

SUSTAIN

**WORKSHOP:
FRUITS & VEGETABLES PROCESSING**

JULY 13 - 15, 1994

GUATEMALA

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

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

Upgrading the Food Processing Industries in Developing Countries.

Why SUSTAIN?

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

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

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

How SUSTAIN Works

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

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

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

SUSTAIN Helps

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

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

SUSTAIN

WORKSHOP: FRUITS & VEGETABLES PROCESSING

Guatemala

July 13 - 15, 1994

by

SUSTAIN Volunteer

**Dr. Pedro Sole, Vice President of Quality Assurance and Control (retired)
Chiquita Brands International**

This publication was made possible through support provided by the Office of Health/Nutrition; Bureau for Global Programs, Field Support and Research; U.S. Agency for International Development, under Cooperative Agreement No. DAN-5120-A-00-1066-00.

NCBA/SUSTAIN Project 111.039

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I. INTRODUCTION

A. SUSTAIN

Sharing U.S. Technology to Aid in the Improvement of Nutrition (SUSTAIN) provides access to U.S. expertise in food processing to help improve the nutritional quality, safety, and availability of food in developing countries. Technical assistance is provided by volunteer professionals from U.S. food companies, universities, and other organizations who donate their time and expertise. In 1991, the Office of Nutrition of U.S. Agency for International Development awarded the National Cooperative Business Association a \$2 million, five-year cooperative agreement to work with SUSTAIN's volunteer leadership to improve, expand, and manage the program.

The assistance SUSTAIN volunteers provide contributes to improved health and nutrition through improved food quality, safety, and availability. In many countries, sufficient food is produced but populations are underserved because much of it goes to waste due to inefficient processing and storage. Improper food handling presents a hazard to human health, and improper waste disposal can contribute to environmental degradation. Strengthening manufacturing practices not only captures scarce resources, but also improves food safety and elevates nutritional status.

B. Fruits and Vegetables Processing Workshop

The Fruits and Vegetables Processing Workshop was taught at the Institute of Nutrition of Central America and Panama (INCAP) by SUSTAIN Volunteer Dr. Pedro Sole, Vice President of Quality Assurance and Control (retired) Chiquita Brands International, from July 13 -15, 1994. The workshop was a hands-on training in preserving fruits and vegetables. Workshop content included a review of processing techniques, canning regulations, and quality control as well as laboratory exercises in canning pineapple juice, papaya concentrate, and black beans in brine. The workshop and course materials, including a good manufacturing practices video, were delivered in Spanish.

Twenty-four food professionals from Central America participated in the workshop. This workshop emphasized proper handling and quality control systems to improve the safety, quality, and nutritional value of locally processed fruits and vegetables. This knowledge will help the processors improve the efficiency of their operations and understand the quality requirements that are needed to ensure a safe food supply and to compete in international markets.

Pilot plant facilities were necessary to give workshop participants hands-on experience in processing techniques. As INCAP's pilot plant is not fully equipped and operational Dr. Luiz Elias, Division Head of Agriculture and Food Sciences contacted the Guatemalan Ministry of Agriculture and was able to secure the use of their mobile food processing pilot plant.

While on other business in Guatemala, Dr. Sole agreed to spend time at his own expense to meet with INCAP staff. As the workshop was originally scheduled to be held at the location of the mobile pilot plant on the Pacific coast of Guatemala, Dr. Sole traveled with Dr. Elias to the site to evaluate the mobile pilot plant equipment. Dr. Sole observed that there were several parts missing and that some equipment required repair. He and Dr. Elias contacted the Ministry of Agriculture and a local processing plant (Kern's). Kern's technicians agreed to help INCAP staff fix the equipment.

Feedback from the evaluations that the workshop participants completed were extremely positive and many requested additional follow-up. Since the completion of this workshop SUSTAIN has received requests from several other countries to have this workshop conducted in their country.

II. REPORT

A. Summary

The workshop was well attended and successful. Some unforeseen mechanical problems in the operation of the Ministry of Agriculture's mobile pilot plant were compensated for by INCAP's equipment and laboratories and were used as opportunities for learning in problem-solving. The program was completed as planned, with trial packs of pineapple juice, black beans, and papaya puree concentrate made.

B. Recommendations

The workshop was well attended and well received. The participants were largely satisfied but feel a longer workshop would be better. The practical part needs better coordination and the equipment better maintenance.

Most participants (all but 2) were from Guatemala. This workshop could be repeated throughout Central America. In Costa Rica, there are probably adequate facilities. In Honduras and Nicaragua, perhaps facilities at a canning operation could be used for the workshop.

C. Participants

There were three distinct groups: industry and university representatives, cooperative members, and Ministry of Agriculture Profruta Program participants. The list is in Appendix IV. One member of the Four Pines Co-op videotaped a significant part of the activities with the intention of using the tape for training of co-op rank and file. Some photographs are attached in Appendix VII.

D. Facilities

The Italian-made mobile pilot plant owned by the Guatemalan Ministry of Agriculture (MAG) was used. INCAP's laboratory facilities and main auditorium were used every day and the pilot plant retort was used on July 14, when a vital air compressor failure did not allow the use of the MAG retort. An INCAP compressor was hooked up for normal operation of the MAG pilot plant on July 15.

E. Workshop Format and Content

As shown in Appendix III, presentations and discussions were held in the mornings and the trial packs were made in the afternoons. The first activity after each trial pack was presentations and discussions with the leaders of the groups of participants, with each making a presentation of their area of responsibility. The non-Profruta participants were divided into five groups of four participants each. The Profruta participants operated the pilot plant. A rotation system allowed

each group to oversee different aspects of the process. It also meant that different members of each group had to make presentations of their group's work. Discussion was lively and positive in a business-like atmosphere. Only rarely was it necessary to cut short a discussion to be able to proceed with the Program.

Appendix V contains workshop notes and materials. Materials which had been sent by SUSTAIN were also distributed; they covered FDA process filing forms and instructions and Good Manufacturing Practices booklet in Spanish from L. J. Bianco and Associates. The booklet is copyrighted material and is on file with SUSTAIN. Forms and selected product labels including the Nutritional Labeling and Education Act required nutrition facts were also covered.

F. Workshop Evaluation

Appendix VI is the tally sheet of the workshop evaluation by the participants. I am flattered by the high number of good and excellent ratings, in particular to the questions:

"Was the attitude of the speaker positive and enthusiastic?"

"How did the workshop motivate you to participate and learn?"

"How do you judge that the environment of the workshop fostered and respected a diversity of opinions and viewpoints?"

In my opinion, in spite of differences in background and education, the participants' response in the evaluation sheets reflects that all feel they profited and learned from it.

Among the "Other comments and suggestions," the most common are:

<u>Comment/Suggestion</u>	<u># of times</u>
"The workshop was too short. It should last 5-10 days."	4
"The workshop fulfilled my expectations" or "was an excellent idea."	4
"Would like more specific subjects and more detailed coverage."	2

Among the answers to "How we can improve the workshop?" are:

"Organize better/provide a manual for the practical part."	5
"The equipment should be in good condition."	2
"More support materials, handouts, and samples."	2

Apparently due to there being two different evaluation sheets (one INCAP's and one mine), some participants got confused and filled out only one. In my opinion, the 12 responses are representative.

APPENDIX I

SUSTAIN Description

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

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

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

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

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

How the Program Works

SUSTAIN receives requests for assistance from individual food companies, research institutions, and USAID. Technical assistance and training is provided by experienced U.S. professionals who donate their time and expertise to the project. Missions are typically one to three weeks in duration. SUSTAIN covers international travel costs. Companies or host organizations requesting SUSTAIN assistance are asked to contribute towards in-country expenses. Due to budget constraints, priority is given to requests that can demonstrate an ability to improve the nutritional quality, safety, and availability of food in the local community. To the extent possible, SUSTAIN coordinates its overseas activities through a local organization. This not only enhances opportunities for technology transfer, but also facilitates coordination of activities and contributes to long-term sustainable development.

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

The program publishes a quarterly newsletter (*SUSTAIN Notes*) on food technology issues. It is provided gratis to over 1900 recipients in more than 50 countries.

For more information, please write to:

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

APPENDIX II

Biography of SUSTAIN Volunteer

PEDRO SOLE, Ph.D. (Chemical Engineering, Polytechnic University of New York, 1965) is an international consultant in fruit processing (especially banana), technical services, quality control, and regulatory compliance. He retired from Chiquita Brands International, Inc. as Vice President of Quality Assurance and Control at the Processed Fruit Ingredients Division. He was responsible for quality control, technical services, and compliance with FDA and EPA regulations affecting the company's food products. Dr. Sole has extensive international experience in business management, fruit processing, equipment and plant design, quality control, and Good Manufacturing Practices. In 1991 he was involved in the design, equipping, and start-up of a new processed banana plant in Costa Rica. As Director of Technical Services for Chiquita, he coordinated technical aspects of purchases of international food ingredients in the Dominican Republic, Costa Rica, Mexico, Guatemala, and Thailand, and served as a liaison between Chiquita's Central American plants and clients in the U.S., Europe, Japan, and the Middle East. Prior to this he served with Chiquita subsidiary companies in Honduras and Costa Rica and with food companies in Puerto Rico, Spain, and Guatemala. Dr. Sole has four U.S. patents involving mechanical peeling, recovery of concentrated clarified banana juice, vegetable oil extraction, and coffee extraction. As a SUSTAIN volunteer, he participated in an assessment mission to Belize.

APPENDIX III

Workshop Curriculum

CURSO TALLER SOBRE PROCESAMIENTO DE FRUTAS Y VEGETALES

I. OBJETIVO

El objetivo de este curso es ayudar al mejoramiento de las técnicas de proceso de frutas y vegetales, con el propósito de utilizar los excedentes de producción, los cuales permitirán ampliar el mercado y la disponibilidad de los productos agrícolas.

II. CONTENIDO

1ER. DIA

- 08:30 - 09:30 Perspectivas del mercado mundial de exportaciones para frutas y vegetales procesados.
- 09:30 - 10:15 Regulaciones que afectan las exportaciones a los países importadores.

U.S.A. (FDA, USDA Y EPA)
EUROPA (CEE, Codex Alimentarius y países individuales).
JAPON
- 10:15 - 10:30 RECESO
- 10:30 - 12:00 Procesamiento y preservación de jugos, productos ácidos y productos acidificados. Parte 114 de las regulaciones FDA de USA.
Llenado en caliente, procesamiento aséptico y concentrados congelados.
Concentrados y jugos de naranja.
Concentrados y jugos de piña.
Concentrados y jugos de mora y otras frutillas
Mezclas de jugos (100% y menos del 100% de contenido de jugo).
- 12:00 - 13:30 ALMUERZO
- 13:30 - 14:00 Actividad práctica, formación de equipo de trabajo.
- 14:00 - 17:00 Enlatado de jugo de piña simple en la planta piloto.

2o. DIA

- 08:00 - 09:00 Discusión y evaluación del proceso realizado el día anterior (Presentación por cada uno de los equipos).
- 09:00 - 10:15 Enlatado y preservación de frutas. Piña (jugo, rodajas, trozos, bocados).
Papaya (verde, cortada en trozos)
Mango (Rodajas maduras, piezas verdes en salmuera)
Otras frutas sugeridas por los participantes.

10:15 - 10:30 RECESO

10:30 - 12:00 Enlatado y preservación de vegetales.
Productos de baja acidez, parte 113 de las regulaciones de FDA, USA.
Arvejas, zanahorias, maíz dulce y judías verdes.
Frijoles, en salmuera.
Frijoles fritos, tamales.
Otros según propuesta de participantes.

12:00 - 13:30 ALMUERZO

13:30 - 14:00 Reunión organizativa para las pruebas de empaque a realizar por la tarde en la planta piloto.

14:00 - 17:00 Enlatado de frijoles negros en salmuera.

3ER. DIA

08:00 - 09:00 Discusión y evaluación del empaque realizado el segundo día.

09:00 - 10:15 Manufactura de purés, jaleas, y mermeladas.
Jalea de fresa y fresas en conserva.
Mermelada de naranja.
Puré aséptico de mango.
Puré aséptico de banano.
Pulpa congelada de guanaba.

10:15 - 10:30 RECESO

10:30 - 11:00 Buenas prácticas de manufactura, parte 110 de las regulaciones FDA, USA.

11:00 - 12:00 Estimación de costos de producción.
Materias primas, rendimientos.
Costos directos.
Costos indirectos.

12:00 - 13:30 ALMUERZO

13:30 - 14:00 Reunión organizativa para las pruebas de empaque a realizar por la tarde.

14:00 - 17:00 Enlatado de mango acidificado o papaya ligeramente concentrado.

17:00 - 17:45 Discusión y evaluación del experimento anterior. Presentación de resultados por cada equipo.

17:45 - 18:00 Evaluación del curso taller y sugerencias por los participantes.

18:00 - 19:00 CLAUSURA

DOCENTE

El curso será impartido por el Dr. Pedro Solé, Ph.D. en Ingeniería Química, Polytechnic University of New York, 1965; Consultor Internacional en procesamiento de frutas (especialmente en bananos), en servicios técnicos, control de calidad y sus regulaciones, fue Vice-Presidente de Chiquita Brands International, Inc. en Aseguramiento y Control de la Calidad en la División de Ingredientes y Frutas Procesadas. Responsable del control de calidad, servicios técnicos, y normas regulatorias del FDA y EPA que involucran a las compañías de alimentos. El Dr. Solé tiene una amplia experiencia internacional en administración de empresas, procesamiento de frutas, diseño de equipo y plantas, control de calidad y buenas prácticas de manufactura. En 1991 estuvo involucrado en el diseño, equipamiento e inicio de una planta procesadora de banano en Costa Rica. Como Director de Servicios Técnicos para Chiquita, coordinó aspectos técnicos de compras internacionales de ingredientes para alimentos en la República Dominicana, Costa Rica, México, Guatemala y Tailandia, y fue el enlace entre las plantas de Chiquita en Centro América y los clientes en los Estados Unidos de América, Europa, Japón y el Medio Este. El Dr. Solé posee cuatro patentes norteamericanas que involucran el pelado mecánico y la recuperación del jugo concentrado de banano, extracción de aceite vegetal y extracción de café. Como voluntario de SUSTAIN, ha participado en una misión de apoyo a Belice, y actualmente en el desarrollo del presente curso-taller.

METODOLOGIA DEL CURSO-TALLER

El Curso-Taller será impartido en idioma español. Se realizarán actividades teóricas y actividades prácticas sobre procesamiento y enlatado. Se utilizará una planta móvil instalada en la sede del INCAP, la cual reúne las condiciones necesarias para los objetivos del curso.

MAYOR INFORMACION

Además de la sede del INCAP en ciudad Guatemala, se disponen de los siguientes centros de información:

GRUPOS TECNICOS BASICOS (GTB)

HONDURAS:

INCAP/OPS; Avenida República de Panamá
No. 2036 Frente a Embajada China, Col. Palmira.
Tegucigalpa. Tel. 323911, 390916.

NICARAGUA:

INCAP/OPS; Complejo Nacional de Salud.
Camino a la Sabana, Managua.
Teléfono: 94200, 97088; Fax. 97324.

EL SALVADOR:

INCAP/OPS; 73 Ave. Sur, # 135
Colonia Escalón, San Salvador.
Teléfono: 791591, 983306; Fax: 981168.

BELIZE:

INCAP/OPS; # 4, Eyre Street, Belize City
Teléfono: 44885, 44852; Fax: 30917.

COSTA RICA:

INCAP/OPS; 4o. Piso, Edificio Norte,
Ministerio de Salud. Región Central Sur
Teléfono 2221468, 2232281

PANAMA:

INCAP/OPS; Calle 35, Oficina No. 2.
Apartado Postal 7260. Ciudad Panamá
Teléfono: 255250, 255238

RECUERDE!!!!

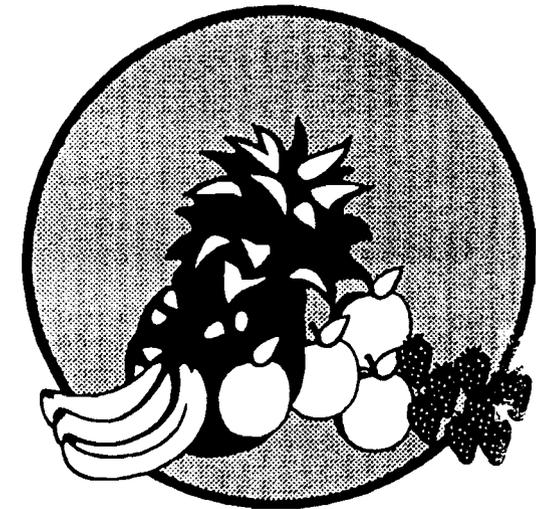
Ultimo plazo de inscripción:

11 julio, 1994



Curso-Taller Internacional

Procesamiento de Frutas y Vegetales



Ciudad de Guatemala
13 al 15 de julio, 1994

Proyecto SUSTAIN

MAGA/IICA

RESPONSABLES Y PATROCINADORES

El Curso-Taller sobre Procesamiento de Frutas y Vegetales, es ofrecido a la industria de alimentos por el Instituto de Nutrición de Centro América y Panamá (INCAP), con el apoyo del proyecto "Sharing United States Technology to Aid in the Improvement of Nutrition" (SUSTAIN). Cuenta con el patrocinio del proyecto PROFRUTA del Ministerio de Agricultura, Ganadería y Alimentación y el Instituto Interamericano de Cooperación para la Agricultura (MAGA-IICA).

Este curso presentará información relacionada con tecnologías de procesamiento, efectos del pH de los productos en el envasado, normas regulatorias en los países importadores, enlatado y preservación así como la importancia de las buenas prácticas de manufactura en el aseguramiento de la calidad higiénica de los productos.

PROPOSITO DEL CURSO-TALLER

Ayudar al mejoramiento de las técnicas de proceso de frutas y vegetales, con el fin de utilizar los excedentes de producción, los cuales permitirán ampliar el mercado y la disponibilidad de los productos agrícolas.

Al finalizar el curso, los participantes habrán aprendido sobre:

1. Procesamiento y efectos del proceso en el producto terminado.
2. Técnicas de enlatado y tipos de procesamiento de acuerdo a las características del producto.
3. Desarrollar mantenimiento preventivo y procedimiento de sanitización e higiene del equipo, la planta y personal.

PARA QUIEN ES EL CURSO-TALLER

El curso-taller ha sido diseñado para:

- * Productores de frutas y vegetales
- * Jefes de plantas procesadoras
- * Gerentes y Supervisores de producción
- * Gerentes y Supervisores de control de calidad
- * Operadores, profesionales y estudiantes en el campo de la Tecnología de Alimentos.

CONTENIDO DEL CURSO-TALLER

- * Perspectivas del mercado mundial de exportaciones
- * Regulaciones
- * Procesamiento y preservación de jugos, productos ácidos y productos acidificados.
- * Llenado en caliente, procesamiento aséptico y concentrados congelados.
- * Enlatado y preservación de frutas.
- * Enlatado y preservación de vegetales. Productos de baja acidez.
- * Manufactura de purés, jaleas y mermeladas.
- * Buenas prácticas de manufactura.
- * Estimación de costos de producción (materias primas, rendimientos, costos directos y costos indirectos).

SEDE DEL CURSO-TALLER

El curso-taller se realizará en las instalaciones del Instituto de Nutrición de Centro América y Panamá, INCAP, Carretera Roosevelt, Zona 11, ciudad de Guatemala.

FECHA DEL EVENTO

El curso-taller se llevará a cabo en tres días de trabajo, del 13 al 15 de julio, con horarios de 08:00 a 17:00 horas.

Las consultas técnicas de la industria serán los días 11 y 12 de julio de 8:00 a 16:00 horas, previa cita.

El último día de inscripción será el lunes 11 de julio.

CUPO MAXIMO

25 participantes

COSTO UNICO DE PARTICIPACION

En el momento de la inscripción, deben cancelarse US\$. 200.00 o su equivalente en quetzales (si es cheque, emitirlo a nombre de INCAP). El costo cubre los materiales educativos, fotocopias, traslados, almuerzos, refrigerios, cócteles de clausura y diplomas de participación.

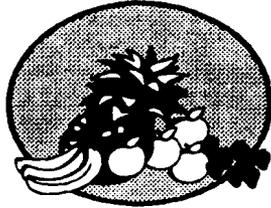
DONDE INSCRIBIRSE

Sede del INCAP, en ciudad Guatemala: Calzada Roosevelt; zona 11.
Teléfono: PBX (502-2) 723762 ó 719912
Facsímil (502-2) 736529

Ref.

Sara de Bonilla
Nidia Barrios
Billy Estrada

BEST AVAILABLE DOCUMENT



Procesamiento de Frutas y Vegetales

1er. Curso-Taller Internacional

del 13 al 15 de julio de 1994

Instructor: Dr. Pedro Solé Ph.D. Polytechnic University Of New York; Consultor Internacional en Procesamientos de Frutas, Servicios Técnicos, Control de Calidad, Normas y Regulaciones.

Dirigido a: Productores de Frutas y Vegetales, Gerentes de Plantas Procesadoras, Gerentes de Control de Calidad, Docentes y Estudiantes en el campo de la Tecnología de Alimentos.

Sede: INCAP, Carretera Roosevelt, zona 11, Guatemala.

Costo: US\$ 200.00 (o su equivalente en quetzales); incluye: almuerzos, traslados, refrigerios y materiales educativos.

Información: PBX 723762 ó 719912; Fax: 736529

Contenido: Perspectivas del Mercado Mundial, Regulaciones, Procesamiento y Preservación, Buenas prácticas de Manufactura y Estimación de Costos de Producción. Habrán presentaciones teóricas y prácticas que se realizarán en una planta móvil.



Proyecto: SUSTAIN

**Proyecto PROFRUTA
MAGA-IIICA**



Norman se impone a Faldo por un golpe en abierto de golf

SUNNINGDALE, INGLATERRA / AP

Greg Norman, favorito para ganar el Torneo Abierto Británico de Golf, disparo ayer un 66, cuatro bajo par, para imponerse por un golpe a Nick Faldo.

Norman inició con el primero de sus seis "birdies" en la vuelta, y para el décimooctavo hoyo llevaba tres golpes de ventaja.

Pero Faldo hizo "birdie" y el golfista australiano debió apelar a un putt de un metro para evitar un doble bogey y un empate.

Norman, quien defendía el título de este certamen, lució muy mal y dijo que le preocupaba su falta de concentración en los últimos hoyos, perdiendo la oportunidad de disparar un 63 por "bogeys" en los hoyos 17 y 18.

Norman es favorito en proporción de 8 a 1 con los apostadores profesionales británicos para ganar su tercer Abierto Británico. El juego de Faldo no fue bueno durante la mayor parte de la jornada, pero así disparo cuatro "birdies", incluso uno desde la arena en el sexto hoyo. "En realidad no jugué muy bien", admitió.

Faldo es segundo favorito para ganar este torneo, en proporción de 12-1, compartiendo ese favoritismo con Nick Price, de zimbabwe, con el ganador del torneo estadounidense Masters José Mará Olazábal de España y con el alemán Bernhard Langer. El ganador del Abierto de los estados Unidos, Ernie Els, de Sudáfrica, es visto con posibilidades de 14-1, y el inglés Colin Montgomerie 16-1. El veterano español Severiano Ballesteros está a 25-1 y el estadounidense Tom Watson, con otros nueve favoritos, incluso John Daly, a 33-1.

APPENDIX IV
List of Participants

<u>Name</u>	<u>Company</u>	<u>Title</u>	<u>Location</u>
Ricardo Blanco	Progualsa	Assistant Manager	Guatemala City
Jose Angel Lopez	Alimentos Maravilla	Plant Chief	Guatemala City
Orlando Harrison	Cayo Tropical Fruits	General Manager	Cayo, Belize
Edgar Fischer	Consolidados	Quality Congrol Mgr.	Guatemala City
Jorge Escobar	Consolidados	Production Manager	Guatemala City
Wendy Bocaletti	Alimentos Maravilla	Quality Control Supervisor	Guatemala City
David Fiorini	Profruta	Plant Manager	Guatemala City
Mynor Castillo	Profruta	Quality Control Rep.	Guatemala City
Frederico Gramajo	Profruta	Plant Manager	Guatemala City
Adolfo Donis		Quality Control Rep.	Guatemala City
Edwin de Leon	Profruta	Process Manager	Guatemala City
Isai Marroquin	Profruta	Technical Director	Guatemala City
Jorge Escobar	Profruta	Performance Director	Guatemala City
Carlos Urrutiar	Profruta	Engineer	Guatemala City
Geraldina de Ceron	University of San Carlos	Nutritionist	Guatemala City
Luisa Alvarado		Student	Guatemala City
Jose Prem	Alimentos Kern	Quality Assurance	Guatemala City
Maynor Gutierrez	Alimentos Kern	Lab Director	Guatemala City
Luis Reyes	ONUDI	Project Coordinator	Guatemala City
Ana Obregon	INCAP	Research Assistant	Guatemala City
Leonardo de Leon	INCAP	Technical Assistant	Guatemala City
Sandr Carrieri	Frutalia	Proprietor	Guatemala City
Jose Montes	Alfinsa	Production Manager	Guatemala City
Carlos Montalvan	Agrovall	General Manager	San Salvador, El Salvador

APPENDIX V

Workshop Notes and Materials

TALLER SOBRE PROCESAMIENTO DE FRUTAS Y VERDURAS (C)

Pedro Solé, Ph.D. 19-VI-94

I. PERSPECTIVAS DEL MERCADO MUNDIAL DE EXPORTACION PARA FRUTAS Y VERDURAS PROCESADAS

A. Países importadores:

Cubrimos acá únicamente los de fuera del area Centroamericana.

	América del Norte	Europa	Cercano Oriente	Lejano Oriente
Países	E.U.A. Canadá Puerto Rico México	CEE Alemania Francia Italia NO CEE Suiza Países del Este	Arabia Saudi Libano Kuwait Emiratos Árabes Uni.	Japón Korea China Australia
Distancia (km)	5,000	12,000	15,000	15,000 a 20,000
Millones de habitantes.	450	600	10	1,200

Excepto por China y algunos otros, los países arriba tienen un producto interno bruto per cápita de 5,000 dólares por año por lo menos.

En todo el globo terráqueo se estima el comercio mundial anual en alimentos en:

US \$ 200,000,000,000, 0

460,000,000 TM

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B. Mercado Latinoamericano en Estados Unidos:
Es grande y tiene un alto poder adquisitivo.

Porcentaje de personas de origen Latinoamericano y estimado del mercado en algunas ciudades de E.U.A.				
Rango	Ciudad	Población (Millones)	% origen Latino	Mercado latino (Millones)
1.	El Paso TX	0.60	69.0	0.41
2.	San Antonio TX	0.94	65.6	0.62
3.	Albuquerque NM	0.38	34.5	0.13
4.	Houston TX	1.63	27.6	0.45
5.	San José CA	2.00	26.6	0.50
6.	New York NY	7.30	24.4	1.80
7.	Denver CO	0.47	23.0	0.11
8.	Dallas TX	1.01	20.1	0.20
9.	Phoenix AZ	0.98	20.0	0.20
10.	Chicago IL	2.78	19.6	0.54

Notar que estas son algunas de las ciudades. Faltan ciudades como San Francisco, Los Angeles, Miami, New Orleans, etc. donde hay también un alto número de consumidores de origen Latinoamericano. Notar también que los datos arriba no incluyen los suburbios.

Es interesante notar que muchos productos que inicialmente son fabricados para el mercado Latino, después se extienden al mercado general de Estados Unidos. Por ejemplo, el producto llamado Salsa (de tomate), que es una especie de "chirmol", se vende ya mas que el famoso "catsup" o "ketchup". Naturalmente yo no recomendaría a nadie tratar de exportar salsa a Estados Unidos. La competencia es muy fuerte!

Otro ejemplo, a pesar que se venden bastantes frijoles refritos, que podríamos llamar estilo Mexicano o "Tex-Mex", creo que hay un mercado de nicho interesante para los frijoles "volteados" estilo Centroamericano en California, entre los emigrados Centroamericanos.

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C. Algunos otros mercados de nicho:

Solo podemos recordar acá algunos otros ejemplos:

1. Mercado para cardamomo en los países árabes.
2. Mercado para concentrados y purés de frutas exóticas en Alemania, Austria y Suiza.
3. Mercado para aletas de tiburón en Japón.

D. Productos que se importan:

Se puede hacer una clasificación a grandes rasgos en:

1. **Ingredientes** para producción de productos de venta en los supermercados al detalle.

a. Tradicionales o de alto volumen

Concentrados de naranja y otros cítricos, piña, tomate, maracuyá, etc.

Puré de banano, coco rallado, mango en salmuera, verduras congeladas IQF, aceite de palma africana, achiote, etc.

b. No tradicionales o de bajo volumen

Concentrados o pures de guayaba, mango, papaya, guanabana, etc.

Bananos o plátanos entero o en trozos congelados.

Fresas enteras y en puré congeladas.

Piña congelada en trozos.

Cardamomo, vainilla, pimienta y otros condimentos.

Hojas de banano y tuzas para envolver tamales y chuchitos.

2. Productos terminados

Sobre esto creo hasta la fecha ha habido mas que nada intentos que no han cuajado.

Alimentos infantiles (Gerber y Nestlé)

Frijoles enlatados (Kern)

Salsas tipo Tabasco picantes (Lizano/CPC)

Palmito en frasco (Del Campo CR. Bien establecido)

E. Datos de exportación de Centroamérica:

Los datos que pude obtener son de la SIECA y solo dan una idea general a grandes rasgos.

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Centroamérica: Valor de la Exportación Clasificación Internacional Industrial Uniforme (CIIU) (Miles \$CA) SIECA				
CIIU	Descripción	1990	1991	1992
3113	Envasado y conservación frutas y legumbres	61,632	72,111	84,320
3119	Fabricación cacao choco-late y confitería	18,311	25,910	29,760
3121	Elaboración productos alimenticios diver	382,379	356,161	89,473
3132	Industrias vinícolas	329	341	382

Las tasas de crecimiento son atractivas para las partidas 3113 y 3119, pero un poco confusas para la 3121, posiblemente debido a re-clasificaciones de algunos productos.

F. Datos de exportación de Guatemala:

Datos del Banco de Guatemala a través de la Gremial de Esportadores de Productos No-tradicionales de la Cámara de Industria.

Ingreso de Divisas por Exportaciones a Guatemala Millones \$EUA										
Año	88		89		90		91		92	
	\$	%	\$	%	\$	%	\$	%	\$	%
Camarón/pescado/langosta	16.8	1.9	15.6	1.7	15.4	1.5	21.4	2.0	20.6	1.9
Frutas y sus preparados	10.6	1.2	16.0	1.7	13.9	1.3	17.3	1.6	23.2	2.1
Productos alimenti.	7.7	0.9	10.7	1.2	13.6	1.4	13.9	1.3	16.4	1.5

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En la tabulación anterior, los porcentajes son en relación a las exportaciones totales. Notar el formato no convencional, la casilla superior izquierda debe leerse como \$ EUA 16.8 millones.

En 4 años se han duplicado las exportaciones de "Frutas y sus preparados" y de "Productos alimenticios". Esto es una tasa de crecimiento compuesta promedio de alrededor de 20 %, naturalmente con sus altibajos. Como porcentajes de las exportaciones totales el crecimiento no es tan alto pero creo es todavía superior al crecimiento de la economía. Para el futuro estimo estos crecimientos deben mantenerse o superarse. Los interesados pueden ahondar mas en la Gremial de Exportadores de Productos No Tradicionales de la Cámara de Industria de Guatemala y en entidades similares o en los Bancos Centrales de sus respectivos países.

En un folleto de Oportunidades de Nuevos Mercados de Abril de 1994 publicado por CEDIME, glosamos la siguiente tabulación:

Requerimiento Alimentos Procesados de Exportación (Excluye café, cardamomo y otros de alto volumen)	
Producto	Origen del Requerimiento
1. Nuez de macadamia	West Hills, Calif USA
2. Brocolí y Vegetales Congelados	Lindhorst, Alemania
3. Mini-vegetales, Ejote Francés, Arveja China, Arveja Dulce. (Congelados)	Los Angeles, Calif USA
4. Frambuesa congelada	Francia
5. Aleta de Tiburón, Mandíbula de Pescado, Mariscos enlatados	New Territories, Hong Kong
6. Derivados de Tiburón	México
7. Polvo de Cebolla	Miami, Florida USA
8. Piña Enlatada	Miami, Florida USA
9. Miel de Abeja	Hamburgo, Alemania

No se incluyó arriba algunos requerimientos de frutas o verduras que parecían ser frescas. En la lista de arriba esperabamos ver USA, Alemania y Francia. Pero noten que aparecieron también México y Hong Kong. En el caso de México, ¿estaremos ignorando un mercado de 90 millones de consumidores con una idiosincracia similar a la nuestra?

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II. REGULACIONES QUE SE APLICAN A LAS EXPORTACIONES EN LOS PAISES IMPORTADORES:

A. Estados Unidos:

1. Administración de Alimentos y Drogas (FDA)

Recordemos que el Congreso de EUA dá al FDA la responsabilidad de velar por que los alimentos y drogas que entren a Estados Unidos sean sanos o por lo menos no nocivos a la salud. Las regulaciones mas importantes, están contenidas en el **Título 21 del Código de Regulaciones Federales** llamado también informalmente solo "Regulaciones del FDA" o "21 CFR".

Las "Partes " siguientes son las mas importantes:

Parte	Título
108	Permisos de Control de Emergencia
110	Buenas Prácticas de Manufactura
113	Alimentos Bajos en Acido, y
114	Alimentos acidificados

Trataremos en mas detalle algunas de las partes arriba en estos días. Se recomienda como referencia "The Almanac" de F. Judge & Sons. Encontrarán la dirección entre el material que recibieron si lo desean pedir.

El 8 de mayo de 1994 entró en vigencia la ley llamada "**Acta sobre el Etiquetado y Educación Nutricional (NLEA)**". Esta ley estipula que los alimentos de venta al público deben llenar ciertos requerimientos sobre el etiquetado, incluyendo información nutricional sobre el contenido. Cualquier producto que se importe a EUA para venta al público debe tener una etiqueta que cumpla con la NLEA. Los ejemplos de etiquetas de productos de los supermercados dentro del material que recibieron nos permiten notar algunos detalles así:

a. Tortillas de maíz

Una porción consiste en dos tortillas (49g). La ley ha regulado como se calculan las porciones para evitar abusos. Los nutrientes mas importantes son: la fibra asimilable ("dietary"), los carbohidratos totales y el calcio. Notar abajo del cuadro la tabla de los valores diarios (DV) para dietas de 2,000 y 2,500 calorías.

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b. Leche con 2% de grasa

Una porción es un vaso (240 ml). Los tres nutrientes mas importantes son el calcio, la vitamina D y las grasas saturadas.

c. Condimento para tacos

Una porción es una cucharadita (3.5 g). Los nutrientes son principalmente sodio, vitamina A y calcio, pero en cantidades bajas los dos últimos. Notar también que esta etiqueta simplificada no tiene los datos de los valores diarios.

d. Agua pura en botella

Una porción es un vaso (240 ml). Notar el 0% en todos los nutrientes y la etiqueta simplificada. Notar también que a pesar de la ausencia de nutrientes, el agua se vende como alimento y está sujeta a la NLEA.

Respecto a **ingredientes** que van a ser formulados en un proceso, la ley **no requiere** que tengan una etiqueta con la declaración nutricional. En la práctica, algunos abogados interpretan que poner la etiqueta es la forma mas fácil de cumplir con la ley. La alternativa es que el vendedor (exportador) tenga un contrato con el comprador (importador) un contrato donde el primero se compromete a dar al segundo, la información nutricional necesaria para que pueda cumplir con la ley (NLEA). Como la ley es reciente, todavía no se sabe como se va a ir sentando jurisprudencia sobre esto.

FDA es responsable de que se cumplan las regulaciones sobre **residuos permisibles de pesticidas ú otras sustancias tóxicas** en alimentos. En realidad, es la Agencia de Protección del Ambiente (EPA) quien fija las tolerancias. En la práctica es FDA quien declara un alimento adulterado si las tolerancias son excedidas. Creo no tengo que recordarles que la mayoría de los problemas de los exportadores de alimentos con el FDA en los últimos años se han debido a residuos de pesticidas. Todos conocemos los casos del Aldicarb en manzanas y del Bromuro de etileno (EDB) en la fumigación de mango fresco entre otros.

2. Departamento de Agricultura de Estados Unidos (USDA)

Sus campos de acción principales son los **productos frescos, los granos y los productos de carne**, incluyendo los de pollo ya sean frescos o procesados. Se entiende que un producto esta sujeto al USDA si tiene mas de cierto bajo porcentaje de carne o de pollo. Por ejemplo, las empanadas de carne y los tamales están sujetos a las regulaciones del USDA. El USDA tiene también patrones de grado voluntarios ("USDA Grade Standards") para productos incluyendo algunos para productos procesados de frutas. Hay uno por ejemplo para jugo de piña enlatado.

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Estos patrones parecen perder terreno frente a las regulaciones del FDA aunque esta última se refiere a ellos en sus patrones de identidad ("FDA Standards of Identity").

Para ilustrar el campo de acción del USDA podemos tomar como ejemplo el mango fresco, para el cual hay regulaciones para prevenir que infestación de mosca de fruta del mediterráneo ("med fruit fly") llegue a EUA. Este caso dá también oportunidad de notar la interacción entre las agencias federales de EUA. EPA fué quién desautorizó el uso del bromuro de etileno que se usaba con anterioridad para fumigar el mango y FDA es responsable de asegurar que se cumpla esta disposición. Esto forzó a USDA a cambiar el método de tratamiento del mango. Ahora se usa inmersión en agua caliente y para el futuro es posible que se use radiación a dosis bajas para destruir las larvas.

3. Oficina de Pesca Commercial del Departamento de Comercio de Estados Unidos

Las inspecciones de pescados y mariscos están aumentando. Eso es lo que hace esta dependencia. Sin embargo, debido a varios problemas relacionados con la salud, se espera que el FDA empiece a tomar mas ingerencia y acción sobre mariscos.

B. Europa - Comunidad Económica Europea (EEC) - Union Europea (UE):

La Unión Europea es la agrupación con mayor número de países, sin embargo la mayor parte de las regulaciones en los libros son de la CEE. Los países compradores mas importantes pertenecen a estos bloques, entre ellos Alemania, Francia, Italia, Inglaterra y España.

1. Codex Alimentarius

Notar que el Codex Alimentarius (Codex) es una iniciativa de la Organización para Alimentos y Agricultura (FAO) de las Naciones Unidas. Los países que participan en los procesos de revisión y aceptación de las regulaciones son los países miembros de la FAO. Es solo recientemente que la CEE empezó a participar como miembro en las deliberaciones del Codex. Los países miembros de la FAO pueden voluntariamente someterse al Codex, pero siempre hay salvaguardas en que la legislación del país individual puede invocarse cuando el país lo considere necesario.

El Codex esta desarrollando regulaciones sobre etiquetado que son distintas pero paralelas con las de la "Comisión europea sobre etiquetado de alimentos". La Lic. Rocio Marbán del ICAITI posiblemente tenga buenos contactos para obtener las normas del Codex Alimentarius. La FDA tiene un mecanismo para revisar y en su caso adoptar normas del Codex a petición de personas o entidades interesadas.

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2. Regulaciones de los Países Individuales

Hay que entender que la aplicación de las regulaciones del Codex es hecha por los países individuales. En algunos casos se pueda tener que llegar a juicios sobre actos criminales.

El exportador se encuentra en dos tipos de situaciones. Algunos países tienen un sistema de aplicación de las regulaciones centralizado como Francia y Bélgica. Estos son los mas fáciles para trabajar. En otros países se aplican las regulaciones a nivel local, ya sea en la ciudad, en el condado o en otra división política. Uno de estos últimos es el Reino Unido (Inglaterra). Estos son mas difíciles para trabajar.

Incluso los métodos de análisis oficiales son diferentes en cada país y solo recientemente se ha formado una comisión que establece "patrones de calidad" para los métodos de análisis.

Como ejemplos de regulaciones distintas en distintos países podemos tomar la de los niveles permisibles de nitratos y nitritos en alimentos infantiles, que varían bastante de país a país.

Se vuelve imposible mantenerse al tanto de todas las regulaciones de todos los países y el exportador se ve forzado a una estrategia de, por ejemplo, cumplir las regulaciones del Codex y hacer los ajustes pertinentes según requerimientos específicos.

3. Restricciones de tipo político y económico

Este tipo de restricciones no tienen como fin proteger la salud de los consumidores. Sin embargo pueden causar grandes distorsiones en el comercio. Algunos ejemplos los vemos en los impuestos de importación y las cuotas para bananos de la EEC a los países hispanoamericanos.

C. Japón, Corea del Sur y otros:

En el caso de Japón, además de tener que enfrentarse con el proteccionismo, como en el caso del arroz, el exportador tiene que afrontar otros obstáculos. Uno de los mas importantes es el de las diferencias culturales y de idiosincrasia. Son bastante inflexibles en aplicar sus regulaciones. Las regulaciones traducidas dejan mucho que desear por lo menos en mi experiencia personal. En resumen mi recomendación es que para exportar a Japón se trabaje a través de un agente ("broker") o se tenga un consultor. Ambos deben conocer bien el medio.

Lo anterior creo es aplicable también a Corea del Sur, a China y a otros países.

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III. PROCESAMIENTO Y PRESERVACION DE PRODUCTOS ACIDOS Y ACIDIFICADOS

A. Alimentos Acidos y Acidificados

Refirámonos a la siguiente tabulación:

Alimentos ácidos, acidificados y bajos en ácido			
Alimento	pH original	pH equilibrio	Reg. FDA
Acido	< 4.6	< 4.6	Parte 110
Acidificado	> 4.6	< 4.6	P. 110-114 108.25
Bajo ácido	> 4.6	> 4.6	P. 110-113 108.35

Ampliando lo de la tabla anterior, los productos que son ácidos naturalmente (pH < 4.6) solo están regulados por la parte 110 y generalmente no son un riesgo para la salud. Si no se procesan bien generalmente se produce una fermentación alcohólica por levaduras. Naturalmente esto no quiere decir que el FDA no actue si vé latas o bolsitas infladas en el supermercado. FDA tiene autoridad para hacerlo bajo la parte 110 de las regulaciones invocando que el producto pudo haber sido empacado "... bajo condiciones donde pudiera haber estado en contacto con suciedad...". Como ejemplos de alimentos ácidos tenemos los jugos de naranja, de piña y otros.

Los acidificados se rigen bajo la parte 114 además de la 110. Notar que estos fueron originalmente bajos en ácido y después de la adición de ácido llegaron a un pH de equilibrio debajo de 4.6. Algunos ejemplos son los encurtidos, las aceitunas en salmuera y el puré de banano acidificado.

Los bajos en ácido se rigen por la parte 113 además de la 110. Estos se mantienen sobre pH 4.6 antes y después del proceso. Los frijoles enlatados, el maíz tierno enlatado y las salchichas enlatadas son ejemplos de esto. Notar de nuevo que en el caso de las salchichas este es un producto sujeto al USDA. Incidentalmente el USDA tiene regulaciones análogas a la 113 pero aplicables a productos conteniendo carne.

Lo anterior esta un poco simplificado pero es suficiente para entender el concepto, todo lo anterior aplica para actividad del agua (a_w) de 0.85 o mayor.

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Parte 114 de las Regulaciones. Alimentos Acidificados.

Para estos productos el parámetro crítico mas importante es el pH de equilibrio del producto. Veamos las "Instrucciones para llenar las formas de registro de proceso con el FDA" p. 19. Cada uno tiene copias de esto dentro del paquete del curso.

"...pH máximo de equilibrio

Insertar el máximo (límite superior) de pH de equilibrio del producto terminado después de acidificado, medido dentro de las 24 horas después del proceso, redondeado a un décimo (Ej. 4.2)..."

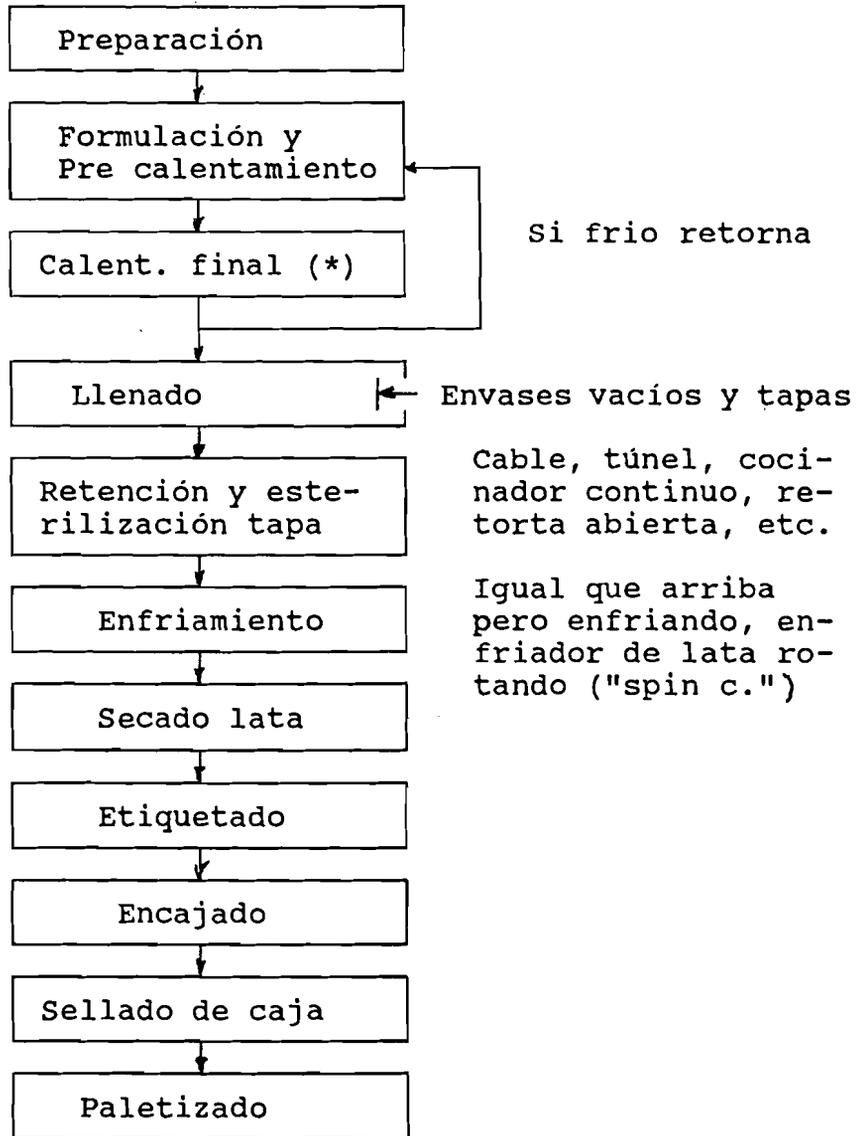
También tienen una forma FDA 2541a, "Food Process Filing for All Methods Except Low Acid Aseptic". Favor referirse a ella. Esta es la forma en que hay que registrar el proceso para alimentos acidificados con el FDA.

