GUIDANCE DOCUMENT

# Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007

SEPTEMBER 2009

Final

**Docket Number:**

FDA-2009-D-0260 (https://www.regulations.gov/docket/FDA-2009-D-0260)

**Issued by:**

(/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug)
Center for Food Safety and Applied Nutrition

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## I. Introduction

This document provides 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, we are issuing 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.

FDA's guidance documents, including this 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 the Food and Drug Administration 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

1. **How will FDA implement the FDAAA requirement to establish an electronic portal?**

   The Reportable Food electronic portal will be implemented as a part of FDA's new electronic system for collecting, submitting and processing adverse event reports and other safety information for all FDA-regulated products: the MedWatch$^{Plus}$ Portal.

2. **When will the Reportable Food electronic portal be available?**

   The Reportable Food electronic portal will be listed and available on the FDA.GOV website on September 8, 2009.

3. **Will the Reportable Food electronic portal as described in this guidance be the final version?**

   FDA will launch release 1.0 of the Reportable Food electronic portal on September 8, 2009. However, new versions (enhancements and upgrades) may be released subsequent to this launch as FDA continues to consolidate and improve its agency-wide data collection systems. 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.

4. **How will I access the Reportable Food electronic portal?**

   When the Reportable Food electronic portal becomes available, it will be accessible through a link on the FDA.GOV web site home page (http://www.fda.gov) under the heading "Report a Problem." Alternatively, you will be able to access the Reportable Food electronic portal directly by entering the following URL into your browser: https://www.safetyreporting.hhs.gov (https://www.safetyreporting.hhs.gov)

   Upon entering the site, you will be asked some general questions pertaining to the criteria for a Reportable Food Registry report and, based on your answers, you will be directed to the appropriate screens for submitting such reports.

5. **What should I do if the Reportable Food electronic portal is not operating?**

   FDA intends to post an announcement on http://www.fda.gov (http://www.fda.gov) as to how to submit a Reportable Food Registry report in the event that the Reportable Food electronic portal is not operating. If http://www.fda.gov is not operating, FDA recommends that you contact the FDA District Office serving your area. To find the phone number for the FDA District Office serving your area, you can look in your local telephone directory under U.S. Government, or call 1-888-SAFEFOOD (Monday-Friday, 10:00 AM to 4:00 PM, Eastern Standard Time) or 1-888-INFO-FDA.

6. **Will there be additional instructions available on how to use the Reportable Food electronic portal?**

   Yes. Instructions for completing the Reportable Food electronic portal screens are attached as an Appendix to this guidance. The same information will be found at the link "Instructions" on every Reportable Food electronic portal screen.

7. **Will the Reportable Food electronic portal allow electronic documents to be submitted in addition to the reportable food report?**

   Yes. After the Reportable Food Report is submitted, the reporter will have an opportunity to submit documents as attachments to an email. The reporter can also email documents at other times after the Reportable Food Report is completed by placing the unique identifier number for the associated report (also known as an Individual Case Safety Report number or ICSR number) in the subject line of an email to "SRPSupport@fda.hhs.gov (mailto:SRPSupport@fda.hhs.gov)".

8. **What file types may be submitted as attachments to the email you may send to FDA after completing the reportable food registry report?**

   The following file types are supported:

   - .pdf - Portable document format.

- .jpg, .jpeg - Image file formats.
- .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.

9. **Will the Reportable Food electronic portal allow partial submissions to be saved and will it save them automatically? Will I be able to review a report that I previously submitted?**

   No, release 1.0 of the Reportable Food electronic portal will not allow partial submissions to be saved, and it will not have an automatic save feature (in case you end your session before submitting your report). Also, you will not be able to use release 1.0 of the Reportable Food electronic portal to retrieve and review previously submitted reports.

   Enhanced features, such as the ability to save partial reports, the ability to retrieve previously submitted reports, and the ability to make edits to previously submitted information are planned for future versions of the Reportable Food electronic portal.

10. **How will future upgrades or enhancements of the Reportable Food electronic portal be announced?**

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

11. **Will the Reportable Food electronic portal be available in other languages?**

    No. The Reportable Food Electronic portal will only be available in English.

## B. Effective Date and Enforcement

12. **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 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 registry.

    You must comply with the requirements of the Reportable Food Registry (Section 417 of the FD&C Act) on September 8, 2009, and the prohibited act provisions of the FD&C Act related to the Registry will apply on that date. However, FDA intends to consider exercising enforcement discretion for a period of 90 days, until December 8, 2009, in circumstances where FDA determines that a responsible party has made a reasonable effort to comply with the requirements of section 417 of the FD&C Act and has otherwise acted to protect public health.

## C. Responsible Party

13. **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).

14. **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).

15. **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.

16. **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 individual submitting the amended report will need the unique identifier number (ICSR number) provided by FDA for the initial report so that this number may be included in any amended reports. FDA also encourages the individual submitting the amended report to provide his or her contact information, especially if it was not included in the initial report.

