# Refusal of Inspection by a Foreign Food Establishment or Foreign Government: Guidance for Industry

## *Draft Guidance*

**This guidance is being distributed for comment purposes only.**

Although you can submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 75 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2017-D-6528 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition at 240-701-5986, or the Center for Veterinary Medicine at 240-402-7001, or the Office of Regulatory Affairs at 202-402-4565.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Food Safety and Applied Nutrition**
**Center for Veterinary Medicine**
**Office of Regulatory Affairs**
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# Refusal of Inspection by a Foreign Food Establishment or Foreign Government: Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## I. Introduction

This guidance provides information for foreign food facilities subject to our inspection as well as foreign governments on how we interpret "refuses to permit entry … to inspect" a foreign food establishment, pursuant to section 807(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384c(b)). The examples used in this guidance are not intended to serve as an exhaustive list. Rather, they illustrate situations that we may encounter in preparing for and conducting inspections.

Terms used in this guidance include:

- The term "U.S." refers to the United States.
- The pronouns "we" and "our" refer to FDA.
- The term "food" means: (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. (Section 201(f) of the FD&C Act (21 U.S.C. 321(f)).
- The term "foreign food establishment" or "establishment" is used in this guidance to refer to a foreign factory, warehouse, or other establishment that manufactures, processes, packs, or holds, food. "Establishments" as used in this guidance include farms (as defined in 21 CFR 1.227 and 112.3).
- The term "owner, operator, or agent in charge" is used in this guidance to refer to the owner, operator, or agent in charge of the foreign food establishment, or an individual authorized by the owner, operator, or agent in charge of the foreign

1 This guidance has been prepared by the Office of Compliance in the Center for Food Safety and Applied Nutrition in cooperation with the Center for Veterinary Medicine and the Office of Regulatory Affairs.

food establishment, to be the contact person for the purposes of our inspection.
- The term, "FDA investigators" refers to "United States inspectors or other individuals duly designated by the Secretary." (Sec. 807(b) of the FD&C Act (21 U.S.C. 384c(b))
- The term, "foreign governments" refers to foreign governments and competent authorities of foreign countries.

Our guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

# II. Background

FDA food establishment inspections are designed to identify potential food safety concerns, both for domestically produced and imported foods

## A. Statutory Authority

Under section 704 of the FD&C Act, duly designated representatives of FDA, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge are authorized to enter and inspect at reasonable times, within reasonable limits, and in a reasonable manner any factory, warehouse, or establishment in which food is manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction. Section 201(b)(1) of the FD&C Act (21 U.S.C. 321(b)(1)) defines interstate commerce, in part, as "commerce between any State or Territory and any place outside thereof." Therefore, food from foreign establishments that is imported into or offered for sale in the United States is in interstate commerce and FDA may inspect such establishments.

The FDA Food Safety Modernization Act (FSMA) (Public Law 111-353), enacted on January 4, 2011, amended the FD&C Act to expand and enhance our ability to ensure that imported food products meet United States standards and are safe for consumers. Section 421 of the FD&C Act (21 U.S.C. 350j), added by section 201 of FSMA, requires us to, among other things, increase inspections of both foreign and domestic food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d).

Section 807(b) of the FD&C Act (21 U.S.C. 384c(b)), added by section 306 of FSMA, provides that FDA shall 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, upon request, to

inspect such factory, warehouse, or other establishment."[2] Section 807(b) of the FD&C Act also provides that "an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after [we submit an inspection request], or after such other time period, as agreed upon by [FDA] and the foreign factory, warehouse, or other establishment."

## B. Scheduling Foreign Food Establishment Inspections

The FD&C Act does not require us to pre-announce our inspections. However, for inspections of foreign food establishments, our general practice is to contact the firm before an FDA investigator arrives at the inspection site. This pre-announcement, although not required, is intended to facilitate the inspection process and ensure that appropriate records and personnel will be made available.