Vamos ahora a emplear algunos minutos hablando de las formas y las instrucciones.

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B. Llenado en Caliente, Procesamiento Aséptico y Concentrados Congelados.

1. Llenado en Caliente Generalmente se hace en latas o en recipientes de vidrio.



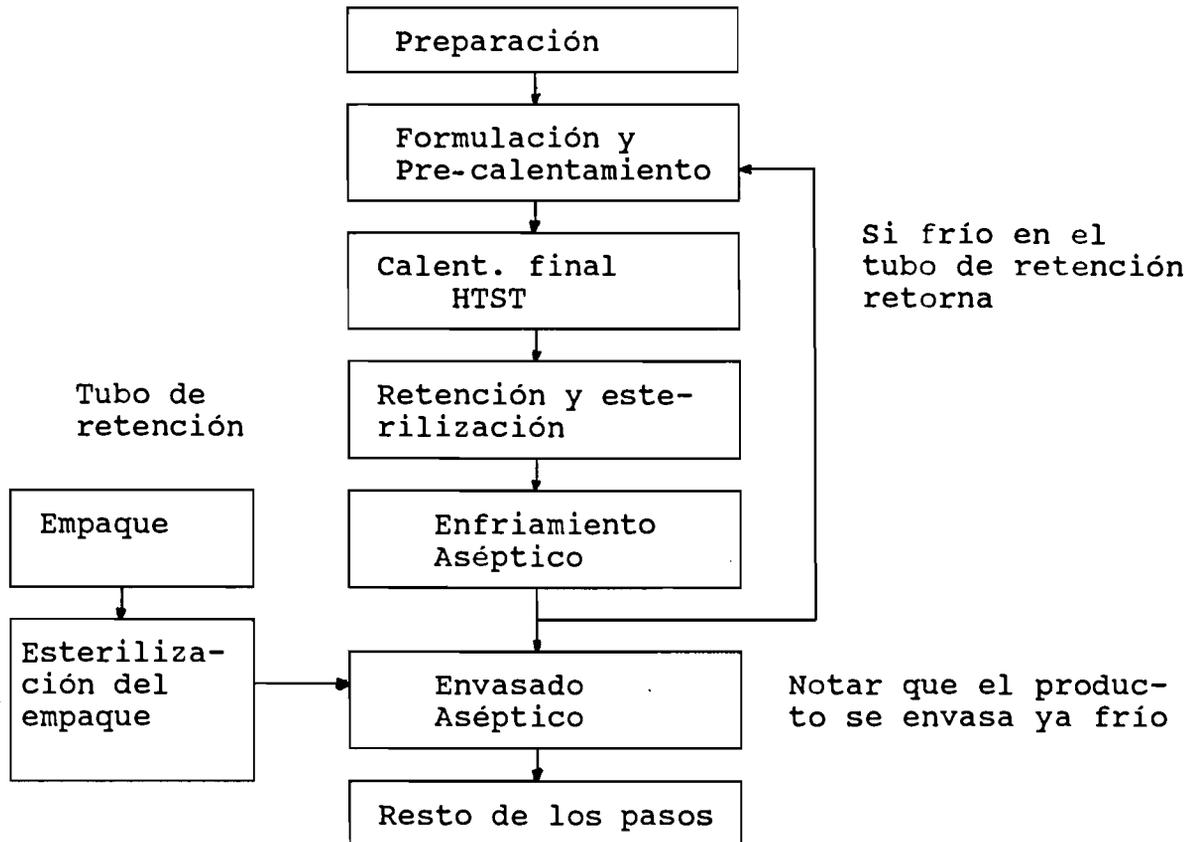
Nota: (*) Puede ser alta temperatura y corto tiempo (HTST)

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2. Procesamiento aséptico

Los pasos son similares con algunas diferencias:



2. Concentrados Congelados

Hay distintos sistemas, pero en general son mas parecidos al procesamiento aséptico, en el sentido de que hay enfriamiento después del tratamiento térmico, excepto que:

- + No se llega a esterilizar el producto
- + Se enfría por debajo de la temperatura ambiente
- + Se envasa, y
- + Se congela

O se pueden almacenar a temperaturas bajas, pero no tanto que se congele el concentrado. Debido a que los sólidos solubles (Brix) son altos, se puede enfriar bastante el producto sin

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congelarlo. Cuando se guarda en tanques grandes, estos tienen un **serpentin de vapor** o agua caliente cerca de la descarga hacia la bomba, para facilitar el bombeo y **poder vaciar los tanques.**

Es posible embarcar digamos un jugo concentrado de manzana de 68-70 Brix a -15°C en Argentina y que llegue a destino solo unos cuantos grados sobre cero a los EUA. Estos embarque se hacen a granel en tanques que son compartimientos de los barcos en cantidades de cientos de toneladas. Muchas personas han dejado este sistema de obvios beneficios porque es **muy difícil fijar quien tiene la culpa** en caso de problemas con el embarque. La mayoría de los embarque se hacen en camiones cisternas, en tanquitos de 325 gal. (1228 l) y en tambores de 55 gal (208 l) con doble bolsa.

C. Concentrados y jugos de naranja

Del punto de vista comercial, lo primero que hay que fijarse es de que existe una **competencia brutal** en este y otros productos llamados "**commodities**" que según el diccionario son "géneros" o "mercancías", palabras que no dan idea de lo riesgoso de esos productos. Un año se puede hacer una fortuna y el otro perder el doble. El café y el algodón son también "**commodities**" que todos conocemos.

Del punto de vista de la manufactura, algunos puntos claves son:

1. **Transporte y almacenamiento de la fruta**
Camiones abiertos con palanganas de baja profundidad.
Pesaje de los camiones completos.
Almacenaje en silos de madera bien ventilados.
2. **Extracción del jugo**
Extractoras FMC
Extractoras Italianas
Ambas con sistema de recuperación de aceite esencial
3. **Evaporación**
Evaporadores TASTE múltiples etapas y múltiples efectos
Estos no son necesarios para jugo de concentración natural.
4. **Almacenamiento**
En tanques a granel a baja temperatura o en tambores de 55 gal con doble bolsa de polietileno congelados. La temperatura de almacenaje y transporte es preferiblemente de -23°C (-10°F).

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5. Patrones aplicables

Entre otros están los siguientes patrones de identidad ("Standards of identity") de FDA.

21 CFR 146.146 "Frozen concentrated orange juice" ("Jugo de naranja concentrado congelado")

21 CFR 146.148 "Reduced acid frozen concentrated orange juice" (lo mismo que arriba pero con ácido reducido)

21 CFR 146.153 "Concentrated orange juice for manufacturing" ("...para manufactura")

Hay varios otros patrones para jugo sin concentrar también, que se pueden encontrar en el primer tomo de "The Almanac".

El USDA reconoce dos grados A y B para concentrado de naranja. Ambos grados deben tener un mínimo Brix de 41.8 para jugo sin azúcar y 42.0 para jugo con azúcar.

Supongo que el ICAITI tiene una norma Centroamericana para concentrado o por lo menos para jugo sin concentrar de naranja.

Para mas detalles del proceso se recomienda consultar la obra en tres tomos "A Complete Course in Canning" ("Un curso completo de enlatado") del Dr. Anthony López, del Politécnico de Virginia. Esta referencia es muy valiosa también para muchos otros productos y aspectos de tecnología de alimentos. La 12ava edición puede obtenerse de

CTI Publications, Inc. Tel 410-467-3338
2619 Maryland Ave. Fax 410-467-7434
Baltimore, MD 21218-4576
USA

Precio \$170 los tres tomos para fuera de EUA.

D. Concentrados y jugo de piña

1. Transporte y almacenamiento de la fruta

Camiones abiertos con palanganas de baja profundidad.
Pesaje de los camiones completos. En algunos lugares todavía se usan grandes cajas con capacidad desde 1/4 hasta 2 toneladas de piña, sin corona, cada una, que se manejan por medio de montacargas de tenedor. El almacenaje es al ambiente bien ventilado de preferencia menos de 24 horas de cuando se cortó la piña.

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2. Extracción del jugo

Cortadoras tipo "Ginnaca" y erradicadores.

Extractores tipo "pinemat"

Extractores de prensa de tornillo "Rietz" ó "Gumaco".

Notar que el jugo de piña se fermenta en muy poco tiempo, de modo que es preferible botarlo cuando hay una parada prolongada.

3. Tamizado o repasado

Se prefiere usar un tamiz fino con agujeros de 0.020 pulgadas de diámetro. Esto es sobretodo para el concentrado. Si se desea una cantidad mayor de pulpa en el jugo se puede usar un tamiz mas grueso.

4. Evaporación

Evaporadores TASTE de múltiples etapas y múltiples efectos.

Evaporadores de placas APV, Schmidt, etc.

Evaporadores de circulación forzada Rossi-Catelli

Estos no son necesarios para jugo de concentración natural.

5. Enlatado de jugo natural

Casi nadie produce ya jugo de concentración natural directamente de la fruta fresca. Se prefiere usar concentrado que se diluye y se envasa. Esto es así también para jugo aséptico en TetraPak o en otro tipo de envase flexible.

Como el jugo tiene alta acidez, un proceso a baja temperatura es suficiente. López recomienda lo siguiente:

Temperatura de llenado: 160 °F (71 °C) mínima

Proceso para lata No 2: 10 min en agua hirviendo (100 °C)

'' '' '' '' : 20 min a 180 °F (82 °C)

Enfriamiento hasta 95-105 °F (35-41 °C)

Notar que empacaremos en este taller jugo de piña en lata 303x406 que es un poco mas pequeña que la No. 2 (307x409), por lo que los procesos arriba son conservadores.

6. Almacenamiento y transporte

En tanques a granel a baja temperatura, en cajas de madera con doble bolsa de plástico de 325 galones (1,228 litros), o en tambores de 55 gal. (208 l) con doble bolsa de polietileno congelados. La temperatura de almacenaje y transporte es preferiblemente de -23 °C (-10 °F). El concentrado de piña se oscurece con el tiempo, mas rápido a mas alta temperatura. Como el color es uno de los atributos mas importantes, es usual que se embarque el concentrado a temperatura ambiente para

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ahorrar dinero en el transporte, pero luego se almacena a baja temperatura al llegar a destino. Recordar que al momento de formular, un concentrado de 72 Brix a baja temperatura es una melcocha muy difícil de manipular. Es conveniente dejarlo varios días a temperatura ambiente antes de usarlo.

7. **Patrones aplicables**

Entre otros están los siguientes patrones de identidad ("Standards of identity") de FDA.

21 CFR 146.185 "Pineapple Juice" ("Jugo de piña")

"US Standards for grades of pineapple juice" ("Patrones de EUA para rangos ó grados de jugo de piña") Este último es para jugo ya sea directo o a partir de concentrado con o sin edulcorante. Tiene grados "A", "B" y "Substandard", o sea debajo del "B". Ver adjunta, una hoja con la Tabla I, donde se pueden ver varios parámetros para los distintos grados y estilos.

Ya veremos como compara el jugo que enlatemos hoy.

ICAITI tiene seguramente una Norma Centroamericana para jugo de piña.

E. Concentrados y jugos de mora y otras frutillas

El mercado para estos productos es mas reducido, pero también los precios son mas atractivos. Ocasionalmente la demanda eleva los precios sustancialmente. Eso sucedió recientemente cuando los proveedores tradicionales de Europa Oriental no suplieron las cantidades acostumbradas.

1. **Recolección, transporte y almacenamiento de la fruta**

El manipuleo de moras y similares debe hacerse en cajas de baja profundidad, ya que el peso de las moras de arriba fácilmente aplasta o destripa las de abajo.

Las moras recolectadas inmediatamente antes de llegar a la madurez plena pueden guardarse uno o dos días pero se ponen mohosas fácilmente según López.

Cierto tipo de frutillas llamadas **arándanos** según el diccionario o "**cranberries**" en inglés, se prestan a un manipuleo mas mecanizado. Se inundan las plantaciones con agua y se arranca las frutillas con maquinaria especial de modo que flotan en el agua. Luego se van congregando a una punta del campo de donde son bombeadas con todo y agua que se recircula a camiones cisterna de acero inoxidable, en los cuales se lleva a la planta de

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proceso. Una empresa cooperativa del estado de Massachusetts en EUA ha sido sumamente exitosa, desarrollando su negocio en base a esta frutilla.

2. **Extracción del jugo**

Como las moras son suaves, el bombeo con una bomba de desplazamiento positivo por una plancha con agujeros seguida del paso por un pulpero o repasador es suficiente para extraer el jugo.

3. **Evaporación**

Debido a las cantidades de fruta, posiblemente el uso de evaporadores de placas al vacío APV o similares sea lo más adecuado. No hay muchos datos sobre esto.

4. **Almacenamiento y transporte**

En cubetas de plástico de 5 gal. (19 l), con o sin bolsa plástica interna, con tapa o en tambores de 55 gal (208 l) con doble bolsa de polietileno congelados. La temperatura de almacenaje y transporte es preferiblemente de -23 °C (-10 °F).

5. **Patrones aplicables**

Los siguientes patrones de identidad ("Standards of identity") de FDA, pueden ser usados como referencia a pesar de no referirse específicamente a jugos o concentrados.

21 CFR 145.120 "Canned berries" ("Frutillas enlatadas" que cubre 10 distintas frutillas, entre ellas: moras, fresas y frambuesas.

21 CFR 145.125 "Canned cherries" ("Cerezas enlatadas")

No hay patrones de grado de EUA para jugos o concentrados de mora u otras frutillas. Los hay nada más para cerezas enlatadas y para fresas congeladas. El segundo puede encontrarse en la pag. 704 del Volumen 2 de "The Almanac" de 1993.

Es posible que el ICAITI tenga normas Centroamericanas para productos de algunas frutillas.

F. Mezclas de jugos (100% y menos de 100% de contenido de jugo)

Este tema es de interés genéricamente para todos los jugos. Personalmente no creo haya muchas posibilidades de que productos de venta directa al público como estos, envasados en Centroamérica puedan competir en EUA y menos en Europa. Sale más barato transportar los concentrados y reconstituirlos. Sin embargo los exportadores de Centroamérica estarán vendiendo concentrados o purés a clientes que si venden jugos al público. Por lo tanto, estarán sujetos a estas regulaciones.

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1. Presentaciones

Las presentaciones son similares a las que existen en Centroamérica, entre ellas

- a. Refrigerados "Purepak" o "Gable top", plástico, vidrio y otros

<u>EUA</u>	<u>Métrico</u>
1 gal.	4 l
0.5 gal.	2 l
0.25 gal.	1 l
0.20 gal.	750 ml
12 oz. fl.	325 ml

Notar que los anteriores son tamaños similares y no equivalencias.

La mayoría de los productos refrigerados son pasteurizados y tienen una vida en la refrigeradora de 40 días o mas. Sin embargo hay productos sin ningún proceso, que se venden refrigerados y tienen una vida de unos 5 a 14 días.

- b. Envasados en caliente estériles Lata y vidrio

<u>EUA</u>	<u>Métrico</u>
N 12 1 gal.	4 l
N 10 0.75 g.	3 l
0.5 gal.	2 l
N 3 Cyl 46 oz fl	1.5 l
0.25 gal.	1 l
0.20 gal.	750 ml
12 oz. fl.	325 ml
8 oz. fl.	250 ml
5.5 oz. fl.	200 ml

Notar que también los anteriores son tamaños similares y no equivalencias.

- c. Envasados asépticamente Lata, TetraPak y otros flexibles

<u>EUA</u>	<u>Métrico</u>
N 12 1 gal.	4 l
N 10 0.75 g.	3 l
0.5 gal.	2 l
N 3 Cyl 46 oz fl	1.5 l
0.25 gal.	1 l
0.20 gal.	750 ml
12 oz. fl.	325 ml
8 oz. fl.	250 ml
5.5 oz. fl.	200 ml

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De nuevo, los anteriores son tamaños similares y no equivalencias.

2. Concentraciones o fracciones de jugo

Los hay desde 100% contenido de jugo hasta unos 3-5% de jugo en unas bebidas carbonatadas. Naturalmente los que no tienen 100 % jugo son llamados con otro nombre tales como "bebida" ("drink"). No obstante, debido a abusos, la ley requiere actualmente declarar el porcentaje de contenido de jugo.

3. Adulteración y sus consecuencias

Cualquier práctica fraudulenta de un exportador de pulpa o concentrado de fruta, puede traer consecuencias muy graves para el importador o productor. En pocas palabras el agua y/o el azúcar con que se adultere un concentrado o jugo va a dar al producto terminado también. Un caso muy sonado hace unos años causo mucho perjuicio a una buena marca de alimentos infantiles en EUA. Por parte de los importadores se hace mucho énfasis en autenticidad ("authenticity") y se han desarrollado varios métodos de detección, entre ellos el de la relación de isótopos de carbón. Si un exportador resulta involucrado, generalmente es descalificado como proveedor por el comprador. También se puede tener demandas costosas.

4. Patrones y regulaciones aplicables

Las regulaciones mas importantes son las de 21 CFR 101.30 "Declaración de porcentaje de jugo..." ("Percentage juice declaration...". Esta regulación entró en vigor el 8 de mayo de 1994. Los porcentajes en la Tabla siguiente están desglosados de la tabulación en esta regulación.

Brix de algunos jugos 100% según el FDA			
Jugo	Brix	Jugo	Brix
Banano	22.0	Mora	10.0
Canteloupe	9.6	Marañón	12.0
Toronja	10.0	Guanabana	16.0
Guayaba	7.7	Mango	13.0
Papaya	11.5	Piña	12.8

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Como ejemplo y en referencia a la tabla arriba, una bebida con 50% de contenido de jugo natural de mora tiene que tener un Brix mínimo de 5.0 y debe ser procedente de mora. Otro ejemplo, un jugo natural 100% de mango y toronja en partes iguales tiene que tener un Brix de $(13 + 10)/2 = 11.5$ mínimo.

Otros patrones aplicables son similares a los ya citados anteriormente. Las declaraciones de la etiqueta deben reflejar el porcentaje de jugo natural y cumplir con las regulaciones de la NLEA.

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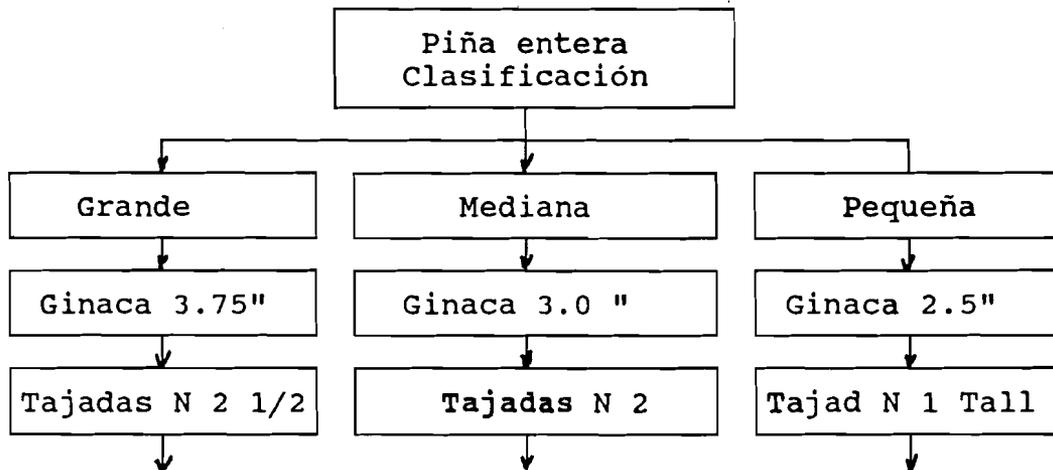
IV. ENLATADO Y PRESERVACIÓN DE FRUTAS

Excepto por algunas variedades de mango y por los bananos la **gran mayoría de las frutas son francamente ácidas**, con un pH < 4.6, por lo que únicamente requieren un proceso en agua hirviendo.

A. Piña:

1. Enlatado y proceso

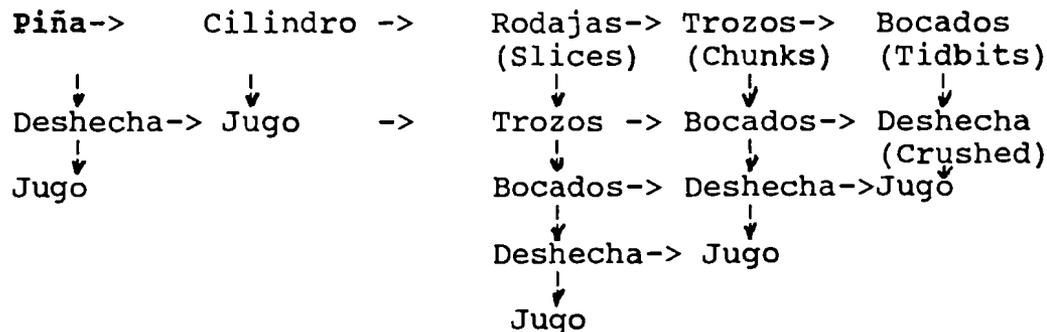
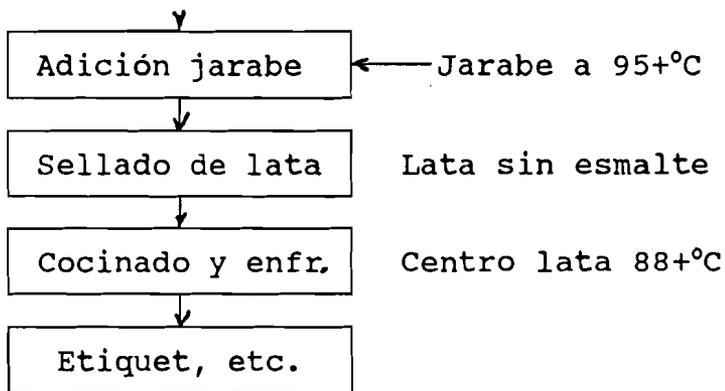
El siguiente esquema dá una idea general:



Una vez en la lata todos los tamaños de tajadas o rodajas siguen un proceso similar

Jarabe hecho de:

jugo de piña
agua, ac. cí-
trico y azúcar



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Todos los "estilos" de estos productos pueden ser procesados en agua hirviendo. Si la lata llena está muy fría hay que pasarla por un tunel de vapor para evacuar el aire y calentar el contenido antes de sellarla. El proceso en agua hirviendo (100 °C) en cocinadores rotatorios es de 12-18 min.

2. Patrones

El patrón de identidad ("Standard of Identity") aplicable, es el 21 CFR 145.180 "Piña enlatada" ("Canned pineapple"). Este patrón define algunos estilos mas que los que hemos citado arriba. Define también los edulcorantes y jarabes permisibles. Ver p. 357 de "The Almanac".

a. Líquidos de empaque

- i. Agua
- ii. Jugo de piña y agua
- iii. Jugo de piña
- iv. Jugo de piña clarificado

b. Edulcorantes que se pueden añadir

- i. Azúcar
- ii. Jarabe de azúcar invertida.
- iii. Cualquiera de los ya citados líquidos o edulcorantes con dextrosa, pero que esta no pase de un tercio de los sólidos solubles del jarabe.
- iv. Cualquiera de los citados jugos o edulcorantes con jarabe de maíz o glucosa o sólidos de los mismos pero que no excedan un cuarto de los sólidos solubles.
- v. Mezclas de los anteriores.

c. Tipos de jarabes

Brix de equilibrio %

- | | |
|-------------------------|--------------|
| i. Jarabe extra liviano | 10-13.99 |
| ii. Jarabe liviano | 14-17.99 |
| iii. Jarabe pesado | 18-21.99 |
| iv. Jarabe extra pesado | 22-35 (max.) |

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El USDA emitió en el pasado patrones de grado ("US Grade Standards") para piña en los distintos estilos. Sin embargo, aparentemente, estos ya no están siendo actualizados. Todavía son una buena referencia y pueden obtenerse en bibliotecas ó incluso posiblemente a través de los agregados comerciales o de agricultura de las embajadas de EUA. En concepto y formato son similares al patrón de grado de jugo que vimos ayer, pero para rodajas y otros.

Los patrones de la compañía Dole ("Castle & Cooke") han sentado la pauta por muchos años para productos de piña.

B. Papaya (verde, cortada en trozos):

Este producto tiene mucha venta en los países caribeños y se sirve generalmente con un pedazo de queso. Varios autores de la Estación Experimental adscrita a la Universidad de Puerto Rico, campus de Río Piedras han publicado detalles del proceso. En los mercados latinos de EUA se encuentra bajo la marca "Goya" y otras.

1. Enlatado y proceso

La siguiente es una fórmula típica para una caja 24/303 de papaya en jarabe pesado:

Papaya verde en jarabe pesado para una caja 24/16 oz		
Item/descripción	Unidades	Cantidades
Caja corrug. 24 lt	c/u	1
Latas 303x 406 sin esmalte	c/u	24
Tapas esmaltadas 303	c/u	24
Etiquetas papaya	c/u	24
Canela	g	0.5
Azúcar	kg	6.87
Hidróxido de sodio	g	0.25
Bicarbonato de sodio	g	21.69
Benzoato de sodio	g	0.3
Papaya fresca verde	kg	4.29

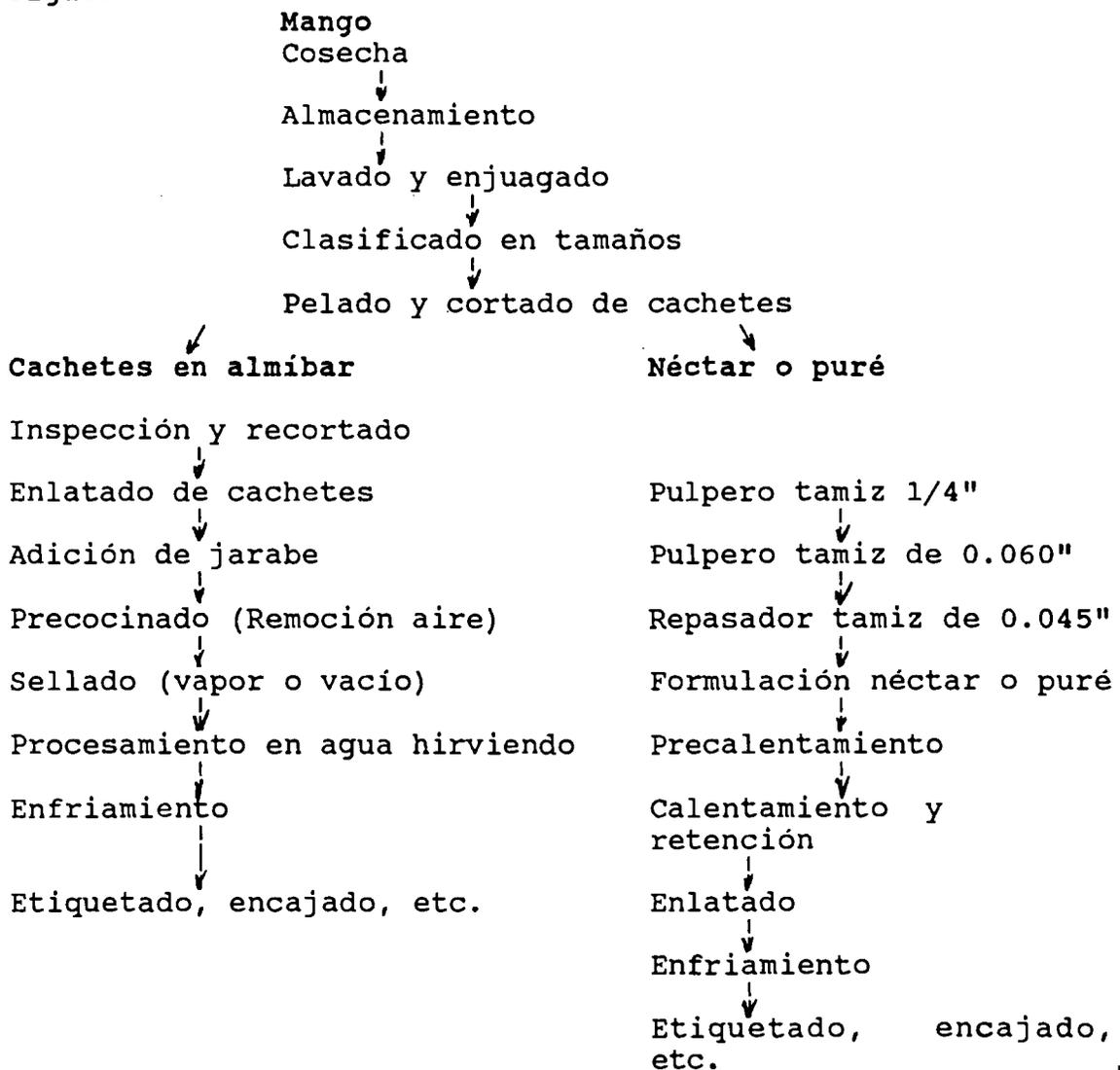
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El Brix calculado de la formula anterior es mas de 55. El cual corresponde casi a una jalea.

El hidróxido de sodio se utiliza en la lejía de pelado nada mas. Hay que lavar la papaya bien después y repasar manualmente el pelado. La fruta entera pelada es partida en dos y las semillas son removidas a mano antes de alimentar las mitades a una cubicadora tipo Urschell o similar. Los pedazos pueden también cortarse a mano si se dispone de mano de obra barata.

C. Mango (rodajas o cachetes maduros):

Los distintos pasos en el procesamiento de mango pueden presentarse como sigue:



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D. Mango (pedazos verdes en salmuera):

Este producto se vende en tambores de plástico de 55 gal. (208 l) o mas. Las tiras o pedazos de mango verde se dejan en salmuera durante semanas en recipientes cubiertos con una tela que les permita respirar. Aparentemente se produce un fermentación láctica similar a la del las aceitunas verdes. Una vez terminada la fermentación se exporta el producto con salmuera en recipientes plásticos cerrados. En los países importadores se usa este mango como materia prima para la fabricación de Chutney.

No pude encontrar patrones para estos productos dentro de lo que tenia disponible. ICAITI probablemente tenga algunas Normas Centroamericanas por lo menos sobre néctar de mango. De la tabla en la página 20 de esta presentación vemos que el "jugo" de mango debe tener un Brix de 13 según el FDA. Es también fácil tomar muestras del mercado y analizar los productos de Kern's y otros competidores.

E. Otras frutas sugeridas por los participantes:

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IV. ENLATADO Y PRESERVACIÓN DE VEGETALES

Todos estos productos son bajos en ácido y requieren un proceso bajo en ácido.

A. Productos de baja acidez, parte 113 de las regulaciones del FDA

1. Definiciones

Referirse a 21 CFR 113.3 pp 290 a 292 de "The Almanac" 1993
Dentro de ellas veamos las mas importantes:

- a. Procesamiento y empaçado asépticos
- c. Tiempo para subir ("Come-up time")
- e. Esterilidad comercial
 - (1) de un alimento procesado térmicamente...
 - i. Por aplicación de calor...
 - ii. Por control de la actividad del agua (a_w) y aplicación de calor...
 - (2) del equipo y recipientes ...
 - Por aplicación de calor, productos químicos u otro tratamiento adecuado...
- f. Factor crítico
- j. Recipiente herméticamente cerrado
- l. Temperatura inicial
- p. Proceso en uso ("Operating process")
- r. Proceso especificado ("Scheduled process")
- s. Debrá ("Shall"). Quiere decir tener que hacerlo
- t. Debiera ("Should"). Quiere decir que sería bueno pero no es obligatorio.
- w. Actividad del agua (a_w) =

$$\frac{\text{Presión de vapor del alimento}}{\text{Presión de vapor del agua}}$$

a la misma temperatura.

Una definición que no esta en las regulaciones pero que casi se ha adoptado como regla general es que "intervalos de suficiente frecuencia" se toma como cada 15 minutos.

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2. Equipo

Existen regulaciones para distintos equipos así:

- Retortas sin agitación de vapor
- Retortas sin agitación de agua
- Retortas continuas agitadas
- Retortas discontinuas agitadas de vapor
- Retortas discontinuas agitadas de agua
- Retortas hidroestáticas
- Procesamiento aséptico
- Esterilizador de llama
- Actividad del agua

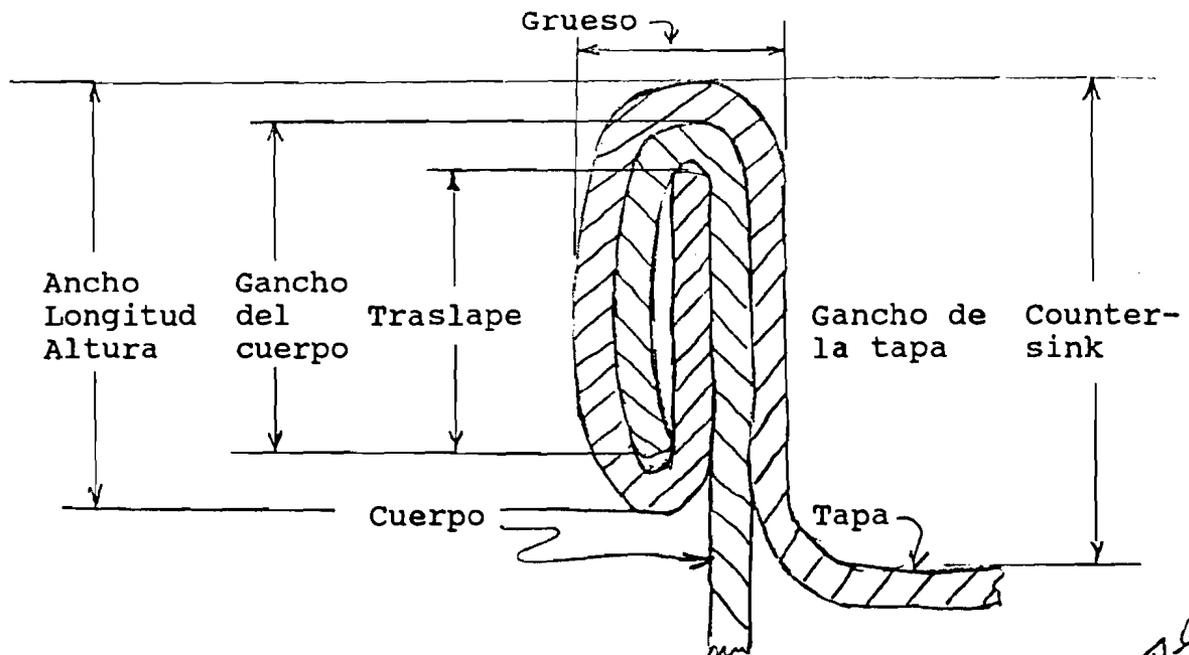
3. Recipientes (Latas o bolsitas) 113.60

Sellos de latas

Sistema micrométrico

Sistema microscópico o visual

Sello de una lata (2da. operación)



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El **Traslape** es una de los parámetros mas importantes para evaluar el sello de una lata. Teóricamente se calcula

$$\text{Traslape} = (\text{GT} + \text{GC} + \text{GLT} - \text{LS})$$

En la cual

- GT = Gancho de la Tapa ("Cover Hook")
- GC = Gancho del Cuerpo ("Body Hook")
- GLT = Grueso Lámina Tapa ("cover Thickness")
- LS = Largo del Sello ("seam Width, height, length)

Se usa también proyectores para ver un corte del sello con aumento y medir el **traslape** visualmente. Esto es mas rápido y no requiere mayores cálculos.

Otro parámetro importasnte para determinar la calidad del sello son las **arrugas**. Un sello bien planchado no debe tener nada de arrugas en latas de alto diámetro y estar caso igual a la de la tapa que puso el fabricante de la lata en las latas de menor diámetro.

Para **bolsas y frascos** no hay mayor detalle en las regulaciones pero siempre hay que llevar control de los cierres.

4. Establecimiento del Proceso Especificado 113.83

Esto debe ser hecho por "Individuos **Expertos en Procesamiento Térmico**" siguiendo procedimientos reconocidos por "Autoridades en Procesamiento, Competentes y Reconocidas" ("Competent Processing Authorities") Ver forma FDA 2541a para registro del proceso con la FDA de EUA, la misma que ya vimos para productos acidificados.

5. Archivos de Procesamiento y Producción 113.100

Especifica los parámetros que deben medirse para cada sistema de procesamiento, y ordena guardar los archivos por lo menos un año en la planta de producción, y otros dos años más, en que pueden guardarse en otro lugar razonablemente accesible.

Notar que lo anterior es únicamente un esbozo de esta Parte 113 y hay que referirse a los detalles en la ley.

B. Arvejas, zanahorias, maíz dulce y habichuelas verdes (ejotes)

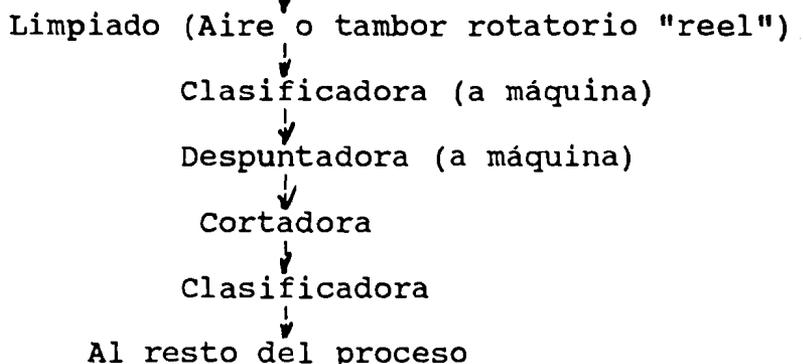
1. Preparación

Se muestra los pasos mas importantes. Los lavados, inspecciones, tamizados pueden variar según sea necesario.

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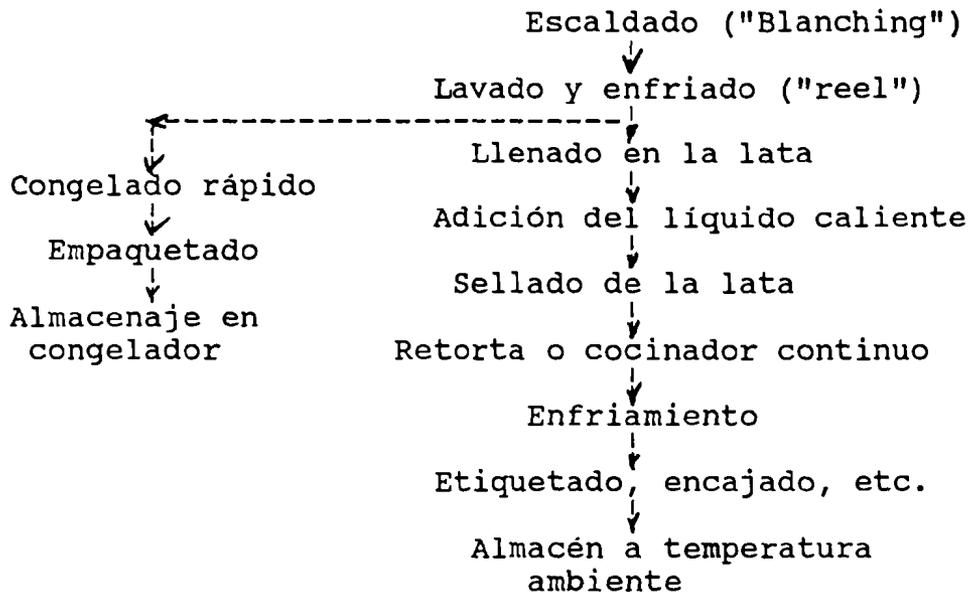
d. Habichuelas verdes (Ejotes)

Cosecha --> Transporte --> Recepción



2. Resto del proceso

Generalizando, podemos decir que el resto del proceso es similar para los cuatro vegetales arriba. algunos detalles serán distintos.



Discutir etiquetas en sus copias.

C. Frijoles en salmuera

Nos referimos acá mas que nada a los negros, pero los otros tipos se envasan en forma similar. Para los otros, los tiempos de remojo en agua fría son mucho mayores, hasta 10 - 12 horas y mas. En esos casos hay que cambiar el agua dos o tres veces para evitar proliferación de microorganismos.

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1. Frijoles negros

Ver etiqueta de "Goya" dentro de sus copias. Notar que estos son como frijoles "parados" pero todavía dejan al ama de casa la oportunidad de darle ella su "toque" personal. Se venden también frijoles negros **guisados** enlatados que ya tienen su ajo, cebolla y otros condimentos.

a. Ingredientes

Frijoles negros, agua y sal.

b. Preparación

Recepción--> Limpieza en seco --> Almacenaje
(Gorgojo no prolifera < 10 °C)
(Rata se disminuye con "pared" hojalata 60 cm alto)

↓
Lavado rápido

↓
Remojo hasta que duplique su peso (drenado)
(Una hora es usual)

↓
Remoción de piedras

Salmuera

Para 100 lts agua

Sal 2 kg

Cloruro Calcio 40g

(Opcional)

↓
Calentamiento (90-95 °C)-->

Escogido en banda (manual o máq.)

↓
Llenado en lata

(Para 303 p. 29 Bol. 26L 8.7 oz máximo peso)

↓
Adición de salmuera

↓
Sellado de lata y codificado

Temp. min. inicial 26L 38 °C

↓
Canasta de retorta

Procesos del 26L

°F (°C)

40 min a 240 (116)

27 min a 245 (118.5)

19 min a 250 (121.1)

↓
Cocinado en retorta

↓
Enfriamiento

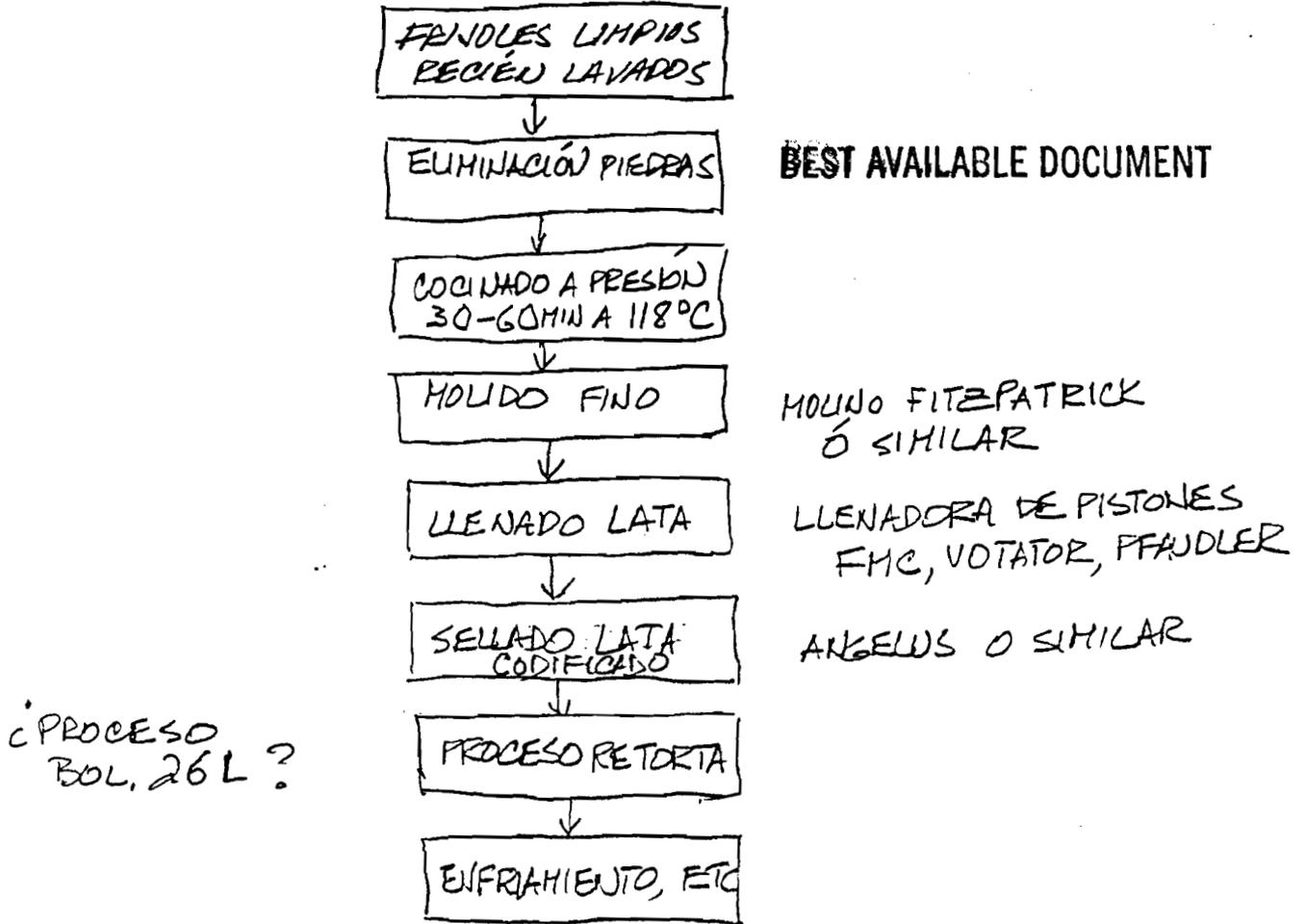
Hasta 43-50 °C

↓
Secado, etiquetado, etc.

