



North American Millers' Association

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March 26, 2001

Ms. Lauren M. Posnick
Center for Food Safety and Applied Nutrition (HFS-306)
Food and Drug Administration,
200 C St. SW.
Washington, DC 20204, 202-205-5321

Rec'd 5/4/01
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Docket No. 01D-0025

Dear Ms. Posnick:

This letter is in response to the document "Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues" published in the *Federal Register* of January 22, 2001.

The North American Millers' Association (NAMA) represents the corn, wheat, oat and rye milling industry. Of NAMA's 45 member companies, 24 companies are engaged in corn dry milling at 30 mills in 15 states. Our members represent more than 85% of the total U.S. capacity for corn dry milling. Corn dry millers use approximately 165 million bushels of yellow and white corn annually.

The milling industry has been at the forefront of all monitoring and testing initiatives for Cry9C protein since the fall of 2000. Corn millers have spent massive amounts of resources to reassure consumers of their continuing commitment to providing corn-based food products that are safe and wholesome. **Millers have adopted a regimen of collecting and testing yellow corn as recommended in the agency's guidance document and detailed further below.**

We recommend that the guidance document be updated to provide for a semiannual review of the situation to determine the need for continued sampling and testing. Since the registration of StarLink corn has been withdrawn, it is expected that the Cry9C protein found in StarLink corn will disappear from the corn supply at some time in the future as it works its way through the distribution system. We believe the requirement for a semiannual review will enable FDA to assess the presence or non-presence of Cry9C in the corn supply. If the Cry9C protein is no longer being detected, the agency should issue a notice withdrawing its guidance for industry for sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues. Without such a statement by FDA, the milling industry will be left in the position of needlessly spending time and money for a problem that no longer exists.

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By way of background, in October 2000, in the absence of regulatory guidance on how to deal with the StarLink problem, NAMA developed voluntary guidelines for minimum testing of in-bound corn. As soon as a test for Cry9C became available, NAMA developed, and the membership adopted, a regimen that included, for each truck, testing two subsamples of 400 kernels each. When both subsamples test negative under this regimen, it results in a 99% confidence that the level of Cry9C protein is 0.58% or less.

Our millers followed this regimen to test corn being delivered from growers as well as raw corn already at their facilities. Such stored corn was typically tested as it was moved from one bin to another. In some cases mills temporarily suspended production until testing was completed. Further, in some cases millers tested at levels even more strenuous than the recommended 2 tests per 400 kernel sample.

With the issuance of FDA's guidance for sampling and testing of December 27, 2000 and final guidance of January 19, 2001; NAMA updated its voluntary guidance document to reflect the FDA recommendations. Millers have now adopted a regimen of collecting and testing 2400 kernels for each vehicle or carrier with the number of subsamples determined by the detection level for which the test has been validated. Current tests are sensitive to 1 kernel in 800, therefore, 3 subsamples of 800 kernels each are being analyzed. At this level of testing the miller will have 99% confidence that the level of StarLink corn present is 0.20% or less.

Within the parameters of the scientific testing capabilities available and the program outlined above, the corn milling members of NAMA, to the best of their knowledge are providing milled corn products that do not contain the Cry9C protein. While the limits of those capabilities do not allow millers to guarantee zero Cry9C protein in any product, we are committed to reducing it to maximum extent possible.

NAMA appreciates the opportunity to comment on the guidance document and to the agency's consideration of our recommendation.

Sincerely,

A handwritten signature in cursive script that reads "Betsy Faga".

Betsy Faga
President