AFFI AMERICAN FROZEN FOOD INSTITUTE

Toolkit: Regulatory Requirements for Food Labeling and Inspection

An Exclusive Resource for AFFI Members

Introduction

The American Frozen Food Institute has developed this toolkit as a member-guide to basic food labeling requirements and food safety inspections. The information contained in this guide covers current U. S. Food and Drug Administration (FDA) and U. S. Department of Agriculture (USDA) regulations pertaining to labeling, food facility and product inspections, and regulatory compliance. This document also covers key aspects of validation and verification activities in food facilities as applicable within the FDA and USDA jurisdictions. Also provided is an overview to assist member companies to understand and manage food safety and regulatory related crises, particularly with respect to market withdrawals and recalls of their products.

The toolkit also provides information on other topics such as bioengineered disclosure requirements, definition of 'Natural', and related topics.

Important Notice

This toolkit represents a user-friendly comprehensive guide designed to assist members of the American Frozen Food Institute with reviewing and understanding key components of food labeling, regulatory inspections, and compliance with food safety regulations for food and beverage products and manufacturing facilities. Federal, state, and local regulations will a *Lm*ost certainly continue to change over time; therefore, members are cautioned that this toolkit does not purport to provide fail-safe solutions for all issues related to food product labeling, regulatory inspections, and compliance. While the toolkit endeavors to present current regulatory requirements, it is not intended to be a substitute for careful review or application of the regulatory framework as it relates to each member's own products and operations. **THIS TOOLKIT PROVIDES GENERAL INFORMATION AND GUIDANCE BUT IS NEITHER INTENDED AS NOR DOES IT SUBSTITUTE FOR LEGAL COUNSEL**.

Contact

For questions about this publication, please contact Dr. Donna Garren, Executive Vice President, Science and Policy, American Frozen Food Institute at dgarren@affi.com or (202) 303-3400.

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Labeling

Definitions

- *Information Panel* – The label panel that is immediately contiguous and to the right of the principal display panel, as seen by the consumer. If that label panel is too small to accommodate all required label information, the information panel is the label panel immediately contiguous and to the right of that panel. If the top of the container is the principal display panel, the information panel may be any label panel adjacent to the principal display panel.
- *Label* – Any written, printed, or graphic matter on or affixed to the immediate container of the food.
- *Labeling* – Includes the "label" and any other written, printed, or graphic matter accompanying the article of food in interstate commerce or while it is held for sale (e.g., store displays, freezer tags, website selling food, website identified on food's label).
- *Principal display panel (PDP)* – The part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. In the case of a rectangular box, the side of the box most likely to be displayed at retail. There can be multiple PDPs. The area of the PDP is the height times the width of that side.

FDA Labeling Requirements

Mandatory Label Information

1. Placement of Label Information

The statement of identity and net contents declaration must appear on the PDP. Other mandatory information (i.e., Nutrition Facts, ingredients declaration, and signature line) may appear on either the PDP or the information panel, but typically appears on the information panel.

All mandatory label information appearing on the information panel must appear together without any intervening non-mandatory label information.

2. Statement of Identity

The statement of identity must appear prominently and conspicuously on the PDP and must comply with the following graphic requirements:

- It must appear in bold type;
- It must appear in a type size that is "reasonably related" to the size of the largest printed matter on the PDP. Under FDA guidance, the statement of identity should generally be at least half the size of the largest printed matter on the PDP; and
- It must appear in lines generally parallel to the base on which the product rests.

The statement of identity must be the name required by law, such as the name required in a standard of identity, if any exists. If none exists, then the statement of identity must be the common or usual name of the food, which may be a name established by common usage. The common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. If there is no common or usual name for the food, it must be an appropriately descriptive name. A descriptive name is one that describes the basic nature or the characterizing properties or ingredients of the food in as simple and direct terms as possible (e.g., "pizza with olives and capers").

3. Net Contents Declaration

The net contents declaration must appear on the PDP and must comply with the following graphic requirements:

- It must appear in bold type;
- It must appear in a type size based on the area of the PDP
    - If the PDP has an area of 5 square inches or less, it must be at least 1/16 inch high;

- If the PDP has an area of more than 5 square inches but not more than 25 square inches, it must be at least 1/8 inch high;
- If the PDP has an area of more than 25 square inches but not more than 100 square inches, it must be at least 3/16 inch high;
- If the PDP has an area of more than 100 square inches but not more than 400 square inches, it must be at least ¼ inch high; and
- If the PDP has an area of more than 400 square inches, it must be at least ½ inch high;

- It must appear in the bottom 30 percent of the PDP;
- It must appear as a distinct item separated from other label information above or below it by a space at least equal to the height of the declaration itself, and separated from other label information to the right or left of it by a space at least equal to two times the width of the letter "N"; and
- It must appear in lines generally parallel to the base on which the package rests.

For solid foods like a waffle, the net contents declaration must be in the form of weight. It must include both avoirdupois (e.g., ounces, pounds) and metric (e.g., grams, kilograms) measures; either may appear first. FDA uses the following conversion factor for compliance purposes: 1 ounce = 28.3495 grams. If there is any difference between the net weight expressed in metric measure and the net weight expressed in avoirdupois measure, FDA will expect the product to meet the higher of the two amounts.

The net weight should use the largest appropriate unit of measure (e.g., 1.5 pounds, 1 ½ pounds, or 1 pounds 8 ounces – not 24 ounces). To facilitate value comparisons between products, FDA generally permits "dual avoirdupois" declarations (e.g., "1.5 pounds (680 gram) 24 ounces").

The net weight must declare the weight of the food exclusive of wrapping and other packaging. It must be accurate. While reasonable variations due to gain or loss of moisture during good distribution practice or unavoidable deviations consistent with good manufacturing practice are permitted, such deviations may not be unreasonably large. Under FDA policy, an average short weight (based on 48 units sampled) of 1% or more is a violation.

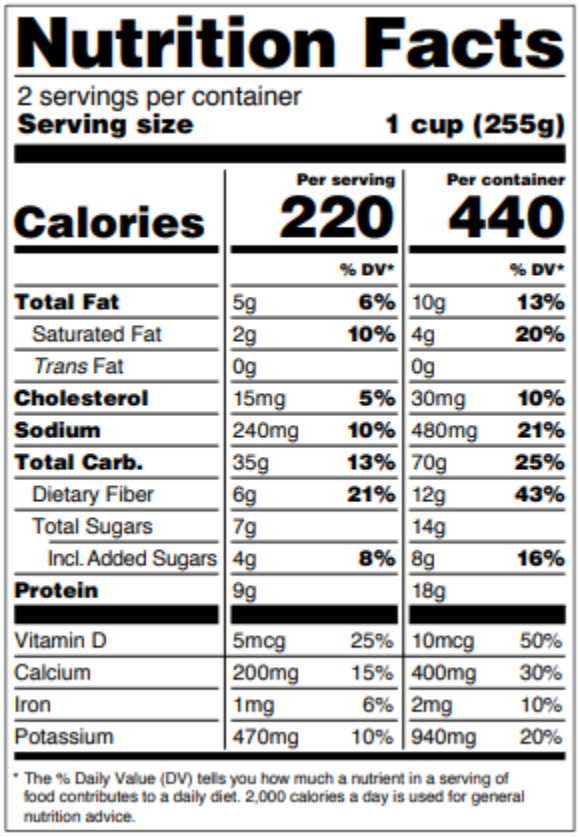
4. Nutrition Facts

A Nutrition Facts panel is required on all foods offered for sale, unless exempt. Proposed revisions to Nutrition Facts requirements are set forth at the end of this section.

a. Serving Size

The Serving Size declared in Nutrition Facts is based on the reference amount customarily consumed (RACC) for that product category. More resources here. For a product that contains less than 200 percent of the applicable RACC, the serving size is the entire container. For a product that contains 200-300% of the applicable

RACC, it must bear dual-column labeling, “per serving” and “per container”, unless one of the exemptions listed in 21 CFR 101.9(b)(12) applies. An example of the dual-column label is below:



Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

b. Determining nutrient values

Manufacturers may determine a food’s nutrient values by nutrient analysis or using an FDA-approved database. For manufacturers that wish to use a database, FDA has published a manual entitled Guidance for Industry: Guide for Developing and Using Data Bases for Nutrition Labeling.

For certain nutrients, manufacturers must make and keep records to verify the amount of the nutrient. For example, when a product contains both naturally occurring and added sugars, a company must keep records of the amount of added sugars added to the food during processing. A similar requirement applies related to dietary fibers, vitamin E, and folate/folic acid. More details are found in 21 C.F.R. § 101.9(g)(10).

c. Nutrient information

Generally, the following nutrients must be declared in Nutrition Facts:

- Total Fat
    - Saturated Fat
    - Trans Fat
- Cholesterol
- Sodium
- Total Carbohydrate
    - Dietary Fiber
    - Total Sugars
    - Added Sugars
- Protein
- Vitamin D
- Calcium
- Iron
- Potassium

Certain other nutrients may also be declared. In addition, if a claim is made about any nutrient, that nutrient must be declared.

If the food contains insignificant amounts of many nutrients (i.e., saturated fat, trans fat, cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and/or potassium), those nutrients need not be separately declared but instead may be listed in a footnote that reads “Not a significant source of [names of nutrients present in insignificant amounts].”

Added sugars was recently added to the list of mandatory nutrients to declare. Added sugars are defined as “either added during the processing of foods, or are packaged as such, and include sugars (free, mono and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type.” There are exceptions for fruit or vegetable juice concentrates that count towards the percent juice declaration or are used for Brix standardization, fruit or vegetable juice concentrated from 100% juices sold to consumers, and certain fruit juice concentrates used in jellies, jams, or preserves. FDA has provided guidance on the scope of the added sugars definition and how to determine the number of grams of added sugars in a product. Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals | FDA.

For dietary fiber, FDA recently changed the definition of this nutrient for purposes of nutrition labeling. Under the new definition, dietary fiber includes only those nondigestible carbohydrates that are either (1) intrinsic and intact in plants, or (2) determined by FDA to have beneficial physiological effects to human health. FDA has provided extensive guidance on which ingredients count as dietary fiber. Questions and Answers on Dietary Fiber | FDA. Guidance for Industry: The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels | FDA. The regulation and guidance currently provide that the following count as fibers under the second

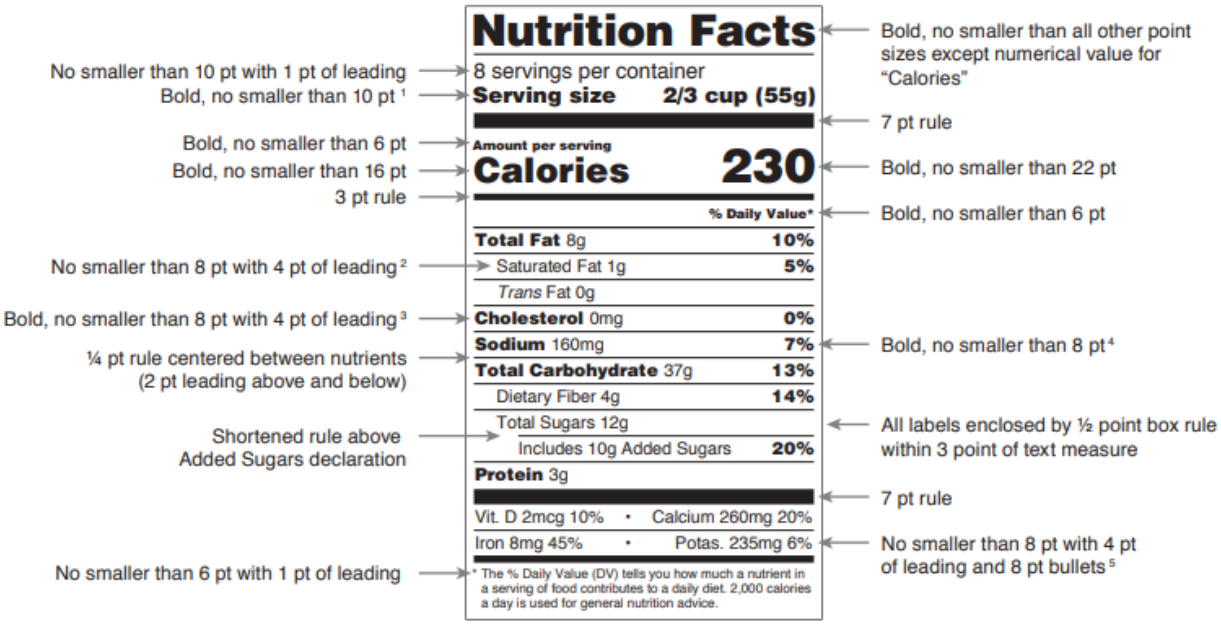
(beneficial health effects) prong: beta-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, hydroxypropy *Lm*ethylcellulose, mixed plant cell wall fibers (a broad category that includes fibers like sugar cane fiber and apple fiber, among many others), arabinoxylan, alginate, inulin and inulin-type fructans, high amylose starch (resistant starch 2), galactooligosaccharide, polydextrose, resistant maltodextrin/dextrin, cross linked phosphorylated RS4, glucomannan, acacia (gum arabic). If a fiber is not "intrinsic and intact," and is not on this list or has not otherwise been recognized by FDA to have a beneficial physiological health effect for humans, it does not count towards the dietary fiber declaration in the Nutrition Facts Panel.

d. Graphic requirements

The Nutrition Facts panel must comply with the following graphic requirements:

- It must be set off by a hairline (i.e., in a box);
- It must use a single, easy-to-read type style in all black or one-color type, with both upper case and lower case letters;
- Letters may not touch;
- A least one-point leading must be used between lines of text;
- A centered hairline must appear below the headings "Amount Per Serving" and "% Daily Value" and must separate nutrients;
- A bar must separate "Amount Per Serving" from the serving size information above it, separate "% Daily Value" from the calorie information above it, and separate "Protein" from the vitamin and mineral information below it;
- All information must appear in at least 8 point type, except: (a) the headings "Amount Per Serving" and "% Daily Value" and any footnotes must appear in at least 6 point type; and (b) the title "Nutrition Facts" must appear in a type size larger than any other information in the box except for calories; (c) the serving size information must appear in at least 10 point type; (d) "Calories" must be in at least 16 point type and the numeric value for calories must be in at least 22 point type; and
- The following information (and no other information) must appear in bold type: "Nutrition Facts," "Serving size" and the amount of the serving size, "Amount per Serving," "Calories," the amount of calories, "% Daily Value," the names of all macronutrients that are not indented, and all % DV amounts for macronutrients.

Below is an example of the format:



† Text in bold font is Helvetica Black; text not bolded is Helvetica Regular; leading may be "at least" the point size indicated in all instances

[1] "Serving size" declaration may be decreased to no smaller than 8 pt bold if additional space is needed for the declaration

[2] Saturated fat, *Trans* Fat, Dietary Fiber, Total Sugars, Added Sugars, voluntary nutrients (if listed) and their g/mg values: No smaller than 8 pt with 4 pt of leading

[3] Total Fat, Cholesterol, Sodium, Total Carbohydrate, and Protein: Bold, no smaller than 8 pt with 4 pt of leading

[4] % Daily Values for nutrients that appear between 7 point rules: Bold, no smaller than 8 pt.

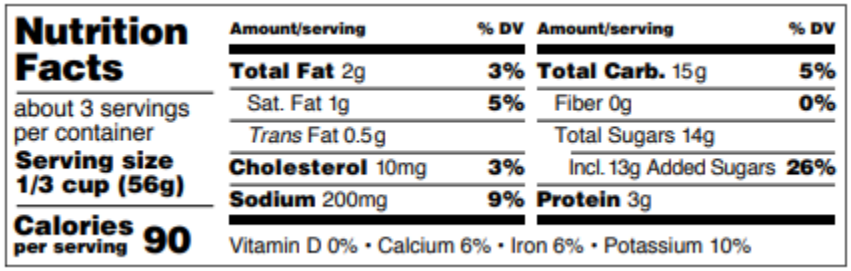
[5] Vit. D, Calcium, Iron, Potas., voluntary nutrients (if listed) and their mg/mcg values and % Daily Values: No smaller than 8 pt and with 4 pt of leading

e. Display Options

The standard or vertical display may always be used for Nutrition Facts. If there is insufficient space to present the footnote below the nutrient declarations regarding daily calorie intake, or any information on voluntarily declared vitamins and minerals, the footnote and/or nutrient information may be placed to the right of the main box.

The tabular display may be used if: (1) the package has available label space of 40 square inches or less; or (2) in the case of larger packages, there is insufficient continuous vertical space (about 3 inches) to accommodate the vertical display up to and including the declaration for iron on any single label panel.

The tabular display for small and intermediate sized packages looks like this:



Nutrition Facts

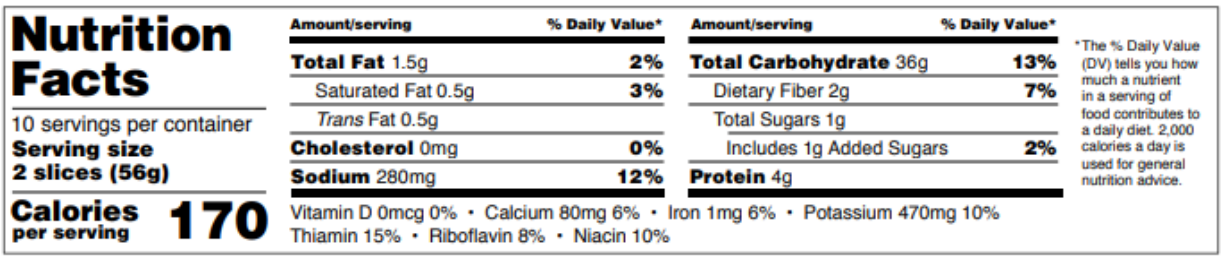
about 3 servings per container
Serving size 1/3 cup (56g)

Calories per serving 90

Amount/serving	% DV	Amount/serving	% DV
Total Fat 2g	**3%**	**Total Carb.** 15g	**5%**
Sat. Fat 1g	**5%**	Fiber 0g	**0%**
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Sodium 200mg	**9%**	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%

The tabular display for larger packages looks like this:



Nutrition Facts

10 servings per container
Serving size 2 slices (56g)

Calories per serving 170

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 36g	**13%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**7%**
Trans Fat 0.5g		Total Sugars 1g	
Cholesterol 0mg	**0%**	Includes 1g Added Sugars	**2%**
Sodium 280mg	**12%**	**Protein** 4g	

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

The linear display may be used only if the package has 40 or less square inches of available label space and cannot accommodate the tabular display on any label panel. The linear display looks like this:

Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5, Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (6% DV).

f. Exemptions

FDA regulations include several exemptions from nutrition labeling. Labeling exemptions that may be relevant to frozen food manufacturers include the following:

- Foods not offered for sale (*e.g.*, donated foods, promotional offerings);
- Foods for sale or use by restaurants or other establishments that prepare food for immediate consumption; and
- Low volume products (fewer than 100,000 units sold annually in the U.S.) that are manufactured, packed, or distributed by a small business (fewer than 100 full-time equivalent

All ingredients used, except for incidental additives, must be declared in descending order of predominance by weight. However, minor ingredients present in amounts of 2% or less by weight may be listed at the end of the ingredients declaration following a statement such as "Contains __% or less of [names of minor ingredients]" (with the blank filled in with 0.5%, 1%, 1.5%, or 2%).

a. Exemption for incidental additives

Incidental additives are exempt from ingredient declaration. "Incidental additives" are defined as ingredients that are present in the finished food at an insignificant level and have no technical or functional effect in the finished food. For sulfite agents, FDA has defined an insignificant level as <10 parts per million (ppm). FDA has not defined an insignificant level for other ingredients, but it is generally considered to be quite low. If an incidental additive is a "major food allergen" (refer to Allergen Labeling section), then the exemption is lost, and allergen labeling is required. There is also an exemption for processing aids.

b. Listing by common or usual name

Each ingredient must be listed using its specific common or usual name. However, certain ingredients may be listed using a generic term (e.g., "spices," "natural flavor," "artificial flavor," "added color"). For ingredients considered by FDA to be spices, see FDA Compliance Policy Guide Section 525.750. Please note that FDA has standard of identity regulations for many cheeses (e.g., "mozzarella cheese," "asiago cheese"), for flours (e.g., "enriched flour," "whole wheat flour"), food dressings and flavorings (e.g., "French dressing", "mayonnaise", "vanilla extract", "vanilla powder"), other dairy products (e.g., "milk", "cream", "butter", "frozen desserts"), cacao products, and other products. If an ingredient is listed using a standardized name, the ingredient must comply with the relevant standard of identity.

c. Composite ingredients

If an ingredient is a composite ingredient (i.e., the ingredient consists of two or more sub-ingredients), it may be listed in either of the following two ways:

- By listing the composite ingredient by its common or usual name, followed by a parenthetical listing of its sub-ingredients in descending order of predominance (e.g., Cheese Sauce (Cheddar Cheese (Cultured Milk, Salt, Enzymes), Water, Whey Powder, Cayenne Pepper, Salt, Disodium Phosphate, Nutmeg, yellow 5), Water, Whey Powder, Salt, Xanthan gum, Citric acid, Lactic acid).

- By listing each of the sub-ingredients in descending order of predominance in the finished food, without listing the composite ingredient (e.g., Water, Cheddar Cheese (cultured milk, salt, enzymes), Whey powder, Salt, Xanthan Gum, Cayenne Pepper, Disodium Phosphate, Citric Acid, Lactic Acid, Nutmeg, Yellow 5)

d. Ingredients subject to special requirements

Chemical preservatives must be listed by their common or usual name, followed by a description of their function (e.g., “preservative,” “to retard spoilage,” “to promote color retention”).

Colorings may be listed simply as “added color” or “artificial color,” except: (a) certified colors must be listed by their specific name (e.g., “FD&C Yellow No. 5” or “Yellow 5”); and (b) two non-certified colors, carmine and cochineal extract, must be listed by their specific names, because some consumers are allergic to them. However, the listing must inform consumers that the ingredient is functioning as a coloring (e.g., “added color,” “annatto extract (color)”).

e. Ingredients eligible for “and/or” labeling

For certain ingredients, where the manufacturer is unable to adhere to a constant pattern of use, FDA will permit so-called “and/or” labeling. For example, if a manufacturer uses three different vegetable oils in its product but is not certain whether all three oils will be used in any given production lot, the manufacturer may list the ingredient as “vegetable oil (canola, soy, and/or sunflower seed oil).” “And/or” labeling is permitted only in the case of foods in which added fats or oils are not the predominant ingredient and only if the manufacturer is unable to predict which fat or oil ingredient will be used.

f. Allergen labeling

FDA considers the ingredients declaration the label location where allergic consumers should look for information about major food allergens. See Allergen labeling section.

g. Graphic requirements

The ingredients declaration must appear in type at least 1/16 inch high. This minimum type size applies to lower case letters (e.g., the letter “o”) if used. You may use all upper-case letters to conserve label space.

6. Signature Line

The “signature line” must include the name and place of business of the manufacturer, packer, or distributor of the food. Specifically, it must include:

- The actual corporate name of the manufacturer, packer, or distributor (which may be preceded or followed by the name of a particular division of the corporation);
- If the company named is not the manufacturer, a qualifying phrase to indicate the company’s relationship to the product (*e.g.*, “Distributed by,” “Manufactured for”);

- The company's place of business (*i.e.*, either the location where the food was manufactured, packed, or distributed or the company's principal place of business), including street address, city, state, and zip code. If the company is listed in a current city or phone directory, the street address may be omitted.

The signature line must appear in type at least 1/16 inch high. This minimum type size applies to lower case letters (e.g., the letter "o") if used. You may use all upper-case letters to conserve label space.

If the product is imported and the signature line contains a U.S. address, the country of origin marking (see Country of Origin Marking section) should appear adjacent to the signature line to avoid misleading consumers about the food's geographic origin.

7. Country of Origin Marking

Depending on the type of food and its origin, a food may be subject to country-of-origin labeling requirements under Customs and Border Protection (CBP or "Customs") regulations or under regulations administered by USDA's Agricultural Marketing Service (AMS).

a. Customs Origin Marking

If the product is imported, country of origin marking (e.g., "Product of Italy," "Made in Canada") is required. Country of origin marking for imported products is required by CBP under its regulations. While it is a Customs requirement, FDA may consider a food that violates country of origin marking requirements to be misbranded and may take enforcement action. FDA Compliance Policy Guides Section 560.200.

Country of origin marking is required to be provided to the "ultimate purchaser" of the product. If the imported food will undergo further processing in the United States, the ultimate purchaser of the imported food may be the U.S. processor, not the U.S. consumer. If the U.S. processing will result in a "substantial transformation" of the imported food (i.e., the processed food has a different name, character, or use from the imported food), or, in the case of an imported food from a North American Free Trade Agreement (NAFTA) country, will result in a tariff shift (i.e., the processed food has a different tariff classification from that of the imported food), then country of origin marking is not required on the label of the finished food. For example, if imported cheese is processed in the United States into pizza, country of origin marking is not required on the label of the pizza.

Country of origin marking, if required, must appear in a conspicuous place on the label as legibly, indelibly, and permanently as possible. The information panel generally is considered a sufficiently conspicuous location. It should appear in type at least 1/16 inch high.

b. AMS Country of Origin Labeling (COOL)

Further, certain foods are subject to COOL under a program administered by the U.S. Department of Agriculture's Agricultural Marketing Service (AMS). Under AMS COOL, the country of origin for "covered commodities" must be declared at retail. AMS COOL applies to both imported and domestic products. AMS COOL labeling requirements technically apply to retail; manufacturers are required to provide origin information to retail customers but strictly speaking are not required to include AMS COOL information on the labels of covered commodities. Some manufacturers decide to provide AMS COOL information directly on product labels.

