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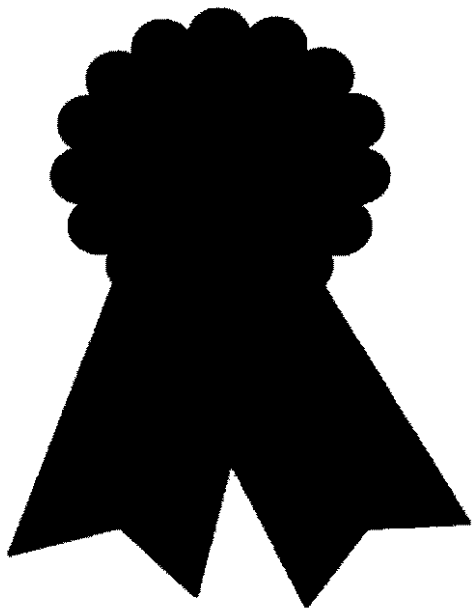
PRINCIPLES OF PRODUCT & PROCESS DEVELOPMENT



April 11-12, 2000

at the

ALEB Training Center

12 Dokki Street, 5th Floor

A Short Course Sponsored by Agriculture Led Export Businesses (ALEB)

Center for Advanced Food Technology (CAFT)

12 Dokki Street, Dokki, Cairo

TEL 02-338-1445/02-348-0728

Presented & Developed

by

Dr. Thomas Butterworth & Dr. Kathleen Nelson Feicht

USAID Contract No. 263-0264

PRINCIPLES OF PRODUCT & PROCESS DEVELOPMENT

INTRODUCTION

All businesses need to keep moving forward to assure that they remain healthy and viable. One means towards this end is the development of new products or the utilization on new processes to product new or improved products. Development of new products is a complex and frequently misunderstood process, which is the reason so many new items fail in the marketplace.

This program will provide attendees with a step-by-step "how to" guide for product and process development. This is a process that begins with good market research and planning, and proceeds through development and commercialization. The instructors will take attendees through this process. Potential pitfalls and areas of concern will be emphasized. The program will be of value to staff from research and development, marketing and all levels of management in that it will provide them with background on the complexity of the process.

PROGRAM OUTLINE

The following topics will be addressed during the program:

- **Product Definition** - Target market, cost profile, concepts & market research
- **Raw Materials & Ingredients** – Availability, purchasing
- **Processing Technologies** – Acid foods, acidified foods, shelf stable, controlled Aw, aseptic, retorting & hot fill
- **Equipment Requirements** – Ideal systems, alternates, formula modifications to match equipment, cost of manufacturing
- Product Development: Lab – Lab equipment for product development, steps in development, nutritional requirements, establishment of process parameters, reverse engineering
- **Pilot Plant Testing** – Purpose, steps for testing, experimental design, shelf life testing.
- **Plant Trials** – Scale up operations, batch sizes for safety & quality, validation, pitfalls.
- **Labeling Requirements** – Regulations required by EC and others, nutritional, copy and panel displays
- **Product Ideas and Brainstorming** – Classwork on new ideas.

INSTRUCTORS

- Dr. Thomas Butterworth

Managing General Partner of Austin FoodTech. 15 years experience at Hunt-Wesson with tomato products, aseptics, sauces, dry mixes, toppings and canned foods/

- Dr. Kathleen Nelson Feicht

Principle at ASTA Food Research. Has developed a wide range of products while working in industry (Pizza Hut) and for her clients at ASTA.

- Dr. David Dyer

Director of ALEB's Market Information Services. Since his arrival in Egypt, has provided private sector companies with market information that has proven invaluable in their decision making process.

FOR MORE INFORMATION CONTACT:

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EMAIL morad@egyptonline.com

April 11-12, 2000 from 9:30 – 17:00 at the ALEB Offices, 12 Dokki Street, 5th Floor Training Room

REGISTRATION INFORMATION
PRODUCT/PROCESS DEVELOPMENT

Name _____

Title _____

Company _____

Address _____

_____

TEL _____

FAX _____

Email _____

Attendees may register by calling in or faxing this registration to ALEB. They may also register on-site.

Registration Fee: There will be a 100LE registration fee for this program. Registrants will receive a course notebook, buffet lunch on each day, coffee breaks morning and afternoon on each day and a certificate of participation.

For further details, contact:

Agriculture Led Export Businesses (ALEB)
12 Dokki Street
Dokki, Cairo, EGYPT
TEL 202-348-0728/338-1445
FAX 202-348-0729

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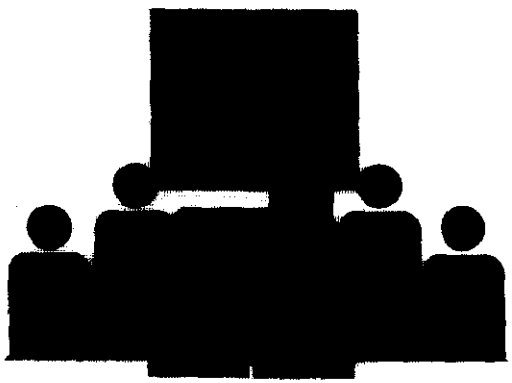


A SHORT COURSE SERIES
SPONSORED
BY THE
AGRICULTURE LED EXPORT
BUSINESS PROJECT (ALEB)
CAIRO, EGYPT

THE CENTER FOR ADVANCED FOOD
TECHNOLOGY
PISCATAWAY, NJ, USA

USAID Project No. 263-0264

April 11-12, 2000 at the ALEB Offices
5th Floor Training Room
9:30 – 17:00

THOMAS A. BUTTERWORTH

Austin FoodTech
114 Pearl Avenue
Newport Beach, CA 92662
TEL (714) 666-8482 FAX (714) 666-1017

EMPLOYMENT EXPERIENCE

1988-Present Managing General Partner Austin Food Tech, Inc.
-Specialists in Food Product Development

1984-1998 Instructor, "FDA Better Process Control School," Chapman University, Orange, CA

1988-1989 Lecturer, "Chemical Engineering Process Design," Department of Chemical Engineering California State University at Long Beach

1973-1988 Associate Director, Research and Development Beatrice/Hunt-Wesson, Inc., Fullerton, California
- Management of product/process development with staff of 24

- Project budget of $1.5 million

- Manpower assignments for product development, technical service, and non-routine regulatory interface for the following brands: Orville Redenbacher, Hunt's, Peter Pan, Fisher, J. Hungerford Smith, and Food Producers

- Experience with state-of-the-art aseptic systems, tomato products, toppings, sauces, dry mixes, drink bases, low-acid canned foods and fruits for both food service and retail product lines

- Staff commercialized 32 new products and line extensions and 30 product improvements in a five year period

1982 Instructor, "Food Engineering" Dept. of Food Science and Technology Chapman University, Orange, California

1980 -1981 Lecturer, "Chemical Engineering Process Design"
Dept. of Chemical, Nuclear and Thermal Engineering
University of California at Los Angeles

1968 -1973 Teaching and Research Assistantship
Dept. of Nutrition and Food Science
MIT, Cambridge, Massachusetts

1968 Chemical Engineer
Western Regional Research Laboratory, Albany, CA
- Work resulted in three publications

1964 - 1967 Chemical Engineer
B.F. Goodrich Chemical Company, Long Beach, CA

EDUCATION

Ph.D., Biochemical Engineering, 1973
Massachusetts Institute of Technology
- Chemical Engineering and Biology minors
- Thesis project concerned separation of protein solutions by ultrafiltration covered in two publications.
- Recipient of Nestle-IFT Fellowship

B.S., Chemical Engineering, 1967
University of California at Berkeley

PROFESSIONAL AFFILIATIONS

Institute of Food Technologists:
-Former Chairman, Food Engineering Division and
Former Member, Annual Program Committee
Institute for Thermal Processing Specialists
American Assoc. for the Advancement of Science
Industry Advisory Council, Food Science and
Technology Department, Univ. Calif. Davis
Food Engineering Advisory Council, Univ. Calif. Davis

KATHLEEN NELSON FEICHT, PH.D.

