Draft Guidance for Industry

Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1500 or the Center for Veterinary Medicine (CVM) at 240-276-9200

U.S. Department of Health and Human Services
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Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
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Contains Nonbinding Recommendations

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you wish to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This document represents a draft of the second edition of guidance intended to assist those parties responsible for complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085). As required by section 1005(f) of this law, in September 2009, FDA issued guidance to industry about submitting reports of instances of reportable food through the electronic portal and providing notifications to other persons in the supply chain of such articles of food. When finalized, this second edition of that guidance document will provide further guidance to industry on those topics and in addition will address inquiries that the agency has received through its Reportable Food Registry help desk and/or by other means since the implementation of the Reportable Food Registry on September 8, 2009. New questions and answers are identified with the date that they were added to the guidance. Questions and answers identified as amended have been changed since their appearance in the earlier version of the guidance in order to improve the guidance's clarity. Questions and answers that have been altered only in non-substantive ways (e.g., by adding citations or making grammatical changes) are not marked as amended. To facilitate adding new questions and answers to future editions of this guidance without requiring every question and answer to be re-numbered, we have changed the numbering system in this

[1] This draft guidance has been prepared by the Office of Food Defense, Communication and Emergency Response in the Center for Food Safety and Applied Nutrition, in cooperation with the Center for Veterinary Medicine, the Office of Regulatory Affairs, the Office of Information Management and the Office of Emergency Operations at the U.S. Food and Drug Administration.

edition from previous editions and therefore the questions and answers in this edition are not numbered the same as in previous editions.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's 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 Agency guidances means that something is suggested or recommended, but not required.

II. Background

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). This law amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) by creating a new section 417, Reportable Food Registry. Section 417 requires the Secretary of Health and Human Services (the Secretary) to establish within the Food and Drug Administration (FDA) a Reportable Food Registry. The congressionally-identified purpose of the Reportable Food Registry is to provide a "reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health" (Pub. L. 110-085, section 1005(a)(4)). The Secretary has delegated to the Commissioner of Food and Drugs the responsibility for administering the FD&C Act, including section 417. To further the development of the Reportable Food Registry, section 417 of the FD&C Act requires FDA to establish an electronic portal by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. After receipt of reports through the electronic portal, FDA is required to review and assess the information submitted for purposes of identifying reportable food, submitting entries to the Reportable Food Registry, issuing an alert or notification as FDA deems necessary, and exercising other existing food safety authorities under this Act to protect the public health.

This guidance document contains questions and answers relating to the requirements under section 417 of the FD&C Act, including (1) how, when, and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food.

III. Questions and Answers

A. Reportable Food Electronic Portal

A.1 [Amended May 2010] How will FDA implement the FDAAA requirement to establish an electronic portal?

The Reportable Food electronic portal was initially implemented as an FDA electronic system for collecting, submitting and processing reportable food

reports. As of May 24, 2010, the Reportable Food electronic portal will be a part of the FDA-National Institutes of Health (NIH) Safety Reporting Portal ("Safety Reporting Portal"). The Safety Reporting Portal facilitates the process of reporting several categories of safety information to the FDA and the NIH, including safety information related to reportable foods, pet foods, animal drugs, and NIH gene replacement therapy centers.

A.2 When did the Reportable Food electronic portal first become available?

The Reportable Food electronic portal has been available on the FDA.GOV website since September 8, 2009.

A.3 [Amended May 2010] Is the new Reportable Food electronic portal as described in this guidance the final version?

This new version of the Reportable Food electronic portal is released as part of the launch of the larger Agency Safety Reporting Portal. We anticipate this to be the final version, subject to minor adjustments and system enhancements.

FDA intends that the Reportable Food electronic portal will stay consistent with current FDA Web policy, which currently includes supporting the most widely used versions of Internet Explorer and Firefox browsers.

A.4 [Amended May 2010] How can I access the Reportable Food electronic portal?

The Reportable Food electronic portal remains available through a link on the FDA.GOV web site home page (http:/www.fda.gov) under the heading "Report a Problem." Alternatively, as of May 24, 2010, you can access the Reportable Food electronic portal through the Safety Reporting Portal by entering the following URL into your browser: http://www.safetyreporting.hhs.gov. Upon entering the site, select "Reportable Food report" and you will be directed to the appropriate portal.

A.5 [Added May 2010] When I access the Reportable Food electronic portal through the Safety Reporting Portal, I am asked if I want to report as a guest or create an account. What are the benefits of creating an account?

The benefits of creating an account are as follows:

- You can save time with data entry for initial reports, as the system pre-populates fields with information (e.g., names, addresses, phone numbers, etc.) you provided when establishing the account.
- You can save a report and finish it at a later time.
- You can see a list of all of your submitted reports.

By comparison, if you report as a guest:

- Reports, or partial reports that you intend to complete later, cannot be saved.
- Previous submissions to the Safety Reporting Portal will not be viewable.

A.6 [Amended May 2010] Are there additional instructions on how to use the Reportable Food electronic portal?

Yes. Instructions for completing the Reportable Food electronic portal screens within the Safety Reporting Portal are attached as Appendix A to this guidance. In the online version of this guidance, Appendix A will be updated as appropriate to reflect future changes to the instructions for completing the Reportable Food electronic portal screens. The online version of this guidance will link to the most current version of Appendix A The same information will be found at the link "Instructions" on every Reportable Food electronic portal screen.

A.7 [Amended May 2010] Does the Reportable Food electronic portal allow electronic documents to be submitted in addition to the reportable food report?

Yes. As either a guest user or a Safety Reporting Portal account holder, you will have an opportunity to submit documents as attachments to both initial and amended reports.

A.8 [Amended May 2010] What file types may be submitted as attachments to the email you may send to FDA after completing the reportable food report?

