum residence time

Furthermore, with laminar flow, the temperature profile of the liquid is not as easily predicted or measured as in the case with good radial mixing (plug flow). As a consequence of the lack of precise control and description of temperature profiles during heating and cooling, FDA with few exceptions has accepted only aseptic thermal processes based on lethality occurring in the hold tube (*i.e.* after the product has attained constant hold temperature and prior to product cooling). Thus, for the process illustrated in, the lethality according to FDA would be

$$F = \text{lethality} = \frac{1}{10^{(121.1-139)/10}} \times \frac{2.3}{60} \text{ min.} = 2.4 \text{ min.}$$

Another complication arises when food liquids are processed. The relationship $v_{max} = 2\bar{v}$ for laminar flow applies only to Newtonian fluids, and most food liquids are non-Newtonian. The defining equation for viscosity relates shear stress to shear rate and, in its most general form, can be expressed as

$$\tau = \tau_0 + K\left(\frac{dv}{dr}\right)^n \qquad (13)$$

where: τ_0 = yield shear stress
K = apparent viscosity
$\frac{dv}{dr}$ = shear rate
n = flow behavior index

If $\tau_0 = 0$ and $n = 1$, the equation represents a Newtonian fluid. If $n \neq 1.0$, the fluids are referred to as power-law fluids. For aseptic processing of liquids under flow conditions $\tau_0 = 0$ and for most foods, $n < 1.0$. These fluids are shear thinning (*i.e.* apparent viscosity decreases as shear rate increases) and are called pseudoplastics. For $n > 1.0$, apparent viscosity increases with shear rate, and these fluids are called dilatant. There are very few dilatant food fluids. Dilatant liquids are usually those containing larger particles which disintegrate during fluid flow, resulting in increases in apparent viscosity. Dilatant behavior may also be exhibited with swelling of particles (*e.g.* starch gelatinization) or thermal aggregation (*e.g.* protein denaturation/aggregation).

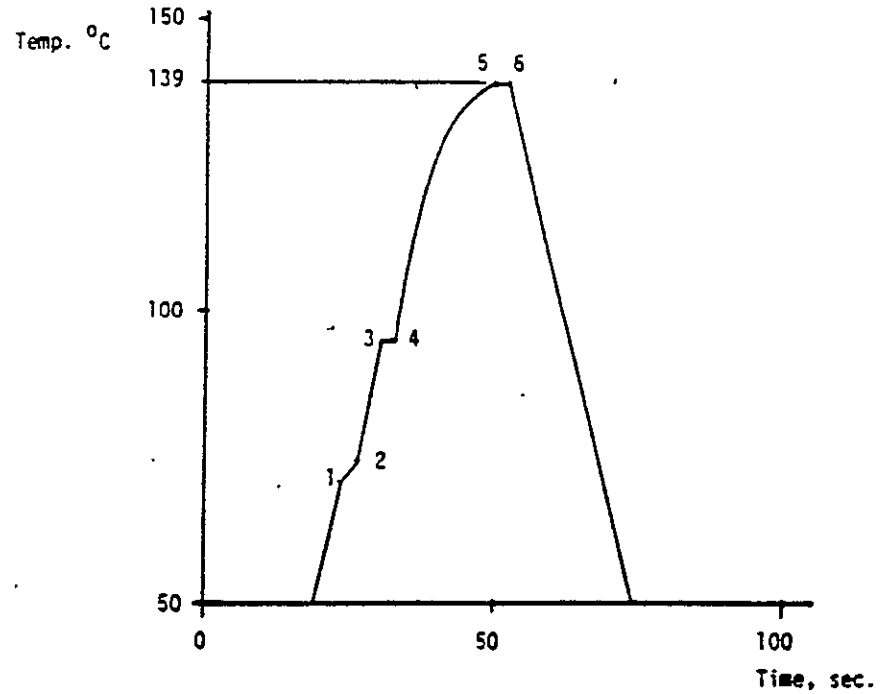
Analysis of velocity distribution for a non-Newtonian fluid in laminar flow in a tube results in,

$$\frac{\bar{v}}{v_{max}} = \left(\frac{1+n}{1+3n}\right) \qquad (14)$$

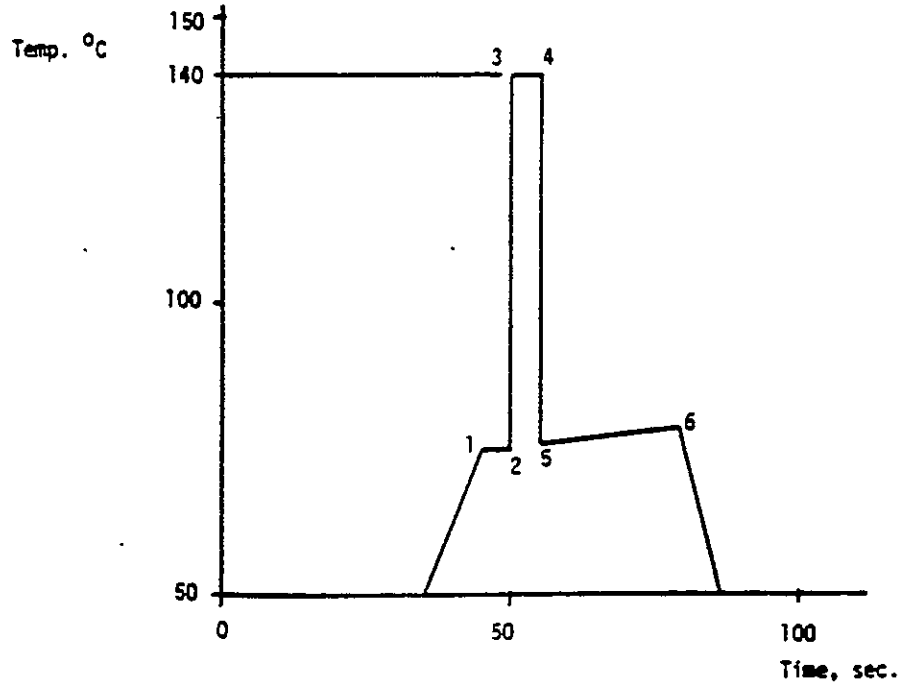
where n = flow behavior index.

For n = 1 (Newtonian fluid), this results in the familiar $v_{max} = 2\bar{v}$. For pseudoplastic liquids (most foods), $v_{max} < 2\bar{v}$. Thus, for most food liquids processed aseptically, a limiting case for the maximum velocity is $v_{max} = 2\bar{v}$. The relationship between $\bar{v}/v_{max}$ and Reynolds number for various values of flow behavior index(n) is shown in *Figure 5* (Palmer and Jones, 1976). It can be seen that for Newtonian (n = 1) and pseudoplastic fluids (n < 1.0) in both laminar and turbulent flow, the limiting case is $\bar{v}/v_{max}$ =

Figure 4. Time-temperature profiles for aseptic processes. (from Hallstrom, 1977, used with permission)

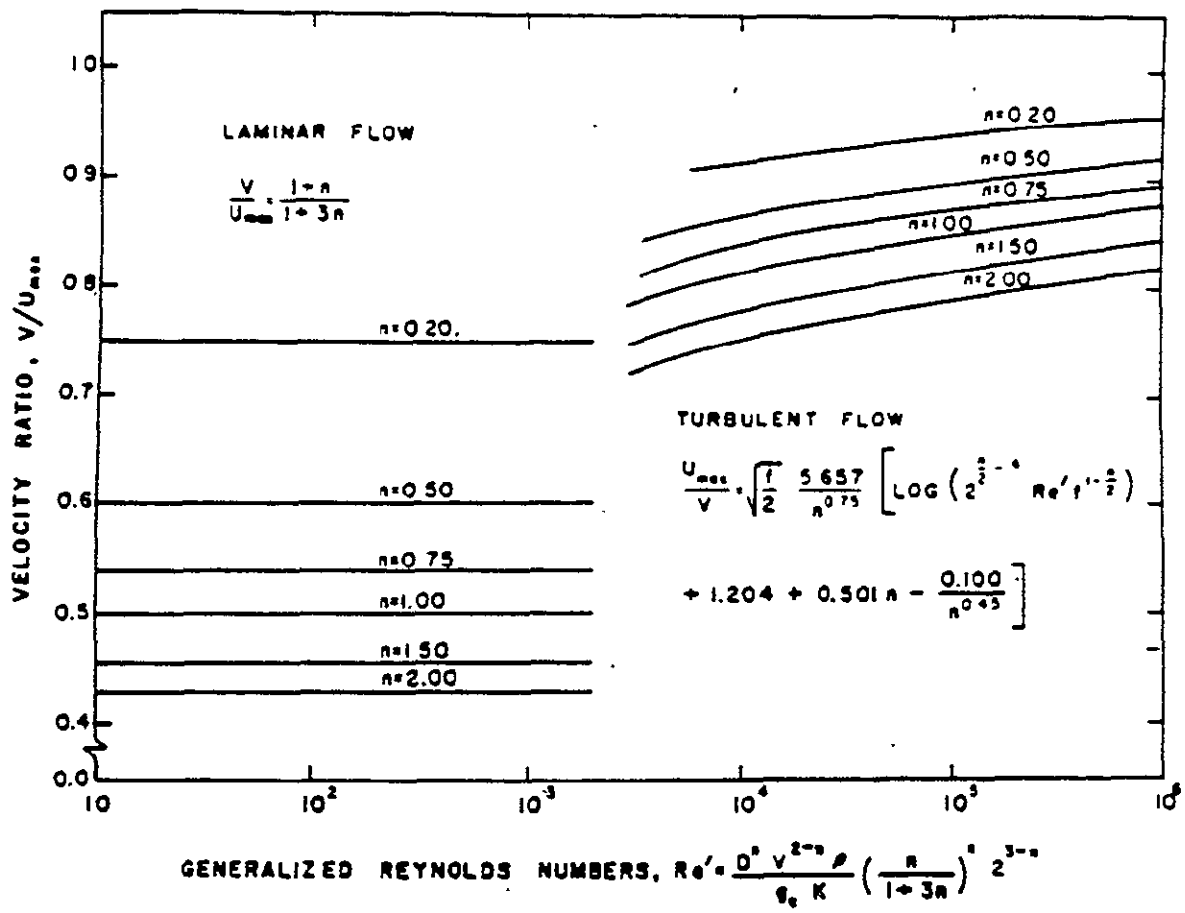


Time–temperature relationship for indirect heated UHT system. 0–1, preheater; 1–2, homogeniser, 71–74 °C, 25 s; 2–3, recuperative heater, 74–95 °C, 4·5 s; 95 °C, 2 s; 4–5, steam heater, 95–139 °C, 17·5 s, $T = 142{\cdot}3[1 - 0{\cdot}3324\exp(-0{\cdot}1524\tau)]$; 5–6, holding tube, 139 °C, 2·4 s; 6–7, recuperative cooler, 139–50 °C, 21·6 s.



Time–temperature relationship for direct heated UHT system. 0–1, preheater; 1–2, 75 °C, 5·1 s; 2–3, steam injector, 75–140 °C, ~0 s; 3–4, holding tube, 140 °C, 5·1 s; 4–5, flash cooler, 140–76 °C, ~0 s; 5–6, homogeniser, 76–79 °C, 24·1 s; 6–7, cooler, 79–20 °C, 15 s.

Figure 5. Velocity ratio-generalized Reynolds number correlation for power-law fluids. (from Palmer and Jones, 1976, used with permission)



0.5. This is also true for dilatant fluids in turbulent flow but *not* in laminar flow. Because of this complication with residence time distribution, the FDA procedure for calculating residence time is based on $v_{max} = 2\bar{v}$ for Newtonian and pseudoplastic liquids in laminar flow. Thus the minimum residence time and tube length are related by

$$v_{max} = 2\bar{v} = \frac{L}{t_{min}} \qquad (15)$$

For a dilatant fluid, in laminar flow it would be necessary to perform experiments to measure the residence time distribution (or minimum residence time) in order to establish the correct holding tube length. As pointed out earlier, there are very few examples of dilatant food fluids.

For fluids in turbulent flow it can be seen that $\bar{v}/v_{max}$ is always greater than 0.5 regardless of the nature of the food fluid (Newtonian, pseudoplastic or dilatant). Consequently, a limiting case for design of the holding tube could be Equation 15. However, it is also clear that using the ratio $\bar{v}/v_{max} = 0.5$ would result in overprocessing the food. For example, if $\bar{v}/v_{max} = 0.75$ rather than 0.5, then,

$$v_{max} = \frac{4}{3}\bar{v} = \frac{L}{t_{min}} \text{ and } t_{min} = \frac{0.75L}{\bar{v}}$$

By assuming $\bar{v}/v_{max} = 0.5$ and designing the hold tube length, the minimum residence time would be

$$v_{max} = 2\bar{v} = \frac{L}{t_{min}} \text{ and } t_{min} = \frac{0.5L}{\bar{v}}$$

Assuming the same tube diameter, the same mean velocity (*i.e.* same mass flow rate), and the same tube length, the actual minimum residence time would be 50% greater than the designed minimum residence time. This increase would lead to overprocessing the food fluid and result in loss of quality factors which the aseptic process was designed to maintain. Thus for turbulent flow, the hold tube length can be designed based on actual minimum residence time.

It is important to recognize that, for non-Newtonian fluids, the Reynolds number must be modified to account for the velocity dependence of viscosity. Using Equation 13, it can be shown that the Generalized Reynolds number is

$$G_{RE} = Re' = \frac{D^n V^{2-n} \rho}{K}\left(\frac{n}{1+3n}\right)^n 2^{3-n}$$

This equation should be used to calculate the Reynolds Number to establish the type of flow in the hold tube

The previous section provides a brief description of residence time distribution in the holding tube which is assumed to be isothermal (*i.e.* no significant heating or cooling of the product). Residence time distribution during heating and cooling is much more complex because of the effect of temperature on the viscous properties of the liquid. Because of this complication, in the past the FDA considered lethality which occurred in the holding tube as the basis for the thermal processes. Lethality contributed by heating and cooling sections are considered safety factors. More recently, FDA will accept lethality occurring in the heating and cooling sections if appropriate data are presented. These exceptions are treated on a case by case basis.

One of the more important aseptic heat transfer units is the scraped-surface heat exchanger (SSHE). Chen and Zahradnik (1967) published one of the first papers on residence time distribution in SSHE and the corresponding effect on lethality. Using a Newtonian fluid, they concluded that, although increased mutator speed resulted in an increased rate of heat transfer, it also resulted in a broadening of the residence time distribution. Subsequently, Milton and Zahradnik (1973) investigated SSHE residence time distribution with a Non-Newtonian fluid. As with a Newtonian fluid, an increase in mutator speed resulted in a broadening of the residence time distribution. Cuevas *et al.* (1982) concluded that thermal processes based on mean residence time in SSHE resulted in gross underprocessing of the fluid. They also concluded that the SSHE they used could best be described as behaving somewhere between ideal plug flow ($v_{max} = \bar{v}$) and laminar flow ($v_{max} = 2\bar{v}$).

Thermal Process Calculation

Two important assumptions are made for thermal process calculations in aseptic processing:

(1) lethality occurring only in the holding tube counts; and

(2) the minimum residence time in the holding tube is based on $v_{max} = 2\bar{v}$ for laminar flow of Newtonian and pseudoplastic food fluids and the relationship v/v_{max} must be determined for turbulent flow.

To illustrate the procedure, consider a product in laminar flow.

Since $t_{min} = L/2\bar{v}$ and F = lethal rate @ $T_{hold} \times t_{min}$

$$F = \frac{1}{10^{(250-T)/z}} \times t_{min} = \frac{1}{10^{(250-T)}} \times \frac{L}{2\bar{v}}$$

where T = temperature in the holding tube.

Since the design F value is known from experimentation or from experience the length of the holding tube can be calculated as follows:

$Q = 7.48\,A\bar{v}$ where Q = volumetric flow rate [=] gal/min

A = cross-sectional area of the tube [=] ft^2

$\bar{v}$ = average velocity [=] ft/min

7.48 = 7.48 gal/ft^3

$\bar{v} = Q/7.48A = 4Q/7.48\pi D^2$

where π = 3.14

D = tube diameter [=] ft

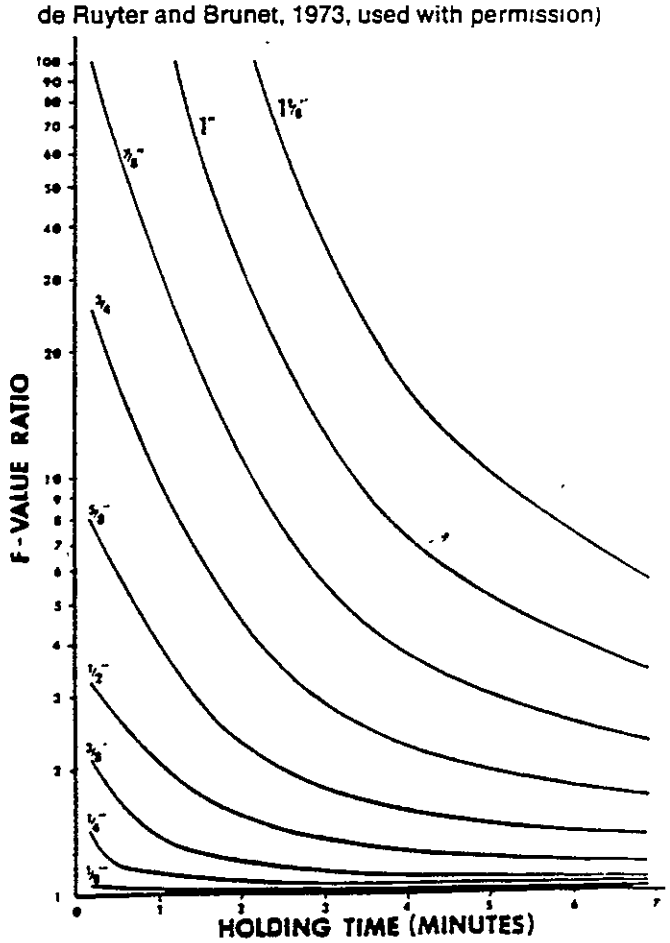
$$L = 2\,F\,\bar{v}(10^{(250-T)/z}) = \frac{8\,F\,Q\,(10^{(250-T)/z})}{7.48\pi D^2}$$

where F = design lethality [=] min @ 250°F

Processing Particulates

Heat transfer in aseptic processing of fluids is governed by forced convection heat transfer. Scraped-surface heat exchangers (SSHE) were developed to increase heat transfer and reduce burn-on (fouling) for viscous liquids. De Ruyter and Brunet (1973) were among the first to consider heat transfer to heterogeneous fluids (liquid plus particles). They presented a model for heat transfer to the fluid and subsequently to the particle in an SSHE. Unfortunately in their model they used an infinite surface heat transfer coefficient at the particle surface (equivalent to saying that the surface of the particle is equal to the surrounding liquid temperature). Although this assumption is not very good, their results clearly illustrate the problem of heating the particle in a liquid. *Figure 6* presents the

Figure 6. F-value ratio (liquid phase/particle center) as a function of holding time and particle diameter. (from de Ruyter and Brunet, 1973, used with permission)



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ratio of the F-value in the liquid phase to the F-value in the particle as a function of holding time with particle diameter (assumed spheres) as the parameter. As particle size increases, the $F_{liquid}/F_{particle}$ increases at all holding times, indicating that the liquid phase would be grossly overprocessed if the process were designed to achieve a desired F-value in the particle.

Manson and Cullen (1974) subsequently considered aseptic processing in SSHE of foods containing discrete particles. The particles were assumed to be cylinders, and the liquid phase was assumed to be either pseudoplastic (shear thinning) or Newtonian. They also incorporated a residence time distribution into the estimation of the integrated lethality which particle and liquid receive in the thermal process. They concluded that it is very important to know the viscometric characteristics of the liquid and the flow regime (turbulent or laminar flow) to assure adequate holding tube length. Unfortunately Manson and Cullen also assumed an infinite heat transfer coefficient at the surface of the particle and thus they overestimated the lethality received by the particles.

An important concept was reemphasized by Manson and Cullen when considering lethality achieved in a system in which there is a distribution of lethalities. To estimate the lethality achieved in a system, the probabilities of survivors in each component are summed, not the lethalities. For example, assume that a product is composed of 50% (v/v) particulates and the container originally has 2,000 spores. Furthermore, assume that the liquid receives an F_S (integrated lethality) of 12 minutes and the particles receive an F_S of 4.0 minutes. If the D-value is 1.0 minute at 250°F, then the probability of survivors (b) can be calculated for each phase.

For liquid

$$FS = D(\log c_i - \log b)$$
$$12 = 1(\log 1{,}000 - \log b)$$
$$b = 10^{-9} = 0.000000001$$

For particulates

$$4 = 1(\log 1{,}000 - \log b)$$
$$b = 10^{-1} = 0.1$$

The F_S for the product is thus:

$$F_S = 1(\log 2{,}000 - \log 0.100000001)$$
$$= 1[3.301 - (-1)]$$
$$F_s = 4.3 < \frac{F\ \text{liquid} + F\ \text{particles}}{2} = \frac{12 + 4}{2} = 8$$

Because of the problem associated with heat transfer from the liquid to the particle, it is obvious that the particle should be heated in a relatively non-viscous liquid or, better yet, in condensing steam. Hersom and Shore (1981) presented this concept in describing the Jupiter system manufactured by APV Co., Ltd. The system utilizes a batch sequential process for the solids and a continuous process for the sauce. Although the heat transfer to the particles is by condensing steam, an adequate description of the time/temperature profile of the particulates has not been developed. The authors checked the lethality achieved in the particles by using small bulbed capillary tubes containing spores of *B. stearothermophilus* suspended in buffer. Complications for calculating the temperature include mixing in the double cone mixer and outgassing which occurs as the vegetables are heated.

Thermal Process Control

Obviously aseptic processing systems must be subject to the same type of fail-safe control strategies that in-container sterilization systems are. Teixeira and Manson (1983) reviewed a computer model for calculating lethality achieved in aseptic processes based on all lethality occurring in the bold tube. They described the application of an Eolkin Plastometer for measuring viscometric characteristics in-line prior to the holding tube. This device could then be used to ensure that the minimum residence time would be achieved in the hold tube. If the minimum residence time could not be achieved, a flow divert valve would activate. A better control system, however, would be to adjust the holding temperature to account for the reduction in hold time. This method would require measuring the viscometric characteristics sufficiently upstream so that temperatures could be changed. Currently, the requirements for control are on the exit temperatures from the hold tube.

Summary

The design to achieve commercial sterility in aseptic processing is based on the well-founded principles of thermal bacteriology and integrated effect of time/temperature treatment on spores of microorganisms. Complications arise because of residence time distribution of liquids flowing in tubes or through channels. As a result of these complications, aseptic thermal processes are designed by considering that (1) lethality occurs only during holding (*i.e.* no lethality during heating or cooling) and (2) the minimum residence time in the holding tube is based on the viscous characteristics of the food fluid and the type of flow. Thus, currently, the basic control unit for the process is a temperature measuring device on the outlet of the hold tube which can control a flow diversion valve (which diverts in the event the temperature is too low) and a metering pump located at the entrance to the holding tube section.

CHARACTERISTICS OF SPECIFIC ELEMENTS

Flow Control

Aseptic processing relies on a continuous flow of product and a continuous flow of packages. Elements associated with the continuous flow of packages will be covered elsewhere. The continuous flow of product relies on pumps, and they are a critical consideration in the design of an aseptic processing system. FDA regulations state, "A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. A means of preventing unauthorized speed

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changes shall be provided." The metering pump (sometimes referred to as the timing pump) is a positive displacement type because this type is less sensitive to pressure drop than are centrifugal pumps. Centrifugal pumps are used in aseptic processing systems especially for initial sterilization of the system with hot water and for clean-in-place

Selection of the type of positive displacement pump is dependent on product characteristics such as viscosity and presence of particulates, pressure drop in the system, and cost. When the pressure drop in the system is less than 150 psi and the product is homogeneous or contains small particles (*e.g.* less than one eighth inch on the maximum dimension), a rotary positive displacement pump is usually the most economical choice. At higher pressure drop with homogeneous products, a high pressure piston type pump would be used, and at pressures over 2,350 psi, this type of pump is the only one capable of performing. For products with particulates up to three inches in size, the reciprocating piston pump is the metering pump of choice.

Heat Transfer (Heating/Cooling)

Increasing the temperature of the product to the holding temperature and subsequently cooling the product prior to packaging is performed continuously using heat exchangers. Various methods are used, but essentially the systems can be divided into direct and indirect heat exchange methods.

Direct Heating/Cooling

In this method, the product is heated by direct contact with steam which condenses giving up its latent heat to increase the sensible heat (temperature) of the product. Steam can contact the product in one of two ways: steam injection or steam infusion. Both systems are used commercially for aseptic processing of food fluids. In steam injection *(Figure 7)* steam is dispersed into the product stream by using an injector. Steam infusion, on the other hand, relies on dispersing the product into a steam atmosphere *(Figure 8)*. The product can be sprayed into the steam or distributed as free falling sheets, depending on equipment manufacturer.

As a rule of thumb, approximately one pound of steam will condense for every 10 pounds of product heated 100°F. Thus the dilution rate of the product is 10%. Added water must be accounted for in product formulation or it must be removed. Usually the water is removed by flash cooling the product. The hot product is dispersed into a vacuum vessel operating at a pressure such that the amount of water that was added during steam heating will flash evaporate. The latent heat for flash evaporation comes from the sensible heat of the product, resulting in cooling the product. Since product volume increases in direct steam heating due to added water, it is necessary to account for this situation in sizing the hold tube to achieve the scheduled process.

Direct heating has several advantages, including: (1) relatively low initial cost; (2) most rapid method of heating and cooling (nearly instantaneously); (3) minimum burn-on (fouling); (4) minimum floor space; (5) no moving parts; and (6) dearation of the product upon flash cooling The disadvantages associated with direct heating are: (1) water from steam condensate dilutes the product; (2) culinary steam is required; free of noncondensible gases; (3) the product may be destabilized due to high shear when steam condenses and is flashed from the product; (4) controls are required to insure no boiler chemical carryover; and (5) it may be difficult to control final temperature and solids content in the product.

Indirect Heating/Cooling

For indirect heating the product does not come into contact with the heating or cooling medium but, rather, heat is transferred through a surface. The surface of choice is stainless steel. For heating/cooling liquids, there are three major types of indirect heating units: plate, tubular, and scraped-surface heat exchangers.

Plate heat exchangers consist of a number of corrugated, gasketed, thin stainless steel plates ordered together in a frame such that the product flows on one side of the plate and the heating or cooling medium flows on the other side *(Figure 9)*. The plate type heat exchanger is commonly used for nonviscous products, such as dairy and juice products. The heating medium is usually hot water or steam. Hot water is used when the product is particularly prone to fouling.

Frequently product-to-product heat exchange is used in plate heat exchangers to reduce the cost of heating and cooling. This practice, called regeneration, cools the hot product while preheating the cold product. Since the hot sterile product is used indirectly to preheat the cold unsterile product, it is absolutely necessary to operate the regenerative section so that the **pressure on the sterilized product side is at least 1 psi greater than the pressure on the nonsterilized product side.** There must be an accurate differential pressure recorder-controller installed on the regenerator. One pressure sensor must be installed at the sterilized product outlet and the other, at the nonsterilized product inlet.

Some advantages of plate heat exchangers are: (1) low initial cost with high efficiency for heat transfer; (2) small hold up volume in the heat exchanger; (3) usually easy inspection of the unit by disassembling; and (4) flexibility of the system since it can be readily expanded or contracted to perform multiple duties. The main disadvantages are: (1) the plate exchanger is generally limited to low viscosity products; (2) regasketing costs can be high; and (3) fouling tendencies exist for some products.

Tubular heat exchangers *(Figure 10)* use concentric stainless steel tubes to separate the product from the heating/cooling medium or consist of a coiled tube in a shell. In the double tube and coiled tube-in-shell types, the product flows inside the tube whereas, in a triple tube style, the product flows in the annular area. In each type, the heating or cooling medium flows countercurrent to the product to maximize heat exchange efficiency. The main advantages of the tubular unit are: (1) there are few gaskets, thereby minimizing maintenance costs; (2) the units are compact; and (3) there are no moving parts. The dis-

Figure 7. Steam injection

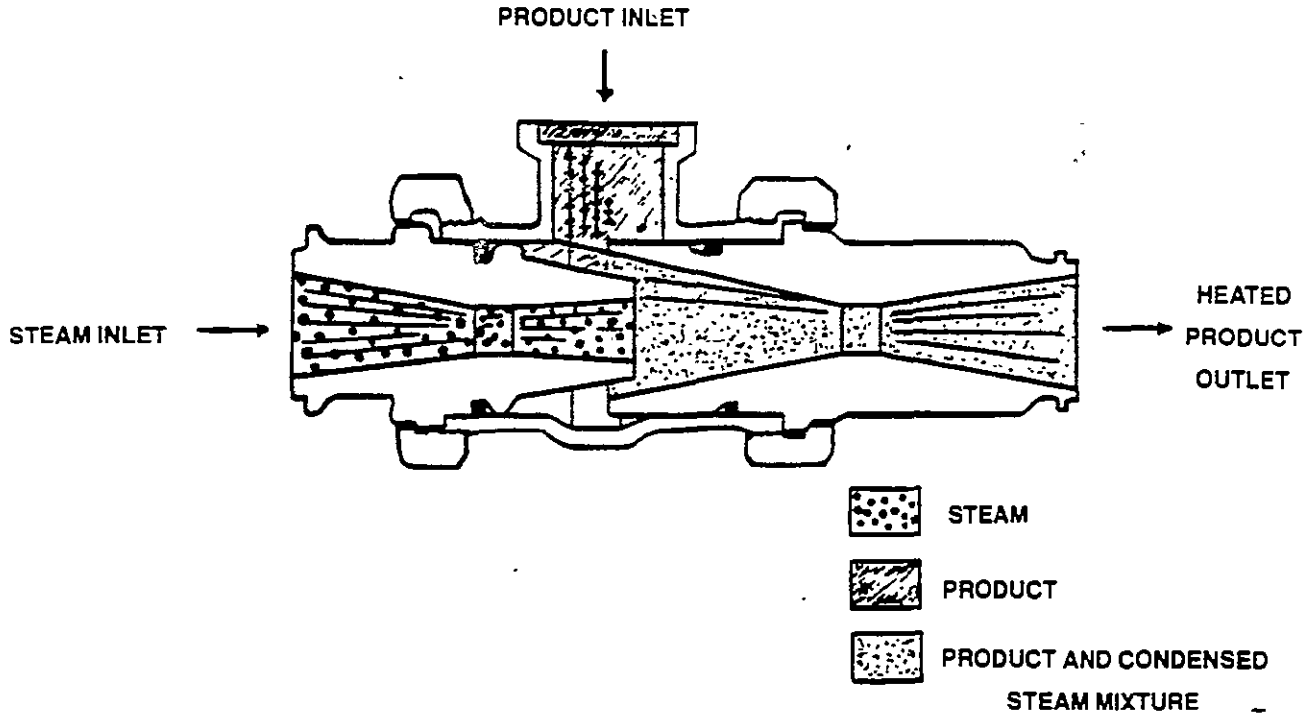
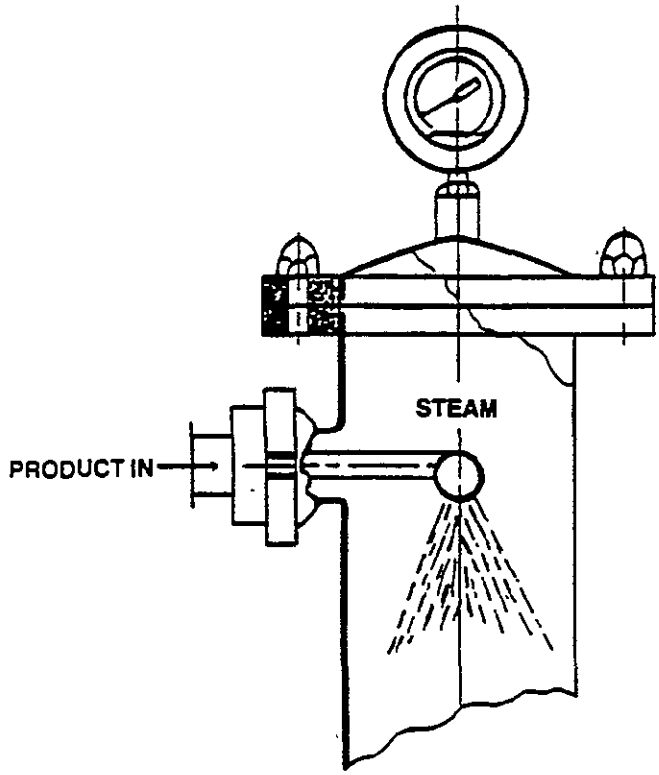


Figure 8. Steam infusion.



advantages include: (1) excessive pressure drops; (2) inability to open and inspect the surfaces; (3) maximum regeneration of 70–75%, which is lower than that for plate exchangers; (4) fouling tendencies because of low shear; and (5) restriction of products by viscosity and particle size.

For more viscous products, the scraped-surface heat exchanger (SSHE) *(Figure 11)* is best suited. It consists of a mutator shaft with scraper blades concentrically located within a jacketed, insulated heat exchange tube with clearances of one-fourth to two inches. The blades rotating at 40–400 rpm continuously remove the product from the wall, increasing heat transfer and reducing burn-on. The heating or cooling medium flows on the outside of the product tube and, in some designs, can also flow through the mutator tube. The units are generally mounted vertically and the product is introduced at the bottom to eliminate air. Advantages of the SSHE include: (1) the ability to process any pumpable product, including those containing particulate matter; (2) flexibility to expand the system by adding surface area; (3) low pressure drops; and (4) ability to process at very high temperatures without burn-on. Significant disadvantages are: (1) high cost per units area; (2) high operating costs; (3) large floor space requirement compared to other types; and (4) disintegration of fragile particles. *Table 1* summarizes the characteristics of the heat exchange systems used for aseptic processing of liquids.

Each of the heat exchangers described above is used in continuous processing systems which require a pumpable product. If particles are present, they must be relatively small (less than one-half inch for the longest dimension) and resistant to shear. For particulate products, two systems have been developed. Acid foods, such as fruits, are subjected to steam heating in a continuous steamer. The operating system consists of a device to evenly feed the product to a chamber maintained slightly above atmos-

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Figure 9. Plate heat exchanger.

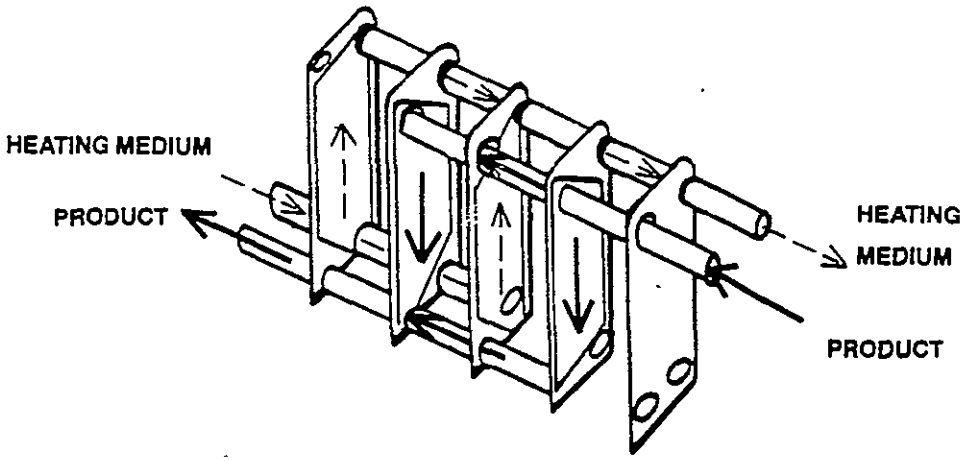


Figure 10. Tubular heat exchangers.

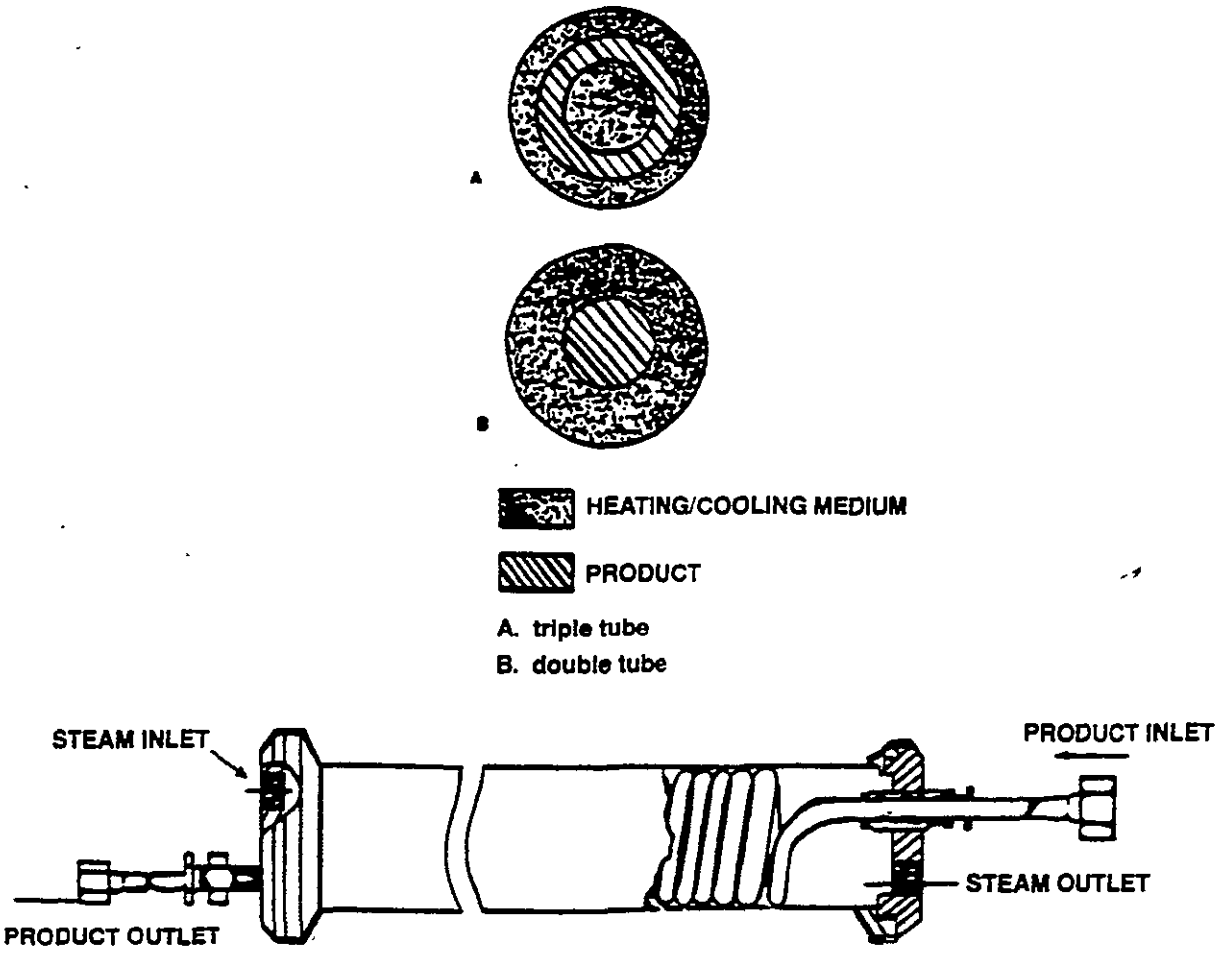
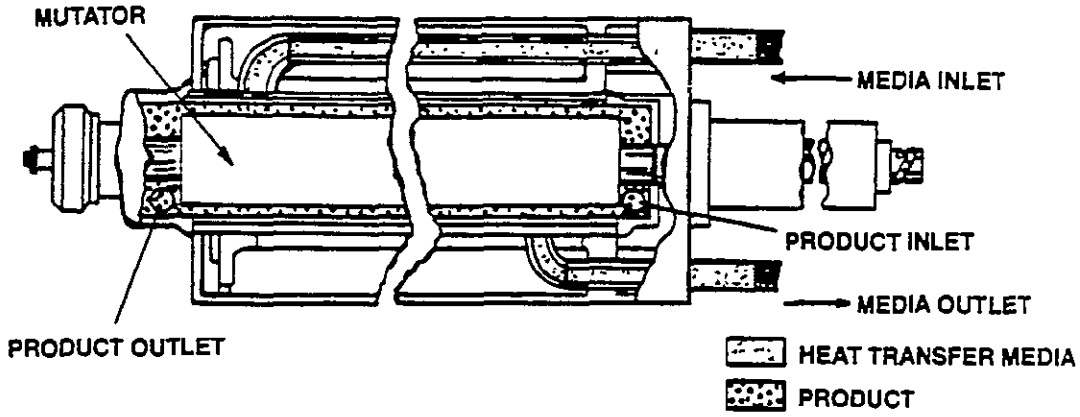


Figure 11. Scraped-surface heat exchanger.



pheric pressure by steam injection. The product is gently conveyed in contact with steam heated surfaces and in hot compatible liquids and juices. The product is held for the required time and is discharged through an aseptic pressure lock to the cooling vessel. The cooling vessel is pressurized with sterile nitrogen, and the product is cooled with sterile cooling media such as syrup, water, juice or brine.

For non-acid piece-form foods, several commercial systems have been designed and built. However, most are wholly unsatisfactory. These systems have generally consisted of a batch-type unit for heating and cooling the particulates, coupled to a continuous system for processing the sauce, water, or other liquid. In one system (Hersom and Shore, 1981) the sterilized liquid is pumped into the vessel with the sterilized particles and, from there, the mixture is transferred to the filling machine. The major advantages of this system are the ability to process large particulates and to heat and cool the particulates without sauce or liquid, thereby eliminating overprocessing of the liquid. The major disadvantages include that it is a batch system, that it is very expensive, and that there are a number of transfers which must be made aseptically.

Hold Tube

For continuous systems, the hold tube is designed to accomplish the design lethality for the product. Thus the temperature must be maintained at a specified minimum in the hold tube, and the minimum residence time must be established so that, at that hold temperature and residence time combination, product sterility is assured. The time/temperature combination is calculated according to principles discussed earlier. Since the hold tube is the heart of the process to insure commercial sterility, certain precautions must be followed. **It must be sloped upwards at least 0.25 inch per foot** to eliminate air pockets and ensure self draining. It must be constructed with good sanitary design criteria, such as a smooth interior without protrusions, easily disassembled for inspection and a fail-safe system for reassembly so the hold tube is not shortened or changed in diameter (this would change the minimum residence time). The tube should not be exposed to condensate drip or draft of cold air, which could affect product temperature in the tube. Heat cannot be applied at any point along the tube. Finally the pressure in the hold tube must be maintained sufficiently above the vapor pressure of the product at the process temperature to prevent flashing or boiling. This is usually accomplished by a back pressure valve.

The temperature of the product in the hold tube is monitored at both the inlet and outlet of the hold tube (*i.e.* at the exit from the final heater and at the end of the hold tube prior to the cooler, respectively). A temperature recorder-controller is used at the inlet so that a deviation of temperature from set point can initiate an appropriate action in the heater to return the temperature to set point. At the outlet of the hold tube, between the exit of the tube and the entrance to the cooler, an automatic recording thermometer must be used with chart graduations not exceeding 2°F (1°C) within a range of 10°F (6°C) of the desired product sterilization temperature. The product temperature measured at the exit of the holding tube is used to determine the adequacy of the process for commercial sterilization.

Deaerators

Most products which are aseptically processed must be deaerated prior to packaging. The air is removed to prevent undesirable oxidative reactions which occur as the product temperature is increased during the process. The deaerator generally consists of a vessel in which the product is exposed to a vacuum on a continuous flow. The location of the deaerator is dictated by the product. At higher temperature the noncondensable gases are less sol-

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Table 1

Equipment Type	Product Quality	Aroma Retention	Energy Saving	Capital Cost	Space	Pulp Capability	Fouling Length of Run	Turndown*
Steam Injection/ Infusion	Excellent	No	Poor	High	Fair	Fair-Good	Excellent	Fair
Plate Heat Exchanger	Good	Yes	Excellent	Low	Excellent	Limited	Limited	Good
Tubular								
Small Tubes	Medium	Yes	Fair	Medium	Good	Good	Limited	Good
Large Tubes	Poor	Yes	Fair	Low	Fair	Good	Good	Good
Swept Surface	Good	Yes	Very Poor	Very High	High	Fair-Good	Good	Good

*Turndown is the capability of the system to process at different rates to accommodate different number of fillers or different package sizes.