ASTA Food Research
3669 W. 240th Street
Torrance, CA 90505
TEL. 310-378-2370 FAX 310-378-7611

EMPLOYMENT EXPERIENCE

1986 – Present	Principal at ASTA Food Research Contract product development, consultation on quality assurance, nutritional labeling, concept development
1985-1985	Owner, Salute A fresh and frozen pasta company and restaurant
1982-1985	Director, Research and Development Pizza Hut, Inc., Wichita, Kansas, a division of PepsiCo Responsible for continuing product and process development with impact on 4300 restaurants in the US and technical assistance for the international group
1978-1982	Food Scientist/Project Leader General Foods Corporation, Tarrytown, New York Broad experience in the large General Foods' product line, two patents on soft-in-the-freezer technology

EDUCATION

Ph.D. Food Science, Cornell University 1978
Food Science major, minors in Nutrition and Business
Thesis on binding iron to protein sources for fortification.

MS Food Science, Cornell University 1976
Food Science major, Marketing minor
Thesis on *Vibrio parahaemolyticus*, a food pathogen

Cornell work funded by a New York State Teaching Assistantship. Working as a lab instructor for food chemistry, instrumental methods of analysis, mycology, and assisted in several other lecture courses. Recipient of the Outstanding Teaching Assistant Award.

BS Food Science/Chemistry 1973
University of California, Davis

PROFESSIONAL AFFILIATIONS

Institute of Food Technologists
-Current Chair-elect for the Southern California Region
-Former Councilor
-Former Chair of the Foodservice Division

American Society of Baking
-Former member of the Executive Committee
-Former Session Chair for the annual meeting

Sigma Delta Epsilon, Graduate Women in Science

Roundtable for Women in Food Service

PRINCIPLES OF PRODUCT AND PROCESS DEVELOPMENT

Kathleen N. Feicht, Ph.D.
ASTA Food Research
April 2000

"Classic" Product Development

- Market Research
- Concept Development
- Product Identification
- Product Development
- Pilot Plant Testing
- Storage Testing
- Market Testing
- Plant Trials
- Product Introduction

Human Resources

- Company Experts
  - Marketing
  - Market Research
  - Sales
  - Research & Development
  - Engineering
  - Quality Assurance
  - Plant Operations
- Outside Experts
  - Market Data
  - Market Research
  - Consumer Testing
  - Product Development
  - Engineering
  - Packaging

I. Market Research

A. Identify Company Strengths
- Products
- Processes
- Packaging
- Distribution
- Unique Expertise

I. Market Research, cont.

B. Identify Target Markets
- European Economic Community
  - Germany, United Kingdom, France
- Asia
  - Japan, Korea, Taiwan, Philippines, Australia
- North America
- China

I. Market Research, cont.

C. Research potential products or product categories in each target market
1. General sales data
   a. In the market
   b. Imports
   c. Exports

I. Market Research, cont.

2. Further market definition
   a. Commodity - [illegible]
   b. Food Service
   c. Retail
      - [illegible] - [illegible]
      - [illegible] - [illegible]

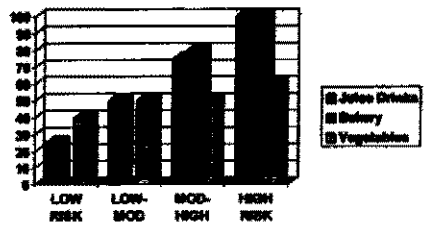
I. Market Research, cont.

3. Pricing in each market
4. Identify additional issues and costs
   a. Shipping
   b. Storage
   c. Tariffs
   d. Other

I. Market Research, cont.

D. Analyze the business opportunity
   1. Ease of market entry
   2. Capital expenditure required
   3. Profit potential

Profit Potential vs. Risk



II. Concept Development

A. Match company strengths to identified market opportunities:

- What can we produce that would sell at a competitive price in these export markets?
- What strengths does our company have to develop new products with added value, to create a new product or acquire market share from an existing product?

II. Concept Development, cont.

B. Establish the Criteria for Success

- Gross sales volume
- Gross sales dollars
- Net profit
- Timing
- Use of existing resources
- Acquisition of new resources

II. Concept Development, cont.

C. List possible products

- Whole fruit - fresh, frozen
- Liquid Juices - packaging
- Juice Concentrates
- Juice Blends - packaging
- "Smoothie" Beans
- Jams and Jellies
- Fruit Concentrates
- Baked Fruit Bars

II. Concept Development, cont.

C. List possible products

- Whole fruit - fresh, frozen
- Liquid Juices - packaging
- Juice Concentrates
- Juice Blends - packaging
- "Smoothie" Beans
- Jams and Jellies
- Fruit Concentrates
- Baked Fruit Bars

D. Evaluate options, rank, and prioritize

- Fast development time
- Low capital expenditure
- Lowest risk

↕

- Long development time
- High capital expenditure
- Highest risk

Ready-to-Drink Orange Juice Products

- There has been a proliferation of ready-to-drink (RTD) orange juice products in the United States.
- Consumption of orange juice has increased to 5.8 gallons/person/year.
- Major players are Pepsico (Minute Maid) and Coca Cola (Tropicana). Others in the market include Dole, Florida's Natural (a grower's cooperative) and Chiquita.
- Main package form is the gable-top waxed carton in quarts and half gallons. Also plastic gallons and individual, aseptic cartons.

Ready-to-Drink Orange Juice Products, cont.

- Products offered include "original," various levels of pulp added (pulp-free to "pulpy").
- Fortification with Vitamin C (increase to 180% and 240% USRDI, normally at 120% USRDI), fortification with calcium (increase to 35% USRDI, "as much as milk," and 120% USRDI, normally at 2% USRDI), fortification with 100% USRDI of Vitamin E.
- Various juice combinations are offered, including: Orange-Tangerine, Orange-Passionfruit, Orange-Strawberry-Banana, Orange-Peach-Mango, Orange-Guava, Pineapple-Orange-Banana, Pineapple-Orange-Strawberry.

III. Product Identification

A. Define product goals and objectives:

1. Claims - health, nutritional, all natural
2. Timing
3. Profit
4. Risk

III. Product Identification, cont.

B. Determine the method of distribution:

1. Shelf stable
2. Refrigerated
3. Frozen

III. Product Identification, cont.

C. Determine shelf life target:

1. Common to the product
2. Allow enough time for transport, distribution, sale, and use

III. Product Identification, cont.

D. Evaluate packaging options

1. Common to the product
2. Minimum to provide mechanical, chemical and microbial protection
3. Extend shelf life with a better package
4. Cost versus the benefit

III. Product Identification, cont.

E. Evaluate ingredient availability

1. Seasonal or year around
2. Cost fluctuations
3. Consistent high quality
4. Other issues - shell free, GMO free

IV. Product Development

What are we developing?

New Product

Reverse Engineering an Existing Product

Steps in Product Development

1. Define the product as completely as possible – there will still be many options to explore.
2. Purchase products that are similar in concept or exactly the product desired.

Steps in Product Development

3. Evaluate these products using the five senses:

See	Size, Shape, Color, Texture, Appearance
Smell	Aroma
Taste	Flavor, Sour, Bitter, Sweet, Salty Mouthfeel
Touch	Viscosity, Texture
Hear	Viscosity, Texture

Steps in Product Development

4. Evaluate these products analytically:

% Moisture	pH
% Titratable Acidity	Water Activity
% Salt	Soluble Solids
Consistency	Density
Others . . .	

Steps in Product Development

5. Identify starting formulations:
   - personal experience
   - label of competitive product
   - literature
   - suppliers
   - consultants

Steps in Product Development

6. Acquire ingredients to be used in the formulation. Also consider alternate ingredients.
   - Allow adequate time for receipt of ingredients
   - Order all ingredients to be evaluated (from each vendor) at one time
   - Think through possible ingredient interactions

Steps in Product Development

7. Formulate using a computer program before entering the laboratory:
   a. Input a starting formulation
   b. Estimate moisture loss from heat treatment
   c. Calculate nutritional label and ingredient declaration
   d. Make formula adjustments to duplicate a target product or meet product objectives
   e. Determine formula limits

Steps in Product Development

8. Laboratory development using the computer aided formulation and ingredients ordered
   a. Design experiments to quickly test:
      - Midpoint and limits of a potential formulation
      - Alternate ingredients
      - Process variations
   b. Continue laboratory research until a product has been developed that meets project objectives

Laboratory Equipment for Product Development

Basic Equipment (will vary by industry)

Balance, scales - weighing pans, papers
Mixers, small/large - bowls, paddle, whisk, scraper
Blender, high speed/high shear
Hot plate or stove - pans, lids, sheetpans
Oven(s) - conduction, convection, microwave
Refrigerator, freezer
Storage containers

