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

June 21, 2022

Sinéad McPhillips
Assistant Secretary General, Agri-Food Strategy
Department of Agriculture, Food and the Marine
Agriculture House
Kildare Street
Dublin 2, DO2 WK12
Ireland

Dear Ms. McPhillips,

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

The mutual goals of FDA and DAFM in establishing certification requirements for caseins, caseinates, and mixtures thereof exported from Ireland to the United States are intended to assure that contaminated products are not imported into the United States and to minimize the need for extensive FDA audit sampling of these products from Ireland. FDA and DAFM 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.

FDA understands that DAFM intends to ensure that caseins, caseinates, and mixtures thereof that are intended for export to the United States are fit for human consumption and are honestly and properly labeled in that they comply with the requirements of the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the Public Health Service Act of the United States. DAFM plans to inspect and analyze samples of these caseins, caseinates, and mixtures thereof to comply with these requirements.

To discharge its responsibilities regarding caseins, caseinates, and mixtures thereof, FDA understands that DAFM intends to:

1. Ensure each lot[i], as defined by the manufacturer has been analyzed to assure that it is Salmonella-negative[ii] and phosphatase-negative[iii].
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 confirm 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 properly labeled. FDA accomplishes this goal in part through inspections of food processors and distributors. In addition, it collects and examines samples to comply 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:

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1. Audit samples of caseins, caseinates, and mixtures thereof certified by DAFM to secure 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 applicable regulatory requirements 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 confirm 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 domestic law, and all cooperation is subject to the availability of appropriated funds, personnel, and other resources. FDA and DAFM each intend to bear their own expenses associated with this cooperation. Either FDA or DAFM may discontinue this cooperation on thirty (30) calendar days' written notice to the other. The cooperation is expected to continue for a period of five (5) years and may be extended for additional five (5) year periods upon written confirmation of FDA and DAFM. This cooperation supersedes the letters between FDA and DAFM regarding this same subject matter dated 23rd June and 25th August 2016.

If the foregoing is acceptable, then this letter, together with your letter of acceptance in reply, constitutes an acceptance of the above arrangement, which commences on the date of your reply letter.

Sincerely,

Mark Abdoo -S

Digitally signed by Mark Abdoo -S
Date: 2022.06.21 10:58:18 -04'00'

_____ _____

Mark Abdoo
Associate Commissioner for Global Policy and Strategy
Office of the Commissioner
The United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
United States of America

Date

[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, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877 USA, telephone +1 301-924-7077, fax +1 301-924-7089, email aoac@aoac.org, and website www.aoac.org.