From: Dinnage (1983)

uble but the flavor constituents are also more volatile. Thus more flavor will be lost as the temperature of deaerating is increased. However, it is more economical to operate the deaerator at higher temperatures if the product will tolerate it. For aseptic processing, the residual oxygen in the product becomes even more important since many of the packaging materials exhibit an oxygen permeability which, even though small and not affecting asepsis, can lead to product quality deterioration over storage time.

Aseptic Surge Tank

Aseptic surge tanks are used in aseptic processing systems to allow the packer to accumulate a sterile product prior to packaging. Ranging in capacity from about one hundred gallons to several thousand gallons, the tanks provide flexibility, especially for systems in which the flow rate of sterile product is not compatible with packaging capacity. Valving that connects the surge tank between the end of the cooling section and the packaging system allows the processor to carry out the processing and packaging functions more or less independently. The product is pumped into the surge tank and is removed by maintaining a positive pressure in the tank with sterile air or other sterile gas. The positive pressure must be monitored and controlled to protect the tank from contamination.

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CHAPTER 3

RESIDENCE TIME DISTRIBUTION IN ASEPTIC PROCESSING

Rakesh K. Singh

INTRODUCTION

As pointed out in the previous chapter, the design of a thermal process to achieve commercial sterility in aseptic processing incorporates the principles of thermobacteriology and integrated effect of time/temperature treatment on microbial spores. However, in continuous systems, except in the cause of an ideal plug flow situation, each fluid element will spend different lengths of time to flow through the heat exchanger or the holding section. Conceivably, each fluid element will receive a different degree of sterility depending on the length of time that particular element spends in the heat exchanger or the holding tube. Therefore, in order to predict the lethality received by each volume element of the product, one must be able to determine the length of time that different elements spend in the system or, in other words, their residence time distribution.

Experimental determination of residence time distribution is carried out by measuring the response of an inert tracer in the feed stream—the so-called stimulus-response technique. There are three general stimulus techniques commonly used in theoretical and experimental analyses of various system networks in order to characterize their dynamic behavior (Hill, 1977). These techniques are:

1. A step function change, in which the input concentration is changed from one steady level to another.
2. A pulse input, in which a relatively small amount of tracer is injected into the feed stream in the shortest possible time.
3. A sinusoidal input in which the frequency of the sinusoidal variation is changed and the steady state response of the exit stream at different input frequencies is determined, thus generating a frequency-response diagram for the system.

In principle any one of the three techniques mentioned above can be transformed into the other two. However, it is experimentally easier to monitor a tracer response that approximates a step change or an impulse function because the measurements associated with sinusoidal variations are much more time consuming and require special equipment. Therefore, in this chapter, only the first two types of stimuli will be discussed.

MEAN RESIDENCE TIME($\bar{t}$)

The mean residence time can be calculated if the product flow rate is known and it is assumed that there is no velocity distribution in the flow stream (*i.e.*, all the particles are traveling at the same speed). In such a situation, the mean residence time is simply the volume of test zone divided by the product flow rate.

Example 1. Orange juice flows through a straight pipe (2" i.d.) 21 feet long, at a flow rate of 3 gal/min. What is the mean residence time of orange juice in the pipe?

Volume of orange juice in the pipe

$$= 21\text{ ft} \times \pi \times \left(\frac{1}{12}\text{ ft}\right)^2$$

$$= 0.458\text{ ft}^3$$

Flow rate of orange juice $= 3$ gal/min

$= 0.482\text{ ft}^3/\text{min}$

Mean Residence time ($\bar{t}$) $= \dfrac{0.458\text{ft}^3}{0.482\text{ft}^3/\text{min}} \times \dfrac{60\text{ sec}}{\text{min}}$

$= 57$ sec

F(t) – CURVES FOR VARIOUS FLOW PATTERNS

This chapter utilizes the F(t) curve, as defined by Danckwerts (1953). For a continuous flow system, F(t) is the volume fraction of the outlet stream that has remained in the system for a time less than t. To obtain an F(t) curve, subject the inlet product stream to a step input of tracer. According to this definition of the F(t) curve, the probability that any element of volume entering the system at time t = 0 has left it within time t is just equal to F(t)

The probability that the element is still in the system and will leave at a time later than t is [1 − F(t)].

It will always take a finite time for a fluid element to traverse the system, so F(t) = 0 at t = 0. Likewise, none of the material can remain in the flow system indefinitely, so F(t) = 1.0 at t = ∞. Let us examine these limiting values of F(t) curves for various types of ideal flow.

a) **Laminar Flow**

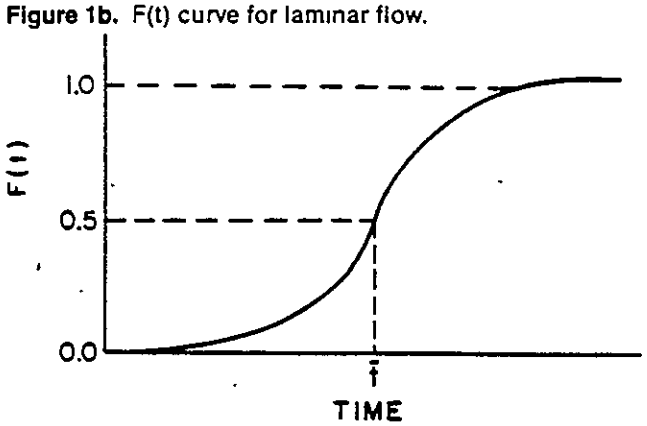
Laminar flow is characterized by its parabolic velocity profile, as shown in *Figure 1a*.

Figure 1a. Velocity profile of laminar flow.

Product elements in the center of the stream move fastest and will thus leave the system before the elements closer to the walls.

An F(t) curve for this type of flow is shown in *Figure 1b*.

Figure 1b. F(t) curve for laminar flow.



Note that the F(t) curve for laminar flow is a smooth sigmoid shape and is symmetrical about t̄. In the ideal situation 50% of the product would exit the system before the mean residence time.

b) **Plug Flow**

Ideal plug flow is characterized by its distinctive flat velocity profile, as shown in *Figure 2a*. In this case all of the fluid elements across a section of the flow system move at the same speed and thus they exit at a time equal to the mean residence time.

Figure 2a. Velocity profile for plug flow.

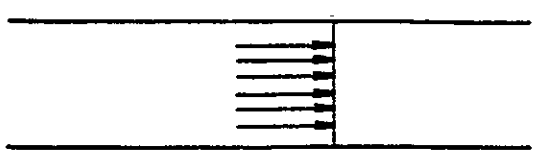
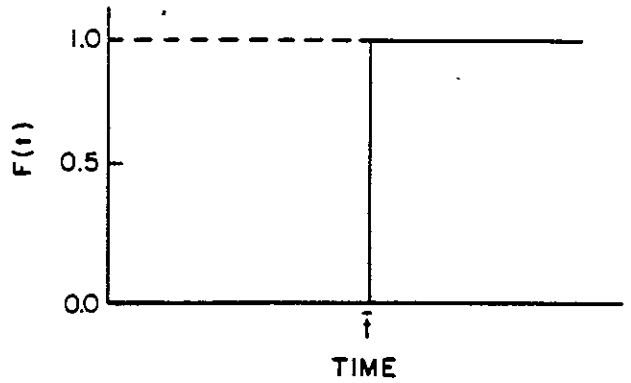


Figure 2b shows an F(t) curve for product in plug flow. Notice the "stair-step" nature of F(t) curve for plug flow.

Figure 2b. F(t) curve for plug flow

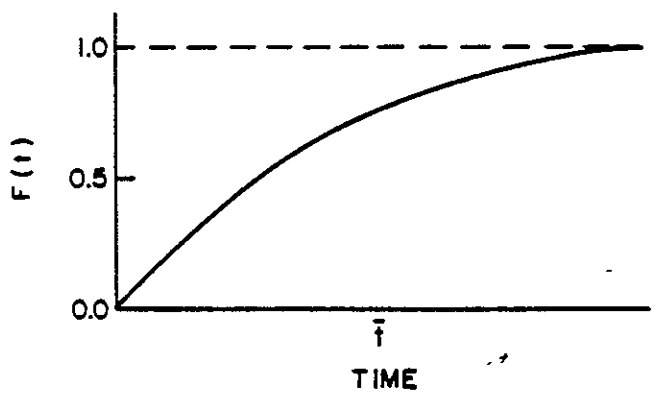


c) **Continuous Stirred Tank Reactor (CSTR)**

If the product flows through a CSTR or a mixing vessel, perfect mixing is assumed in the reactor. This implies that, upon entry in the reactor, an element of volume can instantaneously appear in any portion of the reactor (Levenspiel, 1972).

The response of a single ideal stirred tank reactor to ideal step input is shown in *Figure 3*. Note that any change in the reactor inlet stream shows up immediately at the reactor outlet.

Figure 3. F(t) curve for an ideal CSTR.

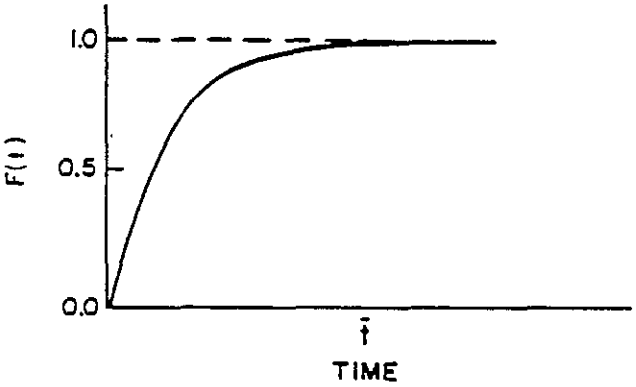


d) **Channeling**

Channeling is encountered when a portion of tracer emerges from a vessel in an unusually short time. The portion of tracer that exits the system before the bulk of tracer exits has found a "short cut" through the vessel. This happens when inlet and outlet of a CSTR are close to each other. In such situations, a portion of input tracer immediately flows out of the vessel before it can be well mixed.

Figure 4 shows a typical F(t) curve for a vessel with channeling. The large initial rise in the F(t) curve is due to the tracer that short-circuits and immediately exits the system.

Figure 4. F(t) curve for a vessel with channeling.



e) **Dead space**
Dead space leads to the situation of a nonideal flow. In this case, part of the fluid entering the zone is caught in the dead space, thus reducing the flow velocity through the pipe. Dead space occurs in corners, baffles, or regions with obstruction to flow. *Figure 5a* shows dead space in a pipe. The F(t) curve for plug flow in a pipe with dead space is shown in *Figure 5b*.

Figure 5a. Dead space in a pipe.

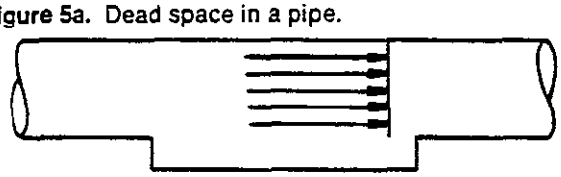
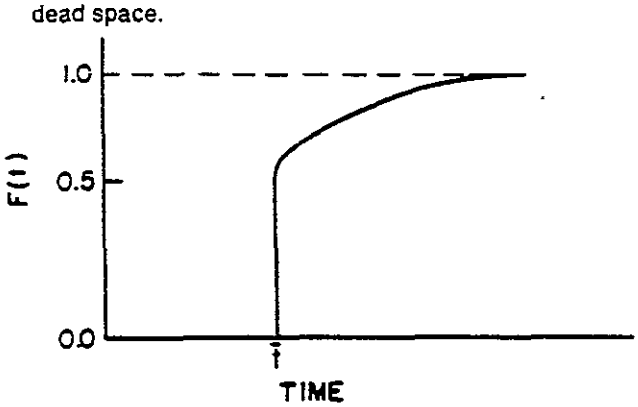


Figure 5b. F(t) curve for a plug flow in a pipe with dead space.



Notice that instead of the usual stair-step associated with plug flow, a step with a curved top is obtained. The curve is due to the portion of fluid which is caught in the dead space. The size and shape of the curve depend on the characteristics of the dead space.

E(t) CURVE

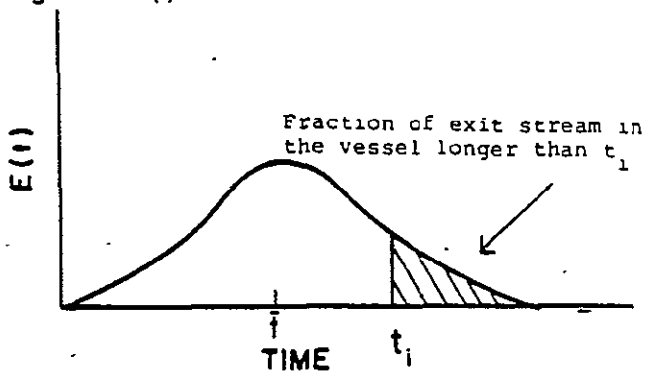
The E(t) curve is obtained from a pulse input. The E(t) curve gives the "fraction" of volume elements exiting the system at a particular time.

The E(t) curve is normalized distribution which means that the total area under the curve is unity or $\int_0^\infty E(t)\,dt = 1$. According to this definition, the fraction of volume elements in the exit stream that have spent less time in the vessel than t_i is $\int_0^{t_i} E(t)dt$.

Likewise, the fraction of volume elements in the exit stream that have spent more time in the vessel than t_i is $\int_{t_i}^\infty E(t)dt = 1 - \int_0^{t_i} E(t)dt$.

A graphical representation of an E(t) curve is shown in *Figure 6a*.

Figure 6a. E(t) curve for laminar flow.



E(t) Curves for Various Types of Flow

E(t) curves for various types of flow will be examined according to their definition as presented previously.

a) **Laminar flow**
The E(t) curve for a laminar flow is a bell shaped curve symmetrical about $\bar{t}$ *(Figure 6a)*.

b) **Plug flow**
The E(t) curves for plug flow under ideal and nonideal situations are shown in *Figures 6b* and *6c*, respectively.

c) **CSTR**
An E(t) curve for mixed CSTR has its maximum at time zero and gradually decreases with time *(Figure 6d)*.

Figure 6b. E(t) curve for an ideal plug flow.

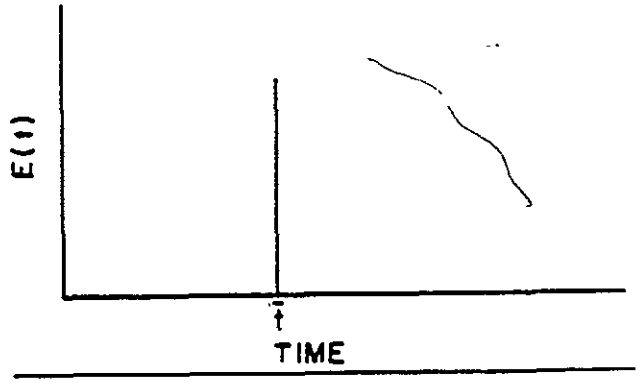


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Figure 6c. E(t) curve for a non-ideal plug flow

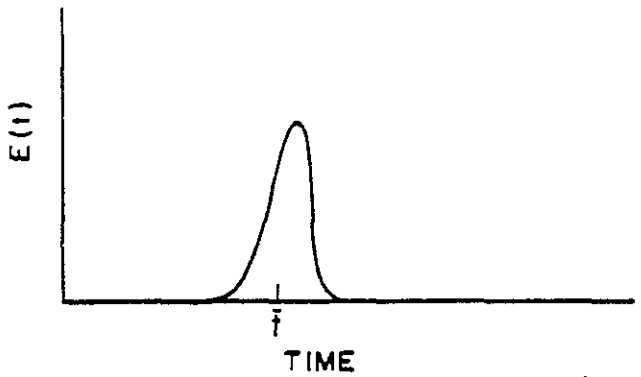
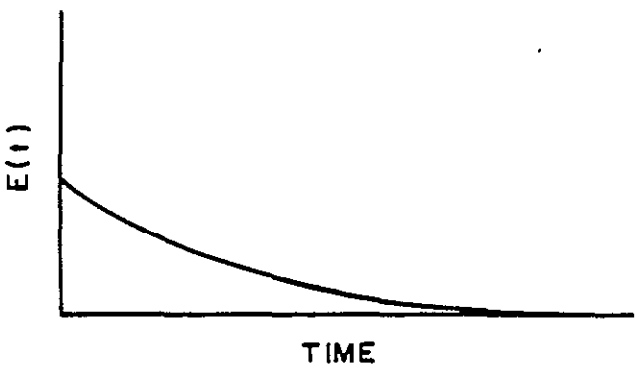
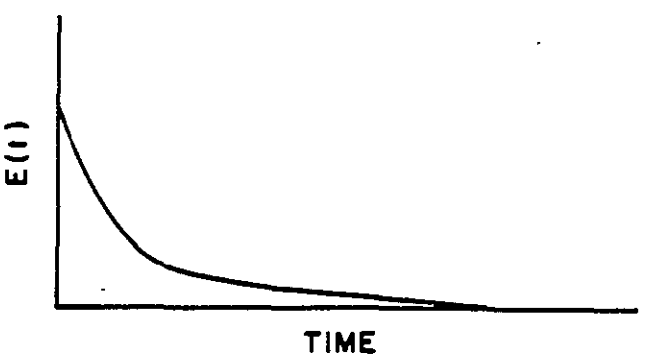


Figure 6d. E(t) curve for a CSTR.



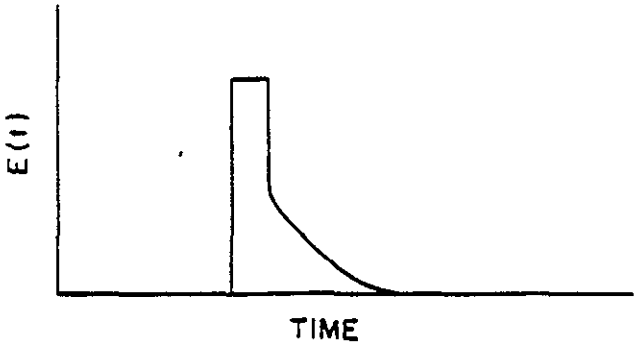
d) **Channeling**
The E(t) curve for a CSTR with channeling has the same shape as the one without channeling, but it has a sharper initial drop *(Figure 6e)*. Short-circuiting fluid that leaves the vessel quickly accounts for the large initial drop.

Figure 6e. E(t) curve for a CSTR with channeling.



e) **Dead space**
An E(t) curve for plug flow with dead space is shown in *Figure 6f*. The tail following the pulse is caused by the volume element that was slowed down due to the dead space.

Figure 6f. E(t) curve for a plug flow with dead space



REDUCED TIME (θ)

Time axis (*i.e.*, x-axis) of both F(t) and E(t) curves can be made dimensionless by dividing it by $\bar{t}$. Reduced time is used to compare systems of different sizes on an equal basis.

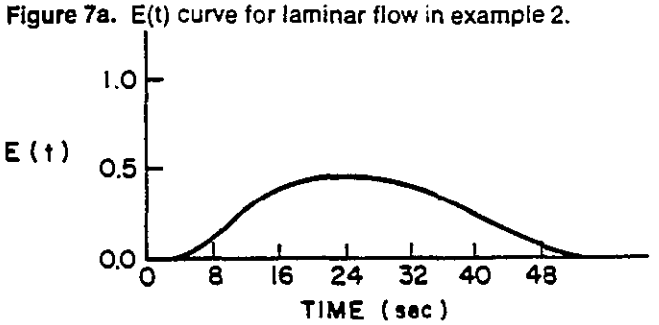
Example 2. A pipe is 10 ft long with a 2" inner diameter. Milk flows through the pipe at a rate of 3 gal/min. The E(t) curve for the milk is given in *Figure 7a*. Draw the dimensionless E(t) curve.

Step 1. calculate $\bar{t}$ as:

$$\bar{t} = \frac{10\text{ ft} \times \pi \times (1/12\text{ ft})^2}{0.482\frac{\text{ft}^3}{\text{min}}} \times \frac{60\text{ sec}}{\text{min}}$$

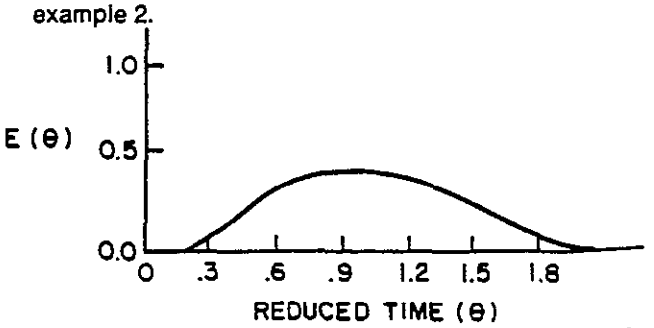
$$= 27\text{ sec}$$

Figure 7a. E(t) curve for laminar flow in example 2.



Step 2. Divide time (t) on the x-axis by 27 sec. to get the dimensionless E(t) curve value on the y-axis *(Figure 7b)*.

Figure 7b. Dimensionless E(t) curve [E(θ) curve] for example 2.



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COMPARISON BETWEEN E(t) AND F(t) CURVES

A simple example will be used to compare the two types of curves E(t) and F(t). Suppose that water is running through a vessel and, at some instant t_0, a 1 M solution of HCl replaces the water. A pH meter is used to measure the concentration of acid in the outlet stream. At any time t_i is greater than t_0, only acid solution in the exit stream could have been in the vessel for a time shorter than $t_i - t_0$. The fraction of acid solution in the outlet stream = Fraction of outlet stream that has been in the vessel for a time less than $t_i - t_0$.

This equation becomes

$$F(t) = \int_{t_0}^{t_i} E(t)dt$$

if t_0 is set at 0

then. $$F(t) = \int_{0}^{t_i} E(t)dt$$

or, $$\frac{dF(t)}{dt} = E(t)$$

Thus, the derivative of the F(t) curve with respect to time gives the E(t) curve. Because of this relationship, an E(t) curve can easily be generated if an F(t) curve is known. Simply take the slope of the F(t) curve for various times and plot the slope vs. time *(Figures 8a* and *8b)*.

Figure 8a. Graphical differentiation of an F-curve.

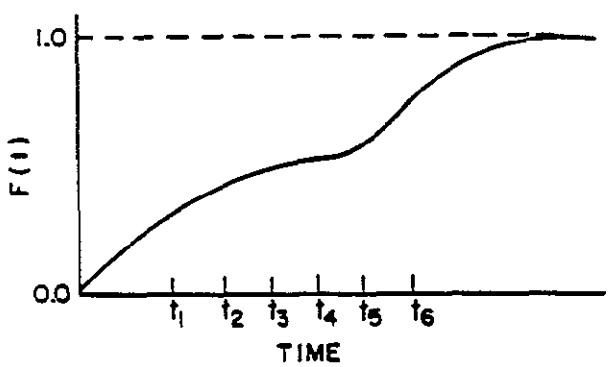
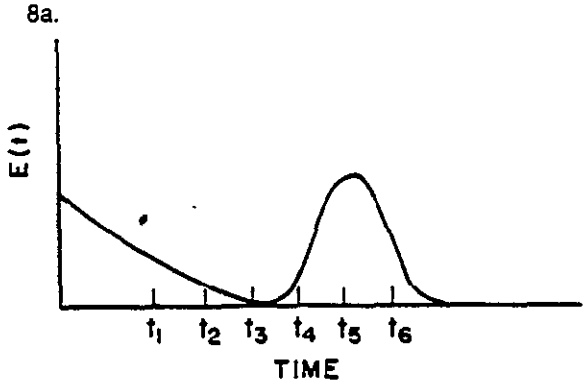


Figure 8b. E(t) curve generated from the F(t) curve in 8a.



Likewise the relationship

$$F(t) = \int_{0}^{t_i} E(t)dt$$

can be used to generate the F(t) curve for a given E(t) curve.

Integrating an E(t) curve gives the corresponding F(t) curve. The integration can be accomplished by either graphical or numerical techniques. In order to use the graphical technique, choose a time t_i and determine the area under the curve from time zero to t_i which generates the value of F for that particular t_i. Thus by choosing a set of t_i, an F(t) curve can be generated *(Figures 9a* and *9b)*.

Figure 9a. Graphical integration of an E(t) curve.

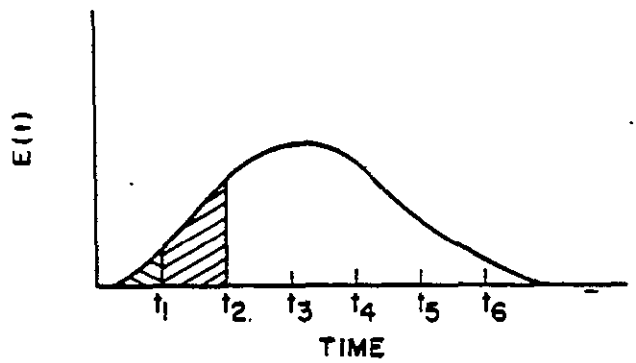
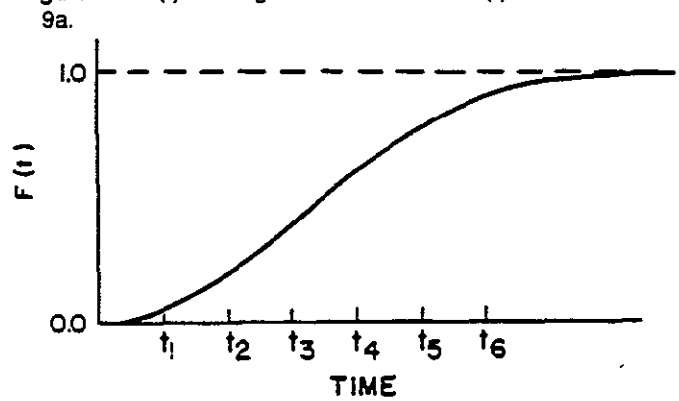


Figure 9b. F(t) curve generated from the E(t) curve in 9a.



Example 3. A pulse tracer of .1 M HCl is injected into the product stream. The pH of the output stream is recorded at 5 sec intervals. The following data are obtained:

Time (sec)	pH	Δ pH (change from initial pH)
0	11	0
5	8	3
10	7	4
15	6	5
20	6	5
25	7	4
30	9	2
35	10	1
40	11	0

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An E(t) curve can be generated from this set of data. The total area under the pH curve is

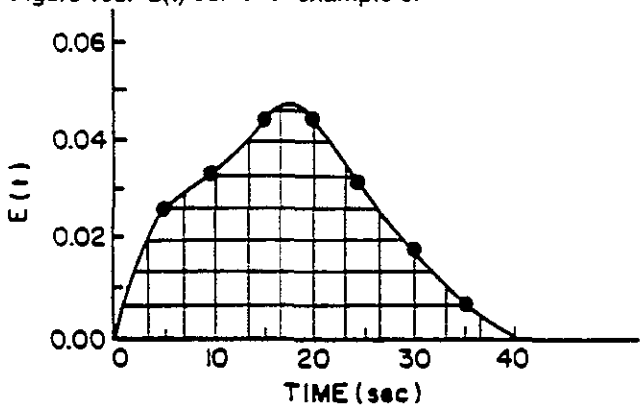
$$A = \Sigma\, \Delta pH \times \Delta t = (3+4+5+4+2+1) \times 5 \text{ sec}$$
$$= 120 \text{ pH} \times \text{sec}$$

The area under an E(t) curve must be unity. This result can be accomplished by plotting ΔpH/120 vs. time.

time	0	5	10	15	20	25	30	35	40
ΔpH	0	3	4	5	5	4	2	1	0
ΔpH/120	0	.025	.033	.042	.042	.033	.017	.008	0

The E(t) curve is plotted in *Figure 10a*. Now use the E(t) curve to determine the F(t) curve for this pulse injection.

Figure 10a. E(t) curve for example 3.

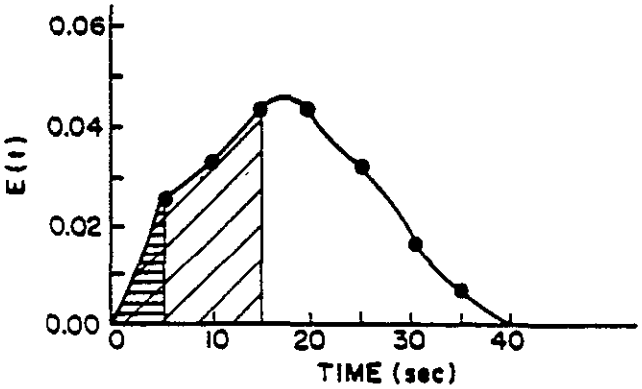


Notice that there are 100 square centimeters under the curve. (Each square cm. is .004 high and 2.5 wide for an area of .01 and the total area under the curve is 1).

The problem now becomes a square-counting game. Pick a time and count how many squares are under the curve from time zero to the chosen time. Multiply the counted squares with the proper scale factor (*i.e.*, 0.01 in this case) to get an F(t) curve value associated with the chosen time. By choosing a set of different times, an F(t) curve for the process is thus generated.

Figure 10b demonstrates the area under the E(t) curves for times of 5 and 15 seconds.

Figure 10b. Graphical counting of the area under the E(t) curve in 10a. (Total area 0 to 5 sec = 7.5 cm². Total area 0 to 15 sec = 32 cm².)

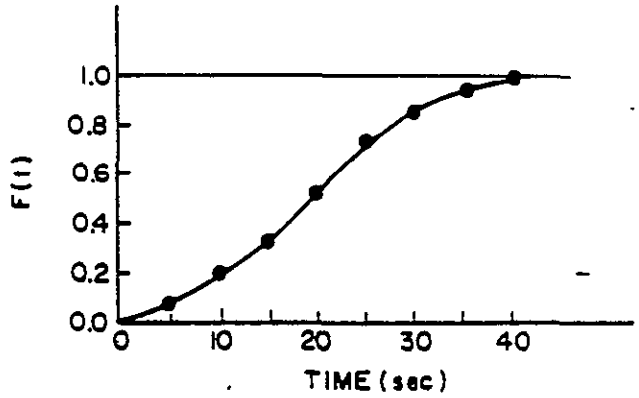


Data at 5 second intervals.

Time	Area	F Value
0	0	0
5	7.5	.075
10	21	.21
15	32	.32
20	52	.52
25	73	.73
30	89	.89
35	97	.97
40	100	1.0

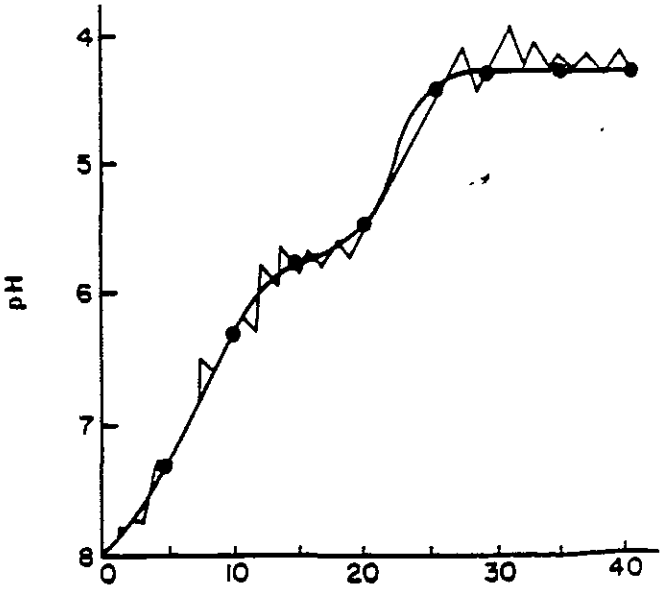
The F(t) values are plotted in *Figure 10c*.

Figure 10c. F(T) curve for example 3.



Example 4. A step change of .1 M HCl solution is introduced into the product stream. The pH is monitored and is recorded by a strip chart. The data and a best fit curve are shown in *Figure 11a*.

Figure 11a. Stimulus response (pH) vs. time curve for example 4.



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To obtain an F(t) curve, all one has to do is adjust the ordinate. When the pH is 4.25, all of the acid has left the system. Therefore, 4.25 is given a value of unity. Conversely a pH of 8 is given a value of 0. The F(t) curve value of any other pH is

$$\frac{8 - pH}{8 - 4.25} \text{ or } \frac{8 - pH}{3.75}$$

The F(t) curve is shown in *Figure 11b*.

Figure 11b. F(t) curve for example 4.

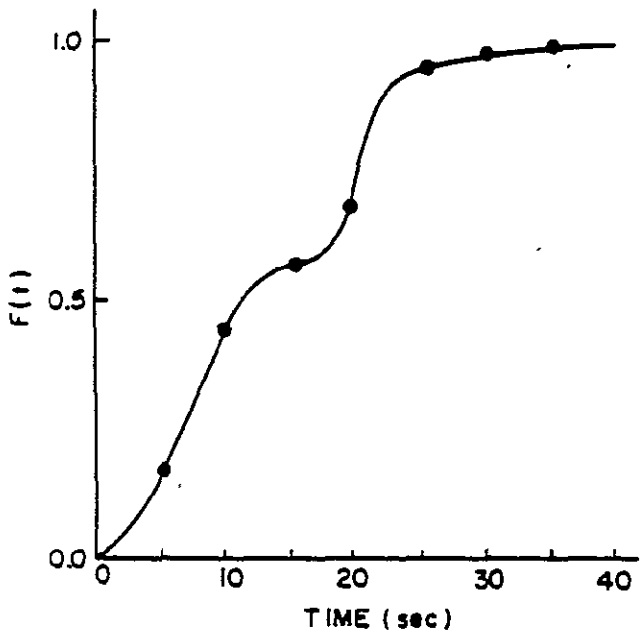
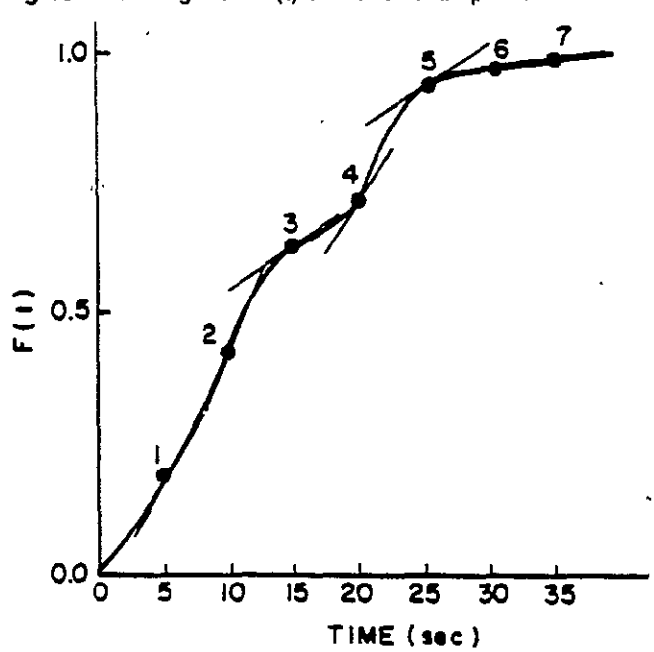


Figure 11c. Tangent to F(t) curve for example 4.

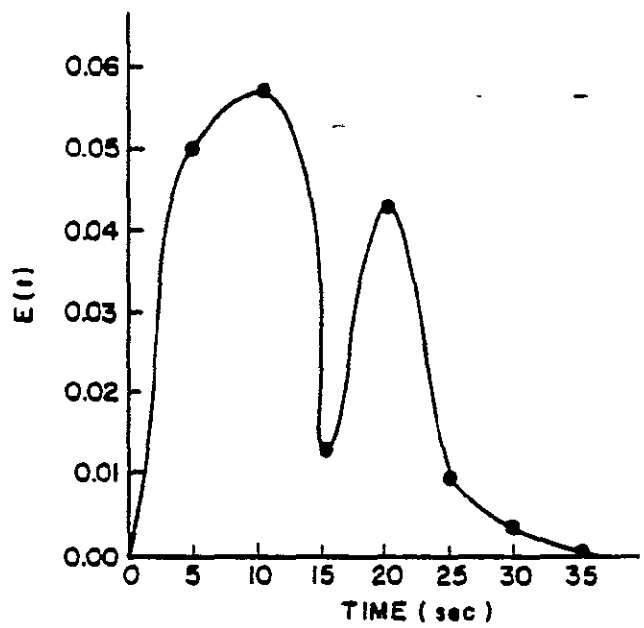


The F(t) curve can now be used to generate an E(t) curve. Choose a time and find its corresponding point on the F(t) curve. Draw a line tangent to the F(t) curve at this point The slope of the line is the E(t) value for the selected time. By choosing a number of different times, one can generate an E(t) curve. This technique is illustrated in *Figure 11c*. The E(t) curve data generated are listed below:

Time	Line #	Slope (E value)
0	0	0
5	1	.050
10	2	.057
15	3	.013
20	4	.044
25	5	.010
30	6	.003
35	7	0

The E(t) values are plotted in *Figure 11d*.

Figure 11d. E(t) curve for example 4.



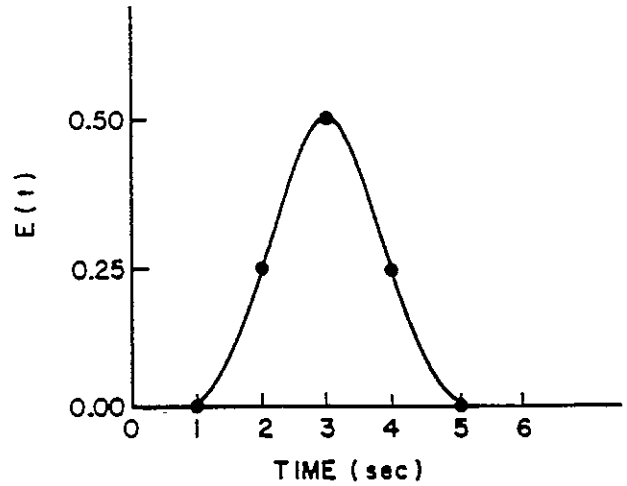
STATISTICAL CONSIDERATIONS

Sometimes it is required to characterize a distribution with just two or three numbers. The most important measure is the mean value of the distribution. The mean value is simply the median of the distribution. For an E(t) curve, the mean is given by

$$\bar{t} = \int_0^\infty t\,E(t)dt = \Sigma t_i E(t_i)\Delta t$$

Example 5. Given the following E(t) curve *(Figure 12)*, calculate the time at which the mean occurs.

Figure 12. E(t) curve for example 5.



Time	E Value	Δt = 1 sec
0	0	
1	0	
2	.25	
3	.50	
4	.25	
5	0	

$\bar{t} = \Sigma t_i\, E(t_i)\, \Delta t = (0 \times 0 \times 1 \text{ sec}) + (1 \times 0 \times 1 \text{ sec}) + (2 \times .25 \times 1 \text{ sec}) + (3 \times .5 \times 1 \text{ sec}) + (4 \times .25 \times 1 \text{ sec}) + (5 \times 0 \times 1 \text{ sec})$

Mean Time = 3 sec

Another important quantity is the variance (σ^2). The variance gives a value to the spread of the distribution and is expressed as units of (time)^2. It is used mainly for comparing experimental curves to theoretical curves. For an E(t) curve, the variance is given by

$$\sigma^2 = \int_0^\infty (t-\bar{t})^2 E(t)dt = \int_0^\infty t^2\, E(t)dt - (\bar{t})^2$$

$$= \frac{\Sigma t_i^2 E(t_i)}{\Sigma E(t_i)} - (\bar{t})^2 = \Sigma t_i^2 E(t_i)\, \Delta t - (\bar{t})^2$$

Example 6. Given the E(t) curve from Example 5, calculate the variance of the curve. Assume Δt = 1 sec and $\bar{t}$ = 3 sec.

Time	E(t) Value
0	0
1	0
2	.25
3	.50
4	.25
5	0

$$\sigma^2 = \Sigma t_i^2\, E(t_i)\, \Delta t - (\bar{t})^2$$
$$= (0^2 \times 0 \times 1 \text{ sec}) + (1^2 \times 0 \times 1 \text{ sec}) + (2^2 \times 25 \times 1 \text{ sec}) + (3^2 \times .5 \times 1 \text{ sec}) + (4^2 \times .25 \times 1 \text{ sec}) + (5 \times 0 \times 1 \text{ sec}) - (3^2 \text{ sec})$$
$$= 9.5 \text{ sec}^2 - 9 \text{ sec}^2$$
$$\sigma^2 = 0.5 \text{ sec}^2$$

FLOW CHARACTERISTICS IN SELECTED HEAT EXCHANGERS

Flow through the product side of a double-tube heat exchanger can be described by flow through a smooth pipe of constant cross-sectional area. The Reynolds number (N_{Re}) is calculated to provide insight into the type of flow in the tube. Laminar flow, where streamlines remain distinct from one another throughout the entire length of the pipe, occurs at N_{Re} below 1,100. Turbulent flow is found at N_{Re} greater than 2,300. The transition region from N_{Re} of 1,100 to 2,300 exhibits characteristics of both laminar and turbulent flow (Bird *et al.*, 1960).

The Reynolds number is a function of tube diameter, fluid density, fluid velocity through the tube, and fluid viscosity. Because tube diameters are relatively constant and liquid densities are similar, velocity and viscosity are the factors that normally have the greatest influence on determining the Reynolds number. If a desired operating range for N_{Re} is chosen, different pump speeds (fluid velocities) can be used to keep products with different viscosities within the range.

A plate heat exchanger is made of closely spaced plates with altered surfaces that can create turbulent flow at Reynolds numbers as low as 200. Each plate is stamped in a way that its surface appears to be corrugated. When clamped together, successive plates form narrow flow channels.

Therefore, flow in a plate heat exchanger is usually turbulent. However, unlike turbulent flow in a pipe, if a tracer is injected into the inlet, the tracer does not flow evenly but is divided in the tiny flow channels and takes different paths across the plate. Although the flow is turbulent, the fact that the tracer can take different paths through the exchanger leads to a wider distribution of residence times than the pulsed tracer associated with turbulent flow in a pipe. In fact, a Gaussian curve similar to laminar flow in a pipe would be expected at low flow rates.

A scraped-surface heat exchanger consists of concentric cylinders with heating or cooling medium between them and a rotating shaft with scraping blades inside the inner cylinder. The scraping blades continuously scrape the heat transfer surface to improve heat transfer rates by the combined action of mechanically induced turbulence, film removal, and mixing of product.

Fluid flow in a scraped-surface heat exchanger is complex since there are two non-zero components of the velocity field which generate "helical flow." In this type of flow, fluid elements might follow a spiral path through the exchanger. Residence time distribution data shows that a scraped-surface heat exchanger behaves somewhere between ideal laminar flow and ideal plug flow, probably closer to plug flow (Cuevas *et al.*, 1982).

Several operating and design parameters affect the residence time distribution in the scraped-surface heat exchangers. The most commonly studied parameters are the fluid flow rate and the mutator speed. The experimental studies on the subject indicate that either a decrease in the product flow rate or an increase in the mutator speed

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causes broadening of the residence time distribution (Chen and Zahradnik, 1967; Manson and Cullen, 1974, Milton and Zahradnik, 1973).

RESIDENCE TIME DISTRIBUTION IN PROCESSING OF HETEROGENEOUS FOODS

Recently, an interest has developed in aseptic processing of heterogeneous food products (*i.e.*, fluids containing discrete particulate food matter). Usually a scraped-surface heat exchanger is employed for aseptic processing of such food products. Sometimes a tubular heat exchanger (double or triple tube) can also be used under highly turbulent flow regimes for this purpose. Furthermore, the type of flow affects the residence time distribution in the equipment and, hence, the quality distribution of the final product.

It should also be pointed out that the heat transfer inside a heterogeneous food product is further limited by multiple factors such as thermal conductivity and by the size of the suspended solid particles.

Taeymans *et al.* (1985) studied the residence time distribution of both phases, the liquid phase and the solid phase, in a heterogeneous model food system comprised of calcium alginate beads and water. The mean residence time as a function of three non-dimensional numbers, *viz* axial Reynolds number, rotational Reynolds number, and centrifugal Archimedes number, was estimated. Using this approach it is possible to predict the variation in the mean residence time with changes in the liquid viscosity, the specific gravity, and the particle diameter. In this study it was observed that, as the rotational speed of the scrapers increases (*i.e.*, as the rotational Reynolds number increases), the mean residence time of the dispersed phase also increases; as the flow rate increases (*i.e.*, as the axial Reynolds number increases), the mean residence time of the dispersed phase decreases and approaches the mean residence time of the liquid phase; and as the concentrations of the dispersed phase (*i.e.*, solids to liquid ratio) increases, its mean residence time decreases.

