GFCO Guidance on the FDA Final Rule: Food Labeling; Gluten-Free labeling of Fermented or Hydrolyzed Foods

On August 13, 2020, the FDA released its Final Rule on gluten-free labeling of products that are fermented or hydrolyzed. The rule has an effective date of October 13, 2020.

The FDA Final Rule contains two major policies, both of which are in line with GFCO's current requirements for certification. To paraphrase, these two policies are:

1. Any product that is fermented or hydrolyzed must be made from gluten-free starting materials, in order to bear a gluten-free claim, unless point 2 applies.
2. Distillation can be used to remove any residual proteins from a fermented or hydrolyzed liquids made from gluten-containing starting materials.

The FDA is requesting that producers of fermented or hydrolyzed materials, or manufacturers that use them as ingredients, be able to document that the starting materials were gluten free prior to the fermentation/hydrolysis step, or that fermented/hydrolyzed liquid materials were adequately distilled to remove all residual proteins. Additionally, it must be documented that the producer of the fermented/hydrolyzed material is taking appropriate steps to prevent the introduction of gluten during the manufacturing process.

In the Comments section, the FDA clarifies that "the final rule does not require testing of ingredients", and indicates that they are asking manufacturers to evaluate the starting materials for fermented and hydrolyzed products, and to "adequately evaluate their processing for any potential for gluten cross-contact." GFCO certification of the fermented/hydrolyzed material is one strong piece of evidence that your facility is actively taking steps to prevent gluten cross-contact.

This new FDA ruling requires the collection of additional documentation that is not required under GFCO certification. GFCO is offering the following suggestions for meeting the requirements of the new final rule, that allow companies to use their assigned GFCO ingredient risk factors to guide the type of evidence they collect for each fermented/hydrolyzed ingredient. *GFCO cannot guarantee that these suggestions will meet all FDA requirements, but you can use them as guidance to begin your document collection.*

A. For fermented or hydrolyzed materials that are NOT made from grains, beans, seeds, pulses or legumes [these would typically be assigned a GFCO risk level of 1 or 2]:

FDA examples in this category would be cheese, yogurt, some vinegars (e.g. apple cider, wine), sauerkraut, pickles (pickled vegetables or fruits), and green olives. GFCO also places wine and cider products into this category, although these are not typically governed by the FDA unless they contain less than 7% alcohol. Yeasts or yeast extracts, bacterial cultures, probiotics and enzymes also fall into this category. Additional examples include fermented milk beverages, fermented fish or fish sauce, kombucha, and fermented meats.

If you manufacture any of these materials:

1. Obtain documents from your raw material suppliers stating that the raw materials are not grown, harvested, transported, stored or processed with, or alongside, gluten-containing grains (wheat, rye or barley). GFCO can provide a template for this purpose. If your supplier cannot confirm these clams, then it may be necessary to request additional documentation or CoAs, or to do your own testing in-house using any GFCO approved test method, to be sure that the starting materials are gluten-free.
2. If spices other than salt are added to any of these products prior to fermentation or hydrolysis, request additional documentation or CoAs from your spice supplier(s), or test the spice blend yourself before using it in production, until you have sufficient evidence to believe they are consistently providing a gluten-free product.
3. Obtain documentation from your culture suppliers to demonstrate that the yeast, bacteria or enzymes used for fermentation or hydrolysis were not grown in media that contained wheat, rye or barley. Some fermented/pickled products rely on airborne bacteria for fermentation, which would naturally be free of gluten – if this is your process, document that you are not using commercial cultures for fermentation.
4. If you are a manufacturer of yeast, yeast extracts, bacterial cultures, probiotics or enzymes, keep records of the ingredients in your culture media, and prepare documents that state that your cultures were grown in media that did not contain a gluten source, or that provide the components in the culture media.
5. Document the steps you take to prevent gluten cross-contact during production – this might include GFCO certification of your products as gluten-free, other third party certifications of gluten control measures, the allowance of audits by your customers, or other documentation of your processes.

If you use any of the materials in this category as ingredients:

Obtain documents or evidence from your suppliers to show that:

1. The raw materials used to make the ingredient were not grown, harvested, transported, stored or processed with, or alongside, gluten-containing grains (wheat, rye or barley). If they cannot make this guarantee, you may want to request additional documentation or CoAs to indicate that the starting materials were gluten-free.
2. Any yeast, bacteria, probiotics or enzymes used in their preparation were not grown in media that contained wheat, rye or barley.
3. The supplier is following all necessary precautions to prevent gluten cross-contact during production. This may be done by requesting a copy of the supplier's GFCO gluten-free certification (or other relevant certification), performing your own audit of the facility, or relying on other documentation from the supplier.

B. <u>For fermented or hydrolyzed materials that are made from grains, beans, seeds, pulses or legumes [these would typically be assigned a GFCO risk level of 3 or 4]:</u>

FDA examples in this category include gluten-free beer, some vinegars, and hydrolyzed plant proteins. GFCO also includes spirits made from grain, and soy sauce in this category. Other examples include fermented bean pastes, fermented grains, and fermented grain beverages.