To schedule inspections of foreign food establishments and to enter the foreign country to conduct the inspections, we coordinate with both the establishments to be inspected and the foreign government or competent authority of the foreign country in which the foreign food establishments to be inspected are located.

FDA recognizes the importance of coordinating with the competent authorities of foreign governments regarding inspections. Before scheduling inspections of foreign food establishments, we send a written request to each foreign government regarding our intent to inspect food establishments in its country. We then notify each foreign food establishment on the list of our intent to schedule and conduct an inspection. We may use several forms of communication, including email, fax, or mail, to send the written request to schedule an inspection to the owner, operator, or agent in charge of the establishment, to the establishment's U.S. agent (if applicable), and to the foreign government. After we request to schedule an inspection, we follow up as necessary using multiple communication mechanisms (e.g., email, fax, mail, and telephone calls) to establish and coordinate the inspection schedule. The inspection request and the pre-inspection communications are intended to facilitate the inspection process and ensure that appropriate personnel and records will be available to us during the inspection. When establishing an inspection date, we consider the establishment's operating schedule, and other factors, such as seasonality, local conditions such as weather and security situations, and holidays and other non-business days.

After scheduling the inspections, we provide the foreign government with written confirmation of the scheduled dates of the inspections. Representatives of the foreign

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2 This authority mirrors remedies that address refusals by domestic establishments. When a domestic firm refuses inspection completely or refuses in a limited area (e.g., refuses to permit photography or sample collection), FDA may seek an inspection warrant. (See FDA Regulatory Procedures Manual Section 6-3 Inspection Warrants).

government may accompany the FDA investigator during an inspection.

### C. Inspection Activities

During an inspection, the FDA investigator typically observes the areas of the foreign food establishment where FDA-regulated foods are manufactured, processed, prepared, packed, or held. The FDA investigator observes the buildings and surrounding areas and equipment, as well as food-related operations, including food production and processing operations, receiving of raw materials, and warehousing. The FDA investigator also may request to interview employees regarding their duties.

During an inspection, the FDA investigator may review hardcopy and electronic records relating to the food and food-related operations (e.g., production and process control records, records relating to raw materials, shipping records, and applicable personnel qualifications). We recognize that an owner, operator, or agent in charge may need some time to produce requested records. Thus, the FDA investigator will attempt to accommodate reasonable delays in response to a request for records or copies of records, provided the delays appear to be in the context of a good faith effort to comply with the request. The FDA investigator also may collect samples during an inspection (e.g., environmental samples, finished product samples, raw material samples, in-line or in-process material samples, and product labeling), and may take photographs to document potential violations.

## III. Refusal of Inspection

We consider the language in section 807(b) of the FD&C Act that states "refuses to permit entry [of an FDA investigator] to inspect" and "does not permit an inspection" to include statements, actions, and passive behaviors that prevent or delay us from scheduling or fully conducting an inspection. Minor delays that result from good faith efforts by the establishment to comply with our requests generally would not be considered a refusal of inspection. Refusal also includes statements, actions, and passive behaviors intended to avoid inspection or to mislead or deceive the FDA investigator. Under section 807(b) of the FD&C Act, FDA shall refuse admission into the United States of a food from a foreign food establishment of which the owner, operator, or agent in charge or the foreign government refuses to permit an inspection.

### A. Refusal of Inspection by a Foreign Food Establishment

#### i. Refusal by a Foreign Food Establishment to Permit Scheduling of an Inspection

We consider an owner, operator, or agent in charge of a foreign food establishment to have not permitted an inspection if the owner, operator, or agent in charge does not respond to us during the 24-hour period after we submit our initial written inspection

request. We may submit the request by email, fax, or mail carrier. We will ordinarily consider that we have submitted an inspection request to an owner, operator, or agent in charge when the establishment receives the request to schedule an inspection or should have received the request based on documentation of delivery. We will use documentation of the time that the owner, operator, or agent in charge initiated or sent the response (e.g., date and time of telephone call, email, fax, or mail delivery) to determine whether the owner, operator, or agent in charge responded during the 24-hour period, or other agreed upon time period, after we submitted the inspection request. We may consider circumstances that may delay delivery of an owner, operator, or agent in charge's response, when known, such as if an establishment is located in an area that has limited access to mail carriers and the Internet or the date of receipt is a non-business day.

