

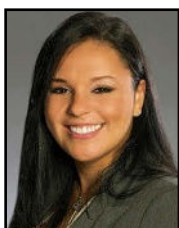


# FDA Issues Final Rule Defining the Term “Gluten Free”: What Food Manufacturers Need to Know for Product Labeling

By Rebecca Rodriguez, M.S., J.D.

**O**n August 5, 2013, with the gluten free marketplace growing at a rate of twenty-eight percent a year, the U.S. Food and Drug Administration (FDA) published a final rule on defining and regulating the term “gluten free” on food product labeling in the United States.<sup>1</sup>

## Why was a Gluten-Free Regulation Necessary?



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One in 133 Americans has Celiac Disease (CD)<sup>2</sup> and currently there are no pharmaceutical cures for CD.<sup>3</sup> A strict gluten-free diet is the only treatment for those with CD.<sup>4</sup> Millions with CD rely on gluten-free labeling to make diet choices, in addition to those that seek the medical benefits associated with a gluten-free diet.<sup>5</sup> The demand for gluten-free products has resulted in a growing 2.6 billion dollar market.<sup>6</sup> Before the rule, there were no federal standards or definitions for the food industry to use in labeling products “gluten free.”<sup>7</sup> An estimated five percent of foods currently labeled “gluten free” contain 20 parts per million (ppm) or more of gluten.<sup>8</sup> TFDA’s new rule addresses this issue.

FDA Commissioner Margaret A. Hamburg, stated that “[a]dherence to a gluten-free diet is the key to treating celiac disease, which can be very disruptive to everyday life . . . FDA’s new ‘gluten-free’ definition will help people with this

condition make food choices with confidence and allow them to better manage their health.”<sup>9</sup>

## What is “Gluten”?

FDA has defined the term “gluten” to mean “the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with Celiac Disease”.<sup>10</sup> The term “gluten-containing grain” is defined as “any one of the following grains or their crossbred hybrids:

- Wheat, including any species belonging to the genus *Triticum*<sup>11</sup>;
- Rye, including any species belonging to the genus *Secale*<sup>12</sup>; or
- Barley, including any species belonging to the genus *Hordeum*<sup>13</sup>.

## What is “Gluten Free”?

FDA has determined that the labeling claim “gluten free” means the food bearing the claim in its labeling does not contain any of the following:

- An ingredient that is a gluten-containing grain<sup>14</sup>;
- An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten<sup>15</sup>; or
- An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food.<sup>16</sup>

“Gluten free” claims also mean that the food inherently does not contain gluten and “any unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten”.<sup>17</sup>

A food that bears the claim “gluten free”, “no gluten”, “free of gluten”, or “without gluten” in its labeling and fails to meet the requirements of the final rule will be deemed misbranded.<sup>18</sup>

Misbranding occurs if a food product’s labeling is false or misleading.<sup>19</sup> Foods such as bottled spring water, fruits and vegetables, and eggs can also be labeled “gluten-free” if they inherently don’t have any gluten.<sup>20</sup>

## Gluten Free Compliance Deadline for Food Manufacturers is August 5, 2014

The final rule for gluten-free labeling becomes effective on September 4, 2013.<sup>21</sup> The compliance deadline for the final rule is August 5, 2014, giving food manufacturers one year after the rule is published to bring their product labels into compliance.<sup>22</sup> Food manufacturers with products bearing such claims should use the next twelve months to conduct testing on these products, to verify the eligibility of gluten-free claims on its labeling and the ppm of gluten that is present in the respective products. “We encourage the food industry to come into compliance with the new definition as soon as possible and help us make it as easy as possible for people with Celiac Disease to identify foods that meet the federal definition of ‘gluten-free,’” said Michael R. Taylor, FDA’s deputy commissioner for foods and veterinary medicine.<sup>23</sup>

Food manufacturers with questions regarding compliance with this final rule are encouraged to e-mail their questions to FDA directly. FDA has established an inquiry email address specifically for gluten regulation questions at [GlutenFreeFinalRuleQuestions@fda.hhs.gov](mailto:GlutenFreeFinalRuleQuestions@fda.hhs.gov).

1. 78 FR 47154 (Aug. 5, 2013) available at <http://www.gpo.gov/fdsys/pkg/FR-2013-08-05/pdf/2013-18813.pdf> (last visited Aug. 25, 2013) [hereinafter “New FDA Regulation”]; *Press Release: FDA Defines “Gluten-Free” for Food Labeling*, U.S. FOOD AND DRUG

ADMINISTRATION, (Aug. 2, 2013) available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm363474.htm> (last visited Aug. 25, 2013) [hereinafter “FDA Gluten-Free Press Release”]

2. *What is Celiac Disease?*, National Foundation for Celiac Awareness, available at <http://www.celiaccentral.org/SiteData/docs/NFCAWhatis/97976cf09194b986/NFCA%20-%20What%20is%20Celiac%20Disease%202-2011.pdf> (last visited Aug. 25, 2013).
3. *Id.*
4. *Id.*
5. 65 Food Drug L.J. 367 (2010).
6. *Id.* at 367, 368.
7. *FDA Consumer Update: What is Gluten-Free? FDA Has an Answer*, U.S. FOOD AND DRUG ADMINISTRATION available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM363276.pdf> (last visited Aug. 25, 2013).
8. *Id.*
9. *FDA Gluten-Free Press Release*, *supra* note 1.
10. 21 C.F.R. § 101.91(a)(2) (2013).
11. 21 C.F.R. § 101.91(a)(1)(i) (2013).
12. 21 C.F.R. § 101.91(a)(1)(ii) (2013).
13. 21 C.F.R. § 101.91(a)(1)(iii) (2013).
14. 21 C.F.R. § 101.91(a)(3)(i)(A)(1) (2013).
15. 21 C.F.R. § 101.91(a)(3)(i)(A)(2) (2013).
16. 21 C.F.R. § 101.91(a)(3)(i)(A)(3) (2013).
17. 21 C.F.R. § 101.91(a)(3)(i)(B) (2013).
18. 21 C.F.R. §§ 101.91(b)(1)–(2) (2013).
19. 21 U.S.C. §§ 343 (a)(1)–(2); 21 C.F.R. § 101.18 (Apr. 1, 2012) available at <http://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol2/pdf/CFR-2012-title21-vol2-sec101-18.pdf> (last visited Aug. 25, 2013).
20. *FDA Consumer Update: What is Gluten-Free? FDA Has an Answer*, *supra* note 7.
21. *FDA Gluten-Free Press Release*, *supra* note 1.
22. New FDA Regulation, Sec. II.B.4 comment 35 and response 35, *supra* note 1.
23. *FDA Gluten-Free Press Release*, *supra* note 1.