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MEMORANDUM

From: Steven B. Steinborn
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Re: **FDA Proposes Rule for "Gluten-Free" Labeling of Fermented or Hydrolyzed Foods**

The U.S. Food and Drug Administration (FDA) proposed a rule to establish requirements for labeling fermented or hydrolyzed foods, or foods that contain a fermented or hydrolyzed ingredient, as "gluten-free." 1/ To compensate for the lack of a scientifically valid test method for measuring intact gluten in fermented or hydrolyzed foods, FDA proposes to evaluate their compliance with the "gluten-free" labeling rule based on records that the food manufacturer would make and then retain for two years. FDA also proposes to evaluate the compliance of distilled foods by verifying the absence of protein or protein fragments in the foods using scientifically valid analytical methods. Food manufacturers would be required to comply with the new requirements within 1 year after FDA publishes a final rule. Comments are due by February 16, 2016.

Background

When FDA defined "gluten-free" in 2013, it recognized that there was no scientifically valid method that could reliably detect the presence of 20 parts per million (ppm) gluten in fermented or hydrolyzed foods. 2/ In this proposed rule, FDA states that it continues to be unaware of a scientifically valid method for detecting gluten in fermented or hydrolyzed foods. FDA tentatively concludes that if a manufacturer begins with foods or ingredients that contain less than 20 ppm of intact gluten before they are fermented or hydrolyzed, then the resulting fermented or hydrolyzed foods or ingredients would also contain less than 20 ppm intact gluten, as long as gluten was not introduced during the fermentation or hydrolysis process. The proposed rule therefore provides an alternative mechanism for FDA to confirm fermented and hydrolyzed foods' compliance with "gluten-

1/ 80 Fed. Reg. 71990 (Nov. 18, 2015).
2/ The definition of "gluten-free" is codified at 21 C.F.R. § 101.91. Foods may be labeled "gluten-free" if the unavoidable presence of gluten in the food is less than 20 ppm and either: (1) the food does not contain an ingredient that is (a) a gluten-containing grain (e.g., wheat, rye, barley); (b) derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); (c) from a gluten-containing grain that has been processed to remove gluten but still contains 20 ppm or more gluten; or (2) the food is inherently gluten free (e.g., bottled water, fresh fruits and vegetables). These requirements also apply to foods labeled "no gluten," "free of gluten," or "without gluten."

free" requirements through new recordkeeping requirements for manufacturers of these products that demonstrate that these conditions are met.

Requirements for Fermented or Hydrolyzed Foods

The proposed rule would require manufacturers of fermented or hydrolyzed foods that seek to make a "gluten-free" claim to develop and retain two types of records. First, manufacturers would have to develop records demonstrating that their food satisfies the "gluten-free" requirements prior to fermentation or hydrolysis. Second, manufacturers would have to make records indicating that the manufacturer has adequately evaluated its processing for any potential gluten cross-contact and, where the potential for cross-contact exists, implemented measures to prevent the introduction of gluten into the food during the manufacturing process. Unlike other types of foods, without these records FDA would have no other means of verifying that the finished fermented or hydrolyzed product contains less than 20 ppm gluten.

Compliance with "Gluten-Free" Requirements Prior to Fermentation or Hydrolysis

When developing records demonstrating that a food satisfies the requirements for "gluten-free" claims prior to fermentation or hydrolysis, FDA has tentatively determined that "it is appropriate to allow a manufacturer to use any means of verification that it can develop, as long as the manufacturer can document that such verification provides adequate assurance that the ingredients comply with [the requirements for 'gluten-free' claims]." These assurances could include records of test results conducted by the manufacturer or other appropriate verification documentation for the food itself or each of the ingredients used in the food. FDA also indicates that it would expect manufacturers, as part of their routine operations, to test their food or ingredients with sufficient frequency to ensure that the gluten level in the food or in each ingredient is below 20 ppm before fermentation or hydrolysis.

Alternatively, manufacturers could rely on records from their suppliers, such as certificates of analysis (COAs), to determine that each ingredient is below 20 ppm gluten. FDA states that the COAs should be based on initial qualification and sufficiently frequent requalification of the supplier through review of the supplier's documentation and practices. For ingredients a manufacturer receives from an outside supplier, FDA anticipates that the manufacturer could also document a visit to a supplier's facility, review a supplier's records, and review written documentation from a supplier to verify the compliance of the ingredients they receive.

