SUBJECT:

Exporting Dry Milk Products to the United States

(FDA Agreement Number 225-78-1001)

(Previously CPG 7156c.03)

Notes:

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

Tel. No. 202-205-4045

This MOU is in effect indefinitely.

See: BAM, 8th Ed., 1995 or Methods of Analysis - AOAC, 16th Ed., 1995

MEMORANDUM OF UNDERSTANDING

Between the

SWEDISH GOVERNMENT CONTROL BOARD OF DAIRY PRODUCTS

and the

UNITED STATES

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 by assuring that contaminated or underprocessed 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 Sweden 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 non-fat dry milk, whole milk powder, dried whey, buttermilk powder, casein and caseinates.

Lot:

A lot is a quantity of dry milk product produced during a discrete period of time not exceeding one day's production by one manufacturer, in one continuous process 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 (including S. arizonae) in 30/25 gram portions each taken from a single lot of dry milk product and reconstituted individually or composited and tested by procedures outlined in the Bacteriological Analytical Manual (BAM), Fourth Edition; or in Methods of Analysis - AOAC, Twelfth Edition, except using 30/25 gram portions instead of the 100 gram portions stated in BAM and AOAC.

Notes:

Phosphatase negative:

Each of the 30 reconstituted 25 gram portions or composited units of dry milk product contains less than 1 microgram of phenol per milliliter of milk when tested by the Sharer Rapid Method indicating no underpasteurization or contamination with raw milk.

Penicillin negative:

Each of the 30/25 gram portions individually reconstituted or composited before reconstituting, contains less than .01 of an International Unit of penicillin G per milliliter of milk when tested by the S. lutea cylinder method, or by the B. stearothermophilus, variety calidolactis, disk assay method normally used in Sweden for this purpose.

OBLIGATIONS OF PARTICIPANTS

The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden

A. The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden, agree to inspect each lot of dry milk product produced in Sweden and offered for certification and exportation to the United States of America to assure that the lot is Salmonella negative, phosphatase negative, and penicillin negative.

B. The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden, agrees to issue a separate certificate for only those lots which meet the criteria of A, above. Any lot offered for certification which fails to meet such criteria will be denied export to the United States of America.

C. The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden agrees to require all containers in each lot exported to the United States of America under certificate, to be identified by a lot number and marked with all the information required by the Food, Drug, and Cosmetic Act.

D. The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden, 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;

Notes:

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.

E. The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden, agrees to furnish to the Food and Drug Administration a copy of the regulations, and procedures used to assure that dry milk products are sanitary.

F. The Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden, agrees to furnish to the Food and Drug Administration a full description of the manufacturing processes and quality controls 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 Resources

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 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 in 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:

A. 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 agreement. 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 other requirements of the Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act.

B. Information obtained by the Food and Drug Administration through its audit sampling will be shared with the Commercial Office of the Royal Swedish Embassy.

C. The Commercial Office of the Royal Swedish Embassy will be promptly notified by the Food and Drug Administration of any detention of dry milk products covered by this Memorandum and also of modification in the regulations.

Notes:

D. 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.

E. 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 Food and Drug Administration may propose termination of the Memorandum of Understanding.

SAMPLE COLLECTION

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

Following aseptic-techniques, 30 subsamples each containing approximately 100 grams will be randomly collected from each lot. If the 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 opinion of the testing laboratory and reconstituted. Examples of compositing combinations are given in Attachment A.1.

A. Salmonella

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

1. Bacteriological Analytical Manual, Fourth Edition, 1976, Chapter VI--Detection and Identification of Salmonella, including S. arizona, or in

2. Methods of Analysis--AOAC - Twelfth Edition, 1975, Chapter 46, Microanalytical Methods, Section 46.013, et. seq. (Note: Both (a) and (b) give methods based upon 100 gram samples.)

Lots of dry milk products that are positive for Salmonella will not be certified for export to the United States.

1. See: BAM, 8th Ed., 1995

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

1/ Filed as part of the original document.

Notes:

See: Std. Methods for the Exam. Of Dairy Products, 16th Ed., 1993

B. Phosphatase

Reconstituted dry milk products 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.

C. Penicillin

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

Reconstituted dry milk products will be tested for penicillin residues by either the S. lutea, cylinder method as described in Methods Analysis, AOAC, Twelfth Edition, Section 42.252 et. seq., p. 812-813; or, by 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 Sweden for this purpose.

While the Swedish Government Control Board of Dairy Products and Eggs, KMA, Sweden 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 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, Fourth Edition, 1976, The Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

2. Methods of Analysis - AOAC, Twelfth Edition, 1975, 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, American Public Health Association, 1015 Eighteenth Street, N.W., Washington, D.C. 20036.

4. The International Standard FIL-IDF 157: 1970 - International Dairy Federation, General Secretariat, Square Vergote 41, Brussels, Belgium.

1. BAM, 8th Ed., 1995 AOAC, 481 N. Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417

2. Methods of Anaysis - AOAC, 16th Ed., 1995

3. Std. Methods for the Exam. Of Dairy Products, 16th Ed., 1993

Notes:

MODIFICATION 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 Memorandum of Understanding will become effective 90 days after signature by the participants, and will remain in effect pending revocation by either participant. Upon its effective date, this Memorandum of Understanding will be published in the FEDERAL REGISTER. A copy will be available for public review at the office of the Hearing Clerk, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

In witness whereof, the countries have executed this Memorandum of Understanding.

FOR THE SWEDISH GOVERNMENT, BOARD OF DAIRY PRODUCTS AND EGGS, KMA, SWEDEN

/s/
Tore Frennborn
Managing Director
Sweden
Date: August 15, 1977

FOR THE FOOD AND DRUG ADMINISTRATION

FDA Commissioner is currently: David A. Kessler, MD

/s/
Donald Kennedy
Commissioner of Food and Drugs
United States of America
Date: November 2, 1977