AMS covered commodities are muscle cuts of, lamb (including mutton), goat, venison, and chicken; ground lamb, ground goat and ground chicken; farm-raised fish and shellfish; wild fish and shellfish; and fruits and vegetables (as well as peanuts; ginseng, pecans, and macadamia nuts).

An item is no longer considered a covered commodity subject to AMS COOL if it has been "processed." For purposes of AMS COOL, processing is defined as combining two or more foods (e.g., combining frozen peas and carrots) or doing something to the food that results in a change of character. Cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g., emulsifying and extruding) are all examples of "processing" under AMS COOL. Adding a component such as salt, sugar, or water that merely enhances the food or represents a further step in preparing the food for consumption is not considered "processing" for purposes of AMS COOL.

For meat and poultry AMS COOL covered commodities, the country of origin must identify the country where the animal was (1) born or hatched, (2) raised, and (3) harvested or slaughtered. Examples include "Hatched, Raised, and Harvested in the U.S."; "Born and Raised in Canada, Slaughtered in the U.S."; "Born, Raised, and Slaughtered in Canada." AMS COOL does not allow general "Product of [Country]" claims or commingling of products for whole muscle cut meat and poultry covered commodities.

For all other AMS COOL covered commodities, the country of origin may be declared as "Product of [Country]" (e.g., "Product of U.S."; "Product of Mexico"). Commingling is allowed so long as all countries named are represented in the product (e.g., "Product of U.S. and Mexico").

For AMS COOL, country name abbreviations are allowed only if they are approved under Customs regulations. The United States may be abbreviated as "U.S." or "U.S.A.", with or without the periods.

Allergen Labeling

A food that contains a major food allergen but fails to comply with FDA allergen labeling requirements is considered misbranded. Moreover, FDA considers undeclared major food allergens to be a violation requiring a Class I recall.

"Major food allergen" is defined as: (a) milk, eggs, peanuts, tree nuts, wheat, soybeans, fish, crustacean shellfish, and sesame (for foods introduced into interstate commerce on or after January 1, 2023); and (b) any food that contains protein derived from one of the "Big 8" foods in (a), except for highly refined oils and ingredients derived from highly refined oils.

If a food contains a "major food allergen," the allergen must be declared in either of the following two ways:

- Declare the name of the food source of the major food allergen in the ingredients declaration, typically in parentheses following the name of the major food allergen (*e.g.*, "Ingredients: wheat flour, tomato paste, whey (milk), natural flavor (peanuts)…."); or
- Provide a "Contains [allergen]" statement immediately after or adjacent to the ingredients declaration in a type size no smaller than that of the ingredients declaration (*e.g.*, "Contains wheat, milk, and peanuts").

Allergen labeling must use the specific type of tree nut (e.g., pine nuts, a *Lm*onds) and the specific species of fish or crustacean shellfish (e.g., anchovies, shrimp).

This allergen labeling requirement does not apply to major food allergens that are unintentionally present in the food (e.g., due to cross-contact between foods that contain major food allergens and those that do not). Where a manufacturer is unable to ensure that a product does not unintentionally contain a major food allergen, the manufacturer may provide an advisory allergen statement on the label (e.g., "May contain eggs," "Produced in a plant that also processes peanuts"), provided that such statements may not be used in lieu of adherence to good manufacturing practice to prevent cross-contact.

Note: Some consumers have allergic-type reactions to the following ingredients that are not major food allergens: MSG, Yellow 5 and 6, carmine, cochineal extract, and sulfites. FDA typically requests a recall if any of these ingredients are present in a food but not declared on the label.

Claims

1. Nutrient Content Claims

Nutrient content claims are terms that expressly or implicitly characterize the level of a nutrient in a food (e.g., "reduced fat," "low sodium," "good source of protein"). Nutrient content claims must be authorized by FDA. FDA has issued general requirements for nutrient content claims at 21 C.F.R. § 101.13. The

content claims approved by FDA are set forth in the FDA regulations at 21 C.F.R. §§ 101.54 through 101.65.

FDA has also authorized a few nutrient content claims based on an authoritative statement of a scientific body of the U.S. government with official responsibility for public health, or the National Academy of Sciences. These are sometimes referred to as "FDAMA claims," because they were authorized by the Food and Drug Administration Modernization Act of 1997 (FDAMA). See the list of authorized claims here.

In addition to the nutrient content claims defined in FDA's regulations, a food may make a factual statement about the amount or percentage of a nutrient in the food, provided the factual statement: (a) is truthful and not misleading, and (b) does not implicitly characterize the level of the nutrient in the food (e.g., "2 grams of fiber per slice," "30 mg of omega-3 fatty acids"). Such factual statements may be used for nutrients like omega-3 fatty acids that have no established Daily Value, and therefore no FDA-approved nutrient content claims. FDA has taken the view that these types of quantitative statements are nutrient content claims, and that they must be accompanied by disclosure statements where required under 21 C.F.R. 101.13(h). Additionally, FDA takes the view that quantitative statements trigger a need to declare additional nutrients or information in the Nutrition Facts Panel (for example, a 0 g trans-fat claim results in a need to declare poly- and mono-unsaturated fats; a 10 g of protein claim results in a need to declare the percent daily value for protein).

2. Health Claims

A health claim is a claim about the relationship between consumption of a food substance and risk of a disease or health-related condition. Health claims must be authorized by FDA. FDA has issued general requirements for health claims at 21 C.F.R. § 101.14. The health claims approved by FDA are set forth in the FDA regulations at 21 C.F.R. §§ 101.72 through 101.83.

FDA has also authorized a few health claims based on authoritative statements of a scientific body of the U.S. government or the National Academy of Sciences. These are sometimes referred to as "FDAMA claims," because they were authorized by the Food and Drug Administration Modernization Act of 1997 (FDAMA). See the list of authorized claims here.

FDA has also authorized several "qualified health claims" by issuing letters of enforcement discretion where the evidence in support of the claim does not rise to the level required for an approved health claim. The qualified health claims authorized by FDA can be found here.

3. Structure/Function Claims

A structure/function claim is a claim that describes the role of a food substance in affecting a structure or function of the human body or characterizes the mechanism

by which the substance acts to maintain the structure or function (e.g., “Calcium helps build strong bones,” “supports a healthy digestive system”). Unlike nutrient content claims and health claims, structure/function claims do not require FDA pre-approval.

A structure/function claim may be made for a conventional food, provided: (1) the claim benefit derives from the food’s nutritive value; and (2) the manufacturer has substantiation for the claim. FDA requires structure/function claims to be substantiated by “competent and reliable scientific evidence.” *See* Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act | FDA (2009) (although this guidance concerns structure/function claims for dietary supplements, it is expected that FDA would apply the same analysis to structure/function claims for conventional foods).

Structure/function claims must be careful not to cross the line into disease claims (i.e., claims to diagnose, treat, cure, prevent, or mitigate a disease), which may only be made for drugs. The key is that structure/function claims describe the normal structure or function of the body.

4. Other Claims

    a. “Natural”

FDA has no regulation defining the term “natural.” Under FDA informal policy, “natural” means that the food contains nothing artificial or synthetic, including colors (regardless of source), that would not normally be expected to be in the product, no added colors (even if from a natural source), and no synthetic substances.

FDA officials have indicated that enforcement of the agency’s policy on “natural” is not a high priority, but in the last decade there have been many class action lawsuits alleging that “natural” claims made for various food products are misleading under state consumer protection laws. In response to requests from federal courts and to several Citizens Petitions requesting FDA create a formal definition of “natural,” FDA issued a request for comment on the term. FDA solicited comments on several questions, including whether certain types of production techniques should make a food ineligible for a natural claim, whether FDA should adopt the FSIS definition of “natural,” and whether food with genetically modified ingredients can be labeled as “natural.” It is unclear if or when FDA would define “natural” via rulemaking. Therefore, manufacturers should be very careful about making “natural” claims and should consult legal counsel if there is any doubt whether their product is “natural.”

    b. “Fresh”

FDA regulations define “fresh” to mean that the food is in its raw state and has never been frozen or subjected to any form of thermal processing or other form of

preservation. The following treatments will not preclude a "fresh" claim: refrigeration, application of a mild chlorine or acid wash on produce, approved waxes or coatings; post-harvest use of approved pesticides, and irradiation up to a dose of 1 kiloGray.

Therefore, a frozen product is not "fresh." However, a frozen product may claim that it is "made with/ from fresh [ingredient]," provided: (a) the "fresh" claim clearly refers to an ingredient and not the finished product; and (b) the ingredient in question met the FDA definition of "fresh" immediately before it was processed into the product. FDA has also defined the term "fresh frozen," which may be used to describe food that was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). Quickly frozen means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place. Blanching before freezing is permitted.

c. "Made in USA"

The Federal Trade Commission (FTC) has issued a policy on "made in USA" and similar claims. FTC, Enforcement Policy Statement on U.S. Origin Claims" (1997) (available https://www.ftc.gov/public-statements/1997/12/enforcement-policy-statement-us-origin-claims). Under the FTC policy, an unqualified "made in USA" claim means the food is "all or virtually all" made in the United States. This means that finished processing must occur in the U.S.; all significant ingredients and processing are of U.S. origin; and the food contains only a de minimis amount of any foreign origin ingredients. Where an unqualified "made in USA" claim is inappropriate, a food may be able to make an appropriately qualified claim (e.g., "made in USA of US origin and imported ingredients"). While this is an FTC policy, a label that makes a "made in USA" claim in violation of the FTC policy may be considered to be false or misleading by FDA.

b. Value-added ingredient claims (e.g., "made with real cheese," "contains olive oil")

Generally, these claims should be considered on a case-by-case basis, in the context of other elements of the label or labeling, and the product should contain a meaningful amount of the named ingredient. There has been significant litigation on these claims, so these statements should be assessed with legal counsel.

FDA has issued a draft guidance document on "whole grain" label statements. Guidance for Industry: Whole Grain Label Statements (2006).

Some claims about value-added ingredients may be viewed by FDA as implied nutrient content claims. For example, a claim that a frozen food "contains oat bran" may be considered an implied "good source of dietary fiber" claim. FDA has stated in the past that a claim that a product is made with "low fat cheese" will be considered to be an implied claim that the product is "low fat." Guidance for

Industry: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-from-Home Foods (2008), #35.

e. Avoidance claims (e.g., “gluten-free,” “no preservatives,” “no partially hydrogenated oils,” “non-dairy,” “vegetarian,” “vegan,” “GMO free”)

FDA has issued a regulation defining the term “gluten-free” for voluntary use in food labeling. Products making “gluten-free” claims must comply with the new regulation. Under the regulation, “gluten-free” means that either: (1) the food and its ingredients are inherently free of gluten, and any gluten present in the finished food is less than 20 ppm; or (2) the food contains ingredients derived from gluten-containing grains (i.e., wheat, rye, barley, and any crossbred hybrids of those grains) that have been processed to remove gluten, and any gluten present in the finished food is less than 20 ppm. If a food label includes a “gluten-free” claim but also uses the word “wheat” on the label (e.g., the word “wheat” appears in the ingredients declaration, because the food contains a wheat ingredient that has processed to remove gluten), the word “wheat” must be followed by an asterisk or other symbol that refers to the following explanatory statement: “The wheat has been processed to allow this food to meet the FDA requirements for gluten-free foods.” There are special recordkeeping requirements for gluten-free claims for foods (including ingredients), that are fermented or hydrolyzed, such as cheese, vinegar, enzymes, and chocolate. The records must provide adequate assurances that (1) the food is gluten free before fermentation/hydrolysis, (2) the manufacturer has adequately evaluated their processing for any potential for gluten cross-contact, and (3) where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

For other “free” claims, FDA takes the view that if not defined, the term “free” implies no detectable levels of the named substance.

FDA has published a final guidance document on claims about the presence or absence of genetically engineered ingredients titled Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants | FDA (2019). As part of the statute requiring disclosure of bioengineered foods, Congress also recognized that (1) certified organic foods may bear a “non-GMO” claim, and (2) simply because a food does not require a bioengineered (BE) food disclosure, does not mean it is necessarily eligible for a “non-GMO” claim. As an example, a food that contains high fructose corn syrup from BE corn would not be required to bear a BE food disclosure if the high fructose corn syrup was processed in a way that rendered the modified genetic material undetectable. It would not, however, be appropriate to make a non-GMO claim for such a food because it contains an ingredient derived from a BE/GMO crop. If the same food were certified organic, it could bear a non-GMO claim.

USDA Bioengineered Food Disclosure Requirements

1. Overview

The National Bioengineered Food Disclosure Standard (NBFDS) was enacted in 2016 and establishes a uniform approach to the disclosure of bioengineered (BE) foods. The law is implemented by USDA's Agricultural Marketing Service (AMS) and applies to foods that are labeled on or after January 1, 2022.

2. Scope of Disclosure Requirement

The disclosure standard does not include all "food" within its scope, but rather is limited to:

1. foods that are subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), and
2. certain foods that are subject to the labeling requirements of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act, but only if either:
    a. the most predominant ingredient of the food would independently be subject to the FFDCA labeling requirements; or
    b. the most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the FFDCA labeling requirements.

All other meat, poultry, and egg products are excluded. To identify the predominance of ingredients, AMS will look to the first ingredient in the ingredient list on the food label, following the FDA requirements for identifying the ingredients in the order of descending predominance by weight.

3. Definition of Bioengineered Food

The term "bioengineered food" is defined as follows (with a separate exclusion for incidental additives discussed below):

> A food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; provided that
>
> Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9..

Importantly, a food only meets the definition of a BE food if it contains detectable levels of modified rDNA. For refined foods or ingredients that are derived from BE sources (e.g., corn syrup derived from BE corn or sugar derived from BE sugar beets), disclosure is not required if the food does not contain detectable modified genetic material. The final rule sets forth the types of records that can be used to demonstrate that modified genetic material is not detectable, discussed further in the recordkeeping section.

The final rule contains a non-exhaustive list of BE foods:

- Alfalfa
- Apple (Arctic™ varieties)
- Canola
- Corn
- Cotton
- Eggplant (BARI Bt Begun varieties)
- Papaya (ringspot virus-resistant varieties)
- Pineapple (pink flesh)
- Potato
- Sa *Lm*on (AquAdvantage®)
- Soybean
- Squash (summer)
- Sugarbeet

The list intended as a starting point or a "tool" to help regulated entities. Even if a food is not on the list, companies with actual knowledge that a food they are selling is bioengineered are subject to the disclosure requirements. AMS gives the example of "enzymes, yeasts, and other similar foods produced in controlled environments." If a regulated entity has actual knowledge that such a food or ingredient is bioengineered (e.g., if the supplier informs a manufacturer that cheese is made with a BE enzyme), it is subject to disclosure unless it is exempt as an incidental additive (discussed below).

Importantly, simply because a crop or food is on the list does not necessarily mean it requires disclosure. For example, if the regulated entity maintains records that they are using a non-bioengineered version of the food or records showing the food does not contain detectable modified DNA, then no disclosure is required.

Incidental additives – i.e., those that are present in food at an insignificant level and that do not have any technical or functional effect in the food – are not considered BE foods. Incidental additives are defined in the same way as in FDA regulations. The definition is copied below:

> Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

Yeasts, enzymes, or any other microorganisms may qualify as incidental additives depending on their function in a particular food. AMS explains:

- If they qualify as incidental additives that are not required to be labeled as ingredients on a food label, then they do not require disclosure as BE foods.
- If they do not meet the incidental additive definition, these substances may require disclosure unless they are otherwise exempt (e.g., if the modified genetic material is not detectable).

At the end of this section, we provide a decision tree to help companies determine whether a food or ingredient is subject to disclosure.

4. Exemptions

In addition to the exclusion for incidental additives, there are several exemptions from disclosure:

- Food served in a restaurant or similar retail food establishment;
- Very small food manufacturers (i.e., with annual receipts less than $2.5 million);
- A food derived from an animal is not considered BE solely because the animal consumed BE feed; and
- Foods certified under the National Organic Program, including 100% organic, organic, and "made with organic ___ [name of specific ingredients or groups of ingredients]" foods with at least 70 percent organically produced ingredients.

There is also a threshold for the inadvertent or technically unavoidable presence of BE substances. The threshold allows up to five percent (5%) inadvertent BE presence for each ingredient, provided that no ingredients are intentionally used in the food that contain a BE substance. There is no threshold for intentionally added BE ingredients (unless the ingredient qualifies as an incidental additive). The 5% threshold is intended to account for comingling among BE and non-BE crops, including in the field,

during transportation, or from processing equipment.

As an example, there is currently no commercially available bioengineered version of wheat. Disclosure is not required for a food that contains wheat flour as an ingredient, when the wheat flour contains no more than 5% of BE substances (such as BE soy or BE corn) due to cross contact.

Only “customary business records” are required to demonstrate compliance with the threshold. In assessing compliance, “AMS will look to the records to determine whether a regulated entity intended to purchase non-BE ingredients and the documentation they have from their suppliers indicating as much.” This means testing is not required to confirm the inadvertent BE content is at or below the 5% per ingredient threshold.

5. Mechanics of Disclosure

For foods that require a disclosure, companies have the option to choose any of the four basic disclosure options summarized below: (1) on-pack text, (2) on-pack symbol, (3) digital or electronic link, or (4) text message disclosure.

Summary of BE Disclosure Options

General Requirements

- Type size: Must appear "prominently and conspicuously." No specific type size requirement.
  - Note: while not required, best practice is to use at least 1/16th inch type size, based on minimum FDA type size requirements for mandatory labeling elements.
- Placement: Three options for on-package placement: (1) on the information panel, directly adjacent to the statement identifying the name and location of the handler, distributor, packer, manufacturer, importer, or similar information, (2) anywhere on the principal display panel (PDP), or (3) if there is insufficient space on the information panel or PDP, on an alternate panel likely to be seen under ordinary shopping conditions.

Option 1 Text Disclosure

"Bioengineered"

- Raw agricultural commodities
- Processed foods that contain only BE ingredients

"Contains a Bioengineered Food Ingredient"

- Foods that do not fall under first category and contain one or more BE ingredients
- May use plural phrasing: "Contains bioengineered food ingredients"

Option 2 Symbol Disclosure

OR

Option 3 Digital or Electronic Link

On package

- QR Code or Link (URL alone not sufficient)
- "Scan here for more food information" (or similar language reflecting technological changes) directly above or below the link
- "Call 1-xxx-xxx-xxxx for more food information" "in close proximity" to the link; number must provide disclosure 24/7
- May also combine statements to read "Scan here for more food information or call [number]".

Accessed by link

- Text or symbol disclosure must appear on product information page (first screen accessed from link) without any "marketing or promotional material."

Option 4 Text Message Disclosure

"Text [command word] to [number] for bioengineered food information."

Must immediately respond to the consumer with the text disclosure (option 1).

Additional Options for Small and Very Small Packages

Small packages (< 40 in^2 total surface area): May use a shortened version of the accompanying text: "Scan for info" (for Option 3), "Text for info" (for Option 3), or "Call for info" (for the telephone disclosure).
Very small packages (< 12 in^2 total surface area): May use shortened text described above. If preexisting label includes a website URL or telephone number that a person can use to obtain other food information, that website or telephone number may also be used for the BE disclosure, provided that the disclosure is consistent with the text or symbol disclosure in written or audio form, as applicable.

Additional Options for Small Manufacturers (≥ $2.5M and < $10M in annual receipts)

1. Telephone number + "Call for more food information." Must provide the disclosure (audio of Option 1) 24/7.
2. "Visit [URL of the website] for more food information." Website must include symbol or text disclosure and must meet the "product information page" requirements for Option 3.

Disclosure for Foods Sold in Bulk Containers

Use Option 1, 2, 3, or 4 – but may provide via signage or other materials (e.g., placard, sign, label, sticker, band, twist tie, or other similar format) that allows consumers to easily identify and understand the BE status of the food.

6. Recordkeeping

There are two types of recordkeeping provisions under the rule; one general, and one that pertains to records needed where the regulated entity does not make a disclosure because modified genetic material is not detectable. The general recordkeeping requirements provide a fair amount of flexibility in terms of the types of records that satisfy the rule and where and how they must be kept.

- Regulated entities must keep "customary or reasonable" records to demonstrate compliance;
    - For example: Supply chain records, bills of lading, invoices, supplier attestations, labels, contracts, brokers' statements, third party certifications, laboratory testing results, validated process verifications, and other records generated or maintained by the regulated entity in the normal course of business
- Records must contain sufficient detail as to be readily understood and audited;
- Records must be in paper or electronic form; may be stored centrally; and
- Records must be kept for two years beyond the date a food is sold or distributed for retail sale.

Importantly, with respect to the relationship between the USDA BE Foods List and recordkeeping, the rule requires the following:

- If a food (or an ingredient produced from such a food) is on the USDA BE Foods List, the regulated entity must keep records regarding the food or ingredient.
- If a food bears a BE disclosure based on actual knowledge and is not on the List, the regulated entity must keep records regarding that food or ingredient
- If the food is not on (or derived from a food on) the List, and the regulated entity does not have actual knowledge that it is BE, no recordkeeping is required.

A regulated entity can demonstrate that modified genetic material is not detectable through (1) records verifying that the food is sourced from a non-bioengineered crop or other food source, such as non-bioengineered sa *Lm*on; (2) records verifying that the food has been subject to a refinement process "validated" to render modified genetic material undetectable; or (3) certificates of analysis or other testing records appropriate to the specific food tested that confirm the absence of modified genetic material.

AMS has established performance standards that must be met for detectability analysis. Specifically, to validate that a refining process renders modified genetic material in a food undetectable, the analytical testing used must meet the following standards:

- Laboratory quality assurance must ensure the validity and reliability of test results;
- Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;
- The demonstration of testing validity must ensure consistent accurate analytical performance; and
- Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of the rule.

Once a refining process has been validated using testing that meets the standards above, additional testing is not required to confirm the absence of detectable modified DNA in a food refined through that process, provided no significant changes are made to the validated process, and provided that records are maintained to demonstrate that the refining process has been validated and that the validated refining process is followed.

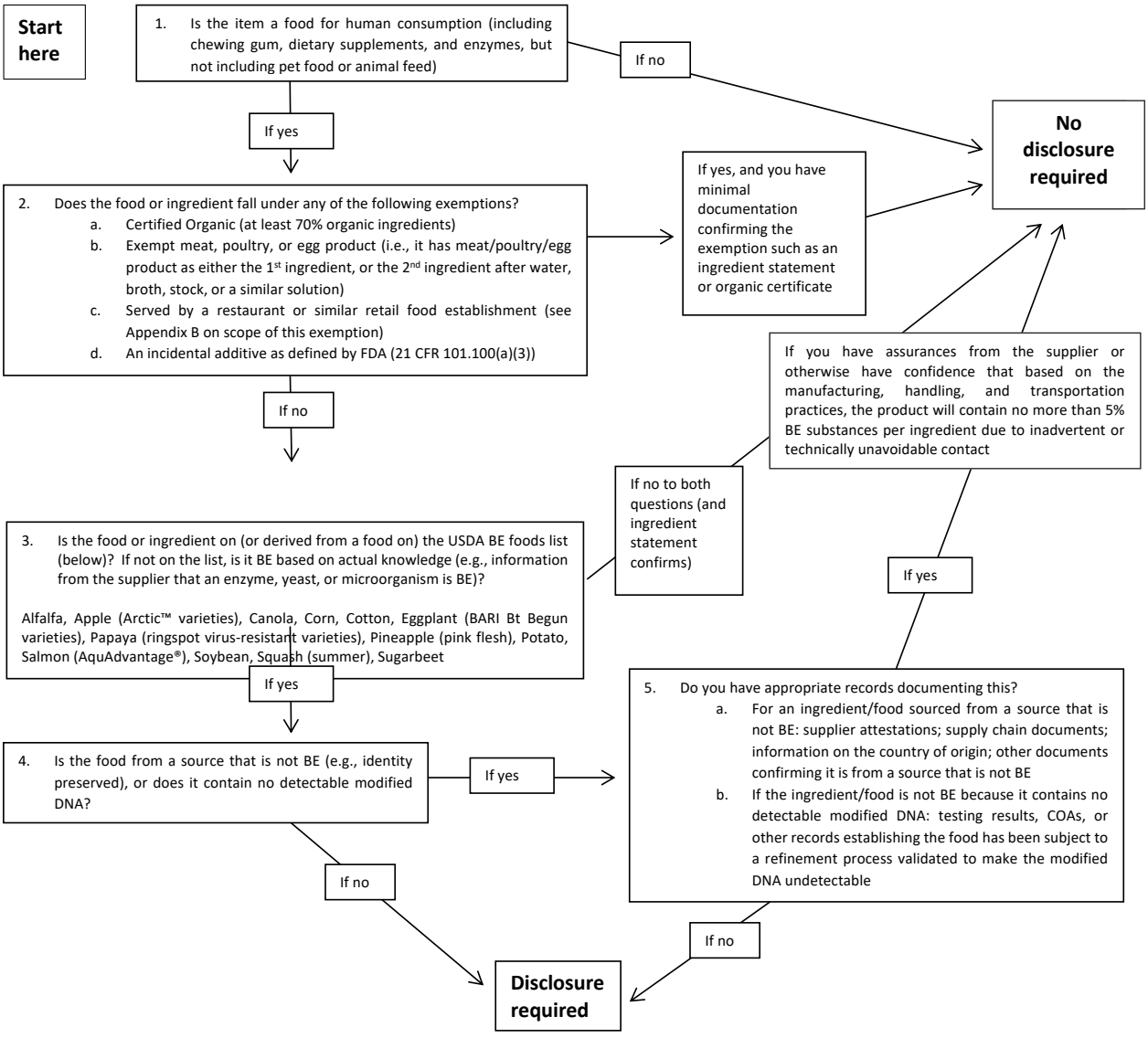
The agency has also issued guidance on detectability testing and process validation. Detectability Testing | Agricultural Marketing Service (usda.gov). The guidance notes that polymerase chain reaction (PCR) is the most widely used test method, but states that it may be limited by PCR-inhibiting compounds and is dependent on isolation of high-quality DNA from a sample. AMS advises the laboratory to ensure that the method is validated for the specific matrix and adequately extracts DNA for each ingredient/matrix and to monitor PCR inhibition.

