



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 03 2008

Audrae Erickson
President
Corn Refiners Association
1701 Pennsylvania Avenue, N.W.
Suite 950
Washington, DC 20006-5805

Dear Ms. Erickson:

This is in follow up to the meeting of April 16, 2008, between the Corn Refiners Association and the Center for Food Safety and Applied Nutrition (CFSAN). The meeting was prompted by a Food Navigator-USA.com article on the use of the term "natural" on products containing high fructose corn syrup (HFCS). You asked CFSAN to reconsider its position on whether the use of the term "natural" can be used to describe products containing HFCS.

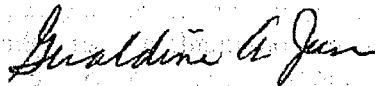
At the meeting Mr. Empie of Archer Daniels Midland Company described the manufacturing process used to make HFCS and following the meeting you sent CFSAN a written description of this production process. During the meeting, we stated that our longstanding policy on the use of the term "natural" is that "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 stated that 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. After reviewing the information about the HFCS production process that you provided, 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 in 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 the manufacturing process described by Mr. Empie. However, 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.

Page 2-Audre Ericson

For your information, 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 our longstanding policy on the use of the term natural that we described above. We also described our regulation on HFCS (Title 21 of the Code of Federal Regulation (CFR), section 184.1866), which states that it 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. We indicated that, 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. We stated that 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." Consequently, we said that we would object to the use of the term "natural" on a product containing HFCS. In addition, we stated that 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. 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, we stated that HFCS produced from such corn starch hydrolysate would not qualify for a "natural" labeling term. Subsequently, we learned that in the process described by Mr. Empie none of the fixing agent (glutaraldehyde) would come in contact with the high dextrose equivalent corn starch hydrolysate. 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. 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 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,



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