

**IRELAND DEPARTMENT OF AGRICULTURE, FOOD AND THE MARINE
LETTER TO UNITED STATES FOOD AND DRUG ADMINISTRATION
REGARDING
CERTIFICATION REQUIREMENTS FOR CASEINS, CASEINATES AND MIXTURES**

June 23, 2016

Howard R. Sklamberg, J.D.
Deputy Commissioner
Office of Global Regulatory Operations and Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Deputy Commissioner Sklamberg:

It is with great pleasure that I express to you the intention of the Department of Agriculture, Food and the Marine (DAFM) of Ireland to cooperate with the United States Food and Drug Administration (FDA) concerning certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States.

The mutual goals of DAFM and FDA in establishing certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States are to assure that contaminated products will not be imported into the U.S. and to minimize the need for extensive FDA audit sampling of these products from Ireland. DAFM and FDA have a history of cooperation on this issue and it is, therefore, desirable that the two agencies continue to cooperate to maintain and improve consumer protection.

DAFM intends 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 Federal Food, Drug, and Cosmetic Act of the United States and the Public Health Service Act of the United States. DAFM 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, DAFM intends to:

1. Ensure each lotⁱ, as defined by the manufacturer has been analyzed to assure that it is Salmonella-negativeⁱⁱ and phosphatase-negativeⁱⁱⁱ.
2. Require that all of the information that is required by the Federal Food, Drug, and Cosmetic Act of the United States and the Fair Packaging and Labeling Act of the United States be included on the label and labeling of individual products.
3. 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.

FDA is charged with the enforcement of the Federal 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

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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 caseins, caseinates, and mixtures thereof, FDA intends to:

1. Audit samples of caseins, caseinates, and mixtures thereof certified by DAFM to ensure that the products exported from Ireland and offered for import into the United States comply with the requirements of the Federal 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 DAFM and the first Secretary of the Embassy of Ireland in Washington.
3. Promptly notify DAFM and the First Secretary of the Embassy of Ireland in Washington of the detention of any caseins, caseinates, and mixtures thereof.
4. Share expertise and provide consultative assistance to DAFM when necessary to assure the safety of the caseins, caseinates, and mixtures thereof exported to the United States.

This letter is not intended to create obligations under international or other law, and all cooperation is subject to the availability of appropriated funds, personnel, and other resources. DAFM and FDA each intend to bear their own expenses associated with this cooperation. Either DAFM or FDA may terminate this cooperation on thirty (30) calendar days' written notice to the other. The cooperation will continue for a period of five (5) years from the last date of signature of this document and may be extended for additional five (5) year periods upon consent of DAFM and FDA. This cooperation supersedes the letters between DAFM and FDA regarding this same subject matter dated November 4 and 10, 2010.

I look forward to receipt of your affirmative reply.

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Mr. Brendan Gleeson
Assistant Secretary General
Livestock Products and By-products

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Agriculture House
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23/6/16.
Date

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ⁱ LOT: A lot is a quantity of casein, caseinates, or mixtures thereof packaged by one manufacturer during a definite period of time not exceeding one (1) week. The manufacturing process, including milling and packaging, is performed by using a perfectly identified processing line. Caseins, caseinates, or mixtures thereof 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.

ⁱⁱ SALMONELLA-NEGATIVE: The absence of Salmonella in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from bags in the same lot of product immediately before closing and tested using the procedures contained in the current edition of the "Bacteriological Analytical Manual." The Bacteriological Analytical Manual can be accessed at:

<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>

ⁱⁱⁱ PHOSPHATASE-NEGATIVE: The absence of phosphatase activity in thirty (30) subsamples, each of twenty-five (25) grams, that have been taken from bags in the same lot of product immediately before closing and tested using the method contained in the current edition of the "Official Methods of Analysis." This method may be obtained from the AOAC International, 2275 Research Boulevard, Suite 300, Rockville, Maryland 20850-3250 USA, telephone +1 301-924-7077, fax +1 301-924-7089, email aoac@aoac.org, and website www.aoac.org.