7. Voluntary Disclosure

The final rule also provides an option for voluntary disclosures for foods that don't meet the BE food definition because they don't contain detectable modified DNA, but that are derived from BE foods. The voluntary disclosure is limited to foods or food ingredients that: (1) don't contain detectable modified genetic material, (2) are not incidental additives, (3) are not subject to any of the exemptions discussed above (i.e., foods sold in restaurants or similar retail food establishments, or by very small manufacturers; foods with no more than 5 percent inadvertent or technically unavoidable BE presence per ingredient; foods derived from an animal that consumed BE feed; or foods certified as organic); and (4) are derived from a food on the USDA List of BE Foods.

The voluntary disclosure must use one of the same methods of disclosure provided in the rule for the mandatory disclosure but must use different terminology. Specifically, it must use the statements, "derived from bioengineering" or "ingredient(s) derived from a bioengineered source." The word "ingredient(s)" may be replaced with the name of the specific crop(s) or food ingredient(s). AMS also has established a unique symbol that can be used on foods derived from bioengineering (it may be used in either color or black and white):

Decision Tree: How to determine whether a food or ingredient is subject to the Bioengineered Food disclosure



USDA FSIS Labeling Requirements

USDA's Food Safety and Inspection Service (FSIS) regulates the labeling of meat, poultry, and egg products. FSIS and FDA generally try to harmonize their labeling requirements, although key differences exist, especially for labeling elements specific to meat and poultry products. For example, FSIS has defined nutrition content claims generally consistent with FDA's nutrient content claim regulations, but FSIS has not defined health claims. Further, all meat, poultry, and egg product labels must bear the USDA mark of inspection and the establishment number of the establishment that produced the product; products must bear a handling statement; and not-ready-to eat products must bear validated cooking instructions and safe handling instructions.

Importantly, all meat and poultry labels must be submitted to FSIS for preapproval unless the label is eligible for generic approval. All egg product labels must be preapproved by FSIS. Because label approval plays such an important role in developing FSIS-regulated labels, this section is presented in the context of receiving approval for a label. Whether a label is sketch approved or generically approved, the same requirements apply to the content of the label.

Checklist for USDA-FSIS Label Approval
1. Can the label be generically approved?
2. Does the label have all mandatory features? a. Product Name b. USDA Inspection Legend c. Net Weight Statement d. Ingredient Statement e. Handling Statement f. Signature and Address Line g. Nutrition Facts (if retail product) h. Safe Handling Instructions (if not ready-to-eat)
3. Do any claims on the label comply with regulations?
4. Is the entire label sketch legible?
5. Has the FSIS label application been completed properly?
6. Have you attached all needed supporting documentation?

Detailed Information for USDA-FSIS Label Approval

1. Does the Label need to be submitted to USDA-FSIS for approval or can it be generically approved? (9 CFR § 412.1). FSIS has developed a Compliance Guideline addressing when generic approval is permitted.
    a. The following four categories of labels must be submitted to FSIS for formal approval:
        i. Sketch labels for product which are produced under a religious exemption;
        ii. Sketch labels for products intended for export whose labels deviate from FSIS regulation (with the exception of foreign language or net weight that complies with foreign requirements);
        iii. Labels that require temporary label approval;
        iv. Labels that bear special statements or claims, defined as:
            1. "Natural";
            2. Negative claims (gluten free);
            3. Other claims not defined in FSIS regulations or the Food Standards and Labeling Policy Book. Examples include:
                a. Health claims;
                b. Structure-function claims;
                c. Animal production claims (e.g., "no antibiotics administered");
                d. 3rd party raising claim or program (e.g., "American Heart Association" claims);
                e. Breed claims (e.g., "Angus");
                f. Certified claims (e.g., "Certified Halal," "Certified Organic");
                g. Gluten free claims;
                h. Implied nutrition claims (e.g., "made without butter");
                i. Instructional or disclaimer statements concerning pathogens (e.g., "for cooking only");
                j. Nutrition Front of Pack Statements (e.g., "0 grams trans fat per serving");
                k. Claims of the use of non-genetically engineered ingredients;
                l. Whole grain claims; and
                m. Omega 3 factual statements

    b. Claims that are not covered by the four categories above may be generically approved. Examples include:
        i. "All," "100%", or "Pure" claims;
        ii. "Contains [ingredients]" statements;
        iii. AMS grading terms;
        iv. Child Nutrition boxes;
        v. Flavor profile claims (e.g., "Made with Real Cheese");
        vi. Foreign language on domestic products;
        vii. Geographical claims in compliance with regulatory requirements;
        viii. Green/Environmental claims;
        ix. "Halal" or "Kosher" claims, provided that it is not qualified by the term "certified;"
        x. "Hand-pulled," "Hand-crafted", "Handmade," and similar type of claims;

xi. "Homestyle;"
xii. Limited use statements (e.g., "For Institutional Use Only," "Not for Retail Sale");
xiii. Defined nutrient content claims (e.g., "low fat"); and
xiv. Oven roasted or similar statements

2. Review label sketch to ensure all mandatory features are present:
    a. **Principal display panel (PDP)**
        i. Product name (9 CFR §§ 317.2(c) & 381.117)
            1. Is the product name accurate (standardized name, common or usual name or descriptive name)?
            2. Does the use of a product name require the product to meet a standard of identity? (See 9 CFR Part 319, Part 381, Subpart P and FSIS Standards and Labeling Policy Book for meat and poultry product standards)
                a. If there is a product standard, does the product meet it?
                    i. Formulation?
                    ii. Processing?
                b. For example, can the beef used as a topping be called "beef" or does it need to be called "beef topping" because of the addition of Textured Vegetable Protein (TVP)?
            3. If your product is an "example," have you included the word "example" in the product name?
            4. If a product contains calcium propionate or sodium propionate, is there a qualifying statement contiguous to the product name stating, "[preservative] added to retard spoilage"?
            5. If an antioxidant is added to the product, is there a qualifying statement contiguous to the product name indicating the common name or abbreviation of the antioxidant and its purpose, e.g., "BHA, BHT, and Propylgallate added to help protect flavor"?
            6. Further information
        ii. USDA Inspection Legend (9 CFR §§ 312.2, 317.2(i), 381.96)
            1. Is there an inspection legend on the label?
            2. Is it the correct legend?
            3. If the wstablishment number is printed in the legend, is it correct?
            4. If it is not in the legend, is it in a location and appears in a manner that is acceptable under 9 C.F.R. §§ 317.2(i), 381.96?
            5. If there are dual legends on the label, is the product only for hotels, restaurants or institutions?

        iii. Net Weight Statement (9 CFR §§ 317.2(h), 381.121)
            1. Is the size, spacing, and location correct?
                a. Should be in a conspicuous, legible boldface print in distinct contrast to other material.
                b. Should appear within the bottom 30% of the PDP (see 9 C.F.R. §§ 317.2(h)(3), 381.121(c)(2) for packaging with a PDP of less than 5 sq. inches) and be parallel to bottom of PDP.

c. Should be expressed in terms of avoirdupois weight or liquid measure
    i. ¾ lb. product – “Net. Wt. 12 oz.”
    ii. 1 ½ lb. product – “Net Wt. 24 oz. (1 ½ lb.)” or “Net. Wt. 24 oz. (1.5 lbs.)”
d. Should be in font size in relationship to area of PDP of the package & uniform by complying with the following basic requirements (see 9 C.F.R. §§ 317.2(h)(6), 381.121(c)(3) for more details and exemptions):
    i. Not less than 1/16th inches in height on packages when PDP is less than area of 5 sq. inches;
    ii. Not less than 1/8th inches in height when PDP has area more than 5 sq. inches but not more than 25 sq. inches;
    iii. Not less than 3/16th inches in height when PDP has area more than 25 sq. inches but not more than 400 sq. inches;
    iv. Not less than ¼ inches in height when PDP has area more than 400 sq. inches.
    v. Ratio of height to width shall not exceed differential of 3 units to 1 unit pertaining to upper case or capital letters. When all upper- or lower-case letters are used, the lower case “o” or its equivalent will be used to meet minimum standards.
e. Should be separated by a space at least equal to height of lettering from other printing and separated from other information to right or left by a space at least equal to twice the width of the letter “N” in the font size used in the weight statement
f. No term qualifying the unit of weight should be used (e.g., “jumbo,” “quart,” “full gallon,” “minimum,” etc.)
g. See 9 C.F.R. §§ 317.2(h)(9), 381.121(c)(9) for information on labeling of random weight containers.

2. If the package does not have a net weight statement, does the label application state that the net weight will be applied at retail prior to its sale?

iv. *Handling Statement* (9 CFR §§ 317.2(k), 381.125 (a))

1. Does the product require special handling to maintain its wholesome condition and thus require a special handling statement (e.g., “Keep Frozen” or “Keep Refrigerated)?
2. Is the statement appropriate for the product?
    a. If needs refrigeration or to be kept frozen:
        i. “Keep Refrigerated” or similar
        ii. “Keep Frozen” or similar.
    b. Product distributed frozen during distribution but thawed prior to or during display at retail shall bear the statement “Keep Frozen” on shipping containers, but consumer size containers would be labeled “Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.”

b. Information Panel (if not displayed on the PDP)

i. Signature or address line (9 CFR §§ 317.2(g), 381.122)
   1. Does the label bear a signature/address line?
   2. If the manufacturer's name is not in the signature line, is the name preceded by the terms "Prepared for" or "Distributed By"?
   3. If the name of the business is listed in the telephone or city directory, does the address show the city, state and zip code of the business?
   4. If the name of the business is not listed in the telephone or city directory, is the street address also provided?
   5. The signature line may appear on the PDP, on the front riser panel of frozen food cartons, or on the information panel (see 9 C.F.R. §§ 317.2(g)(2), 381.122 for additional information).
   6. If appearing on the information panel, is the signature line contiguous to the ingredients statement?

ii. Ingredients Statement (9 CFR §§ 317.2(f), 381.118)
   1. If there are more than two ingredients in the product, are each listed by their common or usual names?
      a. See 9 C.F.R. §§ 317.2(f)(1), 381.118(c) for additional information on spices and natural flavors.
      b. Are all ingredients listed by their common or usual names – not by trade names?
      c. Are purchased ingredients declared as listed in the ingredient statement on the purchased product?
   2. If the product is an imported product, are all spices/natural flavors identified by their common or usual name?
   3. Are the ingredients listed by their order of predominance?
   4. Are you listing ingredients with component ingredients sub-listed or as a composite listing of all ingredients?
   5. Are allergen "Contains" statements transferred from FDA component labels?
   6. If ingredients present in the product at 2% or less by weight are listed in the ingredient statement in other than the order of predominance, is the list preceded by a quantifying statement such as "Contains less than 2% of the following" or similar (see 9 C.F.R. §§ 317.2(f)(1)(vi), 381.118(a)(2)(i) for additional detail)?
   7. If the ingredient statement on containers is placed on the front riser panel, is the words "see ingredients," followed by an arrow placed on the PDP immediately above the statement with no intervening print or designs? This is important on containers of frozen dinners, entrees, pizzas, and other consumer packaged products in cartons.
   8. Were there incidental additives or processing aids that were used in the production of the product? If so, did you obtain confirmation from FSIS that the substances qualified as incidental additives or processing aids as defined in the Food Standards and Labeling Policy Book.

iii. Nutrition Facts (9 CFR §§ 317.300-317.400, 381.400-381.500)
   1. Have you used the correct reference amount customarily consumed (RACC) to determine the serving size of the product?

2. Have you used the correct rounding information detailed in the regulations for the various nutrients expressed on the nutrition facts panel?
3. Have you determined which format of the nutrition facts panel is correct for your package (i.e., full, simplified, or tabular)? (See 9 C.F.R. §§ 317.309(d)(1), 381.409(d)(1) for details on each format and their proper use.)
4. If you make any nutrient content claims (i.e., "light") on the label, do your nutrient facts support the claims?
5. If your product has a "net wt." statement, your "servings per container" must be accurate based on the net wt. and not "varied."
6. Detailed information on the types of nutrients that must be reported and how these are determined may be found in the regulations.
7. Detailed information on the types of "Nutrient Content Claims" (a claim which, expressly or by implication, characterizes the level of a nutrient) that can be made as well as those that cannot be made may be found in the regulations.

c. Displayed Anywhere on Labeling

i. Safe Handling Instructions (SHI) (9 CFR §§ 317.2(l), 381.125(b))

1. Has your product undergone a process which makes it a "ready-to-eat" product (i.e., fully cooked)? If not, the package must have safe handling instructions as detailed in the regulations.
2. Is your safe handling instructions located in the correct portion of your label and in the correct font size (see 9 C.F.R. §§ 317.2(l), 381.125(b) for details)?

ii. Claims

1. Geographical origin claims – if your label bears a term having geographical significance, does the term comply with the requirements in 9 C.F.R. § 317.8(b)(1) and the Food Standards and Labeling Policy Book?
2. "Natural" claims – are you making an "all natural claim" or similar? If so, does your product, ingredients and processing of same comply with the "natural" requirements detailed in the Food Standards and Labeling Policy Book?
3. "Fresh" claims – are you describing the product as "fresh?" If so, are you in compliance with the use of the term as detailed in the Food Standards and Labeling Policy Book and 9 CFR § 381.129(b)(6)?
4. "Organic" claims – the use of the term "organic" on product labeling is regulated under the USDA's Agricultural Marketing Service's (AMS) National Organic Program. The product, ingredients and establishment will require certification under that program and support will need to be provided to use the term "organic" on a product label or the organic seal. (See information about the National Organic Program)
5. Animal Production Claims – information supporting an animal production claim (i.e., "beef raised without hormones," "free range") must be provided with the application. Additional information about animal production claims is available here.
6. The FSIS LPDD staff will review other types of claims on a case-by-case basis along with supporting information. There is additional information on various other "claims" in the Food Standards and Labeling Policy Book.

3. Ensure the ***entire*** label sketch is legible.
   a. If any portion of the label is illegible, FSIS will return the label and application.
   b. Ensure that the print is large enough to read and there is contrast between the print and the background.

4. Ensure the label application form is completed properly. If it is submitted in paper form, it ***must be typed*** or it will be returned without evaluation.
   a. Block #1 – leave blank unless using an Agent to submit the label application
   b. Block #2 & #3 – for USDA use only
   c. Block #4 – Place the establishment number(s) of your facility or facilities where the label will be used
   d. Block #4a – Indicate the type of product
   e. Block #5a – Indicate the common or descriptive name of the product
   f. Block #5b – Indicate the HACCP process category for the product.
   g. Block #6a & #6b – Indicate the type of label approval requested. If applying for a temporary label approval, indicate the number of days requested and the number of labels on hand. Also, for temporary label approvals, ensure that the information required in 9 CFR §§ 317.4(f)(1) or 381.132(f)(1) is also provided
   h. Block #7a – provide the area of the PDP – which is the entire side of the package where the label is affixed
   i. Block #7b – Provide the total available labeling space for the entire package in square inches
   j. Block #8 – Indicate whether the product includes a USDA-Agricultural Marketing Service (AMS) Child Nutrition Program CN logo.
   k. Block #9 – For USDA-AMS use only
   l. Block #10 – Indicate whether there are any claims being made on the label. Check all that apply to the label.
   m. Block #11 – Provide the name and address of the company.
   n. Block #12 & #13 – Sign and date the form.
   o. Block #14 – For USDA use only
   p. Block #15 – Provide the product formula. The ingredients should be listed by weight or percentage in order of predominance. List all ingredients using the same unit of measure. The formula may be provided in the space indicated, using a continuation sheet or may be attached. The total weight must equal the weight of all individual units. Percentage must total to 100%. Do not use fractions. Decimals carried to two places may be used.
   q. Block #16 – Provide the product's complete processing procedures.
   r. Attach any needed supporting documentation such as, for example, a copy of the label from a container of the "all-natural diced chicken white meat" you plan to use as a topping on the pizza.

5. Ensure that the formula provided on or with the label application and the ingredients statement on the label sketch agree.

6. Ensure that the formula, processing procedure and supporting documentation agrees with the information on the label.

7. If the label is in a foreign language, it must be accompanied by an English language translation.

8. FSIS prefers that applications be submitted electronically, as described in the next step. However, if submitted in paper form, ensure that you submit two copies of each completed label application with all accompanying documentation – including the label.

    USDA, FSIS, OPPD, LPDD
    Labeling Distribution Unit
    Stop Code 3786, Patriots Plaza III, 8-168
    1400 Independence Avenue, SW
    Washington, DC 20250-3700

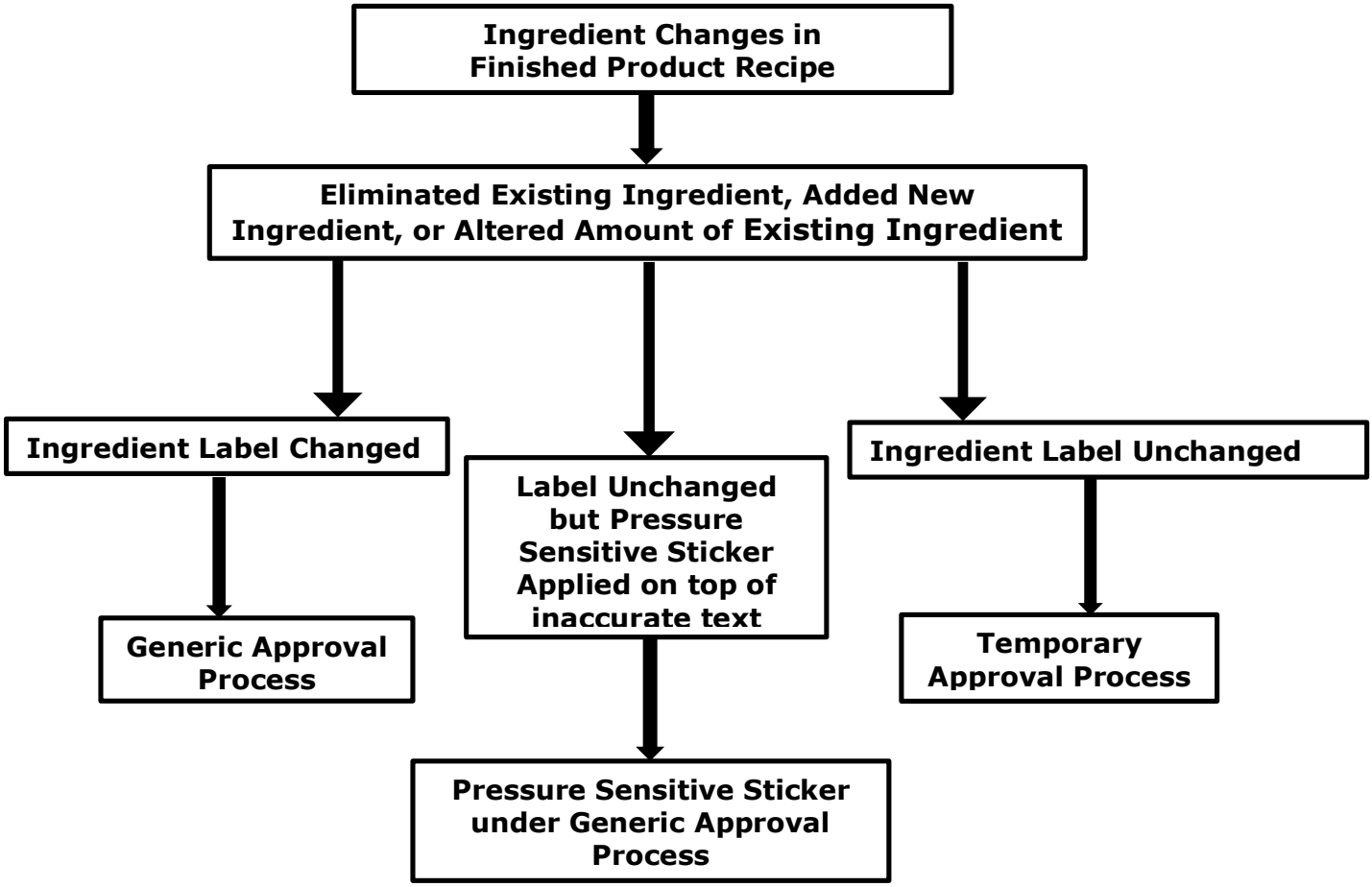
9. If the label is submitted electronically through the Label Submission and Approval System (LSAS), follow the procedures set forth on FSIS website.

Special Considerations for Label Approval – Generic and Temporary Approvals

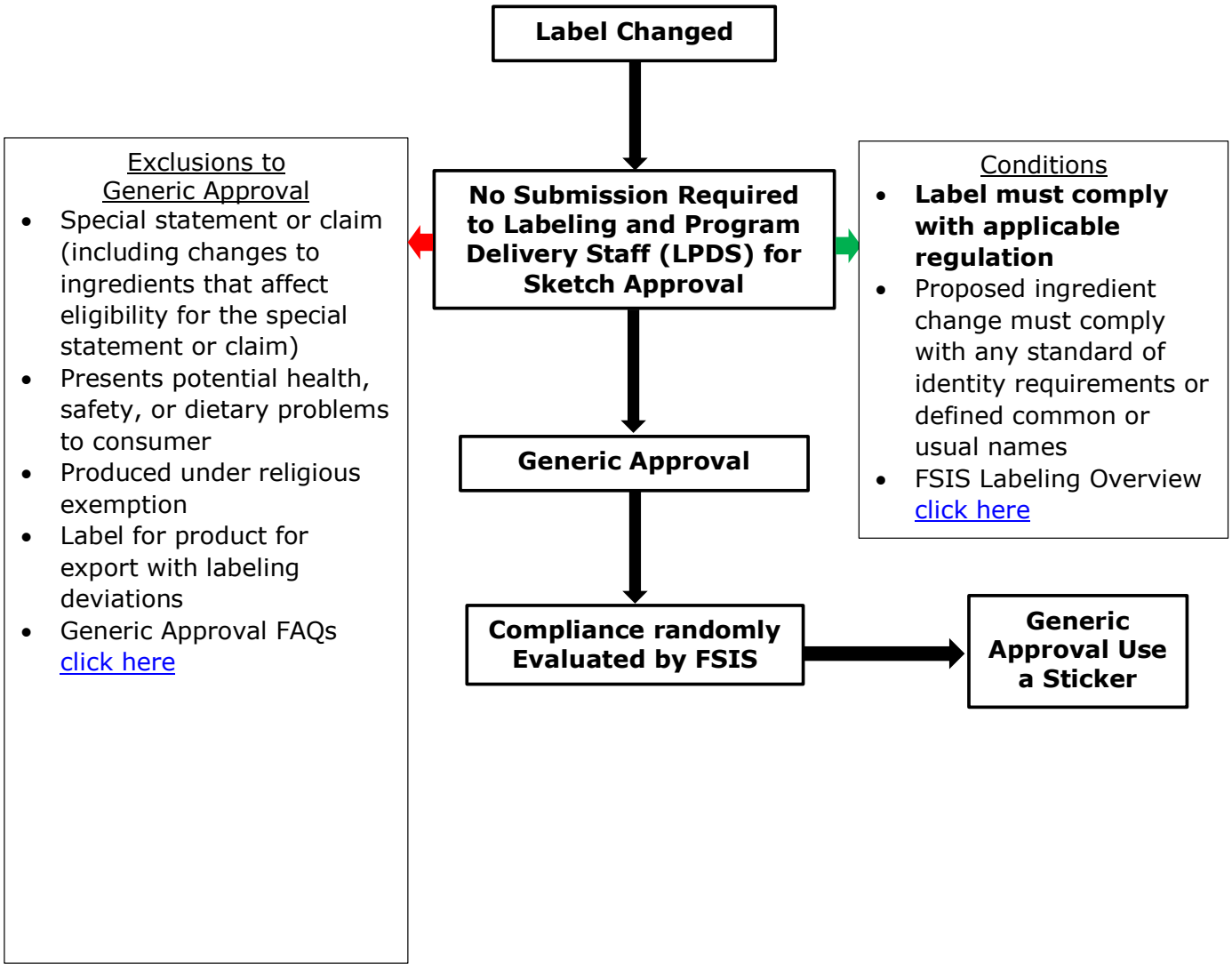
Because label preapproval is required in many situations for FSIS-regulated products, managing labels in situations of last-minute formulation changes can present challenges. In some cases, manufacturers may be able to use a modified label under generic approval or, if product has already been released, request temporary approval from FSIS to use a label that is technically not in compliance with FSIS labeling regulations. Use the following charts to help identify which options may be available.

