ENZYME TECHNICAL ASSOCIATION

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January 7, 2016

Non-GMO Project
1155 N State Street, Suite #502
Bellingham, WA 98225

Re: Non-GMO Project Call for Comments on Proposed Changes to Non-GMO Project Standard

Dear Sir or Madam:

The Enzyme Technical Association ("ETA") is a trade association that represents manufacturers and marketers of enzyme products in North America, including the United States, Canada and Mexico. It has been in existence since 1970 and maintains an active role in assisting in the development of regulations and policies that affect the enzyme industry. Its membership represents the majority of the North American enzyme product industry.

ETA appreciates the opportunity to submit the following comments to the Non-GMO Project ("NGP") in connection with the notice soliciting comments on proposed changes to the NGP Standard ("The Standard" or "Standard"). Among other things, the NGP has requested information as it concerns enzymes derived from genetically engineered (GE) microbes, plants, or animals; specifically, regarding whether there is particular concern about enzymes derived from genetically-engineered (GE) microbes, and inputs using what the NGP refers to as "GE Enzymes." While ETA appreciates the NGP mission to inform the public, ETA respectfully disagrees with current NGP policies which negatively focus attention on enzyme source organisms, and which inaccurately assert that enzymes can be genetically modified organisms (GMO).

The public deserves transparency about what is in the products that they choose to purchase. To that end, ETA is pleased to provide the NGP with background scientific information about enzymes in order to assist the NGP in better understanding the need to revise the NGP Standard. Enzymes, whether sourced from GE organisms or non-GE organisms, are not genetically modified organisms (GMO). Thus, they should be treated similarly to any other microingredient as defined in The Standards, such that they are exempt when the input is lower than the 0.5% threshold. Indeed, when used as processing aids, enzyme inputs are below the 0.5% threshold. ETA is hopeful that the discussion below will further clarify why enzymes should be treated similar to any other microingredients that meet the NGP exemption for labeling, and would appreciate the opportunity to meet with the NGP to answer any questions it may have following its review of this submission.

Enzymes Structure and Activity

Enzymes are specialized proteins that act as catalysts. They are found in nature and are used in many applications including the production of breads and baked goods, pet products, laundry detergent and many other consumer products. They are produced by all living cells and perform fundamental biochemical reactions required to support life. Just like any other protein, enzymes are made up of amino acids. The amino acids link together in a long chain, which is folded up into a complex structure. There are thousands of different enzymes found in nature. Enzymes work best under certain optimal conditions. They require specific temperature, pH and available substrate. Enzymes are susceptible to high temperatures and can be denatured (unfold or broken down into smaller amino acids or chains of amino acids) when subjected to heat processing.

Enzymes serve a wide variety of functions such as the ripening of fruits to breaking down food in the stomachs of humans and other animals. Enzymes are present in nearly all foods consumed by humans including fresh fruits and vegetables, meat, grains and processed foods. Enzyme products have been used in foods, such as cheese, for many years and thus have a very long history of safe use. It is well

documented that the use of enzymes continues to offer critical benefits, such as reduced use of raw materials, water and energy, which results in less waste, improved economy for manufacturers, and the provision of healthful food at affordable cost to consumers, and with reduced environmental impact.

Enzymes are not GMO

ETA is concerned that the NGP Standard does not accurately reflect the scientific nature of enzymes. As noted above, enzymes are proteins. As such, they are not organisms, and thus, by their very nature, they cannot be GMO. Moreover, because formulated enzyme preparations do not contain the production microorganism, they do not contain any GMO. In addition, final enzyme preparations do not contain DNA from the production microorganism, This is a requirement for enzyme products sold in the European Union (EU) under the new Food Improvement Agents Package (FIAP) regulation, and has become the global technology standard for enzymes.[1]

Enzyme Production Process

Commercial microbial enzymes are produced from a contained fermentation process of specially selected nonpathogenic, nontoxigenic strains of microorganisms. A very small number of industrial enzymes are derived from plant or animal sources. The enzyme protein is separated from the spent production biomass which includes the production microorganism and residual ingredients from the fermentation media. Thus, DNA from the production organism is not present in the finished enzyme product.

