

May 5, 2008

Stephen F. Sundlof, DVM, Ph.D.
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W Wiley Building
5100 Paint Branch Parkway
College Park MD 20740

Re: Use of the Term “Natural” with Products of Enzymes Using Synthetic Fixing Agents

Dear Dr. Sundlof:

We are writing on behalf of our client, the Enzyme Technical Association (“ETA”). We submit these comments to respectfully request restatement or clarification of statements made via email by Geraldine June, Supervisor of the Product Evaluation and Labeling team at FDA’s Office of Nutrition Labeling and Dietary Supplements. Specifically, Ms. June’s email was in response to an inquiry submitted by Food Navigator–USA.com regarding the use of the term “natural” with High Fructose Corn Syrup (“HFCS”). In Ms. June’s response to this inquiry, she stated that “the use of synthetic fixing agents in the enzyme preparation . . . would not be consistent with [FDA’s] policy regarding the use of the term ‘natural.’” We strongly disagree with this statement and respectfully request an immediate restatement and clarification by FDA.

Immobilized Enzymes

As FDA is aware, the use of immobilized enzymes does not alter in any fundamental way the natural catalytic function of the enzymes. In other words, immobilizing the enzymes (i.e., holding the enzyme in place with a fixing agent, similar to glue) does not affect the primary natural catalytic function of the enzymes.

The purpose of immobilizing the enzyme is to facilitate continued use of the enzyme for an extended period of time reducing the quantity of enzymes needed overall. Immobilized enzymes are fixed in place, and the substrate is poured through or over the immobilized enzymes. The product is then gathered from the immobilized enzymes, and the enzymes can be used again.

Accordingly, similar to the production of natural flavors by enzymatic protein hydrolysis (see 21 C.F.R. § 101.22(a)(3)) or the use of an alpha amylase enzyme to convert long chain carbohydrates into short chain carbohydrates, there is no difference in production other than the amount of enzyme needed in the production when using an immobilized enzyme versus a traditional enzyme mixture added to a substrate.

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“Synthetic” Fixing Agents

Ms. June specifically commented on the use of synthetic fixing agents as inconsistent with use of the term “natural.” ETA fundamentally disagrees with this assertion. For comparison, this is the equivalent of stating that a product is not natural because the mechanical tools used to stir a mixture are held in place with a synthetic material or that all natural products sold in plastic containers would not be considered natural because small amounts of the plasticizer are known to leach from the containers.

As FDA is aware, and we will be happy to provide data to demonstrate, there are virtually no residues of the fixing agents in the product yielded by immobilized enzyme processing of HFCS (“The manufacturing data indicate that the use of immobilized enzyme preparations results in virtually nil levels of enzymatic processing materials entering the final food product” 48 Fed. Reg. 5716, 5718 (February 8, 1983)). The fixing agent’s sole purpose is literally to “fix,” or glue, the enzyme in place so that a greater amount of the material may be processed by the enzyme.

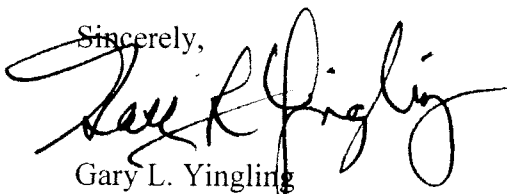
FDA’s Longstanding Natural Policy

ETA understands that FDA has a longstanding policy regarding the use of the term “natural,” that is, that a “natural” product is one that does not have any artificial or synthetic substance added to the product that would not normally be expected to be in the food. Using enzymes, immobilized by synthetic fixing agents, to process HFCS does not add any artificial or synthetic substance to the product. Indeed, the enzymes are used in the processing of HFCS to speed up the natural breakdown of corn starch into glucose and the natural conversion of glucose to fructose. Both of these events (breakdown of corn starch into glucose and conversion of glucose to fructose) occur naturally in the environment with and without enzymes.

Conclusions

The use of synthetic fixing agents to immobilize enzymes does not add any artificial or synthetic substance to a product. Enzymes act in nature to catalyze the natural breakdown of corn starch into glucose and convert glucose to fructose. Therefore, the use of immobilized enzymes (with synthetic fixing agents) in the processing of HFCS does not defeat the use of “natural” in the finished HFCS product. We respectfully request that FDA correct or clarify its statement in this regard.

Sincerely,



Gary L. Yingling

Counsel to the Enzyme Technical Association

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cc: Barbara O. Schneenman, Ph.D.,
Director, Office of Nutrition Labeling and Dietary Supplements

Geraldine June
Supervisor of the Product Evaluation and Labeling, Office of Nutrition Labeling and
Dietary Supplements