We also consider that an owner, operator, or agent in charge has not permitted an inspection by preventing or delaying us from scheduling an inspection if the owner, operator, or agent in charge:

- stops communicating with us at any time after the owner, operator, or agent in charge initially responds to our request to schedule an inspection,
- provides an incomplete or inaccurate response (e.g., an owner, operator, or agent in charge falsely claims the establishment is not operating or does not ship food to the United States),
- rejects FDA's attempt to schedule an inspection by not agreeing to an inspection start date and does not give a reasonable explanation for its failure to do so, or
- agrees to an inspection start date and then requests a later date without giving a reasonable explanation.

We do not consider a request to delay or reschedule an inspection to constitute a refusal of inspection when the delay or rescheduling is based on an unforeseen event or situation, such as a severe weather event, which prevents the establishment from operating on the dates we proposed or scheduled. We may request documentation of the event or situation. An owner, operator, or agent in charge's request to delay or reschedule an inspection should include the earliest possible date an inspection can be scheduled. For example, if the inspection must be rescheduled because the establishment is temporarily closed, we expect the owner, operator, or agent in charge to provide the date the establishment will reopen.

#### ii. Refusal by a Foreign Food Establishment to Permit Conducting an Inspection

We consider that an owner, operator, or agent in charge of a foreign food establishment to have refused an inspection when that owner, operator, or agent in charge:

- prevents the FDA investigator from entering the establishment,
- prevents the FDA investigator from conducting the inspection of the establishment, after entry, either by establishing unreasonable preconditions to allowing the inspection or by preventing or interfering with completion of some

aspect of the inspection, or
- delays the FDA investigator from conducting an inspection of the establishment, either before or after entry into the establishment.

Examples of an owner, operator, or agent in charge refusing an inspection by preventing the FDA investigator from entering the establishment include:
- The owner, operator, or agent in charge refuses to permit entry to the establishment.
- The owner, operator, or agent in charge does not allow the FDA investigator to inspect the facility because certain staff members are not present, without a reasonable explanation.
- The owner, operator, or agent in charge sends staff home for the day and tells the FDA investigator that the facility is not producing any product.
- The establishment is not operating when the FDA investigator arrives at the establishment at the scheduled time, and the owner, operator, or agent in charge does not provide a reasonable explanation.
- The owner, operator, or agent in charge does not answer telephone calls from the FDA investigator who is present at the establishment and is unable to gain entry to the establishment for purposes of conducting an inspection, and there is clear evidence that the establishment is operating.

Examples of an owner, operator, or agent in charge refusing an inspection by preventing the FDA investigator from conducting an inspection of the establishment, either during the inspection or as a condition for allowing the inspection, include:
- The owner, operator, or agent in charge bars the FDA investigator from an area of the establishment where food is manufactured, processed, prepared, packed, or held (e.g., the owner, operator, or agent in charge does not unlock an area of the establishment or does not take other action necessary to permit access by the FDA investigator).
- The owner, operator, or agent in charge states that direct observation of the manufacturing process, in whole or in part, must be limited to an unreasonably short amount of time, thus preventing FDA from inspecting the facility as is usual and customary.
- The owner, operator, or agent in charge orders the discontinuation of all manufacturing for the duration of the FDA inspection without a reasonable explanation.
- The owner, operator, or agent in charge causes the FDA investigator to leave the premises before the inspection is completed.
- The owner, operator, or agent in charge refuses to allow the FDA investigator to collect evidence to document potential violations (e.g., to take photographs; to collect environmental samples or samples relating to observations of insanitation, such as rodents or insect infestation or other pests or debris, that may contaminate the food; or to collect food labels and labeling).
- The owner, operator, or agent in charge refuses or limits access to records