More and more commercial enzymes are being produced by genetically modified microorganisms, although not every available enzyme comes from a genetically

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[1] *Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and the Council on genetically food an d feed*, at 23, COM (2006) 626 final (Oct. 25, 2006) http://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2006/0626/COM_COM(2006)0626_EN.pdf (opposing the GM labeling of products that use GMO during the production process but that are not present in the final product); see also Standing Committee on the Food Chain and Animal Health (EC), *Section on the Genetically Modified Food and Feed and Environmental Risk*, Summary Record of the 3rd Meeting, http://ec.europa.eu/food/plant/standing_committees/sc_modif_genet/docs/summary03_en.pdf. (Sept. 24, 2004).

modified microorganism. However, because, as noted above, the production organisms are physically removed upon conclusion of the fermentation process along with the spent biomass, it would be inaccurate to believe that there is a difference in the enzyme product based solely on the genetic history of the production microorganism. It is important to use genetic modification techniques to enable production of enzymes (not all microorganisms can be cultivated under industrial conditions) and reduce the cost of enzyme production; thereby reducing the cost of food or other consumer products for all consumers. Many enzymes have no economically feasible alternative without the use of genetic modification in the production organism development.

Enzymes Should Qualify for the NGP Standard Microingredient Exemption

Enzymes meet the requirements outlined in the Standard for exemption as microingredients. Enzyme preparations are used in food processing at very low levels, typically below 0.5%. There is little difference between the production of enzymes and the production of many other microingredients that are allowed by the Non-GMO Project Standard.

Enzymes Should Not Be a Prohibited Input in NGP Verified Products

Question six on NGP's public comment form seems to suggest an approach that would "prohibit" use of enzymes as an input in NGP Verification. This approach appears to be based upon the inaccurate concern that enzymes are GMOs or contain DNA. As explained, enzymes are proteins and do not contain genetic material. Thus, neither the science nor NGP's own exemption criteria suggest the need for such a prohibition.

Prohibiting enzymes in the NGP Standard would not benefit consumers who are seeking use of Non-GMO products because, in the absence of enzymes, food and consumer product production costs would increase dramatically by increasing use of water and other raw materials, and by decreasing yields of final commercial products. Enzymes are key to green chemistry processes[2], and thus, prohibiting any enzyme,

[2] Kenthorai R. Jegannathan and Per H. Nielsen (2013), *Environmental assessment of enzyme use in industrial production – a literature review*, Journal of Cleaner Production 42, 228-240; see also Per H. Nielsen, Karen M.

regardless of the source, would be a major detriment to the food industry, as well as textile manufacturers, pulp and paper producers, and detergent manufacturers. Prohibiting enzymes would reduce the sustainability of the food supply by increasing waste, and potentially exposing employees and the environment to more harmful chemicals. Further, there will be many instances in which there will be no commercially available enzyme product that will meet the NGP Standard and there could be no technically feasible non-enzyme solution.

As a result of the impact of such a prohibition, we believe it will be very difficult for food manufacturers to meet the NGP Standard as written.

Closing Remarks

In closing, the ETA requests that the NGP reconsider its current treatment of enzymes, and that it adopt a uniform treatment of such products that is consistent with other inputs made in a similar way. To that end, ETA requests the following:

1) Enzymes should be included in the microingredient exemption where they meet the established 0.5% threshold. As previously noted, enzyme inputs generally are below this threshold.
2) The 0.5% threshold should not be eliminated in the future.
3) The NGP should assure a consistent and scientifically-based approach in its review of enzyme inputs. ETA understands that there have been cases where even those enzymes produced by non-GM production strains have not been accepted.

In light of ETA's commitment to assuring that consumers have the opportunity to make informed choices on whether to consume GE organisms, it is critical that the NGP Standard reflect a system based upon sound science. ETA would be pleased to meet

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Oxenbøll, and Henrik, Wenzel (2007): *Cradle-to-Gate Environmental Assessment of Enzyme Products Produced Industrially in Denmark by Novozymes A/S*, Int J LCA 12(6), 432-438.

with the NGP to further detail the science of enzymes and enzyme production. ETA is confident that when the NGP has a better understanding of these matters, it will agree that revision of The Standard as recommended by ETA is appropriate.

We thank you for your time and consideration and look forward to your response.

Sincerely,

Ann M. Begley
Secretary & General Counsel
Enzyme Technical Association

Cc: John Sedivy
Chair, Enzyme Technical Association

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