Laboratory Equipment for Product Development

Analytical Equipment (will vary by industry)

pH meter	Specific Gravity
Moisture	Water Activity
Titratable Acidity	Salt
Soluble Solids	Hydrometer
Bostwick Consistometer	Thermometer
Brookfield Viscometer	Micrometer
Penetrometer	HPLC
Gas Chromatograph	

Steps in Product Development

9. Basic screening methods useful for prototype evaluation during product development
   a. Benchtop Testing
   b. Descriptive Analysis
   c. Discriminative Testing - Triangle Method
   d. Consumer Focus Group Sessions

Benchtop Testing

PURPOSE	Preliminary screening for general guidance to product development
PROCEDURE	Assess general sensory characteristics of test samples
PANEL	Two or more laboratory/product panelists
PREPARATION	Highly controlled product preparation
ENVIRONMENT	Laboratory benchtop or conference room
ANALYSIS	No formal analysis, description of general product characteristics

Descriptive Analysis

PURPOSE	Determine and describe differences in individual characteristics of products
PROCEDURE	Examine two+ samples for presence and intensity of specific sensory characteristics
PANEL	Formally trained, standardized terminology and techniques
PREPARATION	Controlled product preparation & serving
ENVIRONMENT	Quiet, odor free room
ANALYSIS	Composite based upon majority agreement

Discriminative Testing - Triangle Test

PURPOSE	Determine if a perceptible difference exists between two samples, at a specified statistical significance
PROCEDURE	Present three coded samples, two are the same, ask panelist to identify the odd one
PANEL	No formal training
PREPARATION	Controlled product preparation & serving
ENVIRONMENT	Quiet, odor free, separated booths
ANALYSIS	Statistical analysis, greater than chance

Consumer Focus Group Sessions

PURPOSE	Provide research guidance of experimental formulations
PROCEDURE	Group discussion of general and specific product characteristics
PANEL	Up to ten people, led by a trained discussion leader
PREPARATION	Controlled product preparation & serving
ENVIRONMENT	Neutral location, quiet, private, informal
ANALYSIS	Summary of the discussion

Steps in Product Development

10. Demonstrate new product(s) to marketing and management.

    - Revisions
    - Consumer Evaluation

V. Pilot Plant Testing

Purposes:

- Translate lab formulation and process to manufacturing scale and conditions.
- Identify and correct potential problems
- Establish quality assurance parameters
- Obtain product for storage testing
- Produce product for consumer evaluation

VI. Storage Testing

A. Ambient Testing:
Evaluation of product, in identified packaging, to determine shelf life under possible storage and distribution conditions.

B. Accelerated Testing:
Predictive technique to shorten length of time of standard ambient storage testing.

VII. Consumer Evaluation

A. What and Why?

1. Product evaluation by consumers to provide answers to marketing and management about the new product.
2. The objective is to minimize risk in the new product introduction.

VII. Consumer Evaluation, cont.

B. How?

1. In-Store Testing
2. Central Location Testing
3. Home Use Testing

In-Store Testing

- Executed in supermarkets, warehouse stores, malls, only locations with heavy traffic.
- No screening of testers.
- Advantages of this form of testing are speed and low cost.
- Simple test design; paired comparisons, individual product evaluation of one or two samples.

Central Location Testing

- Consumers are pre-screened for specific product usage and demographic factors.
- Environment and sample preparation can be closely controlled.
- Evaluation can be administered by a professional or self-directed by the consumer.
- The simplest or the most complex methods of testing can be used.
- Consumer involvement can range from merely testing the product to product preparation.

Consumer Evaluation Questions

- Appearance
- Portion Size
- Color
- Aroma
- Flavor
- Sweetness
- Saltiness
- Other
- Improve

- When would you buy. .
- How would you use . . .
- How often would you purchase . . .
- How would you improve
- Would you buy this if it were sold in . . .
- How likely would you be to purchase this product for $ X? for $ Y?

Home Use Testing

- Conducted with products at the end of the development cycle.
- Consumers are pre-screened for specific product usage and demographic factors.
- Consumers evaluate the product as, and where, they would normally use it.
- Consumers evaluate the product in terms of flavor, texture, convenience, ease of preparation, cost, etc.
- Test design can be simple evaluation or paired-comparisons to multiple evaluations of product over a series of weeks.

VIII. Plant Trials

A. Determine final process parameters
B. Establish critical control points and quality assurance parameters
C. Prepare product specification
D. Determine yield
E. Calculate actual product cost

IX. Market the New Product

- Follow sales of the new product by units and dollars
- Evaluate the new product through the actual distribution system and over time
- Make product improvements
- Evaluate alternate ingredients
- Make cost reductions

Product Development: Meal Replacement Bar

Product Description:

- Single-serving, ready-to-eat
- Size about 4" x 2" x 3/4" and 50 g/bar
- Freshly baked, homemade appearance
- Sweet, grainy aroma and flavor
- Calories up to 200/bar
- Fat free (0.5g/bar) or low fat (<3g/bar)
- Protein 5+g/bar, dietary fiber 5+g/bar
- Simple sugars low, <15g/bar
- Fortify to 35% USRDI

Meal Replacement Bar, cont.

Identify starting formulations:

- Competitive products - evaluate
- Personal experience
- Suppliers

Order ingredients

Review packaging alternatives

Meal Replacement Bar, cont.

Begin formulation on the computer

- Input ingredients
- Formulate to nutritional requirements
- Estimate baking loss
- Calculate formula limits

Meal Replacement Bar, cont.

Prepare laboratory batches

- Midpoint and limits of potential formulation
- Evaluate alternate ingredients
- Evaluate process variations

Ongoing product evaluation at bench top and with the project team

Meal Replacement Bar, cont.

Pilot plant testing
- Scale up formula and process
- Identify CCPs and QA
- Evaluate packaging

Product into ambient and accelerated storage testing

Consumer evaluation

Meal Replacement Bar, cont.

Plant Trials
- Determine final process parameters
- Establish CCPs and QA
- Laboratory analysis to verify label claim
- Prepare product specification
- Determine yield
- Calculate actual product cost

Meal Replacement Bar, cont.

Ongoing product improvement:

- Product quality issues - dehydration, shells
- Packaging and packaging equipment
- Insect infestation, mold
- Alternate ingredients

Independent Variables

- VARIETY
- BREAK
- FINISH
- °BRIX
- PARTICULATE
- PROCESS REFINEMENT
- FORMULATON
- PACKAGE

Tomato Variety

- Solids
  - –Products sold by % solids
    - Tomato paste
    - Tomato puree

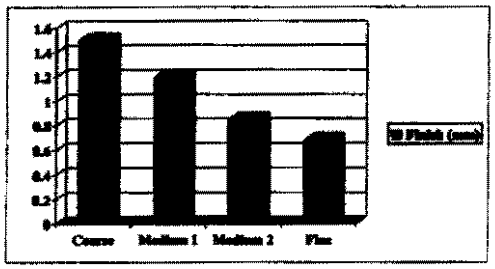
Tomato Variety

- Consistency
  - –Products sold by consistency
    - Tomato sauce

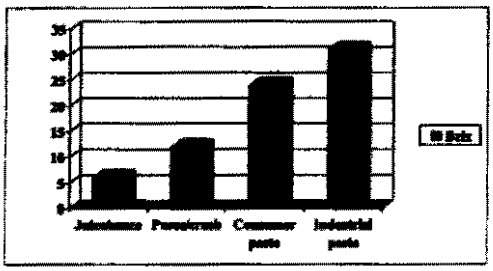
Break Temperature

- Cold break
  - 60 to 80°C
    - Best for color
- Hot break
  - 95 to 120°C
    - Best for consistency

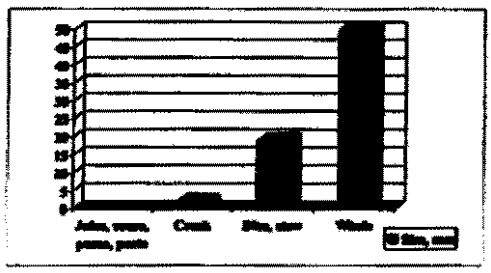
Finish



°Brix



Tomato Particulates



Process Refinements

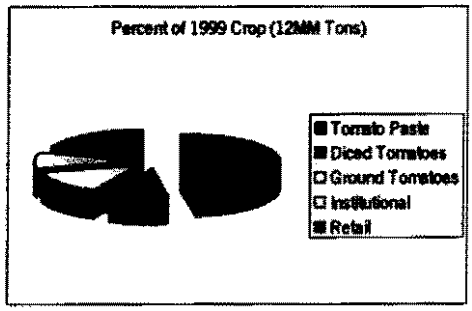
- Homogenization
- Vacuum evaporation
- Rapid hot break
- Aseptic filling