Label Considerations for Finished Products

(Within USDA Jurisdiction)



Generic Approval to Change Labels

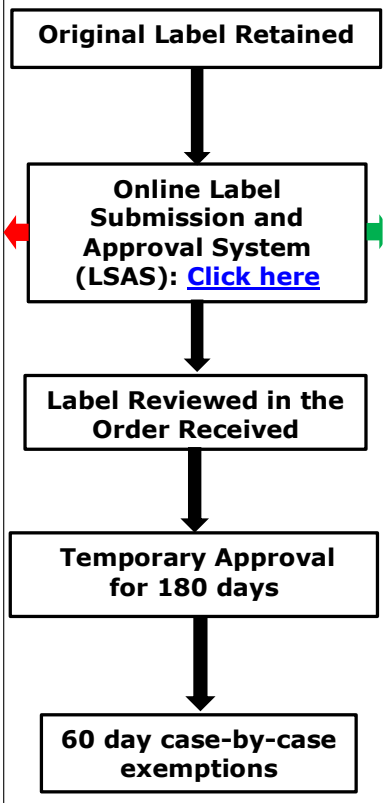


Temporary Approval to Retain Original Label

(FSIS approval discretionary and under limited circumstances)

Temporary Approval Exclusions
Click here

- **Other proteinaceous ingredients, e.g., kind of poultry or species of meat**
- "Ingredients that are known as allergens"
- Cereals containing gluten
- Salt
- Monosodium glutamate
- Restricted ingredients as listed in 9 CFR 424.21
- When undeclared sulfating agents are > 10ppm in an individual product
- Ingredient statement does not adequately represent the product because of drastic formula changes
- A standard is not met
- Cooking instructions are not adequate to render product safe.
- Labeling is missing a mandatory feature.
- When certain errors on label affect nutrition facts, nutrition claims, or nutrient claims.
- Failure to sub-list composite ingredients
- Misuse of the term 'fresh' on poultry
- When mechanically separated poultry in a product is not properly declared in ingredient statement

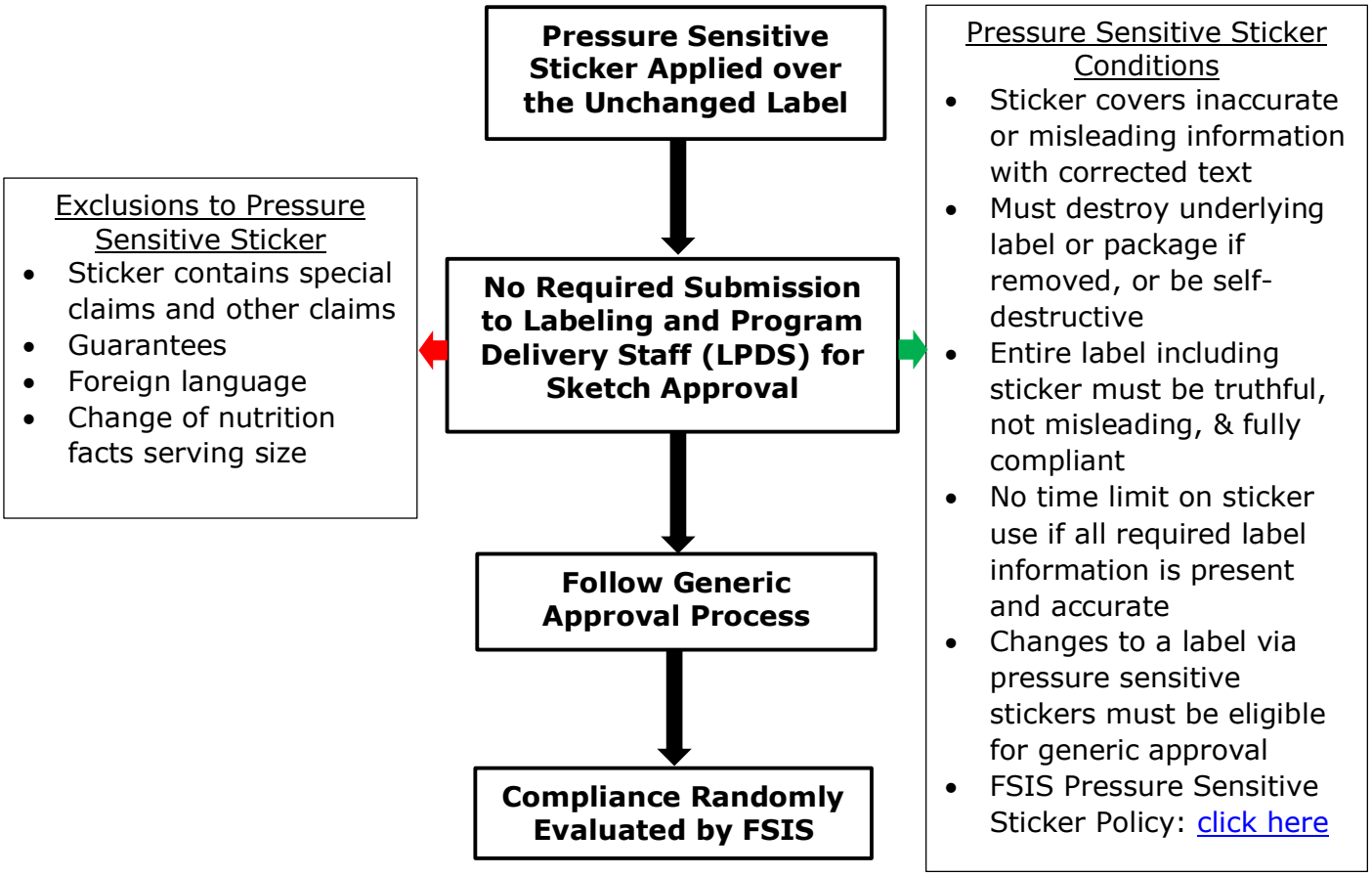


Typically Temporary Approvals are applicable to amend mislabeling, misbranding, pre-printed labels, etc., on products already in distribution.
E.g., can result when supplier fails to notify a label change in their ingredient
***Intentional Substitution of Ingredients are not the norm for Temporary Approvals**

Temporary Approval Conditions
(9 CFR 412.1 (f) (1))

- Label does not misrepresent product
- Use of old label with changed/removed ingredient does not present any potenti health, safety, or dietary problems to consumer
- Denial from Labeling and Program Delivery Staff (LPDS of the temporary approval request would cause undue economic hardship
- The temporary approval wou not result in a company's unfair competitive advantage
- Requesting temporary approval: Click here

Generic Approval Process Using Pressure Sensitive Sticker



Inspection Issues

FDA Inspections

FDA Inspection Authority

Section 704 of the Federal Food, Drug, and Cosmetic Act (FFDCA) gives FDA authority "to inspect, at reasonable times and within reasonable limits and in a reasonable manner" food facilities (including growing, manufacturing, warehousing, and shipping facilities and vehicles used to transport or hold food) and their operations. This encompasses entry into the facility; viewing of equipment; sampling of raw materials, in-process materials, and finished products; and collection of labeling for review. FDA may contract with State regulatory agencies to perform inspections.

1. Scope of inspection

- "Reasonable times"

A facility's normal operating hours are generally considered an acceptable time for inspection. Normal operating hours include any time the plant is in production, as well as performing sanitation. A company's policies may limit FDA inspections to normal operating hours, unless there are special circumstances that demand urgency.

- "Reasonable limits"

FDA's inspection authority is limited to all pertinent equipment, finished and unfinished materials, containers, labeling, and certain records. While the law limits what FDA inspectors are entitled to, it places no limits on what an inspector may seek to inspect.

- "Reasonable manner"

FDA inspectors are instructed to be tactful, courteous, and diplomatic. They are told to be firm but not overbearing.

2. Refusal to allow inspection

Refusal to allow inspection is a "prohibited act" under the FFDCA which may result in an injunction or criminal prosecution. FDA may also seek a warrant for inspection. A refusal to allow inspection includes a refusal to allow FDA inspectors to collect samples or perform other acts within the scope of their authority.

If a foreign facility, or the government of a foreign country, refuses to allow inspection within 24 hours after a request for inspection is made, food from that facility will be refused admission into the United States. FDA has Draft Guidance available outlining activities that may constitute refusal of inspection available here.

3. Reasons for Inspection

The intensity of an inspection generally depends upon the purpose or reason for the inspection. FDA may inspect a facility for the following reasons:

- Routine compliance inspection

Most inspections are part of FDA's routine compliance program and focus on compliance with food safety requirements including current Good Manufacturing Practice (GMPs) and Preventive Controls, and labeling.

The *FDA Food Safety Modernization Act* (FSMA), enacted in January 2011 requires that FDA inspect domestic high-risk facilities at least once every 3 years, and domestic non-high-risk facilities at least once every 5 years. FDA maintains a dynamic inventory of high-risk and non-high-risk domestic food facilities. It determines whether each facility is high-risk based on the following factors:

  - The known safety risks of the food;
  - The type of facility (e.g., manufacturer/processor, packer/re-packer);
  - The facility's compliance history (including recalls, violations, and foodborne illness outbreaks tied to its products);
  - The number of years since the facility's last inspection;
  - The rigor and effectiveness of the facility's hazard analysis and preventive controls plan;
  - Whether the facility has been certified by an accredited third-party auditor (applicable primarily to foreign facilities);
  - Whether the facility is at increased risk of intentional adulteration (applicable only to foreign facilities); and
  - Other criteria deemed appropriate by FDA.

- Complaint follow-up inspection

Complaints from consumers, health care professionals, or competitors may trigger an inspection.

- Recall follow-up inspection

Following a recall, FDA typically inspects a facility to ensure that FDA's recall guidelines are being followed and to ensure that the problem that caused the recall has been corrected. Companies can seek to limit the scope and depth of such recalls by having all relevant documentation and products readily available for review.[1]

[1] Recall requirements can be company- and product-specific and are beyond the scope of this Toolkit.

- FDA surveys and surveillance assignments

FDA sometimes conducts surveys of industries or regions. For example, in 1998, FDA inspected 85 ice cream, bakery, and candy manufacturing plants in Minnesota and Wisconsin for undeclared major food allergens.

- Government-wide Quality Assurance Program (GWQAP)

The GWQAP operates under inter-agency agreements between FDA and other agencies to conduct inspections to determine facilities' qualifications to bid on government contracts. Even though FDA conducts these inspections on behalf of other agencies, it treats any deficiencies uncovered in the same manner as it would if found during a routine inspection.

- Criminal investigation

FDA's Office of Criminal Investigations (OCI) conducts inspections in connection with alleged fraud or intentional misconduct. If an OCI investigator appears at your plant, legal counsel should be consulted immediately.[2]

How To Be Prepared for an FDA Inspection

1. Designation of Inspection Coordinators and Inspection Team

It is recommended that each company designate Inspection Coordinators and an Inspection Team who will be responsible for developing, implementing, and reviewing company inspection policies. The Inspection Team should include members from different facets of company management (e.g., operations, manufacturing, distribution, marketing, regulatory/legal).

The Inspection Team should include Inspection Coordinators, the persons with primary responsibility for managing inspections. The Inspection Coordinators should conduct the entry and exit interviews with the investigators, escort the investigators during the inspection, and direct collection of records and performance of corrective actions. Inspection Coordinators should be familiar with plant layout, plant personnel, and company inspection policies. They should have sufficient authority to answer questions from FDA investigators and direct corrective actions if deficiencies are found. At no time should a facility be without one or more Inspection Coordinators.

2. Preparation of company inspection manual

It is recommended that each company have a written inspection manual that contains the following:

[2] This Toolkit is not intended to provide guidance on handling criminal investigations.

- The Inspection Coordinator and other members of the Inspection Team (including business, home, and cell phone numbers as well as email addresses);
- Procedures for handling inspection (including immediate notification of Inspection Team, corporate HQ, and regulatory counsel, protocol for interacting with investigators);
- A system for documenting the entire inspection (including a daily log of all employees interviewed, questions asked, and responses given, documents copied, samples collected, and corrective actions taken);
- Company policies for issues that may arise during the inspection (e.g., in-plant photography, protection of trade secrets, signing affidavits and statements, and disclosure of certain records); and
- Contact information for relevant FDA officials at the local District Office and outside legal counsel (in case legal advice is needed during an inspection).

3. Establishing inspection policies

A company should have written policies addressing issues that are likely to arise during an inspection.

- In-plant photography

In recent years, FDA has taken a more assertive position regarding its authority to take photos or videos inside of food plants. The 2022 version of FDA's Investigations Operations Manual (IOM) states:

> Don't request permission from firm management to take photographs during an inspection because taking photographs is part of the Agency's authority to conduct inspections as part of Section 704(a)(1) of the FD&C Act [21 USC 374(a)(1)]. If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of firm conditions. Advise management the U. S. Courts have held that photographs may lawfully be taken as part of an inspection. If management refuses, obtain the name and contact information for the firm's legal counsel, and advise your program division management immediately. If the firm does not have legal counsel on retainer, collect the name and contact information for the most responsible individual. Program division management will inform their ORA Regional Counselor in the Office of Chief Counsel (OCC) of the situation, and OCC will then contact the firm's legal counsel or most responsible individual to discuss FDA's legal right to take pictures during inspections.

Although the IOM does not say so, if a company still refuses to allow in-plant photography, FDA could seek an inspection warrant or treat the company's actions as a refusal to allow inspection.

FDA cites two court cases as support for its authority to take photos inside plants, but neither of those cases stands squarely for the proposition that FDA has such authority. Nevertheless, if there were a court challenge today, it is possible that a court would hold that FD&C Act § 704 does authorize FDA to take photos inside of food plants. Given the ubiquity of cameras (e.g., cell phone cameras, video surveillance) in our society today, it is possible a court would find that in-plant photography does not

violate the reasonableness standard in § 704. FDA officials have also claimed that if its investigators cannot take photos, they will be forced to take detailed notes of their observations which will significantly prolong the duration of the inspection.

Absent clear statutory authority to take photographs during routine inspections, many companies have strict policies that prohibit photography inside their facilities, and enforce this policy during inspections. It is up to each individual company to decide whether to comply with a request to take photographs during a routine inspection. Some considerations when evaluating such a request include the following:

- Scope of and adherence to company policy: Do you have an established company policy regarding photography? Does it prohibit all photography or does it allow photography in some instances? Does it apply to employees and all visitors?
- Scope and Nature of FDA's request: Is the request being made before the inspection begins or during it? Is FDA's request to take photographs broad and unlimited or specific to certain places or conditions? Is FDA requesting to take photographs of a production line that contains proprietary equipment and/or processing steps? Is the request to take photographs of swab sites? Is FDA requesting to take photographs of objectionable conditions, and are the conditions likely to be in a Form 483?
- Tone of the inspection: Is the inspection otherwise going well? What was the investigator's response when the company's policy on photography was discussed? Do you expect the investigator to limit the photographs to any agreed upon areas?

Should you allow FDA to take photograph, you may want to adopt certain policies and procedures to protect the company from the risks posed by FDA in-plant photography:

- FDA photos may be used to portray conditions in a plant in a negative light. Companies can counter this by taking their own photos at the same time as the investigator. Photos should be taken from the same angle as the investigator, as well as from different angles, and in the same context so they show conditions more accurately.
- A company may be concerned that FDA photos will become publicly available, revealing trade secrets and confidential information to competitors. A company can protect itself by taking the following steps:

    - Adopt a written policy against in-plant photography, stating that the reason is to protect trade secrets;
    - Post a "No Photography" sign at the entrance to the plant and in appropriate areas of the plant;
    - Provide investigators with written notice of the policy at the start of the inspection;

- If the investigator insists on taking photos in the plant, explain that the company policy is designed not to refuse inspection but only to protect trade secrets, and allow photography under protest;[3] and
- Notify the investigator at the conclusion of the inspection that the company asserts that photographs taken contain trade secret/confidential information the disclosure of which would cause competitive harm and follow up with a written assertion of trade secret protection.

- Affidavits and statements

FDA investigators often ask company officials to sign what appear to be innocuous-sounding documents captioned "Affidavit" or "Statement." These affidavits may simply describe the shipping history of a product or component, how it was labeled, or other facts that appear to be true.

Company officials are under no legal obligation to sign such affidavits. We strongly encourage that no such affidavit be signed without review by legal counsel. The affidavit may recite facts that are basic elements for a civil or criminal case, such as the fact that raw materials traveled in interstate commerce. In addition, buried within the affidavit may be elements of a misbranding or adulteration charge. The Inspection Coordinator should accept the affidavit, without comment, for review by legal counsel. The Inspection Coordinator should explain that company policy prohibits him or her from signing or even commenting on the substance of the affidavit.

- Questioning of employees

Generally, an investigator's questions should be directed to and answered by the Inspection Coordinator. FDA investigators, unlike Occupational Safety and Health Administration (OSHA) inspectors, do not have statutory authority to speak with employees. Continuing attempts by an FDA investigator to speak with employees, rather than the Inspection Coordinator, should be brought to the attention of senior management or legal counsel so that appropriate action may be taken.

Employees should be advised not to volunteer information to the investigator, not to speculate on matters outside their expertise, and not to make idle conversation or joke with the investigator. Jokes may be misinterpreted or even reported as the truth in an investigator's report. Employees should never mislead investigators.

- Trade secret/confidential information

Any information or records provided to the investigator may be disclosed to the public unless it is trade secret or confidential information. ***To avoid public disclosure, the company must designate appropriate information as trade secret or confidential information, in writing, at the time it is***

[3] It is recommended that you document the protest, either in a contemporaneous memorandum to the company's own files or by ensuring the protest is recorded by the FDA inspector. In the absence of a contemporaneous record, a court reviewing the admissibility of FDA's photographic evidence in a subsequent proceeding could determine that the company had 'consented' to the photographs.

provided to FDA or within a reasonable time thereafter. Sensitive documents must be marked "Trade Secret" or "Confidential Information." As previously discussed, the company should request that any in-plant photos be designated as trade secret or confidential information.

FDA defines a "trade secret" as "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." FDA defines "confidential commercial or financial information" as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. § 20.61(a), (b).

While trade secrets and confidential information are exempt from public disclosure, FDA is under no obligation to accept a company's designation of records as trade secrets or confidential information. Therefore, a policy to simply mark every document given to FDA as trade secret or confidential information may be counterproductive.

- Records access

Records Facilities Must Produce During Routine Inspections:

1. Samples of finished and unfinished products and raw materials

2. Samples of product labels

3. Interstate shipping record
    a. Food
    b. Ingredients
    c. Packaging

4. Food Safety Plan and implementation records, including:
    a. Hazard analysis
    b. Preventative controls
    c. Recall plan
    d. Supply chain program, procedures, and implementation records
    e. Monitoring procedures and implementation records
    f. Corrective action procedures and records
    g. Verification procedures and implementation records, including:
        i. Environmental and product testing procedures and records
        ii. Equipment calibration procedures and records
        iii. Record reviews, including the justification for the timeframe for reviewing records
        iv. Reanalysis of the Food Safety Plan
    h. Validations for processing preventative controls and other controls (not for allergen, sanitation, or supply chain preventative controls), including the justification for not validating certain controls and the timeframe for validation

5. Documentation of the Preventative Controls Qualified Individual training, employee training (Qualified Individual training), and Qualified Auditor training

6. Food defense plan and associated documentation

7. Other records for facilities subject to additional food safety regulations (as applicable):
    a. Seafood HACCP records
    b. Juice HACCP records
    c. Low-acid canned food records
    d. Acidified foods records

FDA Emergency Access to Additional Records:

In addition to the above, FDA may access additional records in emergency situations. Pursuant to authority granted by the Bioterrorism Act, if FDA has a reasonable belief that an article of food poses a risk of serious adverse health consequences or death to humans or animals, FDA may inspect and copy any records related to that article of food (or any other article of food FDA reasonably believes is affected in a similar manner) that the agency needs to evaluate the risk, as well as records of the immediate previous sources and immediate subsequent recipients of such food. The investigator must specifically invoke this records access authority by presenting a special Notice of Inspection (Form FDA-482c), which requires the investigator to obtain written authorization from the FDA District Director or someone more senior within the agency. The FDA investigator himself/herself does not have the authority to invoke the Bioterrorism Act records access authority without obtaining this documented authorization. Examples of records FDA has access to under this authority include:

1. Complaint and adverse event records
2. Reports to the Reportable Food Registry
3. Audit reports (both internal and external)
4. Recall and product withdrawal records
5. One-up, one-down tracing records
6. Any records not routinely available related to the manufacturing, processing, packing, holding, or importing of an article of food necessary to determine whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Records Facilities are Not Required to Produce:

1. Product recipes (A recipe is defined in 21 C.F.R. § 1.328 as “the formula, including ingredients, quantities, and instructions necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.”)
2. Financial information
3. Pricing information
4. Personnel records and organizational charts (FDA can access records related to employee training programs)

5. Research data
6. Sales information (including sales attributable to the plant, lists of top customers, and lists of top products, but note that FDA can access shipping records for outbound products)

Handling Records Requests:

FDA investigators sometimes request records to which FDA is not legally entitled (e.g., consumer complaints during a routine inspection). Companies should adopt written policies on how they will respond to such situations. Will records outside FDA's inspection authority be provided and, if so, which records? There is no point in denying investigators catalogs or promotional materials that are publicly available. In other cases, the company may need to weigh the potential risks and benefits of providing the records. If company officials wish to refuse an FDA request for records without antagonizing the investigator, two effective ways to do this are:

- Ask the investigator to put the request in writing; or
- Cite company policy prohibiting disclosure of the record in question and explain that you cannot change the policy without first consulting senior management and legal counsel. If company policy is cited, make sure the company has a written policy in place.

4. <u>Making sure your house is in order</u>

To be prepared for an FDA inspection, a company should have sound GMPs, a QA/QC program, and a rigorous hazard analysis and preventive controls plan. These should be reviewed by the Inspection Team for any weaknesses or gaps. In addition, the Inspection Team should ensure that all registrations required for each facility are accurate and up to date.

The Inspection Team may wish to conduct periodic, unannounced mock inspections to discover any problems that might arise during a real inspection.

Handling FDA Inspections

1. Greeting the investigator

When an investigator shows up at your facility, the receptionist should ask for the investigator's business card (but not his or her official credentials or Notice of Inspection) and ask the investigator to wait in a suitable office or conference room (i.e., one which is isolated to the extent practicable from operational and recordkeeping areas). Receiving an investigator's official credentials or Notice of Inspection (Form FDA-482) may constitute consent to inspection, so it is important that only authorized personnel receive and review them. The Inspection Coordinator or other member of the Inspection Team should then be notified. Don't keep an investigator waiting over 20 minutes. If you will need to keep the investigator waiting longer, explain why to the investigator (e.g., you need to find the Facility Manager).

Upon meeting the investigator, the Inspection Coordinator should review and make note of the investigator's credentials and accept the Notice of Inspection. Federal law prohibits photocopying of official credentials. If there is any doubt as to the identity of the investigator, the FDA District Office should be contacted immediately to verify the investigator's identity.

If no members of the Inspection Team are present, a senior manager should be contacted. This senior manager may ask the investigator to return at a more convenient time, but the investigator does have the legal authority to enter and inspect the facility during normal operating hours, regardless of the presence of any company official.

2. Pre-inspection conference

Although not required, it is advisable to hold a pre-inspection conference to determine the reason for the inspection, the nature of the inspection, and its likely scope. The Inspection Coordinator may wish to prepare an agenda for the inspection and share it with the investigator. This may help prevent the inspection from becoming an unfocused "fishing expedition."

The pre-inspection conference is also the best opportunity to inform the investigator of relevant company policies that may affect the conduct of the inspection. In addition to the policies discussed above, company policies on protective clothing, non-smoking areas, and health status of persons entering sensitive areas should be explained to the investigator. The Inspection Coordinator should also request that the investigator inform him of any observations as they arise during the inspection.

Investigators may accept modest items of food and refreshment (e.g., coffee, soft drinks, donuts), but FDA discourages them from accepting anything beyond that. Investigators may not consume the inspected firm's products, since this might be interpreted as an affirmation of their compliance.

3. Accompanying the investigator

The Inspection Coordinator should accompany the investigator. It is recommended that another employee also accompany them to take notes, copy records, and collect samples so that the Inspection Coordinator is free to focus on the investigator. If there is more than one investigator, a designated employee should be assigned to accompany each investigator.

4. Correcting deficiencies uncovered during inspection

If problems are uncovered during the inspection, the Inspection Team should be prepared to respond to them. Easily correctible problems should be corrected immediately, and the corrective action brought to the investigator's attention. If appropriate, a commitment to correct a minor problem should be made to the investigator. Such deficiencies and responses should be noted by the Inspection Coordinator or other company escort. If there is reason to believe a deficiency is more serious and that affected product may violate the law, the affected product should be immediately segregated and held pending resolution of the issue.

5. Requests for records

If the investigator requests records, the Inspection Coordinator should determine whether the requested record is within FDA's records access authority or, if not, whether company policy allows inspection of the record. If the record is provided to the investigator, the Inspection Coordinator should:

- Provide a copy of the record to the investigator and retain a duplicate copy;
- If the record contains trade secret or confidential information, stamp the document with an appropriate notice of confidentiality (e.g., "Trade Secret and Confidential Information, Not for Public Disclosure"); and
- Provide the investigator with a list of all records provided, noting which ones contain trade secret or confidential information.

If records are provided in electronic form, it is recommended that the record be provided with a company-supplied password and in a format such that it is not possible to alter the record's content. The password should be provided to the investigator separately from the medium containing the electronic record. Do not allow investigators to browse in company files or computer systems.