relevant to the inspection after the FDA investigator makes an authorized request for the records. Examples of such records limitations include:
    - The owner, operator, or agent in charge refuses to allow the FDA investigator to review requested records; provides some, but not all, of the requested records; fails to produce records within the requested timeframe; or produces falsified records.
    - The owner, operator, or agent in charge provides the requested records to the FDA investigator, but the records are edited to remove information that is relevant to our inspection.
    - The owner, operator, or agent in charge does not allow the FDA investigator to make copies of records as allowed by statute or regulation.
- The owner, operator, or agent in charge prevents or limits the FDA investigator's collection of samples for analysis.

Examples of an owner, operator, or agent in charge refusing an inspection by causing a delay during the inspection include:

- The owner, operator, or agent in charge does not allow the FDA investigator access to an area of the establishment until a specific future date or time even though food is being manufactured, processed, prepared, packed, or held in that area of the establishment.
- The owner, operator, or agent in charge leaves the FDA investigator in a conference room or other waiting area for an unreasonable period of time without access to necessary documentation or to a responsible individual.

## B. Refusal of Inspection by a Foreign Government

### i. Refusal by a Foreign Government to Permit Scheduling of an Inspection

We consider a foreign government to have refused an inspection if, upon our request to conduct an inspection, the foreign government prevents or delays us from scheduling an inspection. Examples of such refusal include:

- The foreign government does not allow us to schedule an inspection and does not provide or suggest a reasonable alternative date or time frame for scheduling the inspection.
- The foreign government causes a delay that prevents us from scheduling an inspection in a timely manner and does not provide a reasonable explanation for the delay.
- The foreign government does not allow an FDA investigator to enter the country or to remain in the country for the purpose of conducting an inspection and the foreign government does not provide a reasonable basis for the restriction and does not provide or suggest a reasonable time frame for removing the restriction (e.g., the foreign government denies a visa for an FDA investigator and does not provide a reasonable explanation for the denial).

### ii. Refusal by a Foreign Government to Permit Conducting an Inspection

We consider a foreign government to have refused an inspection when that foreign government:

- prevents the FDA investigator from entering the establishment,
- imposes a condition that delays the inspection or prevents the FDA investigator from conducting an inspection of the establishment, or
- delays the FDA investigator from conducting an inspection of the establishment.

Examples of a foreign government refusing an inspection by preventing the FDA investigator from entering the establishment include:

- The foreign government does not allow FDA investigators into the country.
- The foreign government does not allow our inspection of specific types of food facilities.
- The foreign government requests FDA investigators to leave the country before scheduled inspections are conducted.

Examples of a foreign government refusing an inspection by imposing a condition that delays the inspection or prevents the FDA investigator from conducting an inspection of the establishment include:

- The foreign government bars the FDA investigator from an area of the establishment where food is manufactured, processed, prepared, packed, or held.
- The foreign government refuses to allow the FDA investigator to take photographs to document evidence of potential violations (e.g., rodents or insect infestation, visible contamination of food, faulty construction of establishment or inadequate maintenance of equipment that may lead to food contamination, food storage conditions, and food labels and labeling).
- The foreign government refuses or limits access to relevant records requested by the FDA investigator. Examples include:
    - The foreign government refuses to allow the FDA investigator to review requested records, provides some, but not all, of the requested records, or fails to produce records within the requested timeframe.
    - The foreign government provides the requested records to the FDA investigator, but the records are edited to remove information relevant to our inspection.
- The foreign government prevents or limits the FDA investigator's collection of samples for analysis.

Examples of foreign government refusing an inspection by causing delays during an inspection include:

- The foreign government does not allow the FDA investigator access to an area of the establishment until a specific future date or time even though food is being manufactured, processed, prepared, packed, or held in that area of the establishment.