The following file types are supported:

- .pdf - Portable document format.
- .jpg, .jpeg - Image file formats.
- .bmp - Bitmap image format.
- .png - Portable Network Graphics (bitmap image format).
- .gif - Graphics Interchange Format (bitmap image format).
- .tif, .tiff - Tagged image file formats.
- .rtf - Rich text format.
- .txt - Text format.
- .xls, .xlsx - Spreadsheet file formats.
- .doc, .docx - Word processing document formats.
- .wpd - Word processing document format.

A.9 [Amended May 2010] What should I do if the Safety Reporting Portal is not operating?

FDA intends to post an announcement on http://www.fda.gov as to how to submit a Reportable Food report in the event that the Safety Reporting Portal is not operating. If http://www.fda.gov is not operating, FDA recommends that you contact the FDA district office serving your area. If the FDA district office for your area is not listed in your local telephone directory under U.S. Government, call 1-888-SAFEFOOD (Monday-Friday, 8:00 AM to 4:00 PM, Eastern Standard Time) or 1-888-INFO-FDA.

A.10 [Amended May 2010] How will future upgrades or enhancements of the Safety Reporting Portal or Reportable Food electronic portal screens within the Safety Reporting Portal be announced?

FDA may announce major upgrades, new versions, or enhancements to the Safety Reporting Portal or the Reportable Food electronic portal screens within the Safety Reporting Portal in any or all of the following ways, depending on the circumstances: publishing a Federal Register notice, making web announcements on the Safety Reporting Portal web site, and/or issuing press releases or constituent updates.

A.11 [Amended May 2010] Is the Reportable Food electronic portal available in other languages?

No. The Reportable Food electronic portal is only available in English. However, FDA intends to make its guidance documents regarding the Reportable Food Registry available on the Reportable Food Registry web page (http://www.fda.gov/reportablefoodregistry) in Spanish, French, Chinese and possibly additional languages as appropriate.

A.12 [Added May 2010] Is there a test portal or other training materials for the Reportable Food electronic portal for industry to use for testing or training purposes?

FDA has not developed a "test" Reportable Food electronic portal. However, instructions for completing a reportable food report and frequently asked technical questions are available at http://www.fda.gov/reportablefoodregistry. Interested persons may request a set of screen shots of the electronic portal by sending an email to RFRSupport@fda.hhs.gov.

A.13 [Added May 2010] May I submit a reportable food report and/or attachments to FDA in languages other than English?

FDA recommends that you submit all reportable food report information and attachments in English whenever possible, except (where applicable)

individuals' names, the names of companies, the names of streets, and trade names. If any part of the material you submit is in a foreign language, FDA recommends that you include an accurate and complete English translation.

B. Effective Date and Enforcement

B.1 When must I comply with the requirements of the Reportable Food Registry (Section 417 of the FD&C Act)?

Under section 1005(e) of FDAAA, the requirements of section 417(d) of the FD&C Act (21 U.S.C. 350f(d)) became effective on September 27, 2008, one year after FDAAA was signed into law. Under section 107 of FDAAA, all other requirements related to the Reportable Food Registry became effective on October 1, 2007. On May 27, 2008, FDA announced a delay in implementation of the Reportable Food Registry and acknowledged that the prohibited act provisions would not apply until FDA established the electronic portal to implement the Reportable Food Registry.

On September 8, 2009, FDA implemented the Reportable Food Registry (Section 417 of the FD&C Act), and the prohibited act provisions of the FD&C Act related to the Registry became effective on that date (see section 301(mm) of the FD&C Act (21 U.S.C. 331(mm))). However, FDA announced its intention to consider exercising enforcement discretion for a period of 90 days, until December 8, 2009, in circumstances where FDA determined that a responsible party had made a reasonable effort to comply with the requirements of section 417 of the FD&C Act and had otherwise acted to protect public health.

C. Responsible Party

C.1 Who is the "responsible party" that must submit a report regarding instances of reportable food to FDA through the Reportable Food electronic portal?

The responsible party is the person who submits the registration under section 415(a) of the FD&C Act (21 U.S.C. 350d) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. Persons who are required to submit a facility registration under section 415 of the FD&C Act are the owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States. "Person" is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as including individuals, partnerships, corporations and associations.

(Sections 201(e) and 417(a)(1) of the FD&C Act).

C.2 If the registration information submitted under section 415(a) of the FD&C Act is no longer correct, is a responsible party precluded from submitting a Reportable Food report through the portal?

No. Persons who are required to submit a facility registration under section 415(a) of the FD&C Act are required to update and correct that information in a timely manner (Section 415(a)(2) of the FD&C Act). However, a reportable food report may be submitted, and may be required, even if the responsible party's registration information needs to be updated. FDA also encourages the individual submitting the reportable food report to provide his or her contact information in the reportable food report, especially if the registration information is out of date.

(Section 415(a)(2) of the FD&C Act).

C.3 Can an owner, operator, or agent in charge of a facility authorize an individual to report an instance of reportable food through the Reportable Food electronic portal on their behalf?

Yes. An owner, operator, or agent in charge of a facility may authorize an individual to report an instance of reportable food on their behalf through the Reportable Food electronic portal. FDA notes that an owner, operator or agent in charge of a facility may authorize an individual to register their facility on their behalf (21 CFR 1.225(c)). An individual who is authorized by the responsible party to submit a reportable food report need not be the same individual who is authorized to register a facility. FDA also encourages the individual submitting the reportable food report to provide his or her contact information in the reportable food report, especially if the registration information does not include the individual reporter's contact information.

C.4 [Amended May 2010] Can an individual who did not submit the responsible party's initial report submit an amended report on behalf of the responsible party?

Yes. The method for doing this depends on whether the responsible party submitted their initial report as a Safety Reporting Portal Account Holder or as a guest user.

