SUBJECT:

Establish Certification Requirements for Various Foods to Minimize FDA Audit Sampling of Those Foods Being Exported to the U.S.

(FDA Agreement Number 225-84-8000)

(Previously CPG 7156i.01)

Notes:

The FDA contact for this MOU is Lee Bowers, HFS-605

Tel. No. 202-205-5332

This MOU is in effect indefinitely.

MEMORANDUM OF UNDERSTANDING

Between The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA

And The

BOARD OF CUSTOMS
OF THE REPUBLIC OF FINLAND

I. PURPOSE

The mutual goals of the Food and Drug Administration (FDA) of the United States of America and the Board of Customs of the Republic of Finland in entering into this Memorandum of Understanding are to:

A. Establish certification requirements for the various food products listed in the attachments to this document exported from Finland to the United States to assure that contaminated food products will not be imported into the United States.

B. Minimize the need for extensive FDA audit sampling of these certified products from Finland that would be necessary without this Memorandum.

II. DEFINITIONS

LOT: A lot is a quantity of a product produced by one manufacturer during a discrete period of time not exceeding 1 day. It is produced in one continuous process using a single processing line and packaged in identical containers identified by a unique code traceable to the manufacturer.

DEFECT ACTION LEVELS: The limits at or above which FDA will take legal action to remove adulterated products from the market or prohibit their entry into commerce in the United States. Defect action levels are established for natural or unavoidable defects in food on the basis of no hazard to health and the unavoidability of a substance.

Defect action levels do not represent permissible levels of contamination where it is avoidable. Where no established defect action level or action level for poisonous and deleterious substances or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

SALMONELLA NEGATIVE: The absence of Salmonella in 30/25 gram portions each taken from a lot of product. The portions are reconstituted individually, or composited, and tested by procedures

Notes:

See: BAM, 8th Ed., 1995

See: Methods of Analysis - AOAC, 16th Ed., 1995

outlined in the "Bacteriological Analytical Manual" (BAM), 5th Ed.; or in "Methods of Analysis"--Association of Official Analytical Chemists (AOAC).

III. SUBSTANCE OF AGREEMENT

The Board of Customs of the Republic of Finland

The Board of Customs of the Republic of Finland is the government agency responsible for the inspection necessary for consumer protection purposes of imported or exported foodstuffs and other products. To fulfill its responsibilities under this memorandum, the Board of Customs will direct its activities to ensure that the food products listed in the attachments are fit for human consumption. This will be accomplished by inspecting products before distribution and by collecting and examining samples to ensure compliance with appropriate regulations.

To discharge its responsibilities regarding the food products listed in the attachments and to fulfill this Memorandum commitment:

A. The Board of Customs of the Republic of Finland will have the Customs laboratory in Helsinki inspect each lot of a food product offered to it by the manufacturer for export to the United States. This inspection will be made to determine that the lot of food does not exceed specified contamination levels. The Customs Laboratory will ensure by appropriate procedures that these analyses are completed as described in Section V below.

B. The Board of Customs will issue an export certificate only for those lots that meet the criteria stipulated in each attachment for the particular food.

C. The Board of Customs will have an agreement with the National Board of Health, subordinate to the Ministry of Social Welfare and Health, to the effect that the National Board of Health will inspect for and certify to the Board of Customs that acidified/low-acid canned foods meet the criteria stipulated in the relevant attachment to this document.

D. The Board of Customs will require that all containers of lots of food products exported to the United States, under certification, be identified by a lot number and marked with the lot number. All other information required by the Federal Food, Drug, and Cosmetic Act, as amended January 1980 (21 U.S.C.A., Chapter 9, Sections 301-392) and the Fair Packaging and Labeling Act also will be included.

E. The Board of Customs will include the following information on the certificate for each lot of the food products exported to the United States:

Notes:

1. Lot identification, including name and address of manufacturer;
2. Number and size of containers in the lot;
3. Analytical results of the tests conducted as specified in the attachments to this agreement;
4. Food Canning Establishment (FCE) registration number for all acidified/low acid canned foods;
5. Date of the certificate; and,
6. Name and stamp or seal of authorizing official.

F. The Board of Customs will affix its validated certificates to the shipping manifest and the packing list, supplied by the manufacturer, which indicates those lots physically present in each containerized cargo unit.

G. The Board of Customs will furnish FDA with a copy of the current Finnish regulations and the procedures used to ensure that each product is acceptable.

H. The Board of Customs will furnish FDA, upon request, with a full description of the manufacturing processes and quality controls used to ensure the production of sanitary food fit for human consumption.

The Food and Drug Administration of the United States of America

The Food and Drug Administration (FDA) of the Department of Health and Human Services of the United States of America is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes. FDA directs its activities toward the protection of the public health of the United States by ensuring that foods are safe and wholesome and are honestly and informatively labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to ensure compliance with these statutes. FDA makes a concerted effort to ensure that foods entering the United States meet the same standards as domestic products. To discharge these responsibilities regarding the food products listed in the attachments to this document and to fulfill this Memorandum commitment:

A. FDA may sample those products certified under this memorandum to ensure that the products exported from the Republic of Finland comply with the applicable specifications. FDA may also examine the certified lots for other attributes to determine whether the products comply with other requirements of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Public Health Service Act, and other related statutes.

