SUBJECT:

Rennet Casein Exported to the United States

(FDA Agreement Number 225-82-2001)

(Previously CPG 7156o.01)

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 Anaysis, AOAC, 16th Ed., 1995

MEMORANDUM OF UNDERSTANDING

Between The

FOOD AND DRUG ADMINISTRATION

And The

ROYAL NORWEGIAN MINISTRY OF AGRICULTURE COVERING RENNET CASEIN EXPORTED TO THE UNITED STATES OF AMERICA

I. OBJECTIVES

The mutual goals of the Food and Drug Administration and the Royal Norwegian Ministry of Agriculture in entering into this Memorandum of Understanding are to:

A. Improve the compliance status of rennet casein exported from Norway to the United States, by assuring that contaminated and/or underprocessed rennet casein will not be imported to the United States.

B. Minimize the need for extensive Food and Drug Administration audit sampling of certified rennet casein from Norway that may be necessary without this Memorandum of Understanding.

II. DEFINITIONS

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

Lot- A lot is a quantity of rennet casein 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.

Salmonella-negative- The absence of Salmonella in thirty 25-gram portions each taken from a lot of rennet casein. The portions are reconstituted individually, or composited, and tested by procedures outlined in the "Bacteriological Analytical Manual, "5th Ed., or in the "Methods of Analysis, Association of Official Analytical Chemists," 13th Ed.

Phosphatase-negative-Less than 1 microgram of phenol per milliliter of milk, in each of the 30 reconstituted 25-gram portions or composited units. The Sharer Rapid Method will be used to indicate no underpasteurization or contamination with raw milk.

Penicillin-negative-The absence of detectable residues of penicillin in each of the 30 reconstituted 25-gram portions or composited units. The S. lutea

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cylinder method of the B. stearothermophilus variety calidolactis, disk assay method will be used to test for the presence of penicillin.

III. OBLIGATIONS OF PARTICIPANTS

The Royal Norwegian Ministry of Agriculture.

The Royal Norwegian Ministry of Agriculture (NMA) is the responsible government agency of Norway for the administration of the regulations governing the import and export of rennet casein. To fulfill its responsibilities under these regulations, NMA directs its activities to ensure that the rennet casein is fit for human consumption. This is accomplished by inspecting products before distribution and by collecting and examining samples to ensure compliance with appropriate regulations.

To discharge its responsibilities regarding rennet casein and to fulfill this Memorandum of Understanding commitment:

1. The Royal Norwegian Ministry of Agriculture will have Meierilaboratoriet (ML) in Oslo (Control Institute for Milk and Dairy Products under the supervision of NMA) inspect each lot of rennet casein offered to it by the manufacturer for export to the United States. This inspection will be made to determine whether the lot is Salmonella-negative, phosphatase-negative, and penicillin-negative. The ML will ensure by appropriate procedures that these analyses are completed as described in section V. below.

2. The NMA will have ML issue an export certificate only for those lots which are Salmonella-negative, phosphatase-negative, and penicillin-negative.

3. The ML will require all containers of lots exported to the United States, under certification, to be identified by a lot number and marked with the lot number. All other information required by the Federal Food, Drug, and Cosmetic Act will also be included.

4. The ML will include the following information in the certificate for each lot exported to the United States:

   a. Lot identification, including name and address of manufacturer;
   b. Number and size of containers in the lot;
   c. Packing list indicating those lots physically in each "Containerized Cargo" unit;
   d. Analytical results for Salmonella, phosphatase, and penicillin;
   e. Date of the certificate; and,
   f. Name and stamp or seal of authorizing official. The validated certificate will accompany the shipping manifest.

5. The ML will furnish the Food and Drug Administration with a copy of its current regulations and the procedures used to ensure that the rennet casein is acceptable.

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6. The ML will furnish the Food and Drug Administration with a full description of the manufacturing processes and quality controls used to ensure the production of sanitary rennet casein fit for human consumption.

The Food and Drug Administration

The Food and Drug Administration (FDA) of the Department of Health and Human Services is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. 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. This is accomplished by inspecting the processing and distribution of foods. In addition, it involves collecting and examining 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 rennet casein and to fulfill this Memorandum of Understanding commitment:

1. The Food and Drug Administration will sample rennet casein certified under this MOU to ensure that the exporting country and the exported products comply with the applicable specifications. The frequency of sampling may be reduced when confidence is gained regarding the compliance of the products to the specifications of this Memorandum of Understanding. 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 and the Fair Packaging and Labeling Act.