However, in a subsequent study, Taeymans *et al.* (1986) confirmed that, at a given rotational speed, the residence time distributions for the liquid phase and the solid phase were not identical (*Figure 13a*). The results shown in *Figure 13a* indicate that the measured mean residence time of the solid phase is greater than the calculated mean residence time ($\bar{t}$). The effect of rotational speed on the mean residence time of the dispersed phase is shown in *Figure 13b*. These results indicate that the rotational speed has a great influence on the measured mean residence time

Figure 13a. F(t) curve for the liquid and solid phases of heterogeneous foods in an experimental scraped-surface heat exchanger.

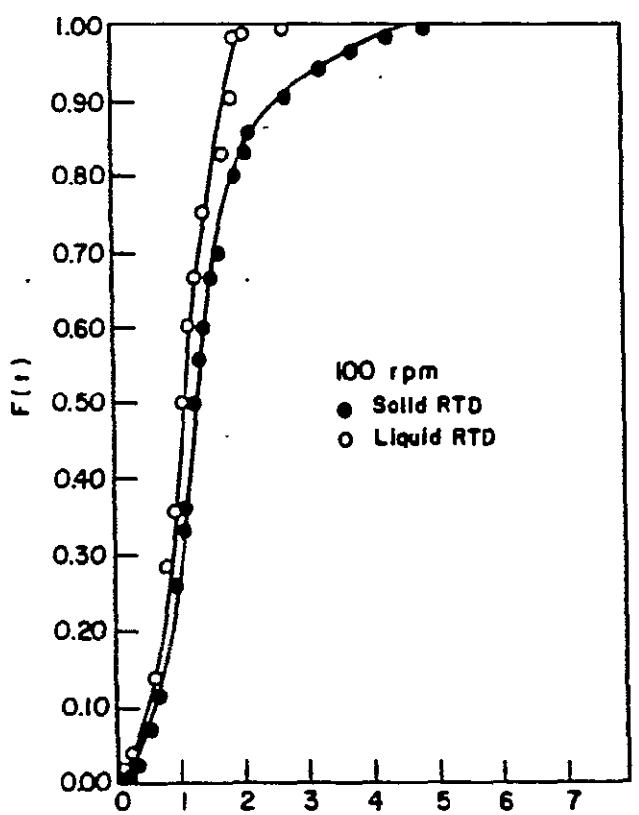
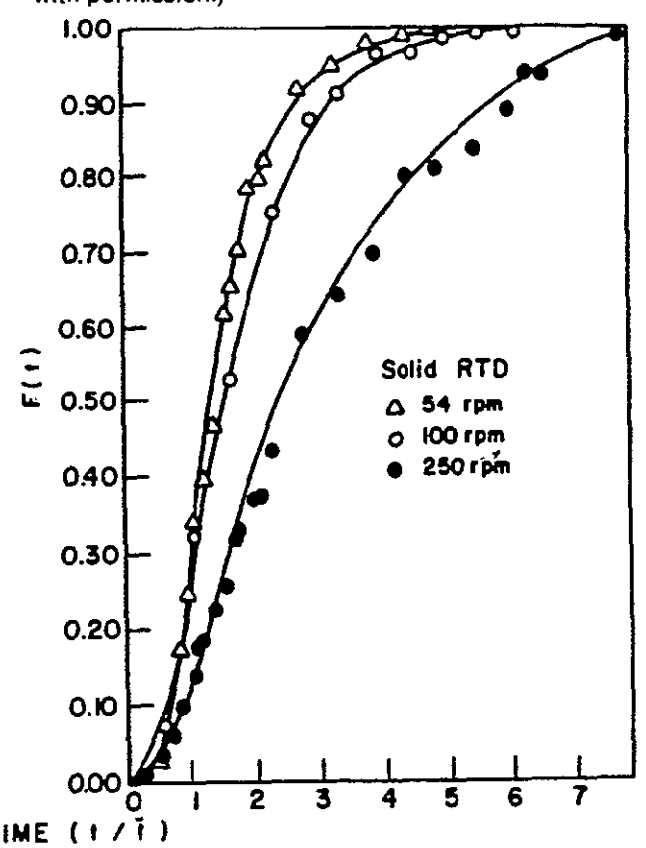


Figure 13b. F(t) curve for solid phase as a function of mutator speed in an experimental scraped-surface heat exchanger. (from Taeymans *et al.*, 1986, used with permission.)



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of the solid phase and that the flow pattern diverges from the ideal plug flow as the rotational speed increases.

It is envisioned that, to obtain a product with adequate homogeneity, the ideal flow would be the plug flow. However, under the plug flow conditions, the heat and mass transfer would be quite slow because this flow lacks radial and axial mixing. On the other hand, the perfectly mixed flow assumes an intensive agitation which will facilitate heat and mass transfer but will broaden the residence time distribution. Since the flow conditions in a scraped-surface heat exchanger lie between an ideal plug flow and an ideal CSTR, intermediate models (*i.e.*, a series of CSTRs) have been used to model its residence time distribution (Taeymans *et al.*, 1985, 1986). Thus it seems critical to have a scraped-surface heat exchanger which can simulate residence time distribution close to an ideal plug flow, maintain heat and mass transfer characteristics of a CSTR, and cause minimum breakdown of the particulate matter.

EFFECT OF RESIDENCE TIME DISTRIBUTION ON STERILIZATION EFFICIENCY

Taeymans *et al.* (1985, 1986) used the following expression to calculate sterilization efficiency (N/N_0) for different flow patterns and temperature profiles:

$$\frac{N}{N_0} = \int_0^\infty \exp(-kt)\, E(t)\, dt$$

where, N_0 = initial spore concentration
N = spore concentration after a time t
k = rate constant for spore destruction (s^{-1})
and, $E(t)$ = residence time distribution

Based on the above equation, Taeymans *et al.* (1985) have presented the theoretical sterilization efficiency for different flow models (*Figures 14a* and *14b*). Obviously the best results are obtained with a plug flow model.

Figure 14a. Theoretical sterilization efficiency using n-CSTR series model. (from Taeymans *et al.*, 1985, used with permission.)

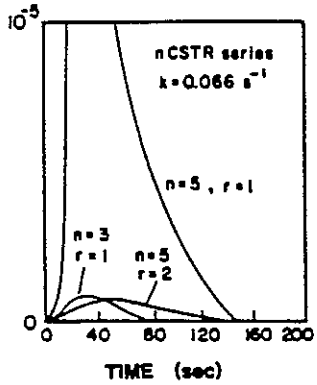
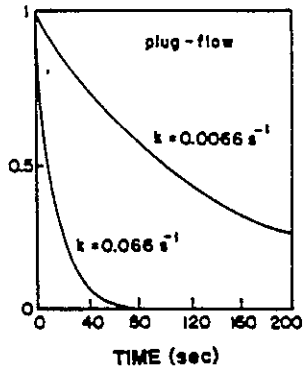


Figure 14b. Theoretical sterilization efficiency using plug flow model (from Taeymans *et al.*, 1985, used with permission.)



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Taeymans, D., Roelans, E., and Lenges, J. 1985. Influence of residence time distribution on the sterilization effect in a scraped-surface heat exchanger used for processing liquids containing solid particles. *In* International Union of Food Science and Technology (IUFOST) Symp. Aseptic Proc. Packag. Foods Proc., September 9–12, Tylosand, Sweden, pp. 100–107.

Taeymans, D., Roelans, E., and Lenges, J. 1986. Residence time distribution in a horizontal SSHE used for UHT processing of liquids containing solids. Food Engineering and Process Applications, Volume 1. Transport Phenomena. GBR, Barking: Elsevier Applied Science Publishers, pp 247–258.

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THIS PAPER WAS AUTHORED BY MS. V. N. SCOTT

NATIONAL FOOD PROCESSORS ASSOCIATION

FDSC631
FALL 1990

HACCP

I. Introduction

A. Overview of HACCP

1. Hazard Analysis Critical Control Point

2. System to ensure product safety by identifying and controlling each hazard at all points from production to consumption.

3. Why HACCP?

a. traditional approaches to control food safety (inspection, laboratory testing of end product, etc.) have not worked.

b. need for higher level of assurance

B. History of HACCP

1. Developed by the Pillsbury Company for first foods to be used in space

a. food which would not crumble
b. close to 100% assurance pathogen-free
c. limited testing of final product

2. Presented to industry in 1971 at the First National Food Protection Conference

3. Applied to the production of low-acid and acidified foods (21 CFR 113 and 114) (1973)

4. Recommended by the National Academy of Sciences three times between 1985 and 1987

5. Addressed recently by Codex Alimentarius, International Commission on Microbiological Specifications for Foods (ICMSF), National Marine Fisheries Service (NMFS) and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

6. USDA FSIS HACCP Implementation Project

II. Principles of HACCP

A. Key definitions

1. Critical control point - any point or procedure in a specific food system where loss of control may result in an unacceptable health risk

2. Hazard - any biological, chemical or physical property that may cause an unacceptable consumer health risk

3. Sensitive ingredient - any ingredient historically associated with a known microbiological hazard

B. Seven principles as defined by NACMCF

1. Assess hazards and risks associated with growing, harvesting, raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation and consumption of the food (see section III)

2. Determine CCP required to control the identified hazards.

   a. limit to points that may affect safety; inclusion of non-critical control points can dilute the attention paid to CCPs

   b. CCPs include temperature, pH, a_w, preservatives, prevention of cross contamination

3. Establish the critical limits that must be met at each identified CCP.

   a. parameters that assure that CCP eliminates or control the hazards

   b. may be more than one critical limit per CCP

4. Establish procedures to monitor CCPs.

   a. 100% monitoring if possible

   b. if 100% monitoring not possible, it must be determined that monitoring frequency reliable enough to indicate the hazard is under control.

5. Establish corrective action to be taken when there is a deviation identified by monitoring a CCP.

   a. Corrective action should eliminate the actual or potential hazard

   b. corrective action must be documented beforehand

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6. Establish effective record-keeping systems that document the HACCP plan.

   a. Ingredients (supplier certification, etc.)

   b. process establishment (challenge studies, heat penetration, distribution, etc.)

   c. process records (time, temperatures, etc.)

   d. package integrity

   e. storage records (temperature, etc.)

   f. deviation file

   g. modifications to HACCP plan

7. Establish procedures for verification that the HACCP system is working correctly.

   a. purpose to assure CCPs under control, remain effective

   b. review of monitoring records and corrective actions

III. Microbiological Risk Assessment and Hazards

A. Determination of risk category

1. Determine how many of the following hazards exist:

<u>Hazard A</u>:

A special class that applies to non-sterile products designated and intended for consumption by at risk populations, e.g., infants, the aged, the infirm, or immunocompromised individuals.

<u>Hazard B</u>:

The product contains "sensitive ingredients" in terms of microbiological hazards.

<u>Hazard C</u>:

The process does not contain a controlled processing step that effectively destroys harmful microorganisms.

<u>Hazard D</u>:

The product is subject to recontamination after processing before packaging.

Hazard E:

There is substantial potential for abuse handling in distribution or in consumer handling that could render the product harmful when consumed.

Hazard F:

There is no terminal heat process after packaging or when cooked in the home.

Note: Hazards can also be stated for chemical or physical hazards, particularly if a food is subject to them.

2. Assign a risk category for a product or an ingredient as follows:

Hazard Characteristics (A,B,C,E,D,F)	Risk Category (VI,V,IV,III,II,I,0)
A + (Special Category)*	VI
Five +'s (B through F)	V
Four +'s (B through F)	IV
Three +'s (B through F)	III
Two +'s (B through F)	II
One + (B through F)	I
No +'s	0

B. Microbiological hazards

1. ICMSF Approaches to risk assessment and sampling of food have classified microorganisms according to degree to hazard and conditions of use of food (Table 1)

2. Microorganisms in hazard classes:

Severe Hazards (high mortality, prolonged convalescence)

Clostridium botulinum
Shigella
Salmonella typhi; paratyphi A & B
Brucella abortus; suis
Mycobacterium bovis
hepatitis A virus
fish and shellfish toxins
certain mycotoxins

Moderate Hazards with Potentially Extensive Spread (small #'s cause disease, readily spread from person to person, serious for susceptible groups)

Salmonella
pathogenic Escherichia coli (PEC)
Streptococcus pyogenes
Listeria monocytogenes

Moderate Hazards with Limited Spread (spread rare, high #'s organisms)

Staphylococcus aureus
Clostridium perfringens
Bacillus cereus
Vibrio parahaemolyticus
Coxiella burnetii
Yersinia enterocolitica
Campylobacter fetus
Trichinella spiralis
histamine (from microbial decomposition of scombroid fish)

IV. Chemical and physical hazards

A. Chemicals used in foods

Use	Types of Chemicals
Growing	Pesticides, growth regulators
Production	Food additives, processing aids
Maintenance	Paints, lubricants, coatings
Sanitation	Cleaners, sanitizers, pesticides

Chemicals of Concern

- Naturally occurring poisonous or deleterious substances
- Added poisonous or added deleterious substances
- Food additives
- Color additives
- Poisonous or deleterious substances from food containers

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B. Physical Hazards
(Extraneous materials, foreign objects)

1. airborne contaminants (dust, leaves, etc.)
2. glass
3. personal effects (jewelry, etc.)
4. metal or plastic fragments
5. pests (insects, etc.)
6. paint flakes, rust

V. Application of HACCP

A. Implementation for a Specific Food

1. Describe the food and its intended use.

2. Develop a flow diagram for the production of the food.

3. Perform a hazard assessment (Principle 1).

a. Ingredients prior to any processing step.

b. End product.

4. Select CCPs (Principle 2).

a. Enter on flow diagram in numerical order.

b. List CCP number and description.

5. Establish critical limits (Principle 3).

6. Establish monitoring requirements (Principle 4).

7. Establish corrective action to be taken when there is a deviation identified by monitoring of a CCP (Principle 5).

8. Establish effective recordkeeping systems that document the HACCP plan (Principle 6).

9 Establish procedures for industrial and governmental verification that the HACCP system is working properly. Verification measures may include physical, chemical, and sensory methods, and when needed, establishment of microbiological criteria (Principle 7).

B. Pancake mix

1. Ingredients - flour, sugar, salt, buttermilk solids, lecithin, etc.

2. Flow diagram (see attachment)

3. CCP's (see attachment)

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C. Refrigerated Snack Dip - Don's Delight (see attachment)

VI. Government agencies and HACCP

A. Government agencies have been familiar with HACCP since 1971 Food Protection Conference

B. FDA implemented the first HACCP based regulations for canned foods in 1973.

C. USDA regulations for canned foods similar to those of FDA were implemented in 1986.

D. USDA's FSIS in August of 1989 announced a 2-year HACCP Implementation Project.

1. Plans to implement the HACCP system in all meat and poultry inspection operations

2. Issued a concept paper describing HACCP and its benefits in October 1989.

3. Issued strategy paper 1990.

a. 6-month consultation process - agency employees, industry, consumer groups

b. public hearings

4. Results of consultation

a. HACCP for food safety only

b. 5 workshops planned - refrigerated food, cooked sausages, fresh ground beef, poultry slaughter, pork slaughter.

5. FSIS proposed "HACCP" regulation related to precooked meat patties - many non-health issues

E. NMFS Model Seafood Surveillance Program

1. Includes HACCP in a much larger program

2. Commodity-based HACCP model developed working with industry.

VII. Industry and HACCP

A. Much of industry has HACCP-based control systems

B. Industry helped develop both USDA & FDA canning regulations based on HACCP

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C. Industry favors HACCP regulations provided

1. meaningful

2. address safety issue

3. not burdensome - recordkeeping requirements and regulatory access limited to issues of product safety.

4. consistent between agencies - uniform definitions, interpretation of principles, etc.

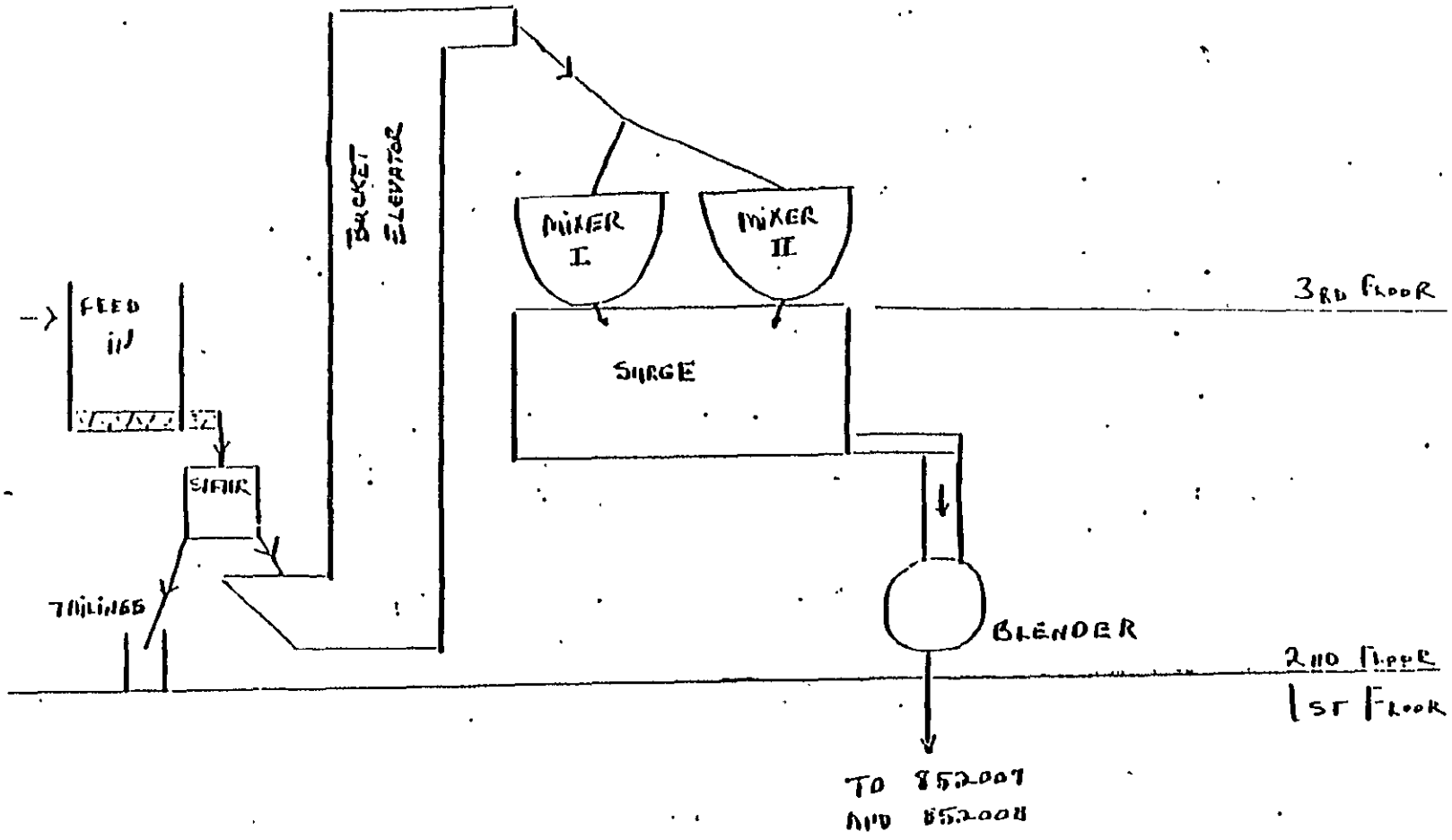
D. FPI presents HACCP courses for industry quarterly

E. NFPA/AMI HACCP program

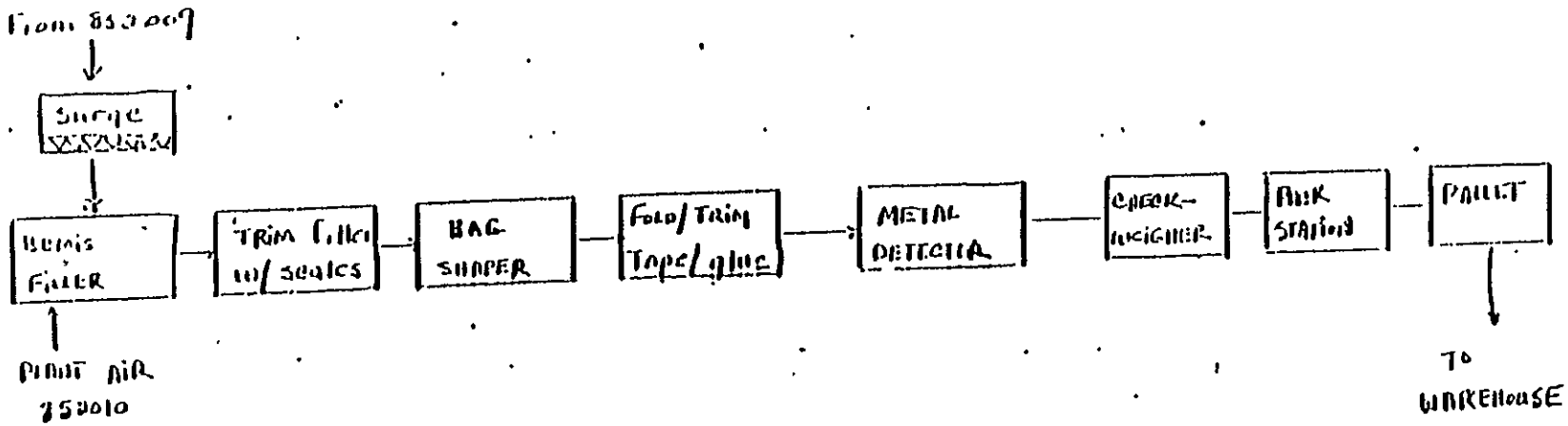
Table 1. Sampling plan stringency for foods

Type of hazard	Conditions in which food is expected to be handled and consumed after sampling, in the usual course of events		
	Reduce degree of hazard	Cause no change in hazard	May increase hazard
NO DIRECT HEALTH HAZARD			
Utility (e.g., general contamination, reduced shelf-life, and spoilage)	Case 1	Case 2	Case 3
HEALTH HAZARD			
Low, indirect (indicator)	Case 4	Case 5	Case 6
Moderate, direct, limited spread	Case 7	Case 8	Case 9
Moderate, direct, potentially extensive spread	Case 10	Case 11	Case 12
Severe, direct	Case 13	Case 14	Case 15

ICMSF, 1986



		SIERRA - PANCAKE
		SYSTEM # 852007



		System-Dog Pillow
		System II - 85 2007

PHYSICAL SYSTEMS HAZARD CONTROL
CRITICAL CONTROL POINT FORM

Issue Date _____
Page 1 of 1

Plant _____
System Name: Pancake & Bag Pancake
System Number: B2009

ITEM	HAZARD	ACTION/FREQUENCY	RESPONSIBLE PERSONNEL
.01 Feed-in	Foreign material	Inspect each bag	Mixer
02 Sifter Screen (10 mesh magnetic	Screen - metal	Inspect weekly - log. Report damaged screen and take appropriate action.	Foreman
.03 Tailings	Foreign material	Inspect each shift - log. Foreign material present to be retained and labeled as to date, time, & product being manufactured. Source to be determined & appropriate action taken.	Foreman QA to document & retain f. material.
.04 Magnets plate (1) bar (1)	Tramp metal	Inspect each shift - log. Unusual metal particles to be retained and labeled as to date, time, location of magnet & product being produced. Source to be determined and appropriate action taken.	Foreman
.05 8 mesh scalping screen	Foreign Material	Insure presence during dumping of ingredients into mixer.	Mixer.

PHYSICAL SYSTEMS HAZARD CONTROL
CRITICAL CONTROL POINT FORM

Plant: _____

System Name: Bag Pancake Packaging

System Number: 052000

Issue Date: _____

Page 1 of 1

ITEM	HAZARD	ACTION/FREQUENCY	RESPONSIBLE PERSONNEL
.01 Filter	Oil - Water	Inspect weekly - log.	Foreman
.02 Filler Tooling	Metal	Inspect once per week and log. Check for scoring or chipping of metal surfaces. Take action if indicated. Note any findings and action on the log sheet.	
.03 Metal Detector	Metal	Check for proper operation each shift - log. Must reject 2MM ferrous sphere. Metal found to be retained and labeled as to product, component, date and time. Source to be determined and appropriate action taken.	QA Manager

APPLICATION OF HACCP PRINCIPLES TO
REFRIGERATED FOODS

DON'S DELIGHT

I. DESCRIPTION

- A refrigerated snack dip.
- Must be held at 45 degrees F or less.
- Has a shelflife of no more than two weeks.
- No reconstitution is needed - it's ready-to-eat.
- Package is a plastic tub with a snap-on top.
- Consumer is retail trade; displayed in grocery refrigerated case.
- There is potential for mishandling, particularly temperature abuse above 45 degrees F.

II. INGREDIENTS

- Raw celery in wooden crates
- Dried mushrooms
- Soft-ripened cheese
- Water
- Salt

III. POTENTIAL BIOLOGICAL HAZARDS

Raw celery	*C. botulinum* spores
Dehydrated mushrooms	*Salmonella*
Soft-ripened cheese	*Listeria monocytogenes* *Salmonella* *Staphylococcus aureus*
Water	Various microbes/parasites

IV. HAZARD ANALYSIS AND ASSIGNMENT OF RISK CATEGORIES

Food	(B) Cont Sens Ingr	(C) No Destr Step	(D) Subj to Recont	(E) Subst Abuse Poten	(F) No Heat Proc	Risk Category
Raw celery	−/+	+	+	−	+	III/
Dried mushrooms	+	+	+	+/−	+	V/IV
Soft rpn cheese	+	+	+	+	+	V
Water	+	−/−	+	−	+	III/
Salt	−		+/−	−		I/O
Don's Delight	+	+	+	+	+	− V

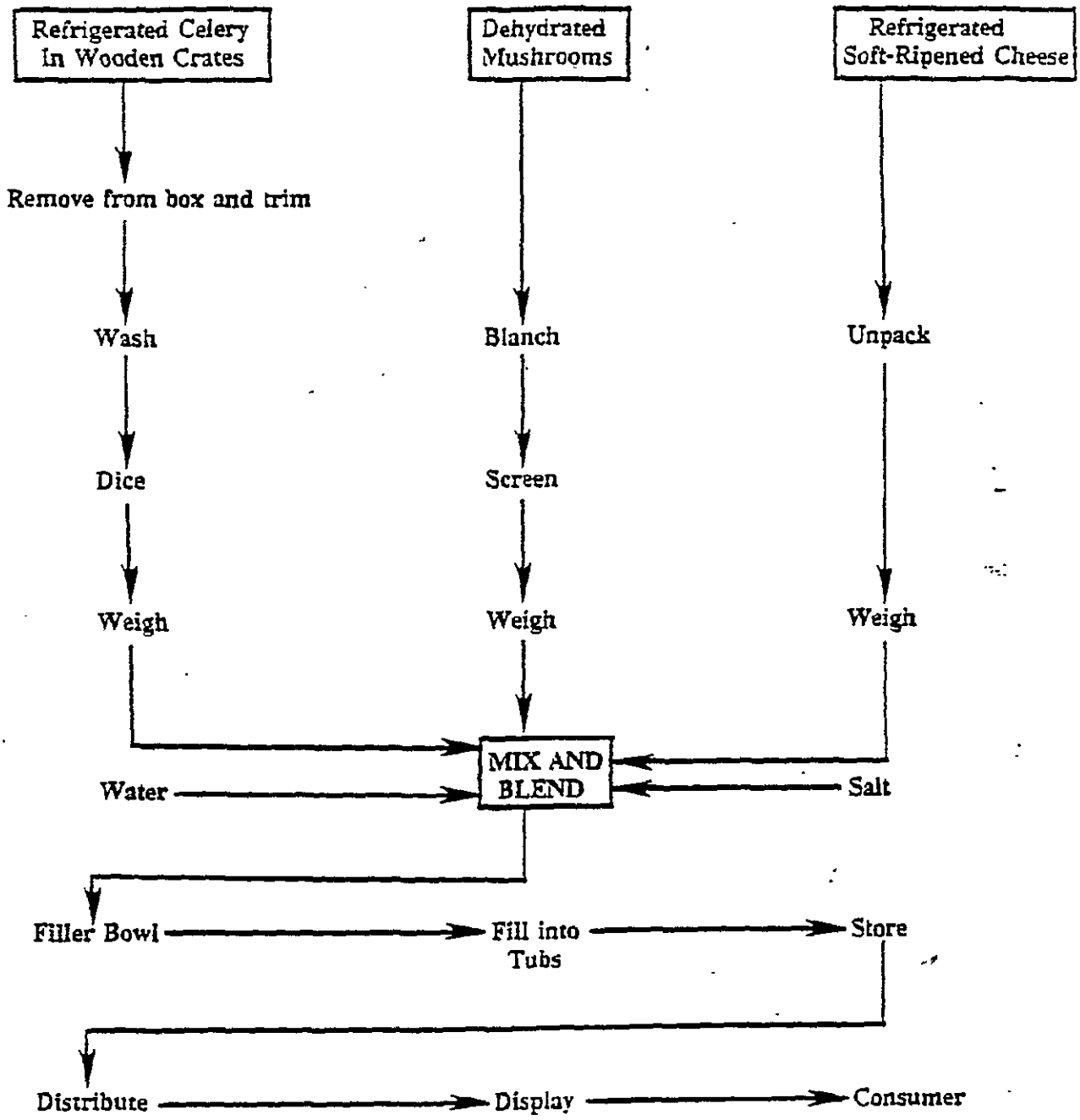
V. OTHER POTENTIAL HAZARDS

Food	Chemical Hazards	Physical Hazards
Raw Celery	Pesticides	Metal, wood, soil, pests
Dehyrated mushrooms	Pesticides	Trash, insects, rodents
Soft-ripened cheese	Antibiotics	Normally none
Water	Various	Normally none
Salt	None	Normally none

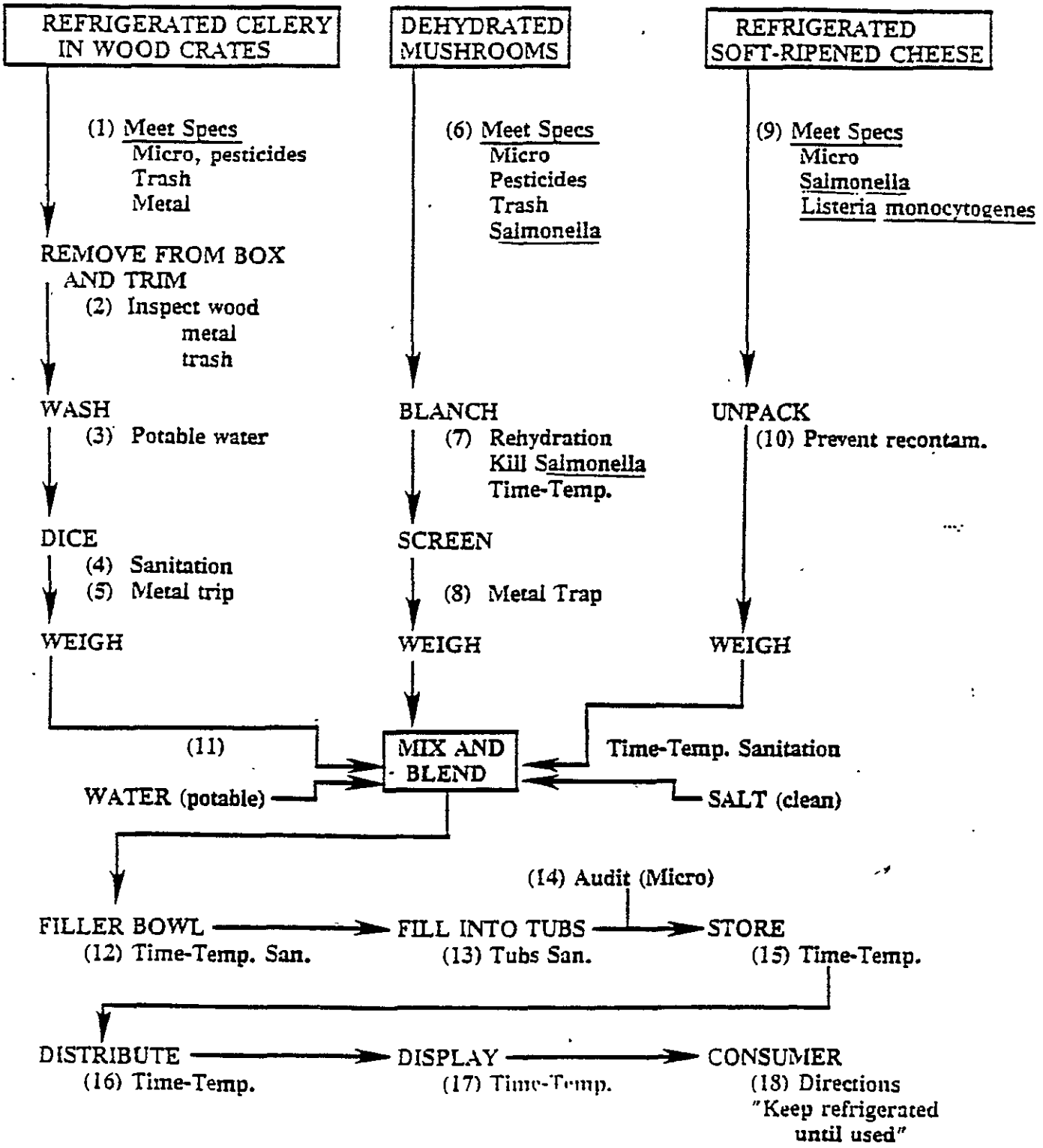
VI. FLOW DIAGRAM AND IDENTIFICATION OF CRITICAL CONTROL POINTS

[See Figures 1 and 2]

"Don's Delight" -- A Refrigerated Snack Dip



"DON'S DELIGHT" – A REFRIGERATED SNACK DIP



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Session I

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CHAPTER 5

ASEPTIC CHEMISTRY

George D. Sadler

INTRODUCTION

Outside of the dairy industry, very little research has been published on chemical changes in aseptically processed foods. Fortunately, for the most part, changes in aseptic foods are the same changes which occur in conventionally processed foods. The aseptic advantage is that the most harmful thermal reactions are minimized (though not eliminated) by efficient high-temperature aseptic treatment. There are, however, certain problems unique to aseptic processing. Rules do exist for predicting which defects will be enhanced by aseptic processing and which ones will be minimized. Elucidation of these rules will be achieved through discussion of activation energy, browning reactions, nutritional and flavor changes, enzyme regeneration, oxygen, and shelf life. It should become clear that aseptic processing is a method which introduces few quality problems and offers many quality advantages.

ACTIVATION ENERGY

In much the same way that pH describes acidity and temperature measures thermal energy, *activation energy* describes the effect of temperature on the rate of chemical reactions. With aseptic processing, microbial inactivation is more sensitive to temperature increases than are chemical reactions which reduce food quality. The activation energy for microbial destruction is high compared to the activation energy of pathways which lead to quality loss.

In chemical reactions, there is an energy barrier between reactants and products. If this barrier did not exist, all matter would revert to its simplest energy state, and the chemical order necessary for complex molecules would not exist. In a sense, activation energies legislate which chemical reactions occur and at what rates.

Essentially all processes in nature that change in response to temperature are mediated by activation energy. Activation energy affects the rate of chemical reactions, the rate of microbial inactivation, and the rate of gas transmission through polymer materials, as well as many other topics important to aseptic processing.

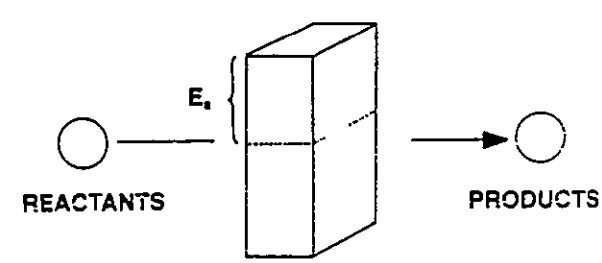
In much the same way that a pole vaulter must propel himself over a bar, a reactant molecule must be elevated above some critical energy level before it can become a product (*Figure 1*). The energy required to take a molecule from its average resting energy to a point where reactants become products is called the activation energy (E_a).

In food systems, the range of E_a's varies widely between 2 and 150 Kcal/mole (Lund, 1975a). The term per mole is significant. There is some quantum of molecules in a given reaction and not all the molecules will spontaneously convert to product at one energy level.

The E_a is commonly picked up by collision with its surroundings (other molecules and container walls) (Tinoco *et al.*, 1978). Complementing collisions increase the energy of reactant molecules; opposing collisions reduce molecular energy. Consequently, at a given energy level, a random sample of individual molecules reveals a whole spectrum of personal energies. If activation energies are low enough, some molecules (those with the highest energies) will be able to make the conversion from reactants to products. Consequently, anything which would further increase the energy level of the reactants or lower the activation energy would hasten the rate of conversion.

In foods, there are three major ways to induce chemical reactions. The first method is concentration. As a product is concentrated, reactant molecules increasingly become more intimate with their adjoining molecules. This increased intimacy among reactant molecules creates a fertile environment for reaction. This molecular scenario translates into reduced shelf life for concentrates (2–6 months) ver-

Figure 1. Activation energy (E_a).



sus single strength juice (4–18 months) packaged in brik pak containers (Carlson, 1984)

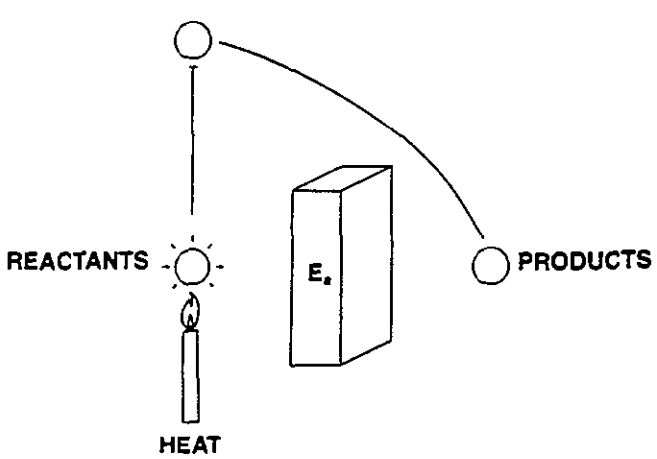
Since bulk aseptic processing often relies on preconcentration, users should be aware that many potential defects are magnified by concentration (Johnson and Toledo, 1975). In particular, concentrated products are much less forgiving of thermal abuse than unconcentrated products.

The second avenue for increasing reaction rates is through catalysts Catalysts lower the activation energy of chemical reactions In foods, the most common catalysts are enzymes and trace ions of transitional metals (*e.g.*, copper and iron). Traditionally, both in aseptic and conventional thermal processing, residual enzyme activity has been undesirable. Recently, however, interest has been generated in adding sterile enzyme downstream of aseptic processing. By tailoring enzyme selection to address quality concerns of a product, it is possible to selectively and significantly improve problem characteristics of certain foods. For example, sterile b-galactosidase can be added to UHT milk to convert lactose to glucose and galactose. The resulting milk is sweeter and, for people with lactose intolerance, much easier to digest.

In aseptic processing, concerns have arisen over enzyme regeneration. Regeneration of thermally inactivated enzymes has been well documented in milk (Adams, 1981; Visser, 1981; Fox, 1982) and to a lesser extent in certain vegetables (David and Shoemaker, 1985). Although the reactivation of enzymes merits concern, historically this has not been a serious problem for most aseptic foods.

The third and most important method of increasing reaction rates is through temperature elevation. Heat increases molecular energy which drives chemical reactions to completion *(Figure 2)*. In aseptic processing, the potential damage of very high temperatures for short periods of time must be weighed against extended heat exposure at lower temperatures (*i.e.*, conventional processing). Although concentration and enzyme activity may play a role in aseptic processing the real novelty of the process is the pattern of rapid heating followed by a quick reduction in temperature. Consequently, the quality advantages of aseptic processing will be approached primarily through thermal arguments. However, enzymes will also be reviewed in another section.

Figure 2. The effect of temperature on molecular energy.



Determining Activation Energies

As mentioned previously, activation energy is the barometer which tells how food reactions are affected by changes in temperature. The activation energies of many quality related reactions can be found in the food literature. One reason they are so plentiful is that they are easily determined. Once an attribute of concern has been identified, its change with time is determined at three temperatures At each temperature there is a reaction constant which describes this rate of change. The reaction may be zero, first, second or mixed order *(Figure 3)*. However, based simply on probability, it will likely be first order. Identifying the correct kinetic order is not essential. Defects are often apparent at very low levels of substrate depletion. In other words, during processing and storage, very small changes in food composition produce blatant defects in food quality. When substrate loss is low (less than 15%), all kinetic orders can be modeled as a straight line (zero order) without serious errors in calculating activation energy. This modeling is possible because activation energy determinations measure the change in reaction rate brought about by a change in temperature. If, for a given temperature change, the reaction constant doubles for a first order reaction, it will also double for a zero order approximation as long as the approximation is fairly good. For low substrate depletion, the approximation will be fairly good.

The mathematical tool used to determine the activation energy is the Arrhenius equation:

$$k = Ae^{\frac{-E_a}{RT}} \qquad (1)$$

$$\ln k = \left(\frac{-E_a}{R}\right)\left(\frac{1}{T}\right) + \ln A \qquad (2)$$

where

- k = the reaction constant (any order)
- A = the pre-exponential factor (the y-intercept)
- E_a = the activation energy of the reaction
- R = the gas constant (1.987cal/mole·deg)
- T = absolute temperature (°K)

The logarithmic form corresponds to the linear equation of a line ($y = mx + b$) in which the y-intercept "b" corresponds with "ln A," the slope "m" with "$-E_a/R$," and the "x" and "y" coordinates with, respectively, "1/T" and "ln k" *(Figure 4a)*. Therefore, a graph of "ln k" versus "1/T" will give a straight line of slope $-E_a/R$ *(Figure 4b)*. Since "R" is a constant, the activation energy can be determined by multiplying the slope ($-E_a/R$) times 1.987 cal/mole·Deg (the gas constant) and taking the absolute value.

Figure 3. Reaction orders.

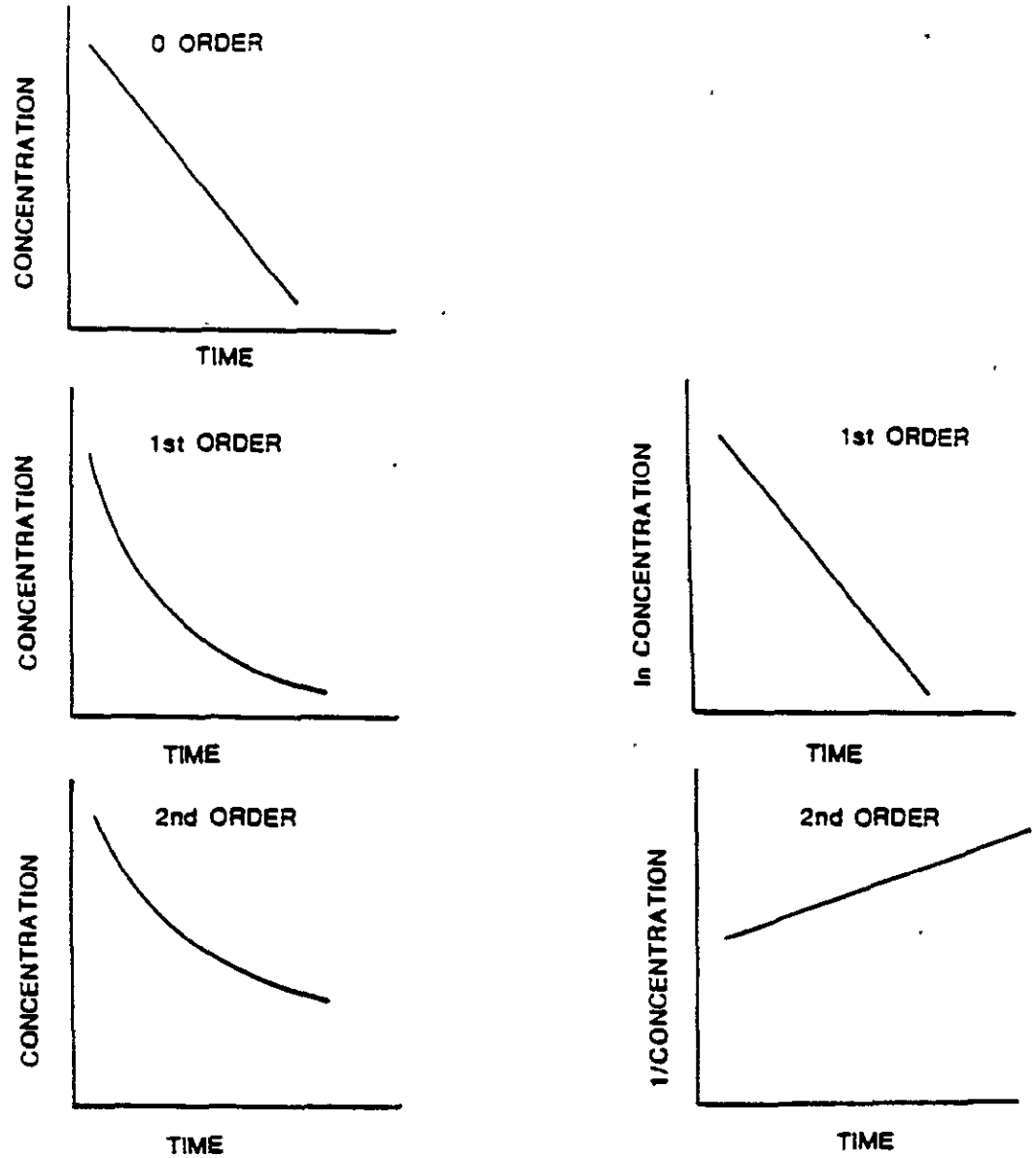


Figure 4a. The logarithmic form corresponds to the linear equation of a line (y = mx + b).

