



8 August 2013

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Committee on Sanitary and Phytosanitary Measures

Original: English

## NOTIFICATION

### *Addendum*

The following communication, received on 7 August 2013, is being circulated at the request of the Delegation of the United States of America.

#### Food Labeling; Gluten-Free Labeling of Foods, Final Rule

The US Food and Drug Administration is issuing a final rule to define the term "gluten-free" for voluntary use in the labeling of foods. The final rule defines the term "gluten-free" to mean that the food bearing the claim does not contain an ingredient that is a gluten-containing grain (e.g., spelt wheat); an ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or an ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or inherently does not contain gluten; and that any unavoidable presence of gluten in the food is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food). A food that bears the claim "no gluten", "free of gluten", or "without gluten" in its labeling and fails to meet the requirements for a "gluten-free" claim will be deemed to be misbranded. In addition, a food whose labeling includes the term "wheat" in the ingredient list or in a separate "Contains wheat" statement as required by a section of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and also bears the claim "gluten-free" will be deemed to be misbranded unless its labeling also bears additional language clarifying that the wheat has been processed to allow the food to meet FDA requirements for a "gluten-free" claim. Establishing a definition of the term "gluten-free" and uniform conditions for its use in food labeling will help ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled. FDA is issuing the final rule under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

The final rule becomes effective on 4 September 2013. The compliance date of this final rule is 5 August 2014. See section II.B.4 (comment 35 and response 35) of the document for an additional explanation of the compliance date and implementation of this final rule.

[http://members.wto.org/crnattachments/2013/sps/USA/13\\_3157\\_00\\_e.pdf](http://members.wto.org/crnattachments/2013/sps/USA/13_3157_00_e.pdf)

#### **This addendum concerns a:**

- Modification of final date for comments
- Notification of adoption, publication or entry into force of regulation
- Modification of content and/or scope of previously notified draft regulation
- Withdrawal of proposed regulation
- Change in proposed date of adoption, publication or date of entry into force
- Other:

**Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)**

Sixty days from the date of circulation of the addendum to the notification and/or (dd/mm/yy): Not applicable

**Agency or authority designated to handle comments:  National Notification Authority,  National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

For further information contact:

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**Text available from:  National Notification Authority,  National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: [us.spsenquiry@fas.usda.gov](mailto:us.spsenquiry@fas.usda.gov)

The complete text, found in the US Federal Register at 78 FR 47154, can also be obtained online at: <http://www.gpo.gov/fdsys/pkg/FR-2013-08-05/pdf/2013-18813.pdf>.

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