B. FDA will share any information obtained through its audit sampling with the Board of Customs of the Republic of Finland.

Notes:

C. FDA will promptly notify the Board of Customs of the Republic of Finland of any detention of any product covered by this memorandum and of any modifications to the statutes or the regulations pertaining to these products.

D. FDA will share expertise and provide assistance to the Board of Customs of the Republic of Finland when necessary. Areas of mutual cooperation will include but will not be limited to: data gathering, technical information updating, and the exchange of new and/or improved methods of sampling and testing of the enumerated food products. This will help ensure the safety of the food products listed in the attachments exported to the United States.

IV. SAMPLE COLLECTION

Whenever possible, the same subsample will be used to determine the levels, if any, of Salmonella and to determine compliance with the established FDA defect action levels in food and compliance with any specified FDA action levels for poisonous or deleterious substances in food. Samples of the food products listed in the attachments will be collected in accordance with the applicable portions of "Bacteriological Analytical Manual", 5th Ed., 1978, Chapter I Food Sampling Plans and Initial Sampling Handling, for Salmonella, and Chapter 4 of the FDA "Inspection Operations Manual" for other attributes.

See: BAM, 8th Ed., 1995

See: Investigations Operations Manual, May 1996

V. ANALYTICAL METHODOLOGY

Compliance with the established FDA defect action levels for natural or unavoidable defects in food and compliance with any specified FDA action levels for poisonous or deleterious substances in food will be determined according to the methods contained in:

A. "Bacteriological Analytical Manual," 5th Ed., 1978, the Association of Official Analytical Chemists, 1111 Nineteenth Street, Arlington, VA 22209.

B. "Official Methods of Analysis, Association of Official Analytical Chemists," 13th Ed., 1980, the Association of Official Analytical Chemists, 1111 Nineteenth Street, Arlington, VA 22209.

A. BAM, 8th Ed., 1995
AOAC -
481 N. Frederick Ave., Suite 500
Gaithersburg, MD 20877-2417
Tel. No. 301-924-7077

B. Official Methods of Analysis, 16th Ed., 1995
See AOAC address above.

VI. PARTICIPATING PARTIES

A. The Board of Customs of the Republic of Finland
Box 512 SF 00101
Helsinki 10, Finland

B. Food and Drug Administration
5600 Fishers Lane,
Rockville, MD 20857

Notes:

VII. LIAISON OFFICERS

A. For the Board of Customs, Republic of Finland
Director, Finnish Customs Laboratory
(currently Mr. Erkki Petaja)
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Helsinki 10, Finland
90-455-03-11, Telex 121559 TULHS SF

B.
Director, Division of Enforcement (HFS-600)
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B. For the Food and Drug Administration
Director, Division of Regulatory Guidance (HFF-312)
(currently John Taylor)
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Washington, D.C.
20204 202-485-0187, Telex 197623 PHS PkIn

VIII. ADMINISTRATIVE PROCEDURES

The parties shall mutually agree on the ways and means of giving instructions and guidance for the practical implementation and application of this Memorandum.

Additional products may be added to the list of products subject to certification under this agreement by mutual consent of the liaison officers.

IX. PERIOD OF AGREEMENT

This Memorandum will become effective upon acceptance by both parties and will continue indefinitely. It may be revised by mutual consent or terminated by either party upon a 30-day advance written notice to the other.

In witness whereof, the agencies have executed this Memorandum covering the food products listed in the attachments to this document.

APPROVED AND ACCEPTED FOR THE BOARD OF CUSTOMS OF THE REPUBLIC OF FINLAND

BY: _____

TITLE: Director General, Board of Customs

DATE: March 8, 1984

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

BY: _____

TITLE: Director, Food Division

Notes:

DATE: March 8, 1984

ATTACHMENT A

PRODUCTS: Puddings.

Criteria: Compliance will be determined by, but will not be limited to, ascertaining if the product is:

1. Salmonella negative; and,

See: AOAC, 16th Ed., 1995

2. Free of filth (Should not contain any insect or animal filth as determined by the AOAC, 13th Ed., 44.053).

ATTACHMENT B

PRODUCTS: Soups: Canned and Dehydrated.

CANNED

Criteria: Compliance will be determined by, but will not be limited to:

1. Determining if the processes have been accepted for filing by FDA for canned soups that are acidified or low acid canned foods as defined in applicable FDA regulations.

2. Examining at the processing location a minimum of 240 unlabeled cans from each lot to be offered for certification for seam defects, dents, scratches, abrasions, and other evidence of improper handling which could cause leakage. Lots exhibiting defects of container integrity will not be offered for certification.

3. Reviewing processing records from each lot to be offered for certification with sufficient frequency to ensure the scheduled filed processes are being followed and any deviations from the scheduled processes are competently handled. The acidified/low-acid canned food from a processor showing deviations from the scheduled, filed processes will not be offered for certification.

