GFCO's Position Statement on Fermented and Hydrolyzed Products

March 30, 2023

Executive summary

The GFCO certification program is updating its position on fermented and hydrolyzed materials used in certified gluten-free products. This change is being made in the interest of public safety, as well as to better align our requirements with the 2020 United States Food and Drug Administration (US-FDA or FDA) amendment to 21 CFR 101.91(c). This change will impact all certified products, not only those sold within the United States.

When a Product, ingredient or ingredient component is fermented or hydrolyzed, the manufacturer must state or demonstrate that the Product, ingredient or component contained no proteins from wheat, rye, barley or oats, and that steps were taken to prevent cross-contact from any of these grains prior to the fermentation or hydrolysis step. GFCO may actively request this documentation for all cultures, yeast, enzymes, probiotics, and other fermented/hydrolyzed materials.

Problem being addressed:

On October 13, 2020 the FDA issued an amendment to 21 CFR 101.91(c) titled Food Labelling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods. The compliance date for this new final rule was August 13, 2021. This regulation provided strong evidence that current test methods are not suitable for products that are fermented or hydrolyzed as part of their manufacturing. The GFCO program is in agreement with the conclusions presented by FDA, and has updated GFCO documentation requirements accordingly. While manufacturers must comply with these updated standards in connection with participation in the GFCO program, the updated FDA regulation imposes on manufacturers certain requirements and recordkeeping obligations, and it is each manufacturer's sole responsibility to ensure its own compliance with all government regulations.

Background information including summary of FDA ruling

With the October 13, 2020 amendment, the following section of the Register, 21 CFR 101.01(c) now reads:

c. Compliance:

(1) When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect and quantify the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products.

(2) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records regarding the fermented or hydrolyzed food demonstrating adequate assurance that:

(i) The food is "gluten-free" in compliance with paragraph (a)(3) of this section before fermentation or hydrolysis;
(ii) The manufacturer has adequately evaluated their processing for any potential for gluten cross-contact; and
(iii) Where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

(3) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food contains one or more ingredients that are fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records demonstrating adequate assurance that the fermented or hydrolyzed ingredients are "gluten-free" as described in paragraph (c)(2) of this section.

(4) Records necessary to verify compliance with paragraphs (c)(2) and (3) of this section must be retained for at least 2 years after introduction or delivery for introduction of the food into interstate commerce and may be kept as original records, as true copies, or as electronic records. Manufacturers must provide those records to us for examination and copying during an inspection upon request.

(5) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is distilled, FDA will evaluate compliance with paragraph (b) of this section by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the food.

Approach to resolving problem

Given the large percentage of certified Products that were likely to be affected by this new ruling, GFCO took action in September of 2020 to begin requesting documentation for fermented or hydrolyzed ingredients, either demonstrating that these ingredients did not contain any wheat, rye or barley components prior to fermentation/hydrolysis, or that any gluten introduced from fermented or hydrolyzed ingredients could not result in a worst-case, calculated gluten level greater than 0.1 ppm in the finished Product. This latter allowance was based on an interpretation statement in the Federal Register announcement of the final rule, discussing the potential exemption of enzymes from the ruling due to the fact that they are typically used in very small quantities. The response to the request for exemption included the statement that "An important consideration is the amount of potential carryover and how much of the enzyme ingredient is used in the production of the final food product". Upon further review of the impact of this ruling on manufacturers and the gluten-free community, GFCO has decided to adopt a stance which can be applied to gluten-free products in every country.

GIG/GFCO position statement (Standard if applicable)

When a Product, ingredient or ingredient component is fermented or hydrolyzed, the Product manufacturer must maintain documentation (and if requested, must provide GFCO with copies of such documentation upon request) that the Product, ingredient or ingredient component, as applicable, did not contain proteins from wheat, rye, barley or oats, and that steps were taken to prevent cross-contact with these grains, prior to fermentation or hydrolysis. If a product, ingredient or ingredient component contains proteins from wheat, rye, barley or oats prior to hydrolysis or fermentation, it may be documented that the material was processed to remove the proteins/gluten and met the definition of Gluten-Free prior to fermentation or hydrolysis. Otherwise, the fermented or hydrolyzed material cannot be, or be used in, a GFCO certified Product.

GFCO may request documentation from clients or their suppliers at any time related to fermented and/or hydrolyzed ingredients, ingredient components, or products. The role of GFCO in reviewing these documents is solely to confirm whether the products, ingredients and/or ingredient components are in compliance with GFCO's requirements for the use of hydrolysis and fermentation, and while GFCO will inform manufacturers of any issues discovered or corrective actions needed, GFCO is unable to determine and makes no representations or guarantees as to whether a manufacturer is in compliance with the FDA regulation.

How and when GFCO will implement our position

Beginning April 1, 2023, GFCO may request documentation from clients or their suppliers for cultures, enzymes, yeast, probiotics and other fermented or hydrolyzed products, ingredients or components, demonstrating that the product, ingredient or ingredient components did not contain proteins from wheat, rye, barley or oats, and that steps were taken to prevent cross-contact with these grains, prior to fermentation or hydrolysis. This requirement will apply to all certified Products no matter the country in which they are sold and/or regulated.

For all Products that had been previously approved under GFCO's previous allowance of up to 0.1 ppm calculated gluten in the finished product, the manufacturer will have until October 1, 2023 to either provide documentation demonstrating compliance with the above or otherwise reformulate away from any fermented or hydrolyzed materials that contained gluten prior to fermentation or hydrolysis.

How companies can meet the position/standard

Companies may meet this requirement by providing documentation to state or demonstrate that all Products, ingredients and ingredient components did not contain proteins from wheat, rye, barley or oats, and that steps were taken to prevent cross-contact with these grains, prior to fermentation or hydrolysis. GFCO has amended our 3070 supplier template to reflect this new wording.

Until such time as either the FDA regulation is amended or there is a method for detecting the level of gluten in fermented or hydrolyzed products or ingredients that is recognized as scientifically valid by the FDA, GFCO can no longer accept or review calculated levels of potential gluten in finished Products as part of the approval of products or ingredients that are fermented or hydrolyzed.

Materials that have been processed to remove protein, such as wheat glucose and wheat dextrose, may be allowed in culture media provided they meet GFCO's definition of Gluten-Free prior to fermentation or hydrolysis.