## D. Reportable Food

17. **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).

18. **Are animal feed and pet food included in the definition of reportable food?**

    Yes. 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."

19. **How is "food" defined in the FD&C Act?**

    The term "food" is defined as (1) articles used for food or drink for man or other animals (other than infant formula), (2) chewing gum, and (3) articles used for components of any such article.

    (Section 201(f) of the FD&C Act).

20. **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).

21. **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 (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.

22. **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.

23. **I received a positive microbiological test result indicating the presence of a pathogen in food. Based on this test result, the food would be "reportable." However, I retested the food for the pathogen and the second test result did not indicate the presence of the pathogen. 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.

## E. Submitting a Reportable Food Report

24. **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).

25. **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).

26. **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 the 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)

27. **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).

28. **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).

29. **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.

30. **If I received a product from my supplier that I found 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 that receives a reportable food is required to submit a report even if the responsible party has not shipped the food. The exception in Section 417(d)(2)(A)-(C) does not apply (see Question 26).

31. **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.

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

## F. Data for Initial Report

32. **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 (ICSR number) as discussed in response to Question 31 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).

33. **Will an initial report that does not include all of the data elements described in (1)-(7) in Question 32 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).

34. **Will the required data elements be clearly indicated in the Reportable Food electronic portal?**

    Yes. Required data elements for initial submissions will be clearly indicated by the Reportable Food electronic portal.

## G. Submitting an Amended Reportable Food Report

35. **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 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).

36. **Will a new unique number be assigned to amended reports?**

    Yes. In version 1.0 of the Reportable Food electronic portal, every submission (initial or amended report) receives a new unique number. FDA recognizes that the responsible party may need to amend the report as additional information or documents become available. When amending a report that was previously submitted, you must include the unique number (ICSR number) that was provided by FDA when the initial report was submitted and received so that FDA can link the amended report to the initial report.

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

37. **How do I amend a report after I have submitted it?**

    In version 1.0 of the Reportable Food electronic portal, you should complete all fields that were required for the initial report, and must include the unique number (ICSR number) that was received from the initial report. The particular information that is required depends on the circumstances.

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

38. **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

39. **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 8.

40. **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

41. **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 45 for more information.

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

42. **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 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).

43. **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 determine that a food is a reportable food, you must submit a reportable food report 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).

44. **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, will the**

**responsible party be required 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 will 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).

45. **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 35 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 35 above.

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

46. **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.

47. **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).

48. **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.

## J. Additional Contacts

49. **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 as specified under Section 417(d)(1) of the FD&C Act.

50. **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.

51. **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

52. **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).

53. **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).

54. **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).

55. **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).

### L. Animal Feed or Food Diversion

56. **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?**

    In the past, FDA has authorized the salvage of human or animal food considered to be adulterated for its intended use by diverting that food to an acceptable animal feed use. See response to Questions 57 and 58 for details about such authorization.

57. **Where should requests for human or animal food diversion to animal feed be submitted?**

    Requests for food diversion should be submitted 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/downloads/ICECI/Inspections/IOM/UCM123522.pdf.

58. **Where can the procedures for submitting requests to FDA for authorization 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 (/inspections-compliance-enforcement-and-criminal-investigations/compliance-policy-guides/cpg-sec-675200-diversion-adulterated-food-acceptable-animal-feed-use).

### M. Federal, State, and Local Public Health Officials

59. **Who else may submit instances of reportable food to FDA?**

    Federal, state and local public health officials may submit instances of reportable food to FDA through the Reportable Food electronic portal.

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

60. **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 that they may be required to submit a report.

## IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 36 minutes per reportable food report, 36 minutes per each notification to the immediate previous recipient and immediate subsequent recipient, and 15 minutes of recordkeeping per record per year, including the time to review instructions, search existing data sources, gather the

data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Food Defense, Communication and Emergency Response, HFS - 005, Center for Food Safety and Applied Nutrition Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information in § 7.46 of FDA's regulations (21 CFR 7.46) has been approved under OMB Control No. 0910-0249.

> An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for this information collection are 0910-0643 (expires 9/30/2017) and 0910-0645 (expires 05/31/2019).

## V. Appendix: Instructions for Completing the Reportable Food Registry Report

See attached instructions (/food/reportable-food-registry/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug).

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This document supercedes the previous version, issued June 2009.

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## Related Information

- Reportable Food Registry Guidance Documents & Regulatory Information (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/reportable-food-registry-guidance-documents-regulatory-information)

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# Submit Comments

Submit Comments Online (https://www.regulations.gov/docket/FDA-2009-D-0260)

You can submit online or written comments on any guidance at any time (see 21 CFR 10.115(g)(5))

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All written comments should be identified with this document's docket number: FDA-2009-D-0260 (https://www.regulations.gov/docket/FDA-2009-D-0260).

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