4. Examining finished stock from each lot to be offered for certification according to the attached sampling schedule for evidence of under processed lots. Under processed lots will not be offered for certification.

Notes:

DEHYDRATED

Criteria: Compliance will be determined by, but will not be limited to, ascertaining if the product is Salmonella negative.

SAMPLING SCHEDULE FOR CANNED SOUPS

1. Examine each finished lot, offered for certification for evidence of under processing, i.e.: leaking cans, wet cases, swollen cans, swarms of fruit flies around isolated pallet, etc.

2. When inspectional evidence indicates that an under processed lot has been produced discontinue examination.

   Under processed lots will not be offered for certification.

3. When the inspectional evidence indicates that the lot contains accidentally damaged containers or cases these will be removed from the lot before offering it for certification.

4. A lot to be examined will be one production code as defined under "II. DEFINITIONS" of this Memorandum of Understanding.

5. Each examination will consist of a maximum of 576 containers. When the inspectional evidence indicates that the lot contains abnormal containers the examination will be discontinued. See paragraph "6. Definitions" below for definitions of abnormal containers. A lot in which the inspectional evidence indicates the presence of abnormal containers will not be offered for certification.

6. DEFINITIONS

   a. Flippers - Only one end is slack or slightly bulged. That end will remain flat if pressed in. Cans which bulge when sharply and squarely struck end-down on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.

   b. Springers - One end of a can bulges. Manual pressure on the bulged end forces the opposite end out or the same end will spring out with release of pressure. If both ends bulge out but only one will remain flat when pressed, the can is a springer. Springers result from a moderate positive pressure in the can. Bulking or extensive denting of the side wall may produce a springer.

   c. Swells - Both ends of the can are bulged. Neither will remain flat without pressure. Soft swells yield to manual pressure, but no impression can be made manually on hard swells. Swells result

Notes:

from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acid products, may result from chemical reaction between the contents and the container.

d. Others - Other abnormalities or defects, not defined in this paragraph, include visibly leaking cans, severe dents around seams, gross seam defects, rusted containers, etc.

ATTACHMENT C

PRODUCTS: Candies: Chocolate and Licorice.

CHOCOLATE

Criteria: Compliance will be determined by, but will not be limited to, ascertaining if the product is:

1. Salmonella negative; and,

2. Contains filth that is less than the mathematical product of the percentage of the characterizing ingredient in the product (chocolate) multiplied by the defect action level for insect filth, rodent filth, or shell in that ingredient. A copy of the defect action levels for chocolate and cocoa powder press cake is attached.

LICORICE

Criteria: Compliance will be determined by, but will not be limited to, ascertaining if the product contains filth that is less than the mathematical product of the percentage of wheat flour in the product multiplied by the defect action level for insect filth or rodent filth in wheat flour. A copy of the defect action level is attached.

Notes:

DEFECT ACTION LEVEL

CHOCOLATE AND CHOCOLATE LIQUOR	Insect filth	Average exceeds 60 microscopic insect fragments per 100 grams, when 6 100-gram subsamples are examined. OR If any 1 subsample contains more than 90 insect fragments
	Rodent filth	If average exceeds 1.0 rodent hairs per 100 grams OR If any 1 subsample contains more than 3 rodent hairs
	Shell	For chocolate liquor, if the shell is in excess of 2% calculated on the basis of alkali-free nibs
COCOA POWDER, PRESS CAKE	Insect filth	Average exceeds 75 microscopic insect fragments per subsample of 50 grams OR Any 1 subsample contains more than 125 microscopic insect fragments
	Rodent filth	Average in 6 or more subsamples exceeds 2 rodent hairs per subsample of 50 grams OR Any 1 subsample contains more than 4 rodent hairs
	Shell	Shell in excess of 2% calculated on the basis of alkali-free nibs
WHEAT FLOUR	Insect filth	Average of 50 or more insect fragments per 50 grams
	Rodent filth	Average of 1 or more rodent hairs per 50 grams

Notes:

FOLLOW THIS SCHEDULE FOR THE EXAMINATION

UNCASED CONTAINERS		PACKED 48/CASE		PACKED 24/CASE		PACKED 10/CASE		PACKED 6/CASE	
LOT SIZE (containers)	NO. TO EXAM-INE	LOT SIZE (cases)	CASES TO EXAM-INE	LOT SIZE (cases)	CASES TO EXAM-INE	LOT SIZE (cases)	CASES TO EXAM-INE	LOT SIZE (cases)	CASES TO EXAM-INE
192 or less	All	1-4	All	1-8	All	1-16	All	1-32	All
193 - 288	192	4-6	4	8-12	6	16-24	16	32-48	32
289 - 384	All-298	6-8	6	12-16	12	24-32	25	48-64	All-50
385 - 576	363	8-12	8	16-24	15	32-48	30	64-96	61
577 - 912	433	12-19	9	24-38	18	48-76	36	96-152	72
913 - 1488	480	19-31	10	38-62	20	76-124	40	152-248	80
1489-3408	529	31-71	11	62-142	22	124-284	44	248-568	88
> 3408	576	>71	12	>142	24	> 284	48	> 568	96