SUBJECT:

Caseins, Caseinates and Mixtures Thereof Exported to the U.S.

(FDA Agreement Number 225-75-2024)

(Previously CPG 7156j.02)

Notes:

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

Tel. No. 202-205-4045

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

MINISTRY OF AGRICULTURE
OF THE REPUBLIC OF FRANCE
COVERING CASEINS, CASEINATES, AND MIXTURES THEREOF
EXPORTED TO THE UNITED STATES OF AMERICA

I. PURPOSE

The mutual goals of the Food and Drug Administration (FDA) and the Ministry of Agriculture of the Republic of France in entering into this agreement are to:

1. Establish certification requirements for the caseins, caseinates, and mixtures thereof exported from France or the United States to assure that contaminated casein, caseinates, and mixtures thereof will not be imported into the United States.

2. Minimize the need for extensive FDA audit sampling of these certified products from France.

This agreement supersedes the Memorandum of Understanding between FDA and the Ministry of Agriculture of the Republic of France that became effective on October 15, 1974.

II. DEFINITIONS

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

Lot: A lot is a quantity of caseins, caseinates, or mixtures thereof packaged by one manufacturer during a definite period of time not exceeding 1 day. The manufacturing process, including milling and packaging, is performed by using a perfectly identified processing line. Caseins or caseinates intended for export to the United States are packaged, after milling, in identical containers identified by a unique code or mark traceable to the manufacturer.

Salmonella-negative: The absence of Salmonella in 30 samples, each of 25 grams, that have been taken from the same lot of product and tested individually, or composited, using procedures contained in the current edition of the "Bacteriological Analytical Manual."

Notes:

Phosphatase-negative: The absence of phosphatase activity in 30 samples, each of 25 grams, that have been taken from the same lot of product and tested using the method contained in the current edition of the "Official Methods of Analysis."

III. SUBSTANCE OF AGREEMENT

A. The Direction de la Qualite, Service Veterinaire d'Hygiene Alimentaire, Ministry of Agriculture

The Direction de la Qualite, Service Veterinaire d'Hygiene Alimentaire (SVHA) of the Ministry of Agriculture of the Republic of France, is the agency of the French government responsible for inspecting those caseins, caseinates, and mixtures thereof that are intended for export. Such inspection is necessary for consumer protection. To fulfill its responsibilities under this agreement, SVHA will direct its activities to ensure that caseins, caseinates, and mixtures thereof that are intended for export to the United States are fit for human consumption in that they comply with the requirements of the Food, Drug, and Cosmetic Act of the United States and of this agreement. SVHA will inspect and analyze samples of these caseins, caseinates, and mixtures thereof to ensure that they comply with these requirements.

To discharge its responsibilities regarding caseins, caseinates, and mixtures thereof and to fulfill its commitment under this agreement, SVHA will:

1. Inspect and analyze each lot of caseins, caseinates, and mixtures thereof produced in France for export to the United States to assure that it is Salmonella-negative and phosphatase-negative, based on the testing of 30 samples of 25-gram units taken from bags of caseins immediately before closing, as determined by the methods cited in Section V. "Analytical Methodology."

2. Issue an export certificate only for those lots that are Salmonella-negative and phosphatase-negative.

3. Require that all containers of lots of caseins, caseinates, and mixtures thereof that are to be exported to the United States be certified as complying with the provisions of this agreement, and identified by a lot number and marked "FOR HUMAN USE ONLY; NOT TO BE USED FOR ANIMAL FEED."

Notes:

4. Require that all of the information that is required by the Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act of the United States is included on the packaging of individual products.

5. Include the following information on the export certificate for each lot of caseins, caseinates. and mixtures thereof exported to the United States:

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

6. Provide the exporter of caseins, caseinates, and mixtures thereof with the validated export certificate. This certificate and the packing list, which indicates those lots that are physically present in each containerized cargo unit, are to be attached to the shipping manifest.

7. Furnish FDA with a copy of the current French regulations and the procedures used to ensure that the caseins, caseinates, and mixtures thereof are in compliance with those regulations and with the Food, Drug, and Cosmetic Act of the United States.

