

# Guidance for Industry<sup>1</sup>

## Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007

This guidance represents 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 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, 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. This guidance document provides further guidance to industry on submitting a single reportable food report to FDA covering reportable food located at more than one of a company's facilities.

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 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 a question and answer addressing the circumstance where reportable food is located at more than one of a company’s facilities. In September 2009, FDA issued a related guidance document entitled "[Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007](#)".

### III. Questions and Answers

**Q. 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?**

A. 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 following file types are supported as attachments:

- .pdf – Portable document format.
- .jpg, .jpeg – Image file format.
- .tiff - Tagged image file format.

- .rtf – Rich text format.
- .txt – Text format.
- .xls – Spreadsheet file format.
- .doc, docx – Word processing document formats.
- .wpd – Word processing document format.

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\*

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<sup>1</sup> 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.