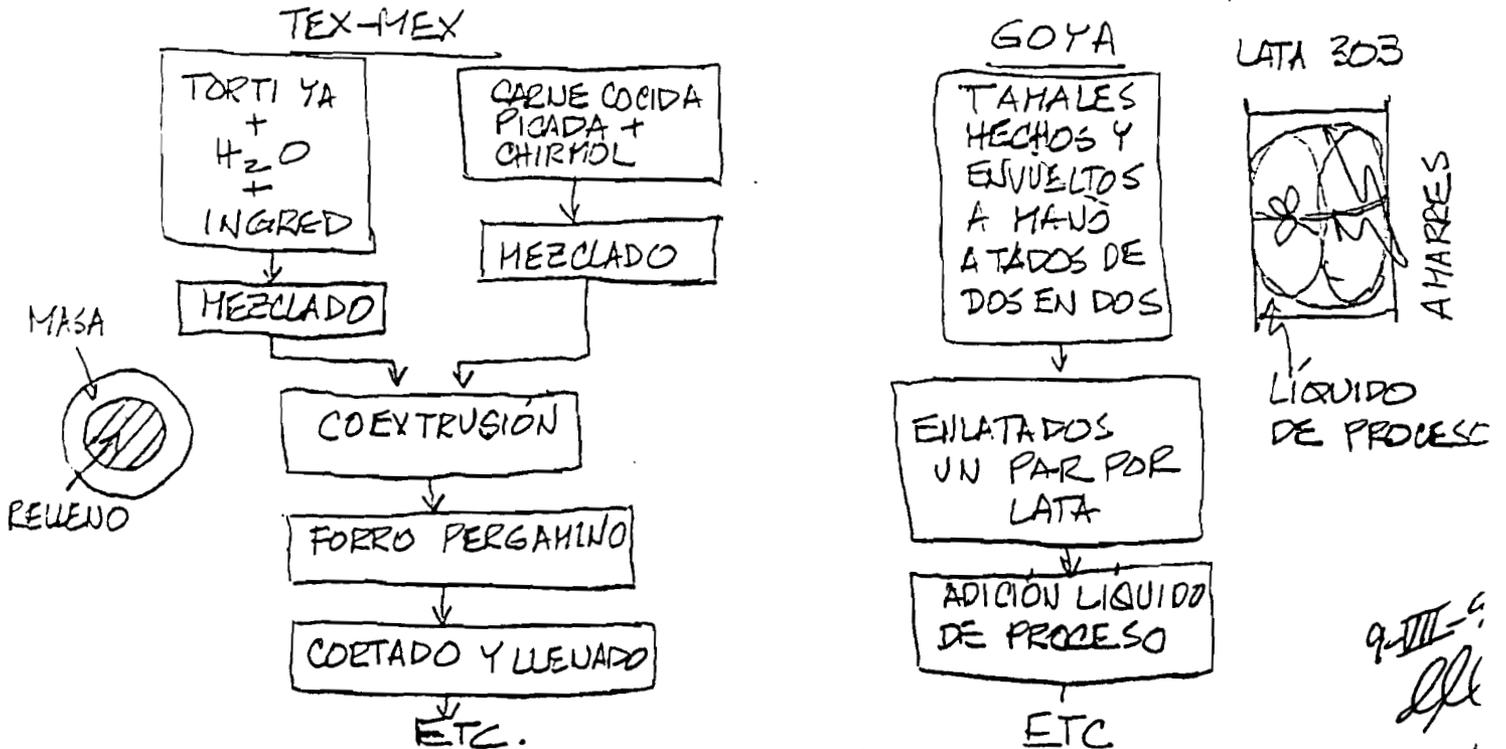
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2. FRIOLES FRITOS Y TAMALES

UN MÉTODO DE PREPARAR FRIOLES "COLADOS" FRITOS ES



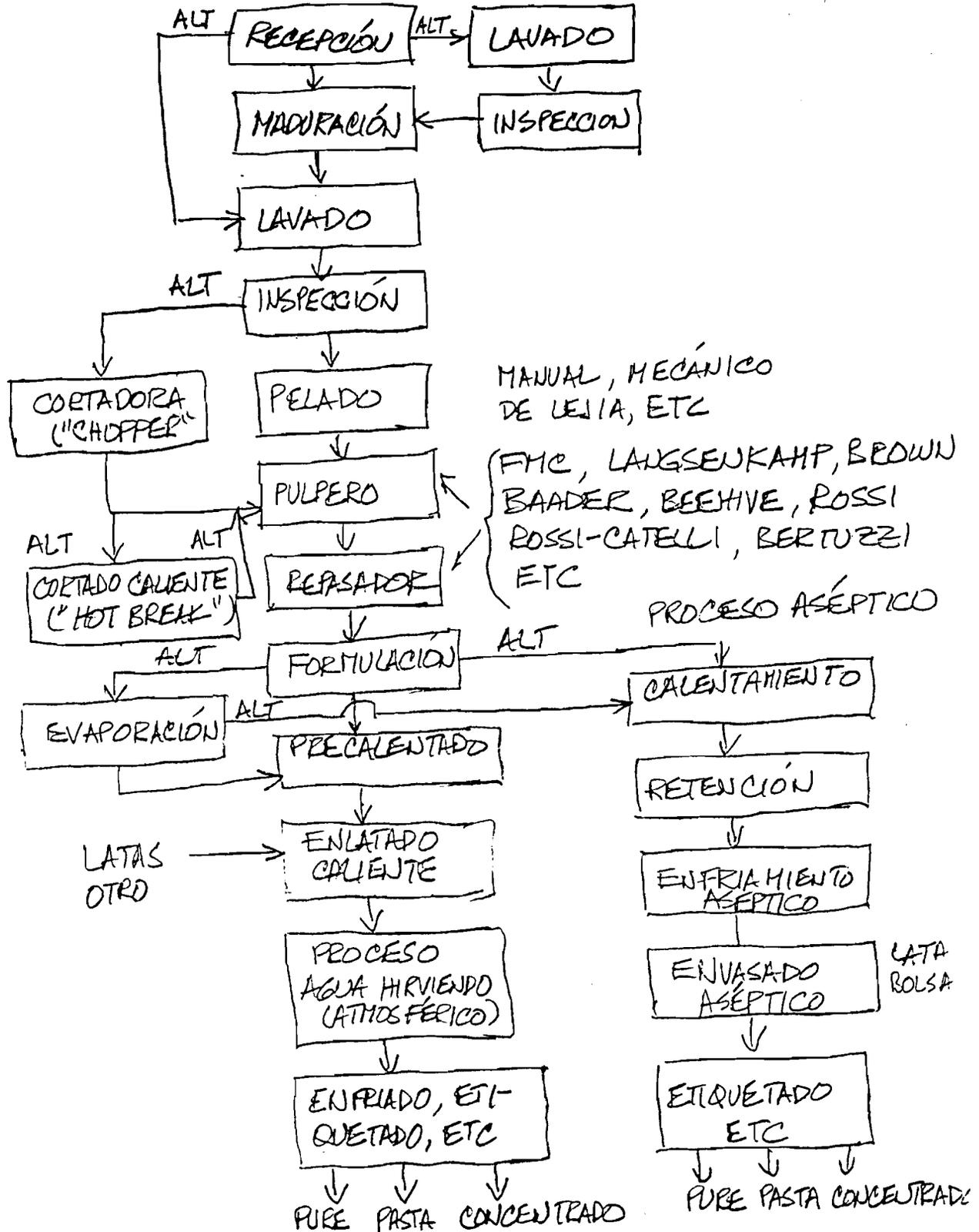
LOS TAMALES, NACATAMALES Ó PASTELES PUEDEN ENLATARSE DE MUCHAS MANERAS. VEAMOS DOS ACA



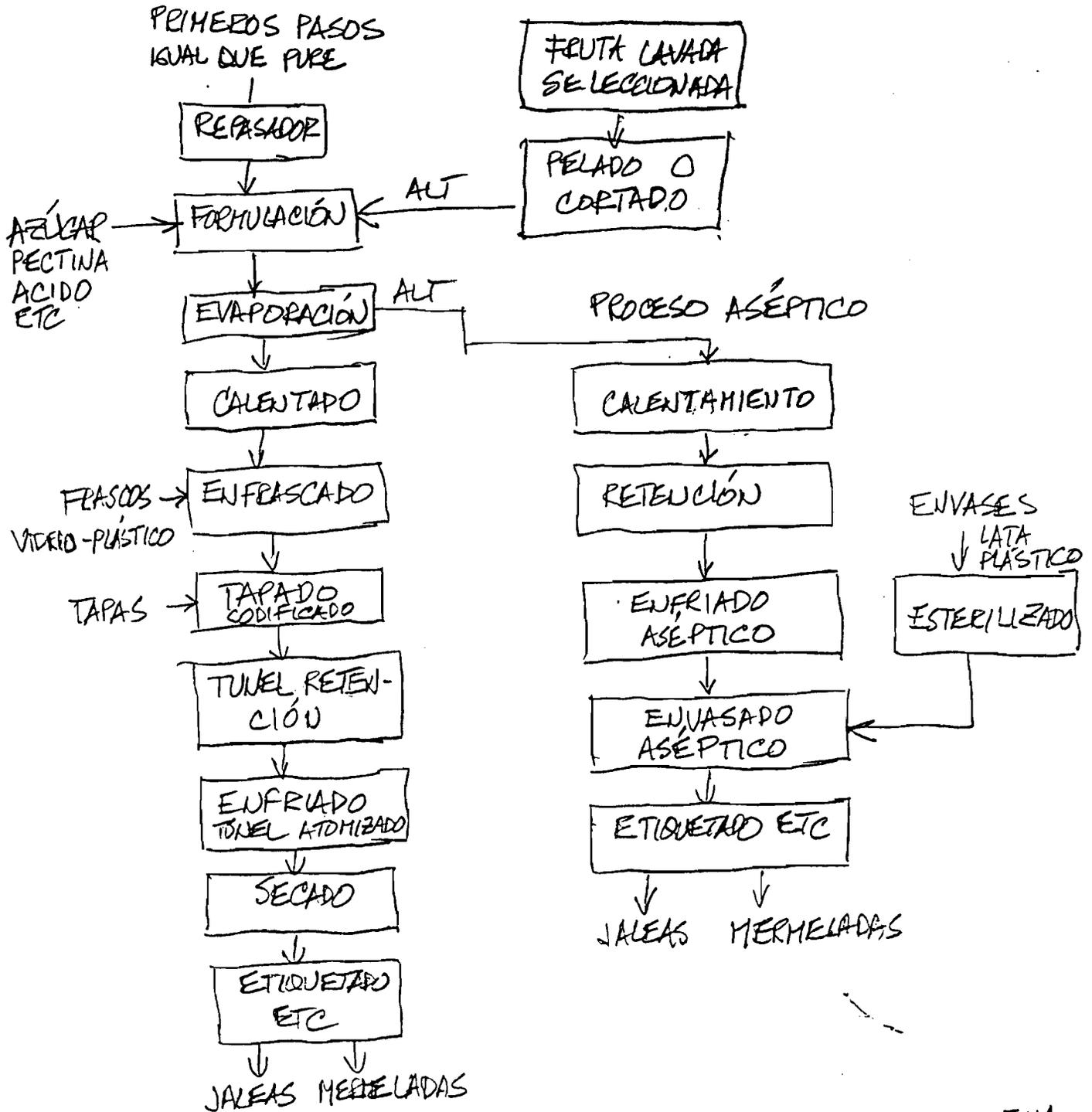
A. MANUFACTURA

I. PURÉS Y CONCENTRADOS

LOS PASOS SON SIMPLES EN GENERAL



2. JALEAS Y MERMELADAS



HAY PATRONES DE GRADO PARA JALEAS Y MERMELADAS DE EHA
ASÍ COMO PATRÓN DE IDENTIDAD 21 CFR 150.160
52.1111 ESPECIFICA "... NO MENOS DE 65 BRX..."

3. JALEA DE FRESAS ("STRAWBERRY JAM") Y FRESAS EN CONSERVA ("STRAWBERRY PRESERVES")

LA JALEA DE FRESA ES UNO DE LOS SABORES MAS POPULARES TANTO EN CENTROAMERICA COMO EN EUA Y OTROS PAISES MEXICO EXPORTA A EUA UNA GRAN CANTIDAD DE FRESAS CONGELADAS QUE EN BUENA PARTE SE CONVIERTEN EN JALEA DE FRESA.

FRESA ESTA EN EL GRUPO 1 DEL ISO.160

47 PARTES FRESA PARA CADA 55 PARTES DE AZÚCAR
FRESA SE REFIERE A FRUTA SOLAMENTE

INGREDIENTES OPCIONALES IGUAL QUE PARA OTRAS JALEAS

1. CARBOHIDRATOS NUTRITIVOS EDULCORANTES
2. ESPECIES
3. INGREDIENTES ACIDULANTES
4. PECTINA
5. BUFFERS
6. PRESERVATIVOS
7. AGENTES ANTIESPUMANES EXCEPTO LOS DERIVADOS DE GRASA ANIMAL

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LO ANTERIOR ES UN RESUMEN

PARA FRESAS EN CONSERVA HAY QUE

SEPARAR JUGO DE FRESA QUE SE OBTIENE AL PONER 4 PARTES DE FRESA Y 1 PARTE DE AZÚCAR LAS FRESAS SE GUARDAN

SE AÑADE MAS AZÚCAR AL JUGO, ALREDEDOR DE 4 PARTES MAS Y SE CALENTA A 82 °C PARA DISOLVERLA EVAPORACIÓN AL VACÍO A 80-85° BRIX DEL JUGO AÑADIR EL JUGO A LAS FRESAS Y HACER EL VACÍO PARA QUE SE IMPREGNEN EN UN TIEMPO CORTO AÑADIR PECTINA Y CALENTAR A 170-190 °F AÑADIR ACIDO CÍTRICO PARA AJUSTAR PH

4. MIEHEMELADA DE NARANJA

SE HACE EN FORMA SIMILAR PERO USANDO CORTEZA DE NARANJA Y JUGO DE NARANJA

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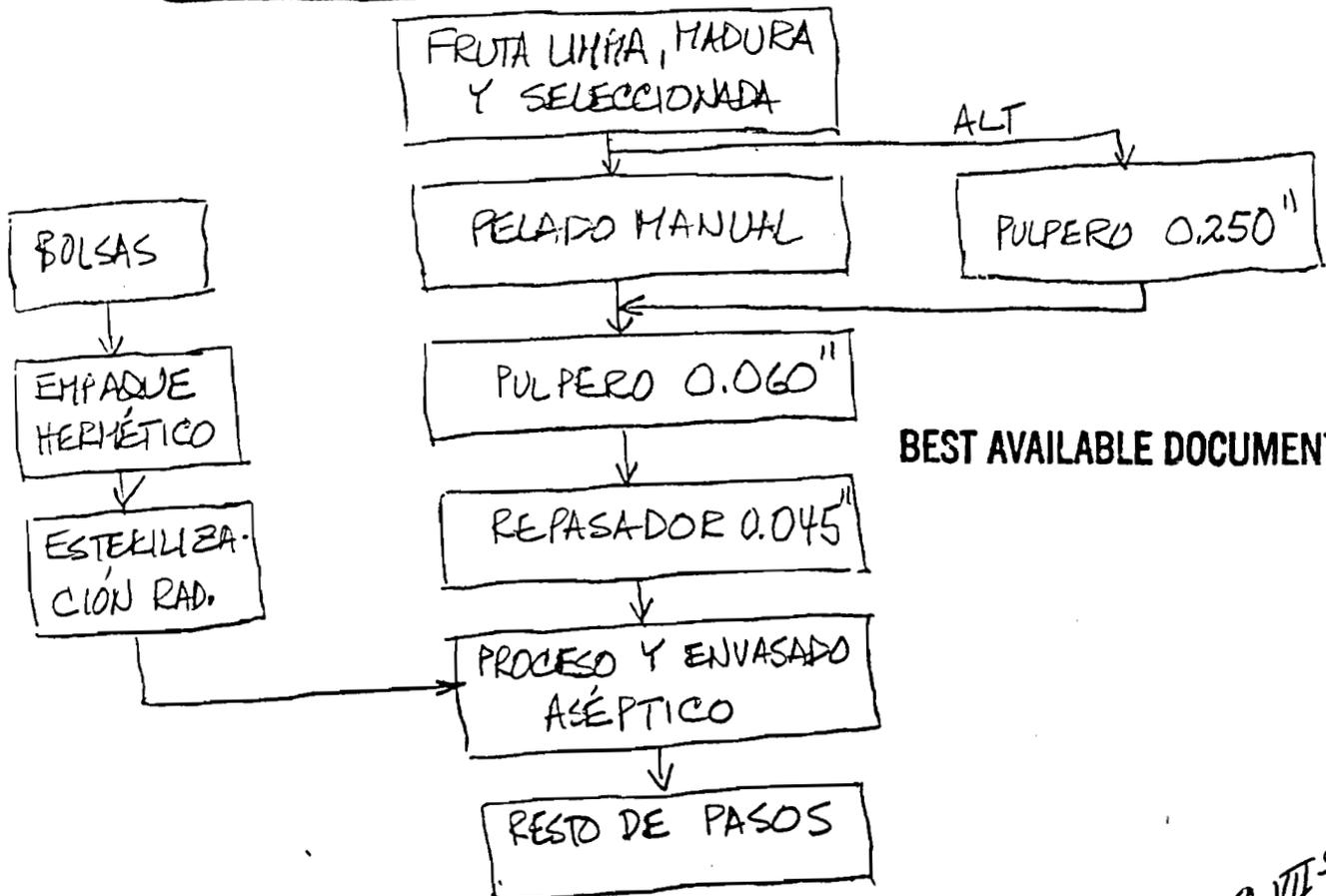
5 PURÉ ASEPTICO DE MANGO

SE EXPORTA DE MEXICO, COLOMBIA, GUATEMALA Y OTROS PAÍSES A EUA Y EUROPA. INDIA ES EL PRODUCTOR MAYOR DEL MUNDO ORIGINALMENTE EN LATA (LLEVADO EN CALIENTE) PERO CAMBIANDO LA PRODUCCIÓN YA A ASEPTICO EN BOLSA DENTRO DE TAMBOR (BAG-IN-DRUM) Ó EN BOLSA DENTRO DE CAJA ("BAG-IN-BOX")

LAS VARIETADES SON "ALPHOUSE" Y "LAS DEMÁS". EL "ALPHOUSE" TIENE UN PRECIO PREFERENCIAL EN EL MERCADO. SE PAGA POR EL, 25-40% MAS.

DENTRO DE "LAS DEMÁS" ALGUNAS SON "TOMMY ATKINS", MANGO DE BREA, MANGO DE MICO Y OTRAS LOCALS. ALGUNOS PRODUCTORES TRATAN DE ALARGAR LA TEMPORADA DE EMPAQUE MEZCLANDO VARIETADES Y USANDO VARIAS, QUE "TRASLAPAN" EN SUS TEMPORADAS DE COSECHA.

LA PREPARACIÓN DEL PURÉ INCLUYE



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6 PURÉ ASEPTICO DE BAJANO

SE EXPORTA DE GUATEMALA, HONDURAS, COSTA RICA, PANAMA BRAZIL, ECUADOR Y OTROS A EUA, EUROPA, JAPÓN Y EL CERCAÑO ORIENTE.

SE EXPORTA NATURAL 21-25 BRIX O CONCENTRADO 32-36 % SÓLIDOS TOTALES.

VARIETADES PRINCIPALMENTE CAVENDISH "VALEBY" Y "GRAN ENANO" ("GRAND NAIN")

EMPAQUADORA → BAJANO DE EXPORTACIÓN

RECHAZO SOBREMADURO

TRANSPORTE

RECEPCIÓN LAVADO

SE USAN CAJAS ≈ 200 KG

MADURACIÓN

≈ 5 DÍAS 13-22 °C

LAVADO Y SELECCIÓN

ALT → PELADO MECÁNICO

PELADO MANUAL

BOMBA DE PURÉ

REPASADOR

PARA PURÉ "CON SEMILLA" PELADO A MANO NO PASA POR REPASADOR

HOMOGENIZADO

DEAIREADO

Especificaciones

Debido a que este producto ha tenido en el pasado pocos productores, no hay generalmente especificaciones afuera de las suministradas por los suplidores. Lo siguiente es un extracto de las de varios fabricantes

Fisico-químicas:

	<u>Natural</u>	<u>Acidificado</u>	<u>Concentrado</u>
Sol. solub. Brix	21-25	21-25	30-34
Sólidos totales	23-27	23-27	32-36
Consistencia			
Bostwick cm/30 s	2.5-7.5	2.5-7.5	3.5-8.5
pH	4.7-5.3	4.2-4.5	4.7-5.1
(Bolsas de) semi- llas (Uni./100g)			
Regular	-	-	No. apl.
Desemillado	0-1	0-1	0-1

Empaque:	<u>Peso neto</u>	
	<u>kg</u>	<u>lbs</u>
5 gal. BIB	20.9	46
6 gal. BIB	25.4	56
55 gal BIB/BID	218-230	480-508
220 gal BIN	930-1050	2050-2314

Generalmente se vende los bolsa dentro de cartón (BIB) solo paletizados. Esto es 48 de 5 o 6 gal. por paleta/tarima o 4 de 55 gal. por tarima.

Microbiología Es normal solo especificar que el producto tiene esterilidad comercial.

Condiciones de almacenamiento

El mayor manufacturero recomienda 15-30 oC. Otro manufacturero importante recomienda menos de 4 oC.

7. Pulpa congelada de guanabana (guanaba)

Este producto tiene bastante demanda y la poca oferta es rápidamente comprada por los enlatadores. Además, el sabor esta solamente empezando a adquirir gran volumen, por lo que creo que puede llegar a volúmenes significativos.

Hay pocos detalles sobre su manufactura, pero se puede colegir que la extracción de la pulpa y la remoción de las semillas de las celdas se hace manualmente. El uso de homogenizado y deaireado es probable. La mayor parte de la pulpa de guanabana de que tengo conocimiento está envasada en bolsas de plástico dentro de cubetas también de plástico de 5 gal con tapa. Estas cubetas son puestas dentro de congeladores donde se dejan para ser almacenadas y

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transportadas preferentemente a - 10 grados F (-23 oC) o menos.

De la tabla vista anteriormente notamos que el FDA espera un Brix de 16 para jugo natural de guanabana.

VI BUENAS PRACTICAS DE MANUFACTURA PARTE 110 REG. FDA

Veamos primero algunas definiciones de las regulaciones (estas son traducciones libres, no oficiales, de las regulaciones):

A. Algunas definiciones

b. "Adecuada" quiere decir lo que es necesario para lograr el fin deseado para mantenerse en buenas prácticas de salubridad..

d. "Escaldado" ("Blanching") Excepto en los casos de nueces de árboles y de manias, quiere decir un tratamiento térmico de alimentos, previo al empaque, por suficiente tiempo y a suficiente temperatura para inactivar parcial o totalmente las enzimas naturalmente presentes y causar otros cambios físicos o bioquímicos en el alimento.

e. "Punto crítico de control" Quiere decir un punto en el proceso del alimento en el cual haya una alta probabilidad de que un descontrol pueda causar, o permitir, o contribuir a un riesgo o a ensuciar o a descomposición en el o del alimento terminado.

i. "Microorganismos" quiere decir levaduras, hongos, bacterias, y virus e incluye pero no esta limitado a especies que tengan significación para la salud pública. El término "microorganismos indeseables" incluye los organismos que son de significación para la salud pública, que sometem el alimento a descomposición, que son indicativos de que el alimento está contaminado con suciedad, o que en otra forma pueden causar que el alimento se considere adulterado dentro del significado del Acta. Ocasionalmente FDA usa en estas regulaciones el adjetivo "microbiano" en lugar de una frase adejetivada incluyendo la palabra microorganismo.

j. "Peste" se refiere a cualquier animal o insecto objetable incluyendo pero no limitado a aves; roedores, moscas y larvas.

o. "Sanear" ("Sanitize") quiere decir medios para tratar adecuadamente superficies de contacto con alimentos por un

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proceso que es efectivo en destruir microorganismos de significación para la salud pública y en reducir substancialmente el número de otros microorganismos pero sin afectar el producto o su seguridad para el consumidor.

B. Personal 21 CFR 110.10

- a. Control de enfermedades
- b. Limpieza
 - 1. Vestido
 - 2. Higiene personal
 - 3. Educación y entrenamiento
 - 4. Supervisión

C. Plantas y sitios 21 CFR 110.20

- a. Sitio
- b. Diseño y construcción de la planta

D. Operaciones sanitarias 21 CFR 110.35

E. Facilidades sanitarias y controles 21 CFR 110.37

F. Equipo y utensilios 21 CFR 110.40

G. Controles de producción y proceso 21 CFR 110.80

H. Almacenaje y distribución 21 CFR 110.93

I. Defectos naturales o inevitables en alimentos para humanos que no presentan riesgo para la salud

Veamos ahora un "video cassette" que luego quiero que comentemos a la luz de lo anterior.

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[Signature]

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MEMORANDUM FOR THE DIRECTOR

VII ESTIMACIÓN DE COSTOS DE PRODUCCIÓN
 SE HA SIMPLIFICADO CON PROGRAMAS DE PAQUETE DE COMPUTADORA
 CASO MAS SENCILLO (HAY QUE USARLOS BIEN)

$$\frac{\text{TOTAL COSTOS ANUALES}}{\text{TOTAL CAJAS ANUALES}} = \text{COSTO POR CAJA}$$

TOTAL COSTOS ANUALES

DIRECTOS EJEMPLOS: MATERIAS PRIMAS, MAT. EMPAQUE
 (CAMBIAN CON EL VOLÚMEN) MANO DE OBRA DIRECTA, COMBUSTIBLE

INDIRECTOS EJEMPLOS: COSTO PERSONAL FIJO, DEPRECIACIÓN
 (HAY QUE PAGARLOS AUNQUE COMBUSTIBLE NO SE PRODUzca NADA)

COSTO DE INTERESES
E IMPUESTOS

COSTO STANDARD

EJEMPLO "NEGRAS A/S 24/303" (VER SUS HOJAS)

LOTE 1000 LBS FRIOLES NEGROS

RENDIMIENTO 140 CAJAS 24/303 (1 LB C/U) POR LOTE

RENGLONES PRINCIPALES	\$/CAJA	\$
INGREDIENTES Y MATERIALES DE EMPAQUE		4,6667
FACTOR DE DESPERDICIO 2%		0,0933
MANO DE OBRA DIRECTA		0,2313
BENEFICIOS MARGINALES DE MANO O. DIR. 46.12%		0,1067
"OVERHEAD" DE MANUFACTURA DIRECTO/VARIABLE		0,3200
COSTO TOTAL DIRECTO (VARIABLE)		5,4180
"OVERHEAD" DE MANUFACTURA FIJO		0,4800
COSTO TOTAL DE MANUFACTURA		5,8980
PRECIO DE VENTA		7,8640
COSTO DE VENTAS		75 %
MARGEN BRUTO (SOBRE EL PRECIO DE VENTA)		25 %

CADA NEGOCIO TIENE SU MARGEN BRUTO DE EQUILIBRIO

SI SE TIENE MAYOR MARGEN SE HACE UTILIDAD SI NO NO

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LOS SIGUIENTES SON ALGUNOS DE LOS COSTOS QUE TIENEN QUE SER CUBIERTOS POR EL MARGEN BRUTO

- COSTO DE DISTRIBUCIÓN
- " " VENTA (COMISIÓN Y SUPERVISIÓN VENTAS)
- " " ANUNCIOS
- " " DESCUENTOS, PROMOCIONES Y DEVOLUCIONES
- " " FINANCIAMIENTO
- " " ADMINISTRACIÓN GENERAL Y GERENCIA
- " " OFICINA MADRE O CORPORATIVA

GENERALMENTE SE CALCULA UNA

UTILIDAD ANTES DE INTERESES E IMPUESTOS
 ("PROFIT BEFORE INTEREST AND TAXES" (PBIT))

PARA GERENTE DE OPERACIONES EN UNA COMPAÑIA GRANDE GENERALMENTE SE FIJA SU PRESUPUESTO Y METAS A NIVEL DE MARGEN BRUTO. SE PRESUPUESTA Y REvisa EN BASE A ESTO. UN EMPRESARIO PEQUEÑO TIENE QUE CUIDARSE DE ESTIMAR HASTA LLEGAR A LA UTILIDAD NETA.

RECORDAMOS ALGUNOS TÉRMINOS Y SU SIGNIFICADO

CONTABILIDAD EN REALIDAD ES ESENCIALMENTE HISTÓRICA. LLEVA CUENTA FIEL DE LO QUE PASO

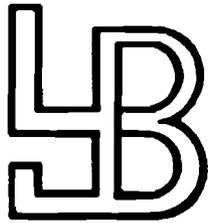
CONTABILIDAD DE COSTOS SE CONCENTRA EN COSTOS. IDEALMENTE AYUDA A FIJAR PRECIOS DE VENTA

INGENIERÍA ECONÓMICA Ó ANÁLISIS ECONÓMICO NO SE PREOCUPA POR ASUNTOS CONTABLES. PROYECTA SITUACIONES INCLUY COSTOS PARA BUSCAR LA RENTABILIDAD Y MAXIMIZAR LAS UTILIDADES.

EJEMPLO: ESCOGER ENTRE DOS ALTERNATIVAS DE OPERACIÓN DE UNA PLANTA CAPAZ DE PRODUCIR 100 TON DE "A" O "B"

	A	B	PRECIO VENTA	% MARGEN	MARG.
ALTERNATIVA 1	50		1000	25	1250
		50	1500	15	1125
MEJOR → 2	100		1000	25	2500

GMP Series (Good Manufacturing Practices)



G.M.P. RULES FOR FOOD PLANT EMPLOYEES

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GENERAL G.M.P. RULES FOR FOOD PLANT EMPLOYEES

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**Current Good Manufacturing
Practice in Manufacturing, Packing,
or Holding Human Food**

21 CFR Part 110

**Industry Activities Section
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, DC 20204**

CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS

This is an abridged compilation of the current Good Manufacturing Practice (CGMP) regulations. The regulations are current through February, 1994. The CGMP regulations are issued under Title 21, Code of Federal Regulations, Part 110 (21 CFR 110). Amendments to the regulations appear in the Federal Register. Information concerning subscribing to the Federal Register appears in the last two paragraphs on this page.

Included in this booklet is the preamble to the final rule document published in 1986. The preamble contains valuable background information concerning the CGMP regulations.

Related Subjects

The CGMP regulations in this booklet are general regulations that apply to all foods. Specific CGMP regulations apply to certain categories of food, as listed below:

1. Quality control procedures for assuring the nutrient content of infant formulas (21 CFR 106).
2. CGMP regulations for thermally processed low-acid foods in hermetically-sealed (air-tight) containers (21 CFR 113), and for acidified foods (21 CFR 114).
3. CGMP regulations for bottled water (21 CFR 129).

The regulations for the categories of foods listed above are contained in Title 21, Code of Federal Regulations, Parts 100 to 169 (21 CFR 100-169). The price for the 1993 edition is \$21.00 (\$26.25 for foreign mailing). Information concerning purchase of 21 CFR 100-169 is contained under "How To Order" at the bottom of this page.

Federal Register

Changes in FDA regulations are published in the *Federal Register*. The *Federal Register* is published Monday through Friday by the Government Printing Office. It is mailed to subscribers at a cost of \$6.00 per issue or each group of pages as actually bound. Subscriptions are available at \$444.00 per year in paper form, or \$403.00 per year in microfiche form. Six-month subscriptions are available at one-half the annual rate. Add 25% surcharge for foreign mailing.

How to Order

You may subscribe to the Federal Register or order 21 CFR 100-169 by submitting the indicated cost, by check or money order to: SUPERINTENDENT OF DOCUMENTS, U.S. GOVERNMENT PRINTING OFFICE, WASHINGTON, D.C. 20402, or by telephoning the Government Printing Office at 202-783-3238 to charge on Visa[®] or Mastercard[®].

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

Subpart A - General Provisions

- 110.3 Definitions.
- 110.5 Current good manufacturing practice.
- 110.10 Personnel.
- 110.19 Exclusions.

Subpart B - Buildings and Facilities

- 110.20 Plant and grounds.
- 110.35 Sanitary operations.
- 110.37 Sanitary facilities and controls.

Subpart C — Equipment

- 110.40 Equipment and utensils.

Subpart D — [Reserved]

Subpart E — Production and Process Control

- 110.80 Processes and controls.
- 110.93 Warehousing and distribution.

Subpart F — [Reserved]

Subpart G — Defect Action Levels

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 (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w 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" (a_w) 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 en

sure 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:

(1) 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.

[51 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, or otherwise 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) (1) 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:

(1) 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.* (1) 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 contami-

nation 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:

(1) 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, or 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 compart-

ment 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

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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 pro-

tect 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, a_w , 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 (72 °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 a_w 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 a_w for preventing the growth of undesirable microorganisms shall be pro-

cessed 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 a_w 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 a_w 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 20 and 110

[Docket No. 78N-0296]

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food; Revised Current Good Manufacturing Practices
AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that revises the current good manufacturing practice (CGMP) regulations for human foods. The primary purpose of the revision is to establish new, updated, or more detailed provisions for the food industry to help ensure a safe and sanitary food supply.

DATES: This final rule will become effective on December 16, 1986; comments by August 18, 1986.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Prince G. Harrill, Center for Food Safety and Applied Nutrition (HFF-210), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0097.

SUPPLEMENTARY INFORMATION:
History

In the Federal Register of June 8, 1979 (44 FR 33238), FDA published a proposal to revise the current good manufacturing practice (CGMP) regulations for the manufacturing, processing, packing, and holding of human foods, the umbrella CGMP regulations (21 CFR Part 110). FDA sought to establish new, updated, and more detailed CGMP provisions concerning food industry personnel; plants and grounds; sanitary facilities, controls, and operations; equipment and utensils; processes and controls; product coding; warehousing and distribution; recordkeeping; and natural or unavoidable defect levels. FDA designed the proposed revision of the umbrella CGMP regulations to address the problems associated with foods for which specific CGMP regulations had not been promulgated and thus better ensure the production of safe and sanitary foods. FDA provided a period of 204 days, ending on December 31, 1979, for the filing of comments on the proposed revision.

To gather information and opinions on the impact of the proposed revision, FDA also held hearings in Chicago, IL, on September 11, 1979, in San Francisco, CA, on October 3, 1979, and in Atlanta, GA, on October 24, 1979. Approximately 250 persons attended the 3 hearings. Of the roughly 50 persons who made presentations at the hearings, nearly two-thirds represented small businesses. Because FDA was particularly interested in the impact that the revised regulations would have on small businesses, the agency solicited comments from small businesses and trade associations representing small businesses. The hearings resulted in a voluminous hearing record.

In addition to the comments received at the hearings, FDA has received 132 written communications reflecting the comments of suppliers, manufacturers and processors, trade associations, operators of small businesses, consumers, and other interested persons.

Revision in Response to Comments

The comments on the 1979 proposal, including those received at the hearings, suggested revisions of practically every section of the proposed rule. In response, FDA has adopted many of these suggestions in the regulation.

The most significant revision responds to comments concerned the proposed requirements for coding and recordkeeping. The vast majority of these comments questioned the need for these requirements for segments of the food industry that contend (1) their products pose little or no risk to the public health and (2) their products, in the rare event a risk arose, could be removed from the market expeditiously and effectively without the need to comply with the costly proposed requirements. Most comments also pointed out that the cost of coding and recordkeeping would be excessive, especially to small businesses.

To evaluate more fully the validity of industry's comments concerning the cost of the proposed regulations, FDA contracted for a study of compliance costs associated with the 1979 proposal as FDA then had considered modifying the proposal in response to comments. The study was conducted by ICF, Inc., Washington, DC, and is part of the record of this proceeding. ICF concluded that total compliance costs were \$61 million. The costs were primarily attributable to the proposed recordkeeping (\$76 million) and coding (\$4.5 million) provisions. (Costs are adjusted to represent 1985 dollars.) ICF also found that 95 percent of the large manufacturers sampled and 93 percent

of the small manufacturers sampled were already coding their products sufficiently to be in compliance with the proposed regulation. The recordkeeping costs would have been high because, although all manufacturers have detailed records, few have recordkeeping systems based on lot numbers which the proposed regulation would have required.

The purpose of proposing coding and recordkeeping was to facilitate a manufacturer's recall of suspect products in case such a recall was recommended by FDA. Although such information is potentially useful in determining the production time period which is effected by a recall, thereby limiting manufacturers' risk exposure, it is not needed to protect consumers from products that have been purchased but not ingested. Furthermore, all manufacturers either currently code all their products or keep shipping records in the ordinary course of business, or do both. As these sources can provide most of the information which would have been required in the proposed rule, and all of the information needed for a recall, it is not necessary to impose other economically burdensome recordkeeping requirements. This decision will save manufacturers and consumers approximately \$80.5 million annually (1985 dollars) in foregone costs, costs which would have been incurred if the regulation had gone forward as proposed in the notice of proposed rulemaking.

For consumer protection, the most effective safeguard is product, not lot, identification and swift dissemination of such information by mass media. These mechanisms will in no way be compromised by the deletion of coding and recordkeeping requirements.

In addition, the products most likely to involve risk of recall (low acid food) are already subject to coding and recordkeeping requirements.

Accordingly, because industry voluntarily codes and keeps records adequate for consumer protection, FDA has decided not to require coding or recordkeeping. FDA, after reviewing comments and the ICF study, has concluded that an industry confronted with little likelihood of recalls of products subject to the proposed rule could decide that removal of all offending products from the market in the presence of a recall would protect the public health and would be more cost effective than maintaining records and coding products. On the other hand, an industry confronted with a high frequency of recalls or with the apparent potential for infrequent, but serious

contamination of a limited quantity of product, could decide that coding and recordkeeping are essential to accomplishing a recall. Under either option, the public would be protected and industry would have the opportunity to decide which recall strategy is appropriate.

Nevertheless, FDA encourages firms to code their products and to maintain appropriate records. FDA also reserves the option to reconsider this decision if future evidence indicates the cost effectiveness of mandatory coding and recordkeeping.

Because FDA is not requiring coding or recordkeeping in the final rule, FDA will not discuss in this preamble the detailed comments received on these topics.

FDA has decided to publish a final rule instead of a tentative final rule or revised proposal. The final rule is "in character with the original scheme" (*South Terminal Corp. v. EPA*, 504 F.2d 646, 658 (1st Cir. 1974)) and contains changes that are "logical outgrowths" of the comments received in response to the proposal (*AFL-CIO v. Marshall*, 617 F.2d 636, 676 (D.C. Cir. 1979)). Thus, FDA concludes that to issue a tentative final rule or a revised proposal is not necessary because it has provided the public "a reasonable and meaningful opportunity to participate in the rulemaking process" (*McCulloch Gas Processing Corp. v. Department of Energy*, 650 F.2d 1216, 1221 (Em. Appl. 1981)).

Although FDA is publishing a final rule, it is providing a comment period. If FDA decides on the basis of the comments received that any changes in the final rule are necessary, it will publish those changes in the Federal Register.

Costs

The industrywide compliance costs associated with this final rule would be between \$272,000 and \$623,000 per year. These costs are for the installation and maintenance of temperature indicating thermometers in industries where food products or processing techniques would allow the growth of microorganisms. The agency concludes that this rule is not a "major" rule under Executive Order 12291 and that it does not impose a significant burden on small businesses. No recordkeeping or reporting requirements are associated with the final rule.

General Comments

1. Several comments suggested that the proposed umbrella CGMP regulations be withdrawn because specific legislation affecting the food

industry was before Congress and may become law.

FDA believes it inappropriate to await enactment of new legislation. Of course, if new legislation is enacted, FDA will make appropriate changes in the regulations.

2. Several comments questioned whether FDA inspectors would interpret the umbrella CGMP regulations differently for different food-processing operations or industries. Some comments expressed concern that inspectors might find violations of regulations that were not applicable to a particular processor or industry. One comment offered to assist FDA in training its personnel in specific food-processing methods.

FDA has an agency review procedure to ensure that any corrective action recommended by investigators is in accordance with agency policy and that a regulation has been properly interpreted before regulatory action is taken. FDA has trained, and will continue to train, appropriate personnel to understand and interpret the umbrella CGMP regulations properly. In the past, industry has been helpful in aiding in training FDA personnel, and FDA hopes that this cooperation will continue.

3. Several comments expressed the opinion that FDA had not fairly considered the wide array of manufactured foods affected by the revised umbrella CGMP regulations.

FDA believes that the agency did consider the wide array of foods, then decided that revising the umbrella CGMP regulations is more efficient than issuing repetitive proposed and final regulations on specific food industries.

4. Many comments suggested that broad or general performance standards that allowed for innovation in achieving the desired result would be more useful to the food industry than specific mandated techniques. Several comments suggested that the umbrella CGMP regulations be rewritten as a series of suggested guidelines, and that the "shalls" be changed to "shoulds," because the regulations are intended to be a broad performance standard for the entire food industry. Other comments stated that several sections were too general and interpretation of the intent would be impossible.

FDA agrees, in part, with the comments. FDA considers the CGMP regulations to have a twofold purpose: (1) To provide guidance on how to reduce insanitary manufacturing practices and on how to protect against food becoming contaminated; and (2) to state explicit, objective requirements that enable industry to know what FDA expects when an investigator visits one

of its plants. The agency has critically reviewed each provision of the regulations to determine which provisions should be mandatory and thereby carry the force and effect of law. Wherever possible FDA has structured the regulations to provide general guidance to industry for ensuring the maintenance of good sanitary practices in the manufacturing, packing, and holding of food. The agency believes that several provisions of the regulations are necessary to ensure the maintenance of good sanitary practices and, therefore, that these provisions should be made mandatory.

5. A number of comments requested that the umbrella CGMP regulations be printed in two type faces to allow industry and FDA inspectors to differentiate more easily between the "shoulds" or general guidelines, and the "shalls" or mandatory requirements.

The Office of the Federal Register is unable to accommodate this request. Therefore, the umbrella CGMP regulations are not printed in two type faces.

6. Numerous comments requested that the term "prevent contamination" be changed to "minimize contamination" or "minimize the potential for contamination" or other similar words in various parts of the regulations.

FDA agrees and has changed the wording to reflect that the regulations are designed to protect against or to minimize the contamination of food. See the response to comment 125.

7. Several comments asserted that suggestions, lists of processes, analytical tests, and other enumerated techniques make the regulations confusing because they do not encompass all the possible relevant options. These comments requested that illustrative examples be deleted from the regulations.

The use throughout the regulations of prefatory phrases such as "includes, but not limited to," "may be accomplished by," and "including" establishes that the enumerated items are not all inclusive. The use of a suggested technique is not required. For these reasons, FDA is retaining in the final rule most of the lists of examples.

8. Several comments suggested that the regulations place greater emphasis on Federal and State agency coordination to help achieve more uniform guidelines and requirements for the food industry. One comment expressed concern that FDA did not expand the preliminary draft review procedures to include State food control agencies.

FDA agrees that interagency coordination is important in the development of CGMP regulations for any regulated commodity. Prior to publishing this final rule, FDA submitted preliminary drafts for review and comment to the Department of Agriculture and the Department of Commerce. FDA included recommendations from these agencies in the proposal. However, FDA did not submit a preliminary draft of the final rule to State food regulatory agencies because 21 CFR 20.81 provides that if a preliminary draft of a regulation is made available to persons outside of Federal agencies, it must then be made available to all interested persons. FDA believes that the comment period for the proposal was sufficient for all interested persons to submit their comments and suggested changes to the agency. FDA has made many changes in the final rule based on the comments submitted by industry, consumers, regulatory agencies at all levels of government, and other interested persons.

9. Several comments from the shellfish industry, including trade associations and other interested persons, stated that the proposed umbrella CGMP regulations would have a severe economic impact on the shellfish industry and, because of this impact, any action to promulgate the regulations without an economic analysis of the effect of such regulations on the shellfish industry, prepared jointly by the Department of Health and Human Services and Department of Commerce, would violate the intent of the Coastal Zone Management Act. This statute provides that:

At least 60 days prior to the promulgation of any regulations concerning the National Shellfish Safety Program, the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, shall publish an analysis (1) of the economic impact of such regulations on the domestic shellfish industry, and (2) the cost of such national shellfish safety program relative to the benefits that it is expected to achieve.

FDA disagrees with the contentions in the comments. The quoted provision is concerned with regulations specifically concerning the National Shellfish Safety Program (NSSP). Neither the statutory language nor its legislative history evinces any intent to require additional scrutiny of regulations of broader impact that do not concern NSSP or otherwise single out the shellfish industry. In any event, FDA's economic analysis of the regulations' effect on the food industry, including the shellfish industry, shows that industrywide the compliance costs are between \$272,000 and \$623,000 per year. A copy of FDA's analysis is on file

in the administrative record of this proceeding.

10. Several comments requested that the CGMP regulations for cacao products and confectionery (21 CFR Part 118), which FDA proposed to revoke on September 7, 1979 (44 FR 52257), be retained because they satisfactorily set forth all the necessary elements for the sanitary manufacture and distribution of confectionery and chocolate products. One comment suggested that FDA incorporate into the umbrella CGMP regulations some of the unique features found in Part 118.

FDA proposed revocation of Part 118 because many of the requirements of Part 118 were incorporated in the proposal to amend Part 110, the umbrella CGMP. Elsewhere in this issue of the Federal Register, the agency is revoking the CGMP regulations for cacao products and confectionery, proposing to revoke CGMP regulations for frozen raw breaded shrimp, as well as withdrawing the proposed CGMP regulations for bakery foods and for peanuts and tree nuts.

11. Several comments requested clarification of whether the umbrella CGMP regulations will be applicable to the retail food store industry.