Formulation

- Simple
  - –Tomato paste
- Complex
  - –Spaghetti sauce

Package

- Rigid
  - –Steel cans
  - –Glass
  - –Steel drums
  - –Tanks
- Flexible
  - –Pouch
  - –Tray
  - –Fiber drum
  - –Tote



Tomato Paste (Industrial)

- 1275 kilo tote
- 31^{0}Brix
- Hot break
- 0.060 in. finish (1.5 mm)

Tomato Paste (Retail)

- Steel can
- 24°Brix
- Hot break
- 0.027 in. finish (0.7 mm)

Diced Tomatoes

- 1276 kilo tote
- Fiber drum
- ¾ in. dice (19 mm)
- 65% drained weight (min)
- Citric acid
- Calcium chloride

Ground Tomatoes

- 1277 kilo tote
- Fiber drum
- 13°Brix
- Citric acid
- Calcium chloride

Retail Tomato Products

- Spaghetti sauce
- Ketchup
- Frozen dinners
- Tomato paste
- Whole & diced
- Miscellaneous sauces

Miscellaneous Sauces

- Tomato sauce
- Sauce for beans
- Ethnic specialties
- Pizza sauce
- Other sauces

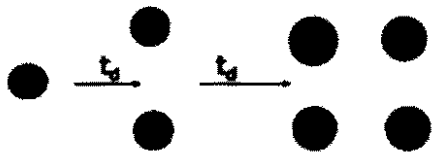
Growth Categories

- Those that offer:
  - –Convenience
  - –High quality
  - –eg:
  - –Frozen entrees

Declining Categories

- Used only as:
  - An ingredient for in-home cooking
  - Eg. retail tomato paste

Microbial Growth



T_d [=] Doubling time

Selected Doubling Times

- Bacteria 15 to 120 min
- Alfalfa 1 to 2 wk
- Chickens 2 to 4 wk
- Hogs 4 to 6 wk
- Cattle 1 to 2 mo

Chemical Reaction

Cell mass + Carbon + Nitrogen + Trace Minerals + (Oxygen)

More cell mass + Water + CO_2 + Heat + Other metabolites

Cell Composition (Dry)

- C 50%
- N 8–12%
- PO_4 3%
- S 1%
- Mg 0.5%
- K (Trace)
- Fe (Trace)
- Mn (Trace)
- Co (Trace)
- Cu (Trace)
- Zn (Trace)
- Mo (Trace)

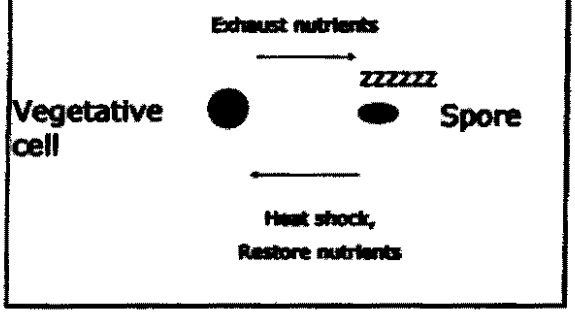
Conditions for Growth

- Temperature
- pH
- Water activity (Aw)

Types of Organisms

- Yeast
- Mold
- Bacteria
  - –Spore forming
  - –Non-spore forming

Spore Formation



Ideal Growth Conditions

	Temp	pH	Aw
Bacteria	37°C	6.0	>0.97
Yeast	30°C	4.5	>0.97
Mold	25°C	4.5	>0.97

Extreme Growth Conditions

Temp (°C)	Acid (%)	Aw
<5 or >60	>2% in water	<0.72

Vegetative Cells

Extreme "Growth" Conditions

Temp (°C)	pH	Aw
5 to 60	<4.6	<0.85

Spores

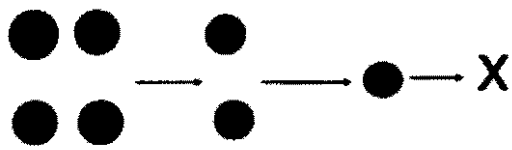
What is Sterilization?

Loss of the ability to divide and multiply; loss of "viability"

Methods of Sterilization

- Heat (wet or dry)
- Filtration
- Radiation (uv; Co^{60}; X)
- Chemical (H_2O_2, Cl_2)

Microbial Death



Sterilizing Temperatures

Organism	pH<4.6	pH ~ 6
Yeast Mold Veg. cells	95°C	95°C
Spores	None required	121°C

Processing Alternatives

- Here "processing" means:
  - Any operation that renders food shelf stable
    - Heat:
      - Mild or severe
    - Acidification
      - In combination with heat or alone
    - Reduction in water activity
      - In combination with heat or alone

Heat Processes

- Mild
  - Hot fill or heat in boiling water
  - For products with pH<4.6
- Severe
  - Retort at 121°C
  - For products with pH>4.6 and Aw>.85 to .90

Hot Fill and Hold

1. Fill temperature 85°C (minimum) at the time of sealing
2. Invert containers after sealing
3. Hold full containers 3–5 minutes in steam
4. Cool

Processing in Boiling Water

1. Hold sealed containers in boiling water to center temperature at 85°C

2. Cool

Retort Processing

- 1. ATMOSPHERIC
- 2. HIGH PRESSURE
  - »Still
  - »Agitating

Heat Processes

- Mild
  - –Tomato paste, fruit juice
- Severe
  - –Canned beans, okra

Acidification

- In combination with heat
  - Reduce pH to 4.6 or below to prevent spores from germinating.
  - Mild heat thereafter
- Acidification alone
  - Total acid to 2.75% in water
  - No heat thereafter

Acidification

- In combination with heat:
  - Hearts of palm, marinated mushrooms
- Acidification alone
  - Salad dressing, pickles

Dehydration

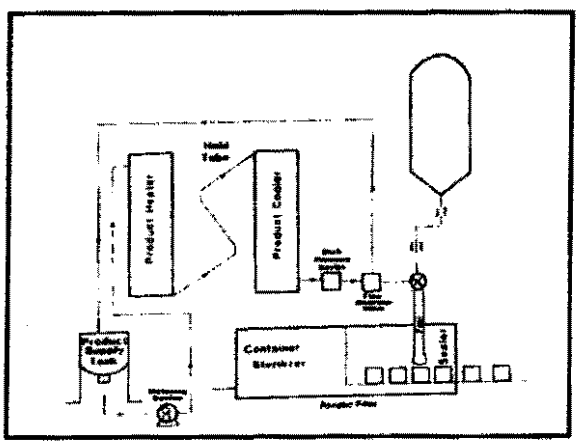
- In combination with heat
  - Reduce Aw to 0.90 or below to prevent spores from germinating
  - Mild heat thereafter
- Dehydration alone
  - Reduce Aw to 0.72 or below
  - No heat thereafter

Dehydration

- In combination with heat:
  - –Chocolate and other syrups
- Dehydration alone:
  - –Packaged bakery items, soy sauce

Aseptic Processing

- Product and package are sterilized separately
- Product sterilized at a higher temperature for a shorter time
  - – (eg. 148^{0}C/10 seconds)



Aseptic Processing: Why?

- Product may not tolerate retort process (eg. milk)
- Consumers may prefer unique package
- Large volume packages (eg. tanks) do not require cooling

§114.3 Definitions.

(a) "Acid foods" means foods that have a natural pH of 4.6 or below.

§110.10 Personnel.

Removing all unsecured jewelry and other objects that might fall into food… …and removing hand jewelry that cannot be adequately sanitized…

§110.10 Personnel.

Washing hands thoroughly in an adequate hand-washing facility before starting work, after each absence from the work station…

§110.10 Personnel.

Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

§110.10 Personnel.

Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

§110.10 Personnel.

…eating food, chewing gum, drinking beverages, or using tobacco.

§110.20 Plant and grounds.

…removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings…

§110.20 Plant and grounds.

Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

§110.20 Plant and grounds.

provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food…

§110.37 Sanitary facilities and controls.

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature

§110.37 Sanitary facilities and controls.