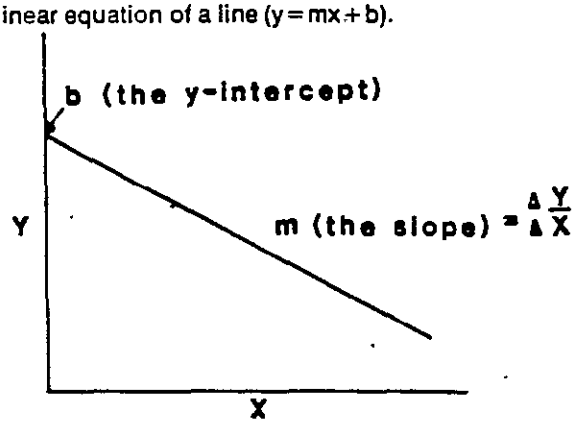


Figure 4b. Plot of the Arrhenius equation.

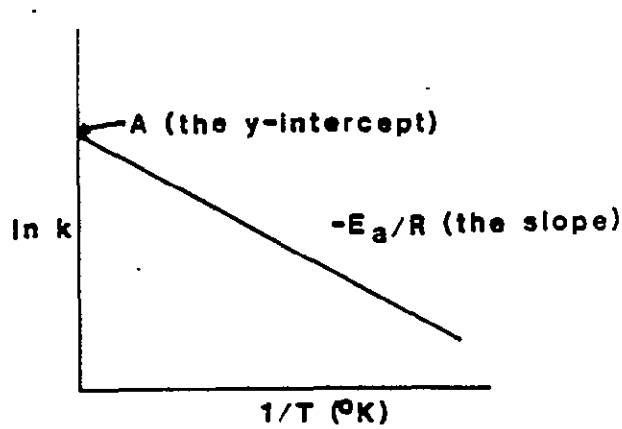


Figure 5. Plot of ascorbic acid oxidation (zero order with respect to ascorbic acid).

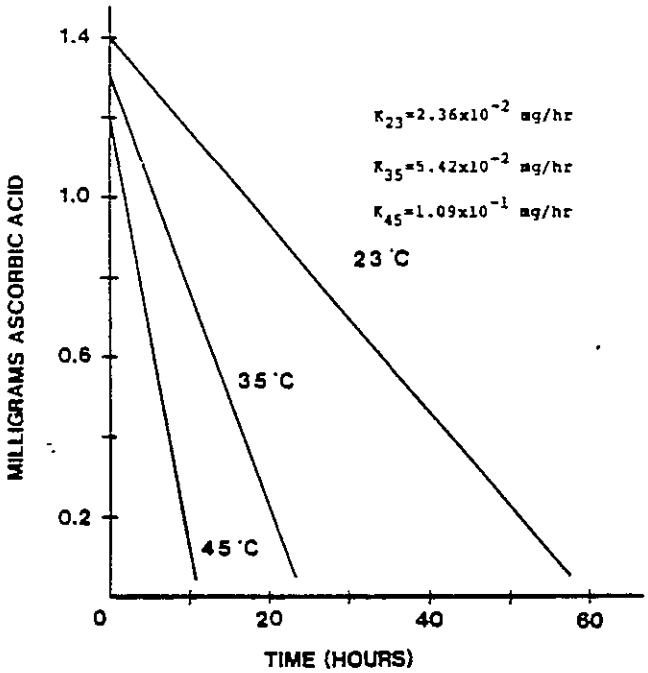
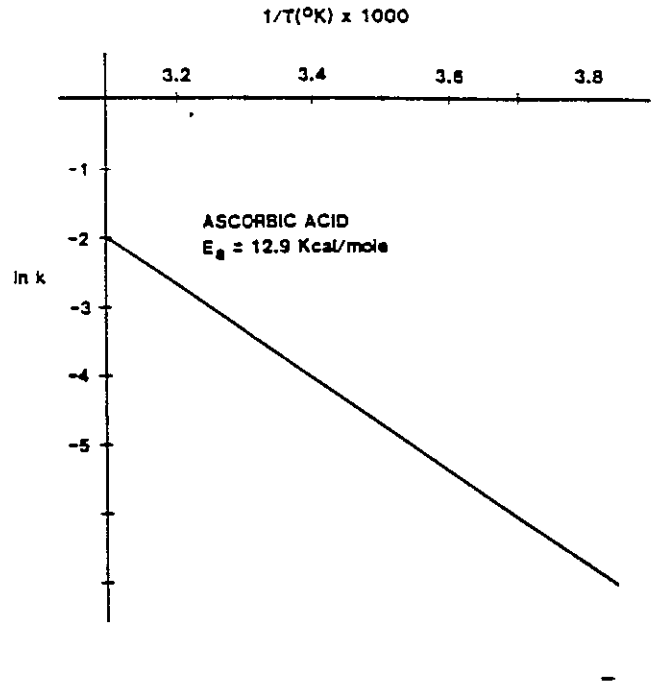


Figure 6. Arrhenius plot of ascorbic acid oxidation



The following is an actual calculation of the activation energy for ascorbic acid oxidative degradation:

Ascorbic Acid Oxidation*

23°C		35°C		45°C	
Hour	mgAA in solution	Hour	mgAA in solution	Hour	mgAA in solution
20	0 948	5	1.029	0	1.20
40	0 476	10	0.758	5	.655
60	0 004	20	0.261	10	.109

Reaction constants

$k_{23} = -0.0236$mg/hr $k_{35} = -0.0542$mg/hr $k_{45} = -0.1091$mg/hr

*See *Figure 5*.

Values for Arrhenius Plot of Ascorbic Acid Oxidation*

Reaction Constant k	ln k	Reaction Temperature °K	1/T°K	Regression Values
2.35×10^{-2}	−3.7405	23+273=296°K	3.38×10^{-3}	r = 0.999
5.42×10^{-2}	−2.9151	35−273=308°K	3.247×10^{-3}	m = −6501
1.09×10^{-1}	−2.2164	45−273=318°K	3.145×10^{-3}	y = 18.2

E_a = 12.9 Kcal/mole
*See *Figure 6*.

Interpreting Activation Energies

In the strictest interpretation, activation energies tell how temperature changes affect the rate of chemical reaction. In this way, they are similar to the z-value used by microbiologists and food chemists to describe the rate of microbial destruction or change in some temperature sensitive attribute. In fact, the E_a can be calculated from the z-value by the following formula (Lund, 1975a):

$$E_a = \frac{2.303\ RTT_1}{z} \cdot 9/5$$

where

R = The gas constant $(\frac{1.987\text{cal}}{\text{mole} \cdot {}^\circ\text{K}})$
T = Reference temperature (°K)
T_1 = Reaction temperature (°K)
z = The z value of the reaction (°F)

Notice that E_a and z-values are reciprocally proportional. Consequently, high z-values calculate to low E_a's and vice versa.

$$E_a \propto 1/z$$

Any reaction whose activation energy is lower than the activation energy for microbial destruction will be minimized by aseptic processing. Simply, aseptic processing is protective of low-activation energy reactions. Here, the point of reference for what is high and what is low is the activation energy for microbial destruction.

As illustrated in *Table 1*, activation energies for microbial destruction are typically in excess of 50 Kcal/mole. By comparison, *Table 2* gives activation energies of common deleterious reactions in foods. For the most part, these reactions have activation energies less than 40 Kcal/mole *(Table 2)*. By the criterion mentioned, these reactions will be less dependent on temperature than will be microbial inactivation.

Recall that activation energy is really the slope of a line on an Arrhenius graph (times the gas constant). High-activation energy reactions get that way because their

TABLE 1
E_a For Inactivation Of Spore Forming Organisms

Organism	z value (°F)	E_a (Kcal/mole)
B. stearothermophilus	12.6	99
B subtilis	13.3–23.4	93–53
B cereus	17.5	71
C perfringens	18 0	69
C sporogenes	23 4	53
PA 3679	19.1	65
C botulinum	17 8	70

(Modified from Lund, 1975b, used with permission of Marcel Dekker, Inc.)

TABLE 2
E_a Of Reactions Which Reduce Food Quality

Component	z value (°F)	E_a
Thiamine	45	27
Riboflavin	50	23.0
Nicotinic acid	45.5	26
Pantothenic acid	56	21
Ascorbic acid	50	23.1
B_{12}	50	23.1
Folic acid	72	14.6
Vitamin A	72	14.6
Chlorophyll	52–143	7.5–22
Maillard Browning	45	27
Lysine	38	30

(Condensed from Lund, 1975b, used with permission of Marcel Dekker, Inc.)

reaction constant k (and therefore ln k) increases rapidly as temperature increases. The result is a large slope on the Arrhenius plot. There is an important, and perhaps subtle, point to be made from this. If the reaction constants are increasing more rapidly in high E_a reactions than in low E_a reactions, then the higher the temperature, the better the protection of low E_a reactions.

So far, E_a has been discussed in terms of the effects that temperature changes have on chemical reaction rates. **By comparing the E_a's of problem reactions with the E_a of microbial inactivation, it is possible to predict the effects of aseptic processing on food quality.** These effects are absolute properties of the activation energy.

The E_a also provides empirical information. Although having many exceptions, $T = E_a/1{,}000$ is a rule which gives an approximate minimum temperature at which a reaction becomes significant in foods. The E_a of ascorbic acid browning, for example, is 20 Kcal per mole. Divided by 1,000 the temperature would be 20°C (68°F). Consequently, ascorbic acid browning would be expected at room temperature but not at refrigerator temperature. Maillard browning with an E_a of 27 to 30 Kcal/mole (27 to 30°C) would become significant at temperatures slightly above room temperature (23°C) but not below.

Typically, reactions involving lipid soluble materials have low activation energies (*Table 3*). This fact probably reflects the low energy free radical mechanisms common to oxidation of lipids and lipid soluble compounds. Also, lipid reactions are often catalyzed by trace metals. It is not uncommon for reactions in this class to proceed significantly at refrigeration temperatures.

Reactions with intermediate activation energies are primarily a problem at room temperature. Oxidation of water soluble compounds tends to be clustered in this energy group. Reactions in this class include color shifts (from water soluble pigments), flavor changes, and vitamin loss Since aseptic technology may allow greater oxygen contamination than does conventional processing, this group of reactions is especially important in aseptic processing.

Reactions with high to very high activation energies do not occur at room temperatures. They may become significant only at process temperatures. Inactivation of microorganisms, microbial spores, and denaturation of enzymes fall into this category.

The activation energy tells how reaction rates change with temperature. Low E_a reactions are comparatively insensitive to temperature change. High-activation energy reactions are normally not significant at room temperature, but as temperatures increase, their reaction rates increase precipitously. Almost all thermal defects have low activation energies compared to microbial destruction. Consequently, for equivalent levels of lethality, the higher the process temperature, the better the final product. Because aseptic processing uses high temperature treatment, microorganisms are inactivated, but product quality is spared.

TABLE 3
Range Of Activation Energies

Low Activation Energy—2–15 Kcal/mole
Reactions involving enzymes and lipid soluble food constituents
1) Enzyme catalyzed reactions
2) Destruction of Carotenoids
3) Destruction of Chlorophyll
4) Oxidation of Fatty Acids

Medium Activation Energy—15–30 Kcal/mole
Reactions involving water soluble food constituents
1) Vitamin Destruction
2) Loss of Water Soluble Pigments
3) Maillard Browning

High Activation Energy—50–100 Kcal/mole
Inactivation of microorganisms, microbial spores, and denaturation of enzymes

Very High Activation Energies—100–150 Kcal/mole
Inactivation of very heat stable enzymes

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CHEMICAL CHANGES IN ASEPTICALLY PROCESSED FOOD

The high temperature short time treatment of aseptic processing minimizes chemical reactions responsible for off-flavor (Parks *et al.*, 1963, Kirk *et al.*, 1968; Scanlan, *et al.* 1968, Zadow and Birtwistle, 1973, Thomas *et al.*, 1975, Gorner *et al.*, 1978, Jeon *et al.*, 1978; Hansen and Swartzel, 1979), off-color (Stadtman, 1948, Joslyn, 1957; Ellis 1959, Clegg, 1964, Hodge, 1967, Thomas *et al.*, 1975), and loss of nutritional value (Ford *et al.*, 1969; Burton *et al.*, 1970; Lee *et al.*, 1977; Metha, 1980; Nagy, 1980, Andres, 1984). For equivalent F_0's aseptic processing gives an almost blanket guarantee of higher quality than does conventional processing. However, from the aseptic literature, one might not reach this conclusion. Much of the work on aseptic defects have focused on UHT milk. Comparisons between aseptically processed and pasteurized milk are made Obviously, this comparison is not equitable since F_0's for the two processes differ widely. For purely equivalent processes, however, the aseptic improves quality.

Color, flavor, nutritional, and other quality losses in foods are impacted simultaneously. For example, the presence of color change without flavor changes is extremely rare. For all thermal processes, the three primary agents mediating quality loss are thermal abuse, enzymatic degradation, and oxidation. Clearly, aseptic processing is less thermally abusive than conventional processing. In most cases, the length of time that enzymes are within their catalytic range is also limited by aseptic processing. Quality losses resulting from oxidating, however, are currently the "Achilles heel" in aseptic systems. Oxygen contamination can be a problem both in processing and in packaging aseptic foods. On the brighter side, color, flavor, and nutritional phenomena have gained special recognition in aseptic processing because of their compatibility (not antagonism) with aseptic systems.

Browning Reactions

Browning reactions in food are normally broken down into enzymatic and nonenzymatic browning. Enzymatic browning is the rapid, enzyme mediated conversion of plant phenolic compounds into dark polyphenolic polymers. The culprit enzyme, polyphenylase, has an absolute requirement for oxygen. Because the browning reaction is very rapid, fruits and vegetables must be blanched and/or pretreated *prior to processing*. Due both to the speed of reaction and thermal susceptibility of the enzyme, aseptic processing offers no unique advantages or disadvantages in containing enzymatic browning. Regardless of the processing method, enzymatic browning must be addressed prior to the thermal treatment intended to bring about commercial sterility

In general, nonenzymatic browning reactions are very complex and poorly understood. Without exception, browning does not occur as the first step in a reaction sequence Browning compounds are typically far removed from the initial reactions which stoke the browning pathway There are several common nonenzymatic browning reactions in foods. These include caramelization, lipid browning Maillard browning, and ascorbic acid browning

In caramelization, dry sugars or heavily concentrated sugar solutions undergo molecular dehydration with subsequent polymerization to create brown pigments. Caramelization temperatures are typically in excess of 320°F. Consequently, caramelization is not likely to occur in aseptic processing or in the long term ambient storage which aseptic processing makes possible. By comparison, Maillard, lipid, and ascorbic acid browning are important both in the timetables for aseptic processing and for the calendar of extended ambient storage. These forms of browning have several factors in common:

1. One of the first stable intermediates arises from the condensation of an amino nitrogen group with an active carbonyl. (A Schiff's base reaction.) (Reynolds, 1963; Moller *et al.*, 1977a, b, c; Turner *et al.*, 1978)
2. They all reduce the nutritional quality of foods.
3. They are minimized by aseptic processing but may become important during long term ambient storage (Stadtman, 1948; Shaw *et al.*, 1977; Kanner *et al.*, 1982).
4. They are all extremely complex and poorly characterized (DeMan, 1976).
5. Along with discoloration, they impart off-flavors to foods (DeMan, 1976).

The main difference in the three reactions is the origin of the reactive carbonyl. In the Maillard reactions, the reactive carbonyl comes from a reducing sugar (glucose, fructose, lactose, maltose, ribose, galactose, but not sucrose) (Ellis, 1959). Browning from lipids occurs when autoxidized polyunsaturated fatty acids react with amines, amino acids, or proteins. In this case, free hydroperoxidic radicals and reactive carbonyls produced by decomposition of lipid hydroperoxides are the precursors of the macromolecular brown pigments (Pokorny, 1981). The first step in ascorbic acid browning is the oxidation of ascorbic acid to dehydroascorbic acid. The dehydroascorbic acid then provides reactive carbonyls which feed the browning pathway (Kurata and Sakurai, 1967).

Clearly, reducing sugars, ascorbic acid, and oxidized lipids are not isolated entities in foods. Inevitably, both they and their reaction products become intermixed. Consequently, in foods, secondary products of a browning pathway tend to intrude on competing browning reactions. Partially, for this reason, unravelling browning pathways in foods has been very difficult. However, a few of the steps in the early stages of browning are known with some certainty. To date no nonenzymatic browning pathways have been totally characterized. Even after seventy years of research, recent investigations are still shedding light on the first steps of Maillard browning.

On the brighter side for aseptic processing, all common browning mechanisms have activation energies below 50 Kcal/mole. Therefore, they develop much less dramatically with aseptic treatment than with conventional processing. In the review which follows, the conditions and early reactions of browning will be discussed.

Maillard Browning. Much of our current browning information originated in the work of a French physician-chemist named Louis-Camille Maillard. He correctly determined that amino acids and reducing sugars somehow condense to form brown pigment with the simultaneous loss of carbon dioxide. He also determined the relative order of reactivity for amino acids and sugars. He found the hierarchy of amino acid reactivity to be as follows: alanine > valine > glycine > glutamic acid > leucine > tyrosine. He also determined the reactivity for reducing sugars to be: ribose > xylose > fructose > galactose > glucose. In general, the order of reactivity was: pentoses > hexoses > disaccharide.

In the first step of Maillard browning, a reducing sugar reacts with a free amino group *(Figure 7.)* The amino group may be contributed by free amino acids, polypeptides, and the ε-amino group of lysine, or by the basic amino acids, arginine and histidine. The resulting glycosylamine undergoes an Amadori rearrangement to yield an aldosamine or ketosamine. These derivatives undergo additional condensations with either other amino groups or additional reducing sugars. The complex compounds formed by these reactions undergo decomposition to produce flavor compounds and color precursors (DeMan, 1976). The overall activation energy for these reactions is around 30 Kcal/mole. Numerically, this value suggests Maillard reactions occur slowly at room temperature.

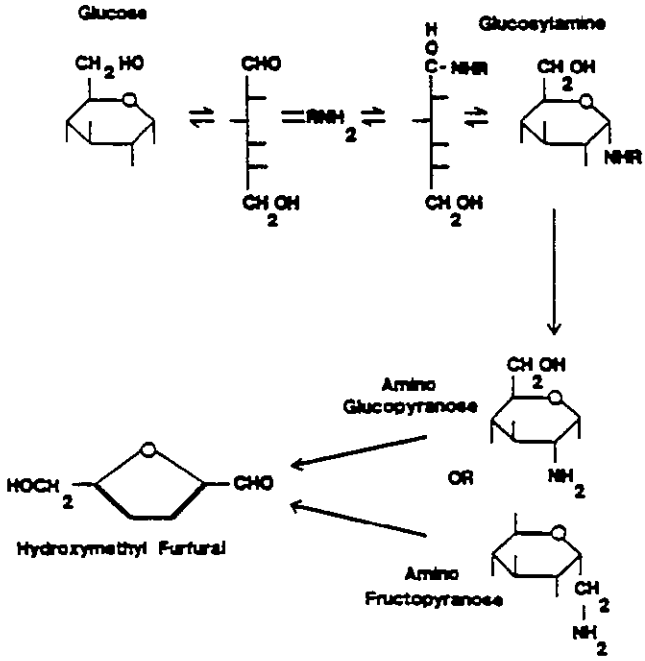
There are three conditions which encourage nonenzymatic browning: high storage temperature (*i.e.* above room temperature), high pH, and low a_w. For aseptic high-acid foods, the most essential parameter to control is storage temperature. Maillard browning is very slow at temperatures below 27°F.

In addition to its active role in off-color and off-flavor production, Maillard browning is also a nutritional concern (Fox, 1982). Since free amino acids are not abundant in most living tissues, the ε-amino group of covalently bound lysine is often the target of attack by reducing sugars. Lysine is an essential nutrient in its own right. In addition, its loss also reduces the susceptibility of proteins to enzymatic attack. Consequently, compared to native protein, Maillard modified proteins have reduced nutritional availability (Hollingsworth and Martin, 1972).

All of the known steps in the Maillard pathway occur before the first evidence of browning. However, nutritional losses occur very early in the reaction cascade. Consequently, once browning becomes apparent, nutrition losses are well underway. The first evidence of underlying Maillard reactions in heated foods is an increased absorption in the near UV region. This parallels the formation of a straw yellow color. With time the yellow deepens into red-brown. Ultimately, brown pigment becomes a very dark and loosely defined colloidal polymer called melanoidin. If a reducing agent such as sodium bisulfide is added early in the browning process, the formation of color is reversed. However once melanoidins are formed, the process is irreversible. The observation that reducing agents inhibit and oxidizing agents (Cu^{++}, Fe^{+++}) increase Maillard browning indicates that some intermediate reactions must be redox in nature.

Recent concerns have been raised about the safety of Maillard browning derivatives. Some of the degradation products, including hydroxymethylfurfural, test positive in the Ames mutigenicity test (Omura *et al.*, 1983). Therefore, Maillard browning may be not only a cosmetic problem, but also a problem in human health.

Figure 7. Maillard browning.



Oxidative Browning. With aseptic processing, entrapped gases in food products must be removed before entering the sterilization step. Aseptic processing by its very nature requires a closed system. Consequently, any extraneous oxygen entering the sterilization system remains in line to contaminate the product during processing and storage.

Most aseptic packages also present an oxygen challenge. The packaging problem rests in the materials which typically make up aseptic containers. To date all polymer packaging materials have some detectable level of oxygen permeation.

Theoretically, impermeable barriers can be achieved with foil laminated paper and plastic. In reality these barriers are very good but not absolute. Creases, breaks, and pinholes inevitably permit some permeation. Consequently, permeation values are somewhat erratic. Foil laminates also tend to be fairly expensive. Since traditional containers of metal and glass are impermeable to oxygen, processors in the past have not been overly concerned with (or even aware of) nonenzymatic, oxidative browning problems. For this reason the volume of research dedicated to oxidation browning is small compared to work on Maillard browning.

There is a difference in end products between Maillard and ascorbic acid browning. At higher temperatures with Maillard browning, there is a conspicuous increase in HMF (5-hydroxymethyl-2-furaldehyde) (Nagy and Randall, 1973; John[illegible] and Tc[illegible] 1975; K[illegible] *et al.* [illegible]) Alth[illegible]

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some HMF will be found in any heat treated product, its level in a product darkened solely by oxidation will be low. In aseptic foods it is important to identify the source of browning. Thermal browning (Maillard reaction) suggests a processing problem. Oxidative browning usually indicates a packaging problem. Often HMF measurements help pinpoint the origin of browning.

Ascorbic Acid Browning. Contrary to popular belief, ascorbic acid is a fairly stable molecule. However, in the presence of oxygen, heat sensitive dehydroascorbic acid is formed. Enzymes and metal (copper and iron) catalysts greatly accelerate this conversion. During the rapid breakdown of dehydroascorbic acid, there is an accumulation of pre-browning compounds. As in the Maillard reaction, there is a lag period between the formation of breakdown products and the first evidence of browning. The pH optimum of ascorbic acid browning appears to be near 4.5 (Clegg, 1964). By comparison, Maillard browning requires a nearly neutral pH. Up to a limit, the addition of amino acids and reducing sugars increases browning. Unlike Maillard browning, however, neither amino acids nor reducing sugars seem to be absolute requirements for ascorbic acid browning.

Lipid Browning. Oxidized lipids and lipid soluble compounds may also decompose to form browning precursors. To date, very little attention has been given this avenue of browning. The pathway is generally assumed to involve free radicals. Consequently free radical initiators such as metal ions, UV light, and singlet oxygen play an important role. Unlike Maillard browning, the free radical oxidation of lipids to generate carbonyls requires only 2–10 Kcal/mole. This level of activation energy may even allow significant reaction at refrigeration temperatures. Although browning will not be a problem at low temperatures, a pool of browning precursors may collect which might later cause problems if temperatures rise.

Reducing Oxidative Browning. Obviously, the most important precaution in reducing oxidative browning is the control of oxygen. Finishing, blending, and filling are common practices which incorporate oxygen. The oxygen load can be reduced significantly through the use of heat and/or vacuum. Centrifugal deaeraters may also be helpful in removing entrained air. In some foods it may be possible to bind catalytic metals with a sequestering agent such as EDTA.

Oxygen contamination in the head space can be reduced with nitrogen, CO_2, or other inert gases or inert gas mixes. For some containers, it may also be practical to purge the headspace with live steam immediately before sealing. If browning is due to permeated oxygen, logically a better barrier can be used. However, pinpointing the area of permeation is necessary. For example, the fitments of some bag-in-box bags can permeate more oxygen in a day than the rest of the package will in a year. It would be futile to improve the barrier of the container if the fitment is the source of contaminating oxygen. In form-fill-and-seal containers, an uneven draw of the base polymer can create isolated pockets of high permeation.

NUTRITIONAL AND FLAVOR CHANGES

In general, the nutritional quality of aseptic products is better than conventionally processed counterparts (Ford *et al.*, 1969; Burton *et al.*, 1970; Lee *et al.*, 1977; Metha, 1980; Chan and Cavaletto, 1982). In fact, for milk, UHT processing compares favorably with pasteurization (Zadow and Birtwistle, 1973). Although pasteurized milk has slightly greater retention of vitamins A and D, UHT treatment is more sparing on vitamin C, folic acid, and B_{12} (Ford *et al.*, 1969; Metha, 1980). Processing methods may also play a role in the final quality of the food (Burton, 1972).

During the first few weeks of storage, milk with low levels of dissolved oxygen taste better than samples with no oxygen (Thomas *et al.*, 1975). Oxygen oxidizes sulfhydryl groups which have become reduced during thermal processing. Reduced sulfhydryl groups impart a "cabbage-like" flavor to the milk. Unfortunately, dissolved oxygen reduces levels of vitamin C, folic acid and B_{12}. It also imparts a "stale" flavor to milk stored over one month. The long term nutritional and flavor benefit from low oxygen greatly outweighs the short term benefits of allowing some oxygen at processing (Thomas *et al.*, 1975).

Some evidence suggests that the overall nutritional quality of aseptic milk is better than pasteurized milk. Newborn infants fed UHT milk had slightly higher weight gains, quicker regain of postpartum weight loss, and less gastric distress than infants fed pasteurized milk (Metha, 1980). UHT treatment reduces the free calcium in milk. However, calcium bioavailability is not altered (Burton *et al.*, 1970; Ford *et al.*, 1969).

In aseptically packaged citrus, ascorbic acid loss is comparable to losses incurred in freeze concentration (Chan and Cavaletto, 1982). As with color, oxygen is the best parameter for predicting the nutritional demise of aseptically processed foods.

As long as processing timetables are correct and dissolved oxygen is held to a minimum, the flavor quality of aseptic foods outshines their conventionally processed counterparts (Rolfe, 1969). However, the shorter process times in aseptic processing leave little latitude for errors in processing schedules. The time buffer between proper processing and over-processing is often very short. An incompatible match between the food and heat exchangers will predispose to thermal damage.

The same reaction pathways which give birth to oxidation and thermal (Maillard) browning also spawn flavor defects (Zadow and Birtwistle, 1973; Thomas *et al.*, 1975). Usually, detectable off-flavors precede the first evidence of discoloration. Removal of oxygen by deaeration, treatment with inert gas, or purging headspace with steam will greatly reduce oxidative flavor defects (Thomas *et al.*, 1975). In orange juice there is a high correlation between furfural and off-flavors (Nagy and Randall, 1973) although furfural itself is an essentially flavorless compound (Kanner *et al.*, 1981). Recall that furfural was also present in nonezymatic browning. This fact indicates that flavor and browning defects share a common lineage (DeMan, 1976).

On the positive side for aseptic processing, sterile essence

can be injected post process to replace volatiles lost in heating or in the flashing step which follows direct steam injection. Flashing may also drive off unwanted volatile compounds (Bassette and Keeney, 1960; Parks *et al.*, 1963; McCarty and Hansen, 1978). Closed aseptic systems seal in aroma and flavor volatiles and greatly decrease the metallic flavors imparted by metal cans (Labell, 1983).

In developing countries where refrigeration is uncommon and expensive, aseptic processing can limit transport damage of delicate fruits (Sanchelima, 1984; Chan and Cavaletto, 1982) which would otherwise be shipped to distribution centers and held in refrigerated storage until processed (Anon., 1983) Comparatively, the color, flavor, texture, and nutritive quality of such aseptic products can be measurably improved.

ENZYMES

The effect of HTST processing on enzymes has both benefits and drawbacks. Rapid temperature increases limit the time enzymes are in their range of optimum activity, but some aseptic products have experienced problems apparently associated with enzyme renaturation (David and Shoemaker, 1985; Adams, 1981; Adams *et al.*, 1976).

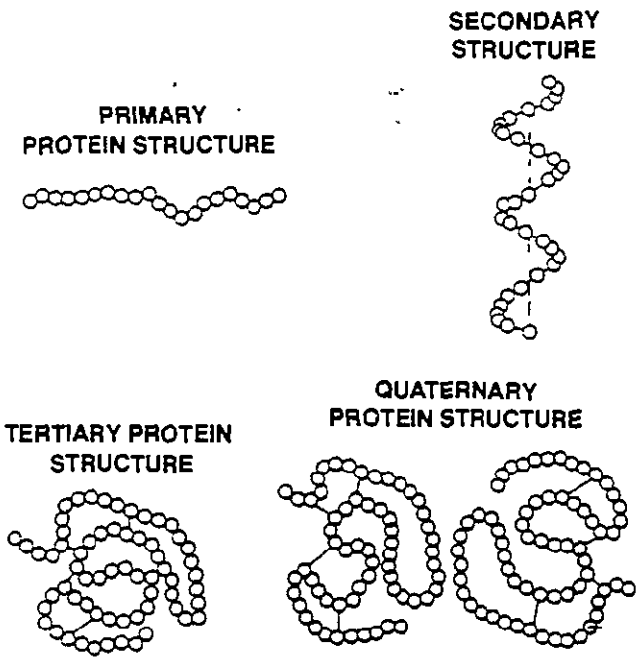
Up to a point, the effect of temperature on enzyme activity follows the pattern discussed in the section on activation energy. For each increase in temperature, the reaction rate increases by some value dictated by the activation energy. With enzymes, however, a thermal limit is reached where enzyme denaturation reduces catalytic activity. If conditions of denaturation are not too extreme, much of the enzyme activity may reappear when the system is cooled below denaturation temperatures. This is especially common with low molecular weight enzymes. For example, one enzyme problem is gelation in UHT milk over time. In both age gelation and enzyme renaturation, proteins are the problem constituent in the food. Consequently, a short review of proteins will be helpful in understanding this phenomenon.

Protein Structure

Proteins can have up to four levels of structure: 1° (primary), 2° (secondary), 3° (tertiary) and 4° (quarternary) *(Figure 8)*. These levels of structure can be explained by comparison to a screen door spring. The wire itself is like the primary structure. In proteins the primary structure is the linear sequence of amino acids covalently linked to form a polypeptide chain. The coil in the spring is like the secondary structure of proteins. In proteins, the secondary structure refers to the highly ordered helical arrangement of peptides in a single dimension.

By turning and folding the spring, it is possible to compress it into a ball which will fit folded in the cup of your hands. This tightly packed spring roughly portrays the arrangement of a polypeptide chain into the tertiary structure which is characteristic of globular (*i.e.* globe-like) proteins. Most biologically active proteins (enzymes, actin, myosin, protein toxins, hemoglobin, myoglobin, etc.) have a very complex 3° structure. Structural proteins (collagen, elastin, bone matrix proteins, fingernail and hair proteins) have little or no 3° structure. The quarternary structure is like two of the folded springs glued together. In proteins the quarternary structure is the combination of two or more polypeptides non-covalently linked.

Figure 8. Protein structure.



Together the 2°, 3°, and 4° structures comprise the protein "conformation." Denaturation is a change in enzyme conformation (*i.e.* 2°, 3°, or 4° structure but *not* 1° structure).

Elevated temperatures are believed to alter the enzymes active site—the location where the enzyme binds with its specific substrate. As heat unravels enzyme conformation, the active site becomes increasingly unable to accommodate its substrate molecules. This situation results in reduced catalytic activity.

Enzyme Regeneration

There are two ways residual enzyme activity can exist in aseptically processed foods. The first possibility is for enzymes to be only partially inactivated. At first this seems to be a clearly viable possibility. The E_a's for enzyme destruction may range up to 150 Kcal/mole. By the minimum activity rule, a process with an E_a of 150 Kcal/mole would not occur significantly until a temperature of 150°C (~300°F) had been reached. Unfortunately, the minimum activity rule is not a very accurate tool for high E_a reactions. If it were, there would be clear reason to blame incomplete enzyme inactivation for residual enzyme activity in aseptic foods. Even though some residual enzyme activity in aseptic foods may be due to extremely heat stable enzymes, there is a more reliable criterion which suggests that heat stability *per se* is not the major problem. Remember that high E_a reactions are more sensitive to

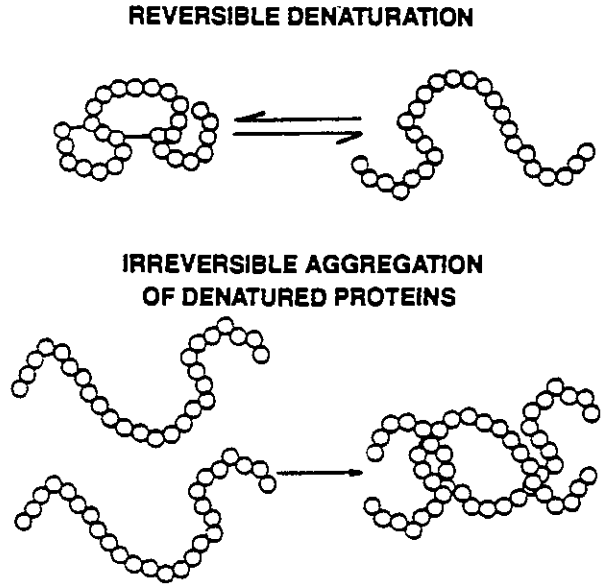
temperature increases than low E_a reactions. If a high E_a reaction occurs at some temperature, increasing the temperature only increases the rate of conversion. We know that conventional processing is not bothered with post process enzyme activity. Since the E_a's of enzyme denaturation are high for heat stable enzymes, the higher temperature of aseptic processing should increase the rate of enzyme destruction. Consequently, the notion that aseptic processing is soft on heat stable enzymes, in the general case, is probably not true.

The second and most plausible explanation for residual enzyme activity in aseptic products is somewhat more subtle. It has to do with secondary reactions which occur while the enzyme is unfolded during denaturation. By analogy, suppose you have two identical balloons. They are both blown up to the same size. In one, the air is let go immediately. In the other, the air is emptied after 24 hours. In a side-by-side comparison the two balloons would not look the same. The balloon which held air the longest would look stretched and flaccid. Even though both balloons were blown to equivalent sizes, some additional process clearly happened in the balloon which received the longer period of stress.

A similar thing happens in enzyme denaturation. Aseptic processing temperatures efficiently denature heat stable enzymes. However, during unfolding the enzyme may not be stressed beyond its elastic limit. On cooling, it may be possible for the 3° structure to snap back before crippling side reactions can occur. *(Figure 9)*.

In conventional processing, enzyme denaturation is initially less efficient. However, the amount of time unfolded enzymes expose their reactive side groups to an alien chemical environment is much greater than in aseptic processing. Therefore, the opportunity for maverick side reactions to occur is substantially increased. It is particularly common for enzymes to aggregate with other denatured enzymes and proteins *(Figure 9)*. Such side reactions freeze the enzyme in a catalytically disabled conformation.

Figure 9. Reversible and irreversible denaturation of proteins.



A list of common heat stable enzymes is given in *Table 4* Most of these enzymes have been problems in blanched or conventionally processed high-acid foods. For the most part, their impact in aseptic processing has not been systematically studied. However, with the possible exception of milk, enzyme reactivation has not been a major problem in aseptic processing.

Age Gelation

The limiting factor of shelf life for UHT milk is a defect called age gelation (Tombs, 1969; Samel *et al.*, 1971; Andrews, 1975; Whittaker, 1977; Fox, 1982). During storage, some (but not all) UHT milk forms a custard-like gel. Many factors have a bearing on gelation. These include: (1) the breed of cow [greatest in Jersey]; (2) length of lactation [early lactation milk has greater gelling than late lactation milk]; (3) time of year [summer milk gels more readily than winter milk]; (4) mastidis [increases gelation]; (5) pasteurization before sterilization [reduces gelation]; and (6) length of refrigeration before sterilization [longer refrigeration increases gelling].

The sequence of events in gelation are initial thinning, a long period with little viscosity change, and a sudden rise in viscosity within 1 to 3 weeks. Early in the viscosity stage and after incipient gelation, agitation will redisperse milk proteins. However, within 24–48 hours, samples revert to their viscous state. After complete gelation, the process is irreversible.

During the low viscosity phase of storage, casein micelles remain round and unassociated. During the high-viscosity stage, before the onset of gelation, micelles show distortion, elongation, and the formation of thread-like extensions. During gel formation, threads become elongated, and identifiable filaments connect a network of micelles.

Preheating the milk to 72°C for 30 sec before sterilization decreases gelation. Although forewarming reduces gelation, it creates sedimentation and flavor defects. Factors which prevent gelation often promote sedimentation during storage. In general, an inverse relationship exists between susceptibility to sedimentation and susceptibility to gelation (Ramsey and Swartzel, 1984).

Despite massive research into the gelation phenomenon, there is still debate over its origin. Many researchers feel that heat stable microbial enzymes are to blame (Adams,

TABLE 4
Selected Heat Stable Enzymes in Foods

Lipase	Peroxidase*
Phenolase	Ascorbic Acid Oxidase
Lipoxygenase*	Pectinase*
Chlorophylase	Protease*
Catalase	Alkaline Phosphatase*

*Strong Impact on Quality

1981) Before treatment, milk is cooled to prevent spoilage. Refrigeration inhibits the growth of most bacteria. However, some psychrotrophic bacteria are still able to grow. Consequently, psychrotrophs ultimately become the predominant microorganism. For many years, it has been known that psychrotrophs have very heat stable proteolytic enzymes. If aseptically drawn milk is seeded with psychrotrophs and submitted to UHT treatment, it gels sooner than the unseeded controls (Snoeren *et al.*, 1979).

However, since proteases are not always detected in gelled UHT milk and since correlation between proteolysis and coagulation is difficult to show, some researchers favor a strictly physiochemical model for storage gelation.

There is also evidence that salt shifts play some role in gelation. UHT processing reduces the amount of unbound calcium in milk. Sodium phosphate, sodium citrate, and other compounds which bind free calcium also increase gelation. On the other hand, multionic polyphosphates stabilize against gelling. Stability from calcium and polyphosphate ion is probably due to the formation of stabilizing bonds between charged sections of the protein micelle. The method of UHT treatment can also influence gelling and protein precipitation (Lyster *et al.*, 1971).

Although there are probably many factors which combine to cause gelation, there are several precautions which can be taken to increase the shelf life of UHT milk. These include:

1. Use of high quality milk;
2. Adequate heat treatment during forewarming;
3. Low temperature storage (<20°C); and
4. Addition of polyphosphates.

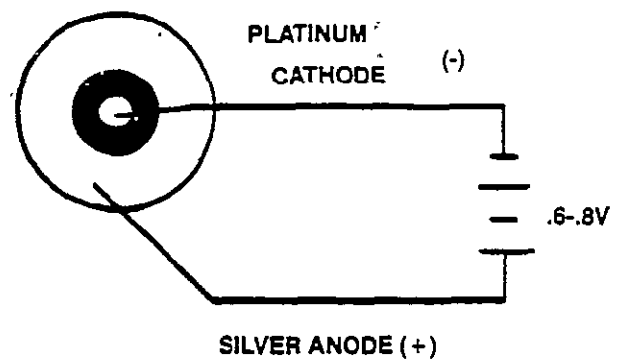
OXYGEN MEASUREMENT

There are basically three methods for measuring oxygen dissolved in liquids. In the gasometric method, entrapped gases are driven from solution and measured volumetrically. Unfortunately, the method is extremely laborious and not suited to routine oxygen analysis. Chemical tests have also been developed to measure oxygen dissolved in waste water. However, cross reactions in foods make this test impractical for standard analysis.

Fortunately, a much simpler method for oxygen analysis, which is fast, accurate, and highly specific to oxygen, has been developed. The sensing unit is enclosed in a probe covered with an oxygen selective membrane.

The probe goes by several names including the Clark probe (after the inventor), the polarographic probe, or dissolved oxygen probe (D.O.P.) *(Figure 10)*.

Figure 10. Clark-type dissolved oxygen probe.



The probe end consists of a cathode (usually platinum) and an anode (usually silver). When current of 0.6–0.8 volts is imposed across the electrode, the small cathode becomes saturated with electrons (*i.e.* it becomes polarized—therefore the name polarographic probe) (Lee and Tsao, 1979).

As oxygen migrates through the cover membrane, it becomes reduced. The cathode gives up 4 electrons in this reaction *(Figure 11)*. In the process a current is generated which is directly proportional to the oxygen present.

It is not obvious from the name of the dissolved oxygen probe what the units of measurement are. An extremely common mistake is to assume that oxygen concentration is being measured. The actual parameter is *oxygen partial pressure*. Fortunately, the driving force for oxidation is oxygen partial pressure, not oxygen concentration.

If desired, the concentration of oxygen in a medium can be determined if its solubility constant is known. This relationship is embodied in Henry's law:

$$\Pi = k'm \rightarrow m = \frac{P}{k'} \rightarrow C = P_s$$

Concentration =
Partial Pressure × Solubility Constant

where

m = C = The molality of the solution (mol $kg^{-1}H_2O$) = concentration
P = The partial pressure of O_2 (atm)
k' = Henry's Law Constant (atm kg H_2O mol^{-1}) $= \frac{1}{s}$
s = Solubility Constant

Figure 11. Half cell reactions of Clark-type dissolved oxygen probe.

Cathode: $O_2 + 2\,H_2O + 4\,e^- \longrightarrow 4\,OH^-$

Anode: $4\,Ag + 4\,Cl^- \longrightarrow 4\,AgCl + 4\,e^-$

Figure 12a. Dissolved oxygen probe in air

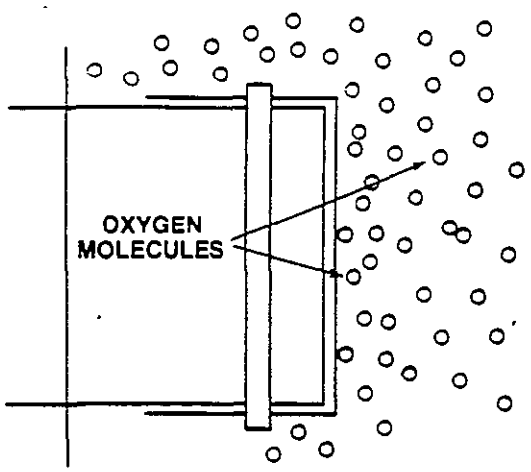
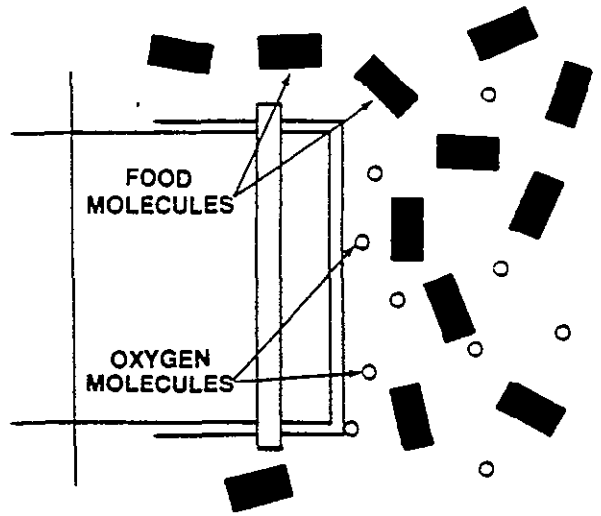


Figure 12b. Dissolved oxygen probe in food



Air at atmospheric pressure contains 21% oxygen. The partial pressure of oxygen in air is .21 atmospheres. Water totally saturated with air at room temperature contains only 0.6% oxygen. However, since the water is saturated with air, the partial pressure of oxygen in water is the same as the partial pressure of oxygen in the air, .21 atmospheres. Consequently, even though the oxygen concentration is vastly different in air and in saturated water, the dissolved oxygen probe should give the same reading in both systems.