6. Taking of samples

FDA investigators are authorized by law to take samples of finished and unfinished products, packaging materials and labeling, and ingredients. FDA may also take "environmental samples" (i.e., swabs of food-contact and non-food-contact surfaces in the plant). The Inspection Coordinator may inquire as to why the sample is being taken and make a note of the sample identity, sampling method, type of container used to hold the sample, and the investigator's comments.

Investigators are required to provide a receipt describing each product sample taken (Form FDA-484),

except for samples of labeling. A receipt must always be obtained by the Inspection Coordinator. It is common industry practice to have a company policy of not signing sample receipts; this allows the Inspection Coordinator to simply state that company policy prohibits signing of any documents. When investigators copy documents but do not take the originals, they do not provide a receipt but will provide a list of the documents copied if requested.

The company may charge FDA for samples taken. Various formulae may be used to calculate the charge, such as cost, cost plus percentage, or lowest customer price charged. However, depending upon the material sampled, the amount of the charge may not be worth the hassle.

The company is not required to segregate or hold lots that have been sampled by FDA. However, if the investigator samples finished product or swabs a food contact surface (FCS), it is recommended that the facility hold that production lot and shut down the line and perform a complete cleaning and sanitization. Otherwise, if the sample tests positive for a pathogen, the company might have to recall that lot. The facility can ask FDA to note on the sample form "product on hold" to try to expedite the receipt of results. If the investigator swabs a non-FCS that is near a FCS, the facility should document that its controls would prevent contamination of the product, even if that non-FCS is positive for a pathogen. In addition, records should be kept to facilitate product retrieval in the event that becomes necessary.

7. Post-inspection conference

The investigator will usually request an exit interview with top management of the plant. During this post-inspection conference, the investigator will discuss observations made during the inspection and issue a Form FDA-483 if there have been any significant observations. The investigator's observations and findings should be reviewed and discussed one by one. If an observation or finding is not understood, ask for clarification. If the observation is not agreed with, explain the reasoning for the disagreement. If an observation or finding has been corrected, tell the investigator, and ask the investigator to note the corrective action in the investigator's written inspection report. If certain observations made by the investigator are intended to be corrected, explain the corrective actions to be taken and the corresponding timeframe for the corrective actions. Be sure to understand whether the investigator has any "discussion points" or feedback that will not appear on a 483 but are potential areas of improvement for the facility. These will be recorded in the Establishment Inspection Report (EIR) and verified at the next inspection.

The company should provide the investigator with any records requested but not already provided. The company should also ask the investigator if he or she has any further questions and if the company has exhibited the appropriate level of cooperation during the inspection. The company should also ask the investigator when it may expect to receive test results of any samples taken during the inspection.

A detailed summary of the investigator's verbal report to management should be prepared and transmitted to the appropriate leadership personnel.

8. Form 483

If significant observations were made during the inspection, the investigator will issue a Form FDA-483 (Inspectional Observations) at the conclusion of the inspection. Observations of lesser significance may be discussed with the company and noted in the Establishment Inspection Report (EIR).

Conditions listed on the Form 483 should be significant and relate to an observed or potential problem with the facility, equipment, process, controls, products, employee practices, or records. Reportable observations include the following:

- Foods consisting in whole or in part of filthy, putrid, or decomposed substances;
- Insanitary conditions or practices which may render food injurious to health;
- Careless handling of pesticides or rodenticides;
- Faulty manufacturing, processing, packaging, or holding of food as related to current GMP and preventive control regulations; or
- Results of tests revealing adulteration.

Investigators are not supposed to characterize conditions as "violations," quote FDA regulations, or report conclusions, because the determination of whether any condition is a violation is an agency decision.

If both the investigator and the company agree, the Form 483 may be annotated. Annotations are succinct comments about the status of an observation and are generally limited to the following four phrases:

- "Corrected and verified"
- "Reported, corrected, not verified"
- "Promised to correct"
- "Under consideration" (meaning that the company and investigator disagree about the validity of the observation)

If the company disagrees with an observation or if there is uncertainty about the significance of an observation, the company may suggest that the investigator not list it. If the investigator refuses, the company should firmly but politely insist that its objection be noted for later inclusion in the EIR. In addition, if the company believes a trade secret or proprietary process is revealed in the Form 483, the Inspection Coordinator should indicate this to the investigator and send a written confirmation to the local FDA District Office requesting trade secret protection.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
	FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

FIRM NAME	STREET ADDRESS
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

List your significant observations ranked in order of significance.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE IS

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 1 of 1 PAGES

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Post-Inspection Follow-Up

After the inspection, the company must take responsible action before the inspection can be closed.

1. Responding to the Form 483

A Form 483 should never go unanswered. The company should respond in writing as soon as possible, but no later than 15 business days after the inspection. This is the timeline FDA has established for issuance of Warning Letters.

There is no formal mechanism or established format for responding to a Form 483. Companies generally respond in the form of a letter with relevant documentation attached. The response should detail any corrective actions that have been taken or will be taken, and when, and provide documentation of such corrective actions (e.g., a copy of revised SOPs). In describing corrective actions, both costs and man-hours should be itemized where appropriate. It is advisable that the response be reviewed by senior management and legal counsel prior to submission.

If the company disagrees with any observations in the Form 483, the basis for such disagreement should be clearly stated, and the company should request that the response to the Form 483 be incorporated into the EIR.

If any corrective actions promised in the response take more time than anticipated, the company should inform FDA of its progress. Failure to keep FDA informed may be seen by the agency as evidence of the company's lack of interest or ability to make the necessary corrective actions. Supplemental responses to the Form 483 may been needed.

2. Obtaining reports of sample analysis

FDA is required to provide a report of analysis of any sample of food taken during the inspection. Reports are not required for non-food items (e.g., rodent pellets). The Inspection Coordinator should follow up with the investigator or laboratory to obtain copies of reports.

3. Obtaining the Establishment Inspection Report

FDA procedures require that the investigator prepare an Establishment Inspection Report (EIR), which is a narrative account of the inspection including the investigator's objective and subjective impressions. The EIR should include copies of all forms issued during the inspection, the investigator's notes, samples and sample test results, records reviewed, and any additional material referred to in the narrative report. It may also include the company's response to the Form 483, in toto or summarized.

It is FDA policy to provide a copy of the EIR to the company once the inspection is closed. If an EIR is not received within 4 to 6 weeks after an inspection, the company should request a copy. FDA's refusal to provide the EIR may be an indication the agency is considering an investigation of the company,

because investigatory records are exempt from disclosure under the Freedom of Information Act. Senior management and legal counsel should be notified of the agency's refusal to provide the EIR.

The EIR should be reviewed for any errors or inaccuracies. Serious errors should be responded to in writing and placed in the record at the FDA District Office. Release of the EIR by FDA does not necessarily mean that FDA does not intend to take regulatory action.

4. FDA actions following an inspection

The EIR, Form 483, and sample test results will be forwarded by the Chief of FDA's Investigations Branch in the District Office to a Compliance Officer for that district. The Compliance Officer will decide whether the observations and test results constitute violations of FDA law and regulations. The Compliance Officer will then make one of the following decisions: (1) no action indicated (NAI); (2) voluntary action indicated (VAI); or (3) official action indicated (OAI). An NAI classification means the investigator found no violations or only insignificant violations. A VAI classification means the investigator found violations, but these are not serious enough to warrant regulatory action. An OAI classification means there are violations that may potentially warrant regulatory action.

Where an inspection is classified as OAI, regulatory action may follow. In most cases, FDA will first take an advisory action rather than proceeding immediately to enforcement action. Advisory actions may include a Warning Letter or untitled letter, or a meeting with company officials (called a "regulatory meeting"). In more extreme situations, or if the company's response to an advisory action is deemed to be inadequate, FDA may take enforcement action. Enforcement actions may include administrative detention of food, seizure of food, injunction, suspension of the facility's registration, or criminal prosecution. FDA may also conduct a re-inspection of the facility to ensure that appropriate corrective actions have been taken and charge the company for the cost of the re-inspection.

Post-inspection review

It is recommended that companies conduct a post-mortem, or after-action review, of the inspection to learn from the experience. This review may consider, for example, what the focus of the inspection was, whether the investigator collected environmental samples, whether the investigator requested records outside the scope of FDA's authority, whether the facility took corrective actions in response to the investigator's observations, and how the facility resolved any disagreements with the investigator. A company with multiple facilities may wish to share this information with its other facilities, particularly if those facilities have similar programs and those programs may need enhancement.

Re-inspection Fees

Under FSMA, if an FDA inspection results in a classification of Official Action Indicated (OAI) due to non-compliance that is materially related to food safety, FDA will re-inspect the facility to confirm that corrective actions have been taken and has the authority to assess re-inspection fees to cover its costs associated with the re-inspection. The responsible party (i.e., the person who submitted the facility's registration to FDA) of each domestic facility, and the U.S. agent of each foreign facility, is liable for any

re-inspection fees. Currently, FDA is not billing for re-inspection fees until the agency issues a guidance document outlining a process whereby companies may request fee reductions because of economic hardship.

RESOURCES

- FDA's inspection webpage
- FDA Inspection Guides
- FDA Inspection Technical Guides
- FDA Investigations Operations Manual
- FDA Guide to International Inspections and Travel
- FDA Compliance Policy Guides (Subchapter 130 – Inspections)
- FDA Form 483 Frequently Asked Questions

USDA Inspections

Dealing with the USDA Inspector

Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, the Food Safety and Inspection Service (FSIS) is charged with maintaining a regular inspection presence at every official establishment processing amenable meat or poultry products.

Given the inspectors will be at the plants, a food manufacturer should understand agency expectations and establishment rights in dealing with inspection program personnel (IPP).

In general, establishments and IPP should maintain a professional relationship. Both parties should treat the other with respect and clearly communicate with each other.

Guiding Relationship Principles

FSIS provides some key relationship principles that may be helpful to both sides, particularly when facing a difficult situation with an inspector.

The following principles are part of the FSIS Directive 4735.1, Rev.1. These principles may also be useful to industry for establishing and fostering better relationships with the IPP.

Maintain open, honest, and straightforward communication. Understand each other's roles and responsibilities – Meaning and intent are conveyed by more than words alone. Voice, tone, expression, listening ability, and apparent receptiveness, impact those you wish to reach. Know and understand the regulations that IPP will be enforcing to make communications more effective.

Have mutual respect – Give respect, get respect.

Be issue oriented; do not personalize – Focus on the issue being discussed and don't let personalities get in the way.

Weekly FSIS Meeting

A primary means of communicating with the IPP is the weekly meeting. The establishment management should take full advantage of this meeting and ensure any issues or concerns are being addressed at this meeting. If FSIS is not scheduling weekly meetings with establishment management, a prudent establishment will reach out to FSIS to schedule such meetings as a mechanism to build a good working relationship with FSIS personnel. FSIS has issued an FSIS Directive on the expectations for this meeting, including the fact that the IPP are to take notes of the meeting and document the notes in a Memorandum of Interview (MOI).

If establishment management disagree with the content of the MOI and would like to add **facts they feel were omitted from the discussion**, it is recommended that the establishment document this information (factual based) and provide a copy to the IPP. The IPP is instructed to reference the attachment in the MOI and provide a copy back to plant management.

Non-compliance Record (NR)

When Should the IPP Issue a NR?

FSIS provided the following response to small and very small plants on the agency website regarding when IPP are instructed to issue an NR:

"When should inspection program personnel write a noncompliance record (NR)?
A. NR is to be completed whenever inspection program personnel determine that an establishment has failed to meet one or more regulatory requirements."

FSIS has provided further clarification regarding numbers of NRs to be written by IPP. FSIS clarifies that there is not a quota or an expected number of NRs to be written.

"Is there a specific number of NRs that inspection program personnel are supposed to write?"
A. No, inspection program personnel will document only the regulatory noncompliance violations that they identify on NRs.

Reviewing NRs

Whenever an establishment receives an NR, it should review the NR to determine whether the document has been completed correctly, whether the description of the noncompliance is adequate to allow the reader to visualize the incident, and whether the inspector has applied the appropriate policy to the facts found.

It is important to review NRs closely to avoid additional regulatory difficulties and to appeal an improperly written or issued NR. While there is no regulatory requirement to respond in writing to an NR – or a time limit – doing so creates a written record of what the establishment has done to correct and prevent the noncompliance or that the establishment disagrees with the NR or parts of the NR as written and intends to appeal the NR or certain parts of the NR.

It is important to respond in a timely manner – especially if the establishment intends to appeal the NR. The NR, as originally documented, will remain in the Public Health Information System (PHIS) to be linked to future NRs, or used to support regulatory actions such as Notices of Intended Enforcement or Notices of Suspension unless changed or rescinded. FSIS details its response times for each step of an appeal and a prudent establishment would not take longer in its response than FSIS. On the following page is an example of an NR.

Block 1 indicates the date the noncompliance occurred. It might not be the date the NR was written.

Block 2 is for the number of the NR. With the advent of the Public Health Information System (PHIS), it is a randomly generated number. When an inspector is conducting an inspection task that takes multiple days to complete and there are multiple noncompliance violations noted for the same task, the IPP are instructed to document the noncompliance using the same NR number and indicate the day the additional noncompliance was noted, e.g., the same 14-character number and /2.

Block 3 is the establishment number followed by a code to designate whether a meat or poultry product was involved (M or P) and which shift the noncompliance occurred on (1, 2, or 3). The latter can give plant management reviewing the NR a clear indication of whether a particular problem is limited to a particular shift or is more general. The establishment number is automatically generated by PHIS.

Block 4 is to be filled in with the name and title of the person to whom the NR is addressed. PHIS contains a "pick list" of establishment contacts from the plant profile, or the name can be manually entered. This may not be the individual who was notified of the noncompliance (that person is identified in box 5). If the noncompliance involves a HACCP or SSOP deficiency, the NR will be addressed to the corporate individual who signed the plan. This could be sufficient to put the responsible official on notice of the failure of the HACCP/SSOP and enable FSIS to take criminal action against the official for repetitive noncompliance.

Block 5 is to be filled in with the name of the plant employee who received the notice of the noncompliance. PHIS contains a pick list of establishment contacts from the plant profile, however, if someone else was notified then the name is to be manually entered.

Block 6 contains the citation to the relevant regulations which have been violated. The block must contain citations to regulations, not FSIS Directives, guidance material, or other informal materials. Inspection personnel are instructed to include all regulations that pertain. This is a "pull down" menu of regulations for the IPP. Establishments should pay close attention and ensure all regulations that are cited are relevant.

Note: PHIS tracks and counts **each** regulation that is verified along with each regulation that is noncompliant. It is important to recognize that an establishment's performance is based on the individual instances of regulatory noncompliance entered into PHIS and **not** on the number of NRs issued.

The request for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9CFR 301 and 9CFR 381, FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

US Department of Agriculture
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☐ Food Safety ☐ Other Consumer Protection

1. DATE | 2. RECORD NO. | 3. ESTABLISHMENT NO.

4. TO (Name and Title) | 5. PERSONNEL NOTIFIED

6. RELEVANT REGULATIONS | 6a. ASSOCIATED NR(s)

7. TITLE(S) OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION | 7a. NAME OF HACCP CCP(S) or PREREQUISITE PROGRAM

8. INSPECTION TASK | 9. VERIFICATION ACTIVITY
☐ Review & Observation ☐ Record Keeping ☐ Both
9a. AFFECTED PRODUCT INFORMATION
9b. RETAIN/REJECT TAGS

10. DESCRIPTION OF NONCOMPLIANCE

11.SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. ESTABLISHMENT MANAGEMENT RESPONSE:

FSIS FORM 5400-4 | DISTRIBUTION: Original & 1 Copy to Establishment, 1 Copy to Inspector

Page 1 Of 2

This document serves as written notification that your failure to comply with regulatory requirements(s) could result in additional regulatory or administrative action.

13.SIGNATURE OF ESTABLISHMENT MANAGEMENT | 14. DATE

15.VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE | 16. DATE

Block 6a contains a location for documenting associated NR(s). The IPP is instructed to include the associated NRs when a developing trend in noncompliance for the same root cause is occurring within the establishment. There is an application within PHIS that permits the IPP to review recent NRs with similar documented noncompliance violations and select one or more of these NRs to be included in Block 6a.

Block 7 contains the cite to the relevant section or page of the establishment's HACCP or SSOP plan (if applicable). The IPP will also include the name of the HACCP plan that was verified. PHIS provides a pick list of the HACCP plan names that are included in the plant profile to be selected or the information can be manually entered.

Block 7a is to be utilized for HACCP verification tasks and is to contain the name of CCP(s) or prerequisite program that was verified.

Block 8 references the five-digit inspection system procedure or "ISP" code. The code is automatically filled in by the PHIS system. The task may be a routine task or a directed task.

Block 9 is the verification activity (review & observation or recordkeeping or both) that was selected by the IPP to verify compliance with the regulations. PHIS will include this information from the inspection results page.

Block 9a is utilized to document affected product information. The IPP are instructed to check the product adulteration box on the NR to indicate that adulterated or misbranded product was identified as part of the noncompliance. For example, if an IPP finds fecal material while performing the Livestock Zero Tolerance task the product adulteration box should be checked. If the adulteration box is checked, the IPP enter the product name, lot number, approximate weight, and any other information available in the data fields to identify the specific amount of product affected by the noncompliance. The block is left blank if there is no adulterated or misbranded product associated with the noncompliance.

Block 9b is completed to when the IPP takes a regulatory control action. The IPP are instructed to enter the reject/retain tag number in Block 9b.

Box 10 is filled out by the inspector to describe the noncompliance. Inspectors have been trained to provide sufficient objective detail to allow the reader "to visualize the incident." There is a supplemental NR form for the inspector to use if more space is needed. Subjective terms, such as "dirty," are not to be used in describing the incident. Establishments should be aware that an inspector may describe the noncompliance in a manner that makes it seem worse than it is. For example, three small contaminants on a product may be described by reference to the area between the specks, rather than the dimensions of the specks themselves. In addition, if the inspector believes there have been previous related noncompliance violations, the NR numbers of these noncompliance violations will be included in this description. This should be taken as notice that the inspector is intending to link the noncompliance violations to demonstrate a systemic failure.

Box 11 is for the signature of the inspector. The inspector is to sign the document after completing the previous boxes. It should be noted that nowhere on the NR is there a box to designate when the NR was written. Although not customary, it is not unusual for an establishment to receive an NR prepared a day or two after the event in question. Since this delay may place the establishment at a disadvantage, the establishment at a minimum should note the date received in box 12. In addition, there is no box to designate whether the NR has been modified by the inspector. There have been situations where an inspector will withdraw an NR after speaking with the plant and then issue a different NR for the same occurrence. If this occurs, the establishment should note this fact in its response.

Establishments are not required to respond to NRs (although they are required to meet the corrective action requirements for HACCP and SSOP, including documentation). However, establishments are encouraged to document a response (even if they plan to appeal the NR) as the response becomes part of the record. Establishments can respond in writing or through PHIS (if they have establishment access).

Box 12 is the plant management response in terms of its immediate actions. This would include appropriate product actions and restoration of control. Often this response was already given orally to the inspector at the time the inspector identified the noncompliance. The IPP can include a brief synopsis of the establishment's verbal response in Block 12, however the IPP is instructed to record a more detailed description of any verbal responses on a Memorandum of Interview (MOI) after the next weekly meeting. However, unless all actions orally promised and subsequently taken are included on the NR, there will be no documentation to prove how the establishment responded. Even if the establishment disagrees with whether a noncompliance occurred, it should briefly describe its immediate actions with regard to product, such as placing the product on hold; otherwise, FSIS supervisory personnel may not consider responding to the appeal until the "immediate" corrective action is performed.

Box 13 and 14[4] is the plant management's signature and date. If the establishment provides a response to the NR, then the IPP will provide the plant manager a printed copy of the NR to sign and date.

Box 15 and 16 are for the IPP signature and date to close the matter once the establishment is back in compliance with all the regulatory requirements documented on the NR as noncompliant.

To Appeal or Not to Appeal

Establishments typically take a case-by-case approach to appealing NRs, although some may decide to appeal more or less often. Failing to appeal an NR with which the establishment disagrees creates a risk that the NR could be used to support additional regulatory action, such as a Food Safety Assessment (FSA), followed by a Notice of Intended Enforcement (NOIE), which could result in suspension of inspection. Since the FSIS District Office will rely on the documentation to decide, NRs in the file will be assumed to be correct and could be used to support action such as a suspension.

[4] FSIS removed the blocks for "immediate and further planned action" that were on previous editions of the NR. These actions are not required by the regulations and therefore FSIS cannot require a written response from establishment management to these requests.

NRs linked to – referencing – previous NRs can be especially troubling and an indication of potential regulatory action. Practically speaking, it is too late to appeal an NR once the suspension process has begun.

Beyond the risk of enforcement action, NRs are releasable under the Freedom of Information Act, creating the potential for NRs with which the establishment disagrees to be released. Although any trade secret/confidential information is to be removed from the NR, a high percentage of the NR content (and the inspector's written descriptions of the incidents) likely would be released, potentially damaging a firm's reputation.

The Procedure for Appeal

Establishments have the right to appeal all or part of the NR or any other inspection decision. The appeal should be addressed through the FSIS chain-of-command. 9 CFR §§ 306.5 and 381.35 state that the establishment shall appeal to the immediate supervisor of the person who made the decision.

A helpful guidance for appeals is the "Compliance Guideline for Small and Very Small Plants Appealing Inspection Decisions." FSIS specifies the chain of command for appeals on page 1 of this Guideline.

Keys to a Successful Appeal:

When appealing an NR, the plant should:

- The establishment should review the regulation cited and ensure it is the correct regulation for the incident.
- Review the description of the noncompliance and read the correct regulation to determine if they agree whether they did or did not comply with the regulation.
- The establishment should review the description documenting the noncompliance and verify that the facts as documented are correct and complete.
- If the establishment disagrees with any portion of the NR they should determine the facts and legal arguments they have to support the appeal of the NR.

Based on the NR review, there are six primary grounds to appeal:

- The NR is not technically correct in some regard, e.g., the IPP cited to the wrong regulation (or to an informal rule) or the wrong page of an establishment's SSOP or HACCP plan. Normally, this can be corrected by pointing the error out to the inspector who will correct the NR.

- The NR is not correct or is misleading as a factual matter. The establishment should read the section below regarding supporting evidence if the dispute is factual.

- The NR is incorrectly classified. Since NRs are trended and can be used to trigger enforcement actions, the establishment should ensure the NR is appropriately classified. For example, an SSOP failure occurs when there was actual direct product contamination or when it is

reasonable to assume direct product contamination would have occurred but for the inspector's action. If direct product contamination has not occurred and it is not likely to occur, the noncompliance should not be identified in the SSOP classification.

- The NR should not have been given since the establishment corrected or would have corrected the deviation on its own. As we understand FSIS policy, the establishment is to be given one opportunity to detect and correct a deficiency through its established plan. Thus, if an inspector detects a HACCP deviation, but the establishment has not yet performed its monitoring check (based on the HACCP plan), the system has not yet failed and the plant should be given the opportunity to detect the problem and respond accordingly, provided, adulterated product is not likely to be shipped before the establishment would detect the deviation.

- The NR does not describe a violation. One example would be condensation dripping from a surface that has been cleaned and sanitized according to the establishment's SSOP.

- The inspector improperly cross-referenced previous NRs. The noncompliance described in the NR is legitimate, but it should not be linked to previous noncompliance violations. Such an appeal will be based on the corrective actions taken in response to prior appeals. If the previous preventive measure was effective on the earlier deviation but would not have prevented the current deviation (due to different root causes), the NRs should not be linked.

Supporting Evidence for Factual Appeals

An appeal involving a factual dispute should include evidence to support the establishment's articulation of the facts.

Supporting Evidence – There are a variety of sources which can be used to support an establishment's articulation of the facts. These can include:

- Statements from employees,
- Plant diagrams,
- Equipment manufacturer instructions or data,
- Scientific articles,
- Supplemental plant records not referenced by the IPP, and
- askFSIS questions that have been posted on a similar factual situation, and statements from employees

Use of Photographs -- Since the facts are relevant to supporting an appeal, it will be important any time a plant feels they might be appealing an inspection decision to make records of the situation. Photographs can often be helpful in this regard. When taking photographs some helpful considerations include:

- Photographs should have time stamps, when possible, to validate the date.
- Photographs should include rulers as appropriate to verify size if documenting an object.

- Photographs should include a reference point if documenting a location.

An appeal should not be merely a “he said/she said” response to the Agency; absent specific facts to support the establishment’s position, the appeal will be denied.

Complaints against Inspectors

An establishment may end up having an issue with an FSIS employee. The Agency has made it clear that it **will not** tolerate retaliation from IPP in response to an appeal action. If the establishment feels there is retaliation (activity perceived as an action to get even or control a particular situation), their concern should be raised to the attention of the District Office, in writing. Meanwhile, if the establishment has subsequent NR appeals, they should continue to base those on the facts of the situation, not on the emotions of the inspection issue. Information is available here.

FSIS expects their employees to act professionally and conduct their regulatory responsibilities in a fair, unbiased, and non-retaliatory manner. If there is an **assault, harassment, intimidation, retaliation, or threat** by an IPP, FSIS provides a process for the establishment to make a formal complaint to the Agency.

There may be situations where the establishment has an issue with an IPP of a lesser nature. In such a case, the establishment may wish to make an informal complaint to the FSIS District Office. Informal complaints are generally less serious in nature and are often related to a situation where the establishment has a disagreement with the IPP.