Rubbish… …shall be so conveyed, stored, and disposed of as to minimize… …odor, (and) the potential for the… …harborage… …for pests

§110.40 Equipment…

Seams on food-contact surfaces shall be smoothly bonded… …to minimize accumulation of food particles, dirt, and organic matter and… …the opportunity for growth of microorganisms.

§110.80 Processes and controls.

1. Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.

§110.80 Processes and controls.

2. Maintaining frozen foods in a frozen state.

3. Maintaining hot foods at 140°F (60 °C) or above.

§113.3 Definitions.

(n) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85...

"Commercial sterility" of thermally processed food means the condition achieved... ...by the application of heat which renders the food free of...
...microorganisms capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution; and

Commercial Sterility (Continued)

And... (*b*) Viable microorganisms (including spores) of public health significance...

Commercial Sterility

- Free of harmful organisms
- Free of only of those harmless microorganisms capable of growth

Personnel

The operators... ...shall be under the operating supervision of a person who has attended a school approved by the Commissioner...

Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge...

Records

Copies of all records... ...shall be retained at the processing plant for a period of not less than 1 year... ...and at the processing plant ~~or other reasonably~~ accessible location for an additional 2 years.

Definitions.

(b) "Acidified foods" means low-acid food(s) to which acid(s) or acid food(s) are added;

these foods include...
...beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish...

They have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below.

Carbonated beverages, jams, jellies, preserves, acid foods… …that contain small amounts of low-acid food(s)

and have a resultant… …pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored… …under refrigeration are excluded from the coverage of this part.

These foods may be called… … "pickles" or "pickled_____."

Acidified Foods

What they are:

...low-acid foods to which acid(s) or acid food(s) are added;

What they are not:

Foods that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and,

And they are not:

Foods that are stored, distributed, and retailed under refrigeration.

Their characteristics are:

They have a water activity (Aw) greater than 0.85, and

They have a finished equilibrium pH of 4.6 or below.

Some examples include:

Beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in combination

Some examples do not include:

Carbonated beverages, jams, jelly, preserves, and acid foods... ...food dressings and condiment sauces.

What they may be called

"pickles" or "pickled_____."

Personnel.

All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner

Processes and controls.

(b) *Coding.* Each container or product shall be marked with an identifying code permanently visible to the naked eye

SY

Establishing scheduled processes.

The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

Deviations from scheduled processes.

Whenever any process operation deviates from the scheduled process… …the commercial processor… …shall either:

(a) Fully reprocess that portion of the food by a process established by a competent processing authority as adequate to ensure a safe product;

55

(b) thermally process it as a low-acid food under Part 113 of this chapter;

or (c) set aside that portion of the food involved for further evaluation as to any potential public health significance.

Acidified Foods:

- What they are
- What they are not
- Foods that
  - –Are examples
  - –Are not examples
- Their pH
- Their A_w
- Their names

ACID IN FOODS CAN SERVE AS A PRESERVATIVE

THERE ARE TWO CLASSES OF "ACIDIFIED" FOODS:

1. THOSE ACIDIFIED BY FERMENTATION

2. THOSE ACIDIFIED BY DIRECT ADDITION OF ACID

ONLY THOSE ACIDIFIED BY DIRECT ADDITION ARE COVERED BY THE ACIDIFIED FOOD REGULATION.

WHY ARE SOME FOODS ACIDIFIED?

WHY?

SHELF STABLE FOODS MUST BE PROCESSED TO NOT ALLOW THE GROWTH OF C. BOTULINUM.

WHY?

SOME FOODS WOULD BE UNMERCHANTABLE IF PROVIDED WITH SUFFICIENT "COOK" TO DESTROY C.BOTULINUM SPORES.

WHY?

C. BOTULINUM SPORES WILL NOT GERMINATE AT pH LESS THAN OR EQUAL TO 4.6.

WHAT ARE THE STEPS IN A TYPICAL PROCESS FOR AN ACIDIFIED FOOD?

- ACIDIFY TO pH EQUAL TO OR BELOW 4.6 TO PREVENT GERMINATION OF SPORES, AND

2. HEAT PROCESS TO DESTROY VEGETATIVE CELLS.

WHAT IS pH?

pH IS A MEASURE OF THE AMOUNT OF ACIDITY IN AN AQUEOUS SYSTEM

MATHEMATICALLY,
$pH = - LOG_{10} (H+)$

THE pH SCALE SEEMS BACKWARDS:

HIGH ACID:LOW pH (LIKE 3)

LOW ACID: HIGH pH (LIKE 7)

LOGARITHMIC pH SCALE:

pH =5

HAS TEN TIMES THE LEVEL OF ACIDITY AS

pH = 6

BUFFERING CAPACITY:

THE ABILITY TO RESISIT CHANGES IN pH.

FOODS HAVE BUFFERING CAPACITY, MOSTLY FROM PROTEIN.

MEASUREMENT OF pH

COLORIMETRIC METHODS

ELECTROMETRIC METHODS

MEASURING pH:

WARM UP THE METER.

STANDARDIZE USING BUFFERS (ALREADY PREPARED) AT pH 4.0 and 7.0.

MEASURING pH:

STANDARDIZE AT LEAST ONCE/HR, OR MORE IF THE PRODUCT CONTAINS OIL.

MEASURING pH:

RINSE ELECTRODES BETWEEN USE:

WITH DISTILLED WATER

WITH A PORTION OF THE NEXT SAMPLE

MEASURING pH:

IF SAMPLES CONTAIN EXCESSIVE AMOUNTS OF OIL, CLEAN PROBE WITH SUITABLE CLEANER.

MEASURING pH:

A STABLE READING IS USUALLY ATTAINABLE WITHIN A MINUTE.

REPORT pH TO THE NEAREST 0.05 pH UNIT.

MEASURING pH:

pH VARIES WITH CHANGES IN TEMPERATURE; BUFFER AND SAMPLE SHOULD BE APPROXIMATELY THE SAME TEMPERATURE.

MEASURING pH:

MANY METHODS OF SAMPLE PREPARATION: THE METHOD OF CHOICE IS ESPECIALLY CRITICAL FOR PRODUCTS WITH PARTICULATS. THESE METHODS ARE GIVEN IN THE REGULATONS.

Methods of acidification (1)

BLANCH LOW-ACID INGREDIENTS IN ACID SOLUTION

BEST FOR LARGE PARTICULATES

CRITICAL FACTORS: TEMP, TIME, % ACID IN BLANCHING MEDIUM

Methods of acidification (2)

IMMERSE BLANCHED FOODS IN AN ACID SOLUTION

CRITICAL FACTORS: TIME, % ACID IN SOLUTION, HOW WELL THE PRODUCT IS BLANCHED.

Methods of acidification (3)

DIRECT BATCH ACIDIFICATION

BEST FOR FLUID MATERIALS

CRITICAL FACTORS:

pH AT BATCH KETTLE

Methods of acidification (4)

ADD A PREDETERMINED AMOUNT OF ACID TO EACH CONTAINER

MOST UNRELIABLE METHOD OF ALL

Methods of acidification (5)

ADD ACID FOODS TO LOW-ACID FOODS IN CONTROLLED PORTIONS

Critical control points

EVERY CONTAINER MUST BE ACIDIFIED TO pH 4.6 OR BELOW.

Critical control points

BE AWARE OF THE BUFFERING CAPACITY OF FOOD

Critical control points

OTHER OPERATIONS WHICH MAY AFFECT FINAL pH MUST BE CONTROLLED AND RECORDED

Critical control points

MONITOR pH BEFORE & AFTER EQULIBRIUM

Critical control points

MONITOR SCHDULED THERMAL PROCESS

Thermal process

ITS OBJECTIVE IS TO DESTROY VEGETATIVE CELLS OR PUBLIC HEALTH SIGNIFICANCE AND VEGETATIVE CELLS OF NON-PUBLIC HEALTH SIGNIFICANCE CAPABLE OF REPRODUCING IN THE PRODUCT.

RECORD KEEPING REQUIREMENTS

ADHERENCE TO THE SCHEDULED PROCESS

ALL PROCESS DEVIATIONS PRODUCT pH ABOVE 4.6

WHAT DO YOU NEED TO REGISTER AND FILE AN ACIDIFIED PRODUCT?

CONDITIONS FOR CONTROL OF pH AND OTHER CRITICAL FACTORS

HEAT PROCESS

§101.1 Principal display panel of package form food.

