SUBJECT:

Dry Milk Products Exported to the United States

(FDA Agreement Number 225-75-2001)

(Previously CPG 7156h.01 Modification #1)

Notes:

The FDA contact for this MOU is Frank MacKeith, HFS-585

Tel. No. 202-205-4045

This MOU is in effect indefinitely.

Dept. of Health, Educ., & Welfate is now Dept. of Health and Human Services

See: BAM, 8th Ed., 1995

MEMORANDUM OF UNDERSTANDING

Between the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

And the

STATE QUALITY CONTROL FOR DAIRY PRODUCTS AND EGGS, ETC., DENMARK
COVERING DRY MILK PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA
REVISED

OBJECTIVES

It is the aim of the parties to this Memorandum of Understanding to facilitate, simplify and expedite the importation of dry milk products into the United States of America; to improve compliance with regulations enforced by the Food and Drug Administration (FDA) by assuring that contaminated or under processed dry milk products will not be exported to the United States; to minimize, and in the future, diminish the risk of lots of dry milk products being denied entry because of failure to comply with FDA regulations; and to eventually reduce the need for extensive sampling of dry milk products from Denmark to assure that they meet the requirements of the laws and regulations enforced by the Food and Drug Administration.

DEFINITIONS

For purposes of this Memorandum, both parties agree to the definitions following:

Dry Milk Products -- Dry milk products include dry whole milk, nonfat dry milk, lowfat dry milk, dry cream, dry whey, dry buttermilk, casein, caseinates.

Lot -- A lot is a quantity of dry milk product produced during a discrete period of time, not exceeding one day, by one manufacturer, in one continuous processing using a single processing line, packaged in identical containers identified by a code or mark traceable to the manufacturer.

Salmonella negative--The absence of Salmonella in 30/25 gram portions each taken from a lot of dry milk product and reconstituted individually or composited and tested by procedures outlined in the Bacteriological Analytical Manual (BAM) 5th Edition; or in Methods of Analysis - AOAC.

Phosphatase negative--Each of the 30 reconstituted 25 gram portions or composited units of dry milk product contains less than 1 microgram of

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phenol per milliliter of milk when tested by the Scharer Rapid Method indicating no under pasteurization or contamination with raw milk. Products found negative by the Storch Test (paraphenylenediamine test) will not be tested by the Scharer Method.

Penicillin negative--Each of the 30 reconstituted 25 gram portions or composited units contains no detectable residue of penicillin when tested by the S. lutea cylinder method; or, by the B. stearothermophilus, variety calidolactis, disk assay method normally used in Denmark for this purpose.

OBLIGATIONS OF PARTICIPANTS

The State Quality Control For Dairy Products and Eggs, etc., Denmark

A. The State Quality Control For Dairy Products and Eggs, etc., Denmark, agrees to inspect each lot of dry milk product produced in Denmark and offered for export to the United States of America to assure that the lot is Salmonella negative, phosphatase negative, and penicillin negative.

B. The State Quality Control for Dairy Products and Eggs, etc., Denmark, agrees to issue an export certificate for only those lots which meet the criteria of 1., above. Any lot which fails to meet such criteria will be denied export to the United States of America.

C. The State Quality Control For Dairy Products and Eggs, etc., Denmark agrees to require all containers of lots exported to the United States of America to be identified by a lot number and marked together with all other information required by the Federal Food, Drug and Cosmetic Act.

D. The State Quality Control For Dairy Products and Eggs, etc., Denmark, agrees to include in the certificate for each lot exported to the United States of America the following information:

1. Lot identification, including name and address of manufacturer;

2. Number and size of containers in the lot;

3. Analytical results for Salmonella, phosphatase, and penicillin;

4. Date of the certificate; and,

5. Name and stamp, or seal of authorizing official.

The validated certificate will accompany the shipping manifest.

