

Guidance for Industry

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

Draft Guidance

This guidance document is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance within 45 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1500.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
[Insert Month and Year]

FDA.2009.D.0260

GDL

Contains Nonbinding Recommendations

Draft — Not for Implementation

Table of Contents

I. Introduction

II. Background

III. Discussion

Guidance for Industry¹

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

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 the approach satisfies the requirements of the applicable statutes and regulations. If you want 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This draft guidance is intended to assist those parties responsible for complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration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 referred to as 417, Reportable Food Registry.

¹ This 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.

Contains Nonbinding Recommendations

Draft — Not for Implementation

Section 417 of the FD&C Act 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.

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

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

Contains Nonbinding Recommendations

Draft — Not for Implementation

Food electronic portal directly by entering the following URL into your browser:

<http://www.accessdata.fda.gov/scripts/ReportableFoodRegistry/>

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

Yes. Additional instructions and detailed directions will be available on the Reportable Food Registry web page on September 8, 2009.

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

You must comply with the requirements of the Reportable Food Registry (Section 417 of the FD&C Act) on September 8, 2009. The prohibited act provisions of the FD&C Act related to the Registry will also apply on September 8, 2009.

7. 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 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.

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

8. 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)).

9. What is a “reportable food?”

A “reportable food” is an article of food (other than 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.

Contains Nonbinding Recommendations

Draft — Not for Implementation

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

10. 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."

11. 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).

12. 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.

13. 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).

14. 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 shall 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).

15. When is a responsible party not required to submit a reportable food report to FDA?

Contains Nonbinding Recommendations

Draft — Not for Implementation

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).

16. 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).

17. What are the data elements that a responsible party must include in an initial report to FDA (i.e., when the responsible party determines that a food is a reportable food other than by receiving a notification under section 417 of the FD&C Act from another responsible party)?

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 16 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).

Contains Nonbinding Recommendations

Draft -- Not for Implementation

18. Will an initial report that does not include all of the data elements described in (1)-(7) in Question 17 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.

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

19. 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.

20. 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 they submitted to FDA to include the contact information for the immediate previous source and/or immediate subsequent recipient of the article of food directly linked in the supply chain and notified by the responsible party;
- Provide notification to the immediate previous source and/or immediate subsequent recipient 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

Contains Nonbinding Recommendations

Draft — Not for Implementation

to the recipient's immediate previous source and/or immediate subsequent recipient), 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).

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

No. 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 that was provided by FDA when the initial report was submitted and received.

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

22. If a responsible party (Party A) notifies the immediate previous source or immediate subsequent recipient of the article of food (Party B), as required by FDA, should Party B submit a report to FDA or provide a notification to Party B's own immediate previous source and/or immediate subsequent recipient?

Yes, if Party B meets the definition of a responsible party, FDA recommends that Party B submit a report to FDA as soon as practicable, and within 24 hours after receiving the notification regarding the reportable food (section 417(d)(1) of the FD&C Act). FDA may also 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 and/or immediate subsequent recipient of the reportable food (section 417(d)(7) of the FD&C Act). See the response to Question 25 for more information.

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

23. 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 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 or immediate subsequent recipient 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).

Contains Nonbinding Recommendations

Draft — Not for Implementation

24. 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 are 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).

25. 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 20 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 or to the immediate subsequent recipient that includes the data elements listed in the answer to question 20 above.

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

26. How do responsible parties provide a notification to the immediate previous source and immediate subsequent recipient of the article of food?

Notification to the immediate previous source and immediate subsequent recipient 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 by one of the above methods and/or documented in an appropriate manner.

27. 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 or immediate subsequent recipient?

- 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;

Contains Nonbinding Recommendations

Draft — Not for Implementation

- 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 provided by FDA.

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

28. 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.

29. 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 electronically 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.

30. 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).

31. 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).

Contains Nonbinding Recommendations

Draft — Not for Implementation

32. 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).

33. 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.

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

34. 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 35 and 36 for details about such authorization.

35. 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/ICECI/Inspections/IOM/ucm124008.htm>.

36. 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

Contains Nonbinding Recommendations

Draft – Not for Implementation

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074694.htm>.

37. 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).

38. 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.