The term "principal display panel" as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents.

Information panel of package form food.

The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel…

101.3 Identity labeling of food in packaged form.

a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity...

a) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity

101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label... ...including foods that comply with standards of identity... ...shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel...

(2) The descending order of predominance requirements... ...do not apply to ingredients present in amounts of 2 percent or less by weight...

appropriate … quantifying statement, e.g., "Contains _____ percent or less of _____"

§101.5 Food; name and place of business of manufacturer, packer, or distributor.

The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor

(d) The statement of the place of business shall include the street address, city, State, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP code shall apply only to consumer commodity labels…

§101.9 Nutrition labeling of food.

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section.

101.12 Reference amounts customarily consumed per eating occasion.

1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

§101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

(a)(1) The term "artificial flavor" … …means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit… … or vegetable, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof.

(2) The term "spice" means any aromatic vegetable substance…
…except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery;

Spices, Continued

…whose significant function in food is seasoning rather than nutritional;

Spices, Continued

Spices include… …such as the following: Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric.

Spices, Continued

Paprika, turmeric, and saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name.

(1) The term "natural flavor"... ...means the... ...extractive... ...which contains the flavoring constituents derived from a spice, fruit..., vegetable..., edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants...

(1) The term "artificial color" or "artificial coloring" means any "color additive"...

(5) The term "chemical preservative" means any chemical that... ...tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.

§101.71 Health claims: claims not authorized.

(a) Dietary fiber and cancer.
(b) Dietary fiber and cardiovascular disease.
(c) Antioxidant vitamins and cancer.
(d) Zinc and immune function in the elderly.
(e) Omega-3 fatty acids and coronary heart disease.

Standard of Identity

- Product name(s)
- Major ingredient(s)
- Method of preparation
- Minor (or optional) ingredients allowed
- How it is labeled
- Quality attributes

(a) *Identity*—(1) *Definition.* Catsup, ketchup, or catchup is the food prepared from…

(i) Tomato concentrate…

(ii) The liquid derived from mature tomatoes…

(iii) The liquid obtained from the residue from preparing such tomatoes…

(iv) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is strained so as to exclude skins, seeds, and other coarse or hard substances in accordance with current good manufacturing practice…

The final composition of the food may be adjusted by concentration and/or by the addition of water.

The food may contain salt and is seasoned with ingredients as specified in paragraph (a)(2) of this section.

The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Ingredients.* One or any combination of two or more of the following safe and suitable ingredients in each of the following categories is added to the tomato ingredients specified in paragraph (a)(1) of this section:

(i) Vinegars.

(ii) Nutritive carbohydrate sweeteners...

(iii) Spices, flavoring, onions, or garlic.

(i (3) *Labeling.* (i) The name of the food is "Catsup," "Ketchup," or "Catchup."

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label... ...except that the name "tomato concentrate" may be used in lieu of the names "tomato puree," "tomato pulp," or "tomato paste"....

(b) *Quality.* (1) The standard of quality for catsup is as follows: The consistency of the finished food is such that its flow is not more than 14 centimeters in 30 seconds at 20° C when tested in a Bostwick Consistometer...

(3) If the quality of catsup falls below the standard... ...the label shall bear the general statement of substandard quality... ..."Below Standard in Quality--Low Consistency."

(c) *Fill of container.* (1) The standard of fill of container for catsup… …is not less than 90 percent of the total capacity except:

(ii) When the food is packaged in individual serving-size packages containing 56.7 grams (2 ounces) or less.

Product Duplication: Tools Available

- Label
- Product characteristics
- Chemistry
- Trial and error

Label: Ingredient Declaration

- Tomato concentrate
- Distilled vinegar
- High fructose corn syrup
- Corn syrup
- Salt
- Onion powder
- Spice
- Natural flavoring

Label: Nutritional Facts

- Serving size 17 g
- Total fat 0 g
- Sodium 190 mg
- Total carb 4 g
- Fiber 0 g
- Sugars 4 g
- Protein 0 g
- Vitamin A 6%
- Vitamin C 0%
- Calcium 0%
- Iron 0%

Product Characteristics

- Color
- Consistency
- Taste
- Texture

Chemistry

- Moisture
- Fat
- Fatty acid profile
- Protein
- pH
- Carbohydrate
- Sugar profile
- Salt
- Sodium
- Total Acid

Formula Estimate: Tomato Paste

Bostwick consistency:

3 to 4 cm/30 seconds

Formula Estimate: Tomato Paste

Ingredient	Formula %
Water	70
Tomato paste	30
Vinegar	0
HFCS	0
Corn syrup	0
Salt	0
Totals	100

Formula Estimate: Salt

Label: 190 mg sodium in 17 g

0.190/0.39/0.17 = 2.9% salt

Formula Estimate: Salt

Ingredient	Formula (%)	Salt (%)	Contribution (%)
Water	67.3	0	0.0
Tomato paste	30	0.3	0.1
Vinegar		0	0.0
HFCS		0	0.0
Corn syrup		0	0.0
Salt	2.7	100	2.7
Totals	100		2.8

Formula Estimation: Acid

Ingredient	Formula (%)	Acid (%)	Contribution (%)
Water	62.8	0	0.0
Tomato paste	30	1.75	0.5
Vinegar	4.5	20	0.9
HFCS		0	0
Corn syrup		0	0
Salt	2.7	0	0
Totals	100		1.4

Formula Estimation: HFCS

Sugar Profile:

Sucrose	None
Glucose	Significant
Fructose	6.6%
Lactose	None
Maltose	Some

Formula Estimation: HFCS

Ingredient	Formula (%)	Fructose (%)	Cont. (%)
Water	40.8	0	0.0
Tomato paste	30	0.7	0.2
Vinegar	4.5	0	0.0
HFCS	22	30	6.6
Corn syrup		0	0
Salt	2.7	0	0
Totals	100		6.8

Formula Estimation: Carbohydrate

Label: 4 gm carbohydrate in 17 gm

4 gm/17gm X 100 = 23% Carbohydrate

Formula Estimation: Carbohydrate

Ingredient	Formula (%)	Carbo. (%)	Cont. (%)
Water	61.7	0	0.0
Tomato paste	30	21	6.3
Vinegar	4.5	0	0.0
HFCS	22	71	15.6
Corn syrup	1.5	80	1
Salt	2.7	0	0
Totals	100		23

Preliminary Capital Estimates

- To determine feasibility
- To obtain financing
- To screen alternatives

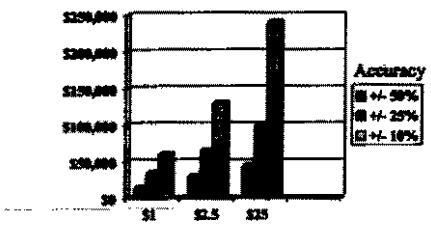
How to Estimate Capital Costs

- Determine the cost of each part
- Add the cost of installation
- Add direct and indirect costs

Accuracy of Estimate

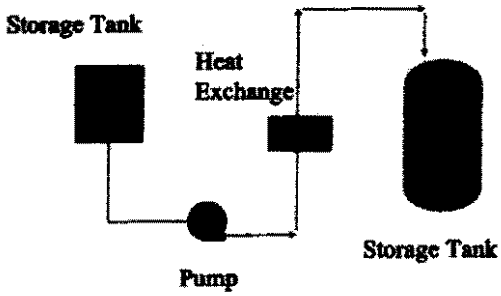
- Accuracy = f (information)
  - The more information required:
    - –The estimate itself:
      - »Costs more and
      - »Takes longer

Costs of Making an Estimate



Cost of Project ($MM)

A Simple Process



Cost of Major Items

• Tank (T-1)	$35,000
• Pump (P-1)	$8,500
• Heat Exch. (H-1)	$45,000
• Tank (T-2)	$100,000
Total	$188,500

Main Plant Items: MPI

- Defined:
  - The major items in a process
- In this example cost of MPI:
  - $188,500; delivered

But What About...

