



CHEESE IMPORTERS
ASSOCIATION OF AMERICA

Bulletin 17-38 December 12, 2017

CIAA Bulletin

**An Exclusive CIAA Member
Update**

FDA Publishes Draft Guidance on "Refusal of Inspection by a Foreign Food Establishment or Foreign Government"

The Food and Drug Administration (FDA) on [December 12 published in the Federal Register](#) its [draft guidance for industry entitled "Refusal of Inspection by a Foreign Food Establishment or Foreign Government."](#) According to FDA's announcement, "(T)his draft guidance, when finalized, will provide information for foreign food establishments subject to our inspection, as well as foreign governments, on when we may consider that a foreign food establishment or a government of a foreign country has refused to permit an inspection by us as provided in the Federal Food, Drug, and Cosmetic Act (FD&C Act). Comments on this draft guidance may be submitted through February 26, 2018.

The Food Safety Modernization Act (FSMA) requires FDA to refuse admission of a food into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary of Health and Human Services, upon request, to inspect such factory, warehouse, or other establishment. An owner, operator, or agent in charge is considered to have refused an inspection if the owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after FDA submits an inspection request, or after such other time period, as agreed upon by FDA and the foreign factory, warehouse, or other establishment. Compliance with these inspections will be an important component of your compliance with the [Preventive Controls for Human Foods Rule](#) and the [Foreign Supplier Verification Program](#).

FDA is not required to pre-announce its inspections of foreign food establishments. However, as a matter of practice, FDA does contact the facility before an inspector

arrives on site. FDA also coordinates with the facility to be inspected and the pertinent foreign government authorities. Representatives of the foreign government may accompany FDA inspectors during the inspection.

Refusal of inspection can occur in the following ways, and is fully discussed in the hyperlinked draft guidance document:

- Refusal by a Foreign Food Establishment to Permit Scheduling of an Inspection;
- Refusal by a Foreign Food Establishment to Permit Conducting an Inspection;
- Refusal by a Foreign Government to Permit Scheduling of an Inspection; and
- Refusal by a Foreign Government to Permit Conducting an Inspection.

Foreign food establishments of which the owner, operator, or agent in charge, or foreign government, has refused an inspection can be included on the Red List established by Import Alert 99-32. Food offered for entry into the United States from an establishment identified on this Red List, is subject to refusal of admission as set forth in section 807(b) of the FD&C Act.

The draft guidance also provides that if the foreign government maintains its refusal following efforts by FDA to secure the inspection, FDA will add each foreign food establishment of which an FDA request to inspect was refused by the foreign government to the Red List of Import Alert 99-32. If the foreign government sustains its refusal of multiple requests to inspect foreign food establishments in the country, FDA will ask the foreign government if their refusal applies to all establishments in their country. If FDA determines that the foreign country's refusals apply to all foreign food establishments in the country, we may include all foreign food establishments in the foreign country ("country-wide") on the Red List of Import Alert 99-32.

All CIAA members are encouraged to review this draft guidance. If you have any recommendations for comments, or if you have any questions, please contact Roger Szemraj at rszemraj@theciaa.org or (202) 789-1212.

DATES TO REMEMBER

December 21, 2017 (approximately)

FAS issues first notice of calendar year 2018 licenses to licensees

December 31, 2017

Last day for licensees to make entries to fulfill the requirement to use 85% of their calendar year 2017 license amount. Last day for which calendar year 2017 licenses are valid

January 21, 2018

CIAA Fancy Food Show Reception

5:00 pm- 7:30 pm

Thirsty Bear Brewery

San Francisco, CA

March 1, 2018 (approximately)

FAS issues final notice of calendar year 2018 licenses to licensees

March 15, 2018

The license fee for each license issued is due and payable in full no later than March 15 of the year for which the license is issued. Licenses issued after March 15 of any quota year are payable in full no later than 10 days from the date of issuance. Fee payments are payable to the Treasurer of the United States and shall be made solely utilizing the electronic software designated for the purpose by the Licensing Authority

July 2, 2018

Last day for an exporting country that is not designating importers for calendar year 2018 to notify FAS

August 31, 2018

Last day to enter dairy products into U.S. Customs territory that may be used to qualify and establish eligibility for a calendar year 2019 license.

* If a deadline date falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day (Section 6.36(a) of the Dairy Tariff-Rate Import Quota Licensing Regulation). This does not apply to dates of entry for eligibility.

Cheese Importers Association of America

Ken Olsson

President

email: president@theciaa.org

phone: 202-547-0899

Cheese Importers Association of America
204 E Street, NE
Washington, DC 20002
202-547-0899 Fax: 202-547-6348
Email: info@theciaa.org

Cheese Importers Association of America, 204 E Street NE, Washington, DC 20002

[SafeUnsubscribe™](#) Imaysonet@thegateam.com

[Forward this email](#) | [About our service provider](#)

Sent by info@theciaa.org in collaboration with

Constant Contact 

[Try it free today](#)