Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories (2016 Edition): Guidance for Industry

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U.S. Department of Health and Human Services
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Table of Contents

I. Introduction

II. Background

III. Discussion

IV. Updates to Food Product Categories

Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories (2016 Edition): Guidance for Industry[1]

I. Introduction

Because of Congress's explicit statutory authorization to effectuate certain binding requirements related to food product categories in food facility registrations based on findings in guidance, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirements that guidances not establish legally enforceable responsibilities and that they prominently display a statement of the document's nonbinding effect. See 21 CFR 10.115(d) and (i). This guidance contains findings that serve as the predicates for binding requirements on industry.

This guidance represents the Food and Drug Administration's (FDA's) conclusion on the necessity of food product categories in food facility registrations submitted to FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d), as added by section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) and amended by section 102 of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353). This guidance also updates the food product categories in food facility registrations.

Section 415(a)(2) of the FD&C Act provides, in relevant part, that a food facility must submit to FDA a registration containing information about the general food category (as identified in 21 CFR 170.3 or any other food categories as determined appropriate by FDA, including "by guidance") of a food manufactured/processed, packed or held at such facility, if the Agency determines "through guidance" that such information is necessary.

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited, and FDA's guidances also ordinarily include the

[1] This guidance has been prepared by the Office of Compliance, Division of Field Programs and Guidance in the Center for Food Safety and Applied Nutrition and the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

following standard paragraph:

> This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

FDA is not including this standard language in this guidance because it is not an accurate description of the effect of this guidance. This guidance contains findings that serve as the predicates for binding requirements on industry. As provided in section 305 of the Bioterrorism Act, this guidance contains FDA's finding that inclusion of food product categories in food facility registrations is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency. Based in part on this finding, FDA's regulations for the registration of food facilities in 21 CFR Part 1, Subpart H require that a food facility submit a registration to FDA containing information on applicable food product categories manufactured/processed, packed, or held at such facility. As provided in section 102 of FSMA, this guidance contains FDA's finding that inclusion of food product categories other than just those identified in 21 CFR 170.3 is also necessary to facilitate such rapid communications. In addition, this guidance sets forth the other food product categories to be included in food facility registrations as determined to be appropriate by FDA, as provided by section 102 of FSMA.

To the extent that this guidance modifies food product categories for food facility registration pursuant to section 415 of the FD&C Act, it has a binding effect. For these reasons, FDA is not including the standard guidance paragraph in this guidance.

II. Background

On October 10, 2003, FDA issued an interim final rule to implement section 305 of the Bioterrorism Act that generally required domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003 (See 68 FR 58894). The interim final rule also required facilities to submit registrations to FDA containing information regarding applicable food product categories as identified in 21 CFR 170.3. On October 3, 2005, FDA issued a final rule for food facility registration, which generally confirmed the interim final rule (70 FR 57505). On July 14, 2016, we published a final rule amending the registration regulations that confirmed the requirement to submit food product category information (81 FR 45912). Under 21 CFR 1.232(a)(7), food facilities must submit the applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537.

Section 415(a)(2) of the FD&C Act, as added by section 305 of the Bioterrorism Act, provided in relevant part that, when determined necessary by FDA "through guidance," a registrant must submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in 21 CFR 170.3) of food manufactured, processed, packed, or held

at such facility. On July 17, 2003, FDA issued a guidance stating that FDA had determined that the inclusion of food product categories in food facility registrations was necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency (see 68 FR 42415).

FSMA, enacted on January 4, 2011, amended section 415 of the FD&C Act. Section 415(a)(2) of the FD&C Act now provides, in relevant part, that, when determined necessary by FDA "through guidance," a registrant must submit a registration to FDA containing information necessary to notify FDA of the general food category (as identified in 21 CFR 170.3 or any other food categories, as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility.

On October 24, 2012, we issued the previous edition of this guidance (77 FR 64999), stating that the guidance contained FDA's determination that information about food product categories in food facility registrations is necessary for a quick, accurate, and focused response to a food safety related issue or incident, an actual or potential bioterrorist incident, or other food-related emergency, and also identifying the additional food product categories included as mandatory fields in food facility registrations.

FDA believes that it is necessary for a food facility to submit to FDA a registration containing the general food category as identified in 21 CFR 170.3 and any other food categories as identified below, for a quick, accurate, and focused response to a food-safety related issue or incident, an actual or potential bioterrorist incident, or other food-related emergency.