Filing a Formal Complaint

A formal complaint by an establishment is made in writing, with the specific accusations, to the District Manager. Filing a Formal Complaint:

The letter should include:

- Name of complainant
- Name of Agency employee(s)
- Statement explaining the nature of the incident(s), including time; day; witnesses (as much detail as possible)
- Describe any previous attempts to resolve concern (such as meetings with the employee; meetings with the Front-line supervisor; discussions at the weekly meetings, etc.)

The accused employee will be advised of the written complaint. Given this:

- If a concern arises involving the FSIS employee, the establishment should immediately bring the matter to the District Manger’s attention.
- We would recommend for the period of time after the complaint and through the pending investigation that the establishment ensure all meetings with the employee are conducted in teams.

- Document all meetings with the employee.

FSIS will investigate of documented formal complaints. The District Manger will provide the establishment a response to the inquiry. It is important to note that the FSIS employee's personal information will be protected in the response.

If the establishment is not satisfied with the outcome of the response, they may refer the matter to the next level – the Executive Associate for Regulatory Operations (EARO). The EARO is expected to review the case file and determine whether additional actions are necessary.

Next steps in the appeal process for the establishment would be the Assistant Administrator for Field Operations and then the Administrator.

Most importantly, throughout this process the establishment should be maintaining documentation of the efforts to maintain the on-going relationship with the inspection personnel. In addition, documentation of any incidents (time, day, witnesses) is also critical. Importantly, if at any point there is concern for the safety of the personnel at the facility, the situation could be elevated to the next level without waiting for the appeal time to be exhausted.

Office of Inspector General (OIG) Hotline

Another avenue for raising concerns regarding FSIS employee misconduct is the OIG Hotline. The OIG Hotline can be used at any time and can be used by phone, e-mail or in writing. With the OIG Hotline the complainant may remain confidential (i.e., known only to the USDA OIG), or allow their name to be used (i.e., included in any investigation that may take place), or anonymous (i.e., unknown even to the USDA OIG). If the complainant chooses to remain anonymous, USDA OIG cannot obtain additional information on the allegation (e.g., testimonial or documentary evidence; identity of witnesses), and cannot inform the complainant as to what action USDA OIG has taken on the complaint. The best chance for a positive outcome with the OIG Hotline requires providing very detailed information to OIG such as described above:

- Name of Agency employee(s)
- Statement explaining the nature of the incident(s), include time; day; witnesses (as much detail as possible)
- Describe any previous attempts to resolve concern (such as meetings with the employee; meetings with the Front-line supervisor; discussions at the weekly meetings, etc.).

The information to reach OIG Hotline

(800) 424-9121
(202) 690-1622
(202) 690-1202 (TDD)
United States Department of Agriculture
Office of the Inspector General
P.O. Box 23399
Washington, DC 20026-3399

Crisis Checklist

Preparing for a Crisis

The reality of a crisis is that there is never enough time. A prudent establishment can mitigate this by preparing in advance.[5]

Have the Crisis Management Team identified

The team should include:

- Management – the Team Leader to make the decisions
- Public Relations Expert (either in-house or consultant) – to deal with media
- Sales – to deal with customers
- Purchasing – to address any raw material issues
- Quality Control – to address any food safety or quality issues
- Operations
- Legal – to deal with regulatory issues and liability
- Subject Matter Experts – to address technical issues depending on the specifics of the crisis, this could include:
    - Toxicologist
    - Medical Doctor
    - Epidemiologist

Note, although your insurance carrier would not be part of your team, communications with the carrier should be maintained so coverage will not be compromised.

Have materials prepared in advance

A crisis is never the time to create documents on how to handle the crisis.

Procedures – At a minimum, an establishment should have written procedures to address how the establishment will respond to recalls, bioterrorism events, regulatory plant closures, and natural disasters. Indeed, both FDA and FSIS require food establishments to prepare written recall procedures. The procedures should define the roles of the team members, the steps the team will take in responding, and the criteria used to make decisions.

Records – all records should be kept current and filed in a manner to permit easy access.

Model Statements – For the more common crises, the establishment can prepare model press statements and statements about the company (its history, its commitment to customers, etc.). The establishment should also have model forms for notifying customers and employees.

Social Media – Given today's social media, having social media pages in advance is a requirement. A company cannot respond to social media attacks if it is not already there.

[5] This is a general discussion of crisis management; it does not constitute, nor should it be used as a recall or an emergency response program.

Media Training – Whenever possible, at least one company official should be media trained. Even if the individual does not go before the media, the training will provide the official with the knowledge of how to develop, package and "sell" the company's public releases to the media.

Have existing relationships with outside parties

The Media – The first time to meet with the press should not be in the middle of a crisis. An establishment may wish to meet the local media to build good will in advance of a crisis.

The Regulators – An adversarial relationship with the regulators can pose problems. The establishment should build and then maintain a professional relationship with the regulators, at least up through the District Offices.

Practice

When the establishment believes it has prepared for the crisis event, it should conduct a "mock crisis." Many media consultants and other experts have developed realistic scenarios which can be used to assess the effectiveness of the establishment's crisis programs. Having practiced will help identify the shortcomings of the programs so they can be fixed. In addition, having run through a crisis, even if only a mock crisis, can help instill confidence and minimize nervousness in the crisis management team.

Notification to the Government

FDA Reportable Food Registry

For FDA-regulated products, if the "responsible party" determines that an article of food it has manufactured, processed, packed, or held is a "reportable food," it must submit an electronic report to FDA's Reportable Food Registry (RFR) within 24 hours of making that determination. FDA has an electronic portal for RFR reporting.

The "responsible party" is the person who submits the FDA registration for the facility where the food was manufactured, processed, packed, or held.

A "reportable food" is an article of food for which there is a reasonable probability that use or exposure will cause serious adverse health consequences or death to humans or animals. Generally, if the food has a hazard that FDA would classify as a Class I recall, it is a reportable food.

RFR reporting is not required if all three of the following conditions are met:

- The adulteration originated with the responsible party;
- The responsible party detected the problem before transferring the food to any other person; and
- The responsible party corrected the problem or destroyed the food.

Legal counsel should be consulted when determining whether a report to the RFR is required.

FDA will issue an Individual Case Survey Report ID (ICSR) number for each RFR report. After reporting, FDA may require the responsible party to notify other companies in its supply or distribution chain. The responsible party is also required to investigate the cause of the problem, to maintain records related to each RFR report and notification for 2 years, and to make such records available to FDA upon request.

For questions about the reporting requirement, email FDA's RFR Center at RFRSupport@fda.hhs.gov. For technical questions about reporting, email support.srp@jbsinternational.com. Guidance regarding the RFR can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food.

USDA Notification

Under FSIS regulation, 9 CFR § 418.2, an inspected establishment must notify the agency within 24 hours with regard to adulterated and misbranded products in commerce. This obligation arises when:

- The establishment learns or determines
- Adulterated/Misbranded product
- Is in commerce.

Learns or determines – The notification requirement does not apply unless and until the establishment learns or determines (or should believe based on the facts) that the product at issue is adulterated or misbranded. The establishment need not notify FSIS merely because there has been a complaint about a product. The establishment has the right to investigate and determine whether the product was indeed violative. The time to notify does not begin until the establishment has made this determination or stopped its investigation.

Adulterated/Misbranded – There is no de minimis exception; an establishment has to report even a single isolated foreign material or a technical labeling non-compliance. This is far broader than the FDA notification requirement under the Reportable Foods Registry discussed below. That said, it should be noted that notification to the District Office does not mean a recall will be required.

In Commerce – The notification requirement applies when the product has left the establishment's control. If product is still at an establishment, a warehouse under establishment (or corporate) control or otherwise in the possession of the establishment or a sister establishment within the same corporation, the product will not be deemed to be in commerce.

Notification – The establishment must notify the District Office within 24 of determining adulterated/misbranded product is in commerce. The notification should include: type, amount, origin, and destination of the product. Many District Offices have set up dedicated reporting email addresses to receive these reports.

Product Retrieval Actions (Recalls, Market Withdrawals, Stock Recoveries)

If an establishment has distributed food in commerce that is adulterated or misbranded, it may have to retrieve the product from commerce. Pursuant to the Food Safety Modernization Act, FDA has the authority to order an establishment to retrieve food from commerce when FDA determines that there is a reasonable probability that the food is adulterated or misbranded, and use of the food will cause serious adverse health consequence or death to humans or animals and the establishment has refused to recall voluntarily. Although FSIS does not have the statutory authority to mandate a product retrieval action, FSIS has authority to take other actions if an establishment refuses to voluntarily retrieve adulterated or misbranded product. This includes detaining the product in commerce, referring the establishment for criminal prosecution, or issuing a press release indicating that the establishment distributed adulterated or misbranded product in commerce and has refused to retrieve it.

There are generally three types of product retrieval actions: recalls, market withdrawals and stock recoveries. As discussed further below, how a product retrieval action is defined often determines the extent to which the regulatory agencies participate in/oversee the retrieval action and the extent to which public notification is made.

Recall

FDA defines a "recall" as a removal from the market of a food product that: (a) violates the law, (b) is a likely candidate for seizure, condemnation, or other legal action by the government, and (c) is outside the control of the recalling firm. Based on this definition, the removal of product that technically violates the law, but is a minor violation, might not be deemed a recall.

FSIS defines a "recall" as the "firm's removal of distributed (i.e., the product has left the firm's direct control) meat and poultry products from commerce when there is a reason to believe that such products are adulterated or misbranded." This definition does not take into consideration whether the adulteration or misbranding is of the kind that is likely to lead to agency action. However, FSIS sometimes does not request recalls for certain minor technical violations, such as minor mislabeling issues that do not present health risks or have the potential to defraud consumers. Moreover, FSIS has sometimes not requested recalls of distributed adulterated or misbranded product when the product no longer "remains in commerce," such as when a producing establishment quickly detects a problem and immediately recovers all the affected product from commerce, or when the product is so far beyond the shelf life that is unlikely to still be available to consumers.

Recalls normally involve government participation/oversight and some type of public notification (but not always)

Market Withdrawal

FDA defines a “market withdrawal” as a removal from the market of a distributed product that involves either: (1) a minor regulatory violation that would not subject the product to legal action by FDA and (2) no regulatory violation.

FSIS defines a “market withdrawal” as a firm’s removal or correction, on its own initiative, of a distributed product that involves a minor company quality program or regulatory program infraction that would not cause the product to be adulterated or misbranded (e.g., the product does not meet company quality standards because of discoloration).

Market withdrawals normally occur with little government participation/oversight and with no public notification.

Stock recovery

Both FDA and FSIS define a “stock recovery” as a firm’s removal or correction of product that has not been marketed or that has not left the direct control of the firm.

Similar to market withdrawals, stock recoveries occur with little to no government oversight/participation and no public notification.

Recall Classifications

Should an establishment have to conduct a recall; both FSIS, through a Directive, and FDA, through enforcement policy regulations, have provided detailed guidance on their expectations. The expectations depend on the public health risk involved in any incident. The agencies have developed recall classifications to rank the health risk. The recall classifications are identical:

“(1) Class I is a situation 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.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.”

Evaluating the Need for a Recall and Potential Recall Classification

The first steps in determining the need for a recall and the potential recall classification are to assess: (1) the problem, (2) the potential health hazard involved (recall classification), (3) the scope of product involved, and (3) the location of implicated product.

Assessing the Problem

The establishment's Recall Coordinator, as well as other appropriate members of the Crisis Management team, should be involved assessing the problem. Information regarding a product problem may be received from a government agency, vendor, customer, consumer, and employee or routine lab result. The Recall Coordinator, with assistance from the Crisis Management Team as necessary, should collect all information regarding the possible problem, including but not limited to:

- How was the problem discovered? By Whom? Where? When?
- What product is involved? Brand? Size or Weight? Product code? Lot number? Volume Involved?
- What is the specific problem? Product tampering? Mislabeling? Major quality problem? Adulteration?
- Were there any reports of illness or death? If so, what were symptoms, when did the consumer consume the product and develop symptoms, and was there a doctor's report?
- If biological or chemical contamination, was a sample of the product tested? By whom? How was the sample taken and maintained? What were the results?
- If physical contaminant was involved, what is its physical description? Color, size, feels like, smells like, looks like, etc.? Where photographs taken?
- What plant manufactured the product?
- What is potential source of problem? Manufacturing or processing control failure? Mishandling during distribution? Customer or consumer abuse? Does production, HACCP and SSOP records indicate process was under control?

The Recall Coordinator may determine that it is necessary to send samples of the product in question or similar product to an accredited lab for analysis. Prior to doing so, the Recall Coordinator should consult with legal counsel as additional sampling may have certain regulatory and product liability implications.

Health Hazard Evaluation

Once the Recall Coordinator has assessed the problem and gathered the preliminary facts, the Recall Coordinator should conduct a health hazard evaluation with the assistance of the Crisis Management Team to determine the risk presented by the product involved. The risk posed by the product is one of the central issues on whether a recall should be initiated and how the recall will be classified. An evaluation of the hazard posed by a particular product should include the following factors:

- The nature of the violation or defect (i.e., whether the product is adulterated, misbranded, or presents a quality concern);
- The occurrence of any reported illnesses or injuries;
- The relative degree of seriousness of the health hazard to which the population at risk would be exposed (paying particular attention to individuals who may be at the greatest risk, e.g., children, the elderly, and immunocompromised individuals);
- The likelihood that illnesses or injuries may result; and
- The type of illnesses or injuries that may result.

Scope of Potential Recall

After the health hazard evaluation is complete, the Recall Coordinator should determine the scope of the potential recall with the assistance of the Crisis Management Team. The scope defines the amount and kind of product in question. For issues involving pathogens in product, the general rule is that all products produced under the same HACCP plan between performance of complete cleaning and sanitation procedures (clean-up to clean-up) is implicated. However, this can be expanded or contracted based on the facts of each case (e.g., use of rework or carry-over on multiple days, use of same source raw materials on multiple days). The fact that only one product code has been identified in a consumer complaint or lab test does not mean that additional product is also not implicated. An investigation must be conducted to determine when the defect occurred and what products are implicated.

If possible, an establishment should not initiate a recall until it has conclusively locked in the scope.

Product Identification and Location

Once the scope is defined, the next question is where is the product? This is determined through examining records and documents, including, but not limited to:

- Shipping records;
- Inventory records;
- Lot records;
- Production records; and
- Consigned distributor or warehouse records

The establishment must reconcile the units produced with the records of shipments and stock, if any. A complete shipment description of the suspect product is to be communicated to the Recall Coordinator, including but not limited to:

- Order number;
- Customer and location;
- Date of shipment;
- Estimated time of arrival (if applicable) or time of arrival;
- Whether the product was shipped further downstream;
- Product code number;
- Lot number;
- Quantity; and
- Amount of product on hold

The Recall Coordinator should assess whether any of the suspect product “remains in commerce.” In this regard, the following questions should be asked:

- When was the product produced?
- To whom has the product been distributed?
- What type of product is involved (e.g., ready-to-eat, frozen, etc.)?
- What is the typical, usable shelf life of the product?

- What are the typical consumer or user practices concerning handling and storing the product in question (e.g., is the product typically prepared for immediate consumption and likely is not stored or frozen for later use)?
- Is the product still available to consumers at retail facilities, restaurants, or other institutions?

The Recall Decision and Government Notification

After the above facts have been collected, the Recall Coordinator and the Crisis Management Team will decide whether there is a need for a recall, a market withdrawal, a stock recovery, or no action at all. The Recall Coordinator and Crisis Management Team should consult with outside counsel in making this determination. Such a determination shall be based upon:

- The potential recall classification (i.e., health hazard involved) and depth of recall;
- The scope;
- Whether the product still remains in commerce;
- The estimated amount of product in distribution or in the consumer's hands; and
- The ability of distributors, consumers, or users to identify the product in question.

If the decision has been made to conduct a recall, the Recall Coordinator should contact the appropriate regulatory agency immediately. As discussed above, there is a regulatory requirement to notify FSIS when an establishment has reason to believe adulterated or misbranded product is in commerce. This would essentially require notification to FSIS of all recalls. Although FDA only requires notification of Class 1 recalls through the FDA Reportable Food Registry, it would be prudent – and FDA expects an establishment -- to notify FDA of all recalls to obtain concurrence regarding recall classification as well as scope of the recall action. Market withdrawal and stock recoveries would not require agency notification

FDA recalls - For recalls of all other food products, the Recall Coordinator should contact the Recall Coordinator in the FDA Division Office nearest to the facility that is recalling the product, or if that person is not available, the Division Director or other appropriate official. A list of FDA Recall Coordinators is available at: ORA Recall Coordinators | FDA.

FSIS recalls - For recalls of meat and poultry products, the Recall Coordinator should contact either the FSIS Risk Management Division at 202-690-1975 or the FSIS District Office in which the recalling facility is located. The telephone numbers for the various FSIS District Offices is available at: FSIS Programs & Offices | Food Safety and Inspection Service (usda.gov)

When either FDA or FSIS is notified of a recall, the regulatory agency will request information relevant to the recall. To that extent, prior to contacting either FDA or FSIS, the Recall Coordinator should compile and document the following:

- Reason for the recall

    i. Explanation of how the product is defective or violative;
    ii. How the defect affects the safety of the product;

iii. How the defect occurred and when it occurred;
iv. How the defect was discovered and the date discovered; and
v. Information regarding consumer complaints.

- Manufacturer information

i. Firm name, address, city, state and zip code;
ii. FDA registration number; and
iii. FSIS establishment number.

- Product identification information

i. Product name;
ii. Brand name;
iii. Package size and type;
iv. Lot/unit codes;
v. Expiration date, use by date, or expected shelf life of product;
vi. UPC codes; and
vii. Copies of Labels.

- Volume of product recalled

i. Total quantity produced;
ii. Dates produced;
iii. Quantity of product distributed;
iv. Dates Distributed;
v. Quantity of product on hold by recalling firm or distribution center; and
vi. Estimated amount of product remaining on the market.

- Location of Product

i. Geographic areas of distribution, including foreign countries;
ii. A list of immediate consignees (including name, address, city, state, contact name and number);
iii. Whether product was sold under a government contract; and
iv. Whether product was sold to any federal state, or local agency involved in the National School Lunch Program.

- Recall plan

i. Depth of recall;
ii. The method of notifying customers (e.g., mail, fax, e-mail, phone);
iii. Instructions to customers regarding disposition of recalled product; and
iv. If recalled product is to be destroyed, proposed method of destruction.

- Recall personnel

    i. Name and telephone number of Recall Coordinator;
    ii. Name and telephone number of Recall Media Contact; and
    iii. Name and telephone number of Recall Consumer Contact.

To ensure companies provide all the necessary information, FSIS has created a worksheet that must be completed in the event of a recall. The Recall Coordinator should use this worksheet in compiling the above information for meat and poultry product recalls. Importantly, this worksheet should only be completed if the decision has been made to conduct a recall. Similarly, FDA recall coordinators will request the recalling firm fill out "Attachment B" and provide that to the agency with the requested information. Companies should carefully consider Attachment B responses, as those have been used as basis for Warning Letters, particularly for allergen labeling recalls.

After contacting the relevant agency, it is typical for the agency to hold a conference call with the recalling firm to verify that it has all the relevant information regarding the recall, and that all the information is accurate. The Recall Coordinator and the Crisis Management Team should participate in this conference call.

Implementation of a Recall

Once it has been decided to conduct a recall and the appropriate regulatory authorities are contacted, the next step is implementation of the recall. This involves notifying customers and/or consumers, retrieving the product, disposing the product, conducting effectiveness checks, and terminating the recall.

Public Notification

FDA - For Class I and certain Class II recalls involving FDA product, FDA will typically expect the producing establishment to issue its own press release. FDA does not expect a press release for Class III recalls. The press release should closely adhere to FDA's model press release for that type of recall. FDA model press releases can be found at: http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

The press release should be issued through the Associated Press (AP). For local or regional recalls, contact the AP offices in the states in which the product was distributed. For recalls needing national media coverage (distribution in 8 states or more), contact AP's Washington, D.C. Bureau at (202) 776-9467. AP contact information can also be found at: http://www.ap.org.

FSIS - For recalls of FSIS regulated product, FSIS will issue its own recall press release for Class I and Class II recalls, unless the recalled product has not reached consumers. If the recalled product has not reached the consumer, FSIS will still issue a Recall Notification Report (RNR) on its website. FSIS will also issue a RNR on its website for Class III recalls. Although FSIS will issue its own press release for Class I and Class II recalls, the producing establishment may decide to issue its own press

release. If the establishment decides to issue its own press release, the press release should not differ substantially from the FSIS press release.

Customer Notification

In cases where recalled product is still with customers, the establishment should immediately notify the customers of the recall orally and in writing. Importantly, a press release issued by the establishment, or a regulatory agency cannot take the place of individual notification to customers. Oral notifications should be documented through a written telephone log. Written notifications should be sent by email, facsimile and/or overnight courier and conspicuously marked “Food Recall” (include the word “URGENT” if warranted). The written notification should include the following:

a. Description of recalled product, including name, code and weight;
b. The reason for the recall (including the precise nature of the problem and the potential risk to consumers);
c. Instructions to customers, including:

    i. To cease distributing or using any remaining product immediately;
    ii. How customers should report the quantity of recalled product in their possession (it is best to provide a return response card or form that customers may return to us by fax or overnight courier indicating that they followed instructions);
    iii. How customers should dispose of recalled product (e.g., return, hold for pickup, destroy or correct);
    iv. If the recalled product was further distributed by the customers, notification that the customer has the responsibility to contact downstream customers regarding the product;
    v. Reimbursement instructions;
    vi. Notification that the customer may be contacted by FDA or FSIS to determine whether recall notification has been received and the customer followed the recall instructions.

Product Retrieval and Disposition

Based on the depth of recall, the Recall Coordinator should direct company employees on the retrieval of product, if applicable. Appropriate transportation should be made available as quickly as possible to affected locations for recovery of product.

Once product is returned to the producing establishment, the product needs to be appropriately disposed or reconditioned. For meat and poultry products returned to establishment, the FSIS Inspector in Charge is to be notified that product has been returned so it can be retained. If meat or poultry products are to be destroyed, the destruction must be done under FSIS compliance supervision. A copy of reports on the disposition and reclamation of recalled products shall be sent to the Recall Coordinator. Similarly, FDA asks to be given the opportunity to witness product destruction and will ask for documentation establishing product destruction.

Effectiveness Checks

Although effectiveness checks are usually conducted by FDA or FSIS to determine whether adequate notice about the recall has been provided to all consignees and the consignees followed all instructions for removing products, the producing establishment should also conduct such checks. Following a recall, the Recall Coordinator should contact each customer and document whether:

a. The recall notice was received;
b. The recalled product was handled as instructed;
c. How much product has been recovered by customer(s);
d. If the product was further distributed, additional consignees were notified; and
e. Any report of illness or injury related to the product were received.

Upon completion, this information is to be evaluated to assess the product recall's effectiveness.

Monthly Progress Reports

Until the recall is complete, FDA will request the recalling firm to file monthly reports on the status of the recall. These reports contain information regarding the number of consignees contacted, amount of product returned, and product destroyed.

Termination of Recall

A recall will be terminated when the relevant regulatory agency and the producing establishment agree that the product subject to the recall has been removed from commerce and proper disposition or correction has been made. When the Recall Coordinator believes that recall should be terminated, the Recall Coordinator should send a letter to the appropriate regulatory agency requesting termination of the recall.

Food Safety Systems

FDA Risk-Based Preventive Controls

FDA CGMPs and Hazard Analysis and Risk-Based Preventive Controls

As required by section 103 of the FDA Food Safety Modernization Act (FSMA) and section 418 of the FFDCA, FDA has revised its existing CGMP regulations and issued new regulations requiring hazard analysis and risk-based preventive controls for human foods. 21 C.F.R. Part 117.

Hazard analysis and risk-based preventive controls is based on HACCP principles, but there are significant differences between the two. For example, a hazard analysis and risk-based preventive controls plan typically includes sanitation controls and other measures that are considered to be "prerequisite programs" under HACCP. A HACCP plan only includes critical control points (CCPs), but a hazard analysis and risk-based preventive controls plan may include preventive controls at points other than CCPs. Therefore, covered facilities operating under voluntary HACCP plans may need to update their Food Safety plans to comply with the hazard analysis and risk-based preventive controls regulations.

Hazard Analysis and Risk-based Preventive Controls Requirements

Domestic and foreign food facilities that are required to register with FDA, unless exempt or subject to modified requirements, are required to have a written food safety plan. The plan must be signed and dated by the owner, operator, or agent in charge of the facility. The facility's food safety plan must include the following elements for each food manufactured, processed, packed, or held at that facility:

- A hazard analysis;
- Preventive controls;
- Monitoring procedures;
- Corrective action procedures;
- Verification procedures; and
- Validation.

Hazard Analysis

The facility must identify and evaluate (based on experience, illness data, scientific reports, and other relevant information) "known or reasonably foreseeable hazards" to determine if they are "hazards requiring a preventive control." Hazards include biological, chemical (including radiological hazards, heavy metals, pesticide residues, drug residues, natural toxins, decomposition, unapproved food or color additives, and undeclared allergens), and physical hazards.

The hazard analysis must consider the potential for economically motivated intentional adulteration (EMA), but only in the rare circumstance where there is a past pattern of EMA involving that type of food.

The hazard analysis must consider environmental pathogens where a ready-to-eat (RTE) food is exposed to the environment prior to packaging and does not receive a treatment or include a control measure that would significantly minimize the pathogen after packaging.