For security purposes, the Safety Reporting Portal links a single individual to an account. Therefore, if the individual (Party A) who submitted the initial report is a Safety Reporting Portal account holder, FDA recommends that the Safety Reporting Portal account holder amend the report submitted using his/her account. If this is not possible, another individual (Party B) should

submit an initial report, and indicate in the descriptive narrative text box located in the "Problem Summary" section (for providing a "full account of the reportable food issue") that this is an amended report related to Party A's initial report. In the same text box, Party B should also include the ICSR number provided to Party A when Party A submitted his/her initial report.

If the responsible party (Party A) submitted his/her initial report as a guest user they will have been provided a 16-digit Report Identification Key as part of the unique number he/she received upon submission of the initial report. This number is used to amend the guest's submitted report. Since in this situation, the initial report is not connected to an individual account, Party A should provide Party B with the Report Identification Key to amend the report on Party A's behalf. If this is not possible, Party B should submit an initial report, and indicate in the descriptive narrative text box located in the "Problem Summary" section (for providing a "full account of the reportable food issue") that this is an amended report related to Party A's initial report. In the same text box, Party B should also include the ICSR number provided to Party A when Party A submitted his/her initial report.

Regardless of who submits the report, FDA encourages the submitter of the amended report to provide his or her contact information, especially if it was not included in the initial report.

C.5 [Added May 2010] If a responsible party has not registered as required under section 415(a) of the FD&C Act, what should the responsible party do before submitting a reportable food report within the 24-hour time limit?

To submit a reportable food report, you will need the Food Facility Registration number for your facility (see section 417(e)(1) of the FD&C Act). Information on how to register and obtain this number is available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm

D. Reportable Food

D.1 What is a "reportable food?"

A "reportable food" is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

(Sections 201(ff) and 417(a)(2) of the FD&C Act).

D.2 [Amended May 2010] Does the term "article of food" include animal feed and pet food?

Yes. Animal feed and pet food are included in the definition of "food" in the FD&C Act (See Question D.3).

(Sections 201(f) and 417(a)(2) of the FD&C Act).

D.3 [Amended May 2010] How is "food" defined in the FD&C Act?

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. Dietary supplements are not "food" for the purposes of the Reportable Food Registry (section 417 of the FD&C Act).

(Sections 201(f) and 201(ff) of the FD&C Act).

D.4 [Added May 2010] Infant formula and dietary supplements are excluded from the requirements of the Reportable Food Registry. Are there other reporting requirements for these foods?

Yes. Manufacturers, packers and/or distributors whose names appear on the label of a dietary supplement marketed in the United States must submit to FDA any report received of a serious adverse event associated with that dietary supplement when used in the United States, accompanied by a copy of the dietary supplement's label, under section 761 of the FD&C Act (21 U.S.C. 379aa-1). Infant formula manufacturers must comply with notification requirements for violative infant formula as established in 21 CFR 107.240.

More information about dietary supplement serious adverse event reporting is available at:
http://www.fda.gov/Food/DietarySupplements/Alerts/ucm111110.htm

More information about infant formula is available at:
http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/InfantFormula/default.htm

D.5 Is a food that presents a Class I recall situation a reportable food?

Yes. FDA interprets the definition of reportable food to include those foods that would meet the definition of a Class I recall situation. A Class I recall situation is one in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1)).

(Section 417(a)(2) of the FD&C Act).

D.6 What are some circumstances under which food might be reportable?

The FDA Enforcement Report is published weekly by the Food and Drug Administration, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities, including recalls. The website lists recalls by classification, with Class I recalls at the top of the list. Contained within the information for each product is the reason for the Class I recall. This information may be helpful in providing examples of foods that FDA has considered to present a reasonable probability of serious adverse health consequences or death. While these examples can be helpful in understanding the standard for reportable foods, they should not be used as a substitute for evaluating the facts of your particular situation in order to determine if a food is reportable. These reports can be accessed via the following link:

http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

Listed below are some examples of previous Class I recall situations:

- Peanut butter contaminated with *Salmonella*.
- Under-processed canned chili that contained *Clostridium botulinum* toxin.
- Smoked salmon contaminated with *Listeria monocytogenes* (Lm).
- Ice cream that did not declare peanut-derived ingredients but contained peanut butter as an ingredient.
- Baby food that posed a choking hazard.
- Horse feed contaminated with elevated levels of monensin.
- Pet food contaminated with elevated levels of melamine and cyanuric acid.
- Sheep feed containing elevated levels of copper.
- Swine feed containing elevated levels of selenium.

D.7 [Added May 2010] Can a human food containing an undeclared allergen be a reportable food?

Yes. A human food containing an undeclared major food allergen as defined in the Food Allergen Labeling and Consumer Protection Act (FALCPA) may be a reportable food as described above (Question D.6). This is the case regardless of how the major food allergen was incorporated into the human food. More information on FALCPA and food allergen labeling can be found at:
http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm .

D.8 Are products regulated exclusively by the USDA subject to the reportable food registry requirements?

No. Food that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.) is excluded from the requirements of the reportable food registry while that food is under the exclusive jurisdiction of USDA.

D.9 [Amended May 2010] I received a confirmed positive microbiological test result indicating the presence of a pathogen in a food. Based on this test result, I determined the food to be "reportable". However, I retested the food for the pathogen and the second test result did not indicate the presence of the pathogen in the food. Should I still consider the food to be reportable?

Yes. There are a number of explanations why a food may test positive for a pathogen in one test and negative in one or more additional tests although the food continues to be contaminated. For example, the distribution of a pathogen in the food may not be homogeneous. Therefore, absent other circumstances clearly demonstrating the inaccuracy of the first test result, the first test result upon which the reportable food determination was made should be considered valid.

D.10 [Added May 2010] If a food facility enters into a contract with a farmer whereby the food facility agrees it will purchase the produce grown by that farmer when that produce is harvested, and the facility tests the produce in the field before it is harvested and determines that it meets the definition of a reportable food, must the food facility that contracted with the farmer submit a reportable food report?