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E. The State Quality Control For Dairy Products and Eggs, etc., Denmark, agrees to furnish to the Food and Drug Administration a copy of the current regulations, and procedures used to assure that dry milk products are sanitary.

F. The State Quality Control For Dairy Products and Eggs, etc., Denmark, agrees to furnish to the Food and Drug Administration a full description of the manufacturing process and quality control used to assure the production of sanitary dry milk products.

The Food and Drug Administration

Dept. of Health, Educ., & Welfare is now Dept. of Health and Human Services

The Food and Drug Administration (FDA) of the Department of Health, Education and Welfare is charged with the enforcement of the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. In fulfilling its responsibilities under the Acts, FDA directs its activities toward the protection of the public health of the United States of America by ensuring that foods are safe and wholesome and that products are honestly and informatively labeled. This is accomplished by inspecting the processing and distribution of foods and by collecting and examining samples to assure compliance with these Acts. To carry out these responsibilities as they relate to imported dry milk products and in fulfillment of its Memorandum of Understanding commitment:

1. The Food and Drug Administration will sample dry milk products certificated under this Memorandum of Understanding to assure that the exporting country and the exported products comply with specifications set forth in this Memorandum. The intensity of sampling may be reduced on gaining confidence in the compliance of the products to these specifications. The FDA may also check for other attributes to make sure the products also comply with the other requirements of the Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act.

2. Information obtained by the Food and Drug Administration through its audit sampling will be shared with the Agricultural Counselor of the Danish Embassy.

3. Also, the Food and Drug Administration will promptly notify the Agricultural Counselor of any detention of dry milk products covered by the Memorandum and of any modifications in the regulations.

4. The Food and Drug Administration will share expertise and will provide consultative assistance to the exporting country when necessary to assure the safety of the dry milk products exported to the United States of America.

5. If audit sampling discloses that certified dry milk products are not conforming to the requirements of the MOU and if adequate steps are not taken to correct the situation after proper notification, the

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Food and Drug Administration may consider termination of the Memorandum of Understanding.

Sample Collection

The same subsamples will be used for determining the presence of Salmonella, phosphatase and penicillin. They will be collected as follows:

Following aseptic techniques, 30 subsamples each containing approximately 100 grams will be randomly collected from each lot. If a lot contains packaged units weighing approximately 225 grams (about 8 ounces) or less, but more than 100 grams, 30 of these units will be randomly collected, unopened, from the lot.

Analytical Methodology

The subsamples of dry milk products will be aseptically reconstituted. To reduce the analytical workload, the subsamples collected from a lot may be combined to give 2 to 10 composites at the option of the testing laboratory and reconstituted. Examples of compositing combinations are given in Attachment A.

1. Salmonella

Reconstituted dry milk products will first be analyzed for presence of Salmonella according to the methods contained in:

a. Bacteriological Analytical Manual, Fifth Edition, 1978, Chapter VI - Detection and Identification of Salmonella, including S. arizonae, or in

a. See: BAM, 8th Edition, 1995

b. Methods of Analysis - AOAC, Twelfth Edition, 1975, Chapter 46, Microanalytical Methods, Section 46.013, et. seq.

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

(Note: Both (a) and (b) give methods based upon 100 gram samples. For this MOU, 30/25 gram samples will be used instead.) Lots of dry milk products that are positive for Salmonella will not be certified for export to the United States.

2. Phosphatase

Only reconstituted dry milk products that are positive by the Storch Test will be tested for phosphatase activity by the Scharer Rapid Method for Phosphatase Analysis, described in Standard Methods for the Examination of Dairy Products, Thirteenth Edition, 1972, Section 18.4 Lots of dry milk products demonstrating positive phosphatase activity will not be certified for export to the United States.

