

# F.D.A. Sets a Standard on Labeling ‘Gluten Free’

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Published August 2, 2013

WASHINGTON — The federal government on Friday set a standard for gluten-free claims on food labels, a step that health officials said would help the three million Americans with celiac disease and bring uniformity to the \$4 billion market for gluten-free products. Gluten is a composite of starch and proteins found in certain grassy grains like wheat, barley and rye. When eaten by people with celiac disease, gluten can trigger the production of antibodies that damage the lining of the small intestine.

To protect people with the disease, Congress passed a law in 2004 calling on the Food and Drug Administration to set standards for how much trace gluten could be in foods whose labels said they were gluten free. A standard became even more urgent, observers said, when broader consumer demand for gluten-free foods drove the rapid expansion of the market.

The F.D.A.’s publication on Friday of the final rule is the culmination of that process. The agency set a gluten limit of 20 parts per million in products labeled gluten free, said Michael R. Taylor, deputy commissioner for foods and veterinary medicine at the F.D.A. The limit had long been discussed and did not come as a surprise to industry or patient advocate groups. It was similar to the level adopted in recent years by the European Union and Canada, Mr. Taylor said.

According to Packaged Facts, a consumer market research company, sales of gluten-free products stood at \$4.2 billion in 2012, nearly triple what they were in 2008. In a poll of consumers in August 2012, Packaged Facts found that the top two reasons people gave for buying gluten-free food was that they believed it was healthier and that it would help them manage their weight. Experts say there is no evidence that such foods help with weight loss.

Dr. Alessio Fasano, the director of the Center for Celiac Research at Massachusetts General Hospital in Boston, helped develop the science to determine how much gluten was too much for celiac disease patients. He said that when he first started researching the topic in the early 1990s, the definition “was all over the map.” He called the rule issued on Friday “a big deal” because it gives people with celiac disease, an autoimmune disorder, confidence that the food they buy will not make them sick. “A gluten-free diet for people with celiac disease is like insulin for diabetics,” Dr. Fasano said. The F.D.A. first proposed the 20 parts per million standard in 2007, Mr. Taylor said, and companies have used that limit as a guide for their products even before the new rule was published.

“We frankly think that the great majority of products have been driven to that level,” he said.

The agency has tools to keep companies in compliance. It can seize products whose gluten level is above the limit, or require companies to recall products. But Mr. Taylor said he doubted much of that would be necessary. Industry favors the rule, he said, as it sets a level playing field and gives consumers peace of mind.

“We don’t think compliance will be a problem,” Mr. Taylor said. “Industry wants this rule. They have huge incentive to comply with it. They want people to be confident.” Boulder Brands, a food company based in Boulder, Colo., that makes the Glutino and Udi’s brands, applauded the new standard, saying in a statement that it would create “a uniform definition for what gluten free means across all products.”