No, the food facility that contracted with the farmer and tested the produce in the field is not required to submit a reportable food report, provided that the facility did not manufacture, process, pack, or hold the produce and therefore never became a responsible party with respect to the produce. However, if the field had been harvested and the contaminated produce had been moved to the food facility, the facility would have become a responsible party because it "held" the food and would be required to submit a reportable food report. Provided that the farm is not a facility required to register with FDA under section 415(a) of the FD&C Act, the farm is not a responsible party under section 417 and is not required to submit a report.

(Section 417(a)(1) of the FD&C Act).

D.11 [Added May 2010] A domestic facility that is required to register with FDA under section 415(a) of the FD&C Act manufactures food for consumption in

the United States and for export. Is the facility required to submit a reportable food report to FDA if it determines that a food that it manufactured solely for export presents a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans or animals?

Yes. If you are a responsible party, as discussed in Question C.1, and you determine that an article of food you manufactured, processed, packed, or held is a reportable food, you are required to submit a report through the Reportable Food electronic portal for such food even if it is intended solely for export, unless you qualify for the exemption from reporting in section 417(d)(2) of the FD&C Act (see Question E.3). A "reportable food" is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. A "responsible party," with respect to an article of food, is a person who submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under that section, at which such article of food is manufactured, processed, packed or held. While food facilities are required to register under section 415(a) of the FD&C Act if they are engaged in manufacturing, processing, packing, or holding food for consumption in the United States, responsible parties' reporting duties with respect to reportable foods under section 417 of the FD&C Act are not limited to food for consumption in the United States.

(Sections 417(a) and 415(a) of the FD&C Act).

E. Submitting a Reportable Food Report

E.1 When is a responsible party required to report an instance of reportable food to FDA?

A responsible party is required to submit a report to FDA through the Reportable Food electronic portal as soon as practicable, but in no case later than 24 hours after determining that an article of food is a reportable food.

(Section 417(d)(1) of the FD&C Act).

E.2 Is a responsible party required to investigate and report the cause of the adulteration?

Yes, if the adulteration of the article of food may have originated with the responsible party, the responsible party is required to investigate the cause of the adulteration and report their findings when known.

(Sections 417(d)(1)(B) and 417(e)(5) of the FD&C Act).

E.3 When is a responsible party not required to submit a reportable food report to FDA for food that would otherwise be reportable?

A responsible party is not required to submit a reportable food report when all of the following criteria are met:

- The adulteration originated with the responsible party; AND
- The responsible party detected the adulteration prior to any transfer to another person of such article of food; AND
- The responsible party
  - corrected such adulteration; or
  - destroyed or caused the destruction of such article of food.

(Section 417(d)(2)(A)-(C) of the FD&C Act).

E.4 When does a "transfer to another person" occur under section 417(d)(2)(B) of the FD&C Act?

A transfer to another person occurs when the responsible person releases the food to another person. "Person" is defined in section 201(e) of the FD&C Act as including individuals, partnerships, corporations and associations.

FDA does not consider an intra-company transfer in a vertically integrated company to be a "transfer to another person," where the company maintains continuous possession of the article of food. For example, if Company A owns a processing plant, warehouse facility, and distribution facility, the intra-company transfer from the processing plant to the warehouse facility and/or the warehouse facility to the distribution facility would not be considered a transfer to another person.

(Sections 417(d)(2)(B) and 201(e) of the FD&C Act).

E.5 If a reportable food is shipped to a third-party warehouse, but the responsible party maintains ownership and direct control over distribution, must the responsible party submit the reportable food report?

Yes. Transfer to another person occurs when the responsible person releases the food to another person. "Person" is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as including individuals, partnerships, corporations and associations. In this situation, the warehouse operator is a distinct legal person.

(Sections 417(d)(2)(B) and 201(e) of the FD&C Act).

E.6 When does the 24-hour reporting requirement start? For example, if I conduct a test that, if positive, would trigger the reporting requirement, does the 24-hour clock start when I receive a presumptive positive result, or when I confirm that positive result?

A responsible party must submit a report to the Reportable Food electronic portal as soon as practicable, but in no case later than 24 hours after determining that an article of food is a reportable food. Some test methods do not yield presumptive positive results with sufficient reliability to create a reasonable probability that the use of, or exposure to, the related article of food will cause serious adverse health consequences or death to humans or animals; however, in some cases a presumptive positive result could indicate such a reasonable probability. In contrast, for a confirmed positive, a test method would be expected to be sufficiently reliable to trigger the reporting requirement. Therefore, you must evaluate your particular circumstances to determine your reporting obligation. FDA recommends that persons in the supply chain use a validated test method whenever possible; follow up any presumptive positive result with additional testing to obtain a final result; and take appropriate action to protect public health when confirmation of a presumptive positive test result is pending.

E.7 [Amended May 2010] If I receive a food from my supplier that I determine to be a reportable food and I contain the problem and do not ship any of the reportable food, am I required to submit a report?

Yes. A responsible party who determines that a food that it received is a reportable food must submit a report even if the responsible party has not transferred the food. The exception in section 417(d)(2)(A)-(C) does not apply (see Question E.3**).**

E.8 [Amended May 2010] Will a reportable food report be issued a number by FDA?

Yes. FDA will issue a unique number for that instance of reportable food to the person who submits the report. For Safety Reporting Portal account holders, this unique number consists of the ICSR number. For guest users, this unique number has two parts: the ICSR number and the 16-digit Report Identification Key.

(Section 417(d)(4) of the FD&C Act).

E.9 [Added May 2010 – this Q&A was previously published by FDA on March 19, 2010 in separate guidance entitled "Guidance for Industry: Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of

2007."] My company determined that it has a reportable food and the food is located at more than one of our facilities. Can my company submit one combined report that includes all of the information that would be submitted in separate reports from each facility?