- Site preparation
- Installation
- Piping
- Insulation
- Instrumentation
- Electrical
- Other utilities
- Buildings

Total Fixed Capital Costs

- MPI + Ancillary equipment, or
- (MPI) X (Factor)

Total Fixed Capital Costs:

Fixed capital = MPI X Factor

Fixed capital = $188,500 X 3

Fixed capital = $565,500

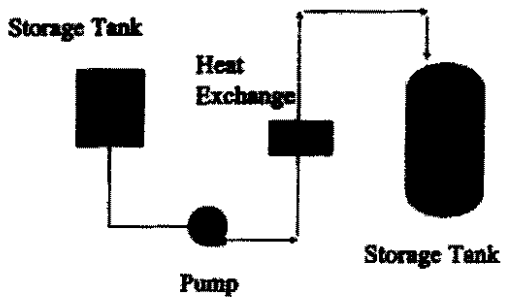
Ancillary equipment cost = $377,000

The Factor Depends On:

- Size (or capacity)
- Materials of construction
- Operating pressure

Each is related to cost of MPI

Another Look



Materials of Construction

	Stainless	Carbon
T-1	$35M	$10M
P-1	$8.5M	$2M
H-1	$45M	$15M
T-2	$100M	$30M
Totals	$188M	$57M

But What About...

- Site preparation
- Installation
- Piping
- Insulation
- Instrumentation
- Electrical
- Other utilities
- Buildings

Total Fixed Capital Costs:

(Stainless)

Fixed capital = MPI X Factor

Fixed capital = $188,500 X 3

Fixed capital = $565,500

Ancillary equipment cost = $377,000

Total Fixed Capital Costs:
(Carbon Steel)

Fixed capital = MPI X Factor

Ancillary equip. cost = $377M

Fixed capital = $57M + $377M

Factor = 7.5

Total Fixed Capital Costs:

Fixed capital = MPI X Factor

As the unit cost of equipment increases the factor decreases

Estimating Techniques

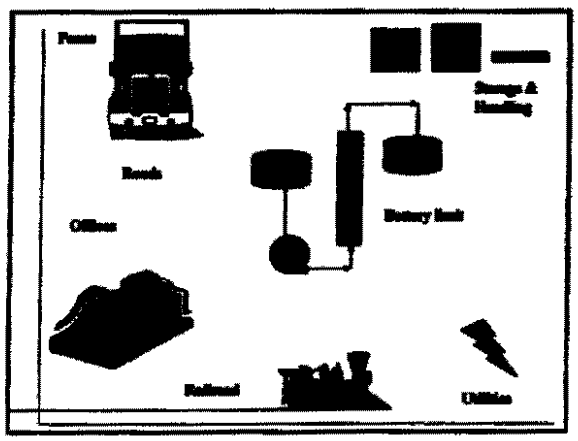
- "Nothing succeeds like excess."

–Oscar Wild

Refined Factor Method

Presumes that the factors vary with the average unit cost of MPI

Also, each part of the factory has its own factor



RATIO FACTORS FOR ESTIMATING BATTERY-LIMIT COSTS

		Range of Factors as Percent of Basic Equipment						
		AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($\times 10^{-3}$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $66M	OVER $66M
BASIC EQUIPMENT: Delivered to site, excluding sales tax	M.P.I. (Main Plant Items):	X	X	X	X	X	X	X
	M.U.E. (Miscellaneous unlisted items):							
	Early flowsheet stage	20 to 10% of M.P.I.'s in all categories						
	Scope of work well defined	10 to 1% of M.P.I.'s in all categories						
	Note: Top of ranges: Complicated processes; many process steps							
	Bottom of ranges: Simple processes; few process steps							
BASIC EQUIPMENT = M P I + M U E		100	100	100	100	100	100	100
FIELD ERECTION OF BASIC EQUIPMENT	High percentage of equipment involving high field labor	23/16	21/17	19/16	18/15	17/14	16/13	15/13
	AVERAGE (Mild steel equipment)	18/12	17/11	16/11	15/10	14/9	13/8	13/8
	High percentage of corrosion materials and other high unit cost equipment involving little field erection	12/7	11/7	11/6	10/5	9/5	8/5	8/5

		AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($X10^{-3}$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $66M	OVER $66M
EQUIPMENT FOUNDATIONS AND STRUCTURAL SUPPORTS	HIGH - Predominance of compressors or mild steel equipment requiring heavy foundations			17/12	15/10	14/9	12/8	11/6
	AVERAGE - Mild steel fabricated equipment			13/7	11/6	10/5	8/4	7/3
	LOW/AVERAGE - Predominance of alloy and other high unit price fabricated equipment	7/3	7/3	9/3	8/3	7/3	6/2	5/1.2
	LOW - Equipment more-or-less standing on the floor	5/0	4/0	3/0	3/0	2/0	2/0	1/0
PIPING (includes ductwork excludes insulation	HIGH-Gases and liquids, petrochemicals, B6plants with substantial ductwork	105/65	90/58	80/48	70/40	58/34	50/30	42/25
	AVERAGE FOR CHEMICAL PLANTS; Liquids	65/33	58/27	48/22	40/16	34/12	30/10	25/9
	LIQUIDS AND SOLIDS	33/13	27/10	22/8	16/6	12/5	10/4	9/3
	LOW - Solids	13/5	10/4	8/3	6/2	5/1	4/0	3/0
INSULATION OF EQUIPMENT ONLY	VERY HIGH - Substantial mild steel equipment requiring lagging and very low temperatures	13/10	12/9	10/7	9/6	8/5	7/5	6/4
	HIGH - Substantial equipment requiring lagging and high temperatures (petrochemicals)	10/17	9/8	8/5	7/4	6/3	5/3	5/3
	AVERAGE FOR CHEMICAL PLANTS	8/3	7/3	6/2	5/2	4/1	3/1	2/1
	LOW	4/0	3/0	2/0	2/0	2/0	1/0	1/0
INSULATION OF PIPING ONLY	VERY HIGH - Substantial mild steel piping requiring lagging and very low temperatures	13/10	12/9	10/7	9/6	8/5	7/5	6/4
	HIGH - substantial piping requiring lagging and high temperatures	18/14	15/12	13/10	11/8	9/6	7/4	4/3
	AVERAGE FOR CHEMICAL PLANTS	16/12	14/10	12/8	10/6	8/4	6/2	4/2
	LOW	14/8	12/6	10/5	8/4	6/3	4/2	2/1

		AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($X10^3$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $86M	OVER $86M
ALL ELECTRICAL except building lighting and instrumentation	Plants with mild steel equipment, heavy drives, solids	26/17	23/15	20/13	14/9	14/8.5	12/7	10/6
	Plants with alloy or high unit-cost equipment, chemical and petrochemical plants	18/10	16/9	13/7	11/6	9/5	7/4	6/3
	NOTE: Above figures include 1 to 3% for B/L outside lighting which is not covered in Building Services							
INSTRUMENTATION	Substantial instrumentation, central control panels,petrochemicals		58/31	46/24	37/18	29/13	23/10	18/7
	MISCELLANEOUS CHEMICAL PLANTS		32/13	26/10	20/7	15/5	11/3	8/2
	Little instrumentation, solids		21/9	17/7	13/5	10/3	7/2	5/1
	NOTE: Total instrumentation cost does not vary a great deal with size and hence is not readily calculated as a percent of Basic Equipment. If in doubt, detailed estimates should be made.							
MISCELLANEOUS Includes site preparation, painting & other items not accounted for above	Top of ranges: large complicated processes Bottom of range: smaller, simple processes	RANGE FOR ALL VALUES OF BASIC EQUIPMENT 6 TO 1%						

BUILDING EVALUATION

when most of process units are located inside buildings

QUALITY OF CONST.	HIGH Brick & Steel	MEDIUM		LOW Economical	EVALUATION
	+4	+2		0	
TYPE OF EQUIPMENT	VERY HIGH UNIT COST EQUIPMENT	MOSTLY ALLOY STEEL	MIXED MATERIALS	MOSTLY CARBON STEEL	
	-3	-2	-1	0	
OPERATING PRESSURES	VERY HIGH	INTERMEDIATE		ATMOS.	
	- 2	-1		0	
			BUILDING CLASS = ALGEBRAIC SUM =		

NOTE: When building specifications and dimensions are known, a high-speed building cost estimate is recommended especially if buildings are a significant item of cost. If a seperate estimate is not possible, evaluate the buildings as above before selecting the features

BUILDINGS: ARCHITECTUAL & STRUCTURAL (excludes building services)

	BLDG. CLASS	AVERAGE UNIT COST OF M.P.I. IN 1999 US$ ($X10^3$)						
		UNDER $12M	$12M TO $20M	$20M TO $27M	$27M TO $40M	$40M to $50M	$50M TO $66M	OVER $66M
MOST OF PROCESS UNITS INSIDE BUILDINGS	+2	92/68	82/61	74/56	67/49	59/44	52/39	46/33
	+1 TO -1	72/49	62/43	56/38	51/33	45/29	41/26	36/21
	-2	50/37	44/33	40/29	35/25	30/21	27/18	23/15
OPEN-AIR PLANTS WITH MINOR BUILDINGS		37/16	32/13	28/11	24/8	20/6	17/4	14/2

BUILDING SERVICES

NOTE: The following factors are for Battery Limit (process) buildings only and are expressed in percent of Building-Architectual & Structural cost. They are not related to the Basic Equipment cost.