2. The Food and Drug Administration will share any information obtained through its audit sampling with the Royal Norwegian Ministry of Agriculture.

3. The Food and Drug Administration will promptly notify the Royal Norwegian Ministry of Agriculture of any detention of rennet casein covered by this Memorandum of Understanding and of any modifications to the statutes, or the regulations pertaining to rennet casein.

4. The Food and Drug Administration will share expertise and provide assistance to Norway when necessary. Areas of mutual cooperation will include: data gathering, technical information updating, and the exchange of new and/or improved methods of sampling and testing rennet casein. This will help ensure the safety of rennet casein exported to the United States.

IV. SAMPLE COLLECTION

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

Using aseptic techniques, 30 subsamples, each of approximately 100 grams, will be randomly collected from each lot. If a lot contains packaging units weighing approximately 225 grams (about 8 ounces) or

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less, but more than 100 grams, 30 of these units will be randomly collected, unopened, from the lot.

V. ANALYTICAL METHODOLOGY

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

A. Salmonella. Reconstituted rennet casein will first be analyzed for presence of Salmonella according to the methods contained in:

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

1. "Bacteriological Analytical Manual," 5th Ed., 1978, Chapter VI--Detection and Identification of Salmonella, including S. arizonae, or

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

2. "Official Methods of Analysis, Association of Official Analytical Chemists," 13th Ed., 1980, Chapter 46, Microanalytical Methods, section 46.054 et. seq. (Note: Both a. and b. give methods based upon 100-gram samples. For this Memorandum of Understanding, thirty 25-gram samples will be used instead.

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

B. Phosphatase. Reconstituted rennet casein will be tested for phosphatase activity by the Scharer Rapid Method for Phosphatase Analysis. This method is described in "Standard Methods for the Examination of Dairy Products," 14th Ed., 1978, section 18.4.

C. Penicillin. Reconstituted rennet casein will be tested for penicillin residues by the following methods:

1. The S. lutea, cylinder method, as described in "Official Methods of Analysis, Association of Official Analytical Chemists," 13th Ed., section 42.278, et. seq.

2. The B. stearothermophilus, variety calidolactis, disk assay method described in the International Standard FIL-IDF 57:1970 of the International Dairy Federation.

ML may choose to use either of these methods for certification of lots. FDA will continue to use the official Association of Official Analytical Chemists method in its regulatory enforcement of rennet casein.

Notes:

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

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

3. See: SMEDP - 16th Ed., 1993

Reference of Analytical Methods Cited in This Memorandum of Understanding

1. "Bacteriological Analytical Manual," 5th Ed., 1978. The Association of Official Analytical Chemists, 1111 No. 19th St. Arlington, VA 22209.

2. "Official Methods of Analysis, Association of Official Analytical Chemists," 13th Ed., 1980. The Association of Official Analytical Chemists, 1111 No. 19th St. Arlington, VA 22209.

3. "Standard Methods for the Examination of Dairy Products," 14th Ed., 1978, section 18.4., American Public Health Association, 1015 18th St., NW., Washington, DC 20036.

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

VI. ADMINISTRATIVE PROCEDURES

This Memorandum of Understanding will become effective upon signature of both parties and will remain in effect indefinitely. It may be modified by mutual consent or may be terminated by either party upon a 30-day written advance notice to the other.

In witness whereof, the Agencies have executed this Memorandum of Understanding covering rennet casein.

FOR THE ROYAL NORWEGIAN MINISTRY OF AGRICULTURE	FOR THE FOOD AND DRUG ADMINISTRATION
By: Magne Stubsjoen /s/	By: Joseph P. Hile /s/
Title: Director General	Title: Associate Commissioner for Regulatory Affairs
Date: February 26, 1982	Date: January 4, 1982

The FDA Assoc. Commisisoner for Regulatory Affairs is currently Mr. Ronald G. Chesemore

Notes:

ATTACHMENT A

The 25-gram portions taken from each of the 30 samples collected from a lot of rennet casein may be composited according to the following options before reconstituting:

Number of Composites to be prepared for analysis from the 30 samples collected.	Samples in each composite	Grams to test product in each composite	Milliliters of sterile distilled water in which the weighed product is to be reconstituted.
2	15	375	3,750
3	10	250	2,500
5	6	150	1,500
6	5	125	1,250
10	3	75	750

Example of compositing:

If the two-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.