Yes, you may submit a combined report for a specific reportable food situation that involves more than one of your facilities, such as manufacturing and processing facilities, storage facilities, and/or distribution facilities. The owner, operator, or agent in charge of each facility may authorize an individual to submit a combined report on their behalf through the Reportable Food electronic portal, in lieu of each responsible party for each facility submitting a separate reportable food report for the specific reportable food. The combined report must include all of the required data elements.

To complete the screens in the Reportable Food electronic portal, the authorized individual may provide the required information for only one of the facilities. The required information relating to all of the facilities, which may also include the facility for which the screens were completed, may be provided in a separate attachment in tabular or spreadsheet format, but should be provided in a manner that clearly associates each facility with the required information that is specific for that facility.

The file types that are supported as attachments are identified in Question A.8.

If using a tabular or spreadsheet format, FDA recommends that responsible parties use the following column headings, in the order listed, for the required (*) and optional information for each facility:

Name of facility*

Food facility registration number*

Contact name

Contact phone number

Street address*

City*

State*

Zip code*

E.10 [Added May 2010] Our manufacturing facility receives bulk trailer shipments of ingredients from our suppliers. A truck driver brings a trailer full of bulk ingredients onto our property, drops off the trailer, and drives away.

However, as company policy, we do not off-load the trailers that are delivered to our facility or take ownership of the food in the trailers until after we test a sample of the food and determine that the food is acceptable. If we "reject" a shipment, i.e., return the food to the supplier, because the sample results indicate that the food is a reportable food, are we required to submit a reportable food report?

Yes, provided that you are a facility required to register with FDA under section 415(a) of the FD&C Act, you must submit a report for the food you determined to be a reportable food, even though you returned the food to your supplier. FDA considers that your facility "held" the reportable food because the trailers were no longer in transit once they were dropped off on your property. Thus, you are a responsible party with regard to the reportable food. Provided that the adulteration did not originate with you, you do not meet the criteria for the exemption from reporting in section 417(d)(2) (see Question E.3).

(Sections 417(a)(1) and (d)(2)(B) of the FD&C Act).

F. Data for Initial Report

F.1 [Amended May 2010] What are the data elements that a responsible party must include in an initial report to FDA?

The following data elements must be included in an initial report:

(1) The registration numbers of the responsible party under section 415(a)(3) of the FD&C Act;
(2) The date on which the article of food was determined to be a reportable food;
(3) A description of the article of food including the quantity or amount;
(4) The extent and nature of the adulteration;
(5) The results of any investigation of the cause of the adulteration if it may have originated with the responsible party, when known;
(6) The disposition of the article of food, when known; and
(7) The product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food.

In addition, upon submission of a report, a unique number as discussed in response to Question E.8 above will be issued through the Reportable Food electronic portal to the person submitting the report. This unique number will be used by responsible parties for submitting amended reports and providing notifications.

(Sections 417(d)(1)(A), 417(d)(4), and 417(e) of the FD&C Act).

F.2 Will an initial report that does not include all of the data elements described in (1)-(7) in Question F.1 above be accepted by the Reportable Food electronic portal?

Yes. The Reportable Food Registry provisions recognize that the responsible party may not have sufficient information to include all seven data elements in its report within 24 hours of becoming aware of a reportable food (i.e., elements (5) and (6) above must be reported "when known"). FDA has designed the Reportable Food electronic portal to accept initial reports with a subset of the required data elements. If a required data element has not been provided or is incorrect, FDA recommends that the responsible party submit an amended report to FDA including the new or corrected information immediately.

(Sections 417(d)(1)(A) and 417(e) of the FD&C Act).

F.3 [Amended May 2010] Are required data elements clearly indicated in the Reportable Food electronic portal?

Yes. Required data elements for initial submissions are clearly indicated by asterisks (*) in the Reportable Food electronic portal.

G. Submitting an Amended Reportable Food Report

G.1 [Amended May 2010] What may FDA require a responsible party to do following FDA's receipt of a report?

After consultation with the responsible party, FDA may require the responsible party to perform, as soon as practicable, but in no case later than the time specified by FDA, one or more of the following actions:

- Amend the report the responsible party submitted to FDA to include the contact information for the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food directly linked in the supply chain and notified by the responsible party;
- Provide notification to the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food that includes some or all of the following data elements:
  (1) the date on which the article of food was determined to be a reportable food;
  (2) a description of the article of food including the quantity or amount;
  (3) the extent and nature of the adulteration;
  (4) the results of any investigation of the cause of the adulteration if it may have originated with the responsible party, if known;
  (5) the disposition of the article of food, when known;

(6) the product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food;
(7) contact information for the responsible party;
(8) the contact information for parties directly linked in the supply chain and notified by the responsible party;
(9) the unique report number issued through the Reportable Food electronic portal to the person submitting the report;
(10) the actions that the recipient of the notification shall perform (i.e., submit a report to FDA, investigate the cause of the adulteration, and/or provide a notification to the recipient's immediate previous source(s) and/or immediate subsequent recipient(s)), as may be specified by FDA; and
(11) any other information FDA may require.

(Sections 417(d)(6) and 417(e) of the FD&C Act).

G.2 [Amended May 2010] Will a new unique number be assigned to amended reports?

Yes. Every submission (initial or amended report) receives a new unique number that is provided in the confirmation.

(Section 417(d)(4) of the FD&C Act).

G.3 [Amended May 2010] How do I amend a report after I have submitted it?

As a Safety Reporting Portal Account Holder, log in into your account. Choose the report you want to amend from your list of submitted reports. The most recent version of the report will load for you to amend. Edit the report as appropriate and click "submit."

