*Contains Nonbinding Recommendations*

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

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to 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 published in the *Federal Register*.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Office of Regulatory Affairs**
**Center for Food Safety and Applied Nutrition**
**Center for Veterinary Medicine**

**October 2022**

# Table of Contents

# Refusal of Inspection by a Foreign Food Establishment or Foreign Government: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA) 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 establishments subject to our inspection, as well as for 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," "our," and "us" 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 grows, harvests, 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 was 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.

This guidance document provides examples of situations that we may consider to be "refuses to permit entry … to inspect" by a foreign food establishment or foreign government, pursuant to section 807(b) of the FD&C Act. FDA staff (e.g., inspection scheduling personnel, investigators) who identify potential refusal of inspection situations will refer the information to agency management to determine whether to refuse admission of food into the United States.

# II. Background

FDA food establishment inspections are, among other things, 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, reflects Congressional intent for an increase in the number of domestic and foreign inspections.

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." In the domestic context, FDA has authority to compel inspection, namely, when a domestic firm refuses inspection completely or refuses to permit us to fully conduct an inspection (e.g., refuses to provide access to applicable records, refuses to permit the investigator to take photographs as necessary or refuses to permit sample collection), FDA may seek an inspection warrant to compel the inspection. (See FDA Regulatory Procedures Manual Section 6-3 Inspection Warrants. See also, Dow Chemical Co. v. United States, 476 U.S. 227, 233 (1986) ("Regulatory or enforcement authority generally carries with it all the modes of inquiry and investigation traditionally employed or useful to execute the authority granted."); United States v. Chung's Prods. LP, 941 F. Supp. 2d 770, 777 (S.D. Tex. 2013)).

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 inspection request to each foreign government regarding our intent to inspect food establishments in its country. We then notify each foreign food establishment of our intent to schedule and conduct an inspection. We may use several forms of communication, including email, fax, mail, or express courier service, to send the written inspection 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 one or more communication mechanisms (e.g., email, fax, mail, express courier service, 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 factors that may impact that schedule, e.g., seasonality; weather, security situations, and other local conditions; 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 government may accompany the FDA investigator during an inspection.

### C. Establishment Inspection Activities

During an inspection, the FDA investigator typically observes the areas of the food establishment where FDA-regulated foods are grown, harvested, manufactured, processed, prepared, packed, or held and areas that may impact these operations. The FDA investigator may observe food-related operations (e.g., food production and processing operations, receiving of raw materials, warehousing, and sanitization of equipment).

During an inspection, the FDA investigator may review hardcopy and electronic records relating to the food and food-related operations, as authorized by applicable laws and regulations. We recognize that an owner, operator, or agent in charge may need some time to procure 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 may take photographs as necessary to present an objective and contemporaneous representation of establishment conditions. Examples of conditions or practices effectively documented by photographs include evidence of rodents or insect infestation; faulty construction or maintenance of equipment or facilities; product storage conditions; product labels and labeling; manufacturing and various control records; employee practices contributing to contamination or to violative conditions; and visible contamination of raw materials or finished products.

The FDA investigator also may collect samples during an inspection (e.g., environmental samples, finished product samples, raw material samples, and in-line or in-process material samples).

## 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. Refusal also includes statements, actions, and passive behaviors intended to avoid inspection or to mislead or deceive the FDA investigator in a manner that prevents the investigator from conducting the inspection.

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 refused an inspection when that owner, operator, or agent in charge prevents or delays the FDA from scheduling the inspection. For example, we consider an owner, operator, or agent in charge of a foreign food establishment to have refused an inspection if the owner, operator, or agent in charge does not respond to us during the 24-hour period after we submit a written inspection request. We may submit the request by email, fax, mail, or express courier service. 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, mail, or express courier service) 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 will ordinarily 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, express courier services, or the Internet, or the date of receipt is a non-business day.

We also generally consider that an owner, operator, or agent in charge has refused 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 relevant to an FDA inspection (e.g., an owner, operator, or agent in charge claims the establishment is not operating or does not ship food to the United States, when FDA has reliable information to the contrary in its databases or from other sources),
- rejects FDA's attempt to schedule an inspection either directly or 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 that prevents the establishment from operating on the dates we proposed or scheduled. We may request documentation of the event or situation. The request by an owner, operator, or agent in charge 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.

FDA's written request to the owner, operator, or agent in charge of the establishment to schedule an inspection will explain the consequences of a refusal of inspection (i.e., section 807(b) of the FD&C Act provides that FDA shall refuse admission of food from the establishment into the United States).

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

We consider 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. Examples of where we would generally consider an owner, operator, or agent in charge to be 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 sends staff home for the day, without a reasonable explanation, and tells the FDA investigator that the establishment 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 unable to gain entry to the establishment for purposes of conducting an inspection, and there is evidence that the establishment is operating.

We consider an owner, operator, or agent in charge of a foreign food establishment to have refused an inspection when an owner, operator, or agent in charge prevents the FDA investigator from fully conducting an inspection of the establishment, by establishing unreasonable preconditions to allowing the inspection or by preventing or interfering with completion of some aspect of the inspection. Examples of where we would generally consider preventing the FDA investigator from fully conducting an inspection include:

- The owner, operator, or agent in charge bars the FDA investigator from an area of the establishment where food is grown, harvested, manufactured, processed, prepared, packed, or held or an area of the establishment that may impact these operations (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 does not allow the FDA investigator to inspect an area of the establishment because certain staff members are not present, without a reasonable explanation.
- The owner, operator, or agent in charge states that direct observation of an establishment, in whole or in part, must be limited to an unreasonably short amount of time, thus preventing FDA from inspecting the establishment 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 as necessary; to collect samples; talk to pertinent staff; or to collect food labels and labeling).
- The owner, operator, or agent in charge refuses or limits the FDA investigator's access to records that are within FDA's authority to review and copy. Examples of such record refusals include:
    - The owner, operator, or agent in charge refuses to allow the FDA investigator to review the requested records; provides some, but not all, of the requested records or fails to produce the records within a reasonable timeframe, as discussed with the owner, operator, or agent in charge.
    - 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.