	HIGH	AVG.	LOW
Compressed air for general service only	4	2	5
Electric lighting	18	9	5
Sprinklers	10	6	3
Plumbing	20	12	3
Heating	25	16	8
Ventilation without air conditioning	18	8	0
Ventilation with air conditioning	45	35	25
TOTAL OVER-ALL AVERAGE*	85	55	20

The above factors apply to those items normally classified as building services. They do not include:
1. Services located outside the building such as sub-stations, outside sewers, outside water lines etc., all of which are considered to be outside the Battery Limit, as well as outside the building
2. Process services

* The totals provide the ranges for the type of building involved and are useful when the individual service requirements are not known.
Note that the over-all averages are not the sum of individual columns

STORAGE AND HANDLING IN PERCENT OF BATTERY-LIMIT COST

	Grass Roots Plant	B/L Addition on Existing Site
	% of B/L Cost	
LOW: Raw material by pipeline. Little warehouse space	2	0
AVG: Average raw material storage & finish-product warehousing	15 - 25	2 - 6
HIGH: Tank farm for raw- material. Substantial warehousing for finished product	70	20

UTILITIES IN PERCENT OF BATTERY-LIMIT COST

		Range for Grass Roots
Utilities buildings		3 - 10
Architectual & Structural	2 - 7	
Mechanical Services	0.5 - 4	
Compressed Air System		0.1 - 4
Electrical Systems		1.5 - 6
Substation	0.5 - 3.5	
Distribution	0.5 - 3	
Outside Lighting	0.15 - 1.5	
Gas System		0 - 0.6
Sewers & Drainage System		1.3 - 3.5
Steam System		1.5 - 11
Generation	1 - 9	
Distribution	0.5 - 3	
Water System		1 - 10
Pumphouse	1 - 8	
Cooling Towers & recirculation	0.5 - 5	
Distribution	0.15 - 3	
Fire Protection	0.2 - 1	
Water Treatment	0.2 - 1.5	
Miscellaneous		0.5 - 3

	Grass Roots			B/L Additions		
	Low	Avg	High	Low	Avg	High

Over-all averages for all utilities	10	23 - 30	50	3	6 - 14	30

SERVICES IN PERCENT OF (B/L + S&H + U)

	Range for Grass Roots
Main Office	1 - 5
Laboratories	0 - 2.5
Shops & Stores	1 - 8
Lunch Rooms	0 - 2.2
Change Houses	0 - 2.2
Personnel & Gatehouses	0 - 1
Roads, Railroads & Fences	1.3 - 5.5
Service Equipment	0.5 - 4.5
Miscellaneous	0.5 - 2

	Grass Roots			B/L Additions		
	Low	Avg.	High	Low	Avg.	High
Over-all averages for total services	5	10 - 16	20	0	2 - 6	15

CALCULATION SHEET FOR FACTOR ESTIMATING

Division & Location	Proj. or Study No. Requested by	TITLE CAPACITY			DATE
NO. of M.P.I.'s	COST INDEXES 1999 / CURRENT	FACTOR OR ACCURACY	LOW	PROBABLE	HIGH
AVERAGE UNIT COST OF M.P.I.'S IN 1999 DOLLARS					
M.P.I (main plant items)		Estimated			
M.U.E. (Miscelleneous unlisted equipment)					
BASIC EQUIPMENT (M.P.I.+M.U.E.) (EXCLUDING SALES TAXES)		100			
	REMARKS				
Field erection of Basic Equipment					
Equipment Foundations & Structural supports					
PIPING					
INSULATION					
Equipment					
Piping					
Electrical					
Instrumentation					
Miscellaneous					
Buildings: Arch'l & Struc'l					
BUILDING SERVICES:					
Low % of Arch'l & Struct.					
Compressed air					
Electrical lighting					
Insulation					
Plumbing					
Heating					
Vent & Air Conditioning					
TOTAL BLD. SVC.					
SUB TOTAL-FACTORED ITEMS					
ADJUSTMENTS LOWS= HIGHS=					
TOTAL FACTORED ITEMS ADJUSTED					
DIRECT COST OF B/L (excluding taxes)					

SUMMARY SHEET FOR FACTOR ESTIMATING

Division & Location	Proj. or Study No. Requested By	TITLE CAPACITY	DATE

	FACTOR OR ACCURACY	LOW	PROBABLE	HIGH
DIRECT COST OF B/L				
STORAGE AND HANDLING				
UTILITIES				
SERVICES (in per cent of B/L + S&H + U)				
TOTAL B/L + AUXILIARIES				
TAXES				
TOTAL DIRECT COST				
INDIRECT COSTS:				
CONSTRUCTION FIELD, O.H. & PROFIT				
ROYALTIES, LICENCES AND PATENTS				
ENGINEERING				
TOTAL INDIRECT COSTS				
TOTAL DIRECT AND INDIRECT				
CONTINGENCIES				
TOTAL APPROPRIATION				

PART 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Note: Subpart G - Defect Action Levels is not included in this reprint.

SUBPART A - GENERAL PROVISIONS

110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the Act) are applicable to such terms when used in this part. The following definitions shall also apply:

a) "Acid foods or acidified foods" means foods that have an equilibrium pH of 4.6 or below.
b) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
c) "Batter" means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
d) "Blanching," except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
e) "Critical control point" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
f) "Food" means food as defined in section 201(f) of the act and includes raw materials and ingredients.
g) "Food-contact surfaces" are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
h) "Lot" means the food produced during a period of time indicated by a specific code.

i) "Microorganisms" means yeasts molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.

j) "Pest" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

k) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

l) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

m) "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

n) "Safe-moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

o) "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

p) "Shall" is used to state mandatory requirements.

q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

r) "Water activity" (Aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

110.5 Current good manufacturing practice.

a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food, or (2) within the meaning of section 402(a)(4) of the act in that the food 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. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces,or food packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(l) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food packaging materials.

(2) Maintaining adequate personal cleanliness.
(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.
FR 24475, June 19, 1986, as amended as 4 FR 24892, June 12,1989]

110.19 Exclusions.

a) The following operations are not subject to this part:
Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, orotherwise processed before being marketed to the consuming public. (b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

SUBPART B - BUILDINGS AND FACILITIES

110.20 Plant and Grounds.

a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (l) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(l) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.
(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.
(ii) Controlling areas over and around the vessels to eliminate harborages for pests.
(iii) Checking on a regular basis for pests and pest infestation.
(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
(7) Provide, where necessary, adequate screening or other protection against pests.

110.35 Sanitary operation.

a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(l) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;
(ii) Those necessary for use in laboratory testing procedures;
(iii) Those necessary for plant and equipment maintenance and operation; and
(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used and disposed of in a manner that protects against contamination of food or food-contact surfaces.
(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12,1989]

110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials or for employee sanitary facilities.
b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.
(2) Properly convey sewage and liquid disposable waste from the plant.
(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.
(2) Keeping the facilities in good repair at all times.
(3) Providing self-closing doors.
(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

(e) Hand-washing facilities. Handwashing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(l) Hand-washing and, where appropriate hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
(2) Effective hand-cleaning and sanitizing preparations.
(3) Sanitary towel service or suitable drying devices.
(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

SUBPART C-EQUIPMENT

110.40 Equipment and utensils

a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.
d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.
f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

SUBPART D - [RESERVED]

SUBPART E - PRODUCTION AND PROCESS CONTROLS

110.80 Processes and Controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operation shall be employed to ensure that food is suitable for human consumption and that food packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients. under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations.

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, Aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140° F (60°C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.
(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
(v) Cooling to an adequate temperature during manufacturing.
(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in 130.3(d) of this chapter.
(iv) Providing physical protection from contamination. Particularly airborne contamination.
(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the Aw of food.
(ii) Controlling the soluble solids-water ratio in finished food.
(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the Aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.
(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.