As a Guest User, enter as a guest again and then select the option "Follow-up on a report previously submitted as a guest portal user." You will then need to enter the 16-digit Report Identification Key you received upon submitting the most recent version of the report. The most recent version of the report will load for you to amend. Edit the report as appropriate and click "submit." Please note that Report Identification Keys are linked to report versions and only the most recent key will function.

See also Question C.4.

(Sections 417(d)(4), 417(d)(6)(A), and 417(d)(8) of the FD&C Act).

G.4 What is the time frame for filing amended reports?

After consultation with the responsible party, FDA may require the responsible party to amend the report. FDA will specify the time frame for completing the amended report during or after the consultation. In addition, if at any time a responsible party determines that a required data element has not been provided or is incorrect, FDA recommends that the responsible party submit an amended report to FDA including the new or corrected information immediately.

(Sections 417(d)(1)(A), 417(d)(6), 417(d)(7), and 417(e) of the FD&C Act).

H. Supply Chain Information

H.1 Will the Reportable Food electronic portal allow the submission of contact information for immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food directly linked in the supply chain and notified by the responsible party as an attachment to a report, or will responsible parties need to directly enter each party's contact information into the portal?

The portal will ask (if applicable) for information for at least one immediate previous source or immediate subsequent recipient. We encourage reporters to enter all distribution information into the portal. However, if you have a large volume of distribution information, you may provide it to FDA in an email attachment using one of the file types listed in Question A.8.

H.2 Are restaurants, delicatessens, supermarkets, and retail outlets considered immediate subsequent recipients within the meaning of section 417 of the FD&C Act?

Yes, if a restaurant, delicatessen, supermarket, or retail outlet is the entity that acquired the reportable food directly from the responsible party, FDA considers that entity to be an immediate subsequent recipient within the meaning of section 417 of the FD&C Act.

(Sections 417(d)(6)(B)(i)-(ii), 417(d)(7)(C)(i)-(ii), and 417(e)(9) of the FD&C Act).

I. Notifications

I.1 [Amended May 2010] If a responsible party (Party A) notifies the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food (Party B), as required by FDA, should Party B submit a report to FDA

and provide a notification to Party B's own immediate previous source(s) and/or immediate subsequent recipient(s)?

Yes, if Party B meets the definition of a responsible party, Party B should submit a report to FDA as soon as practicable, and within 24 hours after receiving the notification regarding the reportable food. FDA may require Party B to submit a report to FDA as soon as practicable, but in no case later than a time specified by FDA, and/or to provide a notification to Party B's own immediate previous source(s) and/or immediate subsequent recipient(s) of the reportable food. See the response to Question I.5 for more information.

(Sections 417(d)(6) and 417(d)(7) of the FD&C Act).

I.2 [Amended May 2010] If a responsible party (Party A) submits a report to FDA as required by section 417(d)(1) of the FD&C Act and receives a notification from another responsible party (Party B) concerning the same article of food that was the subject of Party A's report to FDA, does Party A have to submit an additional report to FDA or provide additional notifications to the immediate previous source(s) and/or immediate subsequent recipient of the article of food?

No. Party A does not have to submit an additional report to FDA or provide additional notifications to the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food. However, Party A is required to amend its report to FDA to include Party B's contact information and the unique ICSR number issued to Party B's report so that FDA can link the two reports in the Reportable Food Registry.

(Section 417(d)(8) of the FD&C Act).

I.3 [Amended May 2010] If I receive allegations of product problems from sources such as consumer complaints and restaurant complaints, but not from a facility registered under section 415(a) of the FD&C Act, am I required to submit a report to the Reportable Food electronic portal?

If you receive allegations of product problems from consumers, restaurants, or other sources, you should follow up on the allegations and investigate to the extent necessary to ensure that the foods comply with the requirements of the FD&C Act and other applicable laws. If you are a responsible party under section 417 and you determine that a food you manufactured, processed, packed or held is a reportable food, you must submit a reportable food report to FDA as soon as practicable, but in no case later than 24 hours after determining that the article of food is a reportable food. Note that FDA considers that you have received a notification within the meaning of section 417(d)(7) of the FD&C Act if a responsible party who is registered under section 415(a) and has previously filed a reportable food report contacts you

and provides you with an FDA-issued ICSR number for linkage to previous report(s).

(Sections 417(d)(1) and 417(d)(7) of the FD&C Act).

I.4 [Amended May 2010] When FDA requires a responsible party to provide notifications, if there are multiple immediate previous sources or multiple immediate subsequent recipients of the reportable food, may FDA require the responsible party to provide notifications to all such parties?

Yes. When FDA requires a responsible party to provide notifications to its immediate previous sources and/or immediate subsequent recipients of a reportable food, such notifications may be required for all of the responsible party's immediate previous sources and/or immediate subsequent recipients of the reportable food.

(Sections 417(d)(6)(B)(i)-(ii) and 417(d)(7)(C)(i)-(ii) of the FD&C Act).

I.5 What activities may FDA require a responsible party that is the immediate previous source or immediate subsequent recipient of an article of food to perform after receiving a notification?

FDA may require such a responsible party to perform, as soon as practicable, but in no case later than a time specified by FDA, one or more of the following actions:

- Submit a report to FDA through the Reportable Food electronic portal that includes the data elements listed in the answer to question G.1 above and any other information FDA deems necessary.
- Investigate the cause of the adulteration, if the adulteration of the article of food may have originated with the responsible party.
- Provide a notification to the immediate previous source(s) and/or immediate subsequent recipient(s) that includes the data elements listed in the answer to question G.1 above.

(Section 417(d)(7)(A)-(C) of the FD&C Act).

I.6 How do responsible parties provide a notification to the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food?

Notification to the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as e-mail, fax or text messaging or by telegrams, mailgrams, or first class letters. Notification may also be accomplished by telephone calls or other personal contacts but FDA

recommends that such notifications also be confirmed in writing and/or documented in an appropriate manner.

