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## Having their say Celiacs, food makers weigh in on "gluten free" By Amy Ratner



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It takes four heavy binders to hold all the comments the Food and Drug Administration received on its proposed definition of the gluten-free label.

The FDA asked for these comments after releasing a proposed definition of what "gluten free" would mean on a food label. According to the proposed definition, foods labeled gluten free can contain up to 20 parts per million (ppm) of gluten.

The comments came from people who have celiac disease, specialty gluten-free food companies, mainstream food makers, and large grocery chains and their associations. Some individuals, organizations and companies wrote in complete support of the FDA proposal. But many who sent comments disagreed. There were three major points of contention:

- How much gluten should be allowed foods labeled gluten free?
- Should there be a two tier system of labeling foods, on called "gluten free" and the other "low gluten?"
- Should foods that are naturally gluten free be allowed to use the gluten-free label?

Most of those who follow the gluten free diet urged the FDA to set the standard lower than the proposed 20 ppm and allow less gluten in foods labeled gluten free. Many said the standard should be 3 ppms.

When the FSA released the proposed definition, it said it set the 20 ppm, limit because currently there are not tests that can reliably and consistently detect gluten at levels below that amount.

Tests that go down as far as 3 ppm do exist, but the agency did note that it is aware that new, more sensitive tests are being developed and could be considered if they are eventually validated.

Tests for gluten do not pinpoint the exact amount of gluten in food. They simply give a positive or negative result. For example, if a food is tested at 20 ppm and the result shows that the food contains more than 20ppm, the test would be positive.

The test would be negative if the food contained less than 20 ppm. In this case, all the test would show is that the food contained somewhere between 19 ppm and zero. Realistically there is no way to determine that any food contains zero gluten.

But many individuals with celiac disease who identified themselves as members of the Celiac Sprue Association said the threshold should be set at 3 ppms. CSA, a national support group, certifies products with a CSA seal if they meet its testing standards for gluten free. Currently, CSA tests foods to 3ppm.

In its comments to the FDA, CSA wrote that "scientifically acceptable research which confirms how much is too much is woefully lacking." Further, CSA said, "gluten free must mean "the absence of gluten, not the measurement of (gluten)."

In the past, CSA has always pushed for zero gluten.

Bruce Ritter, president of Elisa Technologies, a company that makes tests for gluten in food, said some tests can reliably detect gluten at levels as low as 5 ppm. So using a test that measures 20 ppm does not take advantage of the best available science, he said.

Ritter also advocated labels that, rather than saying "gluten free" would tell consumers how low the test for gluten went. For example, a label would say "Contains less than 5 ppms of gluten."

Glutino, one of a handful of specialty gluten-free food companies to weigh in on the proposal, said it is crucial for the FDA to set the most stringent standards possible. The company didn't specify an amount but said it should be lower than 20 ppms. "Legislation is the key to weeding out those who do not and can not keep to the high standards of allergen-free manufacturing," the company wrote.

The National Consumer League, a consumer advocacy group, said that if any level other than zero is used, the label should have qualifying language. For example, "Does not contain more than 20 ppm of gluten."

### A question of safety

The FDA set its threshold for gluten at 20 ppms strictly because that is the lowest level for which it could find accurate testing. But the agency said it wants to study how safe the threshold is for those who have celiac disease before it issues a final definition. It will look at research like a study published this year in the American Journal of Clinical Nutrition that followed 49 adults with celiac disease who ingested varying amounts of gluten every day. It concluded that 20ppm is a safe level.

Other studies, including one from Finland, have found that up to 100 ppm could be considered safe.

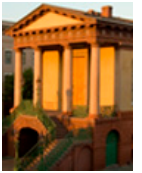
According to the FDA, several factors could lead to an adjustment in the 20 ppm standard even after a final definition is released. For example, the safety assessment might support a higher or lower amount. Or, more sensitive tests could be developed and validated and the threshold could be lowered.

The grocery Manufacturers/Food Processors Association said changing the threshold in response to more sensitive tests could cause problems for food makers and consumers.

The association, a food industry advocacy group, said if the standard is lowered even once, a company might decide to stop making gluten-free products due to the cost associated with adjusting to the new amount. Or they could raise the price of gluten-free foods.