FDA does not interpret the umbrella CGMP regulations as applicable to retail food establishments. Although FDA's regulatory authority extends to food held for sale after shipment in interstate commerce, the agency has concentrated its regulatory efforts on ensuring the safety and sanitation of food up to the point when it reaches the retailer. In the Federal Register of July 23, 1982 (47 FR 31964), FDA announced the availability of a model retail food store sanitation code intended for adoption by State and local governments. The model code provides uniform food protection requirements for the operation of retail food stores.

Definitions

12. A number of comments on proposed § 110.3 suggested that definitions for microorganisms, rapid growth, ingredients, initial distribution, contamination, lot number, packaging lot, confectionery, process, processes, control, raw materials, raw food, and packaging lot be added to the definition section. Several comments suggested that raw materials be differentiated from ingredients. Some comments stated that the umbrella CGMP regulations should be concerned only with microorganisms of known adverse public health significance.

FDA believes that most of the terms are commonly understood. The term "microorganisms," however, seems to be

misunderstood. Accordingly, FDA has added to the final rule § 110.3(i) which defines microorganisms as including yeasts, molds, bacteria, and viruses. The paragraph also defines the term "undesirable" microorganisms to be not just those that are of public health significance but also those 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. The regulations are designed to prevent the growth of undesirable microorganisms. The scope of the definition is not limited to microorganisms of public health significance because these regulations are also concerned with sanitation, decomposition, and filth.

Regarding the second point, it is not possible to categorically distinguish between raw materials and other ingredients because raw materials are ingredients, and both raw materials and ingredients are food within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). To stress this fact, FDA has added a definition for "food" to the regulations. The definition provides, correctly, that "food" includes raw materials and other ingredients. For emphasis and clarity, however, FDA often in the preamble and the final rule refers to "raw materials" or to "ingredients" as appropriate.

FDA also has added a new definition for "pest" (§ 110.3(j)). This definition eliminates any confusion as to the scope of the regulations that may have been caused by the agency's use of such terms as vermin, rodents, insects, etc.

Also, on its own initiative, FDA has modified the definition of "food-contact surfaces" in § 110.3(g). The definition now provides that food-contact surfaces also include utensils and food-contact surfaces of equipment.

13. Several comments suggested that, for clarity and comprehensiveness, the definition in proposed § 110.3(a) on acid foods or acidified foods be made the same as the definitions in the acidified foods CGMP regulations (21 CFR 114.3 (a) and (b)).

The proposed definition for "acid foods or acidified foods" is adequate for these regulations. The more comprehensive definition of acidified foods in 21 CFR Part 114 is necessary to inform processors of the scope of those regulations. The term proposed for the umbrella CGMP regulations is more general because it covers current good manufacturing practice for all foods. Therefore, FDA is making no change in the final rule.

14. One comment suggested that the definition should include only foods with an equilibrium pH of 4.5 or below instead of the 4.6 proposed. No reason was given for the suggested change. The acidified foods CGMP regulations (21 CFR Part 114) defines acid foods and acidified foods as those having a pH of 4.6 or below. This definition has been satisfactory to the agency and industry alike. Therefore, because the comment offered no reason for the suggested change to a pH of 4.5, FDA is making no change in the final rule.

15. Several comments considered the definition of "adequate" in proposed § 110.3(b) to be vague. Two comments were concerned that processors could be subject to inequitable interpretations, depending on the FDA investigator conducting the inspection. Two comments suggested that the definition be changed to "that which is needed to accomplish the intended purpose set forth in the guidelines of this part" instead of " * * * the intended purpose in keeping with good public health practices" as proposed.

The agency recognizes the need for consistency in its inspection programs. Accordingly, FDA thoroughly trains its investigators on how to conduct an inspection and how to interpret and apply the regulations. To further ensure that actions taken by FDA are consistent nationwide, FDA District Offices submit proposed regulatory actions to FDA Headquarters for review and concurrence before regulatory action may be taken. Inconsistent interpretations of the definition of "adequate" are not likely to occur.

FDA does not agree with the suggested change in wording. Although 21 CFR Part 110 contains advisory information, it also specifies requirements that must be met to produce safe and wholesome food and, therefore, is not a guideline. For these reasons, FDA has not made the requested change in the final rule.

16. Several comments requested that batter for bakery items be added to the definition in proposed § 110.3(c).

FDA agrees and has changed the definition accordingly.

17. A number of comments requested that the definition for blanching be amended in proposed § 110.3(d) to permit blanching by dry heat. It also was noted that blanching is used for purposes other than the inactivation of enzymes.

FDA agrees and has changed the definition accordingly.

18. One comment pointed out that proposed § 110.3(d) is inconsistent with the word usage under 21 CFR

164.110(e)(2) concerning the blanching of peanuts.

FDA agrees and has excluded tree nuts and peanuts from this definition in the final rule.

19. A number of comments suggested that the term "corrosion-free" in proposed § 110.3(e) be defined as "corrosion-resistant" or "free of visible rust or scale build-up."

FDA agrees that "corrosion-resistant" is the more appropriate term. FDA believes, however, that as now worded, the term is self explanatory. Accordingly, FDA has deleted the definition from the final rule.

20. One comment suggested that "critical control point" in proposed § 110.3(f) should not be used in the umbrella CGMP regulations because it has a specific definition in training schools and textbooks, in connection with canned foods. The comment also mentioned that the definition used in the umbrella CGMP is slightly different from that given by FDA officials in public statements.

The critical control point concept is significant for all food, not just canned foods. The agency agrees, however, that the definition proposed should more closely reflect FDA's previous use of the terminology. FDA has revised § 110.3(e) of the final rule accordingly.

21. One comment suggested that the applicability of "food-contact surfaces" in proposed § 110.3(g) be restricted to human foods.

The title of the regulations makes it clear that the regulations apply only to "human" foods. FDA has clarified the definition in the final rule so that, in any event, there should be no misunderstanding concerning its scope.

22. Several comments suggested that the size, type, and style of product should not be included in the definition of "lot" in proposed § 110.3(h). Many of these comments recommended that the definitions of lot in 21 CFR 113.3(m) and 114.3(c) would be more appropriate in this regulation. A number of comments expressed the opinion that the responsibility for determining lot size should be with the manufacturer. The size of a lot varies greatly in the food industry and the purpose of any given lot size is to allow segregation of products into identifiable lots that can be effectively recalled from the market. Comments also suggested that lot size should not be limited to a day's production. Other comments suggested that a lot size should be the production of 3 days or a week or more.

FDA agrees that the manufacturer has the primary responsibility for determining the size of a lot. However, FDA also is responsible to oversee the

conduct of recalls and, as the comments recognized, a purpose of designating a lot is to facilitate recalls of a product. In that context, FDA believes that a manageable lot size is advantageous to the manufacturer and the agency. FDA has structured the regulations accordingly. FDA agrees that the definition of lot should be more consistent with FDA practice, and is adopting in this final rule a definition of "lot" that is compatible with that found in 21 CFR Parts 113 and 114.

23. Several comments on proposed § 110.3(h) suggested changing the term "lot" to "consignment" or "batch" in order to be consistent with the terminology in their particular industries.

FDA understands that the term "lot" is most widely used by the food industry, and, therefore, has not incorporated the suggested changes in the final rule.

24. Several comments said that the definition of "plant" in proposed § 110.3(i) (§ 110.3(k) of the final rule) is too broad. The comments pointed out that it would cover all food storage and display facilities of warehouses and retail stores as well as processing facilities, even though in these facilities foods are received in prepackaged form and there may be little or no possibility of contamination of food.

The definition of plant in proposed § 110.3(i) is broad, intentionally. The comments are correct that the definition extends to facilities where there is the possibility of contamination of food and, therefore, applies to facilities where even foods in prepackaged form are received.

Although the definition could apply to retail establishments, FDA does not so interpret the provision.

25. A number of comments on proposed § 110.3(j) "quality control operation" (§ 110.3(l) of the final rule) asserted that it is impossible to ensure that finished food is "free" from adulteration. They pointed out that the purpose of a quality control operation is to minimize contamination in the manufacturing process to the greatest extent possible to reduce the possibility of adulteration in the finished food. One comment requested that the word "ensure" be changed to read "insure that the food is safe and wholesome."

FDA believes that the primary purpose of a quality control operation is to provide a systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act. FDA has revised the definition to clarify this point. See also the agency's response to comment 125.

26. One comment asked whether the definition of quality control reflects recognition of the variety of tests and control procedures that may be used for manufacturing and marketing purposes.

FDA advises that, as discussed above, for the purpose of these regulations, the definition of a quality control operation is limited to actions necessary to prevent food from being adulterated within the meaning of the act. The agency encourages manufacturers to expand these quality control operations to incorporate other procedures to ensure that the quality attributes of the food are maintained throughout production and storage.

27. Another comment suggested replacing the term "quality control operation" with "sanitation control operation" to emphasize that safety measures are a sanitation function.

FDA agrees that an adequate quality control operation carries with it many sanitation responsibilities. However, the agency does not agree that the phrase "sanitation operation" is an appropriate replacement for the proposed phrase "quality control operation." The umbrella CGMP regulations apply to both insanitary production conditions and other practices that might cause food to be adulterated.

28. Several comments on proposed § 110.3(k) "rework" (§ 110.3(m) of the final rule) requested that the definition allow the use of food that can be considered safe and wholesome only after proper treatment or reprocessing.

FDA points out that food that is adulterated because it contains undesirable microorganisms often cannot be successfully reconditioned but agrees that where food has been satisfactorily reconditioned it can be included in the term "rework." FDA has changed the definition accordingly.

29. One comment on proposed § 110.3(k) stated that the definition for rework is vague and asked for clarification of the point at which food would be removed for "rework."

FDA is rephrasing the definition to make clear what is included. However, it would be inappropriate to state the point at which food is to be removed to become "rework." Various manufacturers have different needs concerning "rework," and manufacturers should have the flexibility to use the term in a manner consistent with accepted usage for given operations.

30. One comment on proposed § 110.3(1) "safe-moisture level" (§ 110.3(n) of the final rule) recommended deleting the definition. The comment argued that for purposes of microbial control the concept of

"water activity" (a_w) best reflects the microbial availability of water in a food system and therefore should be the criterion upon which to estimate microbial stability.

FDA disagrees. The definition of "safe-moisture level" is necessary to properly interpret a_w as used in § 110.80(b)(14) because different a_w 's are required to attain a safe moisture level in different foods.

31. Several comments on proposed § 110.3(l) suggested enlarging the definition of safe moisture level to include the level of moisture necessary to prevent the growth of undesirable microorganisms "under the intended condition of processing, storage, and distribution." These comments argue that this change, plus a new definition for "microorganisms," would aid manufacturers in setting appropriate levels.

FDA agrees and has changed the definition to include the level of moisture.

32. Some comments on proposed § 110.3(1) suggested that a particular a_w be considered adequate if data exist in the literature or in company files showing that the a_w is safe for a particular food, rather than requiring the manufacturer to provide such data.

FDA agrees and is replacing the word "provided" with "available" in the final rule.

33. One comment on proposed § 110.3(l) stated: "This definition should be specified, i.e. 'semi-moist' or 'intermediate moisture' type foods. This designation would clarify the difference between foods with naturally high moisture contents and those with lowered (a_w 's) that have been designed for that purpose."

FDA does not agree that the designations are necessary in this regulation. Identification of points like "semi-moist" or "intermediate moisture" along a gradient from a "natural" or "normal" moisture level to the safe moisture level is unnecessary in a document that is intended to specify the point at or below which microorganisms will not grow. Therefore, FDA has not changed the final rule in this regard.

34. Several comments on proposed § 110.3(m) "sanitize" (§ 110.3(o) of the final rule) requested that the definition be revised to refer to effective means of reducing the number of microorganisms because there is no method available to demonstrate absolute destruction of microorganisms.

FDA advises that the definition of "sanitize" relates to a process that is effective in destroying or reducing the number of microorganisms. The definition does not purport to include

the total destruction of microorganisms. Therefore, FDA has made no change in the final rule.

35. One comment on proposed § 110.3(m) suggested that because "The GMPs repeatedly distinguished non-food contact surfaces (see, for example, §§ 110.35(c)(3) and 110.40(a)), it is appropriate that the definition of 'sanitize' contain the inclusive term 'food contact surfaces.'"

FDA agrees and has changed the definition accordingly.

36. One comment on the meaning of proposed § 110.3(n) (§ 110.3(p) of the final rule) suggested that, in the definition of "shall," the term "mandatory requirements" be changed to "food safety requirements."

The umbrella CGMP regulations pertain to more than food safety. For example, the regulations are also concerned with contamination by filth or decomposition which may or may not raise safety concerns. Therefore, FDA has not changed the final rule.

Current Good Manufacturing Practice

37. Some comments on proposed § 110.5 suggested deleting the reference to section 402(a)(3) of the act which provides that a food is adulterated if it has been manufactured under such conditions that it is unfit for food. One comment stated that a food may be unfit due to many things, including changes in texture, flavor, etc., and still not be adulterated.

The comments reflect a misunderstanding of the meaning of proposed § 110.5. Section 402(a)(3) of the act states that a food is adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; * * *". FDA agrees with the comment that a product is not unfit for food because it fails to meet the flavor or texture standards of the manufacturer. Other aspects of the food, however, e.g., contamination with pests, might render it unfit within the meaning of section 402(a)(3) of the act. FDA, therefore, has not changed the final rule.

38. Two comments on proposed § 110.5(b) read this paragraph to provide that the umbrella CGMP regulations are intended solely to prevent and control communicable diseases. A related comment suggested that the reference to the prevention and control of communicable diseases be combined with § 110.5(a) to include the concept of complying with section 361 of the Public Health Service Act, as well as avoiding adulteration within the meaning of section 402(a) (3) and (4) of the act.

FDA believes that the first set of comments have misinterpreted this section. The umbrella CGMP regulations are not designed solely to prevent and control communicable diseases, but are also designed to prevent food adulteration within the meaning of the act. Accordingly, the regulations apply to food that may be harmful as well as to food that may be contaminated, in whole or in part, with filth. As suggested by the one comment, the portion of § 110.5(b) concerning section 361 of the Public Health Service Act has been reworded and is a part of § 110.5(a) in the final rule.

Personnel

39. Several comments on proposed § 110.10(a) "disease control" objected to the proposed requirement that a person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or any other abnormal source of microbial contamination be excluded from working in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated or of disease being transmitted by that person to other individuals. Two comments stated that compliance with the proposed requirement is essentially impossible because a disease may be present in its communicable stage before symptoms are discernible to plant management. One comment noted that this requirement would prevent individuals having mild communicable diseases, such as upper respiratory tract infections, from working in an area such as the boiler room due to the possibility of transmitting this infection to a fellow worker in this same nonfood handling environment. The comment requested that the scope of the requirement be limited to food-borne transmission. Another comment described the "virtual inability of plant management personnel to detect workers with sores or boils covered by clothing * * *"

FDA agrees that the provision should be clarified. The goals of the proposed requirement are met and the concerns expressed in the comments alleviated by changing the final rule to read as follows: "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 this condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors." This wording does not mandate that medical examinations be performed in order to comply with the requirements of § 110.10(a).

40. A number of comments on proposed § 110.10(b) "cleanliness" stated that the term "proper outer garments" is vague and should be deleted or clarified. Another comment suggested that the words "clean and" be added after the word "wearing."

In response to the comments, FDA is changing § 110.10(b)(1) to read as follows: "Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials."

41. Two comments on proposed § 110.10(b)(2) suggested either deleting the phrase "a high degree of" in the proposed statement, or replacing it with "adequate."

FDA agrees and has changed the provision accordingly.

42. One comment on proposed § 110.10(b)(3) suggested revising it to require that hands be washed thoroughly to prevent contamination by "unsafe" microorganisms, not "undesirable" microorganisms as proposed. The comment related this proposed change to other comments urging that FDA be concerned only with microorganisms that are "present at a level sufficient to be of recognized adverse public health significance." The comment asserted that " * * * relatively harmless microorganisms which may cause spoilage but not a health risk should not require the same action."

Because these regulations are based on section 402(a) (3) and (4) of the act, as discussed above, the agency has not limited the application of the regulations only to microorganisms that may be injurious to health. A food may be adulterated under the act if it contains any filthy substance or if it has been prepared, packed, or held under conditions where it may have become contaminated with filth. Accordingly, the word "undesirable" is more consistent with legal requirements than the word "unsafe." Therefore, FDA has not revised § 110.10(b)(3) as requested.

43. One comment addressing proposed § 110.10(b)(4) suggested that jewelry be removed when employees are in food-handling areas where such jewelry "could fall into production handling equipment or empty product containers * * *"

FDA agrees with this comment and also believes that the requirement

should be expanded to include other objects that could fall into equipment or containers. FDA has made appropriate changes in the final rule.

44. One comment favored a prohibition on all jewelry in food-handling areas, while another comment requested that the phrase "or cover with a sanitary glove" be added to accommodate hand jewelry which could not be adequately sanitized.

FDA recognizes that some hand jewelry may not be readily removed, but can be prevented from becoming a source of contamination by sanitizing or by the use of a sanitary covering, such as a clean, sanitized, nonporous glove. Therefore, it is not necessary to prohibit all jewelry in food-handling areas when such items can be prevented from being a source of contamination. FDA agrees that provision should be made for effective covering of hand jewelry and has changed § 110.10(b)(4) of the final rule to that effect.

45. Some comments on proposed § 110.10(b)(6) requested that the paragraph be reworded to eliminate specific examples of hair restraints, such as caps, which these comments did not believe to be effective hair restraints. Several comments stated that some manufacturers maintain restrictive standards and do not allow employees to wear beards or mustaches while working in the plant. These comments suggested that a "broad performance standard" be adopted to allow for the differing policies of various manufacturers. Other comments requested that the final regulation be changed to exempt individuals employed in plant operations where there is no reasonable possibility of their hair contaminating either the food or food-contact surfaces.

It is the manufacturer's obligation to see that effective measures are taken to prevent the adulteration of food. When a manufacturer believes that the use of a particular hair restraint, such as a cap, is ineffective under the conditions of a particular operation, or that the wearing of beards or mustaches will adversely affect the integrity of the food manufactured at that specific installation, the manufacturer must adopt suitable controls. The requirement in no way restricts management from taking appropriate, positive action. The requirement does recognize, however, that in some food-manufacturing operations use of the enumerated hair restraints is an effective means of protecting against contamination of the food. Section 110.10(b) of the final rule requires hair restraints only where a reasonable possibility of contamination

from hair exists. In light of the apparent potential for misinterpretation of the scope of these requirements, FDA has changed § 110.10(b)(6) in the final rule so that this item in the list of methods of maintaining cleanliness reads as follows: "Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints."

46. A number of comments addressing § 110.10(b)(7) suggested that the wording of the requirement prohibiting the storage of clothing or other personal belongings in areas where food is exposed, or in areas used for washing equipment or utensils, be changed to a positive instruction. These comments also suggested that plant management be required to designate areas for the storage of personal belongings.

FDA agrees and has changed § 110.10(b)(7) in the final rule so that this item in the list of methods for maintaining cleanliness reads as follows: "Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed." FDA believes that the comments' request for the language stating that the storage areas for belongings be only those designated by plant management is not sufficiently specific, and therefore FDA has made no change in the final rule in this regard.

47. A number of comments on proposed § 110.10(b)(8) requested that the prohibition against the consumption of food and beverages and the use of tobacco in areas where food is exposed, or in areas for washing equipment or utensils, be changed to a more positive directive, and that these activities be limited to designated areas. Two comments were concerned that chewing gum be among these restricted activities.

FDA has changed § 110.10(b)(8) in the final rule in response to these comments. Also, chewing gum in areas where food is exposed now is a restricted activity.

48. One comment suggested that language be added to § 110.10(b)(8) to clarify that taste testing is allowed in certain areas, to ensure production of a palatable and acceptable product.

FDA recognizes that certain industries use taste testing as a routine quality control operation to ensure that certain textural and flavor characteristics are present in the food. Section 110.10(b)(8) does not prohibit taste testing provided it does not cause food to be adulterated within the meaning of the act. Accordingly, no change in this provision is needed.

49. Two comments on proposed § 110.10(c) "education and training"

requested that personnel responsible for identifying sanitation failures or food contamination be required to have a background of education or experience and that food handlers and supervisors be required to have appropriate training in the principles of food sanitation.

The agency believes that the provisions of this section, if properly applied, are sufficient to maintain our supply of clean and safe food. More education of food handlers is always desirable, but is not always necessary.

50. A number of comments on proposed § 110.10(d) "supervision" requested that the proposed mandatory requirement that competent supervisory personnel be assigned the responsibility for assuring compliance by all personnel with the requirements of these regulations be changed to an advisory statement. Other comments noted that experienced educators and supervisors within the plants need to be competent sanitarians as well.

The agency does not agree that paragraph (d) should be merely advisory. For plant personnel to comply with the requirements for current good manufacturing practice, they must be instructed and supervised by adequately informed plant personnel. Although FDA cannot require that supervisors be trained sanitarians, even though that training is desirable, there is little chance of compliance with the many requirements of these regulations without the clear designation of responsibility for these supervisory functions to qualified persons. Therefore, FDA has made no change in the final rule.

Exclusions and Exemptions

51. Several comments on proposed § 110.19 "exclusions" objected to excluding any operation from coverage under these regulations because consumers deserve the same protection from "raw agricultural commodities" as that expected from food-processing establishments. One comment asked whether the holding or transportation of shell oysters before further processing is an excluded category.

FDA advises that because these regulations are concerned specifically with the manufacturing, packing, and holding of foods it is not reasonable to apply them to raw agricultural commodities. Accordingly, raw agricultural commodities, as defined by section 201(r) of the act (21 U.S.C. 321(r)), will continue to be regulated simply under the adulteration provisions of the act (section 402) and not under these regulations. FDA further advises that oyster shell stock prior to receipt at a processing plant is similarly excluded

from the umbrella CGMP regulations and is regulated under the adulteration provisions of the act.

52. Comments from representatives of specific industries or manufacturers sought exemption of their particular operations. For example, the bakers' association challenged the necessity for good manufacturing practice regulations for their industry in light of the allegedly low health risks associated with bakery foods and the cost of implementing the regulations. Similarly, the molluscan shellfish industry argued that the safety and quality of shellfish are adequately controlled under the National Shellfish Sanitation Program, enforced by State control agencies. The shellfish industry generally urged an exemption for it or alternatively, the addition of a grandfather clause that would allow processors who are producing safe shellfish to continue their present methods of operation.

Likewise, the wine and beer industries emphasized that because they are under the jurisdiction of the Department of the Treasury's Bureau of Alcohol, Tobacco and Firearms they should not be required to comply with FDA's umbrella CGMP regulations. The wine industry added that its voluntary sanitation program provides adequate protection. Soft drink bottlers and their trade associations argued for exemption from the coding and recordkeeping regulations on the grounds that their present methods allow for prompt product recall. Similar arguments were put forth by bakers and other producers of products subject to frequent delivering and frequent removal of outdated merchandise. Ice producers and salt producers also asked for exemption on the ground that their products are less subject to contamination affecting health. Similarly, the dairy industry sought exemption on the ground that sufficient controls already exist to protect the public from unhealthful dairy products. Honey producers also claimed their products are unlikely to be contaminated and, therefore, the proposed regulations should not apply to the honey industry.

FDA is not granting any blanket exemptions as requested by these comments because it believes that the regulations as modified establish reasonable sanitation and health standards for the food industry generally, including those that requested exemptions. Each industry that commented is involved in food manufacturing and, therefore, is subject to the adulteration provisions of the act, as well as to the provisions of the final

rule. This is true even of the wine and beer industries. *CF. Brown-Foreman Distillers Corp. v. F. David Mathews, Secretary of Health, Education, and Welfare*, 435 F. Supp. 5, 6 fn. 2 (W.D. Ky. 1976). Most requests for exemption pertained to the proposed coding and recordkeeping requirements, which the agency has decided not to require.

Plants and Grounds

53. Two comments on proposed § 110.20(a) "grounds" suggested deletion of the sentence "The methods for adequate maintenance of grounds include, but are not limited to:" and subparagraphs (1), (2), and (3) that followed on storing equipment, maintaining roads, draining areas, and related practices, intended to protect against the contamination of food. The comments asserted that the word "shall," which introduces the "grounds" requirement, is incompatible with the language "but are not limited to," which follows. The comments also contended that the phrase "but are not limited to" would open numerous conditions to interpretation.

FDA disagrees. The examples cited describe some ways that a manufacturer can protect food from contamination. Obviously there are many other things that a manufacturer can do, but it is not possible to list all of these. The phrase "but are not limited to" merely points out that the examples cited are not all inclusive. The agency sees no conflict between the mandatory "shall" and the phrase "but are not limited to." Therefore, FDA has not changed the final rule in this respect.

54. One comment on proposed § 110.20(a)(2) requested clarification of the paragraph pertaining to "the maintenance of roads, yards and parking lots * * *." The comment specifically asked whether the plant and grounds areas must be paved and to what extent dust constitutes a source of contamination.

The manufacturer is responsible for the adequate maintenance of roads, yards, and parking lots to ensure that the finished food product is clean, safe, wholesome, and, among other things, free from undesirable microorganisms. Whether to pave the area surrounding the plant is the manufacturer's prerogative. The extent to which dust may constitute a source of contamination depends upon many factors (e.g., plant location and the particular food). FDA considers, therefore, that paving parking lots to prevent dust from being a source of contamination under certain circumstances is consistent with current

good manufacturing practice. Therefore, FDA has not changed the final rule.

55. Two comments on proposed § 110.20 suggested adding a provision for waste treatment or disposal because it is an important part of plant maintenance.

FDA agrees and has added to the final rule new § 110.20(a)(4) which provides: "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."

56. One comment on proposed § 110.20(b) "plant construction and design" suggested that the proposed sentence, "Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-processing purposes," be deleted. Another comment on this provision urged that the "shall" be changed to "should."

FDA disagrees. FDA believes the sentence is not only appropriate, but also instructive. The comment provided no information to alter FDA's belief that the design of a plant in which food is manufactured must facilitate maintenance and sanitary operations. Therefore, FDA has not accepted the suggested change.

57. Several comments on proposed § 110.20(b)(2) interpreted this paragraph to require a separation by location of the various operations enumerated in paragraph (b)(2) (i) through (vii) (receiving, raw material storage, etc.). The comments stated that to create additional partitions would add to sanitation hazards (by catching dirt and dust and by providing harborage for pests). Other comments suggested deletion of the list of the various operations.

Several comments expressed concern that misinterpretation of this paragraph could result in burdensome and unnecessary demands upon food manufacturers. For instance, comments noted that an inspector could construe each of the illustrated operations as mandatory. The comments stated that the language in the proposed provision, "The potential for contamination may be reduced by any effective means including the separation by location, partition, air * * * or other effective means" was ambiguous in that it could be read either of two ways: "(1) as using the separation of operations merely as an example or illustration, or (2) as saying that any such effective means must include such separation." One of the comments contained a proposed amendment to correct any possible

misunderstanding: "The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design including the separation by location or time, or partition, or air flow, or enclosed systems, or other effective means * * *."

FDA agrees with the comments and has adopted the suggestion in revised form in the final rule.

58. One comment on proposed § 110.20(b)(3) requested exempting wine fermentation processes from the requirements of paragraph (b)(3) (i) and (iv). The comment stated that all new wine fermenters are closed, but that some members of the industry still use open fermenters. A requirement that they be covered or replaced would create a genuine hardship for many of the smaller wineries. Further, the comment stated that wine subsequently undergoes a number of processes such as racking, filtration, and centrifugation, prior to its bottling. Therefore, any foreign material which might have entered the product during fermentation would be removed. This and another comment stated that it is not always necessary to skim fermentation vats and suggested changing "frequently" to "where appropriate."

This paragraph of the regulations requires that manufacturers take proper precautions for protecting products in outdoor bulk fermentation vessels. The paragraph does not require that any specific practice be followed. Rather, the paragraph merely suggests what practices may be appropriate, i.e., using protective coverings; controlling areas over and around the vessels to eliminate harborage for pests; checking on a regular basis for pests and pest infestation; and skimming the fermentation vessels, as necessary. Therefore, it is unnecessary to exclude the wine industry in the final rule. FDA agrees that it is not always necessary to skim fermentation vats and is replacing "frequently" with "as necessary" in the final rule.

59. One comment on proposed § 110.20(b)(4) interpreted this paragraph to require that establishments "essentially hose down areas" to clean them, and objected that water is not compatible with the processing of salt.

The comment construed the provision too narrowly. FDA considers acceptable any adequate means of cleaning and, therefore, has not changed the final rule.

60. One comment described proposed § 110.20(b)(4) as vague. Others requested modifying this paragraph to read in part: "aisles or working spaces between equipment and walls shall be

adequately unobstructed and of adequate width to permit employees to perform their duties and to minimize the potential for contamination of food or food-contact surfaces with clothing or personal contact."

FDA agrees, in principle, and has changed the final rule accordingly.

61. One comment on proposed § 110.20(b)(6) suggested that the reference to "steam" as a "noxious fume or vapor" is contrary to the traditional use of steam in food processing.

FDA agrees and has changed the final rule.

62. One comment on proposed § 110.20(b)(6) suggested changing this paragraph to state that fans and other air-blowing equipment shall be located and operated in a manner that "minimizes the potential to cause contamination of raw materials, work-in-process, rework, finished foods, food-packaging materials, and food-contact surfaces."

FDA agrees and has changed the final rule accordingly.

63. Several comments on proposed § 110.20(b)(7) suggested that "adequate" be substituted for "effective" screening against pests because "adequate" is defined in § 110.3(b), and because it would be consistent with other parts of the regulation.

FDA agrees and has changed the final rule accordingly.

Sanitary Operations

64. One comment on proposed § 110.35(a) "general maintenance" suggested that the requirement that the buildings, fixtures, and other physical facilities be kept "in good repair" should be eliminated because the quoted phrase may be subject to a variety of interpretations. The comment suggested that a statement requiring that these items be kept in a sanitary condition would be sufficient.

FDA agrees and has changed the first sentence of the final rule to read as follows: "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."

65. One comment on proposed § 110.35(a) (§ 110.35(b) of the final rule) suggested the deletion of the requirements dealing with (1) the microbial quality, the safety, and the efficacy of cleaning and sanitizing chemicals; (2) the storage of toxic materials in the plant; and (3) the prevention of contamination of food and food-packaging material from the use and storage of cleaning compounds, sanitizing agents, and pesticide

chemicals. The comment reasoned that the proposed requirement that all applicable regulations of the Environmental Protection Agency (EPA) be followed "basically encompassed" the requirements enumerated in the proposed regulation.

FDA cannot compel manufacturers to comply with requirements that FDA cannot enforce. FDA is changing the sentence regarding EPA regulations from mandatory compliance to advisory compliance with all regulations promulgated by Federal, State, and local government agencies other than FDA, provided of course that the regulations are applicable to the umbrella CGMP regulations. However, FDA is retaining the specifically mentioned subjects of concern in the final rule, because failure to comply with these requirements may adversely affect the safety and wholesomeness of food.

66. Several comments on proposed § 110.35(a) concerned the sentence which read: "Detergents, sanitizers and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses." One comment suggested that it is impractical to test detergents for contamination with microbial contamination. Another comment argued that users should be able to rely on the claims or warranties of the manufacturers of these products to satisfy the requirements of the regulations.

FDA is aware that many businesses do not have the resources to verify, through in-house testing procedures, that the cleaning and sanitizing chemicals they employ are of acceptable microbial quality and are safe and adequate for their intended use. For this reason, FDA is adding to § 110.35(b)(1) of the final rule a sentence allowing compliance with the requirement to be verified by any effective means, including purchase under a supplier's guarantee or certification, or examination of these materials for contamination.

67. Two comments on proposed § 110.35(a) suggested that the term "effective" be changed to "adequate." One comment argued that this change is appropriate because an absolute absence of contamination may be unattainable. The comment added that it is important to require that every necessary effort be made to minimize contamination.

FDA agrees and has changed § 110.35(b)(1) of the final rule accordingly.

68. A number of comments on proposed § 110.35(a) noted that the term "plant" could be misinterpreted to

include warehouses and distribution centers.

FDA agrees and has modified the last sentence in § 110.35(b)(1) in the final rule to read as follows: "Only the following toxic materials that are required to maintain sanitary conditions 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 manufacturing operations." FDA advises that requirements regarding maintenance of acceptable conditions specifically during warehousing and distribution are provided under § 110.93.

69. Two comments on proposed § 110.35(b) "animal and vermin control" (§ 110.35(c) "pest control" in the final rule) suggested that this paragraph be modified to exempt guard dogs and guide dogs, under certain conditions, from the requirements of the first sentence of the proposed paragraph.

FDA agrees and has added the following sentence to the final rule: "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."

70. One comment on proposed § 110.35(b) (§ 110.35(c) of the final rule) said that the sentence providing for the use of insecticides and rodenticides under precautions and restrictions that would protect against the contamination of food and food-packaging materials should be deleted since it duplicated existing EPA regulations.

FDA disagrees that the regulation results in an unnecessary requirement. Food that becomes contaminated with these compounds may be actionable under section 402 of the act. Accordingly, regulations specifying current good manufacturing practice for the food industry should stress the need for taking effective precautions in this area and are not duplicative. Therefore, the agency is retaining this sentence in the final rule.

71. Several comments on proposed § 110.35(c) (§ 110.35(d) of the final rule) concerned the proposed requirement that food-contact surfaces used for the processing or holding of low-moisture raw materials or food be in a dry, sanitary condition at the time of use. Some comments suggested that phrases such as "when necessary" or "where applicable" be added to this sentence, but failed to explain the reasoning behind the suggested addition. Other

comments remarked that, just as it is not always necessary to sanitize wet-cleaned surfaces before use, it is not always necessary to dry wet-cleaned surfaces thoroughly before subsequent use. Another comment noted that lubricants, and sometimes moisture, are necessary on certain food-contact surfaces during the baking process. The comments recommended that the phrase "...", unless otherwise required by the demands of the baking process itself" be added to this sentence.

FDA believes that all the concerns raised by these comments can be satisfied by the new wording of the second sentence: "When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use."

72. In reference to the requirement in proposed § 110.35(c)(2) (§ 110.35(d)(2) of the final rule) that food-contact surfaces be cleaned and sanitized after any interruption during which these surfaces may have become contaminated, one comment noted that "any interruption" could be read to include such routine events as quality control checks. Another comment stated that the word "interruption" must be defined as to time period.

FDA recognizes that the possibility of contamination exists even during short, scheduled interruptions, such as quality control checks. The agency does not agree that the length of time of the interruption is of central concern. What is important is whether the utensils and other food-contact surfaces may become contaminated. FDA has changed the final rule to clarify this point.

73. Two comments on proposed § 110.35(c)(2) (§ 110.35(d)(2) of the final rule) criticized the requirement that food-contact surfaces in a continuous production operation be cleaned and sanitized according to a predetermined schedule. The comments claimed that cleaning functions should be based on need, such as a change in bacterial levels, rather than lapse of time.

FDA agrees and has changed § 110.35(d)(2) of the final rule.

74. One comment on proposed § 110.35(c)(5) (§ 110.35(d)(5) of the final rule) suggested that the term "effective," in the proposed requirement that sanitizing agents be effective and safe under conditions of use, be changed to "adequate."

FDA agrees and has changed the provision.

75. One comment on proposed § 110.35(d) (§ 110.35(e) of the final rule) "storage and handling of cleaned portable equipment and utensils" suggested requiring that cleaned and sanitized equipment that has been

stored be rinsed and sanitized before subsequent use.

It is not always necessary to rinse and sanitize equipment with food-contact surfaces or utensils that have previously been cleaned and sanitized, if the equipment has been properly protected from contamination during storage. Therefore, the suggested change is not necessary and no such change is made in the final rule.

76. Another comment on proposed § 110.35(d) requested clarification of whether flour dust in a baking area is included in the phrase "other contamination" in the advisory statement that cleaned and sanitized food-contact surfaces should be stored in such a way as to protect these surfaces "from splash, dust, and other contamination."

The phrase "other contamination" refers to all other substances not specifically listed that may cause the food-contact surfaces to be considered insanitary. FDA does not consider airborne flour which settles on stored equipment to be a contaminant, unless it renders the surfaces of the equipment insanitary. Therefore no such change is made in the final rule.

Sanitary Facilities and Controls

77. One comment on proposed § 110.37 stated that this section should apply only to new construction and that compliance should be deferred for 2 years after the issuance of the final rule. The comment considered these changes necessary to protect small bakeries and to permit a period for design and construction of new facilities.

The proposed requirements of this section were essentially the same as the then existing requirements (21 CFR 110.35), with the exception of a new paragraph that prohibited backflow or cross-connection between piping systems that carry water for food processing and piping systems that discharge waste water or sewage. Because the requirements are not new, FDA believes that the effective date for this final rule provides adequate time for industry compliance.

78. One comment on proposed § 110.37(a) "water supply" suggested requiring that the water supply be obtained from a State-approved source and be monitored for bacterial and chemical contamination as required by the Safe Drinking Water Act, administered by EPA. The comment also suggested a requirement that any water used in the final rinse, fluming, and spray contact of the product or equipment be of potable quality.

FDA believes that the concerns raised by this comment are covered in the

wording of the final rule. The water supply is required to be sufficient for the operations intended and derived from an adequate source. Water contacting food or food-contact surfaces must be safe and of adequate sanitary quality.

79. One comment on proposed § 110.37(a) requested that the requirement that "running water at a suitable temperature and under pressure as needed shall be provided in all areas where required for the processing, the cleaning of equipment, utensils, or containers, or for employee sanitary facilities," be changed by replacing the phrase "at a suitable temperature" with the phrase "suitable and/or ambient temperatures." The comment stated that the use of hot water in a segment of the seafood industry would hinder effective cleaning operations.

The wording of the provision in no way prevents the use of water at ambient temperature for cleaning, provided the temperature is suitable for the specific conditions encountered. Therefore, FDA has made no change in the provision.

80. One comment on proposed § 110.37(b) "plumbing" asked whether all plants would be required to replace standard hand-operated toilets with foot-operated high-pressure sanitary facilities regardless of additional cost.

One should not draw this interpretation from the requirements. If the present plumbing and toilet facilities are adequate and do not present a source of adulteration to the food, they need not be replaced.

81. One comment on proposed § 110.37(b)(5) stated that the word "ensure" in the proposed requirement that there be no backflow from, nor cross-connection between, waste water or sewage systems and water systems for food or food-processing use, should be changed to "provide." The comment suggested the change to alleviate the concern that industry would routinely be obligated to furnish blueprints of plumbing systems. The comment added that this type of submission should not be required unless there is reasonable evidence of a possible contamination problem.

FDA agrees and has changed the final rule accordingly.

82. Also with regard to the requirement in proposed § 110.37(b)(5) that there be no backflow from, or cross-connection between, piping systems that carry water for food or food manufacturing use and piping systems that discharge waste water or sewage, two comments suggested reversing the proposed order in which the piping systems are mentioned.

FDA agrees and has incorporated the changes into the final rule.

83. One comment on proposed § 110.37(b)(5) requested that the phrase "waste water" in the requirement prohibiting backflow from, and cross-connection between, piping systems be defined or differentiated more clearly from the water used for food or food manufacturing. The comment noted the economic importance of the counter current flow design used in some industry processes and expressed concern that the proposed requirement would prohibit this accepted design.

Under the regulations, waste water is water contaminated to a level above that considered acceptable for use in food manufacturing. FDA believes that the modified wording, as discussed in previous paragraphs of this preamble, conveys this meaning. Therefore, FDA has not attempted to expand on the meaning of "waste water" in this requirement in the final rule.

84. One comment on proposed § 110.37(b)(5) requested permitting the use of existing plumbing facilities that are maintained in a sanitary manner because the expenditures necessary to assure that there would be no backflow from piping systems that discharge waste water or sewage into piping systems that carry water for food or food manufacturing use are not justified.

FDA disagrees. Interruptions in water pressure can draw water from nonpotable sources into the processing water supply system unless backflow prevention devices or other suitable means are in effect. FDA considers the points expressed in paragraph (b)(5) to be basic to manufacturing safe and wholesome food. For this reason, FDA has retained the substance and the spirit of this paragraph, as proposed, in the final rule.

85. Comments on proposed § 110.37(c) "sewage disposal" and § 110.37(f) "rubbish and offal disposal" stated that references to appropriate EPA regulations should be added to these proposed paragraphs. One of the comments stated that industry has difficulty locating various agencies regulations governing a specific operation.

FDA is sympathetic to the concerns expressed in the comments, but believes that other agencies need to be the source of information on their applicable regulations to ensure that the information provided is accurate and up-to-date. Accordingly, FDA has not added the requested citations in these regulations.

86. A number of comments on proposed § 110.37(d) requested that the provision allow, because of geographic

location or ground conditions, the location of toilet facilities outside the plant. One comment suggested providing only that the toilet facilities be readily accessible.

The agency agrees with the suggestion and has changed the final rule accordingly.

87. Two comments on proposed § 110.37(e) stated that the requirement of adequate and readily accessible hand-washing facilities and, if necessary, sanitizing facilities for employees handling unprotected food, unprotected packaging materials, and food-contact surfaces could be interpreted to require that hand-washing facilities be installed at receiving stations or in processing areas that could be adequately serviced by sanitizing stations. One comment suggested that the proposed requirement be replaced with the wording of the current CGMP regulations (21 CFR 110.35(e)).

FDA agrees in principle and has modified the final rule accordingly.

88. One comment on proposed § 110.37(e) suggested replacing the phrase "suitable drying services" in the requirement that specifies the components of a suitable handwashing and sanitizing facility, with the phrase "suitable drying devices." One comment requested that cloth towel dispensers be allowed as long as the towel dispensers are so constructed that only a clean and unused portion of towel is provided for each use.

FDA agrees with the comments and has changed the final rule accordingly.

89. Several comments on proposed § 110.37(e) objected to the specificity of "water control valves." One comment interpreted this phrase to describe only foot-operated control valves and stated that these valves are notorious for harboring undesirable microorganisms.

In response to these comments, FDA has expanded the scope of this paragraph to suggest the use of devices or fixtures, such as water control valves, that are designed and constructed to protect against recontamination of clean, sanitized hands. The phrase "water control valves" should not be interpreted as limited to foot-operated valves. For example, valves of the automatic shut-off variety and wing fixtures designed for shut-off of the water flow by pressure from the elbow are other methods that are superior to traditional valves using manual shut-off in minimizing the possibility of recontamination. FDA has no information showing that the valve mechanism of foot-operated water control valves is a source of contamination. However, the agency

encourages anyone having such information to submit it to FDA.

Equipment and Utensils

90. Several comments on proposed § 110.40(a) objected to the proposed requirement that food-contact surfaces be "corrosion-free," suggesting that full compliance would be impossible.

FDA agrees and has substituted the term corrosion-resistant for corrosion-free in the final rule.

91. Some comments on proposed § 110.40(a) suggested that food-contact surfaces, while nontoxic, should be nonreactive with food components to prevent unwanted quality changes.

It is in the interest of the manufacturer to have food-contact surfaces that do not cause unwanted quality changes in food. Therefore, the final rule now requires that food-contact surfaces be made of nontoxic materials and designed to withstand the environment of their intended use.

92. One comment on proposed § 110.40(a) stated that daily cleaning of some equipment is not feasible because the equipment is of an enclosed nature and is operated at elevated temperatures for weeks at a time without shutting down.

The comment misunderstood what was proposed. However, FDA agrees that it is not necessary to clean such equipment on a daily basis as there is no opportunity for growth of microorganisms. However, it is current good manufacturing practice to clean equipment at a frequency that is sufficient to avoid potential contamination. Therefore, FDA is making no change in the final rule.

93. A number of comments on proposed § 110.40(b) objected to the proposed requirement that seams on food-contact surfaces be smoothly bonded.

The provision does not require smooth, bonded seams. As an alternative, seams on food-contact surfaces may be maintained so as to minimize accumulation of food particles, dirt, and organic matter. Therefore, FDA has made no change in the final rule in this respect.

94. One comment on proposed § 110.40(b) urged exclusion of baking pans and conveying systems from the requirement of this paragraph because wire mesh belting and metal "take-apart" joints of canvas conveyor belting, including metal seams, are in common use in the baking industry and do not cause problems.

The regulations allow the use of baking pans and the conveying systems mentioned, provided they are properly

maintained. Because more detail is not needed, FDA has made no change in the provision.

95. A number of comments on proposed § 110.40(d) suggested that it is not always necessary to clean a gravimetric, pneumatic, closed, or automated system. Another comment suggested that the requirement be changed from "to be cleaned" to "to be maintained in an appropriate sanitary condition."

FDA agrees with the comments and has changed the final rule to include the suggested wording.

96. One comment on proposed § 110.40(e) suggested that this paragraph be deleted or combined with proposed § 110.40(g).

FDA agrees and has modified § 110.40(f) of the final rule to combine the two paragraphs.

97. One comment said that proposed § 110.40(e) would apply to ethylene oxide treatment, making it difficult to demonstrate that a measuring device or control is effective in minimizing the growth of microorganisms in the product.

FDA advises that the basis for this comment has been mooted by the change discussed in paragraph 96 above.

98. One comment on proposed § 110.40(e) stated that FDA should suggest, but not require, that plants have temperature control equipment.

Because the regulation of temperature is important in protecting against the growth of microorganisms, FDA has retained the requirement for temperature controls.

99. Some comments on proposed § 110.40(f) (§ 110.40(e) of the final rule) suggested that FDA require temperature-recording devices or an alarm mechanism for all freezers and cold storage compartments rather than permit a thermometer for this purpose. Other comments stated that recorders and alarms should be required only for storage rooms at 45 °F or below and that bakeries do not need temperature-recording devices or alarms on small coolers.

Although it is desirable to have temperature-recording devices or alarms in freezers or cold storage compartments, FDA believes that an accurate thermometer is satisfactory for most coolers, regardless of whether they are kept at, above, or below 45 °F. The requirement for temperature indicating, measuring, or controlling devices applies only to freezing and cold storage compartments used for storing raw materials or foods capable of supporting the growth of microorganisms. Therefore, FDA has not changed the final rule.