I.7 After consultation with the responsible party, what are some specific examples of information regarding the reportable food that FDA may require to be included in a notification to the immediate previous source(s) and/or immediate subsequent recipient(s)?

- Product name, brand name, product description, UPC codes, lot number
- Use-by or expiration date or other date-related information;
- Product label for ease in identifying the product at retail/user level;
- Nature of the problem and the potential health hazard;
- The business's contact details;
- Quantity by lot, dates and amounts shipped or received;
- Instructions on what to do with the product;
- A description of the disposition of the product;
- The unique report number (ICSR number) provided by FDA.

(Sections 417(d)(6)(B) and 417(d)(7)(C) of the FD&C Act).

I.8 Assume that I received notification from another responsible party (Party A), and then submitted a report to FDA through the Reportable Food electronic portal and received my own ICSR number. When I provide notifications to my own suppliers and distributors, either voluntarily or after being directed to by FDA, which ICSR number would I include in my notifications – the ICSR number that I received as part of the notification from Party A, or the ICSR number that I received when I submitted my own reportable food report to FDA after I was notified by Party A?

Under the circumstances described in your question, you should include in your notifications to your suppliers and distributors the ICSR number that was provided to you in the notification from Party A. This ICSR number will allow FDA to link reportable food reports that are related to the initial report and the reportable food.

I.9 [Added May 2010] I was not able to obtain an ICSR number from the facility that notified me that a food I received was a reportable food. An ICSR number is required to complete the report. What should I do to submit the report without the number?

If you received a notification from another responsible party, but that party did not provide the ICSR number and you can not contact that party to obtain the required ICSR number, you should enter up to eleven numeric zeroes (i.e.,

"00000000000") in response to the question "What is the FDA-issued ICSR number for this Reportable Food provided by the site that notified you?

J. Additional Contacts

J.1 Should responsible parties call the FDA district office and notify state and local public health or regulatory officials if they determine that an article of food is a reportable food?

Yes. FDA encourages responsible parties to contact their FDA district office and state or local public health or regulatory officials as soon as possible if they determine that an article of food is a reportable food. Calling the FDA district office and state or local health officials does not relieve the responsible party of the responsibility to submit an electronic report as soon as practicable but in no case later than 24 hours after determining that an article of food is a reportable food.

(Section 417(d)(1) of the FD&C Act).

J.2 Does calling the FDA district office and/or local or state public health officials about a reportable food relieve the responsible party of the responsibility to submit a report?

No. Responsible parties are required to submit a report through the Reportable Food electronic portal to FDA as soon as practicable but in no case later than 24 hours of determining that an article of food is a reportable food (Section 417(d)(1)(A) of the FD&C Act). Calling an FDA district office and/or a local or state public health official does not relieve the responsible party of this responsibility.

J.3 If I have submitted my report within 24 hours, worked with the FDA district office on follow-up questions, or have provided documentation or additional information to the FDA district office, could I be required to submit an amended report?

Yes. After FDA consults with the responsible party, FDA may require the responsible party to amend its report to include the contact information for parties directly linked to the responsible party in the supply chain and notified of the reportable food by the responsible party.

(Section 417(d)(6)(A) of the FD&C Act).

K. Recordkeeping and Documentation

K.1 What are the recordkeeping requirements for responsible parties?

The responsible party shall maintain records related to each report received, notification made, and report submitted to the FDA under section 417 of the FD&C Act for 2 years.

(Section 417(g) of the FD&C Act).

K.2 Can FDA examine or inspect my records related to reports received, notifications made, and/or reports submitted to FDA under section 417 of the FD&C Act?

Yes. FDA may request records related to each report received, notification made, and report submitted to the FDA under section 417 of the FD&C Act, and a responsible party shall permit inspection of such records as provided for in section 414 of the FD&C Act.

(Sections 414 and 417(g) of the FD&C Act).

K.3 Is a report to FDA or notification of instances of reportable food an admission that the food involved is adulterated or caused or contributed to a death, serious injury, or serious illness?

No. A report or notification of a reportable food shall not be considered an admission that the food involved is adulterated or caused or contributed to a death, serious injury, or serious illness. Any report or notification of an instance of reportable food is considered a safety report under section 756 of the FD&C Act (21 U.S.C. 379v), Safety Report Disclaimers, and may be accompanied by a statement, which shall be part of any report that is released for public disclosure, that denies that the report or notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

(Sections 417(i) and 417(j) of the FD&C Act).

K.4 Will the information collected in a reportable food report be available for public disclosure?

Under section 417(h) of the FD&C Act, a record in the Reportable Food Registry is subject to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552), except that FDA registration numbers and information derived from such registrations are protected from disclosure to the extent that they would disclose the identity or location of a specific registered person, as provided by section 415(a)(4) of the FD&C Act. In addition, certain information, including but not limited to trade secrets and confidential commercial or financial information, are protected from disclosure under

FOIA under section 552(b) (5 U.S.C. 552(b)), and by part 20 of FDA's regulations (21 CFR part 20).

(Sections 415(a)(4) and 417(h) of the FD&C Act).

K.5 [Added May 2010] If FDA determines that food for which a reportable food report was submitted through the Reportable Food electronic portal does not meet the definition of a reportable food, will FDA purge the report from its records?

After receipt of reports through the electronic portal, FDA is required to review and assess the information submitted for purposes of identifying reportable food and submitting entries to the Reportable Food Registry. Any report submitted through the electronic portal that is later determined to not be a reportable food will be marked and annotated as such and therefore not entered into the Reportable Food Registry, but will still remain in FDA's records, subject to normal record retention requirements.

L. Animal Feed or Food Diversion

L.1 [Amended May 2010] I am interested in diverting my reportable food to use in animal feed. What has been FDA's position with respect to the use of adulterated food in animal feed?