See: Standard Methods for Examination of Dairy Products, 16th Ed., 1993

Notes:

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

3. Penicillin

Reconstituted dry milk products will be tested for penicillin residues by the following methods. The S. lutea, cylinder method as described in Methods of Analysis - AOAC, Twelfth Edition, Section 42.252 et. seq., p. 812-813; Changes in Official Methods of Analysis made by the Nineteenth Annual Meeting, Oct. 18-21, 1976/Third Supplement to 12th Edition, Journal of AOAC, Volume 60, March 77, pp. 484-485, Section 42(4). The B. stearothermophilus, variety calidolactis, disk assay method described in the International Standard FIL-IDF 57:1970 of the International Dairy Federation normally used in Denmark for this purpose.

While the State Quality Control For Dairy Products and Eggs, etc., Denmark may choose to use either of these methods for certification of lots, FDA will continue to use the S. lutea cylinder method, which is an official AOAC method, in its regulatory enforcement to assure that imported dry milk products are free of detectable penicillin residues. Lots of dry milk products found to be penicillin positive, will not be certified for export to the United States.

References of Analytical Methods Cited in This MOU:

1. Bacteriological Analytical Manual, Fifth Edition, 1978. The Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C., 20044.

2. Methods of Analysis - AOAC, Twelfth Edition, 1975. Changes in Official Methods of Analysis made at the Nineteenth Annual Meeting, Oct. 18-21, 1976/Third Supplement to 12th Edition, Journal of AOAC, Volume 60, March 77, pp. 484-485, Section 42(4). The Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C., 20044.

3. Standard Methods for the Examination of Dairy Products, Thirteenth Edition, 1972, Section 18.4 American Public Health Association, 1015 Eighteenth Street, N.W., Washington, D.C. 20036.

4. The International Standard FIL-IDF 57:1970, International Dairy Federation, General Secretariat, Square Vergot 41, Brussels, Belgium.

1. BAM, 8th Edition, 1995

AOAC
481 N. Frederick Ave.,
Gaithersburg, MD
20877-2417
Tel. No.
301-924-7077

2. See: Methods of Analysis, 16th Edition, 1995

3. See: Standard Methods for the Examination of Dairy Products, 16th Ed., 1993
American Public Health Association
P.O. Box 753
Waldorf, MD
20604

Modifications and Termination of the MOU

Changes in this Memorandum of Understanding may be proposed by either of the participants. When the proposed changes are acceptable to both participants, they will be incorporated into the Memorandum. This revision to the Memorandum of Understanding will become effective 60 days after signature by the participants, and will remain in effect pending revocation by either participant. Upon its effective date, this revised Memorandum of Understanding will be published in the Federal Register. A copy will be available for public review at the Office

Notes:

of the Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, Maryland 20857.

In witness whereof, the Agencies have executed this revision to the Memorandum of Understanding covering dry milk products presently in effect between our governments.

For the State Quality Control For Dairy Products and Eggs, Etc., Denmark

By: /s/

Title: Managing Director

Country: DENMARK
Date: 19 - 1- 1979

For the Food and Drug Administration

The ACRA is currently Mr. Ronald G. Chesemore

By: Joseph P. Hile /s/

Title: Associate Commissioner for Regulatory Affairs

Country: UNITED STATES OF AMERICA

Date: _____

Notes:

ATTACHMENT A

The 25 gram portions taken from each of the 30 samples collected from a lot of dry milk product may be composited according to the following options before reconstituting.

Number of: Composites to be prepared for analysis from the 30 samples collected	Number of: Samples in each composite	Number of: Grams of test product in each composite	Milliliters of sterile distilled water in which the weighed test product is to be reconstituted
2	15	375	3750
3	10	250	2500
5	6	150	1500
6	5	125	1250
10	3	75	750

Example of Compositing:

If the 2 composite option is selected, 25 gram portions are taken from each of 15 samples, weighed and reconstituted in 3,750 milliliters of sterile distilled water; 25 gram portions from each of the remaining 15 samples are likewise weighed and added to an additional 3,750 milliliters of sterile distilled water. Each of these composites contains 375 grams of the test product.