ENZYME TECHNICAL ASSOCIATION™

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www.enzymetechnicalassociation.org

MEMBERSHIP BENEFITS

The enzyme industry is extensively regulated at the state, national, and international levels. At the federal level alone, the U.S. Food and Drug Administration ("FDA"), the Environmental Protection Agency ("EPA"), the U.S. Department of Agriculture ("USDA"), and the Occupational Safety and Health Administration ("OSHA") are just a few of the agencies that are developing policies that will have a significant impact on the enzyme industry and those who sell enzymes as components of their products.

It is therefore vitally important that the enzyme industry have a collective voice, such as the Enzyme Technical Association ("ETA"), to assure the proper development of these regulations and policies. ETA is a non-profit trade association that monitors the activities of the regulatory agencies and actively participates in the development of regulations and policies that affect the enzyme industry. ETA membership is open to North, Central, or South American manufacturers, distributors, and importers of enzyme preparations from any plant, animal, or microbial source.

ETA was formed in 1970, as the Ad Hoc Enzyme Technical Committee ("AHETC"), by concerned manufacturers interested in assisting the FDA in the promulgation of enzyme preparation regulations. In 1985, it reorganized and formed the Enzyme Technical Association.

ETA has taken an active role in the development of regulations that affect you. For example:

- ETA has developed a positive rapport with FDA and continues to work closely with the agency as it develops its Generally Recognized as Safe ("GRAS") criteria and regulations.

- ETA negotiated directly with senior officials at FDA to contain the scope and scale of product recovery during the chloramphenicol contamination, and coordinated industry and media contacts and communication, resulting in limited exposure for the industry.

- ETA has been involved over the years in the publication of documents that outline the requirements for safety testing of enzyme preparations. In 1983, Drs. Pariza and Foster of the Food Research Institute of the University of Wisconsin were commissioned by ETA to author a safety paper that has remained the standard of the industry (Pariza, M.W. and Foster, E.M., Determining the Safety of Enzymes Used in Food Processing, Journal of Food Protection, 46(5): 453-468, 1983). ETA later worked with the International Food Biotechnology Council ("IFBC") in the preparation of a second paper that updated the Pariza and Foster paper to include the safety evaluation of enzymes from genetically modified sources (IFBC, Safety Evaluation of Foods and Food Ingredients Derived from Microorganisms, Regulatory Toxicology and Pharmacology, 12(3): S114-S128, 1990). A third paper providing an update to include new concepts, such as safe strain lineage and site specific mutagenesis, was commissioned by ETA and published in 2001 (Pariza, M.W., and Johnson, E.A., Evaluating the Safety of Microbial Enzyme Preparations Used in Food Processing: Update for a New Century,

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Regulatory Toxicology and Pharmacology 33:173-186, 2001). More recently, a paper to provide guidance for evaluating the safety of enzyme preparations used in animal feeds was commissioned and published in 2010. (Pariza, M.W. and Cook, M., Determining the Safety of Enzymes Used in Animal Feed, Regulatory Toxicology and Pharmacology, 56: 332-342, 2010.)

- ETA has formed multi-trade group coalitions with related industry organizations including IFAC, FEMA, GMA, and CRN.

- ETA published a dietary supplement Best Practices Guide, co-sponsored and endorsed by CRN. The document has gained industry wide support.

- ETA prepared the original specifications of enzyme preparations for the first edition of the Food Chemicals Codex and the enzyme preparation monograph for the fourth edition. The organization continues to work closely with the NAS/NRC as the Food Chemicals Codex is updated.

- ETA is actively cooperating with the Food Chemicals Codex on developing methodologies for enzyme assays.

- ETA has prepared guidelines for the use of enzymes in dietary supplements. ETA is also working closely with the American Cleaning Institute ("ACI") to develop recommended safety testing procedures for consumer products that will contain enzymes.

- As members of the Enzyme and Microbial Task Force, ETA has played a major role in the listing of feed enzymes in the AAFCO manual.

- At the request of the National Institute of Occupational Safety and Health ("NIOSH") of the Centers for Disease Control, ETA participated with NIOSH in a study of various enzyme manufacturer processes in anticipation of needs which may arise in facilities which manufacture enzymes from genetically modified microorganisms.

- ETA developed an industry-wide approach to complying with the requirements of the Hazard Communications Policy of OSHA.

- ETA actively cooperated with the EPA on the listing of enzymes on the TSCA inventory and the development of exemptions and/or expedited review for certain low risk recombinant microorganisms used to produce enzymes.

- ETA has also been active at the international level. The Association has supplied information to the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") and has established liaisons with similar organizations in Europe. ETA supplied JECFA with a complete listing of all enzyme preparations used in the United States as processing

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aids. This listing identifies the enzyme preparations that should be reviewed by JECFA when it undertakes its review of enzyme preparations.

- ETA keeps current on European activities regarding enzyme preparations and promotes international cooperation in the enzyme industry through its contacts with the European trade association, the Association of Manufacturers and Formulators of Enzyme Products ("Amfep").

- ETA successfully petitioned the Environmental Protection Agency to publish a proposed rule to add *T. reesei* to its list of microorganisms eligible for exemption, the first new microorganism to be added in more than a decade.

Recently, ETA has stepped up its interaction with the FDA and is urging the agency to streamline its procedures for the review of enzyme preparations from traditional and genetically modified sources. For the past several years, the ETA has made comments to the FDA in response to the agency's request for priority setting initiatives, stressing the need for FDA to finalize the GRAS Notification regulations.

ETA intends to continue its active participation in all matters relating to the enzyme industry. More importantly, ETA keeps its members informed and up-to-date on regulatory issues of concern and interest.

As a member, you can influence the areas of activity of the ETA. We have enclosed an ETA membership application for your consideration. Full membership allows your company to designate an individual to be a member of the Board and to actively participate in the development and implementation of the ETA strategies designed to affect regulatory policy at the international, national, and state levels. (Other members of your company are welcome to participate in the Board and Committee activities but would not have a vote.) Associate membership affords your company all the benefits of a Full membership except that an Associate member's representative could not hold the position of Chair or President of the Board.

We would be happy to process your application or answer any questions you may have. You can reach us at (202) 719-4585.