FDA has developed procedures for requests to divert human or animal food considered to be adulterated for its intended use to other animal feed use. See also Questions L.2 and L.3.

L.2 Where should I submit a request to divert human or animal food to animal feed?

You should submit a request to divert human food or animal food to animal feed in writing to the FDA district office that is responsible for the geographic area in which the food is located. A directory of FDA District Offices can be found at http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm.

L.3 Where can the procedures for submitting requests to FDA for human or animal food diversion to animal feed be located?

Procedures for requesting diversion are outlined in the Agency's Compliance Policy Guide 7126.20, Diversion of Adulterated Food to Acceptable Animal Feed Use, and can be found on FDA's website at http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm.

M. Federal, State and Local Public Health Officials

M.1 [Amended May 2010] May Federal, state, and local public health officials submit instances of reportable food to FDA?

Federal, state and local public health officials may submit voluntary reports regarding instances of reportable food that are identified through their regulatory or public health food safety activities to FDA through the Reportable Food electronic portal. Reports that may be submitted by federal, state or local public health officials do not satisfy a responsible party's duty to report instances of reportable food to FDA.

(Section 417(b)(1)(A) of the FD&C Act).

M.2 If a federal, state or local public health official identifies a reportable food as part of inspection or regulatory activities, can the public health official inform the facility that they may be required to submit a report?

Yes. The public health official may inform the facility they may be required to submit a report.

M.3 [Added May 2010] Should consumers submit reports to the Reportable Food electronic portal?

No. FDA has established other systems for receiving and responding to consumer emergencies, complaints, questions, and concerns about FDA-regulated foods. In emergencies, consumers should call FDA at 301-443-1240, which is staffed 24 hours a day, every day. For less urgent situations, consumers can call the FDA consumer complaint coordinator for their area. A list of consumer complaint coordinators is posted at http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm. Consumers may also submit reports of pet food (including pet treats and chews) complaints to the Pet Food Report electronic portal in the Safety Reporting Portal. In addition, consumers can address questions and concerns about FDA regulated foods to 1-888-SAFEFOOD (1-888-723-3366) or consumer@fda.gov.

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N. [Added May 2010] Foreign Facility Information

N.1 [Added May 2010] Do the requirements of the Reportable Food Registry apply to foreign human food/animal food producers?

Any foreign food facility that manufactures, processes, packs, or holds food for human or animal consumption[2] in the United States is required to register under section 415(a) of the FD&C Act, unless food from the facility undergoes further manufacturing/processing (including packing) by another facility outside the United States, unless such subsequent activity is of a *de minimis* nature (Section 415(b)(3) of the FD&C Act [21 U.S.C. 350d(b)(3)] and 21 CFR 1.226(a)). A foreign facility that is required to register under section 415(a) of the FD&C act can be a responsible party who is required to report via the Reportable Food electronic portal (http://rfr.fda.gov) within 24 hours of determining that there is a reasonable probability that the use of, or exposure to, an article of food that the facility manufactured, packed, processed, or held will cause serious adverse health consequences or death to humans or animals under section 417 of the FD&C Act.

(Sections 415(a), 415(b)(3), and 417(a)(1) of the FD&C Act.)

N.2 [Added May 2010] Does FDA work with foreign governments when it receives a reportable food report about an imported or exported food?

Yes. FDA works with foreign governments, as needed, to address reportable food reports using existing procedures. FDA reviews and assesses the information submitted in a reportable food report, issues an alert or notification as necessary, and cooperates with other existing food safety authorities to protect public health.

N.3 [Added May 2010] Can an owner, operator, or agent in charge of a foreign facility that is required to register under Section 415(a) of the FD&C Act authorize an individual to report an instance of reportable food through the Reportable Food electronic portal on their behalf?

Yes. See Question C.3.

N.4 [Added May 2010] May a foreign public health official submit a reportable food report?

If a foreign public health official acquires information on a reportable food, that official may submit a voluntary report to the reportable food electronic portal. Section 417(d)(3) provides that Federal, state, or local public health officials may submit voluntary reports to the reportable food registry. FDA considers that foreign public health officials may also wish to voluntarily provide such information to FDA, and FDA will accept such reports through the reportable food electronic portal. Reports that are submitted by foreign government officials do not satisfy a responsible party's duty to report

[2] All food and food products, including animal feed and pet food under FDA's jurisdiction, are required to be reported if they meet the definition of a "reportable food." See Questions D.1 and D.2 for more information on "reportable food."

instances of reportable food to FDA. FDA encourages these officials to follow their report by informing the responsible party that it may be required to submit its own report.

N.5 [Added May 2010] Does a foreign facility that is required to register under Section 415(a) of the FD&C Act and that exports human food/animal food to the United States as well as to other countries need to submit a reportable food report if the reportable food is shipped elsewhere, but not to the United States?

No, the foreign facility is not required to submit a reportable food report but the FDA encourages the facility to notify the recipient of the food and take appropriate action.

N.6 [Added May 2010] If a foreign facility that is required to register under section 415(a) of the FD&C Act received food produced in the United States that is a reportable food, is the foreign facility required to report?

Yes. If the foreign facility receiving the reportable food is a responsible party with respect to the food as defined in 417(a)(1) of the FD&C Act, and determines that the food is reportable, the foreign facility must submit a reportable food report within 24 hours after determining that the food is reportable.

N.7 [Added May 2010] A foreign facility that is required to register under Section 415(a) of the FD&C Act and that exported human food/animal food to the United States subsequently determines that the food it exported is a reportable food. If FDA requires submission of information regarding the immediate subsequent recipients of the food, must the facility submit information about non-U.S. recipients of the food?

No. FDA may require the foreign facility to identify the U.S. recipients of the food. However, FDA encourages the submitter to notify other recipients of the food and take appropriate action.