Preventive Controls

If the hazard analysis identifies any hazards requiring a preventive control, the facility must select and implement appropriate preventive controls to assure that such hazards will be significantly minimized or prevented.

Preventive controls may include:

- Process controls (e.g., heating, freezing, controlling pH, irradiating);
- Sanitation controls;
- Food allergen controls;
- Supply-chain controls;
- A recall plan; and
- Other necessary controls.

If the facility is a "receiving facility" (i.e., a facility that manufactures/processes raw materials or other ingredients that it receives from a supplier), it must implement a supply-chain program for any raw materials or other ingredients for which it has identified a hazard requiring a supply-chain applied control." Generally, a supply-chain program must include:

- Approval of suppliers;
- Written procedures to ensure that raw materials and other ingredients are received only from approved suppliers (except that raw material and other ingredients may be received from unapproved suppliers on a temporary basis when necessary, provided they are subjected to adequate verification activities before acceptance for use);
- Determining appropriate supplier verification activities;
- Conducting supplier verification activities; and
- Taking corrective actions if a supplier is not controlling hazards.

Supplier verification activities may include: onsite audits of suppliers, sampling/testing raw materials or other ingredients, reviewing supplier's food safety records, and/or other appropriate verification activities. Generally, a receiving facility may choose appropriate verification activities. However, where the hazard requiring a supply-chain applied control has a reasonable probability of causing serious adverse health consequences or death, the receiving facility must conduct an onsite audit before using the raw material or ingredient and at least annually thereafter, unless the receiving facility makes a written determination that other verification activities or less frequency audits are adequate. In lieu of an onsite audit, a receiving facility may rely on a food safety inspection of the supplier by FDA, another federal agency, a state, local, tribal, or territorial agency, or a foreign food safety agency in a country whose food safety system FDA has officially recognized as comparable or equivalent to the U.S. Audits must be performed by a qualified auditor.

The facility is not required to implement a preventive control for a "hazard requiring a preventive control" if:

- The facility determines and documents that the type of food cannot be consumed without application of an appropriate preventive control (e.g., a grain that cannot be eaten without first being cooked);
- The facility relies on its customer to control the hazard (the facility must disclose that the food is "not processed to control [hazard]" and obtain appropriate written assurance from its customer); or
- The facility relies on its customer to provide assurance that the food will be processed to control the hazard by an entity later in the distribution chain (the facility must disclose that the food is "not processed to control [hazard]" and obtain appropriate written assurance from its customer). Note, however, that FDA is not currently enforcing this "written assurance" requirement.

Monitoring

The facility must implement written procedures to monitor preventive controls, including the frequency of monitoring. However, the recall plan and supply-chain program are not subject to monitoring. Monitoring must be done with sufficient frequency to ensure that the preventive controls are being consistently performed.

Corrective Actions

The facility must implement written procedures for taking corrective actions if: (1) preventive controls are not properly performed; (2) an environmental pathogen or indicator organism is detected during environmental monitoring; or (3) a pathogen or indicator organism is detected in a RTE food during product testing.

Corrective actions must ensure that:

- Appropriate action is taken to identify and correct the problem;
- Appropriate action is taken to reduce the likelihood the problem will recur;
- All affected food is evaluated for safety; and
- All affected food is prevented from entering commerce if the facility cannot ensure it is not adulterated under FFDCA § 402 or misbranded under FFDCA § 403(w) (undeclared allergens).

If the failure to implement a preventive control involves a sanitation control, a food allergen control, or a minor problem with no impact on food safety, the facility is not required to take corrective actions, provided it corrects the problem in a timely manner.

Validation and Verification

A facility must perform the following activities as appropriate to the nature of the preventive control and its role in the facility's food safety plan:

- Validate that preventive controls are adequate to control the hazards;
- Verify that monitoring is conducted according to the food safety plan;
- Verify that appropriate decisions are made about corrective actions;
- Verify that preventive controls are consistently implemented and are effectively controlling the identified hazards; and
- Reanalyze the food safety plan at least every 3 years and when otherwise required.

Verification that preventive controls are effectively controlling the identified hazards includes:

  - Calibration or accuracy checking of process monitoring and verification instruments;
  - Review of records (i.e., monitoring records, corrective action records, calibration records, environmental monitoring records, products testing records, and supplier verification records);
  - Environmental monitoring (as appropriate); and
  - Product testing (as appropriate).

Training

Certain actions required under the hazard analysis and risk-based preventive controls regulations must be performed by a "preventive controls qualified individual" (PCQI). A PCQI must perform or oversee: preparation of the food safety plan, validation of preventive controls, review of records, and reanalysis of the food safety plan. A PCQI is a qualified individual who has successfully completed training in the development and application of preventive controls at least equivalent to a standardized curriculum recognized by FDA (i.e., the curriculum developed by the Food Safety Preventive Controls Alliance) or is otherwise qualified by job experience to develop and apply a food safety system. Training must be documented in records that include the date of training, type of training, and person trained.

Onsite audits of suppliers performed under a receiving facility's supply-chain program must be performed by a "qualified auditor." A qualified auditor is defined as a qualified individual who has the technical expertise, obtained through education, training, or experience (or a combination of these) to perform the auditing function. FDA has stated that education or training alone is insufficient; an individual must have at least some actual auditing experience to be a qualified auditor.

Records

The regulations require covered facilities to maintain a large number of new records, too numerous to list here. These include: the food safety plan itself, monitoring records, corrective action records, verification records, supply-chain program records, and records documenting training of PCQIs and qualified auditors.

All required records are subject to certain general recordkeeping requirements. Required records must be retained for at least 2 years after the date the record was prepared, except that certain records of ongoing importance (including the food safety plan and records validating preventive controls) must be kept for at least 2 years after their use is discontinued.

All required records must be made available to FDA inspectors for review and copying upon oral or written request.

Given the breadth of company records FDA inspectors will be able to copy under the hazard analysis and risk-based preventive controls regulations, facilities should be sure to identify trade secret and confidential information and request exemption from public disclosure when appropriate. FDA says that it will determine the confidential status of environmental monitoring and product testing records on a case-by-case basis.

Exemptions and Modified Requirements

Certain facilities and activities are exempt from the hazard analysis and risk-based preventive controls regulations or subject to modified requirements. These include:

- Activities subject to FDA's seafood HACCP regulations, provided the facility is in compliance with those regulations;
- Facilities solely engaged in the storage of packaged foods that are not exposed to the environment; and
- Very small businesses.

Sending By-Products for Use in Animal Food

A human food facility that sends by-products to be used in animal food is not required to comply with the regulations on CGMPs and hazard analysis and risk-based preventive controls for animal food, provided: (1) the facility is subject to, and in compliance with, the human food CGMP regulations and all other human food safety requirements; and (2) the facility does not further manufacture/process the by-products.

The facility is required to:

- Hold the by-products under conditions that will protect them against contamination;
- Label the by-products by their common or usual name (with such labeling affixed to or accompanying the by-products when distributed); and
- Examine shipping containers and bulk vehicles used to transport the by-products prior to use to prevent contamination.

FDA Foreign Supplier Verification Programs for Importers

As required by § 301 of FSMA and § 805 of the FFDCA, FDA has issued regulations requiring food importers to implement Foreign Supplier Verification Programs (FSVP). As the name implies, food importers will for the first time be required to verify their foreign suppliers. 21 C.F.R. Part 1, subpart L.

The FSVP regulations for importers parallel the supply-chain program requirements for receiving facilities in the hazard analysis and risk-based preventive controls regulations (see above). If an importer is also a receiving facility subject to the supply-chain program requirements of the hazard analysis and risk-based preventive controls regulations, it may comply with either the FSVP regulations for importers or the supply-chain program requirements for receiving facilities; FDA does not intend to impose duplicative requirements.

Scope

The FSVP regulations apply to "importers." For purposes of the regulations, an "importer" is the U.S. owner or consignee of an article of food offered for import. The "U.S. owner or consignee" is the person in the U.S. who, at time of entry, owns the food, has purchased the food, or has agreed in writing to purchase the food. If there is no U.S. owner or consignee at time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee at time of entry, as confirmed in a signed statement of consent.

The regulations define "food" to include all food (as defined in the FFDCA) except for pesticides. Because the definition of "food" does not exclude food contact substances, importers are required to verify foreign suppliers of food packaging materials.

The regulations define "foreign supplier" as the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the U.S. without any further manufacturing/processing of more than a de minimis nature by another establishment.

Standard FSVP Requirements

The importer is required to develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier is producing each imported food in compliance with processes and procedures that provide the same level of public health protection as those required under the FFDCA and FDA regulations.

For each imported food, the importer is required to:

- Perform a hazard analysis;
- Conduct an evaluation for foreign supplier approval and verification;
- Conduct foreign supplier verification activities;
- Take appropriate corrective actions; and
- Identify the FSVP importer at time of entry.

Some of these activities may be performed by another entity instead of the importer, provided the importer reviews and assesses the results. For example, an importer may rely on a hazard analysis conducted by another entity, including the foreign supplier, provided the importer reviews and assesses the hazard analysis and documents its review and assessment (including documenting that the hazard analysis was done by a qualified individual).

The importer is not required to conduct an evaluation for foreign supplier approval and verification or to conduct foreign supplier verification activities if:

- The importer makes a written determination that the type of food cannot be consumed without application of an appropriate control;
- The importer's customer will control the hazard (and the importer discloses that the food is "not processed to control [hazard]" and obtains certain written assurances from its customer); or
- The importer's customer provides assurances that the food will be processed to control the hazard by a later entity in the distribution chain (and the importer discloses that the food is "not processed to control [hazard]" and obtains certain written assurances from its customer.

Hazard Analysis

For each imported food, the importer must perform (or review and assess) a hazard analysis that identifies known or reasonably foreseeable hazards in the imported food and evaluates whether there are any "hazards requiring a control."

Evaluation for Foreign Supplier Approval and Verification

For each imported food, the importer must evaluate the following:

- The hazard analysis and the nature of any hazard requiring a control;
- The supply chain entity that will control any hazard requiring a control;
- Foreign supplier performance (including any FDA Warning Letters or Import Alerts, food safety practices, food safety history); and
- Other factors, as appropriate, such as storage and transportation practices related to the imported food.

This evaluation is to be used by the importer to determine appropriate foreign supplier verification activities and to approve foreign suppliers.

Foreign Supplier Verification Activities

The importer must conduct appropriate foreign supplier verification activities. These verification activities are the core requirement of the FSVP regulations. Generally, foreign supplier verification activities may include: (1) onsite audits of the foreign supplier; (2) sampling/testing of imported food; (3) review of the foreign supplier's food safety records; and/or (4) other appropriate verification activities. However, if there is a reasonable probability that the hazard requiring a control in the imported food

will cause serious adverse health consequences or death, the default required verification activity is an onsite audit (conducted before initially importing the food and at least annually thereafter), unless the importer makes a written determination that other verification activities or less frequent audits are adequate. In lieu of an onsite audit, the importer may rely on a food safety inspection of the foreign supplier, conducted within 1 year of the date an onsite audit would have been required, by FDA, another federal agency, a state, local, tribal, or territorial agency, or a foreign food safety agency in a country whose food safety system FDA has officially recognized as comparable or equivalent to the U.S. system.

Corrective Actions

The importer must promptly review and assess the foreign supplier verification activities and determine whether corrective actions are needed.

If the importer determines that a foreign supplier is not producing food with at least the same level of public health protection as required under the FFDCA and FDA regulations, the importer must take appropriate corrective actions. Appropriate corrective actions will depend on the specific circumstances but may include discontinuing use of a foreign supplier until the problems are corrected.

Identification of Importer at Time of Entry

The importer must ensure that the FSVP importer is identified at time of entry. For each line entry of food, the following information must be provided electronically when filing entry with U.S. Customs and Border Protection: (1) importer's name; (2) importer's email address; and (3) a unique facility identifier recognized as acceptable by FDA. FDA intends to issue a guidance document recognizing the DUNS number as an acceptable facility identifier.

Training

All FSVP activities must be performed by a "qualified individual." The qualified individual must be able to read and understand the language used in any records that must be reviewed to perform an activity.

Onsite audits of a foreign supplier must be performed by a "qualified auditor."

Records

The regulations require importers to maintain a large number of new records including: the hazard analysis for each imported food; the evaluation for foreign supplier approval and verification; the determination of appropriate verification activities; written procedures for conducting verification activities; records of verification activities; documentation of review and assessment of verification activities; corrective action records; training records; and written procedures to ensure that food is imported from approved foreign suppliers.

All required records are subject to certain general recordkeeping requirements. Required records must

be retained for at least 2 years after the date the record was prepared, except that records related to processes and procedures must be kept for at least 2 years after their use is discontinued.

All required records must be made available to FDA for inspection and copying upon request. In addition, if FDA requests in writing, an importer must send FSVP records to FDA electronically or through other means that delivers the records promptly.

Given the breadth of required FSVP records and FDA's authority to access such records outside of the context of an inspection, importers should be sure to identify trade secret and confidential information and request exemption from public disclosure when appropriate.

Exemptions and Modified Requirements

The FSVP regulations exempt certain imported foods, including the following:

- Seafood products subject to, and in compliance with, FDA's seafood HACCP regulations;
- Raw materials or other ingredients imported for use in manufacturing seafood products by a U.S. facility that is subject to, and in compliance with, FDA's seafood HACCP regulations;
- Food for research or evaluation (provided certain conditions are met);
- Food imported for transshipment;
- Food imported for processing and export;
- Food returned without further manufacturing/processing; and
- Meat, poultry, and egg products regulated by USDA at the time of importation.

The FSVP regulations also include modified requirements for certain imports, including:

- Food imported by a "very small importer" (an importer averaging <$1 million in annual sales of human food plus the market value of human food imported, manufactured, processed, packed, or held without sale);
- Food imported from certain small foreign suppliers (e.g., very small businesses, produce from a foreign farm that grows produce not covered under the Produce Safety regulations); and
- Packaged foods and raw agricultural commodities that will not be commercially processed before consumption imported from a country whose food safety system FDA has officially recognized as comparable or equivalent to the U.S. system.

FSIS HACCP Systems - Validation and Verification

FSIS requires that all meat and poultry products be produced under HACCP plans. The agency has developed substantial guidance on developing HACCP plans, which falls beyond the scope of this Tool Kit. Recent years have seen greater FSIS emphasis on validation and verification of HACCP plans. We discuss key validation and verification activities below.

The combination of Validation and Verification form one of the seven HACCP Principles. In essence, they look to see whether the establishment's total HACCP system (including pre-requisite programs) will address any food safety hazards posed by an establishment's operation, as well as ensuring that the HACCP system is being operated according to the plan. The functions related to validation and verification are distinctly separated.

Validation – The establishment's plan, as written, has adequate support to demonstrate that the plan should address the hazards and the establishment is able to implement the plan at the establishment. Put another way, validation first looks to whether the plan, when followed, will address the food safety concerns posed by the establishment's operations and then focuses on whether the establishment can follow the plan at the plant. A discussion of validation follows this introduction.

Verification – Once the adequacy of the plan has been demonstrated, the establishment still needs to ensure the HACCP system continues to function as intended and it continues to operate consistent with the plan. This is achieved by on-going verification activities, such as direct observation of personnel implementing the plan, review of HACCP records, and calibration of monitoring devices. A discussion of on-going verification follows the validation discussion.

Reassessment – Even if the establishment has an adequate program, effectively implemented, there may be changes which result in the need to reconsider the continued capability of the plan. For example, there may have been changes in the process or the regulatory agency may request reassessment based on a hazard that may be reasonably likely to occur in a particular process category. Additionally, the establishment may have a deviation in its program or an unforeseen hazard. When such events occur, the establishment needs to determine whether the existing plan is adequate to address the changed circumstances or whether a modification to the HACCP plan is needed. The reassessment discussion is the last section of this guide.

Validation

Under the regulations, 9 CFR § 417.4(a)(1), all establishments are required to validate their HACCP systems. To assist establishments in meeting this regulatory requirement, FSIS has prepared a Compliance Guideline on Validation.

Two Elements of Validation

FSIS expects establishments to have validated their HACCP systems. There are two elements of validation:

- Design – Scientific support for the design of the system, and
- Execution – The establishment is implementing the system as written, specifically, it has:
    - Incorporated the critical operating parameters of the support into the system, and,
    - Documented that the establishment can meet these operating parameters under operating conditions.

It should be noted that the validation requirement applies to the entire HACCP system – it is not limited to the critical control points and hazards reasonably likely to occur. Validation is expected of pre-requisite programs that are referenced in the hazard analysis to support a determination that a hazard is not reasonable likely to occur. Common pre-requisites that meet this description include supplier purchase programs, allergen control programs, and/or Sanitation SOPs. If the pre-requisite program is not referenced in the hazard analysis to support the absence of a hazard, it need not be validated. Examples of programs not used in the hazard analysis could include maintenance programs, pest control programs, and/or written recall plans.

System Design

In General

FSIS expects that the design of the system be supported scientifically. The establishment needs to maintain copies of the supporting documentation. The supporting documentation should identify:

- The hazard,
- The expected reduction of the hazard,
- All critical operational parameters from the scientific support,
- The processing steps which achieve the specified reduction, and
- The monitoring of the steps.

Sources of Scientific Support

The following are potential sources for scientific support:

- Scientific articles published in peer review journals,
- Published processing guidelines, including FSIS' Appendix A on lethality and Appendix B for stabilization,
- A challenge or inoculated pack study conducted in a laboratory or pilot plant,
- Best Practice Guidelines often issued by trade associations, or
- Regulatory performance standards, such as poultry chilling requirements or trichinae treatments.

In its validation Notice 78-15, FSIS identified support which would not be adequate:

- No Objection Letters and FSIS Directive 7,120.1 are not adequate, by themselves, to support the plan's design since these documents do not contain all evidence supporting effectiveness or all critical operating parameters.

- Expert Opinion from a processing authority is not adequate if the opinion includes no reference to scientific principles or peer reviewed data.

- Support which does not also include information on "critical operational parameters, such as pH, pressure, contact time, temperature, or relative humidity, critical to achieving that reduction."

- Support which addresses a product other than the product the establishment produces.

Identification of the Critical Operating Parameters

According to FSIS, "critical operational parameters" are the specific conditions under which the intervention must operate for it to be effective. Examples of what could be a "critical operating parameter" include:

- Time
- Temperature
- Concentration
- Humidity
- Dwell Time
- pH
- Contact Time
- Product Coverage
- Pressure
- Point of application

FSIS expects that the establishment will incorporate the same critical operating parameters in its HACCP system as the support. If not, the burden is on the establishment to demonstrate why any difference does not impact effectiveness.

- Some minor differences in operational parameters are acceptable without additional support (e.g., 44.6°F versus 45° F).

- In some cases, the establishment may be able to support effectiveness with a different critical operating parameter as long as the parameter chosen for use in the establishment, when in operation, is at least as effective as the parameters in the supporting documentation.

- In some cases, the establishment's decision-making documents may demonstrate which critical operating parameters need not be monitored as part of a CCP and which do.

For example, if a food company's HACCP plan for refrigerated food containing meat has temperature as a CCP to address the hazard of microbial growth and uses a scientific article that pathogens of concern will not grow when the product temperature is below 45.0°F, the company must either monitor product temperature or be able to demonstrate, with data, that monitoring ambient temperatures ensure product temperatures do not exceed 45.0°F.

Execution

The second element of validation is execution – that the plant has documentation to show that it is following the support. How an establishment shows it is following the support depends on the nature of the scientific support.

- If an establishment is following the supporting documentation, it will meet agency expectations if it has all the following:
  - Identifies the critical operational parameters of the supporting documentation,
  - Incorporates those parameters in the HACCP plan, and
  - Demonstrates that the operational parameters are being met in the establishment.
- To assist establishments in identifying the critical operational parameters, the Guideline provides a set of questions and an Appendix.
- In terms of monitoring critical parameters, if the establishment demonstrated it met all the critical parameters during the initial validation period, it need not monitor all parameters as CCPs.

Importantly, in situations where the establishment is following the scientific support, no microbiological data is required. With regards to when microbiological data might need to be gathered, FSIS indicated it may expect microbial data when an establishment's process is not consistent with the scientific support or when the scientific support does not contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy.

Common Deficiencies

Based on lessons learned from Food Safety Assessments, FSIS has identified common deficiencies:

- The scientific support did not provide the critical operating parameters,
- The process was validated on a different product (matrix), such as a validation for apple cider being used for a food containing meat, and
- The establishment was not using the same critical limits as used in the supporting scientific material (e.g., apply an antimicrobial at a lower concentration than that used in the study).

Initial Validation

The regulations require an establishment conduct an initial validation of its HACCP system. 9 CFR § 417.4(a)(1). Initial validation includes "the in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective."

FSIS recently issued updated guidance on validating HACCP plans, effectively requiring establishments to ensure they have appropriate documentation on file consistent with FSIS recommendations.

To meet this requirement, establishments should:

- Implement critical operational parameters in the actual production process that are consistent with the parameters in the scientific or technical support;
- Collect in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category that is produced at the establishment (the nine HACCP categories are listed at 9 C.F.R. § 417.2(b)(i-ix)); and
- Analyze the data to determine whether the critical operational parameters are being implemented effectively.

In most cases, initial in-plant validation data will consist of data related to critical operational parameters (not necessarily microbiological data).

Depending on the amount of data an establishment has generated already in connection with operating under the HACCP plan (this could include microbial sample results, consumer complaints, audits, inspection findings, decision making documents, etc.), the establishment may need to increase the frequency of its monitoring and on-going verification activities during the 90 day period to demonstrate that the process is being executed effectively.

Agency Inspection Against Validation Requirements

In-Plant

Inspection program personnel (IPP) will verify compliance with the validation requirements when performing the HAV (Hazard Analysis Verification) task. The IPP will continue to use the instructions in FSIS Directive 5000.6 for performing a HAV task, however, information in Notice 78-15 replaces Step 7 in the Directive regarding verification of validation.

The IPP are to review the establishment's support and related documents. It is a non-compliance if the establishment fails to make the support for both parts of validation available.

When conducting the HAV, if the IPP has any concerns as to the adequacy of the establishment validation support, the IPP are to contact their supervisor for assistance.

Food Safety Assessments

EIAOs will also be determining the adequacy of an establishment's validation during Food Safety Assessments; specifically, that the establishment has adequate scientific support for the design of the plan and has in-plant data that demonstrates the establishment can implement its system as designed.

Although the IPP and EIAOs are both reviewing validation and looking for the same information, the EIAO review is more detailed based on the expectations specified in Notice 78-15 and FSIS Directive 5100.1.

Frozen Food Practice Tips

With frozen food products, many hazards may be addressed through pre-requisite programs. As noted above, an establishment needs to validate any pre-requisite program used to support a decision that the hazard is not reasonably likely to occur.

For example, a frozen food manufacturer may determine pathogens are not a hazard reasonably likely to occur on incoming raw materials due to a supplier program. If so, the supplier program needs to be validated (see page 52 of the Guideline). This would entail identifying the components of the supplier program (critical operational parameters) and making sure the establishment has documentation to prove that it is following all the components, such as comparing incoming shipments to an approved supplier list at receipt and obtaining documentation from the supplier as to testing and third-party audits

Given the variations in frozen food products, establishments should validate the cooking instructions for their products. In essence, this means that when the cooking instructions on the label are followed, the product will achieve a temperature necessary to destroy any pathogens. When microwave ovens are identified as a means of cooking, the establishment should "account for variability in microwave wattage and common misconceptions among consumers regarding the nature of not-ready-to-eat foods." (See Page 37 of the Guideline).

On-Going Verification by Establishments

Under the HACCP regulations, 9 CFR § 417.4(a)(2), all establishments are to conduct on-going verification activities to ensure the plan continues to be implemented as written.

Types of On-Going Verification

Any activity designed to ensure the HACCP system is functioning as intended on an on-going basis and the establishment is following the plan as written would constitute on-going verification. FSIS thinks of the "on-going" verification as the activities that occur following the initial 90-days of validation. The most common activities are:

- Direct Observation – The employee verifying the plan watches the establishment employees conducting their HACCP activities, such as observing an employee taking a temperature check and recording the findings.

- Records Review – The employee verifying the plan reviews the records generated under the plan for completeness and to ensure the documented findings are consistent with the operational parameters in the plan. The FSIS regulations require all establishments to conduct a "pre-shipment review" of the records associated with the product to be shipped. Such review could constitute a specific verification activity if specified in the HACCP plan.

- Calibration of Monitoring Instruments – An establishment's HACCP plan will usually call for the use of a monitoring instrument, such as a thermometer. To ensure the instrument remains accurate, the establishment needs to calibrate the instrument on a regular basis. The FSIS regulations require any process monitoring instruments that are used to be calibrated and the results to be documented as part of the HACCP records.

- Direct Observation of Corrective Actions – If an establishment has a deviation from a critical limit, it must take corrective action; specifically ensuring that no adulterated product is shipped and that steps will be taken to prevent future recurrence of the deviation. An establishment needs to verify that appropriate product disposition was made and that any preventive action was both implemented and effective. FSIS regulations require that establishments include direct observations of corrective actions and documentation of this activity as part of the HACCP records.

Note on testing – Testing may be a monitoring activity, a verification activity, a prerequisite program, or not related to the HACCP plan whatsoever (quality testing). Currently, there is no FSIS regulatory requirement that would require the company to conduct testing of not ready-to-eat frozen further processed food. If an establishment chooses to conduct testing voluntarily, FSIS has taken the position that it has access to all microbial test results (FSIS Directive 5,000.2). To avoid any regulatory entanglements, an establishment conducting testing should have a protocol for sampling, identification of the analysis to be conducted, and an action level which, if exceeded, requires action by the establishment.