Prevention of Gluten Cross-Contact

The records related to gluten cross-contact would have to demonstrate that the manufacturer has evaluated the potential for cross-contact during the manufacturing process and that it has implemented measures to prevent the introduction into the food where the potential for gluten cross-contact exists. FDA expects manufacturers of foods bearing "gluten-free" claims to manufacture the foods using whatever controls are necessary to prevent cross-contact, taking into account the type of food and the likelihood that ingredients might come into contact with gluten ingredients. FDA acknowledges, for example, that some foods made from inherently gluten-free ingredients, such as milk or fruit, may have a low probability of cross-contact with gluten-containing grains, especially compared to foods made from non-gluten-containing grains, legumes, or seeds that are susceptible to cross-contact with gluten-containing grains. A manufacturer's evaluation of the risk of cross-

contact would include examination of all phases of operations, including transportation and storage of ingredients and finished product.

FDA expects manufacturers will document their determination regarding the potential for gluten cross-contact, as well as their reasoning and/or support for their determination. FDA also expects manufacturers to document the measures they are using, how they determined what measures to use, and how those measures prevent gluten cross-contact.

Requirements for Foods Containing Fermented or Hydrolyzed Ingredients

FDA explains that when an entire food is not fermented or hydrolyzed, current analytical methods are able to detect intact gluten that has been introduced through the manufacturing process or through ingredients that were not fermented or hydrolyzed. FDA consequently is only requiring manufacturers of foods that contain one or more fermented or hydrolyzed ingredients to prepare records showing that those ingredients satisfy the conditions for "gluten-free" claims.

These records may include documents from the ingredient supplier supporting that the ingredient meets the definition of "gluten-free," including that the ingredient was manufactured or processed to avoid gluten-cross contact and to contain less than 20 ppm gluten. The records also can include documentation of a supplier's manufacturing procedures, records of test results from tests conducted by the ingredient supplier before fermentation or hydrolysis, COAs, or other appropriate documentation. FDA notes that manufacturers may also wish to verify the accuracy and reliability of records by checking how their suppliers document that components used in the fermented or hydrolyzed ingredient meet the definition of "gluten-free."

Record Retention

The proposed rule would require manufacturers to retain the new records for at least 2 years after introducing the "gluten-free" product into commerce. These records would have to be reasonably accessible to FDA during an inspection at each manufacturing facility, even if not stored on site. FDA would consider records that the manufacturer can retrieve immediately from another location by electronic means to be reasonably accessible. FDA asserts that it will protect any confidential information contained in the records from disclosure consistent with applicable statutes and regulations.

Requirements for Distilled Foods

According to FDA, if manufacturers adhere to good manufacturing processes, the process of distillation removes all protein and, thus, all gluten. Scientifically valid test methods exist to measure the protein content of distilled foods. Using these tests, the presence of any protein or protein fragments in the distilled food would point to the potential presence of gluten in the distilled ingredient or product; similarly, the absence of protein or protein fragments should mean the product's gluten level is below 20 ppm. Consequently, the proposed rule would require that FDA evaluate compliance of distilled foods bearing a "gluten-free" claim by using a scientifically valid method to verify the absence of protein or protein fragments in the food or ingredient.

Legal Authority

FDA asserts that it is proposing the rule consistent with its authority under section 206 of the Food Allergen Labeling and Consumer Protection Act (FALCPA) and sections 403(a)(1), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 206 of FALCPA directs the Secretary to define the term "gluten-free" on the labeling of foods, and Sections 403(a)(1) and 201(n) of the FFDCA relate to the determination of whether a food is misbranded. Section 701(a) of the FFDCA grants FDA the authority to issue regulations for the efficient enforcement of the FFDCA. According to FDA, the proposed record requirements would help ensure that the use of the term "gluten-free" is accurate, truthful, and not misleading based on information known to the manufacturer that FDA would not otherwise be able to access, and they therefore help in the efficient enforcement of the FFDCA.

Requests for Comment

In addition to general comments on the proposed rule, FDA requests public comment and data related to a variety of topics, including the following issues.

- Any studies that have been conducted to demonstrate whether fermentation or hydrolysis sufficiently break down gluten into peptides that are harmless to people with celiac disease.
- Data on the feasibility and circumstances under which a food (as opposed to an ingredient) can be processed to remove gluten and the methods by which the absence of gluten can be determined.
- Research regarding whether beer derived from gluten-containing grains that may still contain protein fragments from gluten can be shown by scientifically valid methods to equate to intact gluten on a quantitative basis.
- The potential for source ingredients used in fermentation (e.g., milk in yogurt) to come in contact with gluten-containing grains and manufacturing practices that can prevent the risk of gluten cross-contact.
- Options for records for fermented or hydrolyzed foods or ingredients that are concentrated or dried.

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Please let us know if you have questions or if we can be of any further assistance.