100. One comment on proposed § 110.40(g) (§ 110.40(f) of the final rule) suggested that the word "precise" be changed to "accurate" in the proposed requirement that instruments used for measuring or regulating conditions that control or prevent microbial growth in food "be precise and properly maintained." Another comment requested that "properly" be changed to "adequately."

FDA agrees with the comments and has changed the final rule accordingly.

101. A number of comments on proposed § 110.40(h) (§ 110.40(g) of the final rule) pointed out that compressed air and other gases mechanically introduced into foods may already be suitable for contact with food or food-contact surfaces and may not need to be filtered or washed. The comments further suggested that, since air or gases are sometimes used to add oil or other ingredients to the food, "properly filtered or washed" should be deleted or modified.

FDA agrees and has changed the final rule accordingly.

102. FDA received two comments on proposed § 110.40(i). Section 110.40(i) pertains to the proper control of sources of PCB contamination. The comments suggested that the section should require the use of catchpans to control the leakage of PCB's from sealed electrical transformers and capacitors. The comments also requested clarification regarding what the proposed language "in and around food plant" was meant to include.

FDA has deleted proposed § 110.40(i) from the final rule. The proposed requirements are no longer necessary. In the Federal Register of August 25, 1982 (47 FR 37342), the Environmental Protection Agency (EPA) published a final rule that prohibits the use of PCB transformers with a dielectric fluid PCB concentration of 500 parts per million or greater posing an exposure risk to food or feed. The final rule became effective October 1, 1985. EPA's final rule also prohibits the use of large PCB capacitors after October 1, 1988, unless they are located in restricted access electrical substations or in contained and restricted access indoor installations. EPA's final rule provides, in FDA's view, sufficient safeguards against the risk of contamination of food and feed from PCB-containing electrical equipment. Accordingly, FDA has deleted proposed § 110.40(i). In the Federal Register of July 18, 1985 (50 FR 29233), FDA also withdrew a rule it proposed (45 FR 30984; May 9, 1980) to revise proposed § 110.40(i) and other regulations that deal with PCB's.

Processes and Controls

103. Some comments on proposed § 110.80, *Processes and controls* suggested deleting the reference to quality control operations because they are not always necessary and would add the unnecessary expense of placing a quality control person in each plant or of using an outside laboratory.

FDA disagrees. Even the smallest operation should have some quality control system that results in the production of safe, clean, and wholesome foods. This does not mean that the manufacturer needs to hire a quality control specialist, nor does it mean that an outside laboratory must be used. Therefore, FDA has made no change in the final rule with respect to quality control operations.

104. One comment on proposed § 110.80 suggested the addition of a listing of quality control operations.

FDA advises that it is not necessary to list all possible quality control operations because they include all actions necessary to prevent food from becoming adulterated within the meaning of the act.

105. Several comments on proposed § 110.80 requested that it allow the use of some raw materials that are not fit for food until they have undergone processing or have been processed into an ingredient that is then incorporated into the finished product. Another comment noted that quality control operations should be concerned with both raw materials and ingredients.

FDA agrees with both comments and has changed the final rule accordingly.

106. Some comments on proposed § 110.80 challenged FDA's authority to require that the maintenance of the sanitation of the plant be under the supervision of an individual assigned responsibility for this function. Other comments suggested that the regulations require that the individual assigned be competent. Another comment stated that the term "over-all" is too broad and requested that responsibility for sanitation be allowed to be assigned to more than one individual.

FDA believes that every plant must have one or more individuals responsible for the sanitation of the plant and the personal hygiene of the employees. Courts have observed that the act embodies the simple and understandable expectation of the American public that food be manufactured, packed, and held with a reasonable degree of cleanliness. See, e.g., *United States v. An Article of Food * * * Pasteurized Whole Eggs*, 339 F. Supp. 131, 141 (N.D. Ga. 1972).

Accordingly, courts have encouraged the development of reasonable plant standards specifying steps to be taken to ensure that a reasonable degree of care and cleanliness be accorded the manufacture of food. See, e.g., *United States v. 1,500 Cans More or Less*, * * *, 236 F.2d 208, 212 (7th Cir. 1956). The reasonable requirement that every plant assign one or more competent individuals as responsible for plant sanitation is, thus, clearly authorized.

FDA has made the final rule consistent with the latter comments to provide that the responsible individuals be "competent" and to clarify that the responsibility for the sanitation of a plant and the personal hygiene of the employees may be shared by several individuals.

107. One comment on proposed § 110.80 requested a more specific definition for the phrase "adequate sanitation principles."

The phrase must be broad so that industry can easily adapt adequate sanitation principles to its existing procedures. Therefore, FDA has not made the suggested change.

108. Some comments on proposed § 110.80 suggested that the sentence beginning with "chemical, microbiological or extraneous-material testing * * *" be expanded to include a phrase indicating that supplier's guarantee or certification be permitted to verify compliance with FDA regulations, guidelines, or action levels where applicable.

FDA disagrees. This paragraph refers primarily to sanitation within the plant. FDA has no objection to the manufacturer obtaining a supplier's guarantee or certification, as specifically mentioned in § 110.80(a) (2), (3), and (4).

109. A comment suggested that proposed § 110.80(a) state that although incoming raw materials and other ingredients should be inspected, as necessary, there are also other appropriate means of ensuring the cleanliness and fitness of ingredients.

FDA agrees and has changed the final rule accordingly.

110. A comment on proposed § 110.80(a)(1) suggested that there should be parallel programs by the U.S. Department of Agriculture (USDA) and the Interstate Commerce Commission (ICC) to cover the handling of raw materials and ingredients.

Although parallel programs are desirable, they are not a prerequisite to the proposed provision. Affected firms should contact USDA and ICC directly for information about their programs.

111. A comment on proposed § 110.80(a)(1) stated that the term "fit" is used in an unfamiliar context and

suggested that it be changed to "appropriate" or "suitable."

FDA agrees and has substituted "suitable" for "fit" in the final rule.

112. Other comments on proposed § 110.80(a)(1) questioned whether the proposed provision that "raw materials shall be washed or cleaned as required" applies to grapes and oyster shell stock.

FDA advises that the handling of grapes and oyster shell stock would be covered if they are used as raw materials in a food-processing plant. FDA has clarified the quoted language by changing "required" to "necessary" in the final rule.

113. Several comments on proposed § 110.80(a)(1) pointed out that the conservation of water used for washing, rinsing, or conveying is important. The comments urged that this water be allowed to be reused if any possible microbial contamination harmful to humans has been minimized.

FDA agrees and has changed the final rule to provide that water may be reused for washing, rinsing, or conveying products, so long as it will not increase the level of contamination of food.

114. A comment on proposed § 110.80(a)(2) suggested deleting this paragraph, and other comments suggested that the goal should be to "control" microorganisms not necessarily to "destroy" them.

FDA does not agree that the paragraph should be deleted. The requirement is important because the use of untreated raw materials and other ingredients may contain high levels of potentially toxic microorganisms. FDA agrees in principle with the other suggestions, and has changed the final rule to clarify that if raw materials and ingredients contain levels of undesirable microorganisms, they must either not be used or else must be pasteurized or otherwise treated during manufacturing operations to prevent the food from being adulterated within the meaning of the act.

115. A comment suggested that a supplier's guarantee or certification should be permitted to verify compliance with FDA regulations, guidelines, or action levels for raw materials.

FDA agrees and has changed the final rule accordingly.

116. Several comments on proposed § 110.80(a)(3) stated that there is a lack of technically efficient methods for determining the presence of aflatoxins in spices and many other raw materials. Some of the comments also stated that it would not be practical or necessary to test for aflatoxin in certain commodities. Some comments also argued that this

paragraph not apply to public warehouses.

Although there is a lack of adequate methods for determining the presence of aflatoxins in spices, methods do exist for other raw materials. Without further elaboration, the comment is too vague to respond to. FDA has, however, clarified the paragraph, which now provides:

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 products. 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.

This paragraph does not require public warehouses to test routinely for the presence of aflatoxins.

117. A comment on proposed § 110.80(a)(3) noted that USDA has an average limit of 25 parts per billion (ppb) of aflatoxin in its peanut certification programs, while FDA has established an action level for this substance at 20 ppb. The comment questioned whether a "USDA negative aflatoxin certificate" (i.e., aflatoxin not greater than 25 ppb) would be considered a supplier's certification in light of this difference in action levels.

Since 1969 FDA has taken the position that it will not object to movement in interstate commerce of lots of raw shelled peanuts with aflatoxins not exceeding 25 ppb, provided the peanuts are destined for further processing that will result in levels in the consumer product that meet the FDA guidelines. Therefore, a lot covered by such a USDA certificate and destined for further effective processing would satisfy the requirements of this section if the FDA requirements are met after further processing.

118. A comment on proposed § 110.80(a)(3) asserted that this requirement would place an inflationary burden on smaller wholesale bakers because it would require each baker, regardless of size, to set up a laboratory and to hire trained laboratory personnel.

FDA disagrees. The provision allows compliance to be accomplished by purchasing materials under a supplier's guarantee or certification. The agency believes that this provision, together with the other changes made in the final rule, alleviates the concerns expressed.

119. Several comments on proposed § 110.80(a)(4) stated that the word

"ingredients" should be added just after the words "raw materials."

FDA agrees and has changed the final rule to reflect that the paragraph refers to raw materials and other ingredients.

120. Some comments on proposed § 110.80(a)(4) suggested that, for compliance purposes, raw material suitability may be verified by any effective means, including a supplier's guarantee or certification.

FDA agrees and has modified the final rule accordingly.

121. A comment on proposed § 110.80(a)(4) stated that in this context the word "rework" is confusing, and recommended that the list of possible sources of contamination be removed.

As discussed elsewhere in this preamble, FDA has revised the definition of "rework" in § 110.3(m). Section 110.80(a)(4) identifies "rework" as one of several possible sources of contamination. These examples are consistent with other sections of the final rule and are of assistance to the manufacturer in ensuring an unadulterated product. Therefore, FDA has not changed § 110.80(a)(4) in the final rule.

122. A comment on proposed § 110.80(a)(4) stated that the "requirements" and "action levels" referred to in proposed § 110.80(a)(4) are voluntary, and recommended that the "shall" be changed to "should."

Because the regulations and action levels referred to are mandatory, FDA has not changed the final rule as requested.

123. Some comments on proposed § 110.80(a)(5) suggested adding the terms "ingredients and rework."

FDA agrees and has modified the final rule.

124. A comment on proposed § 110.80(a)(5) said that, in the case of many ingredients, normal ambient conditions are adequate to prevent contamination and that the words "when required" should be added to the reference to temperature.

The requested change in the final rule is unnecessary, because the provision does not mention a specific temperature and is sufficiently general to allow storage of ingredients under normal ambient conditions if this practice prevents a product from becoming adulterated within the meaning of the act.

125. Several comments on proposed § 110.80(a)(5) suggested changing the word "adulteration" to "contamination."

FDA usually uses the word "contamination" in the regulations because industry is more familiar with that word as it may affect a particular practice. FDA recognizes that it may be

impossible to prevent the contamination of food and, accordingly, the regulations stress that one must "protect against" or "minimize" the contamination of food. The level of care that one must exercise to do this is the same as that level necessary to "prevent" food from being adulterated within the meaning of the act. Because the regulations provide procedures for preventing food from becoming adulterated within the meaning of the act, FDA frequently refers in the regulations to the statutory term "adulteration" rather than the word "contamination." FDA believes that the term "adulterated" is appropriate in the context of § 110.80(a)(5).

126. Some comments on proposed § 110.80(a)(5) suggested that, because raw materials arrive at the processing plant in bulk, it is inappropriate to require that they be held in containers designed or constructed to prevent their contamination. One comment suggested that raw materials might be washed or cleaned, before they are held under controlled temperature or humidity, or both.

FDA agrees that raw materials may be held in bulk, and has modified the final rule accordingly. Requirements for washing and cleaning raw materials are discussed in § 110.80(a). There are no restrictions on washing or cleaning raw materials prior to storage. Therefore, FDA has made no additional changes in § 110.80(a)(5).

127. A number of comments on proposed § 110.80(a)(6) pointed out that it is not always necessary to defrost frozen raw materials prior to use in the final food product. Examples given were frozen fish used in frozen breaded fish products and frozen spinach repacked into frozen sauce-in-bag products.

FDA agrees and has changed the final rule accordingly.

128. One comment on proposed § 110.80(a)(6) suggested that the words "except for the period of time actually required for processing" be removed from the regulation.

FDA agrees and has deleted these words from the final rule.

129. Several comments on proposed § 110.80(a)(6) stated that some frozen raw materials need to be defrosted prior to manufacturing. These comments also stated that defrosting may affect the material's organoleptic qualities without rendering the raw materials unsafe. Therefore, they suggested the phrase "have adverse public health consequences" be substituted for "not adversely affect their use as food."

FDA does not consider normal organoleptic quality changes to adversely affect the use of food

materials that are defrosted under current good manufacturing practice. Therefore, FDA is not adopting the suggested change. In addition, the suggested change would be too limiting. The terminology "adverse public health consequences" does not apply to food that consists in whole or in part of a filthy, putrid, or decomposed substance, or is otherwise unfit for food. For clarification, FDA is changing the sentence in question to read as follows: "If thawing is required prior to use, it shall be done in a manner that prevents the food from becoming adulterated within the meaning of the act."

130. A comment on proposed § 110.80(a)(6) suggested limiting the term "frozen raw materials" to those items that are to be used by the plant in other food products, and that the term should not include frozen products that are thawed and held under refrigeration until sold.

The provision covers only frozen raw materials and ingredients.

131. One comment on proposed § 110.80(a)(7) stated that food additives and ingredients should meet the requirements of the Food Chemicals Codex.

Food Chemicals Codex requirements are included in FDA's requirements (21 CFR 170.30(h)(1)). Therefore, FDA has made no change in the final rule.

132. One comment on proposed § 110.80(a)(7) requested the deletion of the modifying terms "direct" and "indirect," in regard to contamination.

FDA agrees and has changed the final rule accordingly.

133. A number of comments on proposed § 110.80(b)(1) pointed out that it is not always necessary to clean all processing equipment and utensils frequently. Several comments suggested that the term "frequent" be changed to "adequate."

FDA agrees with these comments, and has changed the final rule to require that containers be kept in an "acceptable" condition through appropriate cleaning and sanitizing, as necessary.

134. One comment on proposed § 110.80(b)(1) suggested that "finished product containers" be changed to "bulk product containers." The comment gave no reason for this change.

The category "finished product containers" includes bulk product containers. Therefore, FDA has made no change in the final rule.

135. A comment on proposed § 110.80(b)(2) requested that its scope be limited to health matters.

FDA disagrees. The scope of the regulations is broader than suggested

and pertains to other possible causes of adulteration under the act.

136. Two comments maintained that public warehouses are not subject to § 110.80(b)(2). The comments stated further that neither warehousemen nor retail grocers are able to conduct sophisticated water activity tests on merchandise. The comments, therefore, concluded that this reference is intended to apply to processing operations only.

Public warehouses are subject to § 110.80(b)(2) but not to the portions of these regulations that are applicable to food-packing or food-packaging operations. The CGMP regulations do not apply to retail grocers.

137. A comment observed that compliance with proposed § 110.80(b)(2) will involve extensive and costly recordkeeping. Further, the comment stated that, because "water activity" is foreign to baking operations, this provision could be extremely expensive for smaller bakers.

The comment misunderstood the scope of this section for it imposes no recordkeeping requirements. The monitoring of factors such as time, temperature, water activity, humidity, and pH, is a suggested way to minimize the potential for the growth of undesirable microorganisms or for the deterioration or contamination of processed food or food ingredients. Therefore, FDA has made no change in the final rule in this regard.

138. A comment on proposed § 110.80(b)(2) suggested that the phrase "vacuum internal pressure in the containers" be added to the examples listed of ways to minimize the potential for growth of undesirable microorganisms. The comment further stated that the following sentence should be included: "Effective measures shall be taken to prevent contamination of food products by 100 percent monitoring vacuum internal pressure in containers on a production line with electronic vacuum inspectors, or other suitable effective means, where feasible."

The list of physical factors and processing operations is not all inclusive. FDA believes the proposed wording adequately expresses the intent behind this provision and allows use and monitoring of vacuum internal pressure in containers without the suggested additional language. Therefore, FDA has made no change in the final rule.

139. A number of comments on proposed § 110.80(b)(3) noted that not all foods support the rapid growth of undesirable microorganisms or are subject to decomposition. These comments pointed out that certain

foods, like cheese and bakery products, pose no hazard and require no specific treatment. A comment further stated that it is not necessary to maintain frozen foods at 0 °F (-17.8 °C) or below, so long as the foods remain frozen.

FDA agrees that some foods pose no microbial hazard and require no specific temperature storage treatment. These foods are not subject to paragraph (b)(3). FDA also agrees that from a public health standpoint it is not necessary to maintain frozen foods at 0 °F (-17.8 °C). Therefore, FDA has revised the final rule accordingly.

140. A comment on proposed § 110.80(b)(3) suggested that, because the growth of microorganisms is essential in cheese, wine, and beer manufacture, the list of acceptable ways to hold foods should include "Establishment of continuing vigorous fermentation such as in the making and curing of natural cheese."

FDA notes that paragraph (b)(3) now applies to foods that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, or that cause food decomposition. The growth of microorganisms essential to the fermentation of cheese, wine, and beer is not considered to be restricted by § 110.80(b)(3) because this growth is not undesirable. Therefore, FDA has made no change in the final rule.

141. One comment on proposed § 110.80(b)(3) said that the maximum temperature requirement for storing cold foods should be changed from 45 °F to 40 °F and that the minimum temperature requirement for storing hot foods should be changed from 140 °F to 150 °F. Another comment stated that 140 °F is too high a temperature to maintain hot food because it will dry out and become inedible. The comment further asserted that the same problem occurs when food is held at 120 °F, a point above which it has not been established that bacteria of public health significance can multiply. Other comments suggested that the specific values be removed from the regulation, because they are inappropriate for some foods.

FDA agrees that a maximum storage temperature for cold foods of 40 °F and a minimum temperature of 150 °F for hot foods would provide a greater safety margin. However, 45 °F has long been recognized as the maximum value for storage of cold foods, and 140 °F has been recognized as the minimum value for storage of hot food, to minimize the growth of microorganisms. Contrary to one of the comments, studies have shown that some microorganisms of public health significance multiply at temperatures above 120 °F. (Brown, D.F.

and R.M. Twedt, "Assessment of Sanitary Effectiveness of Holding Temperature on Beef Cooked at Low Temperature, *Applied Microbiology*, 24:4, 1972, pp. 599-603.) FDA notes that unprotected food may dry out at any temperature, depending on the relative humidity of the surrounding atmosphere. Therefore, FDA has made no change in this provision of the final rule.

142. Two comments on proposed § 110.80(b)(3) suggested that the introductory wording be changed to make it clear that the indicated storage temperatures and heat treating of acid or acidified foods are merely examples of ways to control the microbial growth.

The proposed regulation already stated that compliance could be accomplished by any effective means. Therefore, in response to these comments, FDA has made no change in the final rule.

143. One comment on proposed § 110.80(b)(4) said that the control of microorganisms of public health significance should also apply to "handling and distribution" of foods.

FDA agrees and has modified the final rule accordingly.

144. Some comments suggested that the following definition of pasteurization be added to § 110.80(b)(4):

"Pasteurization shall mean treatment by any process during manufacturing and packaging which effectively destroys, inactivates or removes microorganisms capable of continued multiplication in the package."

A definition of pasteurization is not needed in the final rule because the term is generally understood by food manufacturers and consumers.

145. One comment on proposed § 110.80(b)(5) stated that it is not necessary and is redundant because § 110.80(a) adequately addresses the matters discussed in it. Several comments stated that "rework" may contain microorganisms that cause it to be adulterated within the meaning of the act, but, with proper heat treatment, may be made entirely acceptable for use. The comments also stated that microbially contaminated rework does not necessarily meet the raw material specifications until the time it is reprocessed. Other comments suggested that rework be stored under sanitary conditions before reprocessing.

FDA believes that § 110.80(a)(5), as revised in the final rule, adequately provides for the handling of rework. Therefore FDA has deleted proposed § 110.80(b)(5). Although food that is adulterated within the meaning of the act cannot always be successfully reconditioned, where it has been

satisfactorily reconditioned it is "rework" as defined in § 110.3(m) of the final rule.

146. Several comments on proposed § 110.80(b)(7) (§ 110.80(b)(6) of the final rule) questioned the practicality and reasonableness of the requirement concerning contamination between finished food and raw materials.

FDA has revised the final rule to provide that effective measures be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.

147. Several comments on proposed § 110.80(b)(7) said that it is not necessary to cover conveyors to protect against contamination from extraneous material. Another comment said that conveyors need to be protected only in those locations where contamination hazards exist.

FDA agrees and has changed the final rule to require that materials and products transported by conveyor be protected as necessary.

148. Two comments on proposed § 110.80(b)(9) (§ 110.80(b)(8) of the final rule) stated that requiring metal detectors, which are not effective under certain circumstances, would place a financial burden on the small manufacturers.

FDA advises that metal detectors are mentioned as examples of a means which may be effective in protecting the food against contamination. The regulation, however, does not require their use.

149. One comment on proposed § 110.80(b)(9) requested the addition of traps as an effective means to prevent the inclusion of metal or other extraneous material in the finished food.

FDA agrees and has changed the final rule accordingly.

150. One comment on proposed § 110.80(b)(9) requested that a 1-to-2-year "grace period" be provided to allow industry time to change processing layouts and to purchase the devices necessary to comply with this requirement.

FDA believes that the delayed effective date for the final rule provides adequate time for industry compliance. The effective date of the final rule is delayed until December 16, 1986.

151. One comment on proposed § 110.80(b)(10) (§ 110.80(b)(9) of the final rule) noted that it may not be practical to reexamine reconditioned food, including raw materials, and other ingredients before their use in finished food. The following example was provided: "If the product is heat treated to reduce bacteria counts, it may not be possible to hold that product until the bacteria test results are available."

FDA agrees and has modified the final rule accordingly.

152. A number of comments on proposed § 110.80(b)(11) (§ 110.80(b)(10) of the final rule) stated that it is impossible to eliminate contamination completely from the food manufacturing process. The comments suggested that either the requirement be changed to an advisory statement or that the phrase "not to contaminate" be modified.

FDA agrees and has modified the final rule to read, in part, as follows: " * * * shall be performed so as to protect food against contamination."

153. Two comments on proposed § 110.80(b)(12) (§ 110.80(b)(11) of the final rule) requested that the advisory statements regarding heat blanching and minimizing growth of thermophilic organisms be changed to mandatory requirements by the substitution of "shall" for "should." The basis for the request was concern that sufficient heat be supplied to inactivate enzymes and that equipment be cleansed and sanitized sufficiently to preclude thermophilic growth.

FDA advises that some foods are heat blanched for reasons other than enzyme inactivation and that sufficient cause has not been demonstrated by the comments to justify making these provisions mandatory. Therefore, except for clarifying editorial changes, FDA is retaining the proposed wording in the final rule.

154. One comment concerning § 110.80(b)(12) of the proposal (§ 110.80(b)(11) of the final rule) stated that the requirement that water used to wash blanched food prior to filling be safe and of adequate sanitary quality was duplicative of the requirement in § 110.80(a)(1).

Section 110.80(a)(1) deals with raw materials and other ingredients. Section 110.80(b)(11) concerns processes and controls. FDA believes that these provisions are distinct and that it is appropriate to include requirements for water quality in both provisions. Therefore, FDA has not made the suggested change in the final rule.

155. One comment on proposed § 110.80(b)(13) (§ 110.80(b)(12) of the final rule) requested clarification of one of the examples given of ways to protect against contamination of batters and similar preparations: "(ii) Employing adequate heat processes where applicable." The comment sought clarification in that filth problems cannot be solved through the use of heat processes.

The regulation requires the use of adequate heat processes only where applicable, not when heat is not useful. FDA believes the regulation is

sufficiently clear and has made no revisions in response to the comment.

156. Two comments on proposed § 110.80(b)(13) suggested that example (vi) be changed to reflect the variability of various food processes.

FDA agrees and has changed the final rule accordingly.

157. Some comments on proposed § 110.80(b)(14) (§ 110.80(b)(13) of the final rule) indicated that the examples of effective compliance measures were interpreted, incorrectly, to be mandatory practices which must be followed by all parts of the food industry.

Compliance with this paragraph may be accomplished by any effective means, including the operations that are presented as examples. FDA believes that a more careful reading of this paragraph would eliminate the concerns of these comments, and has retained, but for editorial changes, the proposed wording in the final rule.

158. Several comments on proposed § 110.80(b)(15) (§ 110.80(b)(14) of the final rule) were concerned about the possible expense entailed in following the enumerated examples of effective means of compliance with the safe moisture level requirement. They stated that the examples of testing controls are beyond the resources of many manufacturers.

The regulation does not require the use of the suggested examples. Other effective, but less expensive, compliance measures may be used.

159. A number of comments on proposed § 110.80(b)(16) (§ 110.80(b)(15) of the final rule) were received regarding the requirement that foods which rely on pH for preventing the growth of undesirable microorganisms be monitored and maintained at a pH of 4.6 or below. Two comments stated that the requirement should be rephrased to read " * * * rely solely on the control of pH * * *" in consideration of those foods in which pH is merely a partial control of microbial growth.

FDA agrees and is inserting the term "principally" in lieu of the suggested term "solely" in the final rule.

160. A comment on proposed § 110.80(b)(16) suggested including the following additional example of an effective practice for preventing the growth of undesirable microorganisms: "rework of the raw foods, ingredients, and finished products in a manner adequate for preventing the growth of microorganisms." No reason was given to support the suggestion.

The enumerated practices are only examples. Additional examples are not necessary.

161. A comment on proposed § 110.80(b)(16) said the term "microorganisms" should be qualified by the phrase "of public health significance" in order to clarify the use of this term.

As previously discussed in the preamble, microorganisms may render a food adulterated within the meaning of the act not only because they are harmful, but also for other reasons, such as they may constitute filth. Therefore, FDA has made no change in the final rule in response to the comment.

162. One comment on proposed § 110.80(b)(17) (§ 110.80(b)(16) of the final rule) interpreted a literal application of the requirement that ice be "manufactured in accordance with adequate standards" to be inappropriate where, for example, retail bakeries use small amounts of ice obtained from small plant freezers.

FDA agrees with this interpretation. Therefore, FDA has changed the final rule to read: "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."

Warehousing and Distribution

163. FDA received several comments on proposed § 110.93, concerning a definition for undesirable deterioration of food. The comments suggested that the regulation should be concerned only with microorganisms at levels that could be clearly identified as constituting a risk to human health. The comments also suggested that the regulations include a definition of microorganisms.

FDA defines the term "microorganisms" in § 110.3(i) of the final rule. As mentioned throughout this preamble, microorganisms may indicate contamination with filth or putrefaction, as well as harmfulness. Accordingly, FDA has not adopted the substance of the comments pertaining to microorganisms in the final rule. However, FDA has made other clarifying changes in § 110.93 of the final rule in response to the comments.

164. A comment expressed concern that manufacturers would be unable to assure completely good storage and transportation practices throughout the distribution chain.

Producers are expected to take reasonable precautions to see that food is transported and stored in such a manner that it does not become adulterated, particularly where the producer has continuing control of the products. Should evidence demonstrate

that the cause of adulteration is due to negligence or illegal practices of the shipper or warehouse operator, FDA has the authority to take appropriate regulatory action against the responsible persons.

Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard

165. One comment on proposed § 110.110 stated that defect action levels (DAL's), which are established by FDA for natural or unavoidable defects that are not hazardous to health, should not be referenced in § 110.110 because they "are considered to be artificial values established by the Commissioner without public hearing."

FDA disagrees. DAL's are calculated and issued only when it is necessary and feasible to do so. DAL's are based on results of plant inspections, surveys, and research which may be performed in conjunction with industry, academia, or other government agencies. It is FDA's policy to publish notices in the Federal Register of the establishment of DAL's. Copies of compilations of current defect action levels may be obtained from FDA, as stated in § 110.110(e) of the final rule. As noted in § 110.110(b), DAL's are subject to change based on additional information or the development of new technology. Although DAL's are not rules that must be adhered to, and certainly are not subject to any requirement of a hearing, they offer reliable guidance on whether a particular defect may result in the product being adulterated within the meaning of the act. It is for this purpose that they are referenced in this section. Therefore, FDA has retained these proposed provisions in the final rule.

166. One comment on proposed § 110.110(c) expressed concern that violation of any of the Part 110 requirements could cause a product to be adulterated even though the levels of natural or unavoidable defects are lower than the established action levels. The comment also argued that section 402 of the act "does not provide for deeming a food to be adulterated if not produced in conformance with current Good Manufacturing Practice."

The purpose of this paragraph in the regulation is to specify that failure to maintain current good manufacturing practice throughout the manufacturing, packing, holding, or storage of food is not overcome by compliance with a DAL, which may or may not be affected by the violative practice. Many significant practices, such as measures that are taken to destroy or prevent the growth of microorganisms of public health significance (as covered under

§ 110.80(b)(4)), may not affect the level of natural or unavoidable defects but are nonetheless crucial to the production of food that is not adulterated within the meaning of the act. The comment concerning FDA's authority in this area overlooks the fact that courts have expressly held that FDA has the authority to promulgate and enforce substantive regulations defining current good manufacturing practice for the food industry. See *National Confectioners Ass'n v. Califano*, 569 F.2d 690 (D.C. Cir. 1978). See also *Nova Scotia Food Products Corp. v. United States*, 568 F.2d 240, 245-248 (2d Cir. 1978).

167. A number of comments on proposed § 110.110(d) objected to the provision that prohibits, without exception, the mixing of food which is above a DAL with another lot of food. Comments stated that there were instances, such as where the contamination is not due to violation of FDA's CGMP regulations, in which blending could be safely accomplished, thereby preventing the destruction of food. Therefore, it was argued that because FDA has allowed blending in individual cases, absolute prohibition of this action is improper, and the final regulations should be modified.

FDA has on rare occasion allowed the blending of food that was unavoidably contaminated with a poisonous or deleterious substance when (1) the food is shown to be safe for consumption after blending and (2) the destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply. The general concern with blending, however, is not solely whether the food after blending is safe, but whether it is otherwise adulterated within the meaning of the act. Accordingly, FDA has not modified the regulation as requested by the comments.

168. The remaining comments requested that portions of the proposal be clarified. In response to these comments and on its own initiative, FDA has made many clarifying editorial changes in the final rule.

As one of the editorial changes, FDA has deleted the word "processing" in favor of exclusive reliance on the word "manufacturing." The words are synonymous, "manufacturing" being the more appropriate for regulations dealing with current good manufacturing practice. As has already been discussed, FDA has broadly defined "food" in the regulations to include raw materials and other ingredients. For clarity and consistency, as well as emphasis, however, FDA does use the words "raw materials" and "ingredients" where

appropriate. Similarly, because the regulations pertain to those systematic procedures to be followed to prevent "food" from being adulterated within the meaning of the act, FDA has generally avoided limiting the word "food" (for example, by using the terminology "finished food"), except where such limitations are appropriate or necessary for clarity or emphasis.

For editorial consistency, FDA is also revising 21 CFR 20.100(c)(8) to reflect a cross-reference to § 110.110(e), which contains cross-referenced action level provisions now located in § 110.99(e).

The final rule becomes effective December 16, 1986.

The agency has previously determined that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has analyzed the effects of this final rule. Compliance costs are estimated to be between \$272,000 and \$623,000 annually depending on the exact number of firms ultimately affected by this action. Thus, in accordance with Executive Order 12291, the agency has determined that this final rule will not result in a major rule as defined by that Order.

In accordance with the Regulatory Flexibility Act, FDA has examined the effect that this final rule will have on small entities including small businesses. Although most of the cost of this action will be incurred by small businesses, FDA does not believe that its estimated cost of \$180 per firm per year is excessive. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

Interested persons may, on or before August 18, 1986, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 20

Freedom of information.

21 CFR Part 110

Good manufacturing practices.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION**

**INSTRUCTIONS FOR ESTABLISHMENT REGISTRATION
AND
PROCESS FILING
FOR
ACIDIFIED AND LOW-ACID CANNED FOODS**

1984

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**IF YOU HAVE ANY QUESTIONS CONCERNING ESTABLISHMENT REGISTRATION AND
PROCESS FILING, PLEASE CONTACT THE LACF REGISTRATION COORDINATOR AT
(202) 485-0282.**

Prepared according to
FDA Contract 223-80-2318

Acidified and Low-Acid Canned Food
Process Filling Improvement Project

by

Bureau of Foods, FDA
Industry Programs Branch

Plant and Protein Technology Branch

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ASEPTIC PACKAGING SYSTEM SUPPLEMENT	(separate document)

NOTE: The Aseptic Packaging System Supplement will be provided on request to establishments which use or plan to use aseptic packaging systems.

L BACKGROUND AND INTRODUCTION

I. PURPOSE OF THIS BOOKLET

Federal regulations require processors of acidified and low-acid canned foods sold in the United States to register each establishment and to file scheduled processes with the Food and Drug Administration. See Title 21, Code of Federal Regulations, Part 108 (21 CFR 108). This booklet is designed to help processors comply with those requirements and contains instructions for completing the required forms.

New forms are being introduced for establishment registration and for process filing for all processing methods except aseptic. A modified version of present form FDA 2541c will be used for filing aseptic processes. Implementation date of new and modified forms is being announced separately to all establishments currently registered with the FDA. In the meantime, continue to use forms and instructions previously furnished to you. Do not use the new forms and instructions until the effective date announced by FDA.

The instructions for completing the revised registration and process filing forms for all processing methods **except aseptic** are contained in this booklet. Please read these instructions thoroughly and follow them carefully after their implementation date even though you may have previously registered and filed process data with the FDA.

Process filing instructions for **aseptic packaging systems** are contained in a separate supplement which is available upon request to establishments using such systems.

Establishments previously registered with FDA who have an assigned Food Canning Establishment (FCE) Number do not have to re-register or re-file processes using the new forms unless they meet some of the conditions described later in this booklet which require re-registration or re-filing of processes.

This booklet also contains answers to some of the more frequently asked questions regarding registration and process filing requirements as well as samples of properly completed forms.

Following this introduction and general information, the instructions are divided into two major sections, with a separate section containing complete instructions for each of the following:

- o Food Canning Establishment Registration (Form FDA 2541)
- o Process Filing for All Processing Methods Except Aseptic (Form FDA 2541a)

Instructions for process filing for aseptic packaging systems (Form FDA 2541c) are contained in a separate supplement.

At the end of each section and the aseptic supplement is a fold-out example of a properly completed form. To gain the maximum benefits from the instructions, you should display the example while reading the section.

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2. THE NEED FOR REGULATIONS

In the early 1970's, several life-threatening botulism outbreaks resulted from inadequate thermal processing of commercially packed low-acid foods packaged in hermetically sealed containers and from improper acidification of commercially packed acidified foods. As a result, the following regulations were published by the FDA:

21 CFR Part 108 (Emergency Permit Control)

21 CFR Part 113 (Thermally Processed Low-Acid Foods)

21 CFR Part 114 (Acidified Foods)

The purpose of these regulations is to protect consumers from microorganisms of public health significance (i.e., harmful bacteria or their toxins), especially Clostridium botulinum. The spores of Clostridium botulinum must be destroyed or effectively inhibited to avoid germination and subsequent production of the deadly toxin which causes botulism. This is accomplished with good canning procedures which must include:

- o The use of thermal processes and/or other means of preservation that are properly designed by a competent processing authority to destroy or inhibit Clostridium botulinum spores;
- o Proper delivery of these thermal processes and/or adequate control of other methods of preservation being used.

3. REQUIREMENTS OF THE REGULATIONS

THIS PUBLICATION CONTAINS ONLY A SUMMARY OF THE PRINCIPAL REQUIREMENTS OF THE REGULATIONS ENFORCED BY THE FOOD AND DRUG ADMINISTRATION. LOW-ACID AND ACIDIFIED FOOD PROCESSORS AND SHIPPERS OF REGULATED IMPORTED PRODUCTS MUST TAKE STEPS TO FULLY INFORM THEMSELVES CONCERNING THE APPLICABLE REGULATIONS BEFORE OFFERING LOW-ACID OR ACIDIFIED FOODS FOR DISTRIBUTION WITHIN OR IMPORTATION INTO THE U.S.

The current Good Manufacturing Practice Regulations (GMP's) for low-acid canned foods (21 CFR Part 113) became effective in March 1973 (revised effective May 15, 1979). Those for acidified foods (21 CFR Part 114) became effective in May 1979. These GMP's outline the equipment, controls, manufacturing, processing, and packing procedures which are required to ensure the production of a safe product.

Food processing establishments in the United States and those which import foods into the United States are subject to regulations which require registration of the establishments and filing of scheduled processes.

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The registration and process filing regulation for thermally processed low-acid foods packaged in hermetically sealed containers is 21 CFR Part 108.35. The applicable registration and process filing regulation for acidified foods is 21 CFR Part 108.25, which became effective in July, 1979.

4. REASONS FOR REGISTRATION AND PROCESS FILING REQUIREMENTS

Since improperly processed low-acid foods or acidified foods present life-threatening hazards, registration of those firms which manufacture, process, or pack low-acid canned foods or acidified foods and filing of the processes they use is necessary to monitor compliance with the regulations and to provide for immediate application of emergency permit control should a public health hazard arise.

PROCESS FILING FORMS ARE TECHNICALLY EDITED FOR COMPLETENESS PRIOR TO COMPUTER ENTRY. NO FORM IS CONSIDERED BY THE BUREAU OF FOODS TO BE FILED UNTIL IT HAS PASSED THIS INITIAL TECHNICAL EDIT. UNDER NO CIRCUMSTANCES DOES FILING OF THE INFORMATION CONSTITUTE FDA APPROVAL OF THE PROCESS AUTHORITY, THE PROCESS, OR ITS ADEQUACY. IT IS THE RESPONSIBILITY OF THE PROCESSOR TO ASCERTAIN THE ADEQUACY OF ANY PROCESS BEFORE USING IT.

5. FOODS NOT COVERED UNDER THE LOW-ACID CANNED FOODS-REGULATIONS (21 CFR 108.35 and 113)

The following foods are not considered low-acid foods. Therefore, processors of these foods do not have to register and file processing information for these products:

- o Acid foods (natural or normal pH 4.6 or below)
- o Alcoholic beverages
- o Fermented foods
- o Foods processed under the continuous inspection of the meat and poultry inspection program of the United States Department of Agriculture under the Federal Meat Inspection Act and the Poultry Products Inspection Act
- o Foods with water activity (a_w) of 0.85 or below
- o Foods which are not thermally processed
- o Foods which are not packaged in hermetically sealed containers
- o Foods stored, distributed, and retailed under refrigerated conditions
- o Tomatoes and tomato products having a finished equilibrium pH less than 4.7.

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6. FOODS NOT COVERED UNDER THE ACIDIFIED FOODS REGULATIONS (21 CFR 108.25 AND 114)

The following foods are not considered acidified foods. Therefore, processors of these foods do not have to register and file processing information for these products:

- o Acid foods (natural or normal pH 4.6 or below)
- o Acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid foods and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid food.
- o Alcoholic beverages
- o Carbonated beverages
- o Fermented foods
- o Foods with water activity (a_w) of 0.85 or below
- o Foods stored, distributed, and retailed under refrigerated conditions
- o Jams, jellies, or preserves.

7. SPECIAL CASES

Figs, pears, or pineapples with a finished equilibrium pH above 4.6 are considered low-acid foods. If they are thermally processed and packaged in hermetically sealed containers, they are subject to Part 113. If figs, pears, or pineapples having a normal pH prior to processing of greater than 4.6 are acidified to a pH of 4.6 or below, they are subject to Parts 108.25 and 114.

8. RELATIONSHIP BETWEEN pH, WATER ACTIVITY, AND LOW-ACID OR ACIDIFIED REGULATIONS

The following table illustrates the relationships between pH, water activity, and current low-acid and acidified regulations. The table indicates whether a product is a low-acid or an acidified food and therefore must meet the registration and process filing requirements of FDA. To use the table, determine the finished equilibrium pH and water activity (a_w) of the product. It is the relationship between pH and water activity that defines a product as low-acid or acidified. For example, if a food product has a pH less than or equal to 4.6 and water activity of 0.85 or below, it would not be covered by the low-acid regulations nor the acidified regulations. Thus, the firm would not be required to file scheduled process information for that product.

NOTE: THIS TABLE DOES NOT APPLY TO FOODS WHICH ARE NATURALLY OR NORMALLY ACID, AS DEFINED IN THE PRECEDING PARAGRAPHS.

Final Equilibrium pH	Water Activity (a _w)	Registration and Process Filing Required as:	
		Low Acid* (21CFR108.35/113)	Acidified** (21CFR108.25/114)
≤ 4.5	≤ 0.85	No	No
≤ 4.5	> 0.85	No	Yes
4.6	≤ 0.85	No	No
4.6	> 0.85	No	Yes
≥ 4.7	≤ 0.85	No	No
≥ 4.7	> 0.85	Yes	No

< less than

> greater than

≤ less than or equal to

≥ greater than or equal to

* A yes under this column defines the product as low-acid, subject to the requirements of 21 CFR, Parts 108.35 and 113, and means that the establishment must register the processing plant and file scheduled process information for that low-acid product.

** A yes under this column defines the product as acidified, subject to the requirements of 21 CFR, Parts 108.25 and 114, and means that the establishment must register the processing plant and file scheduled process information for that acidified product.

9. REGISTRATION OF LOW-ACID AND ACIDIFIED FOOD PROCESSING ESTABLISHMENTS

Registration is accomplished by completing Form FDA 2541 according to the instructions in section II of this booklet. Registration is required for U.S. establishments and for those in other countries which import low-acid or acidified products into the United States. Process filing forms will be accepted only from registered firms. Registration and process filing may be done at the same time.

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10. FILING LOW-ACID AND ACIDIFIED SCHEDULED PROCESS INFORMATION

Filing scheduled process information is accomplished by completion of a separate process filing form for each product. **UNLESS OTHERWISE STATED IN THIS BOOKLET, A SEPARATE FORM MUST BE USED FOR:**

- o Each processing method (still, agitating, hydrostatic, etc.)
- o Each product form or style (whole, diced, French style, strained, solid-pack, syrup strength category, brined, cream style, mature, cured, dry pack, vacuum pack, etc.) **which receives a different scheduled process OR when the characteristics of the food affect heat transfer. In any case, mushrooms must always be separated by product form or style (i.e., a separate form submitted for each form or style).**
- o Each type of container (metal, glass, pouch, etc.) in which the product is packed, even though all other information is exactly the same. However, multiple container sizes of the same type may (and should) be included on a single form for a given product.
- o Each different packing medium (e.g., water, oil, sauce, etc.). Products packed in water, brine, and sweetened brine may be filed on the same form **as long as the scheduled process is exactly the same.**
- o Each process source when all scheduled processes listed were not established jointly.

Product forms or styles receiving the same scheduled process should be included parenthetically after the product name. For example, "Carrots (whole, cut, quartered, sliced, diced, or shoestring) in brine". **Mushrooms must always be separated by product form or style.**

The use of photocopies or similar reproductions of forms with only slight variations is acceptable, as long as each bears a unique **submission identifier (SID)** (see paragraph 11) and is signed by an authorized company representative.

A separate form is **not** required for each different brand name of the product so long as the scheduled process for these brands is **exactly the same.**

Use Form FDA 2541a for all processing methods **except aseptic**, and Form FDA 2541c for **aseptic packaging systems**. Specific instructions are contained in **section III for all processing methods except aseptic and in a separate supplement for aseptic packaging systems.**

Process filing is required for all processing establishments in the United States and those located in other countries which import acidified or low-acid canned foods into the United States.

PROCESS FILING FORMS ARE TECHNICALLY EDITED FOR COMPLETENESS PRIOR TO COMPUTER ENTRY. NO FORM IS CONSIDERED BY THE BUREAU OF FOODS TO BE FILED UNTIL IT HAS PASSED THIS INITIAL TECHNICAL EDIT. UNDER NO CIRCUMSTANCES DOES FILING OF THE INFORMATION CONSTITUTE FDA APPROVAL OF THE PROCESS AUTHORITY, THE PROCESS, OR ITS ADEQUACY. IT IS THE RESPONSIBILITY OF THE PROCESSOR TO ASCERTAIN THE ADEQUACY OF ANY PROCESS BEFORE USING IT.

11. SUBMISSION IDENTIFIER

In order to uniquely identify each separate process filing form submitted by an establishment, a "Submission Identifier" (SID) is used. The SID enables both the firm and FDA to quickly and accurately identify a specific filing form. It is used in conjunction with a firm's Food Canning Establishment (FCE) number and consists of the year, month, and day of the month that a process filing form is submitted, and a unique sequence number within date to allow for multiple forms submitted on the same date. The SID is assigned by the establishment when a process filing form is prepared and is in the following format:

YY-MM-DD/SSS

Where:

- YY represents the last two digits of the calendar year (e.g., 83 for 1983, etc.)
- MM represents the month (e.g., 02 for February, 10 for October, etc.)
- DD represents the day of the month (e.g., 02, 19, 30, etc.)
- SSS represents a unique sequence number within date to provide for times when more than one process filing form is being submitted on one date. If only one process filing form is being submitted on a day, use 001 for the sequence number. If multiple forms are being submitted, assign a different number for each separate form (e.g., 002, 003, 004, etc.).

When a previously submitted process is being discontinued or superseded, the SID will clearly identify which specific submission is so affected. Specific instructions for entering SIDs are contained in the sections dealing with completion of process filing forms.

