

**Memorandum of Understanding
between the United States Food and Drug Administration and the
U.S. Department of Agriculture's Agricultural Marketing Service and
Foreign Agricultural Service**

**Related to the
Export of Milk and Milk Products**

MOU 225-20-017

I. Purpose

This agreement outlines the coordination between the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) and Foreign Agricultural Service (FAS) (referred to collectively hereafter as the Agencies) related to the export of milk and milk products from the United States.

II. Background

Acknowledging the importance of ensuring the public health, food safety and wholesomeness of U.S. milk and milk products, the Agencies herein recognize and reaffirm their commitments under MOUs 225-72-2009, 225-12-0007, and 225-75-4002, as applicable. The Agencies will follow the process for sharing non-public information in Appendix A' of MOU 225-12-0007. This MOU, once effective, will supersede the exchange of letters between FDA and AMS regarding export certification for milk and milk products dated July 3, 2012. Otherwise, this MOU does not affect or supersede any existing agreements or arrangements between the Agencies and does not affect the ability of the Agencies to enter into other agreements or arrangements related to this MOU.

III. Substance of the Agreement

A. Statutory Authority

1. The United States Food and Drug Administration (FDA) is the competent authority for milk and milk products and is responsible for the enforcement of the Federal Food, Drug, and Cosmetic Act (hereinafter the FD&C Act) (21 U.S.C. 301, et seq.), the Public Health Service Act (42 U.S.C. 201, et seq.), and the Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.). In fulfilling its responsibilities under these statutes, FDA's activities are directed toward protecting the public health by ensuring that foods, including milk and milk products, are safe and wholesome, and truthfully labeled. This is accomplished, in part, by inspecting the production, processing, and distribution of foods and examining samples to ensure compliance with FDA's statutory requirements. In addition, FDA engages with international regulators and stakeholders on the safety of U.S. milk and milk products.
2. The Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA), under the authority of the Agricultural Marketing Act of 1946, carries out certain voluntary service functions designed to aid in the efficient marketing of agricultural

voluntary service functions designed to aid in the efficient marketing of agricultural products. These include developing commercial grade standards and specifications for foods, furnishing auditing, inspection and grading services (including the issuance of certificates of quality and/or condition) and auditing reports to producers, processors, shippers, buyers, or other interested parties. The major purpose is to assist producers in preparing quality wholesome products that meet users' requirements and to provide objective information concerning the grade, quality, or condition of a product, which will assist interested parties engaged in marketing functions. In addition to inspection and grading services for products, AMS offers voluntary audit, survey, and verification services at product locations and facilities. AMS' regulatory authority facilitates fair trade practices among the industry through education, mediation, arbitration, licensing and enforcement of the Perishable Agricultural Commodities Act of 1930.

3. The Foreign Agricultural Service (FAS) of USDA has the mandate to link U.S. agriculture to the world to enhance export opportunities and global food security. FAS's responsibilities include, but are not limited to, the responsibility to coordinate the carrying out by USDA agencies of their functions involving foreign agriculture policies and programs and their operations and activities in foreign areas; acting as a liaison on these matters and functions relating to foreign agriculture with the Department of State, the United States Trade Representative (USTR), the U.S. Agency for International Development (USAID) and foreign governments; conducting functions of the Department relating to the World Trade Organization, and legislation affecting international agricultural trade; and administering and directing the Department's programs in international development, technical assistance and training carried out under the Foreign Assistance Act of 1961, as amended.
4. FDA, AMS, and FAS have certain related objectives in carrying out their respective regulatory, marketing, and export service activities that lend themselves to cooperation under this Memorandum of Understanding (MOU). This MOU sets forth the basic principles and guidelines to facilitate the Agencies' collaboration regarding the export of milk and milk products from the United States.

B. Responsibilities

1. The Agencies will, individually and collectively, facilitate the export of milk and milk products by:
 - a. Prioritizing trade facilitation with an emphasis on providing timely responses to foreign governments and developing innovative solutions to foreign measures that may function as trade barriers;
 - b. Considering the time, cost, and burdens of demonstrating compliance for U.S. exporters¹ when developing implementation solutions for foreign measures; and

¹ The term "exporters" refers to producers, processors, or exporters of milk and milk products intended for export.

- c. Maintaining transparent, collaborative, and timely communications relating to issues affecting U.S. exports of milk and milk products, as appropriate, to prevent and/or resolve any barriers to trade.
2. The Food and Drug Administration will:
- a. Enforce the FD&C Act and related statutes and regulatory requirements for milk and milk products, including protecting the public health by ensuring that milk and milk products are safe, sanitary, wholesome, and truthfully labeled;
 - b. As the competent authority, serve as the lead agency for communicating with foreign governments with respect to the safety of exported milk and milk products, including but not limited to foodborne outbreaks, recalls, and providing technical assistance regarding FDA regulatory requirements upon request from foreign governments;
 - c. Issue its Certificate to a Foreign Government or Certificate of Exportability, if requested by a U.S. exporter of milk or milk products;
 - d. Provide information to AMS and FAS related to the public health, safety, production, handling or transport of milk and milk product exports produced under FDA's oversight, including for use related to dairy sanitary certificates that contain attestations drafted by FAS or AMS as soon as practicable, but no later than 7 business days;²
 - e. Refer in a timely manner exporters of U.S. milk and milk products to FAS and AMS who seek information about a service for which AMS or FAS has primary responsibility;
 - f. Provide to AMS on a monthly basis all country lists of facilities exporting milk and milk products or, in the event of significant changes to a facility list, update or establish a list upon request;
 - g. Upon request, provide verification to AMS of whether a U.S. producer or processor of milk and milk products is in good regulatory standing as soon as practicable, but no later than 2 business days;
 - h. Notify FAS and AMS in a timely manner of communications related to U.S. exports of milk and milk products received by foreign governments; and
 - i. Provide information to FAS as soon as practicable, but no later than 7 business days, when foreign governments seek information regarding certification of milk and milk products, in order to facilitate FAS' response to the foreign government in accordance with 4.a of this MOU.

² Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) has primary responsibility for fulfilling this commitment.

3. The Agricultural Marketing Service will:

- a. Of the Agencies participating in this MOU, serve as the lead agency for providing export-related services to exporters of milk and milk products, including the issuance of dairy sanitary certificates for exports of milk and milk products when necessary;
- b. Collaborate with FAS to ensure dairy sanitary export certificates are offered to foreign governments when implementation of new or existing foreign certificate requirements necessitates U.S. government involvement;³
- c. When developing a new dairy sanitary certificate in response to a foreign measure, draw first from the library of attestations previously approved by FDA, relying on the development of new attestations in collaboration with FAS and FDA only when existing certificates and attestations are insufficient to meet the foreign government's requirements;
- d. Implement any dairy sanitary certificate for milk and milk products in a timely manner which ensures that it is available to U.S. exporters of milk and milk products before the foreign government's relevant enforcement date;
- e. Maintain responsibility for managing facility-specific questionnaires or applications required by a foreign government, collaborating with FDA and FAS as needed to provide any necessary U.S. government review or endorsements;
- f. Develop export verification programs to meet foreign requirements and facilitate milk and milk product exports, collaborating with FDA and FAS as needed; and
- g. Communicate with FDA and FAS in a timely manner when foreign governments inquire about the safety of U.S. milk or milk products.

4. The Foreign Agricultural Service will:

- a. Of the Agencies participating in this MOU, serve as the lead agency for communicating with foreign governments regarding the facilitation of export of milk and milk products;
- b. Of the Agencies participating in this MOU, serve as the lead agency for coordinating interagency collaboration related to U.S. exports of milk and milk products, including coordinating the input of and clearance by FDA and AMS before providing U.S. responses to foreign government requirements;

³ For greater certainty, "sanitary export certificates" here refers to those certificates issued by AMS for milk and milk product exports, not veterinary certificates issued by the Animal and Plant Health Inspection Service (APHIS).

- c. In a timely manner, share all relevant information regarding U.S. milk and milk products FAS may receive from foreign governments and provide back to foreign governments with FDA and AMS;
 - d. Of the Agencies participating in this MOU, when facilitating the issuance of dairy sanitary certificates for milk and milk products, receive and analyze the foreign government requirements, lead discussions or negotiations of the certificate with foreign governments seeking to advance the U.S. position that certification is not necessary or justified as appropriate, and when existing attestations are insufficient develop and propose a certificate to the foreign government that has been cleared by the Agencies;
 - e. In collaboration with the relevant agency share information about FDA and AMS export certification programs with foreign governments upon request of either the foreign government, FDA, or AMS; and
 - f. For all foreign measures being implemented on U.S. exporters of milk and milk products, and in collaboration with the U.S. agencies participating in this MOU, attempt to reach agreement with a foreign government to accept an implementation plan that considers the time, cost and burden of implementation for U.S. exporters and, where applicable, U.S. agencies.
5. The Agencies participating in this MOU agree to collaborate on the following future work:
- a. Develop model attestations for dairy sanitary certificates that FAS identifies may address emerging trends in the export of milk and milk products, for addition to the library of cleared, model attestations referenced in 3.c;
 - b. Investigate the feasibility of developing an FDA electronic platform for sharing information with USDA on U.S. dairy facilities in good regulatory standing with FDA, while maintaining compliance with FDA's requirements on information sharing;
 - c. Commit to ensure the relevant technical staff of the Agencies jointly meet on a monthly basis, or another frequency as mutually agreed, or as required to address new or emerging issues; and
 - d. Periodically review the functioning, utility, and necessity of the MOU to ensure it remains an effective and efficient means for facilitating the export of U.S. milk and milk products.

IV. Limitations

This MOU represents the Agencies' intent to collaborate in areas of mutual interest to the Agencies. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which each of the Agencies operate. Nothing in this MOU restricts any of the Agencies from conducting its duties under existing policies, rules,

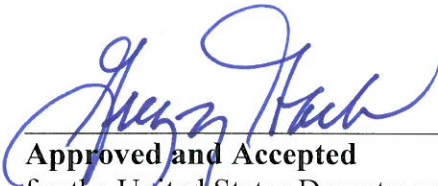
regulations, and statutes under which each of the Agencies operate, nor does it affect the legal responsibilities of any U.S. milk and milk product exporter under the FD&C Act. Nothing in this MOU shall obligate the Agencies to any current expenditure or future expenditure of resources in advance of the availability of appropriations from Congress.

V. Effective Date, Terms, Termination and Modification

This agreement will become effective when signed by all Agencies and it will continue in effect unless modified by mutual written consent at any time or terminated by either party upon a 60 day advance written notice to the other. The agreement will be evaluated at least every 5 years or as needed to ensure it remains an effective and efficient means for facilitating the export of U.S. milk and milk products.



Approved and Accepted
for the United States Food and Drug Administration
Signed by: Frank Yiannas
Deputy Commissioner for Food Policy and Response
Date: October 1, 2020



Approved and Accepted
for the United States Department of Agriculture's Agricultural Marketing Service
Signed by: Gregory Ibach
Under Secretary for Marketing and Regulatory Programs
Date: October 1, 2020



Approved and Accepted
for the United States Department of Agriculture's Foreign Agricultural Service
Signed by: Ted McKinney
Under Secretary for Trade and Foreign Agricultural Affairs
Date: October 1, 2020