Air is rich with oxygen molecules. If a D.O.P. is inserted into a container of air, it would be constantly bombarded with oxygen molecules *(Figure 12a)*. Occasionally oxygen striking the membrane will be absorbed and measured by the probe.

In contrast to air, water has comparatively few oxygen molecules at the same partial pressure. However, it does have something that air does not have—a high molecular density. The tightly packed water molecules act as rebound paddles *(Figure 12b)*. Compared to air, which allows a fairly free path to oxygen movement, oxygen in water is violently battered about. This action increases the likelihood that oxygen will contact the D.O.P. membrane. Obviously, the probe membrane does not know whether it is being impacted occasionally by individual molecules in a large milieu or frequently by a single oxygen bouncing back and forth off nearby water molecules. Similarly, to molecules undergoing oxidation it does not matter how many oxygen molecules are in the reaction vessel. It only matters how many times they actually get struck by oxygen molecules. Thus partial pressure measures the frequency of impact, not the total concentration of oxygen.

As oxygen around the probe is consumed by the electrodes, a zone of oxygen depletion can occur in liquid samples. The dense molecular arrangement which assured a large number of oxygen impacts at the probe membrane now acts as a barrier to oxygen migration toward the probe. Consequently, to attain a steady D.O.P. reading in liquid samples, the solution must be constantly stirred.

Recently, a new probe has been designed by Leeds and Northrup (North Wales, PA) which regenerates oxygen at a third electrode. It has a slower response but does not require agitation.

There are three sources of oxygen in aseptic systems which are not normally a problem in conventionally processed foods. These are dissolved oxygen, entrapped oxygen, and headspace oxygen. Dissolved oxygen is actually in solution within the food matrix. It is the only source of oxygen which participates in the oxidation of liquid based foods. Entrapped oxygen exists as discrete pockets of air suspended within the food. The primary concern over entrapped air is that it acts as a reservoir for dissolved oxygen. For foods sensitive to oxidation, dissolved and entrapped oxygen can be reduced by dearation.

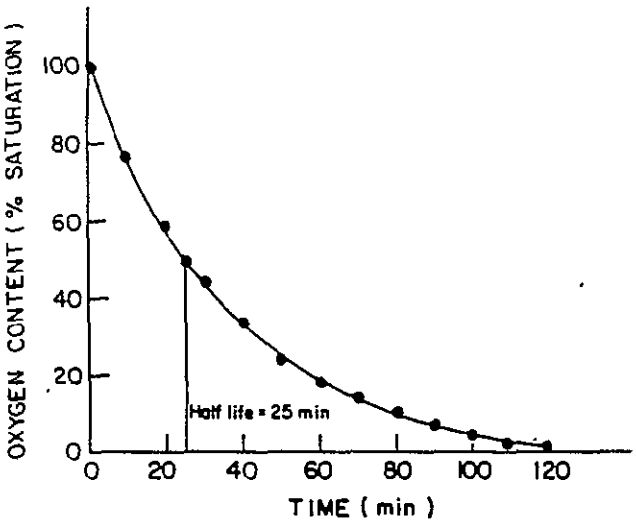
Though dissolved and entrapped oxygen are actually different entities, they share several features which warrant their being included in the same category: (1) both originate from preprocess contamination with oxygen; (2) both tend to be uniformly distributed; (3) entrapped oxygen acts as a source of dissolved oxygen; and (4) in both cases, the impact on food quality may be difficult to assess.

Of the three sources of oxygen, headspace oxygen is the most easily controlled. Technology for headspace flushing was pioneered far before aseptic processing became popular. Unlike dissolved and entrapped oxygen, headspace oxygen is not distributed uniformly. Therefore any damage it may cause will be localized (usually below the lid where defects would be most apparent to consumers).

For flexible and semiflexible pouches, nondestructive tests exist for measuring the total amount of entrained air. Many foods, especially those containing ascorbic acid, react so rapidly with oxygen that accurate D.O.P. readings are difficult to collect *(Figure 13)*.

In standard tests for oxygen permeation through poly-

Figure 13. Consumption of oxygen by orange juice at 25°C



mers, a constant oxygen differential is imposed across the sample. Under these conditions, oxygen permeation usually becomes constant after a short lag period.

In foods, a constant differential of oxygen usually requires weeks to months. When equilibrium has been established, the permeation rate is usually much lower than determined by standard permeation tests. Consequently, polymer permeation values tell only part of the shelf life story.

The food may also have an effect on permeation and shelf life. For example, a 2 mil low density polyethylene (LDPE) film should permeate only half as much oxygen as a 1 mil LDPE film. Does this mean that a 2 mil film adds twice as much protection to the food? This question can be answered mathematically or empirically. An empirical approach will be described here.

Imagine two glass tubes filled with oxygen free water and closed at one end with a rubber stopper containing a D.O.P. On the other end, one is sealed with 1 mil LDPE, the other with 2 mil LDPE. In each tube the D.O.P. is placed 1 cm from the polymer. After about 3 hours the difference in probe readings remains fairly constant (though absolute readings continue to increase).

Since the 2 mil LDPE film has only half the oxygen permeation of a 1 mil LDPE film *(Figure 14a)*, it is tempting to expect about half the dissolved oxygen reading in the 1 mil tube versus the 2 mil tube. Actually, the dissolved oxygen reading in the 2 mil tube is only 5% less than the reading found in the 1 mil tube *(Figure 14b)*. Similarly, there is a five-fold difference in the oxygen permeability of 1 mil LDPE and 1 mil of a certain oriented polypropylene (OPP) film *(Figure 14c)*. But in diffusion tests, the dissolved oxygen reading in the OPP tube is only slightly lower (15%) than in the tube covered with LDPE *(Figure 14d)*.

The explanation for this phenomenon lies in the diffusion properties of the medium. Though the diffusion coefficients for oxygen in LDPE or OPP are respectively 1 and 2 [illegible] greater than [illegible] efficients commonly found in food, the polymer exerts its diffusional resistance over a relatively small unit dimension. Though the diffusional resistance of the food is relatively small, it is exerted over a distance which is many times greater than the polymer's thickness.

The selection of LDPE and OPP in the preceding examples was contrived to emphasize the potential role of oxygen diffusion through food in oxygen uptake. Both LDPE and OPP are very poor barriers. If polymers with very high diffusion resistances are examined, permeation results will be somewhat different.

For example, the oxygen permeation of a certain 2 mil saran is one-half that of a 1 mil saran. When diffusion comparisons are made, the oxygen signal from the 2 mil saran is 55% (or almost half) of the signal from the 1 mil saran. Unlike the more porous barriers, there is almost a proportional relationship between barrier level and oxygen uptake by a food.

There are three main reasons why food diffusion is an important parameter even in high barrier systems. First, no matter how good the polymer, doubling its barrier will never quite provide double protection of a food. Even for very good barriers, the food resistance to oxygen diffusion has a measurable effect. Secondly, the oxygen concentration will be highest near the membrane and lowest toward the center of the container. This situation is equally true of high and low barrier material.

Finally, low barrier materials are used in aseptic containers more often than realized. For example, fitments for bag-in-box packages are almost exclusively made of low barrier polyolefins. Consequently, doubling the barrier of a fitment will not provide proportional protection to a food.

The oxygen diffusion coefficient tells how the food resists the movement of oxygen in its attempt to migrate through the diffusion medium. At the same time, oxygen is constantly being removed through food oxidation. With time, an oxygen equilibrium is established so that there is a high oxygen concentration near the container wall. This concentration drops off toward the center of the container. Consequently, oxidation tends to be much greater near the container wall than toward the center of the container *(Figure 15)*.

This phenomenon is important to keep in mind when trying to assess the impact of oxidation on consumer acceptance. Depending on the food, an overkill of oxidation near the membrane may hasten or prolong the onset of oxidation detectable by the consumer.

SHELF LIFE

For glass and metal containers, the usual method for determining food shelf life is through accelerated storage studies. If proper precautions are taken, such studies can provide important information. However, there are potential hazards with this approach. Even though temperatures are elevated to hasten degradation, storage evaluations may require several months. Specially equipped rooms with precise temperature control are also necessary. Per- [illegible] the [illegible] energy thresholds

Figure 14a. Oxygen permeation rate of a 1 mil LDPE film versus a 2 mil LDPE film.

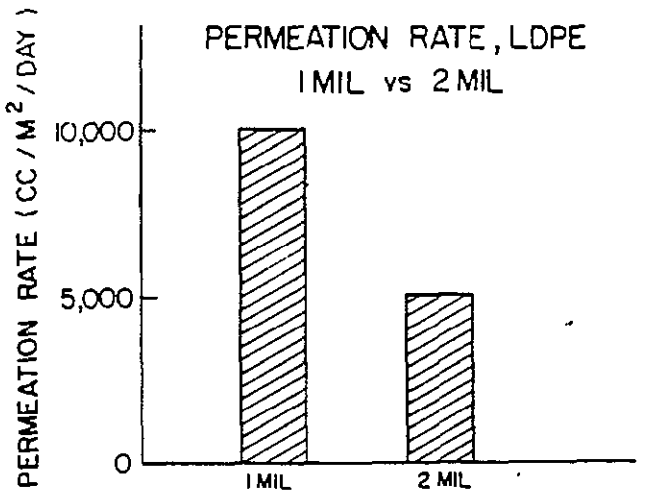


Figure 14b. Dissolved oxygen reading 1 cm from the polymer (1 mil LDPE and 2 mil LDPE film)

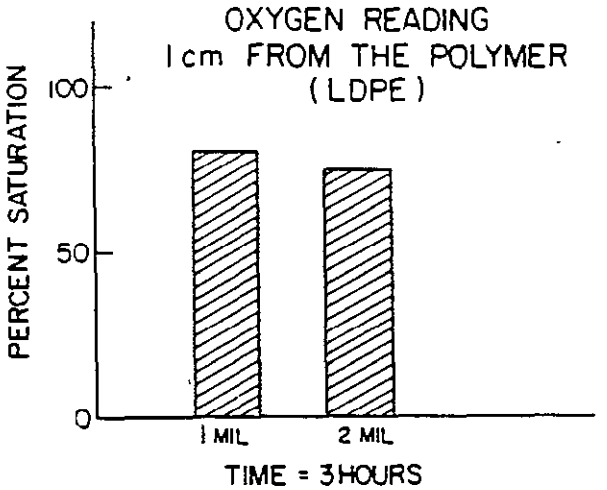


Figure 14c. Oxygen permeation rate of a 1 mil LDPE film and a 1 mil OPP film.

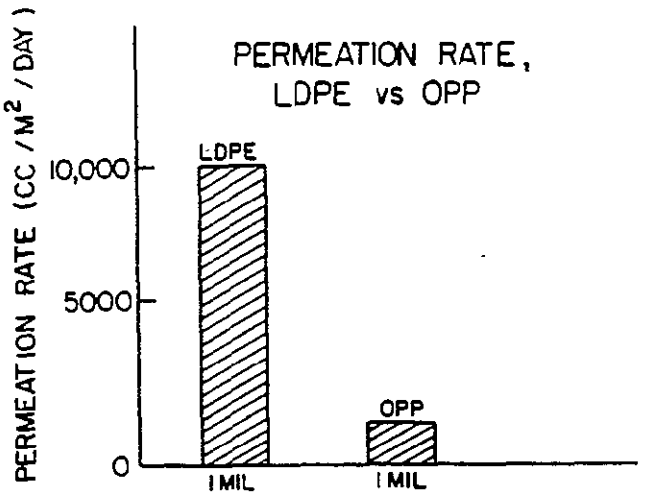


Figure 14d. Dissolved oxygen reading 1 cm from the polymer (1 mil LDPE film and 1 mil OPP film).

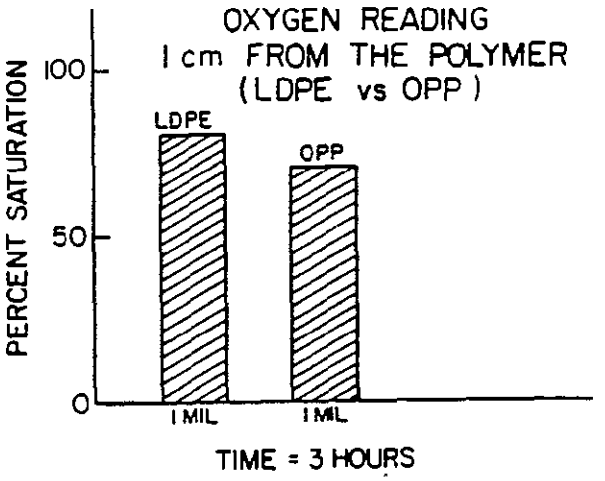
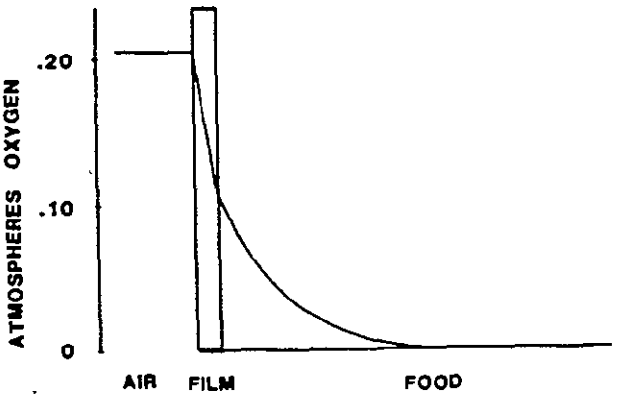


Figure 15. Oxygen profile in packaged foods.



re surpassed which produce reactions not normally found at room temperature.

When gas permeable polymers are substituted for metal and glass, accelerated storage tests are especially prone to error. To some degree, the oxygen permeability of all polymers increases with increasing temperature. This effect causes a subtle problem. Shelf life results no longer reflect a single variable (the effect of temperature on quality) but two variables—the effect of temperature on quality and the effect of temperature on polymer permeation. In addition to the accelerating effects of temperature, increased oxygen permeation will have its own detrimental impact on shelf life. This leads to confusion in interpreting data. Unless the polymer variable is taken into account, predicting ambient temperature shelf life from high temperature data will lead to error. Such predictions would tend to underestimate the stability of food at ambient temperatures.

Ideally, it would be desirable to predict shelf life based on polymer and food properties. Most of the parameters needed to do this have already been discussed. They include the diffusion properties of the food and polymer, the reactivity of oxygen in the food, and the oxygen solubility in the food.

With this information it is possible to make reasonable predictions of shelf life. Mathematical approaches which weigh relevent shelf life variables are especially helpful in such predictions. Tests are currently being conducted to st equations for foods in whole packages (Sadler, 1984).

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TITLE 410 STATE BOARD OF HEALTH

LSA Document #0-27(F)

DIGEST

Establishes minimum standards for the production, handling, processing, packaging and storing of Grade A milk products.

410 IAC 8-14

SECTION 1. 410 IAC 8 is amended by adding a NEW rule 14 to read as follows:

Rule 14. Standards for the Production, Processing, Handling, Packaging and Storing of Grade A Milk Products

410 IAC 8-14-1 Definitions
Authority: IC 16-1-3-13; IC 16-6-6-7
Affected: IC 16-1-23; IC 16-6-6

Sec. 1. DEFINITIONS. The definitions as found in 410 IAC 8-13-1 apply to this rule [*410 IAC 8-14*]. *(State Board of Health)*

410 IAC 8-14-2 Standards for Grade A raw milk for pasteurization
Authority: IC 16-1-3-13; IC 16-6-6-7
Affected: IC 16-1-23-2

Sec. 2. STANDARDS FOR GRADE A RAW MILK FOR PASTEURIZATION. (a) All Grade A raw milk for pasteurization and all Grade A pasteurized milk and milk products shall be produced, processed, and pasteurized to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this section.

No process or manipulation other than pasteurization, processing methods integral therewith, and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms: Provided, that in the bulk shipment of raw cream, skim milk or lowfat milk, the heating of the raw milk to temperatures no greater than 125°F (52°C) for separation purposes is permitted when the resulting bulk shipments of cream, skim milk, and lowfat milk are labeled heat-treated.

TABLE 1 Chemical, Bacteriological, and Temperature Standards

Grade A raw milk for pasteurization	Temperature	Cooled to 45°F (7°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50°F (10°C).
	Bacterial limits	Individual producer milk not to exceed 100,000 per ml. prior to commingling with other producer milk. Not to exceed 300,000 per ml. as commingled milk prior to pasteurization.
	Antibiotics	Individual producer milk: No detectable zone with the Bacillus stearothemophilus disc assay method or the Sarcina lutea Cylinder Plate Method. Commingled milk: No detectable zone by the Sarcina lutea Cylinder Plate Method or the Bacillus stearothemophilus disc assay method.
	Somatic cell count	Individual producer milk: Not to exceed 1,500,000 per ml.
Grade A pasteurized milk and milk products	Temperature	Cooled to 45°F (7°C) or less and maintained thereat.
	Bacterial limits*	20,000 per ml.
	Coliform	Not to exceed 10 per ml.: Provided that, in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.
	Phosphatase	Less than 1 microgram per ml. by the Scharer Rapid Method or equivalent.
	Antibiotics	No detectable zone by the Sarcina lutea Cylinder Plate Method or equivalent.

*Not applicable to cultured products.

(b) Abnormal Milk. Cows which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Cows treated with, or cows which have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgment of the regulatory agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the State Board may direct. To meet these requirements:

(1) The milk from cows being treated with medicinal agents, which are capable of being secreted in the milk shall not be offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

(2) The milk from cows treated with or exposed to insecticides not approved for use on dairy cattle by the U.S. Environmental Protection Agency is not offered for sale.

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(3) The State Board requires such additional tests for the detection of abnormal milk as he deems necessary.

(4) Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other cows and the contamination of milk utensils.

(5) Cows secreting abnormal milk are milked last or in separate equipment which effectively prevents the contamination of the wholesome supply.

(6) Equipment, utensils, and containers used for the handling of abnormal milk are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

(c) Milking Barn, Stable, or Parlor—Construction. A milking barn, stable, or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:

(1) Have floors constructed of concrete or equally impervious material; and

(2) Have walls and ceiling which are smooth, painted or finished in an approved manner, in good repair, ceiling dusttight; and

(3) Have separate stalls or pens for horses, calves, and bulls; and

(4) Be provided with natural and/or artificial light, well distributed for day and/or night milking; and

(5) Provide sufficient air space and air circulation to prevent condensation and excessive odors; and

(6) Not be overcrowded; and

(7) Have dusttight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed. To meet these requirements:

(A) A milking barn, stable, or parlor shall be provided on all dairy farms; and

(B) Gutters, floors, and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned (brushed surfaces permitted) and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools; and

(C) Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident.

Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from loft into the milking portion of the barn, such opening shall be provided with a dusttight door which shall be kept closed during the milking operations; and

(D) Bull pens, maternity and calf stalls, and horse stalls are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

(E) The milking barn is provided with natural and/or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles of light in all working areas shall be provided; and

(F) Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings; and

(G) Overcrowding is not evidenced by the presence of calves, cows, or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn; and

(H) A dusttight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. Feed may be stored in the milking portion of the barn only in such manner as will not increase the dust content of the air, attract flies, or interfere with cleaning of the floor (as in covered, dusttight boxes or bins). Open feed dollies or carts may be used for distributing the feed, but not storing feed, in the milking barn; and

When conditions warrant, the State Board may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirement of Sec. 2(c) [*410 IAC 8-14-2(d)*]. prohibiting animals and fowl entering the barn is satisfied. Cattle-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, wandering sheds) may be of shed-type construction, provided no milking is conducted therein. (They are classified as part of the cowyard under Sec. 2(d) [*410 IAC 8-14-2(e)*].)

(d) Milking Barn, Stable, or Parlor—Cleanliness. The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter, and shall be clean. Swine and fowl shall be kept out of the milking barn. To meet these requirements:

(1) The interior of the milking barn, stable, or parlor is kept clean; and

(2) Leftover feed in feed mangers appears fresh and is not wet or soggy; and

(3) The bedding material, if used, does not contain more manure than has accumulated since the previous milking; and

(4) Outside surfaces of pipeline systems located in the milking barn, stable, or parlor are reasonably clean; and

(5) Gutter cleaners are reasonably clean; and

(6) All pens, calf stalls, and bull pens, if not separated from the milking barn, stable, or parlor, are clean; and

(7) Swine and fowl are kept out of the milking barn.

(e) Cowyard. The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes: Provided, That in loafing or cattle-housing areas, cow droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the cow's udder and flanks. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard. To meet these requirements:

(1) The cowyard, which is the enclosed or unenclosed area adjacent to the milking barn, in which the cows may congregate, including cattle-housing areas and feed lots, is graded and drained; depressions and soggy areas are filled; cow lanes are reasonably dry.

(2) The approaches to the barn door and the surroundings of stock watering and feeding stations shall be solid to the footing of the animal.

(3) The wastes from the barn or milkhouse are not allowed to pool in the cowyard. Cowyards which are muddy due to recent rains should not be considered as violating this item.

(4) Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate therein.in such a manner as to permit the soiling of cows' udders and flanks. Cattle-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered a part of the cowyard. Manure packs shall be solid to the footing of the animal.

(5) Cowyards are kept reasonably free of cattle droppings. Cattle droppings shall not be allowed to accumulate in piles that are accessible to the animals.

(f) Milkhouse or Room—Construction and Facilities. A milkhouse or room of sufficient size shall be provided, in which the cooling, handling, and storing f milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted: Except as provided for in (l) [*subsection (m) of this section*] of this section.

The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner.

The milkhouse shall have an adequate natural and/or artificial light and be well ventilated.

The milkhouse shall be used for no other purpose than milkhouse operations; there shall be no direct opening into any barn, stable, or into a room used for domestic purposes: Provided, That a direct opening between the milkhouse and milking barn, stable, or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided.

Water under pressure shall be piped into the milkhouse.

The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

When a transportation tank is used for the cooling and/or storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance. To meet these requirements:

(1) A separate milkhouse of sufficient size shall be provided for the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils: Except as provided for in (l) [*subsection (m) of this section*] of this section.

(2) The floors of all milkhouses shall be constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints, or other material the equivalent of concrete and maintained free of breaks, depressions, and surface peelings.

(3) The floor shall slope to drain so that there are no pools of standing water. The joints between the floor and walls shall be watertight.

(4) The liquid wastes shall be disposed of in a sanitary manner; all floor drains will be accessible and shall be trapped if connected to a sanitary sewer.

(5) The walls and ceilings are constructed of smooth dressed lumber or similar material, well painted with a light-colored washable paint, and are in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color may be used; the surfaces and joints shall be smooth.

(6) A minimum of twenty (20) foot-candles of light shall be provided at all working areas from natural and/or artificial light for milkhouse operations.

(7) The windows and solid doors are closed during dusty weather; and

(8) The milkhouse is adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils; and

(9) Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas; and

(10) The milkhouse is used for no other purpose than milkhouse operations; and

(11) There is no direct opening into any barn, stable, or room used for domestic purposes; except that an opening between the milkhouse and milking barn, stable, or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting shall be provided.

(12) A vestibule, if used, shall comply with the applicable milkhouse construction requirements.

(13) The transfer of milk from a bulk-holding/cooling tank to a transport tank will be done through a hose port located in the milkhouse wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall, sufficiently large to protect the milk hose from contamination.

(14) Water under pressure shall be piped into the milkhouse; and

(15) Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

(16) The milkhouse shall be equipped with a wash-and-rinse vat having at least two compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one part of the two-compartment vat: Provided, That the cleaning-in-place station rack in or on the vat and the milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment.

(17) A suitable shelter shall be provided for a transportation truck used for cooling and storir milk. Such shelter shall be adjacent to, but not a par of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance.

(g) Milkhouse or Room—Cleanliness. The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and equipment, and other milkroom equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals, and fowl. To meet these requirements:

(1) The milkroom structure, equipment, and other milkroom facilities used in its operation or maintenance shall be clean at all times; and

(2) Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkroom, provided they are kept clean and ample space is available to conduct the normal operations in the milkroom and will not cause contamination of the milk; and

(3) Vestibules, if provided, are kept clean; and

(4) Animals and fowl are kept out of the milkroom.

(h) Toilet. Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply. To meet these requirements:

(1) There shall be at least one flush toilet connected to a public sewer system or to an individual sewage-disposal system or a chemical toilet, earth pit privy, or other type of privy. Such sewerage systems shall be constructed and operated in accordance with plans and instructions of the State Board and comply with the standards outlined in Sec. 6 [*410 IAC 8-14-4*].

(2) A toilet or privy shall be convenient to the milking barn and the milkroom. There shall be no evidence of human defecation or urination about the premises; and

(3) No privy opens directly into the milkroom; and

(4) The toilet room, including all fixtures and facilities, is kept clean and free of flies and odors; and

(5) Where flush toilets are used, doors to toilet rooms are tight and self-closing. All outer opening in toilet rooms shall be screened or otherwise protected against the entrance of flies; and

(6) Vents of earth pits are screened.

(i) Water Supply. Water for milkhouse and milking operations shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate and of a safe, sanitary quality. To meet these requirements:

(1) The water supply for milkhouse and milking operations shall be approved as safe by the Environmental Management Board and, in the case of individual water systems, complies with the specifications outlined in Sec. 7 [*410 IAC 8-14-5*] and the bacteriological standards outlined in Sec. 10 [*410 IAC 8-14-6*].

(2) No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

(3) There shall be no submerged inlets through which a safe water supply may be contaminated.

(4) The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply.

(5) New individual water supplies and water supply systems which have been repaired or otherwise become contaminated shall be thoroughly disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

(6) All containers and tanks used in the transportation of water shall be sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or ground-water storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump hose and fittings are not being used, the outlets shall be capped and stored in a suitable dustproof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dust- and rainproof cover, and also provided with an approved-type vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service.

(7) Samples for bacteriological examination shall be taken upon the initial approval of the physical structure based upon the requirements of this Rule [*410 IAC 8-14*] and when any repair or alteration of the water supply system has been made, and at least every three (3) years: Provided, That water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than six (6) months apart. Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section: Provided, That when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory each month. Bacteriological examinations shall be conducted in a laboratory acceptable to the State Board.

(8) Current records of water test results shall be retained on file with the State Board, or as the State Board directs.

(j) Utensils and Equipment-Construction. All multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported, and handled in a sanitary manner and shall comply with the applicable requirements of Sec. 3(k) [*410 IAC 8-14-3(l)*] of this Rule. Articles intended for single-service use shall not be reused.

Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Sec. 3(k) and (l) [*410 IAC 8-14-3(l) and (m)*] of this Rule. To meet these requirements:

(1) All multiuse containers, equipment, and utensils which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk or milk products shall be made of smooth impervious, nonabsorbent, safe materials of the following types:

(A) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(B) Equally corrosion-resistant, nontoxic material; or

(C) Heat-resistant glass; or

(D) Plastic or rubber and rubberlike materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion, under normal use conditions; are

nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product, and which maintain their original properties under repeated-use conditions.

(2) Single-service articles shall have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Sec. 3(k) [*410 IAC 8-14-3(l)*]; and

(3) Articles intended for single-service use are not reused; and

(4) All containers, equipment, and utensils are free of breaks and corrosion; and

(5) All joints in such containers, equipment, and utensils are smooth and free from pits, cracks, or inclusions.

(6) Cleaned-in-place milk pipelines and return-solution lines shall be self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in 1.d. [*subsection (1)(D) of this section*] above, and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

(7) Detailed plans for cleaned-in-place pipeline systems shall be submitted to the State Board for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the regulatory agency.

(8) Strainers, if used, shall be of perforated metal design, or so constructed as to utilize single-service strainer media.

(9) Seamless hooded pails shall have an opening not exceeding one-third the area of that of an open pail of the same size are used for hand milking and hand stripping; and

(10) All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces can be easily cleaned and inspected; and

(11) Milk cans have umbrella-type lids; and

(12) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks comply with the applicable requirements of Sec. 3(k) and (l) [*410 IAC 8-14-3 (l) and (m)*] of this Rule.

(k) Utensils and Equipment—Cleaning. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each usage. To meet these requirements:

The product-contact surfaces of all multiuse containers, equipment, and utensils used in th handling, storage, or transportation of milk shall b cleaned after each usage.

(l) Utensils and Equipment-Sanitization. The product-contact surfaces of all multiuse container equipment, and utensils used in the handling, storag or transportation of milk shall be sanitized before each usage. To meet these requirements:

All product-contact surfaces of multiuse container utensils, and equipment used in the handling, storage, or transportation of milk shall be sanitized before each usage by one of the following methods, or by an method which has been demonstrated to be equall effective:

(1) Complete immersion in hot water at temperature of at least 170°F (77°C) for at least fi (5) minutes, or exposure to a flow of hot water at a temperature of at least 170°F (77°C) as determined by use of a suitable accurate thermometer (at th outlet) for at least five (5) minutes.

(2) Complete immersion for at least one (1) minute in, or exposure for at least one (1) minute to a flow a chemical sanitizer of acceptable strength. A product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must b filled. Sanitizing sprays may be used. Chemic solutions, once used, shall not be reused for sanitizing but may be reused for other purposes.

(m) Utensils and Equipment—Storage. Al containers, utensils, and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, shall be stored to assur complete drainage and shall be protected fro contamination prior to use: Provided, That milk pipelines and pipeline milking equipment such a milker claws, inflations, weigh jars, meters, mil hoses, milk receivers and milk pumps which are designed for mechanical cleaning may be stored in the milking barn or parlor provided this equipment i designed, installed and operated to protect th product- and solution-contact surfaces from contamination at all times. To meet these requirements:

(1) All milk containers, utensils, and equipment including milking machine vacuum hoses, shall be stored in the milkhouse in a sanitizing solution, or o racks, until used. Milk pipelines and pipelin milking equipment such as: milker claws, inflations, weigh jars, meters, milk hoses, milk receivers and milk pumps which are designed fo mechanical cleaning may be mechanically cleaned sanitized and stored in the milking barn or parlc provided this equipment is designed, installed an operated to protect the product- and solution contact surface from contamination at all times.

Some of the parameters to be considered in determining protection are: proper location of equipment, proper drainage of equipment and adequate and properly located lighting and ventilation. The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of cattle. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse.

(2) Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely; and

(3) Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm; and

(4) Strainer pads, parchment papers, gaskets, and similar single-service articles are stored in a suitable container or cabinet and protected against contamination.

(n) Utensils and Equipment—Handling. After sanitization, all containers, utensils, and equipment shall be handled in such manner as to prevent contamination of any product-contact surface. To meet these requirements:

(1) Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination; and

(2) Any sanitized product-contact surface, which has been otherwise exposed to contamination, is again cleaned and sanitized before being used.

(o) Milking—Flanks, Udders, and Teats. Milking shall be done in the milking barn, stable, or parlor. The flanks, udders, bellies, and tails of all milking cows shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking cows shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be relatively dry before milking. Wet hand milking is prohibited. To meet these requirements:

(1) Milking is done in a milking barn, stable, or parlor; and

(2) Brushing is completed prior to milking; and

(3) Flanks, bellies, tails, and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking; and

(4) Udders and teats of all milking cows are cleaned and treated with a sanitizing solution and are relatively dry just prior to milking; and

(5) Wet hand milking is prohibited.

(p) Milking—Surcingles, Milk Stools, and Antikickers. Surcingles, milk stools, and antikickers shall be kept clean and stored above the floor. To meet these requirements:

(1) Milk stools shall not be padded and shall be constructed to be easily cleaned; and

(2) Milk stools, surcingles, and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable, parlor, or milkhouse, when not in use.

(q) Protection from Contamination. Milking and milkhouse operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers, and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination. To meet these requirements:

(1) Equipment and operations shall be so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact; and

(2) During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions; and

(3) All milk which has overflowed, leaked, been spilled, or improperly handled shall be discarded.

(4) All product-contact surfaces of containers, equipment, and utensils shall be covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping attached to milk storage and transport tanks, pumps, or vats, shall be capped or otherwise properly protected; and

(5) The receiving receptacle is raised above the floor (as on a dolly or cart), or placed at a distance from the cows to protect it against manure and splash when milk is poured and/or strained in the milking barn. Such receptacle shall have a tight-fitting cover which shall be closed except when milk is being poured.

(6) Each pail or container of milk shall be transferred immediately from the milking barn, stable, or parlor to the milkhouse; and

(7) Pails, cans, and other equipment containing milk are properly covered during transfer and storage; and

(8) Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor,

and shall otherwise comply with the applicable standards of Sec. 11 [*410 IAC 8-14-7*].

(9) Antibiotics, medicinals, veterinary supplies, and pesticides approved for milkhouse use shall be stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the equipment, containers, or utensils. They shall be stored in a separate cabinet or shelf designated for that purpose.

(r) Personnel—Handwashing Facilities. Adequate handwashing facilities shall be provided, including a lavatory fixture with running water, soap or detergent, and invididual sanitary towels, convenient to the milking barn, stable, parlor, or flush toilet. To meet these requirements:

(1) Handwashing facilities are located convenient to the milkhouse, milking barn, stable, parlor, or flush toilet; and

(2) Handwashing facilities include soap or detergent, running water, individual sanitary towels, and a lavatory fixture. Utensil wash and rinse vats shall not be considered as handwashing facilities.

(s) Personnel—Cleanliness. Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment. To meet these requirements:

(1) Hands are washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities; and

(2) Milkers and milk haulers wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

(t) Cooling. Raw milk for pasteurization shall be cooled to 45°F (7°C) or less within two (2) hours after milking: Provided, That the blend temperature after the first milking and subsequent milkings does not exceed 50°F (10°C). No milk shall be stored on dairy farm for more than 48 hours, and shall not be stored outside a farm bulk tank. To meet these requirements:

(1) The raw milk for pasteurization shall be cooled to 45°F (7°C) or less within two (2) hours after milking: Provided, That the blend temperature after the first milking and subsequent milkings does not exceed 50°F (10°C).

(2) Recirculated cold water which is used in plate or tubular coolers or heat exchangers shall be from a safe source and protected from contamination. Suc water shall be tested semiannually and shall compl with the bacteriological standards of Sec. 10 [*41 IAC 8-14-6*]; and

(3) Raw milk for pasteurization shall not be stored on a dairy farm more than 48 hours.

(4) No milk shall be stored outside a farm bul milk tank.

(u) Vehicles. Vehicles used to transport milk from the dairy farm to the milk plant or receiving statio shall be constructed and operated to protect thei contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; and n substance capable of contaminating milk shall b transported with milk. To meet these requirements:

(1) Vehicles used to transport milk from the dairy farm to the milk plant or receiving station ar constructed and operated to protect their contents from sun, freezing, and contamination; and

(2) Vehicles have bodies with solid enclosures an tight, solid doors; and

(3) Vehicles are kept clean, inside and out; and

(4) No substance capable of contaminating th milk is transported with the milk.

(v) Insect and Rodent Control. Effective measures shall be taken to prevent the contamination of milk containers, equipment, and utensils by insects an rodents, and by chemicals used to control such vermin. Milkrooms shall be free of insects and rodents Surroundings shall be kept neat, clean, and free o conditions which might harbor or be conducive to the breeding of insects and rodents. To meet these requirements:

(1) Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents During fly season, manure shall be spread directly on the fields; or stored for not more than four (4) days in a pile on the ground surface, and then spread o the fields; or stored for not more than seven (7) day in an impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; o effectively treated with larvicides; or disposed of i any other manner which controls insect breeding; and

(2) Manure packs in loafing areas, stables withou stanchions, pen stables, resting barns, wandering sheds, and free-stall housing are properly bedded and managed to prevent fly breeding; and

(3) Milkrooms are free of insects and rodents; an

(4) Milkrooms are effectively screened o otherwise protected against the entrance of vermin and

(5) Outer milkhouse doors are tight and self-closing. Screen doors shall open outward; and
(6) Effective measures shall be taken to prevent the contamination of milk, containers, utensils, and equipment by insects and rodents, and by chemicals used to control such vermin. Insecticides and rodenticides not approved for use in the milkhouse shall not be stored in the milkhouse.
(7) Only insecticides and rodenticides approved for use by the State Board and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control; and
(8) Insecticides and rodenticides are used only in accordance with manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, equipment, utensils, feed, and water. *(State Board of Health)*

410 IAC 8-14-3 Standards for Grade A pasteurized milk and milk products plants
Authority: IC 16-1-3-13; IC 16-6-6-7
Affected: IC 16-1-23; IC 16-6-6-4; IC 16-6-6-5

Sec. 3. STANDARDS FOR GRADE A PASTEURIZED MILK AND MILK PRODUCTS PLANTS. (a) Receiving stations, transfer stations, and truck washing facilities shall comply with Sec. 3(a) to (o) [*subsections (b) through (p) of this section*] inclusive, and (q), (t) and (v) [*subsections (u), (v) and (w) of this section*], except that the partitioning requirement of (e) [*subsection (f) of this section*] shall not apply.

(b) Floors—Construction. The floors of all rooms in which milk or milk products are processed, handled, or stored, or in which milk containers, equipment, and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleaned material; and shall be smooth, properly sloped, provided with trapped drains, and kept in good repair; Provided, That cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits: Provided further, That storage rooms for storing dry ingredients and/or packaging materials need not be provided with drains: and the floors may be constructed of tightly joined wood. To meet these requirements:

(1) The floors of all rooms in which milk is handled, processed, or stored, or in which milk containers or utensils are washed, shall be constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.
(2) The floor surface shall be smooth and sloped, so that there are no pools of standing water after flushing; and the joints between the floor and the walls are impervious; and
(3) The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients and/or packaging materials need not be provided with drains.

(c) Walls and Ceilings—Construction. Walls and ceilings of rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed, shall have a smooth, washable, light-colored surface, in good repair. To meet these requirements:

(1) Walls and ceilings are finished with smooth, washable, light-colored painted wood, tile, smooth-surface concrete, cement plaster, brick, or other equivalent materials with washable, light-colored surfaces; and
(2) Walls, partitions, windows, and ceilings are kept in good repair and refinished as often as the finish wears off or becomes discolored.

(d) Doors and Windows. Effective means shall be provided to prevent the access of flies and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather. To meet these requirements:

(1) All openings to the outer air shall be effectively protected by:
(A) Screening; or
(B) Effective electric screen panels; or
(C) Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of flies; or
(D) Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or
(E) Any effective combination of A, B, C, or D, or by any other method which prevents the entrance of flies.
(2) All outer doors shall be tight and self-closing. Screen doors shall open outward; and
(3) All outer openings are rat proofed to the extent necessary to prevent the entry of rodents.

(e) Lighting and Ventilation. All rooms in which milk or milk products are handled, processed, or stored and/or in which milk containers, equipment, and utensils are washed shall be well lighted and well ventilated. To meet these requirements:

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(1) Adequate light sources are provided (natural, artificial, or a combination of both) which furnish at least twenty (20) foot-candles of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed, or stored, or where utensils, containers, and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five (5) foot-candles of light; and

(2) Ventilation in all rooms is sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls, and ceilings.

(3) Pressurized ventilating systems, if used, shall have a filtered air intake.

(f) Separate Rooms. There shall be separate rooms for:

(1) The pasteurizing, processing, cooling, and packaging of milk and milk products.

(2) The cleaning of milk cans, bottles and cases.

(3) Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks.

(4) Receiving cans of milk and milk products in plants receiving such cans.

Rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed or stored, shall not open directly into any stable or any room for domestic purposes. All rooms shall be of sufficient size for their intended purposes. To meet these requirements:

(1) Pasteurizing, processing, cooling and packaging are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks. Provided, That in a receiving station, cooling may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized; and

(2) All bulk milk storage tanks are vented into a room used for pasteurization, processing, cooling, or packaging operations, or into a storage tank gallery room, provided that vents located elsewhere which are adequately equipped with air filters so as to preclude the contamination of the milk, shall be considered satisfactory; and

(3) Solid doors installed in required partitions are self-closing; and

(4) Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or mechanical operations. When such facilities are not provided on the plant premises, these operations shall be performed at a receiving station, transfer station, or separate tank washing installation; and

(5) Rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes; and

(6) All rooms shall be of sufficient size for their intended purposes.

(7) Cottage cheese vats shall be located in a separate room, maintained free from flies and other vermin, and kept in clean condition: Provided, That in existing installations, cottage cheese vats may be located in the processing room when there is no evidence of overcrowding, excessive traffic, condensation, or splash. Cottage cheese vats located in processing rooms shall be equipped with multi-service or single-service covers which shall be kept in place at all times during the "setting" operation.

(g) Toilet-Sewage Disposal Facilities. Every milk plant shall be provided with toilet facilities conforming with the regulations of the State Board. Toilet rooms shall not open directly into any room in which milk and/or milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms, and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner. To meet these requirements:

(1) The milk plant is provided with toilet facilities conforming with the regulations of the State Board, and

(2) Toilet rooms do not open directly into any room in which milk and/or milk products are processed and

(3) Toilet rooms are completely enclosed and have tight-fitting self-closing doors; and

(4) Dressing rooms, toilet rooms, and fixtures are kept in a clean condition, in good repair, and are well ventilated and well lighted; and

(5) Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms; and

(6) All plumbing is installed to meet the applicable provisions of the State or local plumbing code; and

(7) Sewage and other liquid wastes are disposed of in a sanitary manner; and

(8) Non-water-carried sewage disposal facilities are not used.

(h) Water Supply. Water for milk plant purposes shall be from a supply properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality. To meet these requirements:

(1) Water for milk plant purposes shall be from an adequate supply, properly located, protected, and

operated. It shall be easily accessible and of a safe, sanitary quality; and

(2) The water supply is approved as safe by the Environmental Management Board, and, in the case of individual water systems, complies with at least the specification outlined in Sec. 5 [*410 IAC 8-14-5*] and the bacteriological standards in Sec. 6 [*410 IAC 8-14-6*]; and

(3) There shall be no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank (such as for cooling or condensing), unless protected by an air gap or effective backflow preventor, constitutes a violation of this requirement.

(4) Condensing water for milk evaporators, and water used to produce vacuum and/or to condense vapors in a vacuum heat processing equipment, shall be from a source complying with (2) above: Provided, That when approved by the State Board, water from sources not complying with (2) above may be used when the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of such equipment or its contents by condensing water or by water used to produce vacuum. Means of preventing such contamination are:

(A) Use of a surface type condenser in which the condensing water is physically separated from the vapors and condensate; or

(B) Use of reliable safeguards to prevent the overflow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least thirty-five (35) feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges, or a safety shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which will shut off the inflowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air, or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

(5) Condensing water for all milk evaporators, complying with (2) above, and water reclaimed from milk or milk products, may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in Sec. 5 [*410 IAC 8-14-5*].

(6) New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, shall be disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected; and

(7) Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each six (6) months thereafter, and when any repair or alteration of the water supply system has been made. Bacteriological examinations shall be conducted in a laboratory acceptable to the State Board; and

(8) Current records of water test results are retained on file with the State Board or as the State Board directs.

(9) Water supply outlets shall be provided immediately available to the cottage cheese vats. The hose for transport of water for washing cottage cheese curd shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product.

(i) Handwashing Facilities. Convenient handwashing facilities shall be provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or other approved hand-drying devices. Handwashing facilities shall be kept in a clean condition and in good repair. To meet these requirements:

(1) Convenient handwashing facilities are provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or other approved hand-drying devices; and

(2) Handwashing facilities are convenient to all toilets and to all rooms in which milk plant operations are conducted; and

(3) Handwashing facilities are kept in a clean condition and in good repair; and

(4) Steam-water mixing valves and vats for washing bottles, cans, and similar equipment are not used as handwashing facilities.