12. IMPORTANT INFORMATION FOR PROCESSING PLANTS IN OTHER COUNTRIES

Imported products, including both acidified and low-acid canned foods, are subject to inspection at the time of entry into the United States. **Shipments which do not comply with U.S. laws and regulations WILL BE DETAINED AT THE PORT OF ENTRY. THEY MUST BE BROUGHT INTO COMPLIANCE WITH THE LAWS AND REGULATIONS, DESTROYED, OR RE-EXPORTED.**

REASONS FOR PRODUCT DETENTION

Low-acid or acidified foods may be **detained at the port of entry** for a variety of reasons, including:

- o Establishment is not registered
- o Establishment has not filed process information for the product with the FDA

In addition to LACF and acidified regulations (21 CFR 108.35, 108.25, 113, and 114), **all other requirements of FDA's laws and regulations must be met** before the product will be allowed entry into the United States. These include sanitation requirements, labeling, etc.

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HOW TO AVOID DELAYS

Importers of low-acid or acidified products can help avoid delay in clearing such products for entry into the United States by ensuring that invoices, manifests, and other shipping documents include the following information:

- o Name of registered processing establishment where the low-acid or acidified product is processed, manufactured, or packed;
- o Food Canning Establishment (FCE) number of the registered establishment;
- o Submission Identifier(s) (SID) of process filing form(s) listing process(es) filed with FDA for this product;
- o Name of low-acid or acidified product, form or style, and packing medium as printed on the container label. For example:

Tuna (chunk style) in oil

Sardines in tomato sauce

Artichoke hearts (quartered) in brine

Mushrooms (sliced) in butter sauce

Both the English and non-English name (when applicable) should be listed as it appears on the label. For example:

Green kidney beans (flageolets) in brine

Fava beans (papdi) in brine

- o Container dimensions for each type or size container, in **inches and sixteenths of an inch**. See chart in Appendix A for converting from Metric units (mm) to English units (inches and sixteenths).

For cylindrical containers, list diameter x height; for example, 0211 x 0400 for a 2 11/16 inch x 4 inch container.

For rectangular containers (including pouches), list length (longest dimension) x width (second longest dimension) x height (thickness in the retort for pouches); for example, 0405 x 0301 x 0014 for a container which is 4 5/16 inches long, 3 1/16 inches wide, and 14/16 of an inch high (or a 14/16 inch thick pouch).

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II. ESTABLISHMENT REGISTRATION (FORM FDA 2541)

WHO MUST REGISTER

All commercial processors of low-acid and acidified food products located in the United States and all processors in other countries who ship their low-acid or acidified products into the United States must register their processing plants with FDA. Wholesalers, distributors, brokers, etc. are not required to register and file processes. However, they must ensure that processing firms they represent comply with all registration and process filing requirements.

WHEN TO REGISTER

Commercial low-acid and acidified food processors in the United States must register with FDA not later than 10 days after first engaging in the manufacture, processing, or packing of acidified or low-acid canned foods. Processors in other countries must register before offering any such products for import into the United States. **PROCESS FILING FORMS WILL BE ACCEPTED ONLY FROM REGISTERED FIRMS.** However, registration and initial process filing may be done at the same time.

HOW TO REGISTER

To register with FDA, processors must complete and submit to FDA a Form FDA 2541 for each processing plant according to these instructions.

HOW TO COMPLETE FORM FDA 2541

Complete each required space on the form according to the following instructions. **TYPE OR PRINT ALL ENTRIES LEGIBLY IN ENGLISH.** The encircled numbers correspond to those on the sample fold-out registration form on page 13.

① FOR FDA USE ONLY

Do not make any entries in this space. FDA will assign a Food Canning Establishment (FCE) number to the plant being registered. A copy of the registration form will be returned to you with the FCE number entered in the space labeled "FCE No.". Include that FCE number on all correspondence with FDA. It will also expedite inspection of imports if the FCE number is included on all shipping documents for these products.

② TYPE OF SUBMISSION

Check "Initial Registration" if this processing plant has never been registered before. Leave the space for "Current FCE" number blank.

Check "Change of Registration Information" if you are submitting changes such as the following for a previously registered firm:

- o Change in firm name
- o Change in mailing address

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- o Change in location address because of renaming of street, renumbering of building, etc. (no actual change in location).

Enter the type of change and the current FCE number in the space provided.

IF A PREVIOUSLY REGISTERED PROCESSING PLANT HAS MOVED TO A NEW LOCATION, the plant must be registered at the new location. To do so, check "Change of Registration Information" and enter "Re-registration" on the same line. Enter your current Food Canning Establishment (FCE) number in the space provided. Complete all other spaces on the form as in an initial registration. FDA will assign a new FCE number and return a copy of the form as for a new registrant. **The old FCE is invalid and may not be used.** Submissions using the old FCE **will not be accepted by FDA** and products submitted for import into the United States under the invalid FCE **will be detained**.

NOTE: WHEN A PLANT IS MOVED AND RE-REGISTERED, ALL PROCESSES TO BE USED AT THE NEW LOCATION MUST BE RE-FILED AS INSTRUCTED IN SECTION III AND THE ASEPTIC SUPPLEMENT TO THIS BOOKLET.

③ **FOOD PROCESSING PLANT LOCATION**

Establishment Name

Enter the name of your establishment as you want it to be registered. Wherever possible, use standard abbreviations such as the following:

Inc (Incorporated)

Ltd (Limited)

Co (Company)

Corp (Corporation)

Number and Street

Enter the address of the physical location of the establishment where your products are manufactured, processed, or packed. Abbreviations such as the following may be used:

St (Street)

Dr (Drive)

Ave (Avenue)

Rd (Road)

Ln (Lane)

Bldv (Boulevard)

RR (Rural Route)

City and State or Province (or other Subdivision)

Enter the appropriate location information on the line provided.

U. S. Firms:

Use the two-letter Postal Service abbreviation for your state.

ZIP (or other Postal Code)

U. S. Firms:

Enter your 9 digit ZIP Code if one has been assigned; otherwise, enter your 5 digit code.

Foreign Firms:

If a postal code has been established by the postal system of your country, enter that code.

Country

U.S. Firms:

Leave blank.

Foreign Firms:

Enter the name of the country in which your establishment is located:

④ PREFERRED MAILING ADDRESS

If you wish all correspondence from FDA to be sent to your plant location address (as entered in ③) check "Same as Plant Location" and leave the rest of the "Preferred Mailing Address" space blank.

If you wish all correspondence from FDA to be sent to an address different than your location address, enter the preferred mailing address in the spaces provided. Use the same guidelines for entries as in ③ except that you may enter a post office (P. O.) box number instead of number and street (if applicable).

NOTE: This preferred mailing address will be used for all FDA correspondence regarding registration and process filing. Therefore, if registration and process filing is handled by someone located in a firm's headquarters, research lab, etc., that address should be listed and all FDA mailings will be sent there.

⑤ LOW ACID AND/OR ACIDIFIED FOODS PROCESSED AT THIS LOCATION

Enter (on a separate line) each low-acid and/or acidified food which your firm produces at this location, and check the applicable column to indicate whether it is a low-acid or acidified product. The product name, form or style, and packing medium should be the same as that printed on the container label.

Foreign Firms:

List the English name as well as the non-English name as it appears on the label. For example:

Green kidney beans (flageolets) in brine

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If necessary, attach additional forms to continue the list of products. On additional forms, complete item ③ and enter "continued" in ⑤ preceding the listing of additional products.

NOTE: This information is used to help FDA to determine if the firm is required to register and file processes, and to help determine the number and type of process filing forms likely to be required.

Do **NOT** submit a change to registration information just to show products which are added later, or to show discontinuance of some which were previously reported. **HOWEVER, SUCH LATER ADDITIONS AND CHANGES (AS WELL AS ALL PRODUCTS LISTED WHEN INITIALLY REGISTERING) MUST BE REPORTED BY USING THE APPROPRIATE PROCESS FILING FORM ACCORDING TO THE INSTRUCTIONS IN SECTION III AND THE ASEPTIC SUPPLEMENT TO THIS BOOKLET.**

⑥ PLEASE SEND THE FOLLOWING

A different process filing form is used for aseptic packaging systems than for other processing methods. If you use aseptic packaging systems at this location, enter the number of process filing forms for aseptic processes you want FDA to send to you (on the line preceding "Process filing forms used for aseptic processes").

If you use other processing methods, enter the number of process filing forms needed on the line preceding "Process filing forms used for all processing methods except aseptic".

If you do not have the LACF and acidified regulations and/or the instructions for establishment registration and process filing and want FDA to send you a copy, check the appropriate space(s). Otherwise leave blank.

⑦ AUTHORIZED COMPANY REPRESENTATIVE

Enter the name, title, area code, phone number, and signature of the authorized representative who is signing this form on behalf of your company, and the date signed in the appropriate spaces. Check appropriate block to show whether phone number is at plant location or mailing address. If the representative is at neither the plant address nor the mailing address, the location may be included in the "Authorized Company Representative" space along with the name and title. **MAIL ALL COPIES OF THE REGISTRATION FORM TO:**

**LACF Registration Coordinator (HFF-233)
Bureau of Foods (FDA)
200 C Street, S.W.
Washington, DC 20204**

A copy of the registration form will be returned to you by FDA, giving your assigned FCE number, and including any forms and/or publications you may have requested.

Instructions for process filing for all processing methods except aseptic are contained in Section III of this booklet, which follows. Instructions for filing processes for aseptic packaging systems are in a separate supplement which is available upon request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES - PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
 FOOD CANNING ESTABLISHMENT REGISTRATION

Form FD-204 (Rev. 10-27-70) Use of this form is authorized after July 31, 1983

2 TYPE OF SUBMISSION

- Initial Registration
 Change of Registration Information (Specify Type of Change)

Enter Current PCE (if applicable)

1

FOR FDA USE ONLY		
PCE No	Date Received by FDA	
OOB Code	Date	District
Reference		

3 FOOD PROCESSING PLANT LOCATION

4 PREFERRED MAILING ADDRESS

Establishment Name ABC CANNING CO.
 Number and Street 111 ST. ROMAIN
 City and State or Province (or other Subdivision) LE GOULET, NEW BRUNSWICK
 Zip (or other Postal Code) G0D 4C0 Country (if other than U.S.) CANADA

Establishment Name ABC HEADQUARTERS INC.
 Same as Plant Location
 Number and Street (or P.O. Box #) P.O. BOX 123
 City and State or Province (or other Subdivision) CTE GASPE EST, QUEBEC
 Zip (or other Postal Code) G0C 380 Country (if other than U.S.) CANADA

5 LOW ACID AND/OR ACIDIFIED FOODS PROCESSED AT THIS LOCATION

Food Product Name Form or Style and Packing Medium
(Do not list foods processed under the continuous inspection of the Meat Inspection Service or the Poultry Inspection Service of the Animal and Plant Health Inspection Service of the United States Department of Agriculture.)

6

Food Product Name Form or Style and Packing Medium	(Check One)	
	Low-Acid	Acidified
<u>MUSHROOMS (BUTTONS) IN BRINE</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>CORN, CREAM STYLE</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>TRASHPOT SOUP</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>BUTTERSCOTCH PUDDING</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>MUSHROOMS (SLICES) IN BRINE</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>MARINATED ARTICHOKE (WHOLE) IN BRINE</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

PLEASE SEND THE FOLLOWING:

- Number of Copies
3 Process Filing forms used for aseptic processes
10 Process Filing forms used for all processing methods except aseptic
 NOTE: A separate form is required for each product-process combination
 Registration and Process Filing Instructions
 LACF & Acidified Registrations (21 CFR 108.113, 114)

See Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods for guidance in completing this form. Forward all copies of completed form to:

LACF Registration Coordinator (HFF-233)
 Bureau of Foods (FDA)
 200 C Street, S.W.
 Washington, D.C. 20204

7 AUTHORIZED COMPANY REPRESENTATIVE

Name and Title of Authorized Representative JOHN DOE, QUALITY ASSURANCE MANAGER
 Phone Number (301) 123-4567 Home Office Signature John Doe Date Sep 6, 1983

NOTE: No commercial processor shall engage in the processing of low-acid or acidified foods unless a completed Form FD-204 has been filed with the Food and Drug Administration, 21 CFR 108.20(c)(1) and 108.20(c)(2).
 Form FDA 204 (2-80)

III. PROCESS FILING FOR ALL PROCESSING METHODS EXCEPT ASEPTIC

Use Form FDA 2541a for filing processes for all processing methods except aseptic. See separate supplement for process filing instructions for aseptic packaging systems. For acidified LACF products which are packaged by aseptic packaging systems, the factor which provides the public health protection (heat or acidification) determines the form to be used (i.e., for a product acidified to a maximum equilibrium pH ≤ 4.6 , use Form FDA 2541a; for one acidified to a maximum equilibrium pH > 4.6 , use Form FDA 2541c).

Complete a separate process filing form (FDA 2541a) for each product. In addition, unless otherwise indicated in this booklet, complete a separate form for:

- o Each processing method (still, agitating, hydrostatic, etc.)
- o Each product form or style (whole, diced, French style, strained, solid-pack, syrup strength category, brined, cream style, mature, cured, dry pack, vacuum pack, etc.) which receives a different scheduled process OR when the characteristics of the food affect heat transfer. Products with minor formulation differences for which processes are identical (e.g., beans in tomato sauce, with or without pork) may be filed on the same form if other factors do not require separate filing. In any case, mushrooms must always be separated (i.e., filed on separate forms) by product form or style.
- o Each different packing medium (e.g., water, oil, sauce, etc.). Products packed in water, brine, and sweetened brine may be filed on the same form as long as the scheduled processes are exactly the same.
- o Each type of container in which the product is packed (i.e., metal cans, glass, etc.), even though all other information is exactly the same.
- o Each process source when all scheduled processes listed were not established jointly.

NOTE: The use of photocopies or similar reproductions of forms with only slight variations is acceptable, as long as each bears a unique submission identifier (see ② on next page) and is signed by an authorized company representative.

A separate form is not required for each different brand name of a product if the scheduled process for the brands is exactly the same. In addition, multiple container sizes for a product should be listed on the same form, as long as the container type, packing medium, and other such information not related to container size is identical.

Complete each required space on the form in English according to the instructions which follow. The encircled numbers correspond to those on the sample fold-out form on page 35.

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PART A. PRODUCT:

① **FCE**

Enter the 5-digit Food Canning Establishment (FCE) Number assigned to your establishment by the FDA when you registered (on Form FDA 2541). If registering concurrently with initial process filing, leave blank (FDA will complete). Upon receipt of your FCE number from FDA, record it on your copies of process filing forms.

② **Submission Identifier (SID)**

Assign a unique SID to each process filing form as follows, based on the date the form is being submitted:

- YY is the last two digits of the year (e.g., 83, 84, etc.)
- MM is the numerical designation of the month (e.g., 05 for May, 10 for October, etc.)
- DD is the day of the month (e.g., 03, 28, etc.)
- SSS is a unique sequence number within the date (e.g., 001, 002, etc.)

③ **Name, Form or Style, and Packing Medium**

Enter the food product name, form or style, and packing medium in that order, e.g., Carrots (whole) in water; Mushrooms (sliced) in gravy; etc.

Product forms or styles receiving the same scheduled process should be included in parentheses after the product name. For example, "Carrots (whole, cut, quartered, sliced, diced, or shoestring) in brine".

- REMEMBER:**
- o Each different packing medium (e.g., water, oil, sauce, etc.) must be filed on a separate form. Products packed in water, brine, and sweetened brine may be filed on the same form as long as the scheduled processes are exactly the same.
 - o Each different form or style of mushrooms must always be filed on separate forms. For example:
 - Whole mushrooms must be filed separately;
 - Mushroom Buttons must be filed separately;
 - Sliced mushrooms must be filed separately;
 - Mushroom pieces and stems must be filed separately.

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Foreign Firms:

List the English name as well as the non-English name as it appears on the label. For example:

Green kidney beans (flageolets) in brine

④ **Raw pH**

Enter the normal or natural pH of the product before processing, to the nearest tenth (e.g., 6.5). For acidified products, enter the highest natural pH of the low-acid component(s).

⑤ **Governing Regulation**

Check the governing regulation under which the process is being filed (i.e., whether the product is low-acid or acidified).

⑥ **Type of Submission**

Check "**new**" if no previous processes have been filed for this product in the container sizes being listed or if these are additional processes for the container sizes listed (i.e., this form does not replace a previously submitted one).

Check "**replaces**" if this is a replacement for a previously submitted process filing form, and enter the SID of the previously filed form being replaced.

Check "**cancel**s" if you are cancelling a previously filed form (not replacing it with another). Enter the SID of the previously filed form being cancelled and the product name (this is an aid in ensuring cancellation of the correct form). Complete the information at the bottom of the form (②⑨ and ③⑩); sign and date it, and send it to FDA.

As an alternative, you may photocopy the form to be cancelled. Assign a new SID in ② (lining out the original one without making it unreadable), check "**cancel**s" in ⑥ and enter the original SID. Sign and date the photocopy above the original signature and date and submit it to FDA.

If you wish to delete one or more container sizes previously filed, submit a "**replacement**" for the previously filed form, listing only the container sizes currently applicable. As explained above for cancellations, you may photocopy the previously filed form and line out the container size(s) no longer used. **However**, you must then:

Assign a new SID reflecting the effective date, lining out the old one;

Check "**replaces**" and enter the SID of the previously filed form;

Sign and date the form above the old signature and date.

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NOTE: If you are replacing or cancelling a form submitted before you began assigning SIDs, use the SID assigned by FDA to identify the form being replaced or cancelled. That SID appears in the upper right portion of the facsimile (furnished to you by FDA) which corresponds to the form being referred to. The SID assigned by FDA is immediately to the right of the words "SUBMISSION IDENTIFIER (SID) FOR THIS FORM."

⑦ Process Use

Check "scheduled" if this is the ordinarily used process for this product under normal conditions.

Check "alternate" if this is a process used regularly in lieu of the ordinarily used (scheduled) process (which is filed separately). Enter the SID of the scheduled process for which this is an alternate. If you are replacing a scheduled process for which you have filed alternate processes, FDA will assume that the alternate processes apply to the replacement scheduled process. If the alternate processes do not apply to the replacement, they should be replaced or cancelled by separate submissions.

Check "emergency" if this is an emergency still process for a separately filed (scheduled) agitating process, and enter the SID of the applicable scheduled agitating process.

FORMS RETURNED BY FDA FOR MISSING DATA

When resubmitting a form which was returned by FDA for missing data, enter the missing data directly on the returned form and send it to FDA. **DO NOT CHANGE THE SID OR TYPE OF SUBMISSION.** Be sure to enter the missing data on your file copy of the form.

PART B. PROCESSING METHOD:

⑧ Name of Sterilizer (Mfg & Type)

Enter the name of the manufacturer and the model number or name (if applicable). Limit to 30 characters when possible. Abbreviations may be used when meanings are clear.

⑨ Check the processing method used (one per form) and provide the additional information indicated below:

If you check:

STILL

AGITATING

Also give the following:

Whether horizontal and/or vertical, or crateless. Also indicate whether divider plates are solid or perforated (for horizontal and vertical), or check "none" if applicable. For crateless, indicate applicable bottom surface.

Whether agitation is end over end or axial, and whether continuous or discontinuous (batch).

If you check:

HYDROSTATIC

FLAME

OTHER

Also give the following:

Type of chain (inner only, outer only, both, etc.).

N/A

Fully describe the type of equipment used.

⑩ Acidified Products

If this is an acidified product filed under 21 CFR 108.25 and 114, check "acidified" and enter the following additional information:

Maximum Equilibrium pH

Enter the maximum equilibrium pH (upper limit) of the finished product after acidification, measured within 24 hours after processing, to the nearest tenth (e.g., 4.2).

Method of Acidification

Enter the method of acidification (e.g., direct acidification, acid blanch, acid soak, etc.). If direct acidification is used, enter the concentration of acid immediately below. For example, "1.5% covering solution, equalized to approximately 0.8%".

Acidifying Agent

Enter acidifying agent(s), e.g., citric acid, acetic acid, malic acid, fumaric acid, tartaric acid, etc.

Pasteurization Method

If a heat treatment (e.g., pasteurization) is recommended by the process source as part of the scheduled process, enter the type of treatment, such as water bath, hot fill hold, etc. If no heat treatment is specified by the process source as part of the scheduled process (i.e., pH control only), enter N/A.

Preservative Used

If a preservative is used along with pH control, specify the preservative (e.g., sodium benzoate, potassium sorbate, etc.) and the concentration. If no preservative is used, enter N/A.

⑪ Container Type

NOTE: Except for tinplate/steel and aluminum cans (which may be submitted on the same form if the processes are identical), USE A SEPARATE FILING FORM FOR EACH DIFFERENT CONTAINER TYPE EVEN IF ALL OTHER INFORMATION IS THE SAME.

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Check the container type used (i.e., Tinplate/Steel Can, Aluminum Can, Glass or Ceramic, Pouch, Semi-rigid Container, or Other) and provide the additional information indicated below:

If you check:

Tinplate/Steel Can
and/or Aluminum Can

Pouch

Semi-rigid Container

Other

Also give the following:

Whether the container is 2-piece or 3-piece AND whether welded, soldered, and/or cemented. NOTE: 2-piece and 3-piece cans may be filed together provided that the processes being filed are adequate for the worst condition (i.e., nesting). Otherwise, 2-piece and 3-piece cans must be filed separately. When nesting is specified as a critical factor by the process establishment source, it must be so reflected in Section C (critical factors).

Material from which constructed (e.g., polyethylene/alum. foil laminate).

Type (cups, tubs, cartons, etc.) and material from which constructed.

Specify the type and (if not clearly indicated by the type of container), the material from which constructed.

NOTE: Minor container material variations that do not affect the scheduled process do not require submission of separate forms.

⑫ Process Establishment Source

NOTE: If more than one process source is listed, the process(es) must have been established jointly by the listed sources. Otherwise, use a separate form for each process source.

Enter the name of the process authority (organization, company, or individual, etc.) which conducted the scientific studies establishing the scheduled process(es) listed on this form, and the type of document in which published (i.e., letter, bulletin, etc.). Use the following guidelines in making entries:

- When possible, limit entries to 30 characters by minimizing punctuation, not using plurals, etc.
- If the process was established as a result of your own firm's studies, enter your firm's name as the source.
- For universities, enter name of university followed by the name of an individual (if appropriate).

Date Last Established

Enter the last two digits of the year (in the spaces over "YY") and the numerical designation of the month (e.g., 05 for May, 10 for October, etc. in the spaces over "MM") of the latest source document issued by the process authority listed under "Process Establishment Source".

Process Recommendations Attached?

If you are including (with this process filing form) a copy of the process as specified by the process establishment source (including any allowable process alternatives which you do not normally expect to use), check "YES"; otherwise check "NO" (foreign registrants must include an English language translation). The process source document should also be kept on file at the processing location.

PART C. CRITICAL FACTORS

- ⑬ Check **All** critical factors as specified by the process establishment source which must be controlled in order to assure commercial sterility and delivery of the scheduled process. If none have been specified, check "**None of the Following**". Where applicable, enter the appropriate value or other additional data specified. For example:

Maximum Water Activity (a_w)

Enter value to the nearest hundredth (e.g., .88) if reduced water activity has been specified by the process source as critical to the delivery of the scheduled process.

Consistency/Viscosity

Value:

Enter the maximum consistency reading, measured to the nearest thousandth (e.g., 85.000), at the temperature specified by the process source. If consistency is given by the process source as a range, report the **highest** value.

Units:

Enter units in which reading is measured. Abbreviate to three characters. For example:

- CPS - centipoise
- C/S - centimeters/second
- INS - inches

Method Name:

Enter instrument used and its characteristics. Limit to 30 characters, if possible. If Brabender is used, include the paddle (e.g., Brabender A Paddle).

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Temperature:

Enter temperature at which reading is taken, to the nearest whole degree (e.g., 180) ($\pm 2^{\circ}$ F is assumed). If temperature is specified by the process source as a range, you may report that range.

Container Position in Retort

Indicate horizontal, vertical, etc. If nesting of containers is a critical factor (e.g., 2-piece containers), so indicate.

Fill Method

Check applicable method; if "Other" is checked, enter method on line following.

% Solids

Enter the maximum percentage, to the nearest tenth (e.g., 75.5).

Solid to Liquid Ratio (wt. to wt.)

Enter the maximum ratio of solids to a unit of liquid (to the nearest tenth), using the same units of weight for both (e.g., 02.6).

Drained wt./Net wt. Ratio

Enter the maximum ratio of drained weight to a unit of net weight (to the nearest hundredth), using the same units for both (e.g., 0.79).

Arrangement of Pieces in Container

Indicate the required arrangement (e.g., tips up).

Formula Changes

Check if specified as critical to assure commercial sterility by the process source.

Preparation Method

Check if specified as critical to assure commercial sterility by the process source.

Product Quality

Check if specified as critical to assure commercial sterility by the process source.

Matting Tendency

Check if specified as critical to assure commercial sterility by the process source.

Layer Pack

Check if specified as critical to assure commercial sterility by the process source (e.g., weight of cream in oz. for layer packed cream style corn).

Max. Pouch Thickness in Retort

Enter maximum thickness (in the retort during processing) in inches (to the nearest hundredth), e.g., 0.92. (Note: Where applicable, the maximum pouch thickness may be controlled by the dimensions of the racking system employed.)

Max. Residual Air (Pouches)

Enter the maximum residual air in cubic centimeters (to the nearest tenth), e.g., 04.2.

Particle Size

Enter maximum and/or minimum particle size specified by the source authority (e.g., "cuts \geq 1/4 inch"; shrimp size; "minimum slice thickness \geq 3/16 inch", etc.) and the food component(s) to which the limitation applies.

Syrup Strength

Enter maximum degrees (Brix) to the nearest tenth of a degree (e.g., for the product "sweet potatoes, syrup pack (20° Brix or less)", enter the value 20.0).

Starch Added

Enter the maximum percentage, to the nearest tenth (e.g., 10.1) and the type of starch in the spaces provided.

Other Binder

Specify the binder (other than starch) used.

Min. % Moisture of Dry Ingredients

Enter the minimum percentage, to the nearest tenth (e.g., 32.2) in the spaces provided.

Other

If a critical factor which is not listed in either Part C or D of the form (and which does not vary by container size) has been specified by the process source, enter that critical factor, along with the appropriate maximum or minimum value (if applicable). For example, "full parchment liner", "air cooled", etc.

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PART D. SCHEDULED PROCESS

⑭ FCE and SID

Enter the same FCE and SID as were entered in ① and ② at the top of the form (so that if the completed form is copied, the upper and lower parts of the copies can be correctly matched).

⑮ Container Dimensions

Enter the dimensions of each container size which is used for the product listed **IN ENGLISH UNITS (inches and sixteenths)** as described below. Use a separate line for each different container size and its process parameters or characteristics, numbering each line sequentially (1, 2, etc.) in the "Cont. No." column. **Do not leave blank lines between container sizes.**

Cylindrical Containers

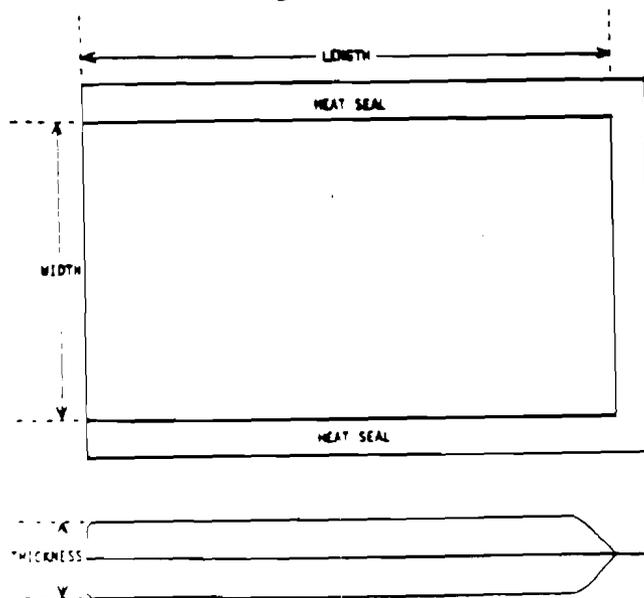
Enter diameter in the first column following container number and height in the second. Leave the next column blank.

Rectangular Containers

Enter length (longest dimension) in the first column following container number, width (second longest dimension) in the second, and height in the third.

Pouches

Enter length (longest dimension, excluding heat seal) in the first column following container number, width (second longest dimension, excluding heat seal) in the second, and maximum pouch thickness (in retort during processing) in the third. See illustration below. (Note: Where applicable, the maximum pouch thickness may be controlled by the dimensions of the racking system employed).



HOW TO MEASURE A FLEXIBLE POUCH WITH A HEAT SEAL

Unconventional or Irregularly Shaped Containers

When one or more of the above dimensions cannot be used, show the units in which volume is measured immediately under "Capacity Units" (in the fourth column heading). Check one of the units shown (or enter appropriate unit under "other"). Enter the volumetric capacity of each container (expressed in those units) in the same column on the appropriate line.

SCHEDULED PROCESS

For each container size identified in ⑮, enter the scheduled process information specified by the process source cited in ⑫ as indicated below. Check only one item in each column under the appropriate heading ("LACF" or "Acidified or a_w Controlled") unless otherwise indicated.

For multiple step processes (in which more than one sterilizer shell is used AND temperatures of the sterilizer shells used are different), see special instructions under that heading on page 30.

For hydrostatic processes in which infeed and exit leg times and temperatures are a part of the process, see special instructions under that heading on page 32.

For all other processes, continue below.

⑯ Step No.

Enter "1" unless:

- This is a multiple step process (see instructions under that heading on page 30).
- This is a hydrostatic process in which infeed and exit leg times and temperatures are a part of the process. See special instructions on page 32.

⑰ Temp (°F)

For LACF processes, check "Min. IT" (Minimum Initial Temperature) in the heading and enter temperature of the contents of the coldest container to be processed (after thorough stirring or shaking of the filled container) at the time the sterilizing cycle begins. Express (in °F) to the nearest whole degree (e.g., 160).

For Flame Sterilizers, enter product temperature at entry to holding section (that area throughout which the temperature is uniform).

For Acidified or a_w controlled LACF processes, check "Min IT", "Fill", or "Center" (whichever is applicable) and enter that temperature (in °F) if any of the above have been specified by the process establishment source. If none are applicable, enter "N/A".

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⑱ Process Time (Minutes)

For LACF processes, check "Process Time" in the heading and enter the minimum process time in minutes, to the nearest hundredth of a minute (e.g., 023.90).

For Flame Sterilizers, enter the minimum time the container is in the holding section

For Acidified or a controlled LACF processes, check "Proc Time" (process time), "Hold", "In Sterilizer", or "Other" as applicable, and enter the time in minutes to the nearest hundredth if any of the above have been specified by the process establishment source. If "Other" is checked, explain on the line following. If none of these are applicable, check "N/A".

⑲ Sterilization Temp (°F)

For LACF processes, check "Process Temp" in the heading and enter the minimum processing temperature in °F to the nearest whole degree (e.g., 260).

For Flame Sterilizers, enter minimum temperature of the container contents through the holding section.

For Acidified or a controlled LACF processes, check "Process Temp" and enter the minimum process temperature in °F to the nearest whole degree if a sterilizer processing temperature has been specified by the process establishment source. Otherwise, check "N/A".

⑳ Least Sterilizing Value of the Scheduled Process

Check appropriate item in the heading to identify the value entered for each container number.

If " F_0 " is checked, express the value to the nearest tenth of a minute (e.g., 015.0).

If "Other F Value" is checked, enter the value for F_T^z and specify the death rate (z) and reference temperature (T) in whole degrees Fahrenheit in the spaces provided.

If "IS Value" is checked, enter the applicable Integrated Sterilizing Value on each line.

If "Other" is checked, indicating that an equivalent scientific basis for process adequacy is applicable, enter that basis immediately following.

For acidified LACF processes wherein a heat treatment is not specified as part of the scheduled process, check "Other" and enter "N/A" in the blank space.

OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY
PER SOURCE AUTHORITY

For each container size identified in (15), enter the scheduled process information specified by the process source cited in (12) as indicated below. If a factor is not specified by the process source or is specifically indicated as being not applicable, check "N/A".

(21) **Thruput**

For continuous systems (continuous agitating, hydrostatic, flame, or any other "non-batch" system), enter the maximum thruput allowable if specified by the process source. Express in whole containers per minute (e.g., 0235).

For Flame Sterilizers, enter the maximum thruput allowable through the holding section.

(22) **Headspace**

If the process source has specified that minimum headspace be controlled in order to assure delivery of the scheduled process, enter the minimum headspace in inches to the nearest ten thousandth (e.g., 0.3750). Check appropriate space in column heading to indicate whether "Net" or "Gross" headspace is given. If minimum headspace is not applicable, check "N/A".

(23) **Speed**

For all continuous systems and batch agitating systems, provide the information specified below. For still processes, check "N/A".

Reel Speed

Agitating Systems

Express in revolutions per minute (RPM), to the nearest hundredth of a revolution (e.g., 035.40).

Other Systems

Leave Blank.

Reel Diameter

Agitating Systems

Express in whole inches (e.g., 050).

Other Systems

Leave Blank.

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Steps Per Turn of Reel

Agitating Systems

Enter the number of container positions around the circumference of the reel.

Other Systems

Leave Blank.

Chain/Conveyor Speed

Agitating Systems

Leave Blank

Hydrostatic Systems

Check applicable space in column heading to indicate whether speed is expressed in feet per minute, carriers per minute, or flights per minute. Express value to the nearest hundredth (e.g., 063.30).

Flame Systems

Check "Feet per minute" space in column heading and enter the value to the nearest hundredth (e.g., 005.25).

24 Maximum Weight

If the process source has specified that maximum fill weight or maximum drained weight must be controlled in order to assure delivery of the scheduled process, check the applicable space in the column heading and enter the maximum weight in ounces, to the nearest hundredth (e.g., 03.10). If not applicable, check "N/A".

25 Minimum Net Weight

If the process source has specified that minimum net weight must be controlled in order to assure delivery of the scheduled process, enter the minimum net weight in ounces, to the nearest hundredth (e.g., 08.25). If not applicable, check "N/A".

26 Minimum Free Liquid at Closing

FOR VACUUM PACK PROCESSES ONLY, enter the minimum free liquid in the container (in ounces) at closing, as specified by the process source. Express to the nearest tenth (e.g., 01.3). If not applicable, check "N/A".

②⑦ Minimum Container Closing Machine Gauge Vacuum

FOR VACUUM PACK PROCESSES ONLY, enter **minimum** container closing machine gauge vacuum **if specified by the process source to be critical to the delivery of the scheduled process**. Express in whole inches of mercury (Hg). In the column heading, enter the temperature at which measured (as specified by the process source). If not applicable, check "N/A".

②⑧ Other

If any other critical factors (whose values vary by container size) have been specified by the process source **as critical to the delivery of the scheduled process** (e.g., minimum RPM), identify them in the column heading under "OTHER", and enter the applicable values on the appropriate line.

This space may also be used to indicate the hydrostat chain(s) to which the process applies by entering a column heading of "chain" and entering "I" for inner, "O" for outer, etc. on the applicable line.

②⑨ Comments

You may use this space to enter any comments which you believe are necessary to clarify any entries on this form.

③⑩ Plant Name and Address

Enter the name of your plant and its location address, corresponding to the FCE Number entered in ① and ⑭ above. This is used by FDA as a check of the FCE number and **may not be used to change the name or address**. Name and address changes must be submitted on an Establishment Registration form (FDA 2541).

An address change resulting from a move to a different location (as opposed to a street name change, etc.) **requires re-registration** (and assignment of a new FCE number) **and re-filing of all scheduled processes**. The old FCE number is **not valid and its use will not be accepted** by FDA.

Authorized Individual

Print (or type) the name of the authorized representative who is signing this form on behalf of the company, and the area code and telephone number at which she or he can be reached. Sign and date the form and mail **the original copy** to:

LACF Registration Coordinator (HFF-233)
Bureau of Foods (FDA)
200 C Street, S.W.
Washington, DC 20204

Keep the second (pink) copy for your files. You are required to maintain a file copy for future reference at the processing plant location.

If you have any questions about any of these instructions, write to the above address, or telephone (202) 485-0282.

4. For the second container size, enter "2" in the container number column and the container dimensions in the appropriate columns. Enter required information as instructed in 1. on preceding page. Follow 2. and 3. on the preceding page for the second container size. Repeat for each subsequent container size.

5. Complete Items 28 and 29 (if applicable) and 30

EXAMPLE

D. SCHEDULED PROCESS:

PCB: 04999 rev: 23-02-21/008

CONTAINER DIMENSIONS				SCHEDULED PROCESS (Check Only One in Each Column)				OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY								OTHER			
Cont. No.	Diameter or Length	Height or Width	Height or Diam. Percent Tolerance	Step No.	Temp. (°F)	Process Time (minutes)	Sanitization Temp. (°F)	Label Retention Value of the Scheduled Process	Temperature	Humidity	Spores				Minimum Weight	Minimum Net Weight	Minimum Fill Lit. or Ounces	Minimum Container Weight	Other
					Autoclave	Pressure Time	Sanitization				Other	Per Spore	Per Spore	Per Spore					
1	0.003	0.100		1	170	017.21	250		0.000	0.2500	0.09	40	0.51	0.10					
				2		018.46	265	0.04.3	0.000		0.09	40	0.51	0.20					
2	0.011	0.212		1	160	014.00	225		0.500	0.3750	0.10	50	0.07	0.08					
				2		016.46	262	0.04.3	0.500		0.10	50	0.07	0.08					
3	0.010	0.000		1	165	015.50	225		0.450	0.3750	0.06	50	0.51	0.08					
				2		017.22	270	0.04.3	0.450		0.06	50	0.51	0.08					

NOTE: THE ABOVE IS AN EXAMPLE ONLY TO ILLUSTRATE ENTRIES AND IS NOT A VALID PROCESS.

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SPECIAL INSTRUCTIONS FOR HYDROSTATIC PROCESSES
IN WHICH INFEED AND EXIT LEG TIMES AND TEMPERATURES
ARE A PART OF THE PROCESS

For such processes, report the data as follows (see example on the facing page). The encircled numbers correspond to the detailed explanation of the data requirements for each item.

1. Enter the container number and container dimensions for the first container (see (15)). On the same line, enter "F" in the "Step No." column (16) to indicate Feed leg. Continuing on the same line, enter:

- o Minimum initial temperature of the product at entry to infeed leg under "Temp" (Min. IT) (17)
- o Infeed leg time under "Process Time" (18)
- o Infeed leg temperature under "Sterilization Temp" (19)

2. On the next line, enter "S" in the "Step No." column (16) to indicate Steam chamber. Do not repeat container number or dimensions. Continuing on the same line, enter the following. If a factor is not applicable per the source authority, check "N/A" in that column.

- o Minimum process time in the steam chamber under "Process Time" (18)
- o Steam chamber temperature under "Sterilization Temp" (19)
- o Thruput in whole containers per minute (if applicable) (21)
- o Headspace (22)
- o Chain or conveyor speed under that column heading (23)
- o Maximum weight under that column heading (24)
- o Minimum net weight under that column heading (25)
- o Minimum free liquid at closing under that column heading (26)
- o Minimum container closing machine gauge vacuum under that column heading (27)
- o Other critical factors specified by the source authority under "OTHER" (28)

3. On the next line, enter "E" for Exit in the "Step No." column (16). Do not repeat container dimensions. Continuing on this line, enter the following:

- o Exit leg time under "Process Time" (18)
- o Exit leg temperature under "Sterilization Temp" (19)
- o The least sterilizing value of the total scheduled process (F_0) under that column heading (20)

4. For the second container size, enter "2" in the container number column on the next available line (13) along with the container dimensions. Continue as in 1., 2., and 3. on the preceding page for the second container size. Repeat for each subsequent container size in the same manner.

EXAMPLE

D. SCHEDULED PROCESS:

PC: 04999 ID: 83-02-21,002

CONTAINER DIMENSIONS				SCHEDULED PROCESS (Check Only One in Each Column)				OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY								OTHER (Specify)		
Step No.	Quantity of Length	Height or Width	Height of Sterile Process Treatment	Yield (%)	Process Time (Minutes)	Sterilization Temp (°F)	Leak Monitoring Value of the Sterilized Product	Prepact	Heatpacks	Spores				Minimum Weight	Minimum Net Weight	Minimum Fills Lit. of Content	Minimum Container Capacity (Liters)	
			Capacity Mark	<input checked="" type="checkbox"/> Min. FT	<input checked="" type="checkbox"/> Process Time	<input checked="" type="checkbox"/> Process Temp	<input checked="" type="checkbox"/> F ₀	<input type="checkbox"/> Other F Value	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	Per Spore	Per Batch	Spore Per Yr of Prod	Other/Container/Other	<input checked="" type="checkbox"/> Min	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Min	<input checked="" type="checkbox"/> Min
				Additional or by Container			Death Rate (d)											Temp (± 3°F)
				<input type="checkbox"/> Min FT	<input type="checkbox"/> Proc. Time	<input type="checkbox"/> Process Temp	<input type="checkbox"/> Other F Value											<input type="checkbox"/> Min
				<input type="checkbox"/> Min FT	<input type="checkbox"/> Proc. Time	<input type="checkbox"/> Process Temp	Death Rate (d)											<input type="checkbox"/> Min
				<input type="checkbox"/> Min FT	<input type="checkbox"/> Proc. Time	<input type="checkbox"/> Process Temp	Ref Temp (T)											<input type="checkbox"/> Min
				<input type="checkbox"/> Min FT	<input type="checkbox"/> Proc. Time	<input type="checkbox"/> Process Temp	IS Value											<input type="checkbox"/> Min
				<input type="checkbox"/> Min FT	<input type="checkbox"/> Proc. Time	<input type="checkbox"/> Process Temp	Other											<input type="checkbox"/> Min
				<input type="checkbox"/> Min FT	<input type="checkbox"/> Proc. Time	<input type="checkbox"/> Process Temp	Other											<input type="checkbox"/> Min

1 0200 0300 F 090 010.00 235
 2 065.00 250 0650 009.30
 3 010 235 046.0

NOTE: THE ABOVE IS AN EXAMPLE ONLY TO ILLUSTRATE ENTRIES AND IS NOT A VALID PROCESS

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A. PRODUCT

FOOD AND DRUG ADMINISTRATION
 FOOD CANNING ESTABLISHMENT PROCESS PLAN FORM
 FOR ALL METHODS EXCEPT ASEPTIC

① 04999 ② 8311-25001
 FCE 880

③ Name, Form or Style, and Packing Medium: Creamy Vegetable Soup (Ready to Serve)
 ④ Raw pH: 6.2
 ⑤ Governing Regulation: low-acid (21CFR 108.35-113)
 acidified (21CFR 108.25-114)
 ⑥ Type of Submission: new
 replaces B 1-0-6-2-2-0-1-4
 carries over
 ⑦ Process Use: scheduled
 alternate for
 emergency for

B. PROCESSING METHOD ⑧ NAME OF STERILIZER (MFG & TYPE) FMC Sterilmatic

⑨ Ster: Agitating Hydrostatic Flame Other (explain)
 Horizontal End over End Inner Chamber only
 Vertical Annular Outer Chamber only
 Divider Plates: None Continuous Both Inner and Outer Chamber
 Solid Perforated Batch Single Chamber
 Crossed Multiple Chambers
 Bottom Surface: Solid Perforated
 ⑩ Acidified:
 Maximum Equilibrium pH: _____
 Method of Acidification: _____
 Concentration: _____
 Acidifying Agent: _____
 Pasteurization Method: _____
 Preservative Used: _____
 Concentration: _____

⑪ CONTAINER TYPE: Tinplate/Steel Can 2-piece Welded Glass or Ceramic
 Aluminum Can 3-piece Soldered Pouch (specify material)
 Cemented Semi-rigid Container (specify material)
 Other (specify) _____

⑫ PROCESS ESTABLISHMENT SOURCE: XYZ Can Corp. Letter
 DATE LAST ESTABLISHED: 198 3 1 1
 Y Y M M
 PROCESS RECOMMENDATIONS ATTACHED? YES NO

C. CRITICAL FACTORS: CONTROLLED TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY (Check or Describe)

Name of the Following: NO _____
 Maximum Water Activity (a_w): (---)
 Consistency/Viscosity: CV
 Value: (0.0860400)
 Units: CPS
 Method Name: Brookfield LVT-1 (12 RPM)
 Temperature: (180)
 Container Position in Retort: CP _____
 Heating of Containers: HC _____
 Fill Method: FM _____
 Hand: _____
 Machine: _____
 Other: _____
 % Solids: SO (25.0)
 Solid to Liquid Ratio (wt to wt): SL (---)
 Dried wt Heat wt Ratio: DW (---)
 Arrangement of Pieces in Container: AP _____
 Formula Changes: FC
 Preparation Method: PM _____
 Product Quality: PQ _____
 Missing Tendency: MT _____
 Layer Pack: LP _____
 Max Pouch Thickness in Retort: MP (---)
 Max Residual Air (Pouches): MR _____
 Particle Size: PS 3/8 inch dice
 Syrup Strength: SS (---)
 Starch Added: SA
 Min %: _____
 Type: modified corn
 Other Blender: OB _____
 Min % Moisture of Dry Ingredients: MI (92.0)
 Other (specify): OT _____

D. SCHEDULED PROCESS:

⑭ FCE: 04999 ⑮ 8311-25001

⑮ CONTAINER DIMENSIONS		⑯ SCHEDULED PROCESS (Check Only One in Each Column)				⑰ OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY					⑱ OTHER (Specify)				
Can No.	Volume or Length	Height or Width	Height of Filler	Process Type (Minutes)	Temperature (°F)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)	Time (Minutes)
1	0211	0300	140	017	45	162	019	2	0255	0	2500	005	18	055	051

⑳ COMMENTS: Critical Factors: % Solids is washed residue; Min % moisture is of dried vegetable dice after rehydration
 FDA USE ONLY

㉑ PLANT NAME & ADDRESS: U.S.A. Canning Company, 123 Main St., Anywhere, CA 96811
 AUTHORIZED INDIVIDUAL: A.B. Jones, Signature: A.B. Jones
 Print Name: A.B. Jones
 Phone Number: (123) 456-7890
 Date: Nov 25, 1983

IV. COMMON QUESTIONS AND ANSWERS CONCERNING REGISTRATION AND PROCESS FILING REQUIREMENTS

1. Q. **WHAT IS A LOW-ACID CANNED FOOD?**

A. A low-acid canned food has the following characteristics:

- 1) Equilibrium pH value greater than 4.6 and water activity greater than 0.85.
- 2) Sealed in a hermetic (air-tight) container (i.e., secure against the entry of microorganisms).
- 3) Receives a heat treatment for the purpose of achieving commercial sterility.
- 4) Normally stored and distributed under non-refrigerated conditions.

