



15 December 2005

ATTN: REGULATORY AFFAIRS / QC
UNIVAR USA, INC.
PO BOX 34325
SEATTLE, WA 98124

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REGULATORY AFFAIRS

Dear Valued Customer:

As you may know, the regulatory requirements surrounding use and labeling of allergenic ingredients in food have changed recently in the United States. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires that foods containing eggs, fish, milk, peanuts, soybeans, tree nuts, or wheat be labeled accordingly as of January 1, 2006.

Most enzymes provided by BIO-CAT, Inc. are fermentation products. The fermentation process by which enzymes are manufactured requires various protein and carbohydrate nutrient sources for the production organism, some of which may be derived from the allergens subject to FALCPA labeling. These nutrients are, however, theoretically used up by the production organism during fermentation and testing of various finished enzyme products for allergens has routinely indicated that the allergenic materials are not present in the enzyme product at detectable limits.

Based on similar information and on recent decisions in the European Union and Japan that allergen labeling of fermentation ingredients is not required for enzyme preparations, the Enzyme Technical Association (ETA, a trade association comprised of enzyme suppliers in North America) has issued a position paper that similarly concludes that allergens utilized in the fermentation step of enzyme production do not require labeling under FALCPA. In keeping with the position of the ETA, **BIO-CAT will not include allergen information pertaining to fermentation raw materials on the labels of our enzyme preparations.**

A copy of the ETA's position paper is attached for your convenience. Please be aware that allergen statements issued by BIO-CAT prior to the date on this letter **did** include fermentation allergens and those statements may be outdated and not match the allergen labels placed on our products after January 1, 2006. We urge our customers to use the allergens listed on the labels of our enzyme preparations when making allergen labels for products that contain our enzymes.

Please feel free to contact us if you have any questions regarding our allergen labeling policy.

Regards,

Kristie Bowman-Jackson
Chief Chemist

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POSITION PAPER

ETA Position On Food Allergen Labeling of Microbially Derived Enzymes Under FALCPA as it Applies to Fermentation Media Raw Materials

It is the position of the Enzyme Technical Association (ETA) that microbially derived enzymes do not fall within the scope of the Food Allergy Labeling and Consumer Protection Act (FALCPA) and that labeling for food allergens is not triggered by the use of a microbially derived enzyme preparation. There may be other reasons why a manufacturer labels a food product with regard to allergen content, but the use of a microbially derived enzyme preparation is not a reason for such labeling.

Enzymes are not one of the eight major allergenic foods, often referred to as the big 8, so they do not fit within the first requirement of FALCPA. In addition, microbial enzymes are not byproducts of nor are they derived from the major food allergens. Although enzymes are not major food allergens,¹ many enzymes are produced with microorganisms and the nutrient media used to feed these microorganisms may contain protein from one or more of the major food allergens. The enzymes are not derived from raw materials containing major food allergens, but rather are obtained from the microorganisms which are used to produce the enzyme proteins. In other words, enzymes obtained from fermentation are directly derived from microorganisms fed on media that may include protein obtained from one or more of the major food allergens. 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 intent of the manufacturer that these raw materials are added to the fermentation as food to be consumed by the microorganism and are not added as formulation ingredients.

In arriving at its position ETA also considered that:

- The regulatory agencies in the EU and Japan have determined that enzyme preparations are not required to have allergen labeling for the raw materials used in the fermentation process. Indeed, the European Commission's Health & Consumer Protection Directorate General has clearly stated that enzymes

¹ To the extent the enzyme producer uses an allergenic material, such as wheat flour diluent in the final product formulation, labeling may be required.

are outside the scope of the Directive 2003/89/EC which amended the EU Food Labelling Regulations.

- Enzyme broths are normally processed to separate biomass and fermentation materials from the enzyme, to concentrate the enzymatic activity, and formulated to achieve a uniform and stable enzyme product.
- The unique role of enzymes in food processing is as a catalyst. Due to the specific nature of enzymes, only small amounts are required to make desired modifications to the property of a food.
- Many enzymes do not become a component of the food ingredient or final food. Some enzymes are used in an immobilized form or are denatured during processing. Further, processing of the food ingredient after the enzyme catalyst has performed the expected function often reduces or eliminates the enzyme from the product.
- ETA has made an extensive review of the published scientific literature and has found no reports that even suggest there has been an allergenic reaction to a component of the fermentation media which was used to feed the microorganism that produced the enzyme.

The above position paper and accompanying report were provided to FDA on September 12, 2005 and to date ETA has received no comment.