



JUN 24 2008

Gary L. Yingling, Esquire
Counsel to the Enzyme
Technical Association
Kirkpatrick & Lockhart Preston
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1601 K Street, NW
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Dear Mr. Yingling:

This is in response to your letter dated, May 5, 2008, to the Food and Drug Administration (FDA) regarding high fructose corn syrup (HFCS). You requested a restatement and clarification of our statement 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.’ ”

When we received an inquiry from Food Navigator-USA.com asking us whether a “natural” claim on a product containing HFCS and natural ingredients would be misleading to consumers, we reviewed our policy on the use of the term “natural” and our regulations on HFCS. In our response we stated that our long-standing policy on the use of the term “natural” is that “natural” means that nothing artificial (including artificial flavors) or synthetic (including all color additives regardless of source) has been included in or has been added to a food that would not normally be expected to be in the food. Additionally, we do not restrict the use of the term “natural” except on products that contain added color, synthetic substances and flavors as provided for in Title 21 of the Code of Federal Regulations (CFR), section 101.22. We also responded by indicating that:

- Title 21 of the CFR, section 184.1866 states that HFCS is prepared from a high dextrose equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation listed at 21 CFR 184.1372;
- Per 184.1372, the glucose isomerase enzyme preparation is fixed (rendered insoluble) using safe and suitable immobilization/fixing agents, including those listed in 21 CFR 173.357;
- The use of synthetic fixing agents in the enzyme preparation, which is then used to produce HFCS, would not be consistent with our policy on the use of the term “natural;”

- We would object to the use of the term “natural” on a product containing HFCS;
- The corn starch hydrolysate, which is the substrate used in the production of HFCS, may be obtained through the use of safe and suitable acids or enzymes; and
- Depending on the type of acid(s) used to obtain the corn starch hydrolysate, this substrate itself may not fit within the description of “natural” and, therefore, HFCS produced from such corn starch hydrolysate would not qualify for a “natural” labeling term.

Your letter states that the purpose of immobilizing the enzyme is to facilitate continued use of the enzyme, and that after the immobilized enzymes are fixed in place, the substrate is poured over the immobilized enzymes and then the product is gathered from the immobilized enzymes.

Subsequent to our response to Food Navigator-USA.com, we obtained additional information on the production of HFCS. After reviewing the additional information about the production of HFCS, it is our understanding that the enzyme used to make HFCS is fixed to a column by the use of the synthetic fixing agent, glutaraldehyde. Any unreacted glutaraldehyde is removed by washing the column prior to the addition of the high dextrose equivalent corn starch hydrolysate, which undergoes enzymatic reaction to produce HFCS. Because the glutaraldehyde does not come into contact with the high dextrose equivalent corn starch hydrolysate, it would not be considered to be included or added to the HFCS. Therefore, we would not object to the use of the term “natural” on a product containing the HFCS produced by this manufacturing process. You should know, however, that we would object to the use of the term “natural” on a product containing HFCS that has a synthetic substance such as a synthetic fixing agent included in or added to it. We would also object to the use of the term “natural” on a product containing HFCS if the acids used to obtain the starch hydrolysate do not fit within our policy on “natural” as stated above.

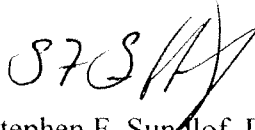
Consistent with our policy on the use of the term “natural,” we have stated in the past that the determination on whether an ingredient would qualify for the use of the term “natural” is done on a case-by-case basis.

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Further, ingredients with the same common or usual name may be formulated in different ways, where a food containing the ingredient formulated one way may qualify for the use of the term "natural" and another food containing the ingredient with the same common or usual name, which has been formulated in a different way may not be eligible for the use of the term "natural."

If we may be of further assistance, please let us know.

Sincerely yours,

A handwritten signature in black ink, appearing to read "SFS", written over a horizontal line.

Stephen F. Sundlof, D.V.M., Ph.D.
Director
Center for Food Safety
and Applied Nutrition