2. Q. **WHAT IS AN ACIDIFIED FOOD?**

A. An acidified food is a low-acid food to which acid(s) or acid food(s) are added. It has a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below. An acidified food is normally stored and distributed under non-refrigerated conditions.

3. Q. **WHO MUST REGISTER WITH FDA?**

A. All commercial acidified and low-acid canned food processors located in the United States and all processors in other countries who import their acidified or low-acid canned food products into the United States must register. **Wholesalers, distributors, brokers, etc. are excluded from the requirement to register.** However, they must ensure that processing firms they represent comply with the applicable regulations.

4. Q. **DO PILOT PLANTS HAVE TO REGISTER?**

A. Yes, pilot plants which produce samples of acidified or low-acid canned foods for market or consumer testing within the United States must also register with FDA.

5. Q. **IS REGISTRATION AND PROCESS FILING THE SAME FOR U.S. FIRMS AND FIRMS LOCATED IN OTHER COUNTRIES?**

A. Yes, registration and process filing is the same for all commercial acidified and low-acid canned food processors located in the United States and processors in other countries. However, processors in other countries need register and file processes only for those foods that are imported into the United States.

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6. Q. IS REGISTRATION A LICENSE OR CERTIFICATION FROM FDA?
- A. No, FDA does not approve processing information or schedules for acidified or low-acid canned foods, process sources, or processing plants.
7. Q. HOW DOES A FIRM REGISTER?
- A. A processing plant registering for the first time completes a **Food Canning Establishment Registration** form (FDA 2541) according to the instructions in section II of this booklet.
8. Q. HOW DOES A PARENT COMPANY WHICH OWNS ONE OR MORE SUBSIDIARY FOOD PROCESSING PLANT(S) REGISTER EACH FIRM?
- A. A separate Food Canning Establishment Registration form (FDA 2541) must be submitted for each processing plant location. A separate Food Canning Establishment (FCE) number will be assigned to each.
9. Q. WHAT LANGUAGE SHOULD BE USED TO COMPLETE THE REGISTRATION FORM?
- A. The registration form must be completed in English.
10. Q. WILL A FIRM BE NOTIFIED WHEN ITS REGISTRATION IS RECEIVED?
- A. Yes. An FCE number will be assigned after receipt of a Food Canning Establishment Registration form (FDA 2541) by FDA. The number will be furnished to the registering firm on a copy of the registration form which will be returned to the mailing address given on the form.
11. Q. HOW MANY TIMES MUST A FIRM REGISTER?
- A. A firm registers each processing plant location once. The firm will retain its FCE number for as long as the plant produces acidified or low-acid canned foods at the registered location.
12. Q. HOW DOES A FIRM CHANGE REGISTRATION INFORMATION?
- A. Changes to registration information such as changes to firm name or **mailing address** are submitted on a Food Canning Establishment Registration form (FDA 2541). A firm going out of business or no longer producing regulated products should submit such notification to FDA by letter.
13. Q. IF A FIRM HAS MOVED, MUST IT RE-REGISTER?
- A. Yes, a change of processing location nullifies the original FCE number since registration is based on processing location. The processing firm must complete a new Food Canning Establishment Registration form listing the new location. Under "TYPE OF SUBMISSION", check "Change of Registration Information" and enter "Re-Registration" on that line. Enter previously assigned FCE Number in the space for "Current FCE" and complete all other spaces on the form as in an initial registration. A new FCE number will be assigned to the processing plant upon receipt of the new registration form.

14. Q. IF A PROCESSING ESTABLISHMENT IS SOLD, MUST THE NEW OWNER RE-REGISTER AND RE-FILE PROCESSES?
- A. The new owner must notify FDA of the change of ownership. However, the firm will retain the FCE number previously assigned to the establishment location. **All processes to be used shall be refiled and any which will not be used shall be cancelled.**
15. Q. WHAT IF A FIRM FAILS TO REGISTER?
- Q. Firms in the United States must register their processing establishment(s) with FDA not later than 10 days after first engaging in the manufacturing, processing, or packing of acidified or low-acid canned foods. Otherwise, the firm and/or its products may face regulatory action. Firms in other countries must register before offering any acidified or low-acid canned food products for import into the United States. **Otherwise, the products will be held (detained) at the port of entry until the firm meets the registration and process filing requirements.**
16. Q. IS REGISTRATION THE ONLY REQUIREMENT FIRMS MUST MEET?
- A. No, processing plants must also submit process filing forms containing scheduled process information for each acidified and low-acid canned food produced, and must meet all other requirements of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.
17. Q. CAN A FIRM REGISTER AND SUBMIT PROCESS FILING FORMS AT THE SAME TIME?
- A. Yes, FDA encourages this procedure. The firm should request the appropriate form(s) from FDA and submit them with the necessary information. FDA will assign an FCE number and enter it on its copies of the process filing forms. When the firm receives its copy of the registration form with its assigned FCE number, the firm should enter that number on its file copies of all forms. **All correspondence with FDA, shipping documents, etc. should include that FCE number.**
18. Q. HOW DOES A FIRM FILE PROCESSES?
- A. A firm must complete the necessary process filing form(s) for each product it produces, listing the scheduled process(es) for each.
- 1) **For all processing methods except aseptic, use Form FDA 2541a.**
 - 2) **For aseptic packaging systems only, use Form FDA 2541c.**
- Detailed instructions for completing Form FDA 2541a are contained in section III of this booklet and in a separate supplement for Form FDA 2541c.

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19. Q. MUST A FIRM SUBMIT A SEPARATE PROCESS FILING FORM FOR EACH ACIDIFIED AND LOW-ACID CANNED FOOD PRODUCT?

- A.** Yes, FDA requires a separate process filing form for each acidified and low-acid canned food produced. In addition, a separate form must be completed for each form or style (including packing medium) receiving a different scheduled process. Further, a separate form must be completed for each container type (metal, glass, etc.). Each process filing form must list all container sizes for each product as well as other information specified by the detailed instructions contained in Section III of this booklet and the aseptic supplement. Products from other countries with unusual names should be described in detail. Process filing forms must list the English name as well as the non-English name of the product as it appears on the label. For example:

Green kidney beans (flageolets) in brine
Fava beans (papdi) in brine

20. Q. IF A FIRM HAS CHANGED ITS PROCESSING LOCATION, WILL NEW PROCESS FILING FORMS HAVE TO BE SUBMITTED TO FDA?

- A.** Yes, a new registration form (FDA 2541) must be submitted, as well as new process filing forms for each acidified or low-acid canned food product produced at the new plant location. A new FCE number will be assigned by FDA. **The old number will no longer be valid and will not be accepted by FDA.**

21. Q. WHEN MUST A FIRM FILE PROCESSES?

- A.** Processes must be filed no later than 60 days after registration and prior to packing a new product, or, in the case of firms in other countries, **before importing into the United States.** Registration and process filing may be done concurrently.

22. Q. WHAT IF A FIRM FAILS TO FILE PROCESSES?

- A.** If a firm in the United States fails to file processes, the firm and/or its products may face regulatory action. Firms in other countries must file processes for each acidified or low-acid canned food product before offering any such product for import into the United States. Products from firms in other countries which do not have processing information on file with FDA **will be held (detained) at the port of entry.** Those firms must be brought into compliance with the registration and process filing requirements before admission of the product into the United States.

23. Q. WHERE CAN A FIRM OBTAIN SCHEDULED PROCESSES?

- A.** A firm should contact a process authority that scientifically establishes scheduled processes for acidified and/or low-acid canned foods. Such authorities may include trade associations, container or equipment suppliers, universities, etc. with the scientific knowledge and experience, as well as adequate facilities, to properly establish processes which will result in commercially sterile products being produced under the actual industry conditions of the process application.

24. Q. HOW DOES FDA HANDLE PROCESS FILING FORMS?

A. An FDA food technologist examines each process filing form for obviously incorrect or missing information. Such forms are returned to firms for correction. Properly completed forms are further technically edited for computer entry, entered, and verified. **Under no circumstances does filing of the information constitute approval of the process source, the process, or its adequacy.** It is the responsibility of the processor to determine and assure the adequacy of any process before using it.

25. Q. WILL FIRMS BE NOTIFIED WHEN FDA RECEIVES THEIR PROCESS FILING FORMS?

A. No, because of the volume of process filing forms FDA receives, FDA will contact firms only when the scheduled process information is incomplete, or the information incorrectly filed.

26. Q. WHAT MUST A FIRM DO WHEN A PROCESS FILING FORM IS RETURNED BECAUSE OF INCOMPLETE OR INCORRECT INFORMATION?

A. Firms will receive a letter with the returned process filing form indicating the problem areas. Firms should contact their process source to obtain adequate process information, where necessary. All process information changes and additions should be made directly on the returned copy whenever possible. If completion of a new form is necessary, the old (incorrect) form should be attached to the new one and both returned to FDA.

27. Q. DOES FDA APPROVE A FIRM'S LOW-ACID OR ACIDIFIED FOOD PROCESSES?

A. No, FDA does not approve processes or process source authorities for low-acid or acidified foods. It is the responsibility of the processor to ascertain the adequacy of any process before using it.

28. Q. IF A FIRM HAS CHANGED A SCHEDULED PROCESS FOR AN ACIDIFIED OR LOW-ACID CANNED FOOD, MUST IT REFILE?

A. Yes, a replacement process filing form must be completed if the firm makes any change to a scheduled process or any factors critical to the adequacy of the process. This includes changes to the minimum initial temperature, process time or temperature, product formulation changes which affect the scheduled process, or any other critical factor. Instructions for submitting replacements for filed processes are contained in Section III of this booklet and in the aseptic supplement. Within 30 days after use, the processor must submit to FDA a complete description of the modifications made and a document showing prior substantiation by a qualified scientific authority as to the safety of the changed process.

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29. Q. IF A FIRM IS PACKING ADDITIONAL CAN SIZES OF ACIDIFIED OR LOW-ACID CANNED FOODS, MUST PROCESS FILING FORMS BE SUBMITTED FOR THESE ADDITIONS?
- A. Yes, a firm must submit a new process filing form listing all additional container sizes which will be used for each product, along with all other process information.
30. Q. IF A FIRM HAS STOPPED PRODUCING SOME ACIDIFIED OR LOW-ACID CANNED FOODS, SHOULD FDA BE NOTIFIED?
- A. Yes, FDA should be notified in writing when acidified or low-acid canned foods are no longer produced by the firm. Detailed instructions for discontinuing or cancelling previously filed processes are contained in Section III of this booklet and in the aseptic supplement.
31. Q. IS THERE A COST FOR FDA FORMS?
- A. No. Registration and process filing forms are available at no cost to the processor. They may be obtained from the LACF Registration Coordinator, whose address is given at the end of sections II and III of this booklet and the aseptic supplement (which is provided on request to firms who use or plan to use aseptic packaging systems).

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V. GLOSSARY OF TERMS

ACID FOOD

A food that has a natural pH of 4.6 or below.

ACIDIFIED FOOD

A low-acid food to which acid(s) or acid food(s) are added and which has a finished equilibrium pH of 4.6 or below and a water activity (a_w) greater than 0.85.

AUTHORIZED COMPANY REPRESENTATIVE

The person authorized by the company to sign the registration and process filing forms on its behalf. That person should possess the knowledge necessary to answer technical questions concerning filed processes.

CRITICAL FACTOR

Any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process delivered and thus the commercial sterility of the product. This does not include factors which are controlled by the processor solely for purposes of product appearance, quality, and other reasons which are not of public health significance.

EQUILIBRIUM pH

The pH of the macerated (thoroughly blended) contents of the product container. (See **MAXIMUM pH** and **NORMAL pH**.)

FILL WEIGHT

The weight of the product particulates before processing. It does not include the weight of the container or covering liquid.

F₀ (LEAST STERILIZING VALUE)

The number of minutes at a reference temperature of 250 degrees Fahrenheit required to kill a known population of microorganisms with a z value of 18 degrees Fahrenheit. This value must be obtained from a scientifically qualified process authority.

HEADSPACE, GROSS

The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

HEADSPACE, NET

The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

HERMETICALLY SEALED CONTAINER

A container which is designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing. For example, a tin, steel or aluminum can; glass jar; bottle; or pouch.

LOW-ACID FOOD

Any food (other than alcoholic beverages) with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, **excluding** tomatoes and tomato products having a finished equilibrium pH less than 4.7.

MAXIMUM DRAINED WEIGHT

Weight of the solid portion of the product after it has been processed and after draining the covering liquid for a specified time with the appropriate sieve.

MAXIMUM pH

For acidified foods, the highest finished product equilibrium pH after processing. For acidified low-acid foods not controlled at pH 4.6 or below, **this does not apply if the food receives a heat treatment which alone achieves commercial sterility.**

MINIMUM NET WEIGHT

The weight of all the product in the container, including brine or sauce, but not including the weight of the container.

NORMAL pH

For low-acid canned foods, the pH of the product or primary ingredient (e.g., green beans) in its natural state **before processing**. For acidified foods, it is the pH of the primary ingredient (e.g., pimientos) in its natural state **before acidification**.

PACKING MEDIUM

The liquid or other medium in which the low-acid or acidified product is packed. For example, for "Peas in brine", the packing medium is **brine**.

PILOT PLANT

A processing plant that produces samples of low-acid or acidified foods for market or consumer testing.

PROCESS AUTHORITY

The person or organization that scientifically establishes thermal processes for low-acid canned foods or processing requirements for acidified foods. The processes are based on scientifically obtained data relating to heat or acid resistance of public health and spoilage bacteria and/or upon data pertaining to heat penetration in canned foods. **The process authority must have expert scientific knowledge of thermal and/or acidification processing requirements and have adequate experience and facilities for making such determinations.**

SCHEDULED PROCESS

The ordinarily used filed scheduled process for a given product under normal conditions.

THERMAL PROCESS

The application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to achieve a condition of commercial sterility (i.e., the destruction of microorganisms of public health significance as well as those capable of reproducing in the food under normal non-refrigerated conditions).

WATER ACTIVITY (a_w)

A measure of the free moisture in a product. It is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

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APPENDIX A

**METRIC (mm) TO ENGLISH (inches and sixteenths)
CONTAINER DIMENSION CONVERSION CHART**

EXAMPLE: A container dimension of 77 mm would convert to 0301 (3 1/16 inches).

<u>mm</u>	<u>dimension (inches + sixteenths of an inch)</u>						
1	0001	25	0100	51	0200	76	0300
2	0001	26	0100	52	0201	77	0301
3	0002	27	0101	53	0201	78	0301
4	0003	28	0102	54	0202	79	0302
5	0003	29	0102	55	0203	80	0302
6	0004	30	0103	56	0203	81	0303
7	0004	31	0104	57	0204	82	0304
8	0005	32	0104	58	0205	83	0304
9	0006	33	0105	59	0205	84	0305
10	0006	34	0105	60	0206	85	0306
11	0007	35	0106	61	0206	86	0306
12	0008	36	0107	62	0207	87	0307
13	0008	37	0107	63	0208	88	0307
14	0009	38	0108	64	0208	89	0308
15	0009	39	0109	65	0209	90	0309
16	0010	40	0109	66	0210	91	0309
17	0010	41	0110	67	0210	92	0310
18	0011	42	0110	68	0211	93	0311
19	0012	43	0111	69	0211	94	0311
20	0013	44	0112	70	0212	95	0312
21	0013	45	0112	71	0213	96	0312
22	0014	46	0113	72	0213	97	0313
23	0014	47	0114	73	0214	98	0314
24	0015	48	0114	74	0215	99	0314
		49	0114	75	0215	100	0315
		50	0115				

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<u>mm</u>	<u>dimension (inches + sixteenths of an inch)</u>						
101	0400	127	0500	152	0600	178	0700
102	0400	128	0501	153	0600	179	0701
103	0401	129	0501	154	0601	180	0701
104	0402	130	0502	155	0602	181	0702
105	0402	131	0503	156	0602	182	0703
106	0403	132	0503	157	0603	183	0703
107	0403	133	0504	158	0604	184	0704
108	0404	134	0504	159	0604	185	0705
109	0405	135	0505	160	0605	186	0705
110	0405	136	0506	161	0605	187	0706
111	0406	137	0506	162	0606	188	0706
112	0407	138	0507	163	0607	189	0707
113	0407	139	0508	164	0607	190	0708
114	0408	140	0508	165	0608	191	0708
115	0408	141	0509	166	0609	192	0709
116	0409	142	0509	167	0609	193	0710
117	0410	143	0510	168	0610	194	0710
118	0410	144	0511	169	0610	195	0711
119	0411	145	0511	170	0611	196	0711
120	0412	146	0512	171	0612	197	0712
121	0412	147	0513	172	0612	198	0713
122	0413	148	0513	173	0613	199	0713
123	0413	149	0514	174	0614	200	0714
124	0414	150	0514	175	0614	201	0715
125	0415	151	0515	176	0615	202	0715
126	0415			177	0615		

<u>mm</u>	<u>dimension (inches + sixteenths of an inch)</u>						
203	0800	228	0900	254	1000	279	1100
204	0801	229	0900	255	1001	280	1100
205	0801	230	0901	256	1001	281	1101
206	0802	231	0902	257	1002	282	1102
207	0802	232	0902	258	1003	283	1102
208	0803	233	0903	259	1003	284	1103
209	0804	234	0903	260	1004	285	1104
210	0804	235	0904	261	1004	286	1104
211	0805	236	0905	262	1005	287	1105
212	0806	237	0905	263	1006	288	1105
213	0806	238	0906	264	1006	289	1106
214	0807	239	0907	265	1007	290	1107
215	0807	240	0907	266	1008	291	1107
216	0808	241	0908	267	1008	292	1108
217	0809	242	0908	268	1009	293	1109
218	0809	243	0909	269	1009	294	1109
219	0810	244	0910	270	1010	295	1110
220	0811	245	0910	271	1011	296	1110
221	0811	246	0911	272	1011	297	1111
222	0812	247	0912	273	1012	298	1112
223	0812	248	0912	274	1013	299	1112
224	0813	249	0913	275	1013	300	1113
225	0814	250	0913	276	1014	301	1114
226	0814	251	0914	277	1014	302	1114
227	0815	252	0915	278	1015	303	1115
		253	0915			304	1115
						305	1200

APPENDIX B

**TEMPERATURE CONVERSION CHART
CELSIUS TO FAHRENHEIT (nearest whole degree)**

<u>°C</u>	<u>°F</u>								
-40	-40	- 3	27	34	93	71	160	108	226
-39	-38	- 2	28	35	95	72	162	109	228
-38	-36	- 1	30	36	97	73	163	110	230
-37	-35	0	32	37	99	74	165	111	232
-36	-33	1	34	38	100	75	167	112	234
-35	-31	2	36	39	102	76	169	113	235
-34	-29	3	37	40	104	77	171	114	237
-33	-27	4	39	41	106	78	172	115	239
-32	-26	5	41	42	108	79	174	116	241
-31	-24	6	42	43	110	80	176	117	243
-30	-22	7	45	44	111	81	178	118	244
-29	-20	8	46	45	113	82	180	119	246
-28	-18	9	48	46	115	83	181	120	248
-27	-17	10	50	47	117	84	183	121	250
-26	-15	11	52	48	118	85	185	122	252
-25	-13	12	54	49	120	86	187	123	253
-24	-11	13	55	50	122	87	189	124	255
-23	- 9	14	57	51	124	88	190	125	257
-22	- 8	15	59	52	126	89	192	126	259
-21	- 6	16	61	53	127	90	194	127	261
-20	- 4	17	63	54	129	91	196	128	262
-19	- 2	18	64	55	131	92	198	129	264
-18	0	19	66	56	133	93	199	130	266
-17	1	20	68	57	135	94	201	131	268
-16	3	21	70	58	136	95	203	132	270
-15	5	22	72	59	138	96	205	133	271
-14	7	23	73	60	140	97	207	134	273
-13	9	24	75	61	142	98	208	135	275
-12	10	25	77	62	144	99	210		
-11	12	26	79	63	145	100	212		
-10	14	27	81	64	147	101	214		
- 9	16	28	82	65	149	102	216		
- 8	18	29	84	66	151	103	217		
- 7	19	30	86	67	153	104	219		
- 6	21	31	88	68	154	105	221		
- 5	23	32	90	69	156	106	223		
- 4	25	33	91	70	158	107	225		

APPENDIX C

"TYPIST TIPS" for completing the NEW process filing form (Form FDA 2541a)

These tips are designed to help you PRIMARILY in completing the NEW process filing form for all processes except aseptic (Form FDA 2541a). Portions (especially paragraphs 3 and 4 below) also apply to Form FDA 2541c, which is used ONLY to file processes for aseptic packaging systems.

1. Form FDA 2541a (process filing form for all processes except aseptic) is designed to be filled out using a 12 pitch ("elite") typewriter (12 characters to the inch horizontally; 6 characters to the inch vertically). Other typewriters may be used, but the characters may not "fit" the spacing. The form (as well as forms 2541c and 2541a - Establishment Registration Form) may also be completed legibly by hand. The pin-feed on the new form facilitates use of a word processor with a pin-feed mechanism; otherwise, the pin-feed tear strip simply serves to keep the two copies of the form aligned.
2. The rectangles in the upper left and right corners of Form FDA 2541a are a guide for positioning the form. Once you have positioned the form so that typed characters are properly positioned in the rectangles, you should be able to type the rest of the form without making any adjustments (provided that the form does not slip in the typewriter!!).
3. When submitting a number of forms which reflect a substantial amount of common information (e.g., process data, container sizes, etc.) but which differ in some ways (e.g., different products, different container types, etc.), you can save yourself some work by entering the common information on one form, leaving off the data which differ among the forms to be submitted. Then photocopy the form the required number of times, and enter the information unique to each form to be submitted on the separate copies (e.g., unique SID, product name, container type, etc.). Be sure to keep a copy of each for your files.
4. Each form must bear a unique Submission Identifier (SID). Be sure not to duplicate any SID because such situations require a great deal of time to resolve and they delay the acceptance of the form(s) by FDA. Any number of forms can be submitted on any date as long as the sequence number portion is unique for each SID.
5. Another step which will reduce the likelihood of FDA returning a form for correction is that of checking for completeness. **Every question must be answered.** If you note a space that is not complete, and "N/A" was not checked, point out the omission to the person who fills out the form. If a form with missing data is noted in the FDA review, it will be returned; therefore, a completeness check can save time.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION**

ASEPTIC PACKAGING SYSTEM SUPPLEMENT

**TO
INSTRUCTIONS FOR ESTABLISHMENT REGISTRATION
AND
PROCESS FILING
FOR
ACIDIFIED AND LOW-ACID CANNED FOODS**

1984

NOTE: THIS SUPPLEMENT CONTAINS INSTRUCTIONS FOR FILING PROCESSES FOR ASEPTIC PACKAGING SYSTEMS. ALL USERS SHOULD BECOME THOROUGHLY FAMILIAR WITH APPLICABLE REGULATIONS FOR REGISTRATION AND PROCESS FILING AND WITH THE GENERAL INSTRUCTIONS IN THE MAIN INSTRUCTION BOOKLET. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT THE LACP REGISTRATION COORDINATOR AT (202) 485-0282.

SEE THE MAIN INSTRUCTION BOOKLET FOR COMMON QUESTIONS AND ANSWERS CONCERNING REGISTRATION AND PROCESS FILING; GLOSSARY OF TERMS; METRIC TO ENGLISH CONVERSION CHART; AND CELSIUS TO FAHRENHEIT TEMPERATURE CONVERSION CHART.

Prepared according to
FDA Contract 223-80-2318

Acidified and Low-Acid Canned Food
Process Filing Improvement Project

by

Bureau of Foods, FDA
Industry Programs Branch
Plant and Protein Technology Branch
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PROCESS FILING FOR ASEPTIC PACKAGING SYSTEMS (FORM FDA 2541c)

Use Form FDA 2541c for filing processes for aseptic packaging systems only for LACF products under 21 CFR 108.35. Use Form FDA 2541a for all other processing methods, including acidified products filed under 21 CFR 108.25. For acidified LACF products packaged by aseptic packaging systems, the factor which provides the public health protection (heat or acidification) determines which form is to be used (i.e., for a product acidified to a maximum equilibrium pH ≤ 4.6 , use Form FDA 2541a; for one acidified to a maximum equilibrium pH > 4.6 , use Form FDA 2541c).

Complete each required block on the form in English according to the following instructions. Unless otherwise indicated, all blocks on the form must be completed, regardless of whether this is a new submission or a replacement for a previously submitted one. The paragraph numbers below correspond to the numbered blocks on the sample fold-out form on page 15. See page 7 in Section I of the main instruction booklet for a complete explanation of the submission identifier (SID).

① FCE

Enter the 5-digit Food Canning Establishment (FCE) number assigned to your establishment by the FDA when you registered (on Form FDA 2541). If registering concurrently with initial process filing, leave blank (FDA will complete). Upon receipt of your FCE number from FDA, record it on your copies of the process filing forms.

② Establishment Name and Location Address

Enter the name of your plant and the plant location address corresponding to the FCE Number entered in ①. This is used by FDA as a check of the FCE number and may not be used to change the name or address. Name and address changes must be submitted on an Establishment Registration form (FDA 2541).

An address change resulting from a move to a different location (as opposed to a street name change, etc.) requires re-registration, assignment of a new FCE number, and re-filing of all scheduled processes. The old FCE number is not valid and its use will not be accepted by FDA.

U. S. Firms:

Enter the two-letter abbreviation for your state or territory; leave "country" block blank.

Foreign Firms:

For "state", enter the name or abbreviation of the province or other subdivision of your country (if applicable). Otherwise, leave blank.

For "ZIP Code", enter the postal code established by the postal system of your country, if one has been established. Otherwise, leave blank.

Enter the name of the country in which your establishment is located.

③ Submission Identifier (SID)

Assign a unique SID to each process filing form, in the format YY-MM-DD/SSS based on when you are submitting the form, where:

YY	is the last two digits of the year (e.g., 83, 84, etc.)
MM	is the numerical designation of the month (e.g., 05 for May, 10 for October, etc.)
DD	is the day of the month (e.g., 03, 28, etc.)
SSS	is a unique sequence number within the date (e.g., 001, 002, etc.)

SEE PAGE 7 IN SECTION I OF THE MAIN INSTRUCTION BOOKLET FOR COMPLETE EXPLANATION OF SUBMISSION IDENTIFIER (SID).

④ New, Replacement, or Cancellation

If this is a new submission of a process for a low-acid canned food product (no previous processes filed for this product in the container sizes listed), check "new" and complete the remaining blocks.

If this is a replacement for a previously submitted process filing form, check "replaces", followed by the SID of the MOST RECENT SUBMISSION WHICH IS BEING REPLACED, and complete the remaining blocks.

If this is a cancellation of a previously submitted process filing form which is not being replaced by another, check "cancels", followed by the SID of the previous submission which is being cancelled. To help ensure that the correct process is being cancelled, enter the food product name as instructed in ⑦ on the next page. Sign and date the form as instructed in ②② and submit it to FDA.

As an alternative, you may photocopy the form to be cancelled. Assign a new SID in ③ (lining out the original one without making it unreadable), and check "cancels" in ④ followed by the SID being cancelled. Sign and date the photocopy below the original signature and date and submit it to FDA.

⑤ Scheduled or Alternate

Check "scheduled" if this is the ordinarily used process for this product under normal conditions.

If this is a process used regularly in lieu of the ordinarily used (scheduled) process (which is filed separately), check "alternate for" and enter the SID of the scheduled process for which this is an alternate.

NOTE: Alternate processes should be reported ONLY WHEN THEY ARE USED REGULARLY. Otherwise, they need not be filed.

If you are replacing a scheduled process for which you have filed alternate processes, FDA will assume that the alternate processes apply to the replacement scheduled process as filed. If the alternate processes do not apply to the replacement, they should be replaced or cancelled by separate submissions.

Additional Container Sizes

Additional container sizes for a previously submitted food product must be reported separately as a **NEW** or **REPLACEMENT SUBMISSION**, even if all other information is the same.

Deletion of Containers Size(s)

Submit a **"REPLACEMENT"** for the originally filed form as instructed above, leaving off the container sizes that are no longer applicable. You may reproduce the original form, if desired, entering the additionally required information for a replacement form as indicated above, lining out the inapplicable container size(s), and signing and dating the form (below the original signature). Assign a unique new SID to the **REPLACEMENT** form and clearly indicate the previous submission being replaced by entering its SID in ④.

Forms Returned by FDA for Missing Data

When resubmitting a form which had been returned by FDA for missing data, enter the missing data directly on the returned form (unless otherwise instructed) and send it to FDA. **DO NOT CHANGE TYPE OF SUBMISSION OR THE SID.** Be sure to enter the missing data on your file copy of the form.

If it is necessary to complete a new form to furnish the missing data, complete blocks ① through ⑥ exactly as originally submitted. Complete all other blocks, entering ALL information specified below. Attach the form which had been returned and mail them both to FDA.

⑥ SUP SID:

Enter the SID of the supplemental information which applies to this process filing form (see **"REQUIRED SUPPLEMENTAL INFORMATION"** on page 11). For example: SUP SID: 81-04-22/015

⑦ Food Product Name, Form or Style, and Packing Medium

Enter the food product name, form or style, and packing medium, in that order, e.g., whole milk; butterscotch pudding; split pea soup (condensed); etc. A separate form must be used for each product form or style (strained, ready-to-eat, high fat, paste, dry ingredient, etc.) which receives a different scheduled process **OR** when the characteristics of the food affect heat transfer or affect microbial heat resistance.

Product forms or styles receiving the same scheduled process should be included parenthetically after the product name.

A separate form is not required for each different brand name of a product so long as the scheduled process for all brands is exactly the same.

Foreign Firms

List the English name as well as the non-English name as it appears on the label. For example:

Whole milk (lait)

⑧ **Name of Product Sterilizer**

In the upper portion of the block, enter the name of the manufacturer, the type of sterilizer, and the model number or name (if applicable). Limit to 30 characters when possible. Abbreviations may be used when meanings are clear. For example:

Cherry Burrell: Swept Surf Ht Ex

Name of Packaging Sterilizer

In the lower portion of the block, enter the name and type of packaging system used and the model number or name (if applicable). For example:

Dole: Superheated Steam

⑨ **Process Origin**

Source

Enter the name of the process authority (organization, company, or individual, etc.) which conducted the scientific studies establishing the scheduled process(es) listed on the form, and the type of document in which published (i.e., letter, bulletin, etc.). List the source for the product sterilizing process in the upper portion of the block and the source for the packaging sterilizer process in the lower portion. Use the following guidelines in making entries for process source:

- o When possible, limit entries to 30 characters for each source by minimizing punctuation, not using plurals, etc.
- o If a process is established as a result of your own firm's studies, enter your firm's name as the source.
- o When processes have been established jointly, list both process sources. For example:

	PROCESS ORIGIN	
	SOURCE	YEAR AND MONTH
(product)	ABC Canning/NFPA	1978-01
(package)	Bric Pak/Tech-S	1981-06

- o For universities, enter name of university followed by the name of an individual (if appropriate).

Date

Enter the year (e.g., 1976, 1980, etc.) and the numeric designation of the month (e.g., 05 for May, 11 for November, etc.) of the latest source document issued by the qualified process authority which established or modified the process used. List date applicable to product sterilizer in the upper portion of the block and the date applicable to the packaging sterilizer in the lower portion.

⑩ Container Type

Except for tinplate/steel and aluminum cans (which may be submitted on the same form if the processes are identical), **USE A SEPARATE FILING FORM FOR EACH DIFFERENT CONTAINER TYPE EVEN IF ALL OTHER INFORMATION IS THE SAME.**

Check the container type used. If a container type other than those listed is used, check "4. other" and describe on the following line, specifying the material from which constructed). For example:

Pouch (polyethylene/alum. foil laminate)

Semi-rigid Container (e.g., cups, tubs, cartons, etc. - describe and specify material from which constructed)

NOTE: Minor container material variations which do not affect the scheduled process do not require submission of separate forms.

⑪ Maximum Water Activity

Enter value to the nearest hundredth (e.g., .88) **ONLY IF REDUCED WATER ACTIVITY IS CRITICAL TO THE DELIVERY OF THE SCHEDULED PROCESS** as specified by the process source cited in ⑨. Otherwise, enter N/A. **IF THIS BLOCK IS COMPLETED, WATER ACTIVITY MUST BE CONTROLLED DURING PROCESSING AND RECORDS OF THE MEASUREMENTS MUST BE KEPT.**

⑫ pH

Normal

Enter normal or natural pH of the product before processing, to the nearest tenth (e.g., 5.1).

Maximum

For products packaged by aseptic packaging systems where pH control is specified by the process source as a critical factor, enter the maximum equilibrium pH (upper limit) of the finished product after acidification, measured within 24 hours after processing, to the nearest tenth (e.g., 4.7).

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⑬ Maximum Consistency or Viscosity

Enter consistency or viscosity data as follows, **ONLY IF CRITICAL TO THE DELIVERY OF THE SCHEDULED PROCESS** as specified by the process source cited in ⑨

Value at 77± 2° F

If consistency or viscosity is not applicable, enter N/A. If consistency is specified by the process source to be measured at 77± 2° F, enter the maximum consistency reading at that temperature, measured to the nearest thousandth (e.g., 3.000). If consistency is given by the process source as a range, report the highest value.

Value at other temp

If consistency is specified by the process source to be measured at another temperature, enter the maximum consistency reading at that temperature, measured to the nearest thousandth (e.g., 30.000). If consistency is given by the process source as a range, report the highest value.

Other temp

Enter temperature (other than 77°) at which reading is taken, to the nearest whole degree (e.g., 160(± 2° F is assumed). If temperature is specified by the process source as a range, you may report that range.

Units

Enter units in which reading is measured. Abbreviate to 3 characters. For example:

CPS - centipoise

C/S - centimeters/second

INS - inches

Method Name

Enter instrument used and its characteristics. Limit to 30 characters, if possible. If Brabender is used, include the paddle (e.g., Brabender A Paddle).

IF THIS BLOCK IS COMPLETED, CONSISTENCY MUST BE CONTROLLED DURING PROCESSING AND RECORDS OF THE MEASUREMENTS MUST BE KEPT.

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Product Viscosity Characteristic

In the block preceding ⑭ (Specific Gravity), enter the viscosity characteristic of the product as follows:

Enter N for Newtonian.

Enter P for pseudoplastic.

Enter D for dilatant.

The product viscosity characteristic can be determined in the following ways:

- o From handbooks (for example, Charm, S. E., 1971, The AVI Publishing Co., Westport, Conn., p. 64);
- o From technical literature (for example, Scalzo, et al., 1970; Food Technology, 24(11):113);
- o By direct measurement as follows:

Measure viscosity at constant temperature and three rates of shear.

- If viscosity decreases with increased rates of shear, the fluid is pseudoplastic (flow-thinning);
- If viscosity increases with increased rates of shear, the fluid is dilatant (flow-thickening).

⑭ Specific Gravity

Enter the specific gravity of the food product measured at $77 \pm 2^\circ\text{F}$. Express to the nearest thousandth (e.g., 1.101).

⑮ Inside Diameter of Holding Tube

Express in inches, to the nearest hundredth (e.g., 1.37).

⑯ Holding Tube Length

Express to the nearest whole inch (e.g., 480).

⑰ Other Critical Factors

Enter other critical factors as SPECIFIED BY THE PROCESS SOURCE WHICH MUST BE CONTROLLED IN ORDER TO ASSURE DELIVERY OF THE SCHEDULED PROCESS. Check all blocks which apply AND, where applicable, enter the appropriate value. For example:

- o If "Percent solids" is checked, enter the percentage (e.g., 80%);
- o If "Ratio of solids to liquids" is checked, enter the ratio (wt. to wt.) to the nearest hundredth (e.g., 1.55);

- o If "Sirup strength" is checked, enter maximum degrees (Brix) to the nearest whole degree.

TO ENTER VALUES: check 71 (OTHER), enter the number of the applicable factor, and the value. For example: 62 = 1.55.

For critical factors not listed, check "other", and enter the factor and critical value (if applicable). For example:

- o pH controlled (specify maximum finished equilibrium value in ⑫)
- o Particle size (shape, dimension, thickness, etc.)
- o Process based on inoculated pack
- o Fully developed laminar flow, temperature corrected to ___ (specify in °F)

⑬ Container Dimensions

Enter the dimensions of each container size which is used for the product listed **IN ENGLISH UNITS**. Use a separate line for each different container size and its process parameters or characteristics. **DO NOT LEAVE BLANK LINES BETWEEN CONTAINER SIZES**. List container dimensions in inches and sixteenths of an inch as described below, using 4 digits (for example, 0301 for a 3 1/16 inch dimension). See Appendix A in the main instruction booklet for metric to English conversion table.

Cylindrical Containers

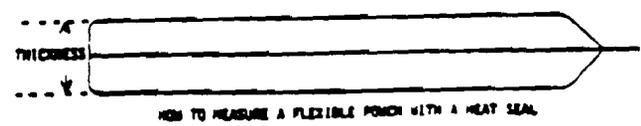
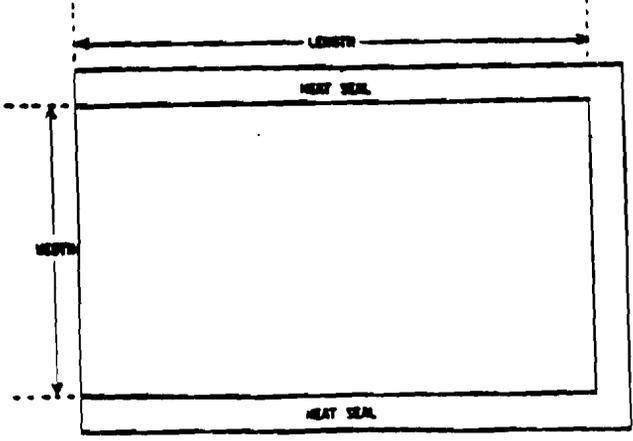
Enter diameter in the first column and height in the second. Leave the third column blank.

Rectangular Containers

Enter length (longest dimension) in the first column, width (second longest dimension) in the second, and height in the third.

Pouches

Enter length (longest dimension, excluding heat seal) in the first column, width (second longest dimension, excluding heat seal) in the second column, and maximum thickness in the third. See illustration below:



Unconventional or Irregularly Shaped Containers

When the specified dimensions cannot be used, cross out "hgt" in third column and enter the English units (fluid oz., gal., etc.). Enter the container volumetric capacity.

⑰ Scheduled Process

For each container size identified in ⑱, enter the scheduled process information specified by the process source cited in ⑨ as follows:

Minimum Initial Temperature

If not applicable, enter N/A. Enter temperature of the coldest product to be processed at the time the sterilizing begins. Express (in °F) to the nearest whole degree (e.g., 180).

Process Time

Enter minimum process time IN SECONDS to the nearest hundredth (e.g., 27.00).

Processing Temperature

Enter minimum processing temperature (measured at the holding tube outlet) in whole degrees (°F) (e.g., 275). NEVER ROUND UP (e.g., 275.9 is reported as 275).

Least Sterilizing Value

Express F_0 to the nearest tenth of a minute (e.g., 7.0). If other than F_0 is applicable, enter value for F_T^z and specify (below the last value) the death rate (z) and reference temperature (T) in whole degrees F (°F). For example, z = 16; T = 240.

If other equivalent scientific basis for process adequacy is applicable (for example, Integrated Sterilizing Value (IS)), specify to the right of the value.

⑳ Maximum Food Flow Rate

Express in gallons per minute, to the nearest hundredth of a gallon (e.g., 18.40). If given in units other than gallons (e.g., lbs. per minute), line out "gal/min" and specify units above the heading for this column.

㉑ Thruput

Enter the maximum thruput allowable, as specified by the process source, expressed in whole containers per minute (e.g., 500).

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② Authorized Company Representative

Enter the name, title, and signature of the authorized representative who is signing this form on behalf of the company and the telephone number (including area code) at which she or he can be reached. Date the form and mail the original (white) copy to:

LACF Registration Coordinator (HFF-233)
Bureau of Foods (FDA)
200 C Street, SW
Washington, DC 20204

Keep the second (pink) copy for your files. You are required to maintain a file copy for future reference at the processing plant location.

REMINDER: A glossary of terms; Metric to English conversion chart; Celsius to Fahrenheit temperature conversion chart; and common questions and answers concerning registration and process filing are contained in the main instruction booklet to which this supplement applies.

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**REQUIRED SUPPLEMENTAL INFORMATION
FOR ASEPTIC PACKAGING SYSTEMS**

Supply the following supplemental information on a separate sheet (or sheets) in two copies. Number each item to correspond to the numbers and letters below. Assign a unique SID according to the instructions in ③ on page 2, entering it at the top left of each sheet following the FCE number. For example:

FCE # 04999
SUP SID: 83-02-20/011

If this supplemental data replaces a previous submission, identify the replaced submission in parentheses immediately following. For example:

FCE # 04999
SUP SID: 83-02-20/011 (replaces 81-04-22/015)

Immediately below, enter the SID of all current processes to which the supplemental information applies. For example:

Applies to: 80-02-12/003, 004, 005; 80-09-15/001, 002, 003; 81-01-03/002;
81-02-02/001, 002, 003; 83-02-20/007

Each unique set of supplemental information must be submitted only once. Each subsequent process filing form submitted to which the supplemental information applies must include the above mentioned supplemental data SID (SUP SID) following the "Type of Submission" data (see ⑥ on page 3).

PRODUCT STERILIZER

1. **Sterilizing medium** used during start-up to sterilize the product sterilizer and all product contact surfaces downstream from the holding tube in the sterilizing system (e.g., steam, water, other medium specified by the process source).
2. **Minimum sterilizing temperature** used during start-up to sterilize the product sterilizer and all product contact surfaces downstream from the holding tube in the sterilizing system. Express in °F to the nearest whole degree.
3. **Minimum time** that the sterilizing medium must be recirculated through the sterilizer to achieve a sterile condition in the sterilizer (in minutes).
4. **Minimum back pressure** required at a specific location in the sterilizer to prevent flashing of water to steam (and hence, a reduced holding time in the holding tube). Specify minimum back pressure in pounds per square inch gauge (psig) and location of measurement.

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**START-UP SPECIFICATIONS TO ACHIEVE COMMERCIAL STERILITY
IN SPECIFIED EQUIPMENT AREAS**

	(a)	(b)	(c)	(d)	(e)	(f)
	Filling Chamber	Filling Equipment	Sterilizing Chamber for Containers	Sterilizing Chamber for Lids	Container Closing Area	Container Closing Equipment
5. Sterilizing Medium used						
6. Minimum Temperature of Sterilizing Medium (°F)						
7. Minimum flow rate (gal/min)						
OR						
8. Minimum pressure of sterilizing medium (psi)						
9. Minimum time for circulating (exposure to) the sterilizing medium (min)						

TEST AVAILABLE ONLY ON REQUEST

**SPECIFICATIONS TO ACHIEVE AND/OR MAINTAIN (AS INDICATED)
COMMERCIAL STERILITY OF SPECIFIED EQUIPMENT AND/OR AREAS**

	(a)	(b)	(c)	(d)
	<u>Achieve and Maintain</u>		<u>Filling Area</u>	<u>Closing Area</u>
	<u>Containers</u>	<u>Lids</u>	<u>Maintain</u>	<u>Maintain</u>
10. Sterilizing Medium used				
11. Minimum temperature of sterilizing medium				
12. Minimum concentration of sterilizing medium (if chemical)			N/A	N/A
13. Minimum exposure time			N/A	N/A
OR				
14. Maximum Conveyor Speed			N/A	N/A
15. FOR STERILIZING GASES ONLY				
Minimum Gas flow rate through chamber			N/A	N/A
OR				
16. Minimum gas pressure required in chamber			N/A	N/A

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17. If HEPA filters are used to obtain sterile air supply for the filling and closing areas, specify the maximum operating time interval permitted between filter changes.

The information requested in 5. through 16. may be submitted either in a list or a tabular form as in the following examples:

List Form

- 5. (a) Steam
 (b) Steam
 (c) etc.
 (d) ...
 (e) ...
 (f) ...
- 6. (a) 260
 (b) etc.
 ...
 ...
- 16. (a) ...
 (b) ...
 ...

Tabular Form

	(a)	(b)	(c)	(d)	(e)	(f)
5.	Steam	Steam	etc.
6.	260	etc.		
...						
...						
16.				

Enter the name, title, telephone number (including area code) and signature of the authorized representative who is submitting this information on behalf of the company (and the date signed) at the bottom of the last supplemental page. Mail two copies to:

LACF Registration Coordinator (HFF-233)
 Bureau of Foods (FDA)
 200 C Street, S.W.
 Washington, DC 20204

KEEP ONE COPY FOR YOUR FILES. You are required to maintain a file copy for future reference at the processing plant location.

NOTE: These instructions are not all-inclusive, particularly for new systems. Therefore, any additional information, critical factors, and/or controls which are specified by the process source (although not specifically addressed above) must also be provided.

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FORM 9499
 USE PREVIOUS EDITIONS OF THIS FORM
 1-800-368-5848

POST OFFICE DEPARTMENT POSTAGE PAID PER ACCEPTED MAILING OFFICES
 (Please refer to each of addresses enclosed. If none then use only one "SA")

9499

ABC Learning Company
 111 Main St.
 Your City, NY 12345

9499-22003

9499-22006

Butterworth Publishing

Cherry Barrell: Sweet Surf in La
 Baker: Supermarket Sales

9499-22003

1978 01
 1988 10

CLASSIFICATION	POSTAGE	PERIOD	DATE	AMOUNT	DATE	AMOUNT	DATE	AMOUNT	DATE	AMOUNT
01	0000	0000		275	27-00	275	18-0	18.00		500
02										
03										
04										
05										
06										
07										
08										

JOHN DOE

QUALITY ASSURANCE NUMBER

John Doe

April 22, 1985

(703) 123-4567

NOTE: THE ABOVE IS AN EXAMPLE ONLY TO ILLUSTRATE ENTRIES AND IS NOT A VALID PROCESS.

