Food

Draft Guidance for Industry: Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories

Draft-Not for Implementation

August 2012

Also available in PDF (36KB)[1].

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1988 or the Center for Veterinary Medicine (CVM) at 240-276-9207.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Foods
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
August 2012

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Draft Guidance for Industry[1]
Necessity of the Use of Food Categories in Food Facility Registrations and Updates to Food Categories

I. Introduction

This draft guidance represents the Food and Drug Administration's (FDA's) conclusion on the necessity of food categories in food facility registrations submitted to FDA under section 415 of the Federal Food Drug and Cosmetic Act (FD&C Act), 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). Section 415(a)(2) of the FD&C Act provides in relevant part that a food facility is required to submit to FDA a registration containing information about the general food category (as identified in 21 CFR 170.3 or any other food category 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. Because of Congress's explicit statutory authorization to establish a binding requirement based on a finding 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) (i).

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 the agency's guidances also ordinarily include the following standard paragraph:

> This guidance represents the Food and Drug Administration'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 appropriate number listed on the title page of this guidance.

FDA is not including this standard language in this draft 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 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 currently require that a food facility submit a registration to FDA containing information on applicable food product categories as identified in 21 CFR 170.3 for food manufactured/processed, packed, or held at such facility. As provided in section 102 of FSMA, this draft guidance contains FDA's finding that inclusion of other food categories in food facility registrations is also necessary to facilitate such rapid communications. In addition, this draft guidance sets forth the other food categories to be included in food facility registrations as determined to be appropriate by FDA for the purposes of food facility registration. Insofar as this guidance, when finalized, modifies food categories for food facility registration pursuant to section 415 of the FD&C Act, it will have binding effect. For these reasons, FDA is not including the standard guidance paragraph in this draft guidance.

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II. Background

On October 10, 2003, FDA issued an interim final regulation 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 regulation 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 regulation confirming the interim final regulation, as corrected by a technical amendment (69 FR 29428 (May 24, 2004)), and responding to comments (70 FR 57505).

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 the agency 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, as amended by section 102 of FSMA, 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.

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, if applicable, for a quick, accurate, and focused response to a food-safety related issue or an actual or potential bioterrorist incident, other food-related emergency, or food safety incident.

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III. Discussion

FDA believes that information about a facility's food 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 assists FDA in conducting 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 categories, in conjunction with the prior notification requirements in 21 CFR Part 1, Subpart I aids FDA in verifying 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 inspect the shipment for verification based on the discrepancy. 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), the agency included food product categories identified in 21 C.F.R. 170.3 as mandatory fields on the food facility registration form. Further, FDA's current food facility registration regulations require registrants to indicate in their registrations which of the food categories listed in 21 CFR 170.3 apply to the foods they manufacture/process, pack, or hold.

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IV. Other Food Categories

Section 102 of FSMA, provides in relevant part that FDA may, through guidance, determine that additional food categories, other than those listed in 21 CFR 170.3, are appropriate for the purposes of food facility registration under section 415 of the FD&C Act. FDA believes that the following additional food categories are appropriate for food facility registration and will include such categories as mandatory fields in the food facility registration form when FDA finalizes this guidance:

Additional Food Categories for Foods for Human Consumption:

- Acidified Food (see 21 CFR 114.3(b));
- 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;
- Fisher/Seafood Product Categories: Fin Fish, Whole or Filet; Shellfish; Ready to Eat (RTE) Fishery Products; Processed and Other Fishery Products;
- 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));
- 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
- Baby (Infant and Junior) Food Products Including Infant Formula.

Additional Food Categories for Foods for Animal Consumption[2]:

- 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-Derived Products;
- Brewer Products;
- Chemical Preservatives;
- Citrus Products;
- Distillery Products;
- Enzymes;
- Fats or Oils;
- Fermentation Products;
- Marine Products;
- Milk Products;
- Minerals or Mineral Products;
- Miscellaneous or Special Purpose Products;
- Molasses or Molasses Products;
- Non-protein Nitrogen Products;
- Peanut Products;
- Recycled Animal Waste Products;
- Screenings;
- Vitamins or Vitamin Products;
- Yeast Products;
- Mixed Feed (e.g., poultry, livestock, equine);
- Pet Food;
- Pet Treats or Pet Chews;
- Pet 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).

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[1] Most of the additional food categories for foods for animal consumption are currently included on the food facility registration form as optional fields.

[2] This draft 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.

The above guidance document supercedes the previous version[3] dated July 2003.

Page Last Updated: 08/15/2012
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