8. Furnish FDA, upon request, with a full description of the manufacturing processes and quality controls used to ensure that the caseins, caseinates, and mixtures thereof that are produced are fit for human consumption, as discussed in III. A. of this agreement.

9. Furnish FDA with a list of the names of those officials who will sign the certificates issued in accordance with this agreement.

B. The Food and Drug Administration

FDA is charged with the enforcement of the Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, certain provisions of the Public Health Service Act, and other related statutes of the United States. FDA directs its activities toward the protection of the public health in 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

Notes:

products. To discharge these responsibilities regarding caseins, caseinates, and mixtures thereof and to fulfill this agreement, FDA will:

1. Audit samples of caseins, caseinates, and mixtures thereof certified by SVHA under this agreement to ensure that the products exported from the Republic of France comply with the requirements of-the Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, the Public Health Service Act, and other related statutes of the United States.

2. Share any information obtained through its audit sampling with SVHA, which includes:

   a. Providing prompt notification of the detention of any casein products covered by this agreement.
   b. Explaining the reasons for the detention of any lot of certified products.
   c. Providing copies of the laboratory worksheets developed in determining the reasons for detention.
   d. Providing information regarding the serotype of any detected Salmonella, when these results are available.
   e. Supplying a reserve sample of any lots determined to be Salmonella-positive when available and requested by SVHA or the Embassy of France.
   f. Providing notification of changes in applicable analytical procedures.
   g. Providing information on modifications of the statutes and regulations that affect the certified products.

3. Share expertise and provide assistance to SVHA when necessary.

IV. SAMPLE COLLECTION

The same subsamples will be used to determine both the presence, if any, of Salmonella and the level of phosphatase activity.

Thirty samples of caseins, caseinates, or mixtures thereof, each sample consisting of approximately 25 grams, will be collected in accordance with the applicable portions of the current edition of the "Bacteriological Analytical Manual."

V. ANALYTICAL METHODOLOGY

Compliance with the established criteria for Salmonella and phosphatase will be determined according to the methods contained in the current editions of "Bacteriological Analytical Manual" for Salmonella and "Official Methods of Analysis" for phosphatase.

Notes:

Currently:
AOAC
481 North
Frederick Avenue,
Suite 500
Gaithersburg, MD
20877-2417
Tel. No.
301-924-7077

These publications are available from:

Association of Official Analytical Chemists
1111 North 19th St.
Department 55
Arlington, VA 22209

VI. PARTICIPATING PARTIES

A. The Direction de la Qualite
Service Veterinaire d'Hygiene Alimentaire
Ministry of Agriculture
175 rue du Chevaleret
75646, Paris Cedex 13, France

A.
Currently:
Mrs. Marin Guillou,
Director General
D'alimentation

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

VII. LIAISON OFFICERS

A. FOR SVHA:

Agricultural Attache
(Currently Mr. Ralph Ichter)
Embassy of France
4101 Reservoir Rd. NW.
Washington, DC 20007-2173
Telephone: 202-944-6360; Telex 248320 FRCC UR

A.
Currently: Mr.
Claude Chereau,
Counselor for
Agriculture

B. For FDA:

Director, Division of Regulatory Guidance (HFF-310)
(Currently Howard N. Pippin)
200 C St. SW.
Washington, DC 20204
Telephone: 202-485-1186;
Telex 197623 PHS PKLN

B.
Director, Division
of Enforcement
(HFS-605)
(Currently: Lee
Bowers)
Tel No.
202-205-5332
Fax No.
202-260-0133

VIII. ADMINISTRATION PROCEDURES

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

Notes:

IX. PERIOD OF AGREEMENT

This agreement 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,

APPROVED AND ACCEPTED FOR THE DIRECTION DE LA QUALITE SERVICE VETERINAIRE D'HYGIENE ALIMENTAIRE, MINISTRY OF AGRICULTURE OF THE REPUBLIC OF FRANCE

Currently:
Mrs. Marin Guillou,
Director General
D'alimentation

BY: /s/
M. Gilbert Jolivet

TITLE: Directeur de la Qualite

DATE: Septembre 10, 1986

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

The ACRA is currently
Mr. Ronald G.
Chesemore

BY: /s/
John M. Taylor

TITLE: Associate Commissioner for Regulatory Affairs

DATE: January 15, 1987