III. Discussion

Information about a facility's food product categories is a key element to allow for rapid communications between FDA and facilities directly impacted by actual or potential bioterrorist attacks, other food-related emergencies, or food safety incidents. Information about the categories of food a facility handles currently helps FDA conduct investigations and surveillance operations in response to food-related emergencies. These categories also enable FDA to quickly alert facilities potentially affected by such an incident if FDA receives information indicating the type of food affected. For example, if FDA receives information indicating that soft drinks could be affected by a bioterrorist incident or other food-related emergency, FDA is able to alert soft drink manufacturers/processors, packers, and holders about the incident. Additionally, the food product categories, in conjunction with the prior notification requirements in 21 CFR Part 1, Subpart I, help FDA verify that imported products are correctly identified by where and by when they were produced. For example, if the registration information identifies a facility as producing only dairy products and FDA receives a prior notice for a shipment of nuts purporting to have been produced at that facility, FDA can examine the shipment to verify its contents based on the discrepancy between the registration information and prior notice data. FDA finds that requiring food product category information as part of a facility's registration is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency.

Based on section 305 of the Bioterrorism Act and FDA's finding that the inclusion of food

product categories in a facility's registration is necessary (see 68 FR 42415), FDA included food product categories as mandatory fields on the food facility registration form (see 68 FR 58894 at 58924). As specified in 21 CFR 1.232(a)(7), FDA's food facility registration regulations require registrants to indicate food product category information.

IV. Updates to Food Product Categories[2]

Section 415(a)(2) of the FD&C Act, as amended by section 102 of FSMA, provides in relevant part that a registrant must submit a registration to FDA containing certain information and when determined necessary by FDA "through guidance," the general food category (as identified in 21 CFR 170. 3 or any other food categories as determined appropriate by FDA, including by guidance) of any food manufactured, processed, packed, or held at such facility. FDA believes that the following additional food product categories are necessary and appropriate for food facility registration and has included such categories as mandatory fields in the food facility registration form:

Additional Food Product Categories for Foods for Human Consumption:

- Acidified Food (see 21 CFR 114.3(b)) (Deleted);
- Baby (Infant and Junior) Food Products Including Infant Formula;
- Cheese and Cheese Product Categories: Soft, Ripened Cheese; Semi-Soft Cheese; Hard Cheese; Other Cheeses and Cheese Products;
- Dietary Supplement Categories: Proteins, Amino Acids, Fats and Lipid Substances; Animal By-Products and Extracts; Herbals and Botanicals;
- Fishery/Seafood Product Categories: Fin Fish, Whole or Filet; Other Shellfish; Ready to Eat (RTE) Fishery Products; Processed and Other Fishery Products; Molluscan Shellfish*
- Fruit and Fruit Products: Fresh Cut Produce; Raw Agricultural Commodities; Other Fruit and Fruit Products;
- Fruit or Vegetable Juice, Pulp or Concentrate Products;
- Low Acid Canned Food (LACF) Products (see 21 CFR 113.3(n)) (Deleted);
- Nuts and Edible Seed Product Categories: Nut and Nut Products; Edible Seed and Edible Seed Products;
- Shell Egg and Egg Product Categories: Chicken Egg and Egg Products; Other Egg and Egg Products;
- Vegetable and Vegetable Product Categories: Fresh Cut Products; Raw Agricultural Commodities; Other Vegetable and Vegetable Products; and
- If none of the human food categories listed in the registration form apply, print the applicable food category or categories.

Additional Food Product Categories for Foods for Animal Consumption:

[2] Food product categories for foods for human and animal consumption marked with asterisks are new. In addition, we have listed categories that we are deleting by marking them as "deleted," and we have noted where we are replacing certain categories with new categories.

- Grain or Grain Products (i.e., barley, grain sorghums, maize, oat, rice, rye, wheat, other grains or grain products);
- Oilseed or Oilseed Products (i.e., cottonseed, soybeans, other oilseeds or oilseed products);
- Alfalfa Products or Lespedeza Products;
- Amino Acids or Related Products;
- Animal Protein Products* (Replaces Animal Derived Products);
- Botanicals and Herbs*;
- Brewer Products;
- Chemical Preservatives;
- Citrus Products;
- Distillery Products;
- Direct Fed Microbials*;
- Enzymes;
- Fats or Oils;
- Fermentation Products;
- Forage Products*;
- Human food by-products not otherwise listed*;
- Marine Products;
- Milk Products;
- Minerals or Mineral Products;
- Miscellaneous or Special Purpose Products;
- Molasses or Molasses Products;
- Non-protein Nitrogen Products;
- Peanut Products;
- Processed Animal Waste Products* (Replaces Recycled Animal Waste Products);
- Screenings;
- Technical Additives*;
- Vitamins or Vitamin Products;
- Yeast Products;
- Mixed Feed (e.g., poultry, livestock, equine);
- Pet Food;
- Pet Treats or Pet Chews;
- Pet Nutritional Supplements (e.g., vitamins, minerals); and
- If none of the above food categories apply, print the applicable food category or categories (that does not or do not appear above).

To view Form FDA 3537 (OMB No. 0910-0502), please click on the following link at https://www.access.fda.gov. If you would like to request a paper copy of Form FDA 3537 be sent to you, please contact the FDA staff responsible for this guidance as listed on the title page.