- The foreign government leaves the FDA investigator in a conference room or other waiting area for an unreasonable period of time without access to necessary documentation or to a responsible individual.

# IV. FDA Enforcement of Section 807(b) of the Federal Food, Drug, and Cosmetic Act

Our Import Alert 99-32 Detention Without Physical Examination of Products From Firms Refusing FDA Foreign Establishment Inspection includes a Red List that identifies foreign food establishments of which the owner, operator, or agent in charge, or foreign government, has refused an inspection. Food offered for entry into the United States from an establishment identified on the Red List of Import Alert 99-32, is subject to refusal of admission as set forth in section 807(b) of the FD&C Act. When an imported article of food appears to be subject to refusal of admission under section 807(b) of the FD&C Act, (including foods from establishments identified on the Red List of Import Alert 99-32), FDA intends to follow the same notice and hearing requirements laid out in section 801(a) of the FD&C Act (21 U.S.C. 381) and 21 CFR 1.94(a) that apply to imported articles that appear to be subject to refusal under 801(a) of the FD&C Act.

## A. Refusal by a Foreign Food Establishment

A foreign food establishment of which the owner, operator, or agent in charge refuses an inspection may remain on the Red List of Import Alert 99-32 until we schedule and conduct an inspection. Therefore, to have us remove an establishment from the Red List of Import Alert 99-32, the owner, operator, or agent in charge of the establishment should request and permit an FDA inspection of the establishment. To schedule an FDA inspection after being placed on Import Alert 99-32, the owner, operator, or agent in charge of the establishment should send an email request to schedule the inspection to Importalerts2@fda.hhs.gov or a written request to schedule the inspection to:

Food and Drug Administration
Division of Import Operations
12420 Parklawn Drive
ELEM 3109
Rockville, MD 20857

If an establishment has refused, but later requests for FDA to reschedule an inspection, we will attempt to reschedule an inspection as soon as possible after the request. However, when planning any foreign food establishment inspection, we still need to weigh and consider factors that affect scheduling (e.g., current inspection priorities, availability of inspection personnel, U.S. State Department Travel Warnings and Alerts and other foreign travel considerations, including coordination with the foreign government). Therefore, in some situations, it may be at least a year before FDA can return to inspect an establishment who refused, but later requests an inspection.

### B. Refusal by a Foreign Government

When the foreign government indicates it will refuse to allow inspection of one or more food facilities in that country, we will:

- advise the foreign government of our authority under section 807(b) of the FD&C Act to refuse admission of a food into the United States if such food is from an establishment in a foreign country of which the foreign government refuses to permit FDA investigators to enter and inspect the establishment;
- inform the foreign government and the foreign food establishment of our intention to list the establishment on the Red List of Import Alert 99-32 based on the foreign government's refusal to permit an FDA inspection; and
- advise the foreign government of the impact of this action (i.e., we may refuse entry into the United States for all food from the foreign food establishment while the establishment is identified on the Red List of Import Alert 99-32).

If the foreign government maintains its refusal, we 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, we will ask the foreign government if their refusal applies to all establishments in their country. If we determine 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.

We will advise the foreign government and the foreign food establishment that we will remove the establishment from the Red List of Import Alert 99-32 when the foreign government provides us with written notification that we can schedule and inspect the establishment (unless the establishment is also on the Red List of Import Alert 99-32 due to a refusal of inspection by the owner, operator, or agent in charge of the establishment).

## V. References

FDA. Regulatory Procedures Manual. Chapter 6: Judicial Actions Section 6-3 Inspection Warrants. 2015. Accessed online at https://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/

FDA. Import Alert # 99-32: Detention Without Physical Examination of Products from firms Refusing FDA Foreign Establishment Inspection. March 2017. Accessed online at https://www.accessdata.fda.gov/cms_ia/importalert_521.html