Under the FSIS *Listeria* regulation, if an establishment produces ready-to-eat frozen food that did not receive a post-packaging lethality treatment, the establishment needs to conduct microbial testing of food contact surfaces to demonstrate the establishment's control program is effective. This testing typically is conducted for an indicator organism, such as *Listeria* species, not for *Listeria* monocytogenes (*Lm*) itself (for a positive *Lm* would automatically adulterate the entire day's production). For this sampling, as with voluntary sampling, the sampling needs to be conducted according to the sampling protocol and the establishment needs to react to positive findings.

Regulatory Requirements

As with all other HACCP requirements, FSIS regulations specify that an establishment document all its verification activities. The documentation for each activity must be filled out when the event occurred and include the date and time of the entry. The document also must be signed or initialed by the person making the entry. 9 CFR § 417.5.

Common Deficiencies

Based on regulatory non-compliance and Food Safety Assessment, there are several common deficiencies with on-going verification:

Frozen Foods Practice Tips

If there is a situation where reassessment is required, the establishment should summarize, in writing, the thought process used to determine whether any change to the plan is needed. This written summary of the decision-making process, when signed and dated, will be sufficient to meet regulatory expectations.

Policies on *Listeria monocytogenes* – Product testing and Environmental Monitoring

FDA and USDA-FSIS Policies on Listeria monocytogenes and Product and Environmental Testing

Food products considered ready to eat (RTE) products are adulterated if they contain *Listeria* monocytogenes (*Lm*). At present, the Food Safety and Inspection Service (FSIS), as well as the Food and Drug Administration (FDA) regulate foods based on the absence or presence of *Lm* on RTE product or in the manufacturing environment. There is no regulatory tolerance level for *Lm* recognized at this time by either agency in RTE products.[6]

[6] Facilities are expected to demonstrate that a finding of Lm in the environment has been eliminated through corrective actions. The presence of Lm on a food contact surface may render product passing over the surface between scheduled sanitation adulterated. A positive finding on a non-food contact surface would not automatically render product adulterated.

FDA Regulations and Guidance

Background on FDA Response to Lm

In 1985, FDA established a "zero tolerance" policy for *Lm* in RTE foods. Under this policy, detection of *Lm* in an RTE food renders the food adulterated under sections 402(a)(1) and (4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Then in 2008, FDA released a draft compliance policy guide (CPG) that would establish a policy distinguishing between RTE foods that do and do not support the growth of *Lm*. For foods that support *Lm* growth, FDA would require no detectible *Lm* in 25 g samples of food. For foods that do not support *Lm* growth, FDA would not take regulatory action provided the food does not contain more than 100 CFU/g of *Lm*. The draft CPG has not been finalized, but as described below, no longer reflects current FDA policy.

In 2015, FDA published a reassessment of the dose-response data from its 2003 risk assessment to adjust for variations in strain virulence and host susceptibility. The reassessment found that, while most cases of listeriosis are linked to consumption of foods with medium to high concentrations of *Lm*, a small number of cases result from consumption of foods with 100 CFU/g or less. Therefore, FDA believes that available data do not provide sufficient certainty to adequately predict a low level of *Lm* that is safe for highly vulnerable individuals.

The 2015 dose-response reassessment combined with several outbreaks of listeriosis have caused FDA to further consider whether an allowance of 100 CFU/g for foods that do not support growth of *Lm*, as set forth in FDA's 2008 draft CPG, adequately protects susceptible subpopulations.

FDA is in the process of updating the 2008 draft Compliance Policy Guide on *Listeria* monocytogenes. This document is expected to be released soon and likely will no longer allow for the presence of up to 100cfu/g of *Lm* in foods that do not support the growth of the pathogen.

Requirement for Listeria Control Program

Under the FDA Food Safety Modernization Act's (FSMA) Final Rule for Preventive Controls for Human Food, facilities are required to conduct a hazard analysis to identify any food safety hazards requiring a preventive control. While there are many different types of controls that may be applied during the manufacturing process, "preventive controls" are risk-based and focus on those hazards that present the greatest risk to food safety for that particular food product.

Although there is no specific regulatory requirement in the final rule for Preventive Controls for Human Food that a facility have a *Listeria* Control Program, if a facility is making a food that may be considered ready-to-eat, it would be expected to address the potential that *Lm* could occur in its food or the processing environment. Based on the information available, a prudent facility should have a *Listeria* Control program or scientific support for why such a program is not needed.

In addition, although the Preventive Controls regulations do not explicitly require an environmental or finished product testing program for *Listeria*, because a facility manufacturing an RTE food would be expected to have preventive controls in place to address *Listeria*, it also would need to conduct verification activities to demonstrate those controls are properly implemented and effective. Specifically, 21 CFR 117.165 states:

> You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system: . . . (2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard; (3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples . . .

The regulations also include specific elements any product and/or environmental testing program must include.

Key Definitions (21 C.F.R. § 117.3)

- Environmental pathogen: A pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria* monocytogenes and Sa *Lm*onella spp. but do not include the spores of pathogenic spore forming bacteria.
- Food-contact surfaces: Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
- Hazard: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
- Hazard requiring a preventive control: A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.
- Known or reasonably foreseeable hazard: A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

- Microorganisms: Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.
- Pathogen: a microorganism of public health significance.
- Preventive controls: Those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging or holding at the time of the analysis.
- Ready-to-eat food (RTE food): Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

FDA Guidance on Listeria Control Programs

In 2017, FDA released Draft Guidance for Industry on Control of *Listeria* monocytogenes in Ready-to-Eat Foods https://www.fda.gov/media/102633/download. This guidance is intended to help facilities comply with the CGMP and PCHF requirements of part 117 with respect to measures that can significantly minimize or prevent the contamination of RTE food with L. monocytogenes whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to L. monocytogenes) that would significantly minimize L. monocytogenes. This guidance includes recommendations on:

- Controls for personnel
- Design, construction, and operation of the plant
- Design, construction, and maintenance of equipment
- Sanitation practices
- Controls on raw materials and other ingredients
- Process controls
- Storage practice and time/temperature controls
- Transportation
- Environmental monitoring programs, including corrective actions
- Product testing
- Analyzing data for trends
- Training
- Procedures for collecting and preparing samples for testing
- Records
- Potential sources of *Lm*
- Example scenarios that could lead to contamination of RTE foods
- Schedules for cleaning and sanitation

With respect to environmental testing, FDA recommends that companies take a "seek and destroy" approach to *Listeria*. In particular, in the 2017 draft guidance, FDA has updated its position with respect to the actions a company should take in response to a positive result for *Listeria* species on

a food contact surface. In its previous guidance, FDA recommend that, if a food processor tests for *Listeria* species and detects it on a food-contact surface, the food processor should either: (1) conduct additional testing to determine whether it is *Lm* (i.e., "speciate"); or (2) assume the positive test is *Lm*. FDA has since recognized that this position discouraged food contact surface testing. As result, FDA now recommends that a facility react to a single positive test for *Listeria* species with a root cause investigation, cleaning and sanitizing at the site where the positive occurred and retesting at the site and surrounding area where the positive occurred during the next production cycle. If the follow-up tests at the site and surrounding sites are negative, the facility would return to its normal sampling frequency and would not need to stop production, hold and test product, or speciate the *Listeria* detected. However, if the facility finds *Listeria* species at the positive site or nearby sites during the follow-up activities, more intensive corrective and investigative measures would be expected. This approach to the first positive detected on a food contact surface is sometimes referred to as "a free pass" or "a mulligan." More details on environmental monitoring programs and corrective actions are included in the Draft Guidance.

Best Practices in Controlling Lm

There have been a number of articles published regarding best practices for controlling *Lm* in a food manufacturing environment. Many of the key articles and best practices are included in the FSIS Compliance Guideline. In addition, AFFI has developed a *Listeria* Control Program: https://affi.org/safety/Listeria-control-program/. AFFI's *Listeria* Control Program© (LCP) presents over 100 recommendations for food manufacturers aimed at *Listeria monocytogenes* (*Lm*) prevention and control. The program is developed by industry professionals for the frozen food industry to be comprehensive, easy to use, and augmented with supplementary resources and tools to implement. The LCP is a holistic approach encompassing seven core areas of hygienic design, sanitation controls, environmental monitoring, process validation, hygienic zoning, freezer management and good manufacturing practices. The LCP tool includes a multi-faceted library of resources, guidelines and procedures which include detailed guidelines, videos and standardized procedures. The tool and its content were developed by subject matter experts and food safety professionals from across the industry to address challenges in frozen food facilities.

A brief summary of some best practices are referenced below:

Product Sampling

- Prior to pulling any samples; understand what the product lot is and retain control of the lot if testing could cause the lot to be considered adulterated;
- It is suggested that you not test duplicate samples if a regulatory agency has sampled product
    - Consider pulling samples and retaining for possible future use
    - If analyzed, results will need to be reported – even if the regulatory samples were all negative
- Product should be tested only for *Lm – not Listeria species*
    - Should result in faster turn-around of samples
    - Only information needed on product is whether positive or negative for *Lm*

Environmental Sampling

- Ensure program requires a periodic review of sites list
- Ensure program details actions to be taken in the event of a positive
- Ensure the program reviews how production in the facility is done regarding length of production and product lots.
    - Detailing how production and lot determination is done alleviates any later regulatory concerns that could arise about whether you followed your program on sampling
- Use a random number generator program for selecting sites to sample
- Ensure you have information supporting your sampling frequency and number of sites sampled
    - "Best practice" suggests picking the last product contact site to be sampled each time as a constant while the other sites on the production line are randomly chosen
    - Test non-contact and near-contact surfaces at a frequency to identify issues before they move to FCS
- **Sample to find** – minimum size of 12 inches x 12 inches
- Best practice is to sample a minimum of three (3) hours into production[7]
    - Research has shown this allows time for any *Listeria* that may be inside equipment to work its way out
    - Each shift should have equal opportunity to be sampled
- Sampling should be representative of routine processing conditions
- It is recommended that the number of samples be increased if an event such as construction occurs that may increase the risk of *Lm*
- Trend all results and review over time to determine if there is a connection between positive sites and whether there may be a harborage
- Treat all positive *Listeria* species as if they are *Lm* and do a proper root cause investigation
- Take through corrective actions
- Verify that your corrective actions were effective; this may include not only taking samples on the next three consecutive production runs; but also conducting re-checks at a future date to ensure the corrective actions are sustainable

Manufacturing Environment

- Sanitation
    - Have detailed and documented cleaning and sanitizing procedures
    - Ensure you have a documented intensified cleaning and sanitization procedures if you state intensified cleaning and sanitization is done in response to a positive – what is different from the normal cleaning procedure
    - Ensure you consider the order in which equipment, floors and drains are cleaned and sanitized
        - Rough removal of debris from equipment and floors
        - Clean drains
        - Foam and scrub equipment, floors
        - Rinse

[7] If production runs are shorter than three hours, sample at the end of the run.

        - Inspect
        - Sanitize
    - Processing lines/equipment - must include provisions to properly store parts, pieces, panels, guards, etc., off the floor during cleaning and sanitizing.
        - Must focus on preventing these items contacting the floor.
    - Is sanitation gear (tools, rain suits, “green” pads) cleaned after use or disposed of?
        - All cleaning tools - squeegees, brooms, brushes, etc. stored in 1000 PPM quaternary ammonium
        - Vinyl sanitation and production raingear replaced with the lighter nylon type (i.e., Washrooms, tank wash, other washroom personnel) - laundered daily with no chlorine in the wash cycle; gas or electric dryers setting reduced or set to “air fluff” to avoid damaging the nylon.
        - “Best practice” is to remove sanitation water and cleaning hoses from RTE at end of sanitation
            - Sanitation hoses left or staged in production areas should be cleaned and sanitized along with the rest of the room’s equipment.
    - Do you have separate personnel clean the raw versus the RTE area? If not, do they change gear before cleaning RTE?
    - Are the appropriate chemicals for the types of equipment and soil present being used?
        - Elimination of all soft metals including exposed high carbon steel, aluminum, brass, copper, bronze, and possibly galvanized surfaces is best practice
    - Do you have a definite “end” of cleaning before the sanitizing step begins?
    - Are you using the appropriate sanitizing chemical? Do you verify it is at the proper strength and is applied so that it contacts all sides of the equipment? Is it left on the appropriate contact time?
    - Do you have a schedule for completely disassembling all equipment on some verified frequency?
    - Do you have the ability to “steam” or bake” equipment if a harborage is identified?
    - Chemical Foot Dips/Baths entering RTE areas
    - Chemical Foot Dips/Baths exiting Raw areas – areas of highest micro levels
    - Elimination of floor mats whenever possible
        - Floor mats are not easily or effectively cleanable

- Facility
    - RTE area is separate from raw
    - “Flow through” from raw receiving to finished product shipping with no cross-over
    - Separate facilities for raw versus RTE employees
        - All personnel required to follow GMPs
            - Anyone entering RTE area must be outfitted like a RTE employee
        - Documented training
        - Captive footwear for RTE employees at minimum
        - Different colored frocks/uniforms for raw versus RTE and non-food handlers
        - Require the use of gloves, aprons and arm guards in addition to frocks when handling RTE

        - No cross-over (employees, equipment, tools, etc.) between raw and RTE
        - Sterilization of RTE tools weekly - batch oven thermal process as an example
        - Replacement of maintenance leather tool belts with cleanable tool holders, trays, nylon, etc. that can be cleaned
    - Impervious walls and floors with minimum penetrations
    - Zero tolerance for any un-sleeved, unsealed penetrations into stainless steel tubing such as hollow legs on equipment
    - All conduits, framework, etc. is off set to allow adequate cleaning
    - Adequate air handling to remover moisture form areas prior to startup
    - Controls to limit humidity and condensation
    - Use of plastic pallets in RTE (no wood in RTE), cleaned and sanitized daily;
    - No corrugated goes into RTE;
        - Items such as code daters, knives, scales, thermometers, etc., can be carried in plastic tubs

- Equipment
    - All equipment is reviewed prior to purchase for clean ability
    - All equipment should meet sanitary design standards
        - North American Meat Institute design standards
        - NSF design standards
        - 3-A Sanitary Standards, Inc.
        - Agriculture Marketing Service – design of dairy equipment
    - Equipment is reviewed for sanitary welds
    - Equipment is reviewed for asset tags that have been riveted on
        - This provides an un-cleanable area behind the tag that provides a perfect harborage
        - Weld these on or hang by a plastic zip tie, or weld the number directly onto the equipment
    - All conveyors and belting are reviewed for damage, hidden and un-cleanable areas
        - Bearings are checked for hollow rollers, cracked seals
        - Guide bars are removed frequently for cleaning
        - Installation of tension release mechanisms on belts and conveyors to allow greater access for hand scrubbing, detailed cleaning, sanitizing, and inspection
    - No rubber wheels on carts, stands, equipment, tanks
        - Remove and replace with plastic type (Chlorinated alkaline detergents attack the phenol-containing compounds in the hard rubber wheels)
    - Electrical motor housings and transfer cases should be made of stainless steel where applications include production areas where daily wash downs are required
    - Equipment start and stop buttons are reviewed for damage and removed frequently for cleaning
    - Electrical boxes are wiped out with alcohol wipes to clean
        - If boxes get damp, suggest rigging a “Christmas tree” size bulb in the space to keep the area dry
        - Ensure seals are intact
    - Ensure all seals/gaskets used on equipment doors are not of open cell foam design which allows moisture to be trapped

As with all documented policies and procedures, ensure that they say what you are doing and also that you actually do what the policy or procedures say. Moreover, always, always have someone verify and document on a routine basis that each policy and procedure is being followed as written. If a deviation is observed, document the corrections or corrective actions and preventive measures.

FSIS Regulations and Guidance

The USDA-FSIS regulatory requirements regarding *Lm* can be found in 9 CFR Part 430 & "Control of *Listeria* monocytogenes (*Lm*) in RTE Meat and Poultry Products" (the *Listeria* Rule) that was published in 2003 as an interim final rule. On June 19, 2015, FSIS affirmed this interim final rule with minor changes8.

Complying with the Listeria Rule

Key Regulatory Definitions:

- *Antimicrobial agent (AMA)*: A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *Lm* or that has the effect of suppressing or limiting growth of *Lm* in the product throughout the shelf life of the product (9 C.F.R. § 430.1). Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.
- *Antimicrobial process (AMP)*: An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *Lm*, in the product throughout the shelf life of the product (9 C.F.R. § 430.1). Antimicrobial agents and processes are referred to together as "AMAP."
- *Deli product*: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.
- *Hotdog product*: A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR §§ 319.180 and 319.181.
- *Lethality treatment*: A process, including the application of an antimicrobial agent that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.
- *Log Reduction*: A 90% reduction of a pathogen. For example, a 2-log10 reduction is a 99% reduction of a pathogen.
- *Post-lethality exposed product*: RTE product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.
- *Post-lethality processing environment*: The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.
- *Post-lethality treatment (PLT)*: A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 C.F.R. § 430.1).

[8] The minor changes in the affirmed rule were based on comments received, and because FSIS now receives establishment profile information routinely through its Public Health Information System (PHIS).

- *Prerequisite program*: A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary to produce safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan (9 C.F.R. § 430.1).
- *Ready-to-eat (RTE) product*: A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR §§ 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.
- *Rework*: Rework is the process of recooking, reprocessing, or repackaging the product. This could also include temporary packaging of the product. FSIS considers any process that removes the product from the package and exposes it to the environment as rework.
- *Sanitation Standard Operating Procedure (Sanitation SOP)*: Written procedures for sanitation that describe all of the procedures the establishment will perform daily, before, and during operations, sufficient to prevent direct contamination or adulteration of products, according to 9 C.F.R. § 416.12(a).

Regulatory Requirements of 9 C.F.R. Part 430:

- Requires establishments to control *Lm* through their HACCP plans, Sanitation Standard Operating Procedures (SSOPs), or through their prerequisite programs.
- Requires establishments to comply with one of three *Listeria* Alternatives to maintain sanitary conditions (9 C.F.R. § 430.4(a) and (b)):
    - Alt. 1 – requires use of a post-lethality treatment and an antimicrobial agent or process.
        - If you use a post-lethality treatment; it must be included in the HACCP plan
        - The effectiveness of the post-lethality treatment must be validated in accordance with 9 C.F.R. § 417.4
    - Alt. 2 – requires use of a post-lethality treatment or an antimicrobial agent or process.
        - If using an antimicrobial agent or process – you must test FCS and you must indicate when you will implement hold and test
        - If you use a post-lethality treatment; it must be included in the HACCP plan
    - Alt. 3 – control using sanitation measures
        - Requires establishments to identify when they will hold and test product after a positive FCS
    - Hotdogs & Deli
        - Requires FCS testing and surrounding sites follow-up sampling
        - Requires hold and test after 2nd positive

The organism which is sampled for FCS and non-FCS sites routinely is *Listeria* species which is considered an "indicator organism." The genus *Listeria* now includes at least 18 different species thereby increasing the odds of finding an organism of interest. If an establishment production line is under intensified sampling, programs generally require that a "hold and test" of product that is run over the site that tested positive is triggered. Anytime that product testing is called for, product should be

tested directly for presence or absence of only *Listeria monocytogenes* – the only *Listeria* species thus far considered pathogenic.

Chapter 4 in the FSIS Compliance Guideline: Controlling *Listeria monocytogenes (Lm)* in Post-lethality Exposed Ready-to-Eat (RTE) Meat and Poultry Products provides the following chart to detail the requirements based on receipt of a FCS positive for *Listeria* species:

Table 4.1 Timeframe for Follow-up Sampling, Intensified Sampling, and Hold and Test Performed in Response to Positive Food Contact Surface Results

Alternative	After the 1st positive	After the 2nd positive	After the 3rd Positive	After Multiple Positives
Alternative 1	Follow-up sampling	Intensified sampling		Hold and test recommended
Alternative 2 , Choice 1 (2a)	Follow-up sampling	Intensified sampling		Hold and test recommended
Alternative 2, Choice 2 (2b)	Follow-up sampling	Intensified sampling	Hold and test **required*** (recommended after 3rd positive)	
Alternative 3	Follow-up sampling	Intensified sampling	Hold and test **required*** (recommended after 3rd positive)	
Alternative 3 (deli or hotdog)	Follow-up sampling **required**	Intensified sampling Hold and test **required** after 2nd positive.		

*Establishments in Alt. 2b and 3 (non-deli or hotdog producers) are **required** to identify when they will hold and test product. FSIS recommends that they do so after the **3rd** consecutive

These alternatives increase in the stringency of their control from Alternative 3 to Alternative 1. FSIS will sample establishments in Alternative 3 at a higher rate than those in Alternative 1. The *Listeria* Rule ***only*** applies to products that are RTE and exposed to the environment after the lethality step (post-lethality exposed). The lethality step can be defined as cooking or another process (such as fermentation or drying) that results in a product that is safe for consumption without further preparation.

If an establishment produces a variety of products classified as different Alternates, such as an Alternative 3 product and an Alternative 2 product, on the same production line on the same day, the establishment would follow its more rigorous sampling program for Alternative 3 products.

NOTE: The FSIS chart above seems to indicate that the only action required when a sample is positive is follow-up sampling. THIS IS NOT THE CASE! In fact, the very first thing that is required is a root cause investigation into why the site or sample was positive. What this means is determining how the *Listeria* was introduced to the site. This is important, as cleaning and then sampling to verify the effectiveness of the cleaning will eliminate the *Listeria* from the site; the key is to prevent it from being re-introduced.

An investigation must be completed for every positive to try to determine how it became contaminated to then be able to prevent it from occurring again. As part of the investigation, additional sampling

around the site may occur. Also included would be a review of equipment, product, and personnel flow to determine if *Listeria* was introduced through one of these movements. Even a drain positive must be investigated in the same manner as *Listeria* in a drain was likely introduced there by water carrying it from someplace else.

Resources

FSIS has published a number of documents to assist establishments in complying with the *Listeria* regulation. The main document is the FSIS Compliance Guideline: Controlling Listeria monocytogenes (Lm) in Post-lethality Exposed Ready-to-Eat (RTE) Meat and Poultry Products. The compliance guideline provides specific recommendations that establishments producing post-lethality exposed RTE meat and poultry product may follow to meet the requirements of the *Listeria* Rule. Others are:

- Resource 1 - Chart of RTE vs. NRTE Products: This provides information on how to determine whether or not your product falls under the *Listeria* rule.
- Resource 2: This provides information on determining if your product would be considered a "deli meat" or a "hotdog."
- RTE Product Group Flowchart: This flowchart has been designed to help an establishment select the single best representative product category/group in which a given product might be classified.
- FSIS Directive 10,240.4 Rev. 3, "Verification Activities for the *Listeria* monocytogenes (*Lm*) Regulation and the Ready-to-Eat (RTE) Sampling Program: This FSIS Directive provides information on how FSIS will verify compliance with the *Listeria* Rule.[9] It discusses how product and environmental samples will be taken and addresses FSIS' response to *Listeria* species positives.

Design of a Listeria Sampling Program

Establishments may control *Lm* through their HACCP plan, Sanitation SOP (SSOP), or using a prerequisite program. The *Listeria* control program would be incorporated into the SSOP or prerequisite program if either of these is used. If using the SSOP, the *Listeria* control program can be a part of the actual SSOP or it can be designed to work with the SSOP.[10]

If an establishment chooses to use a prerequisite program for controlling *Lm* in the environment, it must be included as part of the documentation the establishment maintains under 9 CFR § 417.5 (see 9 CFR § 430.4(c)(6)). Results from an establishment's *Listeria* control program or other prerequisite program may be used as support for the decision in its hazard analysis that *Lm* is not a hazard reasonably likely to occur in its product.

[9] The Directive also provides information on how FSIS will verify that establishments are holding and controlling RTE product if the product or a food contact surface the product touched is sampled by FSIS.

[10] The majority of establishments have programs designed to work with the SSOP and do not have them embedded in the SSOP as any change to the Listeria program would require that the SSOP be re-signed.

The *Listeria* control program should be designed to meet the requirements of the *Listeria* Rule. For establishments in Alt. 2b and 3, the *Listeria* Rule (9 CFR § 430.4(b)(2)(iii) and (3)(i)) requires that establishments:

- Test FCS sites,11
- Identify the conditions under which the establishment will hold and test product,
- State the frequency that testing will be done,
- Identify the size and location of the sites that will be sampled, and
- Provide an explanation of why the testing frequency is sufficient to control *Lm*.

In addition, Alt. 3 deli and hotdog processors are required to perform follow-up sampling and hold and test product **after a second positive** (9 CFR § 430.4(b)(3)(ii)(B)). The *Listeria* control program should also identify the sampling and testing methods used to analyze samples, and actions taken in response to positive test results, including disposition of contaminated product.

Best practice is to also include any non-food contact surfaces (NFCS) and product samples collected as part of the routine sampling program (though not required by regulation). (Sampling such as this is described in Sections 3.3-3.6, pages 88-100; and 4.1-4.3, 115-121 of the Compliance Guideline.) *Listeria* control programs are expected to be designed based on the relative risk of the product, depending on the alternative. FSIS recommends that establishments take corrective and preventive actions and perform enhanced sampling in response to any positive findings, which is also an industry best practice.

[11] **NOTE**: A finding of Listeria spp. on a FCS indicates conditions where Lm may be present, but the product is not considered adulterated. However, establishments are expected to take corrective action, according to their control alternative, to address Listeria spp. positives so that product does not become adulterated.