Materials made from gluten-containing grains that are not distilled after fermentation or hydrolysis cannot make a gluten-free claim. As examples, a soy sauce made using wheat, or an un-distilled malt vinegar, can never bear a gluten-free claim or certification mark.

If you manufacture any of these materials that are <u>not</u> distilled following fermentation/hydrolysis:

1. Obtain documents from your raw material suppliers stating that the raw materials are not grown, harvested, transported, stored or processed with, or alongside, gluten-containing grains (wheat, rye or barley). GFCO can provide a template for this purpose. If your supplier cannot confirm these claims, then it may be necessary to request CoAs to be sure that the starting materials are gluten-free. GFCO recommends the use of visual examination of the intact grains, alongside antibody-based testing methods (ELISA or lateral flow rapid tests) to confirm the gluten-free status.
2. If spices other than salt are added to any of these products prior to fermentation or hydrolysis, request additional documentation or CoAs from your spice supplier(s), or test the spice blend yourself before using it in production, until you have sufficient evidence to believe they are consistently providing a gluten-free product.
3. Obtain documentation from your culture suppliers to demonstrate that the yeast, bacteria or enzymes used for fermentation or hydrolysis were not grown in media that contained wheat, rye or barley. Some fermented/pickled products rely on airborne bacteria for fermentation, which would naturally be free of gluten – if this is your process, document that you are not using commercial cultures for fermentation.
4. Document the steps you take to prevent gluten cross-contact during production – this might include GFCO certification of your products as gluten-free, other third party certifications of gluten control measures, the allowance of audits by your customers, or other documentation of your processes.
5. If your product is not distilled, and you are using testing as a means to verify the effectiveness of your gluten control program either as required by GFCO or your own internal policies, the R-BioPharm RIDASCREEN Gliadin Competitive assay may be used. GFCO recognizes the limitations of this assay, as described in detail in the FDA final rule, and understands that different fermentation and hydrolysis conditions will affect the results. All test methods have limitations, which is why GFCO certification is not based on testing. If you are appropriately controlling gluten in your facility, and vetting your incoming ingredients, then the use of the RIDASCREEN Competitive is an available verification option for fermented and hydrolyzed products, even with its limitations. Testing should never be used in place of other gluten control methods.

If you manufacture materials that are distilled following fermentation/hydrolysis:

1. Perform an analysis of your distillation process to ensure that it is adequately removing all proteins.

As described in the FDA ruling, this should be done using "scientifically valid analytical methods that can reliably detect protein or protein fragments…". The FDA declined to name acceptable methods for protein analysis, and a review of the literature and AOAC Official Methods indicates that there are no current protein methods validated for distillates with a suitable limit of detection. The TTB Official Method for Protein in Low Solids Distilled Spirits (SSD:TM:506) describes a Kjeldahl analysis method with a protein quantitation limit of 88 parts per million (ppm), which is higher than the FDA gluten threshold of 20 ppm, and higher than the GFCO threshold of 10 ppm for gluten.

The European Food Safety Authority's 2007 opinion on allergen safety in distilled spirits describes protein analyses done using the Bradford Microassay, and amino acid analysis (AAA). Both of these methods have limits of detection that are below the FDA and GFCO gluten thresholds. The Bradford assay has two known limitations for the current purpose: it is not efficient at detecting small protein fragments, and ethanol interferes with detection, requiring an additional step to dry the solids from the distillate and rehydrate them in water prior to analysis. Therefore, GFCO recommends the use of amino acid analysis for total protein determination in distilled spirits. This method is performed by several commercial laboratories – please contact laura.allred@gluten.org for a list of some of the available labs.

At this time, GFCO's recommendation is to use amino acid analysis to validate the performance of your normal distillation process, not to test every lot of product. Distillation is commonly known to remove residual proteins to a level well below the thresholds for gluten-free labeling, so GFCO recommends a single test to confirm that your distillation process is effective. Testing should be repeated if anything changes with your distillation equipment or process.

If you use any of the materials in this category as ingredients:

Obtain documents or evidence from your suppliers to show that:

1. Their distillation process was effective at removing residual proteins, to a level below the GFCO or FDA threshold (for ingredients that are distilled after fermentation).
2. The raw materials used to make any un-distilled ingredient in this category were not grown, harvested, transported, stored or processed with, or alongside, gluten-containing grains (wheat, rye or barley). If they cannot make this guarantee, request additional documentation or CoAs to indicate that the starting materials were gluten-free. Submitting this type of documentation to GFCO will allow for the risk factor of that ingredient to be reduced, potentially removing your testing requirement for that ingredient.
3. Any yeast, bacteria, probiotics or enzymes used in the preparation of any un-distilled ingredient in this category were not grown in media that contained wheat, rye or barley.
4. The supplier is following all necessary precautions to prevent gluten cross-contact during production. This may be done by requesting a copy of the supplier's GFCO gluten-free

certification (or other relevant certification), performing your own audit of the facility, or relying on other documentation from the supplier.

While this new FDA rule includes some additional documentation requirements, it does not result in any changes to the requirements or allowances for GFCO certification. GFCO will be updating its Scheme Manual in the coming months to address this guidance.