

MEMORANDUM

From: Martin J. Hahn

Date: January 23, 2007

Re: FDA's Proposed Rule on Gluten Free Labeling of Foods

Today, the Food and Drug Administration (FDA) proposed a rule defining the term "gluten free" that would establish uniform conditions for its use in the labeling of foods. ^{1/} FDA's proposed rule would prohibit the use of "gluten free" on products containing a prohibited grain, which is defined as including wheat, rye and barley. The proposal also would prohibit the use of the term on foods containing 20 parts per million (ppm) or more gluten. FDA issued the proposed rule in response to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) that directed the Secretary of Health and Human Services (HHS) to issue a rule to ensure that individuals with celiac disease are provided with truthful and accurate information about gluten free products.

1. PROPOSED DEFINITIONS

A. "Prohibited Grain"

"Prohibited grain" would be defined to mean any of the following grains or their crossbred hybrids: (1) wheat, meaning any species belonging to the genus *Triticum*; (2) rye, meaning any species belonging to the genus *Secale*; and (3) barley, meaning any species belonging to the genus *Hordeum*. Examples of prohibited grains include: barley, common wheat, durum wheat, einkorn wheat, emmer wheat, kemut, rye, spelt wheat, and tritical, which is a crossbred hybrid between wheat and rye.

Notably absent from the FDA definition are oats and millet, which under the proposed rule could be found in products labeled as "gluten free," provided the finished product contains less than 20 ppm gluten. Although oats have been identified by some experts as a trigger for celiac disease, FDA states the unconditional exclusion of oats from the diet of individuals with celiac disease is

^{1/} 72 Fed. Reg. 2795 (January 23, 2007).

not supported by the *National Institutes of Health Conference Development Conference Statement on Celiac Disease* or by the American Dietetic Association.

It appears that most of the harm from oats comes from the widespread co-mingling of oats with other grains during harvest, transport or storage. While FDA characterizes the co-mingling of oats with gluten-containing grains as “widespread,” the agency notes it is possible to prevent this co-mingling and is aware of at least two sources of oats that do not contain co-mingled grains. FDA notes food manufacturers can produce oats that do not contain gluten from wheat, rye, barley, or any of their crossbred hybrids, and FDA believes that allowing such oats to bear a gluten free labeling claim would make them easier to identify and perhaps would encourage other manufacturers to produce such oats.

B. “Gluten”

FDA proposes to define the term “gluten” to mean the proteins that naturally occur in a prohibited grain and that may cause adverse health effects in persons with celiac disease (e.g. prolamins and glutelins).

C. “Gluten Free”

The proposed rule would define the term “gluten free” to mean that a food bearing the claim in its labeling does not contain any of the following:

1. An ingredient that is a prohibited grain.
2. An ingredient that is derived from a prohibited grain and that has not been processed to remove the gluten.
3. An ingredient that is derived from a prohibited grain and that has been processed to remove the gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food.
4. 20 ppm or more gluten.

FDA identifies farina, hydrolyzed wheat protein, vital gluten, wheat bran, wheat germ, barley malt extract or flavoring and malt vinegar as examples of products that would be ineligible for the claim under (2) above because the product has not been processed to remove gluten. Modified food starch and wheat starch are provided as examples of ingredients that have been processed to remove gluten and could be used in a gluten free product provided the ingredient contains less than 20 ppm gluten.

In the regulatory impact analysis section, FDA explains it would consider a “gluten free” claim misleading under its existing statutory requirements when the claim appears on any food containing a detectable level of gluten when analyzed by a consistent and reliable method. The agency statement suggests companies currently using “gluten free” claims should limit that claim to products providing less than 20 ppm gluten

2. PROPOSED LABELING RESTRICTIONS

A. Foods That Inherently Do Not Contain Gluten

FDA proposes that foods that inherently do not contain gluten should only bear the claim “gluten free” in their labeling if: (1) the wording of the claim in the labeling of the food clearly indicates that all foods of the same type, not just the brand bearing this labeling claim, are gluten free (e.g. “milk, a gluten free food,” or “all milk is gluten free”) and (2) the food does not contain 20 ppm or more gluten. Examples of foods that inherently do not contain gluten include: milk, 100 percent fruit and vegetable juices, fresh fruits and vegetables not coated with wax or resin, frozen or canned fruits and vegetables not made with added ingredients that include gluten, a variety of single ingredient foods such as butter, eggs, lentils, legumes, seeds, tree nuts, fish, honey, water, and non-gluten containing grains such as corn, millet, and rice.

Although oats inherently do not include gluten, to avoid misperceptions the proposal would deem misbranded a food made from oats that bears a gluten free labeling claim that refers to all such foods as being gluten free.^{2/} This proposed restriction is based on the high rate of co-mingling of oats with prohibited grains. The proposal, therefore, would not allow the use of statements such as “oats, a gluten free food.”

B. Threshold Gluten Levels

The establishment of the 20 ppm level threshold is one of the more interesting aspects of the proposal. FDA based the 20 ppm threshold on the limit of detection for gluten methods of analysis. FDA tentatively determined the ELISA-based methods reliably and consistently detect gluten at a level of 20 ppm. FDA notes the ELISA-based methods are currently under review by AOAC, but are not yet established. The *Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food* identified the method of analysis as one of the methods for setting threshold for major allergens and gluten.^{3/} FDA seems reluctant, however, to use the analytical method solely as the legal basis for the 20 ppm threshold.

FDA states it plans to conduct a safety assessment for gluten. FDA asks for clinical research and other data designed to measure chronic exposure that would satisfy the data requirements found in the Thresholds Report on Allergens. FDA notes it intends to announce the availability of the draft safety assessment in a future Federal Register. FDA also notes it will consider the draft safety assessment on gluten and comments submitted in response to this proposed rule when developing the final rule on “gluten free.” Regardless of the agency's announced intent to conduct a safety assessment, the preamble establishes the precedent of using the detection limit of a reliable and consistent method of analysis as a basis for setting thresholds.

^{2/} 21 CFR § 101.91(b)(3)

^{3/} See, <http://www.cfsan.fda.gov/~dms/alrgn2.html>, last visited January 23, 2007 (hereinafter “Threshold Report on Allergens”).

3. REQUESTS FOR PUBLIC COMMENT

FDA has requested comments on the following specific issues:

- The proposal to restrict gluten free labeling claims relating to oats.
- Whether a gluten free claim relating to inherently gluten free foods, aside from oats, would be misleading in the absence of additional qualifying language (e.g., consumers might mistakenly believe that a certain brand is gluten free and not understand that other brands of the same type of food are also gluten free if they fail to make such a claim).
- Whether the use of additional qualifying language would be necessary to inform individuals with celiac disease that a food labeled “gluten free,” nonetheless, may contain the amount of gluten permitted under 20 ppm (e.g., “gluten free contains less than 20 ppm gluten per gram”).
- The effects of lowering the threshold from 20 ppm as more sensitive analytical methods become available.
- What effects the adoption of a lower threshold level would have on individuals with celiac disease and on the industry (e.g., how a lower threshold level would affect the commercial availability of foods labeled gluten free).
- Whether there is a possible scientific basis for setting a level of gluten to be defined as “low gluten” or whether such a claim should be prohibited.
- The planned safety assessment, including clinical research and studies designed to measure chronic exposure to gluten.

The FDA will be accepting public comments until April 23, 2007. If you wish to file comments with the agency or simply to discuss these issues further, please do not hesitate to contact us.

Attachment