The group said the FDA proposal of 20 ppms is "both supported by science and is workable in food processing operations." It urged the FDA to address celiac concerns without unnecessarily restricting the number and variety of foods that could be labeled gluten free.

The proposed definition repeatedly notes the FDA's concern about balancing safety, effects on compliance with the diet, costs and availability of gluten-free food when it puts a final proposal together.



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## Two-tier label system

Some comments to the FDA suggested two labels – one “gluten free” and the other “low gluten.” They came from food companies and associations who maintain that two levels of gluten would create more choices for consumers.

General Mills, the sixth largest food company in the world, encouraged the FDA to establish a definition for “low gluten.” Allowing a low gluten label would provide more food choices, General Mills said, and the incentive for companies to develop more food to meet the nutritional needs of those with celiac disease.

European groups favor a two-tier labeling system, because in theory it would enable food processors to use wheat starch in gluten-free foods at a level higher than 20 ppm. The gluten-free foods that contained wheat starch would be labeled “low gluten.”

In Europe, products that contain wheat starch specially processed to contain 200ppm of gluten or less are allowed on the gluten-free diet. In its comments, the Ministry of Finland, said these products are readily available, widely used, result in better compliance with the diet, and have no associated health problems.

Wheat starch is not currently allowed on the gluten-free diet in the US. It could be allowed under the proposed definition if products containing wheat starch met the 20 ppm standard.

The FDA proposal says it “tentatively” concluded that it would not be scientifically possible to specify a level of gluten for a low-gluten label. The agency specifically asked for comment on any scientific basis for defining low gluten.

## Naturally gluten free

There are many packaged foods that are “naturally gluten free,” including plain canned vegetables, fruits plain meat and grains like rice and corn. And there are many opinions as to how they should be labeled.

The FDA proposal says these foods cannot be labeled gluten free unless the label also includes a statement that says all foods of the same type are gluten free. In other words, a can of peaches could be labeled gluten free but would have to add the phrase, “all peaches are gluten free” or “peaches, a gluten free food.”

The FDA argues that it is confusing to consumers when a gluten-free label appears on something that is naturally gluten-free. For example, if one can of plain peaches was labeled gluten free and another was not, a consumer might conclude that the first was gluten free and the second was not.

But food makers said they are trying to make it as easy as possible for gluten-free shoppers to identify safe products by using gluten-free labels.

The Food Marketing Institute (FMI), which represents 1,500 food sellers, said FALCPA is supposed to make allergen information simpler and more widely available.

It said the food industry would be restricted from using a very simple and straight forward way of telling shoppers exactly what items are gluten free if it can't label naturally gluten free products that way.

The FMI says some retailers have come up with simple symbols that customers can use to quickly tell if any product is gluten free. The symbols eliminate the need to read detailed ingredients lists and are popular with customers, especially those who are newly diagnosed and uncertain about exactly what is gluten free.

## Cross contamination issues

Cross-contamination issues led the Gluten Intolerance Group, a national support group, to ask that the same guidelines for oats should also be applied to other processed gluten-free grains.

Oats, which are not included in the list of gluten-containing grains, are specifically mentioned as having to meet the 20 ppms standard. Those who commented on oats largely said they support the FDA's decision not to include them as a prohibited grain.

GIG, which has its own program for certifying foods a gluten free, said it has identified two large producers of gluten-free flours that would not be able to meet the proposed definition for gluten free. The group maintained it is especially important to makers of gluten-free foods to have confidence the gluten-free grains they buy and use are in fact gluten free.

For example, GIG said rice as a whole grain is naturally gluten free and has low risk for cross contamination. But when it is processed into flour it has high risk of cross contamination.

## What's next?

The FDA is now evaluating the comments and looking into the safety of the gluten threshold set in the proposed definition. FALCPA gives the agency until August 2008 to come up with a final definition.

Until then, it will continue to be largely up to food makers to decide when a food can have a gluten-free label. But many are already testing their products in anticipation of new FDA rules and preparing for the changes that will come once the final definition becomes law.

This article appeared in the Fall 2007 issue of Gluten Free Living. [www.glutenfreeliving.com](http://www.glutenfreeliving.com)

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