We generally consider 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 causes a delay after the inspection has begun that interferes with the FDA investigator conducting an inspection as is usual and customary. Examples of where we would generally consider an owner, operator, or agent in charge to be 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 grown, harvested, manufactured, processed, prepared, packed, or held in that area of the establishment or does not allow access to an area of the establishment that may impact these operations (e.g., a room where equipment is sanitized; an area where cleaning materials or other chemicals are stored).
- The owner, operator, or agent in charge leaves the FDA investigator in a non-production area of the establishment (e.g., conference room) without access to records, to a responsible individual, or to other areas of the establishment that would be subject to inspection for an unreasonable period of time that interferes with the investigator's ability to complete the inspection.

## 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 what we would generally consider to be such a 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 (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 the foreign government prevents the FDA investigator from entering the establishment. Examples of what we would generally consider to be such a refusal include:

- The foreign government does not allow the FDA investigator to inspect a specific type of food establishment.
- The foreign government requests the FDA investigator to leave the country before a scheduled inspection is conducted.

We also consider a foreign government to have refused an inspection when the foreign government prevents the FDA investigator from fully conducting an inspection of the establishment by establishing unreasonable preconditions to allowing the inspection or by preventing or interfering with completion of some aspect of the inspection. Examples of what we would generally consider to be preventing the FDA investigator from fully conducting an inspection include:

- The foreign government bars the FDA investigator from an area of the establishment where food is grown, harvested, manufactured, processed, prepared, packed, or held.
- The foreign government refuses to allow the FDA investigator to take photographs as necessary.
- The foreign government refuses or limits access to records requested by the FDA investigator that are within FDA's authority to review and copy. Examples include:
    - The foreign government refuses to allow the FDA investigator to review the requested records, provides some, but not all, of the requested records, or fails to produce the requested 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.

In addition, we generally consider a foreign government to have refused an inspection when the foreign government delays the FDA investigator from conducting an inspection of the establishment after the inspection has begun and the delay interferes with the FDA investigator conducting an inspection as is usual and customary. Examples of where we would generally consider a foreign government to be 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 grown, harvested, manufactured, processed, prepared, packed, or held in that area of the establishment or does not allow access to an area of the establishment that may impact these operations (e.g., a room where equipment is sanitized; an area where cleaning materials or other chemicals are stored).
- The foreign government leaves the FDA investigator in a non-production area of the establishment (e.g., conference room) without access to records, to a responsible individual, or to other areas of the establishment that would be subject to inspection for an unreasonable period of time that interferes with the investigator's ability to complete the inspection.

# 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 for 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 FDA makes a preliminary determination that an imported article of food is subject to refusal of admission under section 807(b) of the FD&C Act (including food from establishments identified on the Red List of Import Alert 99-32), FDA intends to follow the same notice and hearing process laid out in section 801(a) of the FD&C Act (21 U.S.C. 381) and 21 CFR 1.94(a) that applies to imported articles under section 801(a) of the FD&C Act.

## A. Refusal by a Foreign Food Establishment

As explained in section III.A. of this guidance, FDA's written request to the owner, operator, or agent in charge of the establishment to schedule an inspection will explain the consequences of a refusal of inspection (i.e., section 807(b) of the FD&C Act provides that FDA shall refuse admission of food from the establishment into the United States). Additionally, if an FDA investigator who is attempting to conduct an inspection believes that the owner, operator, or agent in charge of the establishment, or the foreign government, is refusing the inspection, the FDA investigator will make reasonable efforts to inform the owner, operator, or agent in charge of the establishment of the consequences of the refusal.

Based on FDA's review of the evidence of a refusal of inspection, FDA may determine that the foreign establishment refused the inspection under section 807(b) of the FD&C Act. After FDA makes this determination, we may place the establishment on the Red List of Import Alert 99-32. We will notify the owner, operator, or agent in charge of the establishment of FDA's determination of the refusal of inspection and of our decision to place the establishment on the Red List of Import Alert 99-32.

The owner, operator, or agent in charge of the establishment may at any time contest, in writing, FDA's decision to place them on the Red List of Import Alert 99-32. For example, they may present evidence to FDA to support their claim that the Agency should not have considered them to have refused an inspection. In addition, the owner, operator, or agent in charge may ask FDA to remove them from the Red List of Import Alert 99-32 by submitting a request (which may include copies of inspection reports for inspections performed by third parties) to schedule an FDA inspection of the establishment. To contest FDA's decision or to schedule an FDA inspection, the owner, operator, or agent in charge of the establishment should send a written request by email to Importalerts2@fda.hhs.gov or by mail or express courier service to:

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

If an establishment has refused an inspection, but later requests FDA to reschedule an inspection, we will attempt to reschedule an inspection. 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 that refused, but later requests, an inspection.

## B. Refusal by a Foreign Government

When the foreign government indicates it will refuse inspection of one or more food establishments 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 that the foreign government refuses to permit FDA investigators to inspect;
- 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 until an inspection is performed).

If the foreign government maintains its refusal after being informed of the consequences, we may add each foreign food establishment for which an FDA inspection request 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 one or more 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 consider removing the establishment from the Red List of Import Alert 99-32 when the foreign government provides us with written notification that we can 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. Access 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. Access online at https://www.accessdata.fda.gov/cms_ia/importalert_521.html.