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CIAA Bulletin

An Exclusive CIAA Member  
Update

## FDA Finalizes Rule Related to Gluten-Free Labeling for Foods Containing Fermented or Hydrolyzed Ingredients

The U.S. Food and Drug Administration issued a [final rule](#), effective October 13, 2020, to establish compliance requirements for fermented and hydrolyzed foods, or foods that contain fermented or hydrolyzed ingredients, and that are labeled “gluten-free.” The rule pertains to foods such as: cheese, yogurt, sauerkraut, pickles, soy sauce, green olives, FDA-regulated beer and wine, and hydrolyzed plant proteins used to improve flavor or texture in processed foods such as soups, sauces, and seasonings.

The rule requires manufacturers of the fermented and hydrolyzed food products to make and keep records providing adequate assurance that:

1. The food meets the definition of “gluten-free” before fermentation or hydrolysis;
2. The manufacturer has adequately evaluated the potential for cross-contact with gluten during the manufacturing process; and
3. If necessary, measures are in place to prevent the introduction of gluten into the food during the manufacturing process.

FDA chose a recordkeeping approach for “gluten free” claims on these products because currently available analytical methods cannot be used to determine, with precision, if these products meet the “gluten-free” definition codified at 21 C.F.R. § 101.91. Once a scientifically valid

method has been developed that can accurately detect and quantify gluten in fermented or hydrolyzed foods or ingredients, it will no longer be necessary for the manufacturer of foods bearing the “gluten-free” claim to make and keep these records. FDA believes that this approach will ensure that individuals with celiac disease are not misled and receive truthful and accurate information because gluten breaks down during fermentation and hydrolysis.

The rule also discusses that the FDA will monitor compliance of distilled foods, such as vinegar, 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.

The definition of “[gluten-free](#)” for other foods, established in 2013, is not changed by this new final rule. As a reminder, the FDA defines “gluten-free” as food that is either inherently gluten free; or does not contain an ingredient that is:

1. A gluten-containing grain (e.g., spelt wheat); f
2. Derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour); or
3. Derived from a gluten-containing grain 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.

Any members making “gluten free” claims on cheese or other fermented products should review this new regulation in detail to ensure that sufficient records are maintained to continue using this claim on the product. s

Should you have any questions regarding this alert, contact the Husch Blackwell LLP team at [CIAAGeneralCounsel@huschblackwell.com](mailto:CIAAGeneralCounsel@huschblackwell.com).

**Cheese Importers Association of America**

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## Dates to Remember

**AUGUST 31, 2020**

Last day to enter dairy products into U.S. Customs territory that may be used to qualify and establish eligibility for a calendar year 2021 license.

**SEPTEMBER 1, 2020**

First day of license eligibility period for next quota year-plus one. Example: entries made on or after September 1, 2020 can be used to establish eligibility for a license for calendar year 2022.

**SEPTEMBER 3, 2020**

Last date to request globalization of a calendar year 2020 license. First transmission date for applications for reallocated license amounts for calendar year 2020. First transmission date for all applications for calendar year 2021 licenses.

**SEPTEMBER 15, 2020**

Last transmission date for licensees applying for reallocated license amounts for calendar year 2020.

**OCTOBER 1, 2020**

Last transmission date for licensees to surrender all or the unused portion of their calendar year 2020 licenses.

**OCTOBER 15, 2020**

(no exceptions!) Last transmission date for all applications for calendar year 2021 licenses.

**OCTOBER 31, 2020**

Exporting countries that are designating U.S. importers for calendar year 2021 must submit their designations to FAS by this date.

**DECEMBER 20, 2020**

(approximately) FAS issues first notice of calendar year 2021 licenses to licensees.

**DECEMBER 31, 2020**

Last day for licensees to make entries to fulfill the requirement to use 85% of their calendar year 2020 license amount. Last day for which calendar year 2020 licenses are valid.

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