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Public reporting burden for this collection of information is estimated to average .17 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Reports Clearance Officer, PHS and to Office of Management and Budget Paperwork Reduction Project (0910-0037) Washington, DC 20503

Please **DO NOT RETURN** this report to either of the two addresses to the left.

FORM APPROVED: OMB No. 0910-0037
EXPIRATION DATE: November 30, 1995

<p>TYPE OF SUBMISSION</p> <p><input type="checkbox"/> Initial Registration</p> <p><input type="checkbox"/> Relocation (<i>new registration required</i>)</p> <p><input type="checkbox"/> Change of Registration Information</p> <p>Specify Type of Change _____</p>	<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Food and Drug Administration</p> <p>FOOD CANNING ESTABLISHMENT REGISTRATION</p> <p>Enter Current FCE: (if applicable) _____</p>	<p style="text-align: center;">FOR FDA USE ONLY</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">FCE No. _____</td> <td style="width:50%;">Date Received by FDA _____</td> </tr> <tr> <td>OOB Code _____</td> <td>Date _____ District _____</td> </tr> <tr> <td colspan="2">Reference _____</td> </tr> </table>	FCE No. _____	Date Received by FDA _____	OOB Code _____	Date _____ District _____	Reference _____	
FCE No. _____	Date Received by FDA _____							
OOB Code _____	Date _____ District _____							
Reference _____								

FOOD PROCESSING PLANT LOCATION

Establishment Name _____

Number and Street _____

City and State or Province (or other Subdivision) _____

Zip (or other Postal Code) _____ Country (if other than U.S.) _____

Telephone No. (____) _____ Telefax No. (____) _____

PREFERRED MAILING ADDRESS Same as Plant Location

Establishment Name _____

Number and Street _____

City and State or Province (or other Subdivision) _____

Zip (or other Postal Code) _____ Country (if other than U.S.) _____

Telephone No. (____) _____ Telefax No. (____) _____

LOW ACID AND/OR ACIDIFIED FOODS PROCESSED AT THIS LOCATION		
Food Product Name, Form or Style, and Packing Medium <small>(Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture.)</small>		
	(Check One)	
	Low-Acid	Acidified

PLEASE SEND THE FOLLOWING:

Number of Copies _____

_____ Process filing forms used for low-acid aseptic processes

_____ Process filing forms used for all processing methods except low-acid aseptic.
NOTE: A separate form is required for each product-process combination.

_____ Registration and Process Filing Instructions

_____ LACF & Acidified Regulations (21 CFR 108, 113, 114)

See "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods" for guidance in completing this form. Forward *all* copies of completed form to:

LACF Registration Coordinator (HFS-618)
Center for Food Safety & Applied Nutrition (FDA)
200 C Street, SW
Washington, DC 20204

AUTHORIZED COMPANY REPRESENTATIVE

Name, Address and Title of Authorized Representative: _____

Phone Number: (____) _____ at Plant Location Mailing Address Signature: _____ Date: _____

NOTE: No commercial processor shall engage in the processing of low-acid or acidified foods unless completed Forms FDA 2541 and FDA 2541a or FDA 2541c have been filed with the Food and Drug Administration, 21 CFR 108.25(c)(1) and (2) and 108.35(c)(1) and (2)

FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC

(Use FDA booklet titled "Instructions for Establishment Registration and Process Filing for Acidified and Low Acid Canned Foods" for completing Form FDA 2541a.)

FORM APPROVED OMB No. 0910-0037 EXPIRATION DATE: November 30, 1995	
FCE	SID

A. PRODUCT

Name, Form or Style, and Packing Medium: _____

Raw pH: _____

Governing Regulation:

- ___ low-acid (21 CFR 108.35/113)
- ___ acidified (21 CFR 108.25/114)

Type of Submission

- ___ new
- ___ replaces _____ / _____
- ___ cancels _____ / _____

Process Use

- ___ scheduled
- ___ alternate for _____ / _____
- ___ emergency for _____ / _____

B. PROCESSING METHOD

NAME OF STERILIZER (MFR. & TYPE) _____

HEATING MEDIUM (e.g., Steam, water immersion or spray, steam-air) _____

<p>1. Still</p> <p>a. ___ Horizontal b. ___ Vertical</p> <p>Divider Plates (complete for a or b)</p> <p>___ None</p> <p>___ Solid ___ Perforated</p> <p>c. ___ Crateless</p> <p>Bottom Surface (complete for c)</p> <p>___ Solid ___ Perforated</p>	<p>2. Agitating</p> <p>a. ___ End over End</p> <p> ___ Axial</p> <p>b. ___ Continuous</p> <p> ___ Batch</p>	<p>3. Hydrostatic</p> <p>___ Inner Chain only</p> <p>___ Outer Chain only</p> <p>___ Both Inner and Outer Chain</p> <p>___ Single Chain</p> <p>___ Multiple Chains</p>	<p>4. Flame</p>	<p>5. Other (explain)</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>6. Acidified</p> <p>Maximum Equilibrium pH: [] [] []</p> <p>Method of Acidification: _____</p> <p>Concentration: [] [] [] [] [] []</p> <p>Acidifying Agent: _____</p> <p>Pasteurization Method: _____</p> <p>Preservative Used: _____</p> <p>Concentration: [] [] [] [] [] [] [] [] [] []</p>
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CONTAINER TYPE:

1. ___ Tinplate/Steel Can ___ 2-piece ___ Welded	3. ___ Glass or Ceramic	5. ___ Semirigid (specify material): Lid _____ Body _____
2. ___ Aluminum Can ___ 3-piece ___ Soldered	4. ___ Flexible Pouch (specify material):	Seal Method _____
___ Cemented		6. ___ Other (specify): _____

PROCESS ESTABLISHMENT SOURCE (Limit entry to 30 characters)

DATE LAST ESTABLISHED
19 ____ Y Y M M

PROCESS RECOMMENDATIONS ATTACHED?
___ YES ___ NO

C. CRITICAL FACTORS: AS DELINEATED BY PROCESS AUTHORITY TO ASSURE COMMERCIAL STERILITY (Check or Describe)

None of the Following NO ___	Arrangements of Pieces in Container AP ___
Maximum Water Activity (a _w) MW (. -)	Formulation Changes FC ___
Consistency / Viscosity CV	Preparation Method PM ___
Value (- - - - -)	Product Quality PQ ___
Units _____	Matting Tendency MT ___
Method Name _____	Layer Pack LP ___
Temperature (- - -)	Max. Flexible Pouch/Semirigid Container Thickness in Retort MP (. - -)
Container Position in Retort CP ___	Max. Residual Air (Flexible Pouch/Semirigid Container) MR (. - -) c.c.
Nesting of Containers NC ___	Particle Size PS _____
Fill Method (check applicable method) FM	Syrup Strength SS (. - -)
Hand _____	Starch Added SA _____
Machine _____	Max. % (- - -)
Other (specify) _____	Type _____
% Solids SO (- - -)	Other Binder OB _____
Solid to Liquid Ratio (wt. to wt.) SL (- - -)	Min. % Moisture of Dry Ingredients MM (- - -)
Drained wt./Net wt. Ratio DW (. - -)	Other (specify) OT _____

625



GRANOS COMERCIALES

Frijol en grano

ICAITI
34 048
1a. Revisión

Esta norma constituye la primera revisión a la norma ICAITI 34 048 "Granos comerciales. Frijol elaborado" de fecha abril de 1969, la cual queda anulada y sustituida por la presente.

1. OBJETO

Esta norma tiene por objeto establecer la terminología, las características y las calidades del frijol en grano para sus transacciones comerciales.

2. REFERENCIAS

ICAITI	34 037	Granos comerciales. Frijol en bruto
ICAITI	34 051	Granos comerciales. Muestreo
ICAITI	34 052 h1	Granos comerciales. Método de referencia para la determinación de la humedad y métodos rápidos
ICAITI	34 052 h4	Granos comerciales. Frijol. Métodos de ensayo y análisis
ICAITI	34 052 h8	Granos comerciales. Frijol. Determinación del tiempo de cocción

3. DEFINICIONES

3.1 Frijol en grano. Es el conjunto de granos enteros, quebrados o abiertos longitudinalmente, de cualquier variedad de la leguminosa Phaseolus vulgaris.

3.2 Aflatoxinas. Es un grupo de metabolitos carcinogénicos altamente tóxicos producidos por algunos tipos de los hongos Aspergillus flavus, así como también por otros hongos relacionados con el deterioro de alimentos y forrajes.

4. TERMINOLOGIA

4.1 Granos enteros. Son los granos de frijol que tengan completas todas sus partes constitutivas y aquellos granos a los cuales se les haya removido su cutícula en una cuarta parte o menos de su tamaño normal.

4.2 Granos partidos. Son los granos de frijol que tienen sus cotiledones parcial o totalmente separados.

4.3 Granos quebrados. Son los pedazos de grano de frijol y los granos a los que se les haya removido su cutícula en más de una cuarta parte de su tamaño normal.

Nota. Esta definición no incluye el grano partido.

Continúa

Prohibida su reproducción total o parcial

4.4 Granos dañados. Son los granos enteros de frijol que estén germinados, deteriorados por acción de insectos, hongos, fermentaciones, calentamiento o materialmente dañados por otras causas.

Nota. El grano decolorado se tomará como dañado y no como grano contrastante.

4.5 Granos contrastantes. Son los granos de frijol de otro color, que difieren del frijol de la clase que se considera, a tal punto que hacen variar su valor comercial.

4.6 Lote de grano de frijol infestado y dudosamente infestado. Se considerará como infestado el lote de grano de frijol que contenga insectos vivos dañinos para el grano almacenado.

Nota 1. Cuando el frijol en grano se encuentre en dicha condición se hará constar este hecho anotando en el informe la palabra "infestado".

Nota 2. Cuando el grano contiene solo insectos muertos se considera dudosamente infestado y se hará constar este hecho anotando en el informe la frase "dudosamente infestado".

4.7 Grano sano. Se entiende como tal todo grano de frijol que no presente ataque por hongos, que no esté dañado, caliente, fermentado o germinado, y que se encuentre libre de insectos vivos capaces de producir daño al grano almacenado.

4.8 Grano limpio. Para los efectos de esta norma se considera grano comercialmente limpio el que haya sido limpiado por los medios mecánicos convencionales existentes.

4.9 Humedad de almacenamiento. Se entenderá como tal el contenido de humedad de un lote de frijol en grano que permita su almacenamiento adecuado.

4.10 Impurezas. Se entenderá por impurezas todo material diferente al grano de frijol y otros granos.

4.11 Otros granos. Se entiende por otros granos todos los granos que no sean frijol.

4.12 Tiempo de cocción. Es aquel en que por lo menos el 90% de los granos de la muestra sometida a la prueba de cocción estén cocidos.

4.13 Granos cocidos. Se considerarán granos cocidos los que cedan fácilmente a una presión moderada entre los dedos índice y pulgar, y presenten una consistencia pastosa suave que vaya desde fina hasta ligeramente grumosa; aquellos granos que al oprimirse entre los dedos sus cotiledones escapen o fraccionen en pedazos no grumosos se tomarán como no cocidos.

5. CLASIFICACION Y DESIGNACION

5.1 Clasificación. El frijol en grano se clasificará en base a su color en las clases siguientes:

- a) frijol negro
- b) frijol rojo
- c) frijol blanco
- d) frijol mezclado

Continúa

5.1.1 Frijol negro. Se entenderá por frijol negro todo lote de frijol en grano que presente dicho color en una tonalidad uniforme; éste no podrá contener más de 5% de frijol de otras clases.

5.1.2 Frijol rojo. Se entenderá por frijol rojo todo lote de frijol en grano que presente dicho color en una tonalidad uniforme; éste no podrá contener más de 5% de frijol de otras clases.

5.1.3 Frijol blanco. Se entenderá por frijol blanco todo lote de frijol en grano que presente dicho color en una tonalidad uniforme; este no podrá contener más de 5% de frijol de otras clases.

5.1.4 Frijol mezclado. Se entenderá por frijol mezclado a todo lote de frijol en grano que no reúna los requisitos de color y/o tonalidad, exigidos para las otras clases de frijol.

5.2 Designación. El frijol en grano se designará por su nombre, clase y calidad, seguido de la referencia de esta norma. Ejemplo: frijol en grano, blanco, calidad 1, ICAITI 34 048 1a. Revisión.

6. ESPECIFICACIONES

6.1 Grados de calidad. El frijol en grano deberá ser sano y limpio, y deberá cumplir con los grados de calidad de acuerdo con la tabla siguiente:

Tabla 1.- Grados de calidad del frijol en grano

Grado de calidad (1), (2)	Tolerancias máximas, en porcentaje en masa						grano infestado	grano dudosamente infestado	tiempo de cocción, minutos
	humedad (3)	impurezas	grano dañado (4)	grano partido	grano quebrado	grano contrastante			
1	13	1	4	1	1	2	no se acepta	se acepta	90
2	13	2	5	2	2	3	no se acepta	se acepta	110
3	13	3	6	3	2	4	no se acepta	se acepta	130
4	13	4	7	4	2	5	no se acepta	se acepta	150

- (1) El grado de calidad estará determinado por el factor que se encuentre en condiciones más desfavorables conforme a esta tabla, sin tomar en cuenta el factor humedad.
- (2) El frijol en grano de cualquier clase que no reúna ninguno de los grados de calidad indicados, o que por cualquier motivo se considere de calidad inferior, se designará como "calidad según muestra."
- (3) El porcentaje de humedad no constituye un factor de calidad; los valores para tal porcentaje, que aparecen en este cuadro, se deberán tomar como cifras de comparación en las transacciones comerciales para bonificar o castigar el precio.
- (4) Dentro de estas tolerancias máximas no se aceptará más de 4% de grano dañado por insectos.

Continúa

6.2 Masa unitaria. En toda transacción comercial la masa del frijol en grano se expresará en kilogramos netos. Cuando las estipulaciones de compra venta lo especifiquen o cuando el comprador lo solicite, se determinará la masa del frijol en grano en kilogramos por hectolitro.

Nota. La expresión "masa" se refiere a lo que comunmente se entiende por "peso" de una sustancia.

7. MUESTREO

La muestra con base a la cual deben hacerse todas las determinaciones se obtendrá de acuerdo con la norma ICAITI 34 051.

8. METODOS DE ENSAYO

8.1 Los ensayos aplicables al frijol en grano se efectuarán de acuerdo con la norma ICAITI 34 052 h4 1a. Revisión.

8.2 Tanto en el lugar donde se toma la muestra, como en el laboratorio de análisis de granos se hace un examen preliminar de la misma con la vista, el tacto y el olfato, de los factores siguientes: apariencia general del grano, olor a moho y otros olores objetables, y si tiene hongos visibles, insectos e impurezas. La determinación de la temperatura se efectuará en la totalidad del lote a muestrear.

8.3 El examen preliminar indicado en 8.2 y las determinaciones del grado de infestación por insectos y del contenido de impurezas se hace sobre la totalidad de la muestra original de laboratorio, o sea sobre un mínimo de 1000 g.

8.4 La determinación de la humedad se hace sobre grano limpio, utilizando la cantidad de muestra que se indica en la norma ICAITI 34 052 h1. En transacciones regionales y cuando se solicite, se indicará el método y el equipo utilizados para la determinación de la humedad.

8.5 Las determinaciones del grano quebrado, grano dañado, grano partido y grano contrastante, se hacen sobre una misma porción de 100 g de frijol limpio.

8.6 La determinación del tiempo de cocción se realiza sobre una muestra limpia de frijol en grano, de 500 g, siguiendo el método indicado en la norma ICAITI 34 052 h8.

9. ENVASE

El frijol en grano podrá ser transportado a granel o envasado en sacos. Se recomienda el uso de sacos de 50 kg.

10. CORRESPONDENCIA

Para la elaboración de la presente norma se ha tenido en cuenta:

- a) "Informe del grupo de trabajo de la XIV reunión ordinaria de la Comisión Coordinadora de Mercadeo y Estabilización de Precios (CCMEP) para la revisión de las normas uniformes de calidad de granos básicos". SIECA, 27 y 28 de Septiembre de 1977. Guatemala.

Continúa

b) Informe del grupo de trabajo de la VI reunión extraordinaria de la Comisión Coordinadora de Mercadeo y Estabilización de Precios (CCMEP) para la revisión de normas uniformes de calidad de granos básicos. 15 al 17 de junio de 1978. San Salvador.

11. ANEXO

11.1 Tolerancia máxima de aflatoxinas. La tolerancia máxima permitida de aflatoxinas en el frijol en grano para consumo humano y animal, aun no ha sido establecida por aquellas organizaciones que están realizando investigaciones al respecto.

A manera de información y para disponer de algunos criterios mientras se tiene una cifra confiable específica para el frijol en grano, se dan en la siguiente tabla algunos valores establecidos para diferentes productos en varios países.

Tabla 2.- Límites de aflatoxinas en diferentes países - 1976

País	Producto	Límite de aflatoxina $\mu\text{g}/\text{kg}$
Bélgica	Piensos	40
Brasil	Torta de semilla oleaginosa de maní (exportación)	50
Canadá	Nueces y sus productos derivados	15 (1)
Dinamarca	Maní y nueces de Pará	5-10
Francia	Piensos	700
India	Alimentos	30
	Harina de maní para uso alimentario	120
	Torta de maní (exportación)	60-120
Israel	Todos los alimentos	20
Italia	Maní	50
Japón	Todos los alimentos	10
	Torta de maní para mezclas de piensos	1.000
Malasia	Todos los alimentos	0
Malawi	Maní	5
Países Bajos	Alimentos y piensos	5
Noruega	Torta de semillas oleaginosas	600
Polonia	Todos los alimentos y piensos	5
Rodesia	Maní	25
	Piensos	50-400

Continúa

Tabla 2.- Límites de aflatoxinas en diferentes países - 1976 (conclusión)

País	Producto	Límite de aflatoxina $\mu\text{g}/\text{kg}$
Suecia	Todos los alimentos, particularmente nueces de Pará, maní, manteca de maní	5
	Materias primas para ulterior elaboración en Suecia	20
Reino Unido	Maní de confitería	50
	Harina de maní para piensos	0-500
EE.UU.	Maní de confitería	20 (2)
	Todos los alimentos y piensos	20-25

(1) Total de aflatoxina B₁, B₂, G₁, G₂

(2) Aflatoxina B₁

FUENTE: Conferencia Mixta FAO/OMS/PNUMA sobre micotoxinas, Nairobi, Kenia, 19-27 septiembre 1977. Tema 4, MYC-4c.

THE ALMANAC

OF THE CANNING, FREEZING, PRESERVING INDUSTRIES

1993

VOLUME 2

(Published November 1993)

**77th Annual Compilation of Basic References
for the Canning, Freezing, Preserving
and Allied Industries**

Published in Two Volumes
Volume 1 in May, and Volume 2 in November

■
\$45 per Volume in USA; \$50 Canada & Mexico; \$57 All Other
\$65 Two Volume Set in USA; \$75 Canada & Mexico; \$89 All Other

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Volume 2 Updated to September 1, 1993

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DATE : 01-01-78

PAGE : . 4

~~XXXXXXXXXX~~ FOODS, INC.

CODE : GRCA532
 COST-CENTER : 20-08
 ACCT CLAS : 20

PRODUCT : NEGRAS A/S 24/303
 YIELD : 140.00

STANDARD

! RAN MAT !	! !	! STD. UNIT !	! STD. COST !	! STD. COST !
! CODE !	! DESCRIPTION !	! QUANTITY !	! COST !	! FORMULA !
! !	! !	! !	! !	! PER CASE !
! CTC907 !	! PLAIN 4L 24/303 !	! 140.0000 !	! .15254 !	! 21.3556 !
! ECCN006 !	! PLAIN 303-N 406-16 02 !	! 3360.0000 !	! .07583 !	! 254.7088 !
! ECTA022 !	! ENAMEL 303 !	! 3360.0000 !	! .01425 !	! 49.8960 !
! LACA532 !	! NEGRAS A/S 24/303 !	! 3640.0000 !	! .00525 !	! 19.1100 !
! NPC0864 !	! SAL TABLETS !	! 28.7200 !	! .28495 !	! 8.1838 !
! IMPGR206 !	! HABICUELAS NEGRAS !	! 1000.0000 !	! .30000 !	! 300.0000 !
! COST-INGREDIENTS AND PACKING MATERIAL !				! 4.8667 !
! RAN MATERIAL WASTE FACTOR (%) !				! 2.00% !
! DIRECT LABOR !				! .2313 !
! FRINGE BENEFITS OF DIRECT LABOR !				! .1087 !
! MANUFACTURING OVERHEAD-VARIABLE !				! 40.00% OF TOTAL !
! OVERHEAD OF 8000 !				! .3200 !
! TOTAL VARIABLE COST !				! 5.4180 !
! MANUFACTURING OVERHEAD-FIXED !				! 50.00% !
! TOTAL MANUFACTURING COST !				! 5.8580 !
! SELLING PRICE !				! .0000 !
! COST OF SALES !				! .00% !
! GROSS MARGIN !				! .00% !

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FOODS, INC.

CODE : ESC0541
 COST-CENTER : 31-01
 ACCT CLAS : 35

PRODUCT : PAPAYA 24/303
 YIELD : 95.00

-----STANDARD-----

RAW MAT !	DESCRIPTION !	QUANTITY !	STD. UNIT !	STD. COST !	STD. COST !
CODE !	DESCRIPTION !	QUANTITY !	COST !	FORMULA !	PER CASE !
CTPL911 !	PLAIN 24/303 !	55.0000 !	.15550 !	15.3104 !	.1539 !
ECCN005 !	PLAIN 303 X 405 - 15 OZ !	2304.0000 !	.07558 !	175.6707 !	1.8403 !
ECTA022 !	ENAMEL 303 !	2304.0000 !	.01404 !	32.3482 !	.3370 !
LAC0541 !	PAPAYA 303 !	2304.0000 !	.00455 !	10.7135 !	.1115 !
INPC0082 !	CANELA !	.1200 !	2.50000 !	.3000 !	.0031 !
INPC0810 !	AZUCAR !	1454.5700 !	.22000 !	320.0054 !	3.3334 !
INPC0224 !	HIDROXIDO DE SODIO !	.0500 !	.55000 !	.0335 !	.0004 !
INPC0225 !	BICARBONATO DE SODIO !	4.5500 !	.10000 !	.4550 !	.0048 !
INPC0227 !	BENZOATO DE SODIO !	.1000 !	.42000 !	.0420 !	.0004 !
INVE113 !	PAPAYA FRESCA (VERDE) !	908.0000 !	.18750 !	170.2500 !	1.7734 !
COST-INGREDIENTS AND PACKING MATERIAL :				727.1329 !	7.5743 !
RAW MATERIAL WASTE FACTOR (%) :				2.00% !	.1515 !
DIRECT LABOR :					.5500 !
FRINGE BENEFITS OF DIRECT LABOR :				45.13% !	.2599 !
MANUFACTURING OVERHEAD-VARIABLE :				40.00% OF TOTAL !	
				OVERHEAD OF 1.3000 !	.5200 !
TOTAL VARIABLE COST :					9.1957 !
MANUFACTURING OVERHEAD-FIXED :				50.00% !	.7500 !
TOTAL MANUFACTURING COST :					9.9757 !
SELLING PRICE :					.0000 !
COST OF SALES :					.00% !
GROSS MARGIN :					.00% !

BENEFITS OF DIRECT LABOR

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GOYA®

A COOK'S TOUR OF SPAIN
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SEND NAME, ADDRESS AND TWO GOYA LABELS WITH \$2.00 TO: GOYA COOK'S TOUR, SECAUCUS, N.J. 07096. ALSO AVAILABLE IN SPANISH.

NET WT. 16 OZ. (1 LB.) 454 g

BLACK BEANS

NUTRITION INFORMATION PER SERVING
SERVING SIZE 8 OZ (227g) 1 CUP
SERVINGS PER CONTAINER 2
CALORIES 250
PROTEIN 17 gm
CARBOHYDRATE 42 gm
FAT 1 gm
SODIUM 810 mg

PERCENT OF U.S. RECOMMENDED DAILY ALLOWANCE (U.S. RDA)
PROTEIN 25 RIBOFLAVIN 2
VITAMIN A NIACIN 8
VITAMIN C 6 CALCIUM 10
THIAMIN 20 IRON 25

*Contains Less Than 2% of the U.S. RDA of These Nutrients

INGREDIENTS: BLACK BEANS, WATER & SALT
INGREDIENTES: FRIJOLE NEGROS, AGUA Y SAL

BEANS & RICE CUBANO 16 servings!
1 large green pepper chopped 1/2 teaspoon oregano
2 cloves garlic, crushed 3 tablespoons vinegar
3 tablespoons GOYA olive oil 3 GOYA pimientos minced
2 cans (1 lb. ea.) GOYA black beans 3 cups hot cooked rice

Saute pepper and garlic in oil until softened. Add other ingredients except rice. Cover and simmer until heated through. Taste for seasoning. Serve over rice.
Note: For thicker sauce, mash 2 tablespoons beans and stir into mixture.

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GOYA®



PESO NETO 16 OZ. (1 LB.) 454 g

FRIJOLE NEGROS

GOYA FOODS INC.
SECAUCUS, N.J. 07096 U.S.A.
DISTRIBUTORS



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PREPARATION

To warm the pre-cooked corn tortillas use a pan on the stove or pre-heat grill to medium temperature. Place each tortilla on pan or grill turning them until warm (five to ten seconds per side). After warming wrap tortillas in a cloth to maintain temperature until ready to serve. The tortillas may also be steamed or put into a microwave between paper towels.

Corn tortillas may be eaten in place of bread to accent any meal or follow the suggestions below.

Chicken Molé Enchiladas

- 2 cans (10 1/2 oz. size) Mexican Red or Green Molé Sauce
- 3 lbs. Chicken Breasts
- 1 medium Onion (whole) & 1 stalk of Celery
- 3 oz. Lemon Juice & four cubes Chicken Bouillon
- 1 or 2 packages of Fontova's Corn Tortillas
- Cheese (shredded) Onions (chopped) & Sour Cream

Coat chicken with lemon juice & let stand 10 minutes. Place Chicken Breasts into a pot with enough water to cover. Add Onion (whole) Celery & Bouillon Cubes & bring to a boil. Cover & cook over moderate heat for 50 minutes or until tender. Drain liquid & reserve. Shred the chicken & add 1 to 1 1/2 can of Molé sauce with 1 1/2 cup of the reserved liquid. Simmer until warm.

Fry tortillas in oil until soft (not crisp). Coat both sides of the tortillas with warm Molé sauce (1 can). Put the tortillas around the chicken mixture & top with your choice of Cheese (shredded). Place under broiler until Cheese is melted. Remove & garnish with the Sour Cream & chopped Onions. Allow two per serving.

Nachos

- 1 package Fontova's Corn Tortillas
- 1 can (15 oz. size) Mexican Style Refried Beans
- 12 slices of Cheese (your choice)
- 1 lb. Guacamole Dip & 8 oz. of Sour Cream

Quarter the Tortillas & the Cheese. Use frying pan to heat oil, lard or shortening. Fry all the tortillas (4 to 6 at one time) until golden crisp. Spread Re-Fried Beans on all chips & top with a piece of Cheese. Without overlapping put all chips onto a cookie sheet & place into a preheated oven at 375 degrees. You may also use a microwave. Remove when Cheese is melted & garnish with jalapeno Peppers, Sour Cream, Guacamole Dip or your favorite toppings.

Nutrition Facts

Serving Size: 49 Grams

(2 Tortillas)

Servings Per Container: 8

Amount Per Serving

Calories 140 Calories from Fat 15

% Daily Values*

Total Fat 1.5g 3%

Saturated Fat 0g 1%

Cholesterol 0mg 0%

Sodium 0mg 0%

Total Carbohydrate 16g 5%

Dietary Fiber Less Than 1g 4%

Sugars 0g

Protein 2g

Vitamin A 0% • Vitamin C 0%

Calcium 6% • Iron 2%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,800
Total Fat	Less than	65g	80g
Sat Fat	Less than	30g	38g
Cholesterol	Less than	300mg	380mg
Sodium	Less than	2,400mg	3,000mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

Fontova Corn Tortillas is another of the authentic products from the Mexican Chef Pedro Fontova. Satisfaction guaranteed or your money back with proof of purchase and explanation.

FONTOVA FOODS

P.O. Box 236

Loveland, Ohio 45140



0 43806 00620 1

INGREDIENTS: CORN, WATER AND LIME.

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NET WT. 8 1/4 OZ. (234g)
WT. OF PINEAPPLE
5 1/2 OZ. (156g)†



Pineapple
Chunks
IN HEAVY SYRUP

NUTRITION INFORMATION
PER SERVING SIZE 1/2 CUP WITH SYRUP
CONTAINS APPROX. 2 SERVINGS

CALORIES	90	FAT	0g
PROTEIN	0g	SODIUM	10mg
CARBOHYDRATES	23g		

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)

PROTEIN		RIBOFLAVIN	
VITAMIN A	6%	NIACIN	6%
VITAMIN C	6%	CALCIUM	6%
THIAMIN	6%	IRON	6%

CONTAINS PINEAPPLE CHUNKS, WATER AND SUGAR

MANUFACTURED FOR
© 1990 DOLE PACKAGED FOODS CORPORATION
SAN FRANCISCO, CA 94111

QUESTIONS, COMMENTS?
CALL 1-800-232-8888

PRODUCT OF THE PHILIPPINES



38900



NET WT. 8 1/4 OZ. (234g)



Crushed
Pineapple
IN HEAVY SYRUP

NUTRITION INFORMATION
PER SERVING SIZE 1/2 CUP WITH SYRUP
CONTAINS APPROX. 2 SERVINGS

CALORIES	90	FAT	0g
PROTEIN	0g	SODIUM	10mg
CARBOHYDRATES	23g		

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)

PROTEIN		RIBOFLAVIN	
VITAMIN A	6%	NIACIN	6%
VITAMIN C	6%	CALCIUM	6%
THIAMIN	6%	IRON	6%

CONTAINS CRUSHED PINEAPPLE, SUGAR, WATER AND CITRIC ACID

MANUFACTURED FOR
© 1990 DOLE PACKAGED FOODS CORPORATION
SAN FRANCISCO, CA 94111

PRODUCT OF THAILAND



38900 00609

NET WT. 8 1/4 OZ. (234g)
WT. OF PINEAPPLE
5 1/4 OZ. (149g)†



Pineapple
Slices
IN HEAVY SYRUP

NUTRITION INFORMATION
PER SERVING SIZE 2 SLICES WITH SYRUP
CONTAINS 4 SLICES (2 SERVINGS)

CALORIES	90	FAT	0g
PROTEIN	0g	SODIUM	10mg
CARBOHYDRATES	23g		

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)

PROTEIN		RIBOFLAVIN	
VITAMIN A	6%	NIACIN	6%
VITAMIN C	6%	CALCIUM	6%
THIAMIN	6%	IRON	6%

*CONTAINS LESS THAN 2% OF THE U.S. RDA OF THIS NUTRIENT

CONTAINS PINEAPPLE SLICES, WATER AND SUGAR

MANUFACTURED FOR
© 1990 DOLE PACKAGED FOODS CORPORATION
SAN FRANCISCO, CA 94111

PRODUCT OF THE PHILIPPINES

QUESTIONS, COMMENTS,
RECIPES? CALL DOLE
FREE: 1-800-232-8800
IN CALIFORNIA
1-800-232-8888

†WEIGHT OF PINEAPPLE
MEANS WEIGHT BEFORE
ADDITION OF LIQUID
NECESSARY FOR CANNING



38900 00109

NUTRITION INFORMATION — PER 1/2 CUP SERVING
SERVINGS PER CONTAINER APPROX. 4

CALORIES	70	FAT	0g
PROTEIN	0g	SODIUM	0mg
CARBOHYDRATE	18g		

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA) PER 1/2 CUP SERVING

VITAMIN C	6%	THIAMINE (VT. B1)	6%
-----------	----	-------------------	----

CONTAINS LESS THAN 2% OF THE U.S. RDA OF PROTEIN, VITAMIN A, RIBOFLAVIN, NIACIN, CALCIUM, AND IRON.

© 1989 DISTRIBUTED BY DEL MONTE CORPORATION
SAN FRANCISCO, CA 94105
PRODUCT OF THE REPUBLIC OF THE PHILIPPINES
WHEN WRITING TO US, ENCLOSE THE CAN END
BEARING THE STAMPED CODE.

*WT. OF PINEAPPLE (10% OZ.) BEFORE ADDITION OF
PINEAPPLE JUICE NECESSARY FOR PROCESSING.



0 24000 01777

DEL MONTE PROOF OF PURCHASE
15 1/4 OZ. PINEAPPLE TIDBITS

**Elegant Fruit
Compote**

- 1 can (15-1/4 oz.) DEL MONTE® Pineapple Tidbits In Its Own Juice
- 1 DEL MONTE Banana, sliced
- 1 cup quartered strawberries
- 1 kiwifruit, sliced or seedless grapes
- 1 cup jicama pieces or apples
- Orange-flavored liqueur

Drain pineapple reserving juice. Moisten banana with juice to prevent browning; drain. Arrange fruits in dish; drizzle with liqueur. Garnish with sprigs of fresh mint, if desired.

4 to 6 servings

To maintain product quality after opening,
store in glass or plastic container.



*NET WT. 15 1/4 OZ

1697

PUSH UP

HERE

Thank You
FOR SELECTING

HERE

PUSH UP



TO OPEN

2% MILKFAT LOWFAT MILK

VITAMINS A & D ADDED • GRADE A
PASTEURIZED • HOMOGENIZED

Nutrition Facts

Serving Size 8 fl oz (240mL)
Servings Per Container 4

Amount Per Serving

Calories 120 **Calories from Fat 45**

% Daily Value*

Total Fat 5g	8%
Saturated Fat 3.0g	15%
Cholesterol 20mg	7%
Sodium 120mg	5%
Total Carbohydrate 12g	4%
Dietary Fiber 0g	0%
Sugars 11g	

Protein 8g

Vitamin A 10% • Vitamin C 4%

Calcium 30% • Iron 0%

Vitamin D 25%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

INGREDIENTS: MILK, SKIM MILK, VITAMIN A PALMITATE, AND VITAMIN D₃.

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202
PROCESSED AT LOCATION STAMPED ON TOP OF CARTON

QUART - 946mL

Nutrition Facts

Serving Size 8 oz. (240ml)
Servings Per Container about 16

Amount Per Serving

Calories 0

% Daily Value*

Total 0g **0%**

Sodium 0mg **0%**

Total Carbohydrate 0g **0%**

Protein 0g **0%**

Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

BEST AVAILABLE DOCUMENT

Freshlike®

• WHOLE KERNEL •
SWEET CORN

**NUTRITION
INFORMATION
PER SERVING**

SERVING SIZE 1/2 CUP
SERVINGS PER CONTAINER 2
CALORIES 80
PROTEIN 2 g
CARBOHYDRATE 19 g
FAT 1 g
SODIUM 320 mg
POTASSIUM 150 mg

**PERCENTAGE OF U.S.
RECOMMENDED DAILY
ALLOWANCES (U.S. RDA)**

PROTEIN 4
VITAMIN A 6
VITAMIN C 10
THIAMINE 2
RIBOFLAVIN 4
NIACIN 6
CALCIUM 0
IRON 2
PHOSPHORUS 6
MAGNESIUM 4

MICROWAVE DIRECTIONS:

Pour Contents Into Glass or Ceramic Dish, Cover and Microwave On HIGH For 2 to 2 1/2 Minutes. Season and Serve.

CONTAINS RECYCLED STEEL.
PLEASE RECYCLE AGAIN.



0 14500 04002 2

*WEIGHT OF CORN (5.0 OZ.) BEFORE
ADDITION OF LIQUID FOR PROCESSING.

INGREDIENTS: CORN, WATER, SUGAR AND SALT

PACKED BY © THE LARSEN COMPANY
P.O. BOX 19027 GREEN BAY, WISCONSIN 54307-9027

NET WT 8.75 OZ • WT OF CORN 5.0 OZ

Freshlike®

**SWEET PEAS
& CARROTS**

**NUTRITION
INFORMATION
PER SERVING**

SERVING SIZE 1/2 CUP
SERVINGS PER CONTAINER 2
CALORIES 50
PROTEIN 3 g
CARBOHYDRATE 12 g
FAT 0 g
SODIUM 340 mg
POTASSIUM 170 mg

**PERCENTAGE OF U.S.
RECOMMENDED DAILY
ALLOWANCES (U.S. RDA)**

PROTEIN 4
VITAMIN A 100
VITAMIN C 8
THIAMINE 6
RIBOFLAVIN 4
NIACIN 4
CALCIUM 2
IRON 4
PHOSPHORUS 4
MAGNESIUM 4

MICROWAVE DIRECTIONS:

Pour Contents Into Glass or Ceramic Dish, Cover and Microwave On HIGH For 2 1/2 to 3 Minutes. Season and Serve.

CONTAINS RECYCLED STEEL.
PLEASE RECYCLE AGAIN.



0 14500 04152 4

*WEIGHT OF VEGETABLES (5.5 OZ.) BEFORE
ADDITION OF LIQUID FOR PROCESSING.

INGREDIENTS: WATER, SWEET PEAS, CARROTS, SUGAR AND SALT.

PACKED BY © THE LARSEN COMPANY
P.O. BOX 19027 GREEN BAY, WISCONSIN 54307-9027

NET WT 8.5 OZ • WT OF VEGETABLES 5.5 OZ

Freshlike

**SWEET PEAS
& CARROTS**

BEST AVAILABLE DOCUMENT

198

Nutrition FactsServing Size 1/4 Cup (62g)
Servings Per Container 7**Amount Per Serving****Calories 20 Fat Cal. 0**

% Daily Value*

Total Fat 0g 0%**Sodium 14mg 1%****Total Carb. 5g 2%**

Fiber 1g 4%

Sugars 3g

Protein 1g

Vitamin A 15% • Vitamin C 20%

Iron 4%

Not a significant source of cholesterol, saturated fat or calcium.

*Percent Daily Values are based on a 2,000 calorie diet.

**NET WT. 15 OZ. (425 GRAMS)****YIELD: MEAT FOR 10-12 TACOS**

1. In a large package TACO SEASONING and 3/4 cup water.

3. Bring to a boil. Reduce heat and simmer 15 minutes, stirring occasionally.

Spoon 2 to 3 Tablespoons Taco Meat Filling into 10 to 12 prepared Taco shells or over 1/2 cup corn chips or tortilla chips, per serving. Top with shredded lettuce, cheese and chopped tomatoes. Add chopped onion and sour cream if desired. Top with salsa.

9043

Taco Burgers

Place meat filling topped with lettuce, cheese, onions and tomatoes between hamburger buns.

Nutrition FactsServ. Size 1 tsp(3.5g)
Servings about 10
Calories 10
Fat Cal. 0

Amount/serving	%DV*	Amount/serving	%DV*
Total Fat 0g	0%	Total Carb. 2g	1%
Sat. Fat 0g	0%	Fiber 0g	1%
Cholest. 0mg	0%	Sugars 0g	
Sodium 230mg	9%	Protein 0g	

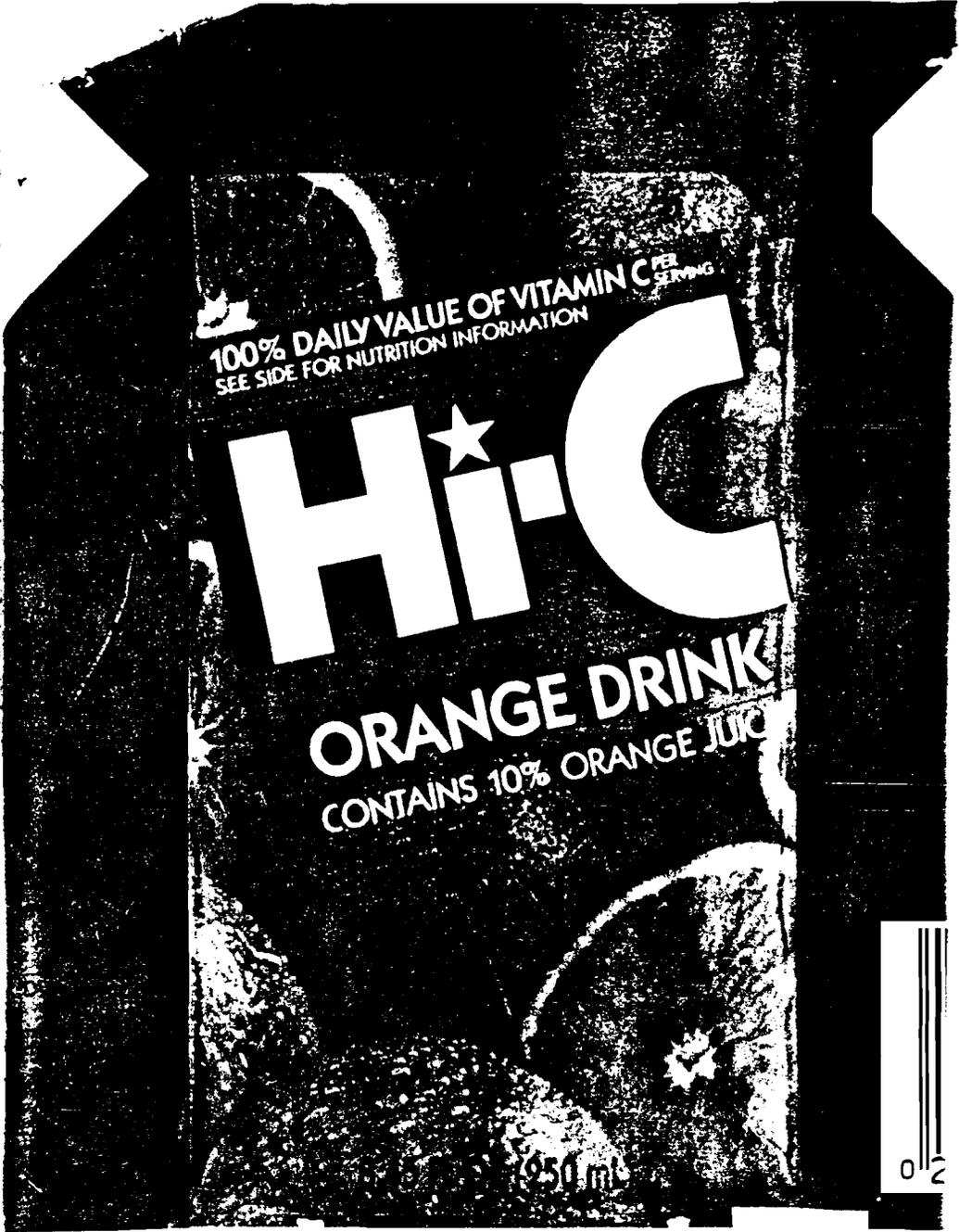
*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Vitamin A 4% • Vitamin C 0%
Calcium 2% • Iron 2%

INGREDIENTS: CHILI PEPPER AND OTHER SPICES, DEXTROSE, CORN MASA, SALT, ONION, GARLIC, PAPRIKA, COCOA, HYDROLYZED SOY PROTEIN, NATURAL FLAVORS, CITRIC ACID, AUTOLYZED YEAST EXTRACT. NOT MORE THAN 2% TRICALCIUM PHOSPHATE ADDED AS AN ANTICAKING AGENT.

DISTRIBUTED BY: STAFF SUPERMARKET ASSOCIATES, INC.
GENERAL OFFICES: NORCROSS, GA. 30092 U.S.A.

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100% DAILY VALUE OF VITAMIN C PER SERVING
SEE SIDE FOR NUTRITION INFORMATION

Hi-C

ORANGE DRINK

CONTAINS 10% ORANGE JUICE

950 ml



2-Z639



BEST AVAILABLE DOCUMENT

APPENDIX VI

Workshop Evaluation Questionnaire and Tally Sheet
EVALUACION DEL CURSO-TALLER

PROCESAMIENTO DE FRUTAS Y VEGETALES
INCAP P. Solé 8-VII-94

Favor de evaluar los siguientes aspectos del taller. Favor de marcar la calificación apropiada según su estimación. Poner una "X" donde corresponda. No es necesario poner su nombre o firmar.

Pregunta	Excel.	Bueno	Regular	Malo	TOT
¿Se comunicó claramente los objetivos del taller?	= 3	= 7	= 2		12
¿Cómo le motivó el taller para participar y aprender?	= 8	= 4			12
¿Fue la actitud del conferencista positiva y entusiasta?	= 10	= 2			12
¿Cómo aprovechó el conferencista el tiempo?	= 6	= 6			12
¿Cómo juzga los ejemplos e ilustraciones que usó el conferencista?	= 6	= 5	= 1		12
¿Cómo juzga la capacidad del taller en crear una buena comprensión de conceptos y principios?	= 5	= 6	= 1		12
¿Cómo juzga que el ambiente que hubo fomentó y respetó una diversidad de opiniones y puntos de vista?	= 7	= 5			12

OTROS COMENTARIOS Y SUGERENCIAS

7-12-94
P. Solé

¿COMO CREE USTED QUE SE PODRÍA MEJORAR ESTE TALLER?

8-VII-94
P. Solé

APPENDIX VII

Photographs



Workshop discussions in INCAP's conference room



Some workshop participants, SUSTAIN Volunteer Dr. Pedro Sole (top center), Dr. Luis Elias, (INCAP) (bottom left), pilot plant personnel with the Guatemalan Ministry of Agriculture mobile plant in background



Sorting beans for canning



Discussing thermal processing at INCAP's pilot plant