SUBJECT:

Sanitary Quality of Dry Milk Products

(FDA Agreement Number 225-75-2027)

(Previously CPG 7156g.01)

Notes:

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

Tel. No. 202-205-4045

This MOU is in effect indefinitely.

U.S. Dept. of Health, Education and Welfare is now U.S. Dept. of Health and Human Services

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

b. See: AOAC, 16th Ed., 1995

MEMORANDUM OF UNDERSTANDING

Between

THE MINISTRY OF AGRICULTURE OF BELGIUM
REPRESENTED BY THE
NATIONAL DAIRY OFFICE

And

THE FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
UNITED STATES OF AMERICA

This Memorandum of Understanding has been developed and agreed to by the respective agencies to control the sanitary quality of dry milk products exported to the United States of America.

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

Lot - A lot is a quantity of dry milk product produced during a period of time, 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 and the other parameters listed above.

Salmonella -negative -The absence of Salmonella will be determined by methodology contained in:

a. Bacteriological Analytical Manual for Foods -Third Edition, June 1972, Chapter VIII *

b. AOAC 11 - Section 41.026 (b), et. seq. **

c. With exceptions as provided in FDA Compliance Program Guidance Manual, October 13, 1972, Section 3 "The sampled lot is acceptable only if analysis of all the composite units are negative for Salmonella."

Phosphatase activity - negative - The absence of phosphatase activity will be determined by AOAC 11, Section 16.081, et. seq.

The National Dairy Office (Belgium)

1. We agree to inspect each lot of dry milk produced in this country and offered for export to the United States of America to assure that it is negative for Salmonella based upon examination of 30/100-gm

Notes:

sample units and analyzed by methods prescribed above under "Salmonella - negative," and that it contains no phosphatase activity by methods prescribed above under "Phosphatase activity - negative."

2. We agree 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.

3. We agree to require all containers of all lots exported to the United States of America to be identified by lot number, and marked "FOR HUMAN USE ONLY! NOT TO BE USED FOR ANIMAL FEED" together with all other information required by the Food, Drug, and Cosmetic Act.

Currently:
BAM, 8th Edition, 1995

* Bacteriological Analytical Manual for Foods, - Pub. No. 1712-00-162, U.S. Government Printing Office, Washington, D.C. 20402.

Official Methods of Analysis - AOAC 16th Edition, 1995

** Official Methods of Analysis, - 1970, Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

AOAC:
481 N. Frederick Ave., Suite 500
Gaithersburg, MD 20877-2417
Tel. No. 301-924-7077

4. We agree to include in the certificate for each lot exported to the United States of America the following information:

   a. Lot identification
   b. Number and size of containers in the lot
   c. Analytical results for Salmonella and phosphatase activity
   d. Date
   e. Name and stamp or seal of authorizing official.

5. We agree to furnish to the Food and Drug Administration a copy of the regulations, and procedures we use to assure that dry milk products are sanitary.

6. We agree 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.

Food and Drug Administration

1. The Food and Drug Administration is responsible for the safety and quality of dry milk products imported into this country for human consumption.

2. We will sample products certificated under this program to assure that the exporting country and the exported products comply with specifications set forth in this Memorandum of Understanding and all other requirements of the Food, Drug, and Cosmetic Act.

Notes:

3. We will share information about our audit sampling with the exporting country.

4. We 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 us.

It is to be noted that according to the structure of the Administration in Belgium, the National Dairy Office is the official agency able to control the sanitary quality and to grant the certificates for the above mentioned dairy products.

The National Dairy Office and the Food and Drug Administration agree that this Memorandum of Understanding shall become effective on the date it is signed by the Food and Drug Administration. It shall remain in effect, and govern all dry milk products exported to the United States of America pending revision or revocation at the request of either agency.

For the National Dairy Office

By: /s/

Agricultural attache is currently Mr. Jan Adriansens

Title: Agricultural attache

Country: Belgium

Date: November 6, 1974

For the Food and Drug Administration

By: A.M. Schmidt, M.D. /s/

FDA Commissioner is currently David A. Kessler, M.D.

Title: Commissioner of Food and Drugs

Country: The United States of America

Date: November 6, 1974