(j) Milk Plant Cleanliness. All rooms in which milk and milk products are handled, processed, or stored, and/or in which containers, utensils, or equipment are washed or stored, shall be kept clean, neat, and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils, and equipment shall be permitted in the pasteurizing, processing, cooling, packaging, and bulk milk storage rooms. To meet these requirements:

(1) Only equipment directly related to processing operations or the handling of containers, utensils,

and equipment is permitted in the pasteurizing, processing, cooling, packaging, and bulk milk storage rooms; and

(2) All piping, floors, walls, ceilings, fans, shelves, tables, and the nonproduct-contact surfaces of other facilities and equipment are clean; and

(3) No trash or solid waste is stored within the plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during operation of such equipment; and

(4) All rooms in which milk and milk products are handled, processed, or stored, and/or in which containers, utensils, or equipment are washed or stored, are kept clean, neat, and free of evidence of insects and rodents.

(k) Sanitary Piping. All sanitary piping, fittings, and connections which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk or milk products, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping. To meet these requirements:

(1) All sanitary piping, fittings, and connections which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk products, consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material.

(2) All sanitary piping, connections, and fittings consist of:

(A) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(B) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(C) Heat resistant glass. Provided, That plastic, or rubber and rubberlike materials, which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the products; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications, and for short flexible takedown jumpers or connections where flexibility is required for essential or functional reasons; and

(3) Sanitary piping, fittings, and connections are designed to permit easy cleaning, kept in good repair, and free of breaks or corrosion, and contain no dead ends of piping in which milk may collect; and

(4) All interior surfaces of demountable piping including valves, fittings, and connections are designed, constructed, and installed to permit inspection and drainage.

(5) All cleaned-in-place milk pipelines and return-solution lines are rigid, self-draining, and so supported to maintain uniform slope and alignment. Return solution lines shall be constructed of material meeting the specifications of (2) above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in (2) above, and designed, finished, and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks, or inclusions.

In the case of welded lines, all welds shall be inspected by the use of a borescope or other appropriate available inspection device as they are made; and such welds shall be approved by the State Board.

Each cleaning circuit shall have access points for inspection in addition to the entrances and exits. These may be valves, removable sections, fittings, or other means or combinations that are adequate for inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the line.

Detailed plans for welded pipeline systems shall be submitted to the State Board for written approval prior to installation. No alteration or addition shall be made to any welded milk pipeline system without prior written approval from the State Board.

(6) Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary milk piping.

(7) Provided, That cottage cheese, cheese dressings, or cheese ingredients may be transported by other methods which protect the product from contamination.

(l) Construction and Repair of Containers and Equipment. All multiuse containers and equipment with which milk or milk products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which milk or milk products come in contact shall be nontoxic, and shall have been manufactured, packaged, transported, and handled in a sanitary

manner. Articles intended for single-service use shall not be reused. To meet these requirements:

(1) All multiuse containers and equipment with which milk or milk products come into contact are of smooth, impervious, corrosion-resistant, and nontoxic material; and

(2) All milk-contact surfaces of multiuse containers and equipment consist of:

(A) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(B) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(C) Heat resistant glass; or

(D) Plastic or rubber and rubberlike materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent, and do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions; and

(3) All joints in containers, equipment, and utensils shall be flush and finished as smooth as adjoining surfaces. Where a rotating shaft is inserted through a surface with which milk or milk products come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Where a thermometer or temperature sensing element is inserted through a surface with which milk or milk products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices; and

(4) All openings in covers of tanks, vats, separators, etc., are protected by raised edges, or otherwise to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as close to the tank or vat as possible on all pipes, thermometers, or temperature sensing elements, and other equipment extending into a tank, bowl, vat, or distributor, unless a watertight joint is provided; and

(5) All surfaces with which milk or milk products come into contact are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining. Wing nuts, bayonet locks, and similar devices shall be used whenever possible in lieu of bolts and nuts, to promote easy disassembly; and

(6) There shall be no threads used in contact with milk or milk products except where needed for functional and safety reasons, such as in clarifiers, pumps, and separators. Such threads shall be of a sanitary type.

(7) All multiuse containers and other equipment shall have rounded corners, are in good repair and free from breaks, crevices, and corrosion. Milk cans shall have umbrella-type covers.

(8) Strainers, if used, are of perforated metal design, and so constructed as to utilize single-service strainer media. Multiple-use woven material shall not be used for straining milk: Provided, That when required for functional reasons inherent to the production of certain milk products, such as buttermilk, whey, and dry milk products, woven material may be used where it is impractical to use perforated metal. However, woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product; and

(9) All single-service containers, closures, gaskets, and other articles, with which milk or milk products come in contact, are nontoxic; and

(10) The manufacture, packing, transportation, and handling of single-service containers, closures, caps, gaskets, and similar articles comply with the requirements of Appendix J, Sanitation Guidelines for the Manufacture of Single-Service Containers for Milk and Milk Products, Pasteurized Milk Ordinance—1978 Recommendations. Inspections and tests shall be made by the State Board or any agency authorized by them.

(m) Cleaning and Sanitizing of Containers and Equipment. The product-contact surfaces of all multiuse containers, utensils, and equipment used in the transportation, processing, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. To meet these requirements:

(1) All multiuse containers and utensils shall be thoroughly cleaned after each use, and all equipment is thoroughly cleaned at least once each day used: Provided, That storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Storage tanks which are used to store raw milk longer than twenty-four (24) hours and silo tanks used for the storage of raw milk, and which are installed after the adoption of this Rule [*410 IAC 8-14*], shall be equipped with a seven (7)-day temperature recording device complying with the specifications of Sec. 11 [*410 IAC 8-14-7*].

Whenever a milk tank truck has been cleaned and sanitized, as required by the State Board, it shall bear a tag or a record shall be made showing the date, time, place and signature of the employee or contract operator doing the work, unless the truck delivers to only one receiving unit where

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responsibility for cleaning and sanitizing can be definitely established without tagging. The tag is to be removed at the point of receipt of the milk and kept on file for the State Board.

(2) Pipelines and/or equipment designed for mechanical cleaning shall meet the following requirements:

(A) An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.

(B) A temperature recording device, complying with the specifications in Sec. 11 [*410 IAC 8-14-7*], shall be installed in the return solution line to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing.

(C) Temperature recording charts shall be identified, dated, and retained for three (3) months.

(D) During each official inspection, the State Board shall examine and initial temperature recording charts to verify the time of exposure to solutions and their temperatures.

TABLE 2—Combinations of Causticity, Time and Temperature of Equal Bactericidal Value, for Soaker Tank of Soaker-Type Bottle Washers

(Based on NSDA specifications for beverage bottles)

Time in Minutes	Temperature, degrees							
	F	170	160	150	140	130	120	110
	C	77	71	66	60	54	49	43
	Concentration of NaOH, percent							
3		0.57	0.86	1.28	1.91	2.86	4.27	6.39
5		0.43	0.64	0.96	1.43	2.16	3.22	4.80
7		0.36	0.53	0.80	1.19	1.78	2.66	3.98

NOTE: The National Soft Drink Association (NSDA) Washington, DC 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly by the State Board.

When caustic is so used, subsequent final rinsing of the bottles shall be with water which has been treated with heat or chemicals to assure freedom from viable pathogenic or otherwise harmful organisms, to prevent contamination of the treated bottle during the rinsing operation.

(3) Plants in which containers shall be washed manually are equipped with a two-compartment wash-and-rinse vat for this purpose. Such plants shall also provide a steam cabinet or individual steam-jet plate with hood for sanitizing of cleaned containers, or, if sanitizing is done with chemicals, a third treatment vat.

(4) In plants utilizing automatic bottle washers such washers must provide for bactericidal treatment by means of steam, hot water, or chemical treatment. In soaker-type bottle washers, in which bactericidal treatment depends upon the causticity of the washing solution, the caustic strength for a given soaking time and temperature shall be as specified in table 2 listing combinations of causticity, time, and temperature equal bactericidal value, for soaker tank of soaker-type bottle washers.

(5) All multiuse containers, equipment, and utensils shall be sanitized before use. Assembled equipment must be sanitized prior to each day's run. Tests to determine the efficiency of sanitization should be made by the State Board at intervals sufficient to satisfy the State Board that the sanitization process is effective.

(6) The residual bacteria count of multiuse and single-service containers used for packaging pasteurized milk and milk products shall not exceed one per milliliter of capacity, when the rinse test is used, or not over fifty (50) colonies per eight (8) square inches (one per square centimeter) of product-contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All multiuse and single-service containers shall be free of coliform organisms.

(7) Plants which utilize multiuse plastic containers for pasteurized milk and milk products shall comply with the following criteria:

(A) The plastic material from which the containers are molded shall be of safe material.

(B) The plastic material shall comply with the material specifications of Sec. 3(k) [*subsection (l) of this section*] of this Rule.

(C) All containers shall be identified as to plant of manufacture, date of manufacture, and type and class of plastic material used. This information may be by code: Provided, That the code is revealed to the regulatory agency.

(D) A device shall be installed in the filling line capable of detecting in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so that it may be sealed by the State Board to prevent the changing of its sensitivity functioning level. Models using an air

injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system the operator needs to be able to adjust the sensitivity. However, those models utilizing an external testing device must be sealed. Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be interconnected so that the system will not operate unless the detecting device is in proper operating condition: Provided, That any other system so designated and operated that will provide equal assurance of freedom from contamination and recognized by the U.S. Food and Drug Administration to be equally efficient may be accepted by the State Board.

(E) A standard must be available for the use of the State Board for testing the proper sensitivity functioning levels of the detection device.

(F) The containers shall comply with the applicable construction requirements of Sec. 3(k) [*subsection (l) of this section*] of this Rule. The closure for the container shall be single-service. Screw-type closures shall not be used.

(G) The container shall not impart into the product pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the Federal Food, Drug, and Cosmetic Act, as amended and regulations issued thereunder.

(H) The phrase "Use Only For Food" shall appear on all containers.

(n) Storage of Cleaned Containers and Equipment. After cleaning, all multiuse milk or milk product containers, utensils, and equipment shall be transported and stored to assure complete drainage, and shall be protected from contamination before use. To meet these requirements:

(1) All multiuse containers, equipment, and utensils, after cleaning, shall be transported and/or stored on metal racks or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively nonabsorbent, corrosion-resistant, nontoxic materials, or otherwise protected from contamination; and

(2) Floors are not flushed or washed when crates of clean bottles are stacked on them.

(o) Storage of Single-Service Containers, Utensils and Materials. Single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk and milk products shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner. To meet these requirements:

(1) Single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk and milk products are purchased and stored in sanitary tubes, wrappings, or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner; and.

(2) Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once unless other methods are employed to protect the containers from contamination; and

(3) Tubes or cartons are not refilled with spilled caps, gaskets, or parchment papers; and

(4) Cartons or boxes from which contents have been partially removed are kept closed; and

(5) Suitable cabinets are provided for storage of tubes after removal from the large outer box, and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures, or containers.

(p) Protection from Contamination. Milk plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, equipment, containers, and utensils. All milk or milk products or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than milk and milk products in the pasteurization plant shall be performed to preclude the contamination of such milk and milk products. The storage, handling, and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products or ingredients of such milk and milk products or the product-contact surfaces of all equipment, containers or utensils. To meet these requirements:

(1) Equipment and operations are so located within the plant as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact; and

(2) During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions; and

(3) All milk and milk products which have overflowed, leaked, been spilled, or improperly handled are discarded. Milk and milk products drained from processing equipment at the end of a run, or collected from a defoamer system which does

not continuously return such product to the filler bowl, or milk solids rinsed from equipment, containers, or pipelines, shall be repasteurized only if such milk or milk products are handled in a sanitary manner and maintained at 45°F (7°C) or less. When the handling and/or refrigeration of such milk and milk products are not in compliance with this requirement, they shall be discarded. Returned packaged milk and milk products shall not be repasteurized for Grade A use: Provided, That the repasteurization of milk and milk products shipped in transport tankers which have been pasteurized at another Grade A plant and have been handled in a sanitary manner and maintained at 45°F (7°C) or less is permitted; and

(4) All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping attached to milk storage and milk tank trucks, pumps, or vats, etc., shall be capped or otherwise properly protected. While unloading at a receiving station, transfer station, or pasteurization plant, one of the following conditions shall be met:

(A) If the area is completely enclosed (walls and ceiling, with doors closed) during the unloading process and the dustcover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required. However, if the dustcover and/or manhole cover(s) are opened in excess of that provided by the metal clamps or the covers have been removed, then a suitable filter is required for the manhole.

(B) If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. Direct connections from milk tank truck to milk tank truck must be made from valve to valve and not through the manhole and the manhole and the dustcover (dome) of the milk tank truck being filled must be closed.

Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.

(5) Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials, and odor, and shall otherwise comply with the applicabl standards of Sec. 11 [*410 IAC 8-14-7*]. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products, it shall be of culinary quality and shall comply with the applicable standards of Sec. 11 [*410 IAC 8-14-7*]; and

(6) Standardization is done before the pasteurization process is started, unless pasteurized milk or milk products are used for standardization. Such pasteurized milk products shall be protected against contamination. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients. Standardization of Grade A milk and milk products with other than Grade A milk and milk products is prohibited. This Rule [*410 IAC 8-14*] permits standardization as a process of adjusting the milkfat of milk in a milk plant by the addition or removal of cream or skim milk; and

(7) The processing of foods and/or drinks other than Grade A milk and milk products are performed to preclude the contamination of such milk and milk products; and

(8) Means are provided to prevent contamination of milk containers, utensils, and equipment by drippings, spillage, and splash from overhead piping, platforms or mezzanines; and

(9) All ingredients and nonproduct-contact materials used in the preparation or packaging of milk and milk products are stored in a clean place and are so handled as to prevent their contamination; and

(10) Pasteurized milk is not strained or filtered except through a perforated metal strainer; and

(11) Only those poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids, and related cleaning compounds, and medicinal agents necessary for the maintenance of the dairy plant are present in the dairy plant; and

(12) Those poisonous or toxic materials that are necessary are not stored in any room where milk or milk products are received, processed, pasteurized or stored, or where equipment, containers or utensils are washed or where single-service containers, closures, or caps are stored; and

(13) Those poisonous or toxic materials that are necessary are stored in a separate area of the plant in prominently and distinctly labeled containers: Provided, That this does not preclude the convenient

availability of detergents or sanitizers to areas where equipment, containers, and utensils are washed and sanitized; and

(14) Only insecticides and rodenticides approved by the State Board and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, containers, equipment, and utensils.

(q) Pasteurization. Pasteurization shall be performed as defined in IC 16-1-23. To meet these requirements:

(1) Every particle of milk or milk product shall be heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Temperature	Time
*145°F (63°C)	30 minutes
*161°F (72°C)	15 seconds
191°F (89°C)	1 second
194°F (90°C)	0.5 second
201°F (94°C)	0.1 second
204°F (96°C)	0.05 second
212°F (100°C)	0.01 second

*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C). Provided, That eggnog shall be heated to at least the following temperature and time specifications:

Temperature	Time
155°F (69°C)	30 minutes
175°F (80°C)	25 seconds
180°F (83°C)	15 seconds

Provided further, That nothing shall be construed as barring any other pasteurization process which has been recognized by the U.S. Food and Drug Administration to be equally efficient and which is approved by the State Board.

(2) The design and operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of subitems (A) through (D) as follows:

(A) Batch Pasteurization. All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications set forth in Sec. 11 [*410 IAC 8-14-7*]. Specifications for test thermometers and other test equipment appear in Sec. 12 [*410 IAC 8-14-8*].

(i) Time and Temperature Controls for Batch Pasteurizers

(AA) Temperature Difference.—The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product at the center and the coldest milk or milk product in the vat will not exceed 1°F (0.5°C) at any time during the holding period.

The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

(BB) Location and Required Readings of Indicating and Recording Thermometers.—Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer.

The thermometers shall read not less than the required pasteurization temperature throughout the required holding period. The plant operator shall check daily the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer; this comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk or milk products shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometers.

(CC) Assurance of Minimum Holding Periods.—Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least 30 minutes. When milk or milk products are raised to pasteurization temperature in the vat, and cooling is begun in the vat, simultaneously with or before the opening of the outlet valve, the recorder chart shall show at least 30 minutes at not less than minimum pasteurization temperature. When milk or milk products are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least 30 minutes at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder bulb. When cooling is begun in the holder after the opening of the outlet valve, or is done entirely outside the holder, the chart shall show at least 30 minutes at not less than the minimum

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pasteurization temperature plus the time of emptying to the level of the recording-thermometer bulb.

When the recorder time interval on the recorder chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recorder chart by the operator, by removing the recording-thermometer bulb from the milk for a sufficient time to depress the pen, or by turning cold water into the vat jacket at the end of the holding period, or by inscribing the holding time on the chart. The filling time and the emptying time for each holder so operated shall be determined by the State Board, initially and after any change which may affect these times.

No milk shall be added to the holder after the start of the holding period.

(ii) Airspace Heating

(AA) Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and milk products at a temperature not less than 5°F (3°C) higher than the minimum required temperature of pasteurization during the holding period.

(BB) Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk product shall be at least one (1) inch below the bottom of the thermometer bulb when the vat is in operation.

(CC) The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart each time the pasteurizer is in operation.

(iii) Inlet and Outlet Valves and Connections. The following definitions shall apply to inlet and outlet valves and connections:

(AA) "Valve stop" shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

(BB) "90° stop" shall mean a stop so designed as to prevent turning the plug more than 90°.

(CC) "120° stop" shall mean a stop which prevents turning the plug more than 120°.

(DD) "180° stop" shall mean a stop which prevents turning the plug more than 180°, but which permits two fully closed positions, each diametrically opposite the other.

(EE) "Valve with an irreversible plug" shall mean one in which the plug cannot be reversed in the shell.

(FF) "Single-quadrant stop" shall mean a 90° stop in a valve with an irreversible plug.

(GG) "The fully open position" shall mean that position of the valve seat which permits the maximum flow into or out of the pasteurizer.

(HH) "The closed position" shall mean ar position of the valve seat which stops the flow or milk into or out of the pasteurizer.

(II) "The fully closed position" shall mean tha closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

(JJ) "The just-closed position" shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped, c any closed position within 0.078 inch thereof a measured along the maximum circumference of the valve seat.

(KK) "Leakage" shall mean the entrance c unpasteurized milk into a batch pasteurizer during the holding or emptying period, or the entrance of unpasteurized milk into an pasteurized milk line at any time.

(LL) "Leak-protector valve" shall mean a valve provided with a leak-diverting device, which when the valve is in any closed position, wi prevent leakage of milk past the valve or, in the case of batch pasteurizers filled or emptied by suction or compressed air, will prevent leakage c milk past the valve or the leakage of milk due to the leakage of air past the suction valve or the compressed air valve, as the case may be.

(MM) "Close-coupled valve" shall mean a valve the seat of which is either flush with the inner wall of the pasteurizer, or so closely coupled that no milk in the valve inlet is more than 1°F (0.5°C colder than the milk at the center of the pasteurizer at any time during the holding period. A close-coupled valve which is not trul flush, shall be considered as satisfying thi requirement when:

(aa) The vat outlet is so flared that the smalles diameter of the large end of the flare is not les than the diameter of the outlet line, plus the depth of the flare; and

(bb) The greatest distance from the valve seat t the small end of the flare is not greater than the diameter of the outlet line; and

(cc) In the case of batch pasteurizers, the outle and the agitator are so placed as to insure that milk currents will be swept into the outlet.

(iv) Design and Installation of Valves an Connections. All valves and connections shal comply with the following requirements:

(AA) Valves and pipeline connections shal meet the requirements of Item 3(j) [*subsectio (iv)(JJ) of this section*].

(BB) All pipelines and fittings shall be so constructed and so located that leakage will no

occur. Dependence shall not be placed on soldered joints to prevent leakage.

(CC) To prevent clogging, and to promote drainage, all leak-protection grooves shall be at least 0.187 inch wide, and at least 0.094 inch deep at the center. Mating grooves shall provide these dimensions throughout their combined length whenever the valve is in, or approximately in, the fully closed position. All single-leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat, so as to divert leakage occurring at all points throughout the depth of the seat, and so as to prevent air bindings. Washers or other parts shall not obstruct leak-protector grooves.

(DD) A stop shall be provided on all plug-type outlet valves and on all plug-type inlet valves in order to guide the operator in closing the valve so that unpasteurized milk may not inadvertently be permitted to enter the outlet line or the holder, respectively. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent, unless duplicate. diametrically opposite grooves are also provided. In the case of 2-way, plug-type valves (i.e., those having only one inlet and one outlet), a 180 degree stop, or any combination of stops permitting two fully closed positions, may be substituted for a 90 degree stop, provided that there are no air-relief grooves in the plug and that all leak grooves are located symmetrically with respect to the valve inlet. Stops shall be so designed that the operator cannot turn the valve beyond the stop position, either by raising the plug or by any other means.

(EE) Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized milk in the milk passages of the valve when the valve is in any closed position.

(FF) All inlet pipelines and outlets from vat pasteurizers shall be equipped with leak-protector valves: Provided, That installations not equipped with leak-protector inlet valves shall be accepted when the piping is so arranged that only one vat can be connected to the inlet line at a time, and such piping is disconnected during the holding and emptying periods.

(GG) Inlet and outlet connections other than through close-coupled valves shall not enter or leave the pasteurizer below the level of the milk therein.

(HH) In cases where the inlet line enters the holder above the milk level, and in which the inlet line may be submerged and thus prevent its complete emptying when the inlet valve is closed, the inlet line shall be provided with an automatic air-relief, or vent located either at the valve or elsewhere, and so designed as to function in every closed position of the valve. A vent may be provided by drilling a hole at least 0.125 inch in diameter in the vat pipe, below the vat cover, but above the maximum milk level.

(II) All leak-protector valves shall be installed in the proper position to insure the function of the leak-diverting device. Inlet valves shall not be located in vertical pipelines, unless they can be so installed that one of the groove systems is at the lowest level of the valve; and pipelines between the inlet valve and the pasteurizer shall be as short as practicable and shall be sloped to drain.

(JJ) All outlet valves shall be kept fully closed during filling, heating, and holding periods; and all inlet valves shall be kept fully closed during holding and emptying periods.

(v) Recording Charts. All recording thermometer charts shall comply with all the applicable requirements of Sec. 3(p)(D) [*subsection (q)(E) of this section*].

(B) HIGH—TEMPERATURE, SHORT-TIME, (HTST) CONTINUOUS-FLOW PASTEURIZATION

(i) Indicating Thermometers and Recorder/Control Instruments. All indicating thermometers and recorder/controller instruments and devices used in connection with the high-temperature, short-time, continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications set forth in Sec. 7 [*410 IAC 8-14-7*].

(ii) Automatic Milk Controller.—Each high-temperature, short-time, continuous-flow pasteurization system shall be equipped with an automatic milkflow control of the diversion type, which complies with the following definition, specifications, and performance requirements:

(AA) "Automatic Milkflow Controls."—The term "automatic milkflow controls" shall mean those safety devices which control the flow of milk in relation to the temperature of the milk, or heating medium and/or pressure, vacuum, or other auxiliary equipment. Milkflow controls shall not be considered as part of the temperature control equipment. Milkflow controls shall be of the flow-diversion type which automatically cause the diversion of the milk in response to a sublegal pasteurization temperature. At sublegal temperatures, flow-diversion devices return the milk to the raw milk side of the heating system continuously until legal pasteurization

temperatures are obtained; at which time, the device restores forward flow through the pasteurizer.

(BB) Flow-diversion devices.—All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(aa) Forward flow of subtemperature milk, due to the omission of looseness of the connecting clip, shall be prevented by making the valve and its actuating mechanism integral; or, where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism, except in such manner that it will function properly; or, where there is a connecting device which may be omitted or shaken loose by providing for pushing, instead of pulling, the valve to the diverted position; or by providing that the pump will shut down when the milk is below the pasteurization temperature and the valve is not in the fully-diverted position; or by any other equally satisfactory means.

(bb) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

(cc) A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the milkflow is being diverted, the leak escape should lie between two valve seats, or betweeen two portions of the same seat, one upstream and the other downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line: Provided, That when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

(dd) The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

(ee) The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.

(ff) The flow-diversion device shall be located downstream from the holder. The flow-control sensor shall be located in the milk line not more than eighteen (18) inches upstream from the flow control device.

(gg) In the case of higher-heat, shorter-time (HHST) pasteurizing systems utilizing the temperatures of 191°F (89°C) and above and holding times of one (1) second and less, the flow-diversion device may be located downstream from the regenerator and/or cooler section: Provided, That when the flow-diversion device is located downstream from the regenerator and/or cooler section, the flow-diversion device shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in IC 16-1-23.

(hh) The pipeline from the diversion port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the diversion line cannot occur.

(ii) When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the leak detector line cannot occur.

(CC) Milk-flow controller instrumentation.—The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

(aa) The thermal limit controller shall be set and sealed so that forward flow of product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in IC 16-1-23 for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the State Board after testing, and shall not be removed without immediately notifying the State Board. The system shall be so designed that no milk can be bypassed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the plant operator.

(bb) In the case of HHST pasteurization

systems, utilizing the temperatures of 191°F (89°C) and above, the holding times of one (1) second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in IC 16-1-23. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required pasteurization temperature. The seal shall be applied by the State Board after test, and shall not be removed without immediately notifying the State Board. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

(cc) Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required pasteurization temperature as defined in IC 16-1-23 for the milk or milk product and the process used, or when the diversion device is in the fully-diverted position.

(DD) Holding tube. (aa) Holders shall be designed to provide for the holding of every particle of milk or milk product for at least the time required in IC 16-1-23 for the milk or milk product and the process used.

(bb) The holder shall be so designed that the simultaneous temperature difference between the hottest and coldest milk in any cross section of flow at any time during the holding period will not be greater than 1°F (0.5°C). This requirement may be assumed to have been satisfied without test in tubular holders of seven (7) inches or smaller diameter which are free of any fittings through which the milk may not be thoroughly swept.

(cc) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of milkflow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

(dd) The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 0.25 inch per foot.

(ee) Supports for tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

(ff) The holder shall be so designed that no portion between the inlet and the flow-control temperature sensor is heated.

(gg) The holding time for the HHST processes must be determined from the pumping rate rather than by the salt conductivity test because of the short holding tube. The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time. Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during pasteurization of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard.

(hh) With the steam injection processes, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized product is cooled in the vacuum chamber. For example, with a 120°F (66°C) increase by steam injection which is probably the maximum temperature rise that will be used, a volume increase of twelve (12) percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the pasteurizer does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

(ii) With the steam injection process a pressure limit indicator is needed in the holding tube to keep the heated product in the liquid phase. The instrument must have a pressure switch so that the flow-diversion device will move to the divert position if the product pressure falls below a prescribed value. For operating temperatures between 191°F (89°C) and 212°F (100°C) the pressure switch must be set at ten (10) pounds per square inch (psi). For units which have operating temperatures above 212°F (100°C) the pressure switch must be set at a pressure ten (10) psi above the boiling pressure of the product at its maximum temperature in the holding tube.

(jj) With the steam injection process a differential pressure limit indicator across the

injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below ten (10) psi.

(EE) Indicating and recording thermometers. (aa) An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk between the two thermometers does not differ significantly in temperature.

(bb) The temperature shown by the recorder/controller shall be checked daily by the plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.

(cc) The recorder/controller charts shall comply with the applicable provisions of Sec. 3(p)(D) [*410 IAC 8-14-3(q)(E)*].

(FF) Flow-promoting devices. (aa) The pump, or pumps, and other equipment which may produce flow through the holder shall be located upstream from the holder, provided that pumps and other flow-promoting devices may be located downstream from the holder if means are provided to eliminate negative pressure between the holder and the inlet to such equipment. When vacuum equipment is located downsteam from the holder, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the flow-diversion device and the vacuum chamber, shall be acceptable.

(bb) The speed of pumps or other flow-promoting devices governing the rate of flow through the holder shall be so controlled as to insure the holding of every particle of milk for at least the time required as defined in IC 16-1-23 for the milk or milk product and the process used. In all cases, the motor shall be connected to the metering pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box, the pulley box, or the setting of the variable speed protected in such a manner that the holding time cannot be shortened without detection by the State Board. This shall be accomplished by the application of a suitable seal(s) after tests by the State Board and such seal shall not be broken without immediately notifying the State Board. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the metering pump shall be so constructed tha wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive displacement type.

(cc) The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization temperature as defined in IC 16-1-23 for the milk or milk product and the process used, throughout the holder section, i.e., that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the downstream direction, and is located upstream from the flow-diversion device. Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. Where bypass lines are provided, either upstream or downstream from the metering pump, the holding time shall be tested with both the regular and bypass line open, unless the bypass valve is so designed that both lines canno be open at the same time. The holding time shall be tested during both forward and diverted flow. If necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow, and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested in both forward and diverted flow by the State Board initially, semiannually thereafter, after any alteration or replacement that may affect the holding time, and whenever the seal of the speed setting has been broken.

(GG) Heating by direct addition of steam.—Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper designed criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below pasteurization temperature. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to

achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(aa) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 10 psi product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

(bb) The product pressure in the holding tube must be of sufficient magnitude to condense the steam and keep the heated product in the liquid phase. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times. A minimum product pressure in the holding tube of ten (10) psi for operating temperatures from 191°F (89°C) through 212°F (100°C) is satisfactory. For units which have operating temperatures above 212°F (100°C), the pressure of the product in the holding tube must be at least ten (10) psi above the boiling pressure of the product at its maximum temperature in the holding tube.

(cc) The process should be as free as possible of noncondensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible of noncondensable gases.

(HH) Prevention of product adulteration with added water. (aa) When culinary steam is introduced directly into the milk or milk product downstream from the flow-diversion device, means shall be provided to preclude the addition of steam to the product, unless the flow-diversion device is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the flow-diversion device controls that steam cannot flow unless the flow-diversion device is in the forward-flow position.

(bb) When culinary steam is introduced directly into the milk or milk product, automatic means shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(cc) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the backup and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the inflowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air, or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

(C) PASTEURIZERS EMPLOYING REGENERATIVE HEATING. Milk to Milk Regenerative Heating. Pasteurizers employing milk-to-milk regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

(i) Regenerators shall be constructed, installed, and operated so that pasteurized milk in the regenerator will automatically be under greater pressure than raw milk in the regenerator at all times.

(ii) The pasteurized milk, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of twelve (12) inches above the highest raw milk level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation.

(iii) The overflow of the top rim of the constant-level raw milk tank shall always be lower than the lowest milk level in the regenerator.

(iv) No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized milk outlet from the regenerator and the nearest downstream point open to the atmosphere.

(v) No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank, unless it is designed and installed to

operate only when milk is flowing through the pasteurized milk side of the regenerator, and when the pressure of the pasteurized milk is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

(AA) The metering pump is in operation;

(BB) The flow-diversion device is in forward-flow position; and

(CC) The pasteurized milk pressure exceeds, by at least one (1) psi, the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk inlet to the regenerator and the pasteurized milk outlet of the regenerator or the outlet of the cooler. The accuracy of required pressure gauges shall be checked by the State Board on installation, quarterly thereafter, and following repair or adjustment.

(vi) The motor, casing, and impeller of the booster pump shall be identified, and such records thereof maintained as directed by the State Board. All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections), with no electrical connections to defeat the purpose of any provisions of this Rule [*410 IAC 8-14*].

(vii) All raw milk in the regenerator will drain freely back into the constant-level raw milk tank when the raw milk pump(s) are shut down and the raw milk outlet from the regenerator is disconnected.

(viii) When vacuum equipment is located downstream from the flow-diversion device, means shall be provided to prevent the lowering of the pasteurized milk level in the regenerator during periods of diverted flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized milk inlet to the regenerator.

(ix) In the case of HHST pasteurization systems utilizing the temperatures of 191°F (89°C) and above the holding times of one (1) second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to vertical elevation of twelve (12) inches above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated: Provided, That a differential pressure controller is used to monitor the highest pressure in the raw product side of th regenerator and the lowest pressure in th pasteurized side of the regenerator, and th controller is interlocked with the flow-diversio device and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automaticall prevented and will not start again until a product-contact surfaces between the holding tube and flow-diversion device have been held a or above the required pasteurization temperatur continuously and simultaneously for at least the required pasteurization time as defined in IC 16-1-23.

(x) When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurizatio temperature, and vacuum equipment is locate downstream from the holding tube, the requirement that a vacuum breaker be installe at the inlet to the pasteurized side of th regenerator may be eliminated: Provided, That the differential pressure controller is installed and wired to control the flow-diversion device a described in paragraph nine of this section [*41 IAC 8-14-3(ix)*].

(xi) When the differential pressure controller i installed and wired to control the flow-diversio device as described in paragraph nine [*subsection (ix) of this section*] of this section, the raw produc booster pump may be permitted to run at a times: Provided, That the metering pump is in operation.

(D) Milk-to-Water-to-Milk Regenerative Heat ing. Milk-to-water-to-milk regenerators with both the milk and the heat-transfer water in the raw milk section closed to the atmosphere sha comply with the following or equally satisfactory specifications:

(i) Regenerators of this type shall be s designed, installed, and operated that the heat transfer-medium side of the regenerator in the raw milk section will, automatically, be unde greater pressure than the raw side at all times

(ii) The heat-transfer water shall be a safe water and the heat-transfer water shall be in covered tank which is open to the atmosphere a an elevation higher, by at least twelve (12) inches, than any raw milk level downstream from the constant-level tank. The heat-transfer wate between its outlet from the regenerator and th nearest point downstream open to the atmosphere shall rise to a vertical elevation of at leas twelve (12) inches above any raw milk in th

system and shall be open to the atmosphere at this or a higher elevation.

(iii) The heat-transfer water circuit shall be full of water at the beginning of the run, and all loss of water from the circuit shall be automatically and immediately replenished whenever raw milk is present in the regenerator.

(iv) The overflow of the top rim of the constant level raw milk tank shall always be lower than the lowest milk level in the raw milk section of the regenerator. The regenerator shall be designed and installed so that all raw milk shall drain freely back to the upstream supply tank when the raw milk pumps are shut down and the raw milk line is disconnected from the regenerator outlet.

(v) No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator, and when the pressure of the heat-transfer water is higher than the pressure of the raw milk. This may be accomplished by wiring the booster pump so that it cannot operate unless:

(AA) The heat-transfer water pump is in operation;

(BB) The heat-transfer water pressure exceeds, by at least one pound per square inch, the raw milk pressure in the regenerator. Pressure gauges shall be installed at the raw milk inlet and the heat-transfer water outlet of the regenerator. The accuracy of the required pressure gauges shall be checked by the State Board on installation, quarterly thereafter, and following repair or replacement.

(E) TEMPERATURE RECORDING CHARTS, EQUIPMENT TESTS, AND EXAMINATIONS.

(i) Temperature Recording Charts.—All temperature recording charts shall be preserved for a period of three (3) months. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this item. The following information shall be entered on the charts as applicable:

(AA) Batch Pasteurizers:

(aa) Date.

(bb) Number or location of recorder when more than one is used.

(cc) Extent of holding period, including filling and emptying times when required (Sec. 3(p)(A)[*410 IAC 8-14-3(q)(A)*]).

(dd) Reading of airspace thermometer within the holding period at a given time or reference point as indicated on the chart (Sec. 3(p)(A)[*410 IAC 8-14-3(q)(A)*]).

(ee) Reading of indicating thermometer within the holding period at a given time or reference point as indicated on the chart (Sec. 3(p)(A)[*410 IAC 8-14-3(q)(A)*]).

(ff) Quarterly, the initials of the State Board opposite the required readings of the indicating thermometer and airspace thermometer (Sec. 3(p)(A)[*410 IAC 8-14-3(q)(A)*]).

(gg) Quarterly, the time accuracy of the recorder, as determined by the State Board (Sec. 12, Test 3 [*410 IAC 8-14-8, Test 3*]).

(hh) Amount and name of pasteurized milk or milk product represented by each batch or run on the chart.

(ii) Record of unusual occurrences.

(jj) Signature or initials of operator.

(kk) Name of milk plant.

(BB) High-Temperature, Short-Time Pasteurizers.—Recording thermometer charts shall contain all the information specified in (a) [*subsection (AA) of this section*] above, except (3), (4), and reference to airspace thermometers in item (6) [*subsections (cc), (dd) and (ff) of this section*], and in addition, shall include the following:

(aa) A record of the time during which the flow-diversion device is in the forward-flow position.

(bb) The cut-in and cut-out milk temperatures recorded daily by the operator at the beginning of the run, and initialed quarterly by the State Board (Sec. 3(p)(B)[*410 IAC 8-14-3(q)(B)*]).

NOTE: The recorded temperature shown on the controller chart shall be used to determine that the required temperature for milk products containing higher fat and/or sweeteners has been achieved.

(ii) Equipment Tests and Examinations.—The State Board shall perform the indicated tests on the following instruments and devices initially on installation, and at least once each three (3) months thereafter, and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device: Provided, That the holding time test shall be conducted at least every six (6) months.

TABLE 3

Instrument of device	Test#	Test objective
Batch pasteurizer indicating thermometer	1	Accuracy.
Batch pasteurizer recording thermometer	2	Temperature accuracy.
Batch pasteurizer recording thermometer	3	Time accuracy.
Batch pasteurizer recording thermometer	4	Check reading of recording thermometer against indicating thermometer.
Airspace thermometer	1	Accuracy.
Valves	6	Leakage in plug type leak-protector valves and poppet type valves.
HTST indicating thermometer	1	Accuracy.
HTST indicating thermometer	7	Thermometric response.
HTST recording thermometer	2	Temperature accuracy.
HTST recording thermometer	3	Time accuracy.
HTST recorder controller	2	Temperature accuracy.
HTST recorder controller	4	Check reading of recorder controller against indicating thermometer.
HTST recorder controller	8	Thermometric response.
HTST recorder controller	10	Confirm cut-in and cut-out temperatures.
HTST flow diversion device	5	Assembly and function.
HTST auxiliary (booster) pump	9	Function of automatic control devices.
HTST auxiliary (booster) pump	9	Accuracy of pressure gauges.
HTST system	11	Check holding time.
HHST system	12	Thermal limit control for sequence logic.
HHST system	13	Setting of control switches for product pressure in the holding tube.
HHST system	14	Setting of control switches for differential pressure across the injector.

(r) Cooling of Milk. All raw milk and milk products shall be maintained at 45°F (7°C) or less until processed. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging in approved equipment to a temperature of 45°F (7°C) or less. All pasteurized milk and milk products shall be stored at a temperature of 45°F (7°C) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 50°F (10°C). Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer. To meet these requirements:

(1) All raw milk and milk products are maintained at 45°F (7°C) or less until processed; and

(2) All pasteurized milk and milk products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 45°F (7°C) or less. All pasteurized milk and milk products shall be stored at a temperature of 45°F (7°C) or less. On delivery vehicles the temperature of milk and milk products shall not exceed 50°F (10°C); and

(3) Each refrigerator room in which milk or milk products are stored is equipped with an indicating thermometer which complies with the applicable specifications of Sec. 11 [*410 IAC 8-14-7*]. Such thermometer shall be located in the warmest zone of the refrigerator room; and

Each storage tank shall be equipped with a indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains

no more than twenty (20) percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Sec. 7 [*410 IAC 8-14-7*].

(4) All surface coolers comply with the following specifications:

(A) The sections of open-surface coolers shall be so installed as to leave a gap of at least 0.25 inch between the header sections to permit easy cleaning.

(B) Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk products by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers, or by shortening the bottom trough, or by some other approved method.

(C) The location of supports of cooler sections shall prevent drip from entering the milk or milk products.

(D) All open-surface coolers shall be provided with tight-fitting shields which protect the milk and milk products from contamination by flies, dust, drip, splash, or manual contact; and

(5) Recirculated cold water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Sec. 6 [*410 IAC 8-14-6*]. Recirculated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, when used in recirculating systems, shall be nontoxic.

(s) Bottling and Packaging. Bottling and packaging of milk and milk products shall be done at the place of pasteurization in approved mechanical equipment. To meet these requirements:

(1) All milk and milk products, including concentrated milk and milk products are bottled and packaged at the plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization; and

(2) All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery but is interpreted to exclude methods in which the bottling and capping devices are not integral in one system; and

(3) Bottling or packaging machines are designed to minimize the need for adjustment during operation. All pipes, connections, defoaming devices, and similar appurtenances shall comply with Sec. 3(j) and (k) [*410 IAC 8-14-3(k) and (l)*]; and

(4) Bottling or packaging machine supply tanks and bowls have covers which are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

(5) A drip deflector shall be installed on each filler valve. Such drip deflector shall be designed and adjusted to divert condensation away from the open container; and

(6) Container infeed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. Such shields shall extend from the bottle washer discharge to the bottle feed star or, in the case of single-service packaging machines, from the forming unit discharge to the filling unit and from the filling unit to the closure unit. Overhead shields shall be required on can infeed conveyors when the cans are fed to the filler with covers off; and

(7) Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation; and

(8) Bottling and packaging machine floats are designed to be adjustable without removing the cover; and

(9) The filler pipe of all bottling and packaging machines have an apron or other approved device as close to the filler bowl as possible to prevent condensation or drip from reaching the inside of the filler bowl; and

(10) Filling cylinders on packaging machines are protected from contamination by the use of overhead shields. When any lubricant is applied to the filler pistons, cylinders, or other milk-contact surfaces, the lubricant shall be nontoxic, sterile, and shall be sparingly applied in a sanitary manner; and

(11) Cottage cheese, dry curd cottage cheese, and lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one plant to another for creaming and/or packaging.

(t) Capping. Capping or closing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with

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respect to fluid product containers, removal cannot be made without detection. To meet these requirements:

(1) The capping or closing of milk and milk product containers is done in a sanitary manner on approved mechanical capping/closing equipment. The term "approved mechanical capping and/or closing equipment" shall not exclude manually operated machinery. Hand-capping shall be prohibited: Provided, That if suitable mechanical equipment for the capping or closing of specific container(s) of three (3) gallons or more is not available, other methods which eliminate all possibility of contamination may be approved by the State Board; and

(2) All mechanical capping or closure mechanisms are designed to minimize the need for adjustment during operation; and

(3) Bottles and packages which have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 45°F (7°C) or less, and subsequently repasteurized or discarded; and

(4) All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened; and

(5) Caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock, and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps which are left in the cappers at the end of an operating period after removal from the cap tubes shall be a violation of this item; and

(6) If suitable equipment is not available for capping cottage cheese, dry curd cottage cheese, and lowfat cottage cheese, other methods of capping which eliminate possible chance of contamination may be approved by the State Board.

(7) Closures for cottage cheese, dry curd cottage cheese, and lowfat cottage cheese containers shall extend over the top edges of the container so as to protect from contamination during subsequent handling: Provided, That this requirement(s) shall not apply to cottage cheese, dry curd cottage cheese, and lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures.

(u) Personnel—Cleanliness. Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his hands. All persons while engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products shall wear hairnets, facial hair restraints, caps, or other effective hair restraints, and shall not use tobacco. To meet these requirements:

(1) Hands are thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination; and

(2) Each employee washes his hands following a visit to the toilet room and prior to resuming work and

(3) All persons while engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils wear clean outer garments; and

(4) All persons while engaged in the processing of milk and milk products shall wear hairnets, facial hair restraints, caps, or other effective hair restraints, and shall not use tobacco.

(v) Vehicles. All vehicles used for transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 45°F (7°C) or less, and are protected from sun, from freezing and from contamination. To meet these requirements:

(1) All vehicles are kept clean; and

(2) Material which is capable of contaminating milk or milk products is not transported with milk or milk products; and

(3) Vehicles have fully enclosed bodies with well-fitted solid doors.

(w) Surroundings. Milk plant surroundings shall be kept neat, clean, and free from conditions which might attract or harbor flies, other insects and rodents, or which otherwise constitute a nuisance. To meet these requirements:

(1) There is no accumulation of trash, garbage, or similar waste in areas adjacent to the milk plant. Waste material stored in suitable covered containers shall be considered in compliance; and

(2) Driveways, lanes, and areas serving milk plant vehicular traffic are graded, drained, and free from pools of standing water; and

(3) Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain, and equipped with trapped drains of sufficient size; and

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Stirred cells for use with Diaflo membranes or microporous filters feature gentle magnetic action to control concentration polarization of retained

—Continued on page 50

Measure solid concentrations, density, or specific gravity of your process liquids and gases with the Paar DMA55 density meter to assure consistent product quality. Small 0.7 ml samples from the process are injected, pumped, vacuum-suctioned or continuously flowed into the sample tube. In less than a second, the instrument calculates and displays a 5-place digital result on the readout. This can be automatically transferred to other instruments. The method is fast, simple and accurate. No need for separate temperature, weight or volume measurements. No pycnometer filling. Mettler Instrument Corporation, Box 71, Hightstown, NJ 08520.

