



20 November 2015

(15-6155)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	<b>Notifying Member:</b> <u>UNITED STATES OF AMERICA</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Food and Drug Administration (FDA), Health and Human Services (HHS) [1069]  <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> Please submit comments to: USA WTO TBT Enquiry Point Email: <a href="mailto:usatbtep@nist.gov">usatbtep@nist.gov</a>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Food labeling. Food products in general (ICS: 67.040)
5.	<b>Title, number of pages and language(s) of the notified document:</b> Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods (17 pages, in English)
6.	<b>Description of content:</b> The Food and Drug Administration (FDA or we) is proposing to establish requirements concerning "gluten-free" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the "gluten-free" labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as "gluten-free." There is uncertainty in interpreting the results of current gluten test methods for fermented and hydrolyzed foods on a quantitative basis that equates the test results in terms of intact gluten. Thus, we propose to evaluate compliance of such fermented and hydrolyzed foods that bear a "gluten-free" claim with the gluten-free labeling rule based on records that are made and kept by the manufacturer of the food bearing the "gluten-free" claim and made available to us for inspection and copying. The records would need to provide adequate assurance that the food is "gluten-free" in compliance with the gluten-free food labeling final rule before fermentation or hydrolysis. In addition, the proposed rule would require the manufacturer of fermented or hydrolyzed foods bearing the "gluten-free" claim to document that it has adequately evaluated the potential for gluten cross-contact and, if identified, that the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process. Likewise, manufacturers of foods that contain fermented or hydrolyzed ingredients and bear the "gluten-free" claim would be required to make and keep records that demonstrate with adequate assurance that the fermented or hydrolyzed ingredients are "gluten-free" in compliance with the gluten-free food labeling final rule. Finally, the proposed rule would state that we would evaluate compliance of distilled foods by verifying the absence of protein using scientifically valid analytical methods that can reliably detect the presence of protein or protein fragments in the distilled food.

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7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety
8.	<b>Relevant documents:</b> 80 Federal Register (FR) 71990, 18 November 2015; Title 21 Code of Federal Regulations (CFR) Part 101. Will appear in the Federal Register when adopted.
9.	<b>Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> To be determined
10.	<b>Final date for comments:</b> 16 January 2016
11.	<b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b> <a href="https://members.wto.org/crnattachments/2015/TBT/USA/15_4628_00_e.pdf">https://members.wto.org/crnattachments/2015/TBT/USA/15_4628_00_e.pdf</a>