ENZYME TECHNICAL ASSOCIATION™

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ETA Position
On
Microbially Derived Enzymes Used as Food Processing Aids and Food Allergen Labeling Under FALCPA as it Applies to Fermentation Media Raw Materials[1]

Microbially derived enzymes themselves do not fit within the requirements of FALCPA because enzymes are not one of the eight major allergenic foods, often referred to as the Big 8. In addition, microbial enzymes are neither byproducts of nor are they derived from the major food allergens. Most commercial food enzymes are produced by fermentation using selected microorganisms. Most importantly, food enzymes are predominately used as processing aids in the production of food ingredients or final foods.

The enzymes are not derived from raw materials containing major food allergens but rather are produced by the microorganisms. While enzymes produced by microbial fermentation use media that may include protein from one or more of the major food allergens, these proteins and other nitrogenous material are consumed by the microorganisms for cell growth, cell maintenance, and production of enzyme protein. It is the intent of the enzyme manufacturer to supply enzymes; therefore, it is critical that the ratio of nutrient to enzyme yield is carefully controlled. It is also the intentof the manufacturer that these raw materials are added to the fermentation as food to be consumedby the microorganism. Further, down-stream processing typically includes filtration and purification steps enabling the further removal of any residual nutrients. Thus, the final food enzymes typically will not contain residual amounts of the media used during fermentation.

Even though microbially derived enzymes do not fit within the requirements of FALCPA, are neither byproducts of nor are they derived from the major food allergens, and are predominately used as a processing aids in the production of food ingredients or final foods, it is the responsibility of the food enzyme manufacturer to conduct a risk assessment regarding raw materials from food allergenic sources used in fermentation and to comply with labelling provisions for food enzyme preparations.

For consideration in the risk assessment process, ETA suggests the following:

The risk assessment should follow the weight-of-evidence approach and the following should be considered:

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[1] This ETA position statement only pertains to IgE mediated food allergy responses subject to labeling requirements under FALCPA (e.g., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans). The FDA final ruling on Gluten-Free Labeling of Fermented or Hydrolyzed Foods (21 CFR Part101.91) is out of the scope of this document as it concerns a non-IgE related food allergy response specificto gluten, which presents a different immune response.

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(1) Enzymes themselves are not one of the eight named proteins.

(2) Enzymes are not derived from any of these eight named proteins.

(3) Microbially derived enzyme preparations either do not contain or contain only negligible amounts of a major food allergenic protein.

(4) The separation and/or purification process substantially removes non-enzyme substances, including materials used in the fermentation process.

(5) The quantity of enzyme use in food processing is extremely low.

(6) ETA conducted a review of the published scientific literature and found no reports that suggest there has been an allergenic reaction to a component of the fermentation media used to feed the microorganism that produced the enzyme.