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Industrial Modeling and Production Estimates Of the Beef Processing Industry

J.D. SINK

□ NO INDUSTRY is more vital to the well-being of a people or a planet than the food industry. The meat industry ranks as the largest single component of the U.S. food industry with regard to total assets, value added to product by processing, total employment, and total business receipts, earning approximately 30% of the total food industry receipts (Forrest et al., 1975). As a species-oriented subsystem of the meat industry, the beef industry segment is the largest (Acker, 1971). The beef industry supplies nutrition for consumers and satisfies the American taste for high-quality meat. It concentrates plant material to produce a nutritionally dense product, creates a natural "grain reserve," and converts otherwise unusable forage and industrial byproducts into protein. In addition, the beef system provides a diverse range of non-food byproducts, and creates meaningful jobs for people (Veblen, 1977). Recently, a great deal of interest has been expressed with regard to the U.S. beef industry, its organization, operation, and outputs (Bray, 1977). The purpose of the study described here was to model the primary processing portion (SIC 20111) of the U.S. Beef System and to develop methods of estimating important production parameters.

A MODEL OF INDUSTRIAL PRODUCTION

The U.S. Beef System is extremely complex. Its size and geographic distribution, the interdependence of its biological and industrial processes, the perishable nature of its products, and the fragmentation of the various sectors create difficulties for those who seek to understand how the system works. The segments of the system are interrelated and, in a sense, interdependent. Actions taken in one segment of the system affect the other segments which respond in turn. Lack of agreement on the part of system participants as to the system's outcomes, present and future, creates conflicts.

The beef processing industry begins with raw material inputs of live cattle of foreign as well as domestic origin (Fig. 1). In 1976, more than 2 million cow-calf producers and 130,000 feeders collaborated to deliver all the domestic cattle slaughtered. Australia and New Zealand supplied approximately 70% of U.S. beef imports. Of the three principal forms, *imported boneless beef* is a more important component than *imported carcass beef* or *imported lean beef.* Imported beef supplies upon reaching the U.S. are processed in the same manner as domestic beef and becomes indistinguishable from it in most respects. Following slaughter and inspection (and grading as appropriate), carcass beef supplies move through two main channels. In the first channel, the breaking operations, the higher USDA quality graded carcasses—Prime, Choice, Good, Standard—and "house" graded carcasses are destined to end up as *domestic lean beef* for home, restaurant, and/or institutional menus. Throughout the breaking process, fat and usable trimmings are generated; it is these *domestic fat/rough trimmings* that are used as inputs into further processed products. Occasionally, however, when some primals/subprimals such as chucks, briskets, and plates are in excess supply, they will become an additional raw material for further processing. In the second channel, the lower quality USDA graded —Commercial, Utility, Cutter, and Canner—and ungraded carcasses, primarily cows and bulls, are put through the boning operation. With the exception of a few preferential primals/subprimals which are removed initially, the entire carcass is deboned of all usable meat. This *domestic boneless beef* then is used in further processing operations.

A possible future output—of both the breaking and boning operations—for further processing is *mechanically deboned beef.* However, for the moment, the USDA has its use under review (Angelotti, 1977).

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ESTIMATES OF INDUSTRIAL PRODUCTION

There are various parameters used to estimate industrial production. The following discussion identifies some of these parameters and proceeds to list computed estimates, accordingly.

• **Carcass Beef.** Total domestic beef production has been continuously increasing from the 19[illegible] level of 26 million to the 1976 level of 42.6 million head representing 25.7 billion lb of carcass beef (Table 1). In addition, the proportion slaughtered under federal inspection has risen from 75% in 1960 to over 90% in 1976 (SRS 1960-76). Total production of carcass beef can be divided into four categories: (a) high quality, federally-graded beef; (b) low quality federally-graded beef; (c) high quality, house-graded beef; and (d) low quality, ungraded beef. USDA figures indicate that over the last fifteen years, between 50 and 6[illegible]% of all domestic cattle have also been federally graded (Table 2). The actual proportion rose from 49% in 1960 to 65% in 1970; since then, the figure has fallen steadily to the 1976 level of approximately 55% (FSQS, 1977).

The USDA has annual data on total carcass beef production, high quality, federally-graded carcasses (category a), and low quality, federally-graded carcasses (category b). Thus, the amount of federally-graded carcass beef (CB_U) may be subtracted from total carcass beef (CB_T) to obtain the amount of non-graded carcass beef (CB_N), as

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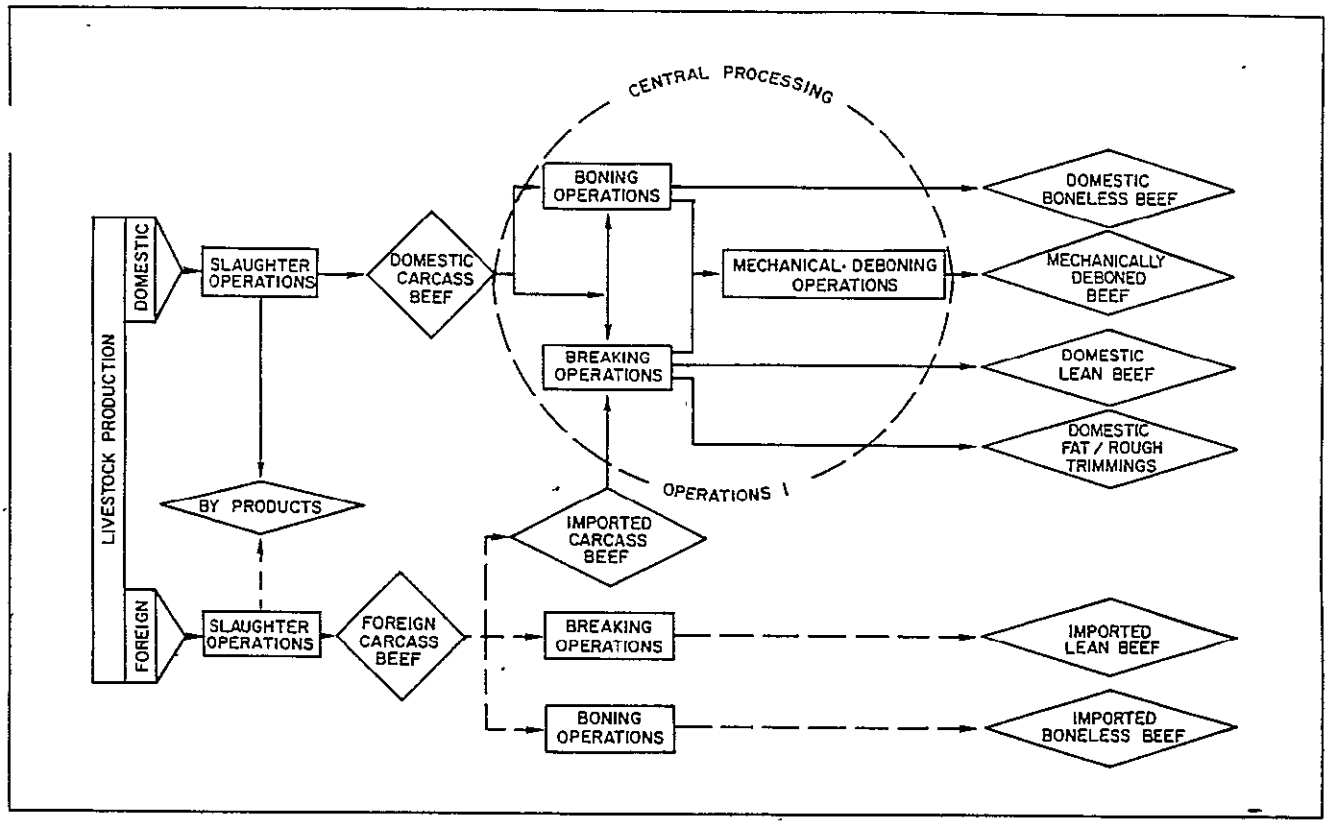

Fig. 1—**INDUSTRIAL MODEL** *of the beef processing segment of the meat industry with emphasis on its primary production outputs*

shown in the following equation:

$$CB_{\setminus} = CB_T - CB_G \quad (1)$$

The amounts of high quality, house-graded beef (category c) and low quality, ungraded beef (category d) can be estimated from the $CB_{\setminus}$ data. Assuming all the low quality, ungraded carcass beef (CB_L) is deboned, the amount of this category may be estimated from USDA (C&MS, 1967-76) data on boneless beef production under federal inspection (BB_F). Total BB_F production must be converted to the equivalent weight of carcass beef by multiplying by a factor of 1.5 (ERS, 1960-76). Thus, the quantity of high quality company- or "house"-graded carcass beef (CB_H) may be estimated by subtracting CB_L from $CB_{\setminus}$, according to the following equation:

$$CB_H = CB_{\setminus} - 1.5\ (BB_F) \quad (2)$$

• **Domestic Lean Beef.** The quantity of primals/subprimals or lean beef destined for domestic consumption as major menu entree items in homes, restaurants, [illegible] other institutions can be [illegible]ulated using the data in Table 2. First, it is necessary to know the total production of quality carcass beef (CB_Q) from all sources. This can be estimated by adding the amount of high quality, federally-graded carcass beef (category a) to the amount of high quality, house-graded carcass beef (category c). Secondly, it can be assumed the

Table 1—**CARCASS BEEF** *production data for selected years (in billions of pounds, carcass weight)*

Beef supplies/type	1960	1965	1970	1975	1976
Carcass beef (domestic)	14.73	18 69	21 65	23 67	25.66
federally inspected	11 44	15 42	19.15	21.70	23.16
Carcass beef (exported)	0 01	0.03	0.02	0.04	0.08
Carcass beef (imported)	0.01	0.03	0.02	0.01	0.02
Total carcass beef[a]	14.73	18.69	21 65	23.64	25.60

[a]Carcass beef (domestic + imported) — carcass beef (exported)

Table 2—**CARCASS BEEF GRADING** *data for selected years (in billions of pounds, carcass weight)*

Carcass grade/type	1960	1965	1970	1975	1976
Federally graded	7.06	10.30	13.93	10.27	13.91
High quality[a]	6.83	9.97	13.73	9.86	12.88
Low quality[b]	0.23	0.33	0.20	0.41	1.03
Non-federally graded	7 67	8.39	7.72	13.37	11.69
House graded[c]	3.23	2.91	1 34	5.79	2.84
Ungraded	4.44	5.48	6.38	7 58	8.85
Total high quality[d]	10.06	12.88	15.07	15.65	15.72

[a]USDA Prime, Choice, Good, and Standard Quality Grades
[b]USDA Commercial, Utility, Cutter, and Canner Quality Grades
[c]Probably the equivalent of the top end of the USDA Choice, Good and Standard Quality Grades, generally, those offerred for Federal Grading but not graded
[d]High Quality, federally-graded plus high quality, house-graded carcass beef

greater bulk of these carcasses will yield approximately 48% (low estimate) to 52% (high estimate) of closely trimmed retail cuts (FSQS personal communication). Thirdly, a crude estimate of about 22% represents the amount of selected primals/subprimals removed prior to deboning the low quality, federally-graded carcass beef (CB_L) (Unpublished research). Thus, the amount of beef primals/subprimals or domestic lean beef (LB_D) produced can be estimated from the following equations:

low estimate

$$LB_D = 0.48\ (CB_Q) + 0.22\ (CB_L) \quad (3a)$$

high estimate

$$LB_D = 0.52\ (CB_Q) + 0.22\ (CB_L) \quad (3b)$$

Some production estimates for this output of the beef processing industry are listed in Table 3.

• **Domestic Fat/Rough Trimmings.** Another output of carcass beef breaking operations is the trimmings. These include fat as well as muscle materials for use in further processing. Generally, the amount of fat/rough (muscle) trimmings obtainable from most high quality beef carcasses ranges from 36% (low estimate) to 39% (high estimate) (AMS, 1977). Thus, the quantity of fat/rough trimmings produced can be calculated from the following equations:

low estimate

$$FT_D = 0.36\ (CB_Q) \quad (4a)$$

high estimate

$$FT_D = 0.39\ (CB_Q) \quad (4b)$$

Some production estimates for this output of the beef processing industry are listed in Table 3.

• **Domestic Boneless Beef.** The major sources of boneless beef for further processing are the low-quality, federally-graded (CB_L) as well as the ungraded (CB_U) carcass beef. Generally, 54-61% of CB_L and 70-75% of CB_U beef carcasses are deboned for use in manufactured meat products (Unpublished research). Thus, the amount of domestic boneless beef may be estimated as follows:

low estimate

$$BB_D = 0.54\ (CB_L) + 0.70\ (CB_U) \quad (5a)$$

high estimate

$$BB_D = 0.61\ (CB_L) + 0.75\ (CB_U) \quad (5b)$$

Some production estimates for this output of the beef processing industry are listed in Table 3.

Table 3—**DOMESTIC LEAN BEEF,** *fat/rough trimmings and boneless beef pro[illegible] tion estimates for selected years (in billions of pounds)*

Domestic Production	1960	1965	1970	1975	1976
Lean beef cuts					
High estimate	5.28	6 77	7 88	8 23	8 40
Low estimate	4.88	6 25	7 27	7.60	7 78
Fat/rough trimmings					
High estimate	3 92	5 02	5.88	6 10	6.13
Low estimate	3 62	4.64	5.43	5 63	5.66
Boneless beef					
High estimate	3.47	4.31	4 91	5.94	7 27
Low estimate	3.23	4 02	4 58	5 53	6 76
Federally inspected	2 97[a]	3.65[a]	4 25	5 05	5 90

[a]Estimated as 31% of the total carcass beef production

Table 4—**POTENTIAL PRODUCTION** *estimates of domestic mechanically deb[illegible] beef for selected years*

Production Category	1970	1974	1975	1976
Beef carcasses (No. X10^6)	35.0	36.8	40 9	4[illegible]
Mechanically deboned beef (lb X10^6)				
High estimate	577.5	607.2	674.9	702 9
Low estimate	448 0	471.0	523 5	545 3

• **Domestic Mechanically Deboned Beef.** Although the use of mechanical deboning technology in the meat industry is currently under study (Angelotti, 1977), the potential production of such beef materials for further processing can be calculated. Goldstrand (1975) has shown an additional 12.8 to 16.5 lb/carcass yield can be obtained if beef bones are mechanically rather than hand deboned of the remaining edible meat after the usual breaking and boning operations. Thus, the amount of potentially available domestic mechanically deboned beef can be estimated from the following equations:

low estimate

$$DB_D = 12.8\ (\text{No. of beef carcasses}) \quad (6a)$$

high estimate

$$DB_D = 16.5\ (\text{No. of beef carcasses}) \quad (6b)$$

Some production estimates for this potential output of the beef processing industry are listed in Table 4.

• **Imported Beef.** Most (ca. 87-92%) of the imported beef is in the form of fresh or frozen carcass beef (quarters, primals) and boneless beef. As can be noted from the data presented in Tables 1 and 5, imported boneless beef is the most important category. Although it is possible to import lean "block" beef (closely trimmed subprimals), as shown in Figure 1, this categor[illegible] of output from the foreign bee[illegible] processing industry is not sig[illegible]f[illegible] cant in the U.S. market.

PRODUCTION TRENDS AND PROSPECTS

Over the past thirty year[illegible] several production trends an[illegible] structural changes have occu[illegible] in the beef processing industry[illegible]

• **General Trends.** In the ea[illegible] 1950s, beef replaced pork as [illegible] single most important meat [illegible] sumed in the United States. S[illegible] then, it has maintained a clear le[illegible] in consumer preferences. By 19[illegible] 52.9% of the total U.S. [illegible] consumption consisted of va[illegible] types of beef; this proportion ha[illegible] increased to slightly more tha[illegible] three-fifths, or 61% by 1966. S[illegible] that time, relative consump[illegible] has fluctuated within one or tw[illegible] percentage points of the 60% mar[illegible] However, in 1976, the figure ro[illegible] 66.8%. For the most part, [illegible] consumption of beef has more tha[illegible] kept pace with population growt[illegible] On a carcass weight basis, [illegible] sumption has risen from 85.[illegible] person in 1960 to 128.8 lb/perso[illegible] by 1976. For meat in general, t[illegible] overall increase has been [illegible] erratic (AMI, 1977). Althoug[illegible] production of carcass beef [illegible] increased dramatically in the la[illegible] decade, the biggest increase [illegible] been in the amount of low-qu[illegible]

Table 5—**IMPORTED BONELESS** *beef data for selected years (in millions of pounds)*

Year	Product weight basis	Carcass weight equivalent basis
1960	371 2	556 8
1965	489 5	734 3
1970	989 5	1484 2
1975	1074 0	1611 0
1976	1131.7	1697 5

Table 6—**STRUCTURAL CHARACTERISTICS** *of the beef processing industry for selected years*

Structural characteristic	1958	1963	1967	1972
Specialization index[a]	87	86	81	80
Production index[b]	—	88	77	83
Concentration index[c]				
CR-4	31	26	26	30
CR-8	38	34	35	42
Organization index[d]	106	106	107	108
Automation index[e]	101	139	191	227
Processing index[f]	22	20	18	25

[a]Ration (in percent) of all primary meat processing firms that process beef
[b]Ratio (in percent) of the production output to the rated capacity of firms
[c]Ratio (in percent) of all primary beef processing accounted for by the 4-largest and 8-largest firms
[d]Ratio (in percent) of the total number of establishments to the total number of firms
[e]Ratio (in 10^3 lb of carcass weight/person) of the total production output to the total number of production employees
[f]Ratio (in percent) of the output of primals/subprimals to that of carcass beef on firms

Table 7—**SIZE OF PRIMARY BEEF** *processors and their relative output for selected* [illegible]*s*

Processor size	1974		1975		1976	
	n	% Total	*n*	% Total	*n*	% Total
Large (> 50,000 head/yr)	198	82.0	211	81.1	217	82.7
Medium (10-49,999 head/yr)	187	14.1	212	14.9	202	12.9
Small (< 9,999 head/yr)	965	3.9	1124	4.1	1246	4 3

[a]Percent of total primary beef processing volume accounted for by the number (*n*) of processors indicated

ungraded carcass beef (up 62%). As would be expected from the increase in low-quality, ungraded carcass beef being produced, the domestic production of boneless beef has almost doubled since 1965. Further, an estimated 86-92% of domestic boneless beef was produced under federal inspection in 1960 whereas in 1976 it had decreased to 81-87%.

The production of high quality carcass beef has remained relatively constant at approximately 15 billion lb since 1970. This is evident also when comparing the production of materials from such carcasses: since 1970 domestic lean beef processing has remained relatively constant at approximately 8 billion lb/year, and the fat/rough beef trimmings output level has remained fairly constant, during the same period, at approximately 6 billion lb/year.

While the volume of imported carcass beef has remained relatively stable over the past fifteen years, the annual imports of boneless beef have more than tripled from 371.2 million lb in 1960 to 1131.7 million lb in 1976, in spite of the quota limitations in effect since 1964.

• **Structural Changes.** There is little doubt that the beef processing industry has grown and yet undergone substantial structural changes in the past 15 years. Two significant changes worthy of note are (a) the decreased competitiveness (and thus more influence exerted by the large beef processing companies within the industry), and (b) the increased development of centralized processing operations at the primary level of production (Table 6).

Although the total number of primary beef processing firms has increased, their numbers have decreased relative to the total number of all primary meat processors (SRS, 1960-76). Yet, the industry continues to operate at less than its rated capacity (NCFM, 1966; SCNHN, 1975). Concomitant with this decrease in industry specialization has been a change in the concentration ratio (CR). This index is defined as the cumulative percentage of total industry output that is produced by a specified number (4, 8, etc.) of the largest firms of that industry, and it is used for detecting the presence of market power in the industry. From 1952-1964 there was a steady decline in the percentage of beef processing accounted by the four (CR-4) and eight (CR-8) largest firms (NCFM, 1966). Then, the number of firms accounting for 30%, 40%, and 50%, respectively, of total carcass beef output decreased for the period 1969-1973 (SCNHN, 1975). Thus, the beef processing industry became less competitive. However, in recent years, 1974-76, there has been an increase in the number of large beef primary processors and yet there has been almost no change in the relative amount of total beef processing accounted for by this group (SRS, 1960-76) (Table 7). However, the organizational structure of the industry has remained relatively unchanged with regard to the number of establishments per firm (USBC, 1963, 1972).

Regional concentrations are generally much higher than their comparable national levels. With the exception of the West Coast and East North Central states, regional concentration (CR-4) on steer and heifer carcass beef output is at least 12 points higher than the national average of 26.1. While the national concentration (CR-4) of cow and bull carcass beef output is a very low 14.7, regional levels are at least 11 points higher; in New England, cow and bull processing is a very high 81.6. Regional concentrations for total beef processing are quite comparable to those for steers and heifers alone; the West Coast and the East North Central levels are less than or comparable to the national (CR-4) level of 23.2, while all other regions show levels ranging from 29.5 in the South Atlantic states to

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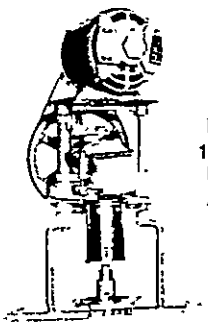

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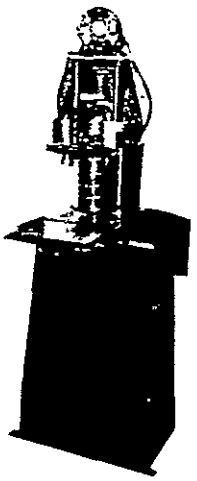

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79.5 in the New England area (SCNHN, 1975).

AUTOMATION INCREASES PRODUCTIVITY

The increase in central processing of carcass beef is evident from Census Bureau data indicating that the production of beef primals/subprimals has almost tripled from a level in 1958 of 1.9 billion lb to the 1972 figure of 3.7 billion lb. Further, and more important, the quantity of beef primals/subprimals compared to the quantity of carcass beef shipped by first or primary production level beef processors has increased from 19.8% in 1963 to 25.2% in 1972 (USBC, 1963, 1972). Currently, perhaps this amounts to 30-35%. This figure could double or go all the way if hot boning/on-the-rail boning and/or boxed beef processing systems are universally adopted by the industry (Alaimo, 1977). As noted (Table 6), the primary beef processing industry continues to move in the direction of increasing productivity through automation.

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News Notes

Pollution Control

—From page 43

macrosolute and to concentrate or desalt proteins, polypeptides, and polysaccharides.

Thin-channel systems minimize accumulation of retained species on the membrane surface and can be used with the membranes or microporous filters to separate colloidal or particulate systems at high solids content. High-performance, high-yield, on-line column eluate concentrator, and special thin-channel equipment are available.

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Water Supply, Plant Drainage, and Sewage Disposal System

Water Supply

Potable Water Supply

1. The water supply must be ample and potable. A certificate showing that the water is potable must be obtained from the appropriate health authorities prior to granting inspection.

Water from public water supply systems is usually acceptable. If the water is supplied from private wells, they should be certified as potable and protected from pollution. This certification should be made by the appropriate health authorities or by other government agencies acceptable to the Administrator.

If chlorinators are required to assure a continuous potable supply, they should be automatic and equipped with devices that inform the plant management and inspector when they have ceased to function. Poultry plants must have specified, in terms of gallons-per-minute, the water available for the processing needs of the plant.

Water must be distributed throughout the plant under adequate pressure and in quantities sufficient for all operating needs. Both hot and cold water must be provided. Hot water must come from a central heating plant of sufficient capacity or from other facilities capable of furnishing an ample supply. Hand-operated mixing valves for mixing steam and water are not acceptable for producing hot water used for such purposes as sanitizing equipment or areas contaminated by diseased material. If automatic mixing valves are utilized, a thermometer must be located at a point after mixing has occurred.

Nonpotable Water Supply

2. Nonpotable water lines shall not be cross-connected with the potable water supply. Nonpotable and potable lines must be physically separated to assure against accidental contamination. There can be some method of quickly connecting the two, if necessary for fire protection, but it should be located outside the plant.

Vacuum Breakers

3. Vacuum breakers of an acceptable type should be provided on all steam lines and water lines connected to various pieces of equipment.

Plant Waste Disposal

4. An efficient method of disposing of plant wastes is essential. If a private septic tank or sewage disposal system is used, it must be efficiently designed and operated so as to not produce objectionable conditions. The system must be acceptable to those authorities having jurisdiction.

Disposal of Paunch Contents, Hog Hair, Feathers, Blood, and Similar Waste Material

5. Waste material such as paunch contents, hog hair, feathers, blood, and pen manure must be disposed of without creating objectionable conditions, and the drawings or specifications should indicate how this will be accomplished.

Acceptance of Plant Waste System

6. The sewage disposal facilities must be acceptable to those having jurisdiction over such matters (local or State pollution control agencies or the U.S. Environmental Protection Agency). A letter from such authorities indicating that the proposed sewage system is satisfactory to them must be submitted to the area supervisor before inspection can be inaugurated at the plant.

Catch Basins for Grease Recovery

7. Catch basins for recovering grease should not be located in or near edible products departments or areas where edible products are shipped or received. When a catch basin is within a building, it should be adequately gasketed and sealed and located in a ventilated room. To permit easy cleaning, such basins should have inclined bottoms and a removable cover. They should be constructed so that they can be completely emptied of their contents for cleaning. Hot water hose connections should be provided at convenient locations near the basins for cleanup purposes. The area surrounding an outside catch basin should be paved with impervious material, such as concrete, and provided with proper drainage. Suitable facilities, such as a blow tank, should be provided for the transfer of grease to the point of disposal after it is skimmed from the basins.

Plant Drainage

8. All parts of floors where wet operations are conducted should be well drained. As a general rule, one drainage inlet should be provided for each 400 square feet (37 square meters) of floor area. A slope of about ¼ inch per foot (6.35 cm per 3.05 m) to drainage inlets is usually required. In areas such as beef sales coolers and other departments where a limited amount of water is used, the slope may be about 1/8 inch per foot (3.18 cm per 3.05 m).

It is important that the floors slope uniformly to drains with no low spots where liquids could collect.

Floor drains are not required in freezer rooms or dry storage areas. When floor drains are installed in rooms where the water seal in traps is likely to evaporate unless replenished, they shall be sealed with removable plugs.

Special Drainage Requirements

9. In certain departments, special floor drainage is required. For example, floor drainage valleys are essential under the dressing rails for hogs, calves, and sheep. Such valleys in the floor should be about 24 inches (61 cm) wide, and should slope at least 1/8 inch per foot (3.18 cm per 3.05 m) to floor drains within the valleys. In on-the-rail cattle slaughtering departments, floor valleys under the dressing rails are required unless the floor drainage is carefully localized, with drainage inlets placed advantageously beneath the dressing rail.

In poultry picking rooms and poultry eviscerating rooms, for example, drains must have adequate capacity and slope (counter to the product flow) to accommodate the operational and cleanup demands without overflow or backup of effluent. All drains should have effluent flow in the reverse direction from edible product flow.

Traps and Vents on Drainage Lines

10. Besides blood drains, each floor drain must be equipped with a deep-seal trap approved by the appropriate plumbing code. Drainage lines must be properly vented to the outside air and be equipped with effective rodent screens.

Trunk Lines

11. Where several drainage lines discharge into one trunk line, this line must be proportionately larger so as to efficiently handle the drainage into it.

Sanitary Drainage Lines

12. Soil lines from toilet bowls and urinals should not be connected with other drainage lines within the plant and may not discharge into a grease catch basin. Such lines should be located so that if leakage develops, it will not affect product or equipment.

Size and Construction of Drainage Lines

13. Drains for cattle paunch contents should be at least 8 inches (20.32 cm) in diameter to avoid clogging. Drains for hog, sheep, and calf stomach contents should be at least 6 inches (15.24 cm) in diameter. Such drains should not be connected to the regular plant drainage lines or to toilet lines. All other lines must have an inside diameter of at least 4 inches (10.16 cm). Drainage lines within the plant must be constructed of cast iron, galvanized metal, or other acceptable material.

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Plant Construction

Energy Conservation

1. Energy conservation measures should be considered in the design and construction of the plant. When utilizing conservation measures, it is necessary to submit descriptive details for evaluation.

Minimum Requirements

2. The design concepts listed in this handbook represent minimum requirements. Variations are acceptable, provided substitutions equal or exceed these standards.

Materials

3. Building materials should be impervious, easily cleanable, and resistant to wear and corrosion. Wall and ceiling surfaces should be white or light colored for light reflection and sanitation. Whenever practical, materials that do not require painting should be used. Materials that are absorbent and difficult to keep clean are generally unacceptable. Examples of such unacceptable materials are wood, plaster board, and porous acoustical-type panels or tiles.

Floors

4. Floors should be constructed of durable water-resistant materials. Commonly used acceptable material are concrete, ceramic floor tile, floor brick, and synthetic material approved by FSIS. As a safety precaution, excessively smooth floors must be avoided. Good results are obtained by using brick or concrete floors with abrasive particles embedded in the surface. Concrete floors should have a wood float (rough) finish. Concrete or mortar floors that incorporate an approved latex or synthetic resin base have better than ordinary resistance to meat fats and acids.

Coves

5. Coves with radii sufficient to promote sanitation should be installed at the juncture of floors and walls in all rooms.

Interior Walls

6. Interior walls should be smooth, flat, and constructed of impervious materials such as glazed brick, glazed tile, smooth-surfaced portland cement plaster, plastic, or other USDA-accepted nontoxic, nonabsorbent material applied to a suitable base. Walls should be provided with suitable sanitary type bumpers or curbs to protect them from damage by handtrucks, carcass shanks, and the like.

Ceilings

7. Ceilings should be of sufficient height—10 feet (3.05 m) or more is desirable in workrooms. So far as structural conditions permit, ceilings should be smooth and flat. Ceilings should be constructed of portland cement plaster, large-size cement asbestos boards with joints sealed with a USDA-accepted impervious material. If the ceiling has exposed joists, the joists should be at least 36 inches (91.44 cm) on center and designed so that there are no excessive ledges or crevices which would be difficult to keep clean.

Window Ledges

8. Window ledges should be sloped about 45° to promote sanitation. To avoid damage to window glass from impact of handtrucks and similar equipment, the window sills should be at least 3 feet (0.91 m) above the floor.

Doorways and Doors

9. Doorways through which product is transferred on rails or in handtrucks should be wide enough so that there is no contact between the doorways and the product. In most cases 4.5-foot-wide (1.37 m) doorways are necessary.

Doors in such doorways must be constructed of either rust-resistant metal or other USDA-approved material. If made of wood, they should be clad on both sides with rust-resistant metal having tightly soldered or welded seams. Door jambs should be clad with rust-resistant metal securely affixed so as to provide no crevices for dirt or vermin. The juncture at the walls should be effectively sealed with a USDA-approved flexible sealing compound. For safety reasons, double-acting doors should have a reinforced glass or transparent plastic panel at eye level.

Plastic Strip Doors

10. Available information indicates that plastic strip doors or curtains require extensive and continuous cleaning to be maintained in an acceptable sanitary manner. Associated with cleaning difficulty is the tendency to crack, scratch, and break. Therefore, this type of door is not acceptable for openings in new construction or as a replacement for doors in existing facilities through which exposed product or personnel handling exposed product will be moving. However, the use of plastic strip doors through which packaged product will be moving is acceptable.

Screens and Insect Control

11. All windows, doorways, and other openings that would admit insects should be equipped with effective insect and rodent control devices (screens, fans, seals, etc.).

Plant Lighting, Ventilation, Refrigeration, and Equipment

Rodent Proofing

12. Effective means should be provided to exclude rats and other rodents.

Interior Woodwork

13. Dressed lumber may be used for exposed interior woodwork. Any exposed interior wood surfaces should be painted with a USDA-accepted coating or plastic base paint, or treated with hot linseed oil, or a clear wood sealer.

Stairs

14. Stairs in edible product-handling departments should be of impervious construction with solid treads and closed risers and should have side curbs of similar material, 6 inchs (15.24 cm) high measured at the front edge of the treads.

Lighting

1. Well-distributed and good-quality artificial lighting is required at all places where natural light is unavailable or insufficient. The overall intensity of artificial illumination in workrooms should be no less than 30 foot-candles. At all locations where inspections are made or where special illumination is required to enable employees to properly prepare products to meet the requirements of inspection, the illumination should be not less than 50 foot-candles.

2. Specific requirements for certain locations in meat plants include:

(a) General Ante-mortem Inspection. Ten foot-candles in the pens, alleys, or areas where ante-mortem inspection is performed Readings are taken 3 feet (0.91m) above the floor.

(b) Suspect Pen. Twenty foot-candles over the entire suspect pen including restraint facilities if separate. Readings are taken 3 feet (0.91m) above the floor.

(c) Headwashing Cabinet (Beef). Fifty foot-candles at the level of the head hook.

(d) Beef Cervical (Head Rack). All areas of head illuminated to 50 foot-candles down to the symphysis of the mandible.

(e) Beef Cervical (Head Chain). Fifty foot-candles at the lowest inspection point on the hanging heads.

(f) Swine Cervical. Fifty foot-candles at the level of the mandibular lymph nodes of the lowest hanging heads.

(g) Beef Viscera (Truck). Fifty foot-candles with meter resting at bottom of the pan of lower portion of truck.

(h) Viscera (Moving Top Tables). Fifty foot-candles with meter resting in pan or on table top. (All species.)

(i) Rail Inspection. Fifty foot-candles at levels of the shoulders. (All species.)

(j) Final Inspection. Fifty foot-candles at shoulder level, viscera pan, and head rack. (All species.)

(k) Carcass Coolers. Ten foot-candles at level of front shank of carcasses in cooler.

(l) Offal Coolers. Twenty foot-candles general illumination at lowest level of open product storage. Fifty foot-candles at packing point and reinspection area.

3. Specific requirements for poultry plants include:

(a) Traditional Inspection. All rooms in which poultry is killed, eviscerated, or otherwise processed shall have at least 30 foot-candles on all work surfaces, except at the inspection stations where at least 50 foot-candles of light is required.

(b) Modified Traditional Inspection. A minimum of 150 foot-candles of shadow-free light shall be available

at the inspection surfaces of the bird to facilitate inspection.

Protection Devices

4. Light fixtures in rooms where exposed meat or poultry is handled should have a protective shield of suitable nonshattering material to preclude contamination of product with broken glass.

Ventilation

5. Adequate means for ventilation should be provided in work rooms and welfare rooms. This may be accomplished with ventilating-type windows, skylights, or both, or by mechanical means such as air conditioning or a fan and duct system. In locations subject to dust and objectionable odors, such as those adjoining livestock pens, runways, and inedible departments, windows should be of the fixed-type.

Refrigeration

6. Sufficient refrigerated space should be provided to handle carcasses and product properly. A maximum temperature of 50°F. (10°C.) should be maintained in such areas.

The type of refrigeration should be indicated in the drawings. If wall coils are installed, a drip gutter of concrete or other impervious material properly connected with the drainage system should be placed within curbed and separately drained areas unless located adjacent to floor drains.

Equipment

7. Equipment intended for use in plants operating under Federal inspection must be reviewed, evaluated, and accepted by the Equipment Standards and Review Branch, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Spacing from Floor and Walls

8. All permanently mounted equipment should be installed far enough above the floor to provide access for cleaning and inspection or should be completely sealed (watertight) to the floor. Likewise, such equipment should be installed at a minimum of 12 inches (30.48 cm) (greater distances for large equipment items) from walls, support structures, and other stationary fixtures or should be completely sealed (watertight) to walls, etc.

9. Wall-mounted cabinets and electrical connections (such as switch boxes, electrical control panels, conduits, and cables) should be installed at least 1 inch from equipment or walls, or should be completely sealed to the equipment or walls.

Control of Waste Water

10. Water-wasting equipment, such as soaking and cooking vats, sausage stuffing tables, can sterilizers, and casing preparation equipment, should be installed so that waste water from each unit is delivered through an interrupted connection into the drainage system without first flowing over the floor. Valves on drainage lines serving such equipment should be easily cleanable and mounted flush with the bottom of the equipment. Soaking and cooking vats should be equipped with overflow pipes at least 2 inches (5.08 cm) in diameter. Overflow pipes should be equipped with cleanout tees.

Vent Stacks from Hoods

11. Vent stacks from covered cooking vats or hoods over cook tanks should be arranged or constructed to preclude drainage of condensate into the vats.

Height of Work Tables

12. Working surfaces of tables and other equipment should be at a height of not more than 34 inches (86.36 cm) above the floor where employees stand to conduct operations. If tables and equipment have higher working surfaces, suitable metal foot platforms should be provided for employees to stand on.

Water on Work Tables

13. All tables or other equipment having water on the working surfaces should have turned-up edges. The height of the turned-up edge depends on the volume of water used and the operations conducted. In no instance, should the turn-up be less than 1 inch.

Hand-Washing Facilities, Sterilizers, Drinking Fountains, and Connections for Cleanup Hoses

Lavatories

1. Each processing room or area should have conveniently located handwashing facilities (lavatories) with a bowl large enough to prevent splashing. Lavatories should be supplied with hot and cold running water delivered through a combination mixing faucet with outlet about 12 inches (30.48 cm) above the rim of the bowl to facilitate washing arms as well as hands; liquid soap; an adequate supply of sanitary towels in suitable dispensers; and a suitable receptable for used towels. Lavatories in workrooms and welfare rooms should not be hand operated. One lavatory should be provided for every two sausage-stuffing tables, and they should be convenient to the stuffer operators. Lavatories should be directly connected to the drainage system. On eviscerating lines in poultry plants, a continuous flow or other acceptable handwashing facility must be provided at each inspection station. The supply of water shall be of adequate quantity and at proper temperature.

Sterilizers in Meat Plants

2. Sterilizers should be constructed of rust-resistant metal, and of sufficient size for complete immersion of knives, cleavers, saws, and other implements in 180°F. (83°C.) water. They should adjoin the lavatories in slaughtering departments and elsewhere as required. Each sterilizing receptacle should be provided with a water line, a steam line or other means of heating, an overflow, and a means for completely emptying the receptacle.

Drinking Fountains

3. Sanitary drinking fountains should be provided in large workrooms and in dressing rooms. If desired, they may be located at lavatories and arranged so that the overflow discharges into the bowls of the lavatories. if so located, they should be placed sufficiently high above the bowls to avoid water and soap splashing on them when the lavatories are used.

Hose Connections

4. Adequate and conveniently located hose connections for cleanup purposes should be provided throughout the plant. The use of long hoses should be avoided. Suitable racks or reels for storing the hose when not in use should be provided.

Location of Facilities

5. The location of lavatories, lavatory-sterilizers, drinking fountains, and other similar features must be shown on the drawings.

Facilities for Processing Edible Product

Size of Department

1. Meat and poultry preparation and processing departments should be of sufficient size to permit the installation of all necessary equipment with ample space for plant operations and truckways.

Flow of Operations

2. For efficiency, the processing departments should be arranged to allow a proper flow of product without undue congestion or backtracking, from the time raw materials and supplies are received until the finished product is shipped from the plant. Areas in which raw products are handled should be separate from areas used for handling ready-to-eat product. Ready-to-eat product and raw product cannot be exposed in the same room at the same time.

Perishable Product Departments

3. Facilities for holding perishable product under refrigeration should be provided. To insure proper care of product and to prevent growth of molds and bacteria, operations such as beef boning and trimming, deboning or otherwise processing of raw poultry, bacon slicing, pork cutting, prepackaging meats, and sausage chopping and mixing should be conducted in departments having a temperature not higher than 50°F. (10°C.) Such operations should be located in rooms separate from carcass or product holding coolers to avoid contamination of product by cleanup water and condensation during the cleanup period.

Freezers

4. Freezers should have adequate space and capacity to properly freeze and store product. Product should be stored well above the freezer floor and in such a manner so as to preclude congestion or other conditions which may lead to contamination or adulteration.

Incubation Room for Canned Product

5. A room for incubating samples of fully processed canned meat or poultry should be provided in a suitable location in all plants conducting regular canning operations. The room should have adequate size and equipment for holding the necessary samples. A 7-day recording thermometer should be mounted on the outside wall of the room. The sensing elements for the thermostat and the recording thermometer should be below the bottom shelf. The shelves should be made of expanded metal or heavy gauge (No. 9) wire mesh and be removable for cleaning. The floor in the room should be pitched to a floor drain equipped with a removable metal screw-plug. The door of the room should be equipped for sealing by USDA.

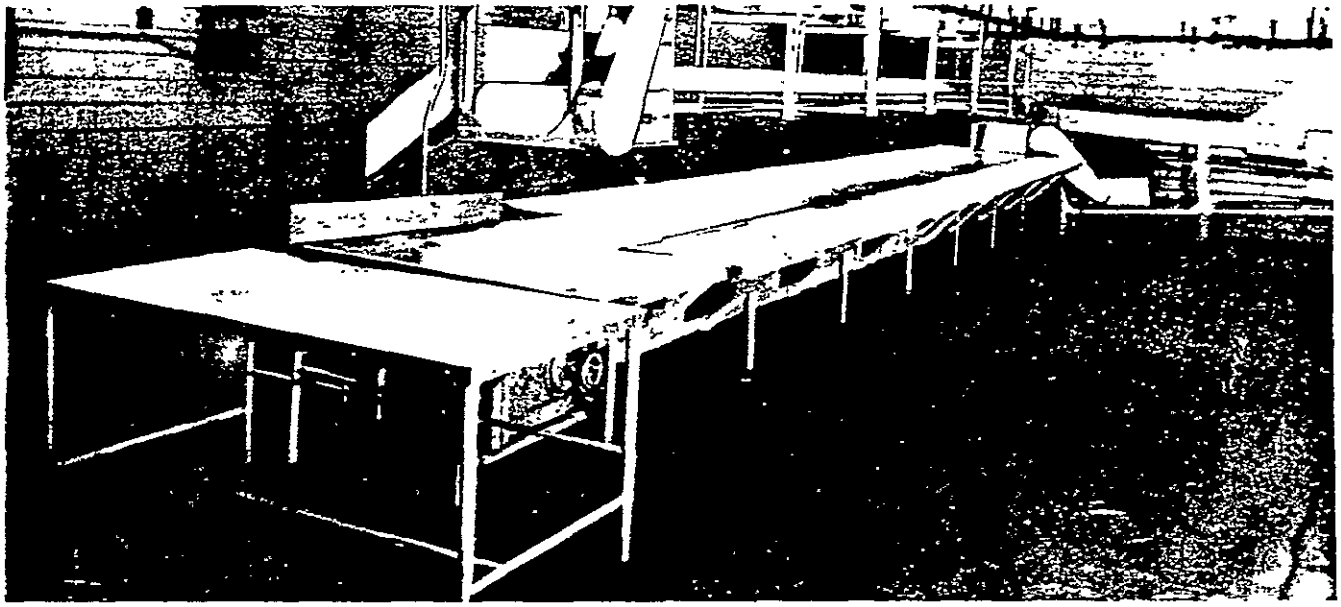

Figure 2—Boning department.

Dry Storage Space for Supplies

6. Suitable and adequate space for holding supplies such as boxes, paper, and cans should be provided in a convenient location in each plant. Establishments that slice bacon, slice and prepackage luncheon meat, bread and batter chicken, and prepare turkey loaves, sandwich steaks, and the like, generally use a large volume of packaging and labeling material. Adequate dry storage space should be provided for holding such supplies in a location convenient and preferably adjacent to the department where used. Supplies should be stored on racks about 12 inches (30.48 cm) above the floor.

Truckways within the Plant

7. Truckways should be unobstructed passageways having a minimum width of 5 feet (1.52 m) without overhead storage rails. When truckways are in coolers having overhead rails, a horizontal distance of 7 feet (2.13 m) should be provided between an adjacent wall and the vertical of the nearest rail and between boning tables and the vertical of the nearest rail. Truckways should be clearly designated on the drawings.

Vehicular Areas for Trucks and Railroad Track Gutters

8. Concrete-paved or other acceptable hard surface areas, properly drained and extending at least 20 feet (6.10 m) from buildings, loading docks, poultry han-

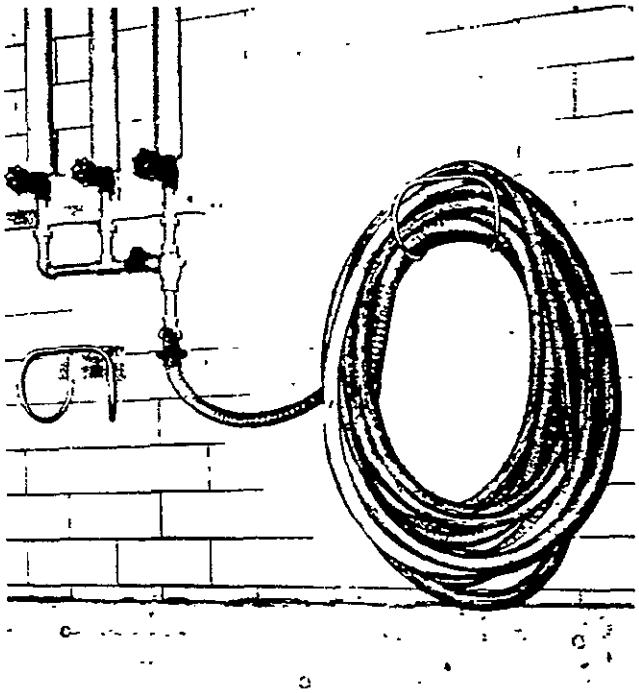

Figure 3—Cleanup hose and storage rack.

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dling docks, or livestock chutes and platforms, should be provided at places where vehicles are loaded or unloaded.

9. Railroad track gutters with suitable drainage should be provided where refrigerated railcars are loaded and unloaded. The top of the gutter should be below the bottom of the railroad ties unless the entire track area is paved. This feature should be clearly illustrated on the drawings by a typical cross section of the gutter and adjacent railroad ties and rails.

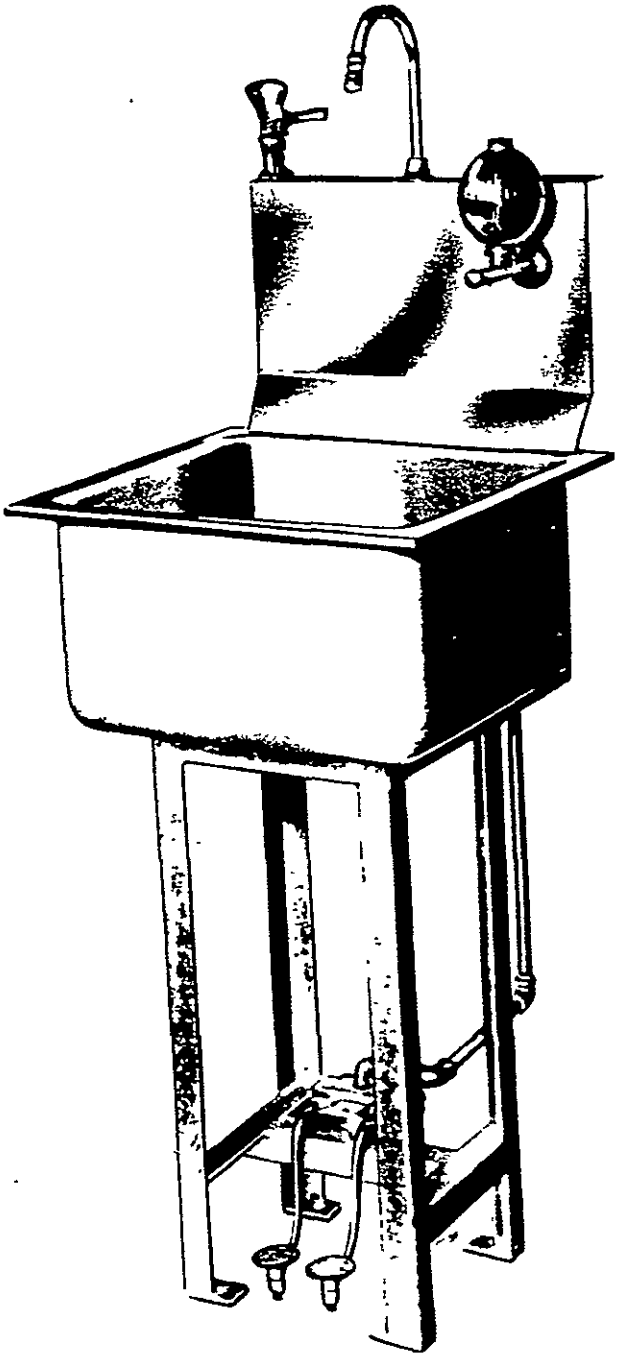

Figure 4—Handwashing basin.

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Design, Equipment, and Operation of Meat and Poultry Slaughtering Departments and Related Areas

Meat

Livestock Pens

1. To avoid delays in slaughtering operations, pens for ante-mortem inspection should have the capacity for holding the maximum number of animals of the various kinds that will be slaughtered in a single day. The pens, ramps, unloading chutes, and runways should be paved with concrete or brick and be equipped with adequate cleanup connections and suitable drainage facilities. Except at gateways, they should have side curbs of impervious material 12 inches (30.48 cm) or more in height. Water troughs should be provided with suitable overflows located above or adjacent to pen floor drains.

Ante-mortem Inspection Facilities

2. To facilitate the ante-mortem inspection of animals, ample natural or artificial lighting should be available, and a suitable suspect pen, with a squeeze chute where the temperature of the animals may be taken, should be provided. A reasonable portion of the livestock pens, including the area where the suspect pen and squeeze chute are located, should be under a weathertight roof to provide an area for proper ante-mortem inspection in inclement weather.

Location of Holding and Shackling Pens

3. To avoid dust and odors, holding and shackling pens should be located outside the slaughtering department or should be separated from the department by full-height partitions of impervious material.

Facilities for Crippled Animals

4. Suitable facilities should be furnished for conveying crippled animals into the slaughtering department.

Slaughtering Departments

5. Slaughtering departments should have adequate floor space and should be arranged to facilitate the sanitary conduct of operations and efficient inspection. Truckways over which products are conveyed from the slaughtering department to rooms such as the offal cooler, the edible products tank charging room, and the inedible products tank charging room should be located so that the material is not trucked beneath rails from which dressed carcasses and products are suspended. Personnel traffic should not move through lines of carcasses.

Maximum Rate of Slaughter Permitted

6. The rate of slaughter is dependent on the ability of the establishment to present carcasses, their viscera, and parts in an orderly and clean manner, permitting a complete and efficient inspection without congestion or other objectionable conditions.

The drawings or specifications should indicate the proposed maximum slaughter rate. Drawings should also indicate if more than one species of animal will be slaughtered simultaneously or consecutively and if the kosher method of slaughtering will be used.

Figure 5—Paved vehicular area.

Facilities for Handling Viscera

7. Adequate space and suitable, properly located facilities should be provided for separating and handling the viscera of the various species of animals slaughtered. The cattle paunch-emptying table should be equipped with a power-operated lift. If paunches are saved for edible purposes, the top of the table should extend over the emptying hopper about 12 inches (30.48 cm), and the sides of the hopper should extend vertically below the top of the table at least 3 ½ feet (1.07 m), to avoid soiling the paunches. (See drawings on page 53.)

Edible Byproduct Cooler

8. Suitable facilities for holding edible organs and parts (offal) under refrigeration in a separate cooler or in a separately drained part of a carcass cooler are required. Such areas should be accessible to the slaughtering department without passing through a line of carcasses or through a congested carcass cooler.

Carcass Chilling Coolers

Rail Arrangement

9. Cooler rails should be placed at least 2 feet (0.61 m) from refrigerating equipment, walls, columns, and other fixed parts of the building. To promote cleanliness of product and to protect walls from damage by carcass shanks, it is desirable to place rails (especially header or traffic rails) at least 3 feet (0.91 m) from the walls.

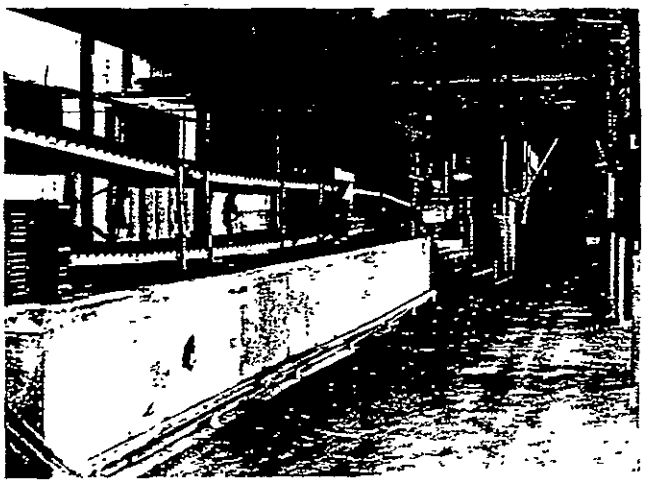
Height of Cooler Rails

10. The tops of cooler rails should be at least 11 feet (3.35 m) above the highest part of the floor for halves of beef; 9 feet (2.74 m) above for headless hog carcasses and calves (trolleys 12 inches long); and 7 ½ feet (2.29 m) above for quarters of beef. Sheep and goat carcasses should be suspended so that the hooks or gambrels are at least 6 ½ feet (1.98 m) above the floor. The rail height should be at least 12 ½ feet (3.81 m) for horse carcass sides and 8 ½ feet (2.59 m) for quarters.

Retaining Compartments

11. A suitable compartment should be provided in a cooler for holding retained carcasses or parts and retained products. The compartment may be separated from the remainder of the cooler by partitions of rust-resistant wire screen (No. 9 gauge, 1-inch mesh), or flat expanded metal of comparable gauge and mesh, extending from 2 inches (5.08 cm) above the floor to the ceiling. The compartment should have a door of similar material at least 4 feet wide (1.22 m),

Figure 6—Livestock pens.



Figures 7 and 8—Bird unloading area.

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equipped for sealing or locking by USDA. For cattle carcasses retained because of infestation with cysticercus bovis, a similar compartment should be provided for holding such carcasses in a freezer at a temperature not higher than 15°F. (-10°C.) for at least 10 days.

USDA Post-Mortem Inspection Station

12. An inspection station consisting of 5 feet (1.52 m) of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet (2.44 m) for each viscera inspector on the inspector's side of the table should be provided.

13. Hand wash lavatory, sterilizer, chain or conveyor control switch, and facilities to position tally sheets or other recording devices should be provided in a location convenient to the inspector.

14. For a swine slaughter line, one 5- by 5-foot (1.52-m by 1.52-m) distortion-free mirror is required at the carcass inspection station for the inspector to view the back of the carcass.

Poultry

Holding Sheds, Truck Maneuvering Areas and Loading Dock Bays

15. The holding sheds should be sufficient in size to facilitate the prescribed ante-mortem inspection, to assure a continual smooth flow of poultry into the plant, and to provide for the welfare of birds awaiting slaughter.

Artificial lighting should be provided in the holding sheds as necessary to facilitate inspection. The roofs should be weathertight and the road surface should be paved with an impervious material such as concrete. Any additional truck parking area and the truck maneuvering area should be surfaced with an impervious material such as concrete. The loading dock bays should be surfaced with an impervious material such as concrete which extends outward from the building at least 20 feet (6.1m). Suitable slope and drainage must be provided on all surfaces to prevent the collection of water or other obnoxious substances and to facilitate cleanup. Cleanup hose connections should be well located and adequate for the purpose.

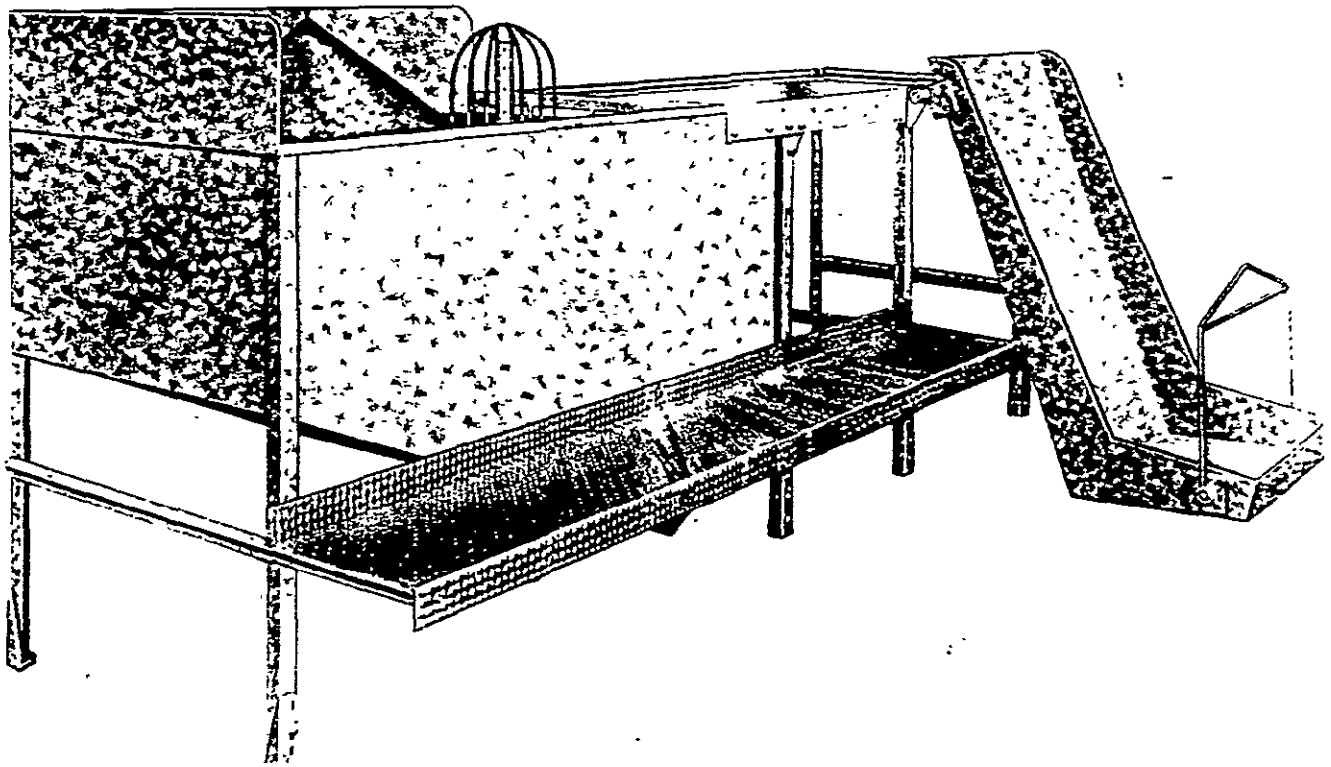

Figure 9—Compact facility for cleaning cattle paunches.

Docks for Receiving and Hanging Live Poultry, Slaughtering Area, and Picking Area

16. To prevent dust, feathers, and other obnoxious substances from entering other parts of the plant, the live hanging dock should be separated from the rest of the plant by full height impervious walls, self-closing impervious doors, and openings limited to those necessary for poultry conveyor systems.

The slaughtering area should be separated from the rest of the plant by full height impervious walls, self-closing impervious doors, and only such other openings as are necessary for conveyance of the poultry. Facilities should be provided to contain the blood in an area as small as feasible. The picking and scalding operations should be separated from the eviscerating and other area of the plant by full height impervious walls, self-closing impervious doors, and openings limited to those necessary for poultry conveyor systems.

Maximum Rate of Slaughter

17. The rate of slaughter is dependent upon the number of inspectors; the line arrangement; the spacing of birds; the incidence of disease; and the ability of the plant to present carcasses for inspection which are properly dressed and drawn, permitting complete and efficient inspection. The specifications or drawings should indicate the proposed maximum hourly rate of slaughter for each class of poultry.

USDA Post-Mortem Inspection Station

18. An inspection station of 8 feet (2.44m) unobstructed line space should be provided for each inspector and inspector's helper.

19. Hand-wash facilities, conveyor control switch, and facilities to position tally sheets or other recording devices shall be within easy reach of the inspector.

20. Hang back racks and receptacles for condemned carcasses and parts shall be provided at the inspection station.

21. A 3- by 2- foot (0.91-m by 0.61-m) distortion-free mirror properly mounted (see drawing on page 77) is required for Modified Traditional Inspection procedure.

Facilities for Handling Animal or Fish Food

22. Slaughtering establishments which process certain byproducts into animal or fish food should provide adequate facilities for decharacterizing, chilling, packing, or otherwise preparing the material separate and apart from facilities used in preparation of edible products. The material should be decharacterized promptly as a part of the dressing or viscera-separating operations to avoid extra supervision by inspectors. After the material has been packed in properly marked liquid tight containers, it may be stored in the edible products freezer, provided it is held separately and does not interfere with handling or storage of edible products.

Facilities for Handling Meat and Poultry Inedible and Condemned Materials

23. Well-arranged and adequate facilities for handling inedible and condemned material should be provided at slaughtering plants. The layout should permit inspectors complete control of condemned material with a minimum of travel and supervision.

Inedible products departments should be separate and distinct from the areas used for edible products, except that one connecting doorway equipped with a solid, self-closing door completely filling the opening is allowed between the inedible products departments and the slaughtering or eviscerating departments.

If rendering facilities are not located at the establishment, condemned materials must be denatured. Sufficient watertight storage facilities must be provided to hold such materials pending daily removal to a rendering plant (or more frequent removal if deemed necessary by the inspector-in-charge). These storage facilities must be located separate and apart from edible products departments, and they must be constructed to prevent insanitary conditions, including attraction or harborage for vermin. Permission to transport condemned material over public streets and highways should be obtained from State and local authorities having jurisdiction in such matters.

In meat plants, the most desirable facilities include hooded, vented, closed chutes that lead directly from the slaughtering department to the hashers or prebreakers. This equipment is also recommended for nonrendering plants to prevent objectionable odors from inedible and condemned product destined for an outside renderer, from entering edible departments.

If other techniques for transferring inedible materials are used (auger), appropriate methods of odor control must be used.

In low-volume slaughter operations where plant personnel perform a number of different duties including the handling of condemned viscera, mechanical devices must be used to eliminate the manual transfer of condemned viscera. Areas for inedible trucks should be paved and enclosed.

Required Cattle Slaughtering Facilities

Cattle Dressing Layouts

1. Cattle dressing layouts are of three principal types: (a) double-rail hang-off, (b) single-rail hang-off, and (c) "on-the-rail" dressing.

2 Drawings of slaughtering and allied departments using single-rail hang-off and various "on-the-rail" facilities are included in this handbook.

A summary of principal minimum rail heights and floor space, some of which appear on the drawings, is also included and should be carefully followed in preparing layouts.

Requirements for Various Types of Cattle Slaughtering Layouts

Stunning or Kosher Shackling Pens

3. Efficient facilities should be provided for confining animals for stunning before bleeding or, if kosher operations are conducted, for confining animals for shackling.

Dry Landing Area

4. A dry landing area at least 7 feet (2.13m) wide should be provided in front of the stunning pen to receive stunned animals ejected from the pen. The area should be separately drained and sufficiently removed from the bleeding area. The dry landing area should be enclosed by a fence at least 4 feet (1.22m) high to prevent escape of improperly stunned animals. The fence should be constructed of rust-resistant metal pipes and may be installed either as upright pipes 16 inches (40.64 cm) on center without crossrails, or, if desired, crossrails may be used and the number of upright pipes reduced to the number necessary for adequate and proper support (see page 54).

Bleeding Area

5. A curbed bleeding area of adequate size should be provided. It should be located so that blood will not be splashed on stunned animals lying on the dry landing area or on carcasses being skinned on the siding beds.

Bleeding and Dressing Rails

6. The top of the bleeding rail should be at least 16 feet (4.88m) above the floor or the metal grating over the bleeding area. Dressing rails should be at least 11 feet (3.35m) above the floor. When moving-top viscera inspection tables are used, dressing rails should be at least 12 feet 3 inches (3.73m) high.

Facilities for Handling Heads

7. Suitable facilities and adequate floor space should be provided for dehorning, flushing, washing, and inspecting heads; for storing heads on racks or trucks after removal from carcasses; and for head workup.

If conveyors are used for cattle head inspection, the spacing and heights should conform to the illustration on page 55.

Hide Chute or Other System of Hide Removal

8. A properly constructed hide chute should be provided near the point where hides are removed from carcasses. The chute should have a hood of substantial rust-resistant metal with a push-in door closely fitting a metal frame inclined so as to be self-closing by gravity. A vent pipe at least 10 inches (25.4 cm) in diameter should extend from the hood vertically to a point above the roof. If hides are removed by means other than a chute, the facilities should be designed so as to prevent sanitation problems.

9. When a down hide puller is used, the head drop and head removal area shall be curbed and drained. Also, sufficient space must be provided between hide pulling and carcass evisceration to permit cervical inspection prior to viscera inspection.

Carcass Washing and Shrouding Facilities

10. A separately drained area or an area of sufficient size sloped ½ inch per foot (1.27 cm per 3.05 m) to a floor drain should be provided where passed carcasses are either washed or shrouded. A platform to permit proper washing shall be provided.

Header Rail—Clearance

11. At least 3 feet (0.91 m) should be provided between the header rail and the adjacent wall for the clearance of dressed carcasses transferred on the rail.

Trim Rails

12. The kill floor layout should be designed so that carcasses railed out for trimming or touchup will be reintroduced onto the carcass line prior to the rail inspection position so that a final rail inspection can be performed.

Retain Rail

13. A suitable space for holding retained carcasses for final disposition will be provided along with the necessary platforms and handwashing facilities.

Floor Drainage

14. Efficient drainage facilities should be provided for the entire slaughtering department. See suggested layouts on pages 52-72 for acceptable drainage arrangements.

Figure 10—Cattle carcass cooler.

Figure 11 — Evisceration of cattle with aid of rail "dropper."

Requirements for Double-Rail and Single-Rail Hang-Off Dressing Systems

Space Between Bleeding Area and Dressing Beds

15. The dressing bed or cradle should be located at least 5 feet (1.52 m) from the curb around the bleeding area.

Space Between Drop-Off to Dressing Beds and Evisceration Hoists

16. For layouts of two dressing beds, a distance of 16 feet (4.88 m) should exist between the vertical of the drop-offs to the dressing bed area and the vertical of the line of the hoists where carcasses are eviscerated. For three or more beds, a distance of 18 feet (5.49 m) or more should exist between the verticals. This is necessary to provide space for the evisceration of carcasses and trucking of product, and for the inspections made at this point.

Requirements for "On-the-Rail" Dressing Systems

Disposal of Feed and Udders

17. An efficient method should be provided for disposing of feet and udders removed from carcasses. Chutes to a lower level are highly desirable, if structurally possible.

Metal Foot Platforms

18. Metal foot platforms installed for establishment employees performing various carcass dressing operations may be either stationary or the elevating type. If elevating, they should be located so as not to touch skinned portions or carcasses. If stationary platforms are used, they should be set far enough away from the dressing rail, and be constructed with the legs sufficiently set in to prevent contact with the forelegs of cattle. Alternatively, they may be suspended from overhead structures.

Spacing of Carcasses on Dressing Rails When Powered Conveyor or Gravity Flow Rails Are Used

19. To prevent contact between carcasses and to provide adequate space for operation, cattle carcasses should be separated by fingers at least 5 feet (1.52 m) on center on conveyor-type dressing rails or by rail "stops" 5 feet (1.52 m) on center on gravity-flow dressing rails, except that such spacing should be at least 8 feet (2.44 m) on center alongside the viscera inspection table (if used).

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Viscera Inspection Facilities

Viscera Trucks for Small Layouts

20. In small layouts with a limited rate of slaughter, viscera is usually placed in a specially designed handtruck for inspection. Such trucks should be constructed of stainless steel. An inspection pan at least 24 ½ by 26 by 3 inches (62.23 by 66.04 by 7.62 cm) in size is required for inspecting hearts, lungs, livers, and spleens. This pan should be placed with its bottom 34 inches (86.36 cm) above the floor. A compartment designed to facilitate evisceration and large enough to contain paunches and intestines is required beneath the inspection pan. The bottom of the lower compartment should be about 14 inches (35.56 cm) above the floor (see figure 15).

Viscera Truck Cleaning and Sterilizing Facilities

21. When viscera inspection trucks are used, a separately drained area about 7 by 8 feet (2.13 by 2.44 m) in size is required for washing and sterilizing such equipment. The facilities should be located at or near the point where condemned material is discharged from the trucks. When placed where splash might contaminate edible product, the truck washing area should have walls 8 feet (2.44 m) or more in height. The floor in the area should be pitched about ½ inch per foot (1.27 cm per 3.05 m) to a drain in a rear corner. A hose with an ample volume of water at a temperature of at least 180°F. (83°C.) is required for washing trucks in the washing area. The hot water should be obtained from a central supply rather than by mixing steam and water at or near the hose connection. A dial-type thermometer with its temperature-sensitive element located in the hot water line near the hose connection is required.

Flight-Top Inspection Tables for Medium or Large Layouts

22. Construction. In a layout for a high slaughtering rate, viscera is usually placed on a flight-top table for inspection. (Moving tables are required when the rate of slaughter is 40 or more per hour.) The table should be constructed with stainless steel flights about 5 feet (1.52 m) wide. The table should be of sufficient length for efficient evisceration, inspection, and viscera removal.

23. Washing and Disinfection. Cold water sprays should be provided beneath the discharge (unloading) end of the table to remove blood and animal tissues and fluids. A suitable compartment-type sterilizer is required at the loading end which is vented to the outside air. The vent duct should be at least 10 inches (25.4 cm) in diameter, and constructed of rust-resistant metal. Additional cold water sprays are necessary to cool the flights after the exit from the sterilizing compartment.

A thermometer is required with its sensing element in the hot water line as the water enters the sterilizing compartment. The temperature recording scale of the thermometer should be located so that it can be readily observed by the inspector working alongside the inspection table.

24. Synchronization With Carcass Conveyor. The movement of the inspection table must be carefully synchronized with the movement of the carcass and head conveyors.

25. Location of Table. The viscera inspection table should be located over a separately drained floor area. A floor drain is required beneath the sterilizing chamber.

26. Eviscerators' Facilities. A foot platform, handwashing facilities, a handtool sterilizer, a boot washing cabinet, and a boot storage locker are required for the eviscerator alongside the loading end of the table. (See drawing of these facilities on page 53.)

Required Sheep, Goat, and Calf Slaughtering Facilities

Bleeding Rail

1. The top of the bleeding rail should be at least 11 feet (3.35 m) above the floor for handling sheep, goats, or calves. If only sheep are handled in the bleeding section, the bleeding rail may be about 9 feet (2.74 m).

Dressing Rails

2. Dressing rails should be of such height that gambrels or leg hooks from which carcasses are suspended are about 7½ feet (2.29 m) above the floor or the inspector's platform. If calves are slaughtered by the Kosher method and dressed with the skin on, space is required for removing the heads before the carcasses are washed, and for placing the heads on a head truck after they are flushed and washed for transfer to the viscera inspection station. An unobstructed route for conveying the heads to the point of inspection should be provided.

Dressing Space and Operations

3. Adequate space should be provided along the rail for skinning legs and for skinning and removing calf heads before carcasses are transferred from shackles to gambrels. (The transfer point and the places where the principal dressing operations are performed should be indicated on the drawings.) If a moving carcass conveyor and combination viscera and head inspection table are used in the calf-dressing layout, and if the carcasses are suspended high enough to prevent contamination of the heads through contact with the floor or splash from the floor, the head skinning, removal, flushing, and washing should be deferred until the carcass reaches a point adjacent to the charging end of the inspection table. Heads from koshered calves, however, should be handled as described in item 2 above.

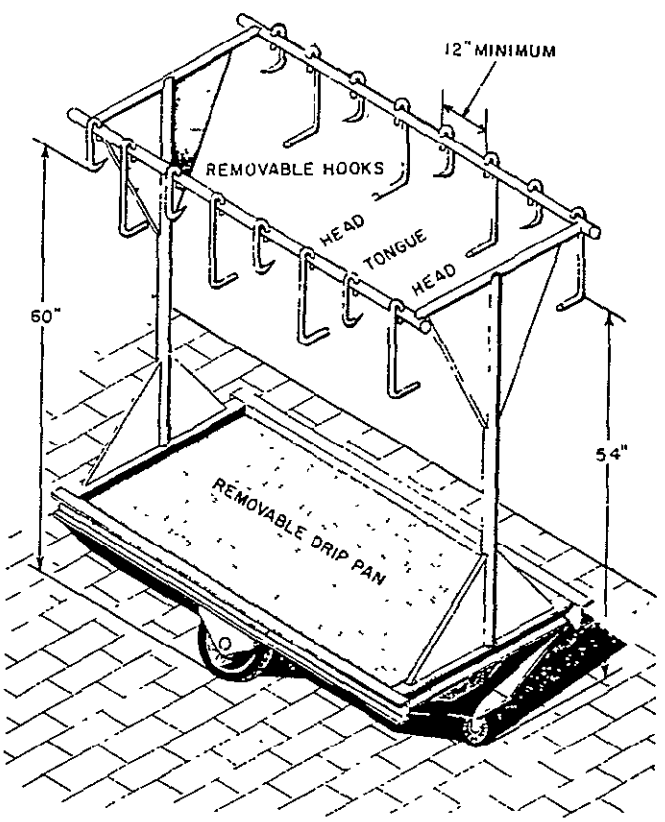

Figure 12—Cattle head inspection truck.

Calf Washing Facilities

4. If calf carcasses are dressed with the hides on, proper facilities must be provided for washing the hides before any incisions (except the sticking wounds) are made.

Calf Head Handling Facilities

5. Suitable facilities should be provided for flushing, washing, inspecting, and storing calf heads.

Carcass Washing Facilities

6. Suitable facilities should be provided for washing unopened sheep carcasses after pelts have been removed, and for washing the internal surfaces, breasts, and necks of calf, sheep, or goat carcasses after inspection has been completed.

Viscera, Head, and Carcass Inspection Facilities

7. (a) When the rate of slaughter for calves, sheep, or goats requires only one inspector, facilities for the inspection of viscera and calf heads should consist of a hoppered metal stand of the proper size to accommodate an inspection unit of two pans.

The height of the stand should be such that the bottoms of the pans are about 34 inches (86.36 cm) above the floor or the inspector's foot platform. The stand should be directly connected to the drainage system through a deep seal trap, or it may discharge through a waste pipe directly into a floor drain. The stand should be placed about 2 feet (0.61 m) from the vertical of the dressing rail, with the smaller of the two pans nearest the rail.

The large pan for the inspection of abdominal viscera should be 24 by 36 by 3 inches (60.96 by 91.44 by 7.62 cm); the small pan for thoracic viscera (or heads, if calf heads are placed on the table for inspection) should be 12 by 36 inches (30.48 X 91.44 cm). The pans should be located so they do not interfere with the movement of the inspector and eviscerator along-

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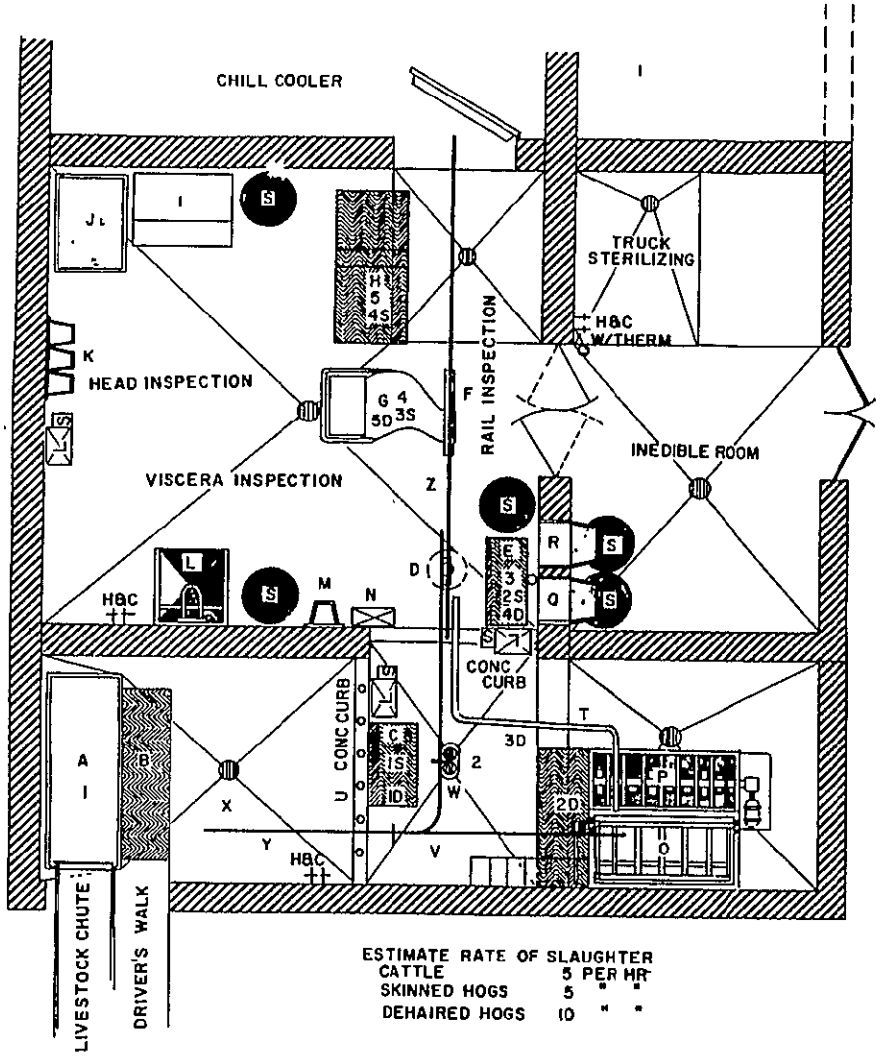
SHEET L

On-the-Rail Layout for Cattle and Hogs



ESTIMATE RATE OF SLAUGHTER

CATTLE	5 PER HR
SKINNED HOGS	5 " "
DEHAIRED HOGS	10 " "

0 2 4 6 8 10 12 14 16 18 20

SCALE

OPERATIONS

CATTLE

1_____DRIVE, STUN, SHACKLE & HOIST.
2___ STICK, SCALP, REMOVE HEADS, SAW HORNS, FLUSH HEADS & PLACE ON RACK.
3___ REMOVE HIND FEET, TRANSFER, RUMP, REMOVE UDDERS & PIZZLES, CUT AITCH BONE, RIM OVER, CUT OFF FRONT FEET, CLEAR FRONT LEGS & SHOULDERS, REMOVE HIDE
4_____SAW BRISKET, EVISCERATE, TRIM GRUBS ON MEDIAN LINE, SPLIT
5_____TRIM BRUISES, WASH & SHROUD

SKINNED HOGS

1_____DRIVE, STUN, SHACKLE & HOIST
1S. STICK
2S_ REMOVE HIND FEET, TRANSFER, DROP BUNG, OPEN, REMOVE PIG BAGS & PIZZLES, RIM OVER, CUT OFF FRONT FEET, REMOVE HIDE, REMOVE HEAD, WASH & PLACE ON RACK
3S_____SAW BRISKET, EVISCERATE, SPLIT, TRIM BRUISES
4S_____WASH HOGS

DEHAIRED HOGS

1_____DRIVE, STUN, SHACKLE & HOIST
1D_____STICK
2D_____OPERATE SCALDER & DEHAIRER, SHACKLE & HOIST
3D_____RESHAVE, WASH, REMOVE HEADS & PLACE ON RACK
4D_____TRANSFER, OPEN, REMOVE PIG BAGS & PIZZLES, SPLIT BRISKET
5D_____EVISCERATE, SPLIT, TRIM BRUISES

EQUIPMENT SCHEDULE

A_____STUNNING PEN
B_____STUNNER'S PLATFORM (MOUNTED ON GATE)
C_____STICKER'S PLATFORM
D_____TURN-AROUND
E_____ELEVATING PLATFORM
F_____DROP RAIL SECTION
G_____VISCERA TRUCK
H_____TWO LEVEL PLATFORM
I_____HEAD WORK-UP TABLE
J_____OFFAL TRUCK
K_____HEAD RACK
L_____HEAD FLUSH BOOTH
M_____HORN SAW RACK
N_____SAW STERILIZER
O_____SCALDING TUB
P_____DEHAIRING MACHINE
Q_____FEET CHUTE
R_____UDDER, PIZZLE, PIG BAG CHUTE
S_____INEDIBLE DRUM
T_____MONORAIL WITH BUDGIT HOIST
U_____PIPE SAFETY FENCE
V_____BLEEDING AREA
W_____BLOOD & WATER DRAIN
X_____DRY LANDING AREA
Y_____BLEEDING RAIL, HEIGHT 16'-0"
Z_____DRESSING RAIL, HEIGHT 11'-0"

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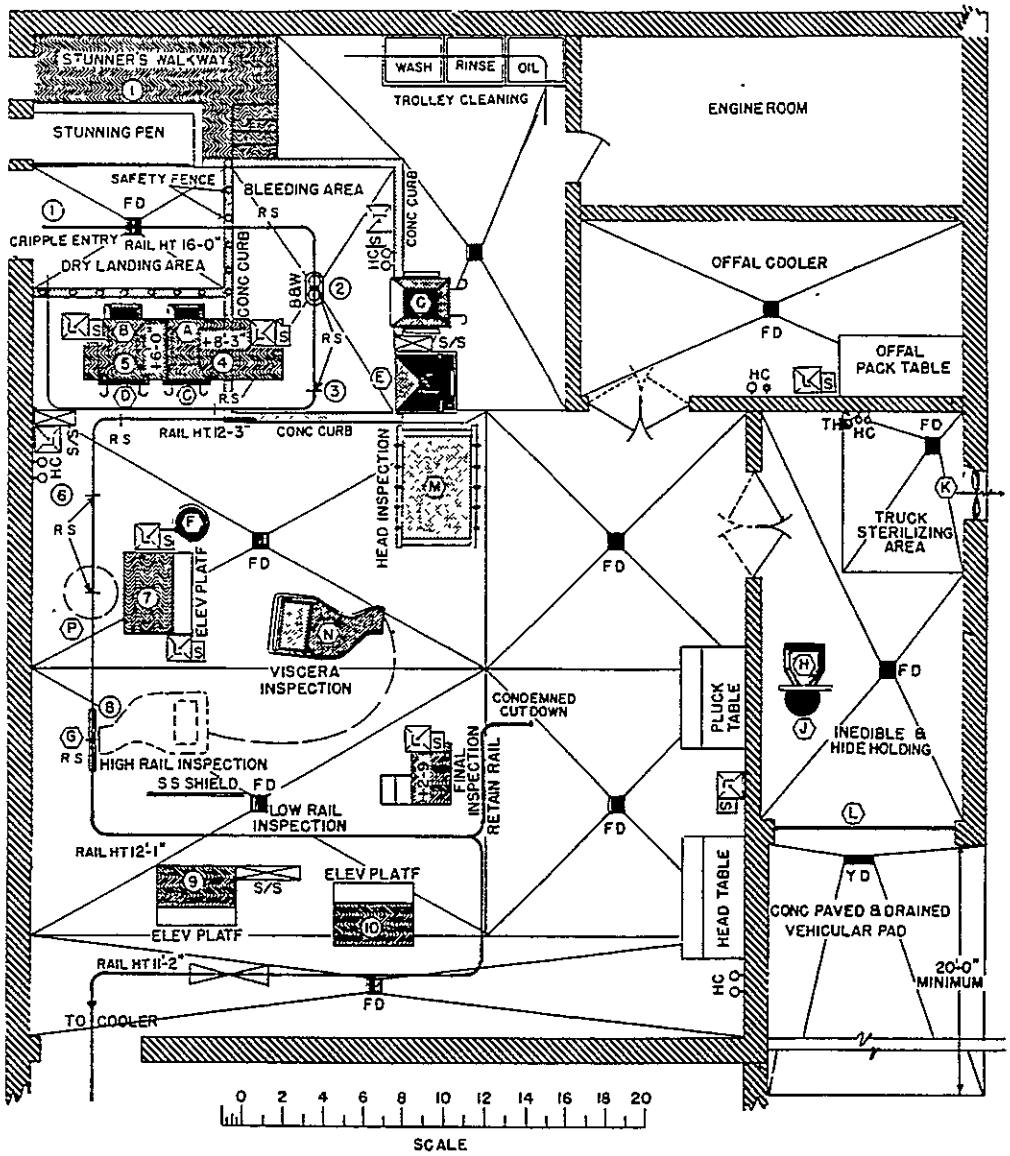
On-the-Rail Layout for Cattle with Slow Slaughtering Rate (1)



KEY TO OPERATIONS

1. DRIVE & STUN, SHACKLE & HOIST
2. STICK, SKIN HEAD, REMOVE FRONT FEET & ROD & TIE WEASAND
3. TAG, REMOVE HEAD, SAW HORNS, FLUSH HEAD & REMOVE TONGUE
4. REMOVE HIND FEET, BUTT, RUMP, DROP BUNG, TRANSFER
5. REMOVE UDDER & PIZZLE, FLANK, RIP OPEN & SPLIT AITCH BONE
6. RIM OVER, CUT PATTERN, SKIN SHANKS, CLEAR NECKS & SAW BRISKETS
7. SIDE, BACK, REMOVE HIDE, TURN CARCASS
8. EVISCERATE, TRIM GRUBS
9. SPLIT, TRIM BRUISES
10. WASH & SHROUD

KEY TO EQUIPMENT

A. FEET CHUTE
B. UDDER & PIZZLE CHUTE
C. FEET TRUCK
D. UDDER & PIZZLE TRUCK
E. HEAD FLUSH CABINET
F. HIDE DRUM
G. DROP RAIL SECTION
H. SKIP HOIST
J. INEDIBLE DRUM
K. EXHAUST FAN
L. DOOR EQUIPPED FOR USDA SEAL
M. HEAD & TONGUE TRUCK
N. VISCERA INSPECTION TRUCK
P. CARCASS TURNAROUND
S/S. SAW STERILIZER
TH. THERMOMETER
HC. HOSE CONNECTIONS
L. HAND WASHING FACILITY
S. KNIFE STERILIZER
FD. FLOOR DRAIN
B&W. BLOOD & WATER DRAIN
RS. RAIL STOPS

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Note on Dates of Course

This course was originally planned for June 29 through July 2. Due to the health concerns of one SUSTAIN volunteer and the political situation in Guatemala, it was postponed to August 3 though 6.

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Programa de Mercadeo y Servicios Técnicos
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18. Lic. Eugenia Canahuí
LUCAM, INCAP

19. Lic. Zoraida Anabella Morales
LUCAM, INCAP

Miss Liz Turner
Fax No. 202-6286726
U.S.A.

INSTITUTO DE NUTRICION DE CENTRO AMERICA Y PANAMA GUATEMALA FAX. No. (502-2) 736529	MENSAJE VIA FAX No. de Correlativo 1718
Fecha:May 10, 1993 Originado por:Luiz G. Elias Referencia: TF-VM-VC-93-043 No. de Páginas:five(this one included)	Destinatario:Interamerican Development Bank Atención:Miss Laura Ramirez Ramos Operation Officer, Micro Enterprise Division, WASHINGTON, D.C. No. del Destinatario:202/6233489

Dear Miss Ramirez:

I was informed by Miss Liz Turner, Program Director of the SUSTAIN project, that you are going to start soon a micro enterprise program in Belize.

Our institution, the Institute of Nutrition of Central America and Panama (INCAP) together with the Guatemalan Association of Food Technologists (ASTA) and SUSTAIN are working in a training program on quality control and quality assurance for the food industry in Central America. The idea is to emphasize quality control of the food supply offered for sale in the region. The short courses will be designed in a two part series: (1) training for trainers (advanced level course (2) offering a course to local food industries (at the basic level).

The advanced level course is planned to be offered on June 29-July 2 and the goal is to have a "cuore" of trainers that will be offering in the future the basic level course.

I wonder if you are interested in identify a person in Belize to participate in the advanced level course, which I think it is an special opportunity to have a qualified person in this area for future activities.

There will be no charge for the advanced course activities, however transportation and living expenses should be covered by the participants. I am also sending to you a proposed curriculum for the advanced course.

Hoping that this information will be useful, and looking forward to hear from you, I remain,

Sincerely,

Luiz G. Elias
Program Coordinator

c.c. Miss Liz Turner

P.S. My address is as follows:
Luiz G. Elias
INCAP
P.O. Box 1188
Guatemala, City, Guatemala
Fax Number: 736529

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Note on Participants from Belize

At the same time that this training course was in preparation, SUSTAIN was planning a mission in Belize to assess two non-governmental organizations (NGOs) and their capacity to assist their members in the agribusiness sector. At the invitation of INCAP and SUSTAIN, Belize Enterprise for Sustained Technology (BEST) sent two people: Henry Gill, Project Coordinator, and Steven O'Brien.

NCBA

National Cooperative Business Association

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