

December 3, 2007

**North American
Export Grain
Association, Inc.**



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Office of Pesticide Programs
Regulatory Public Docket (7502P)
US Environmental Protection Agency

Via Federal eRulemaking Portal: www.regulations.gov

Attention: Docket EPA-HQ-OPP-2007-0832

Dear Madam/Sir:

This letter is submitted in response to EPA's October 17, 2007 Federal Register notice, page 58978. That notice solicited comments on the draft White Paper that reviews data on the level in the human food supply of the Cry9C protein from StarLink corn grain.

The North American Export Grain Association (NAEGA) is comprised of grain and oilseed exporters and interested parties, whose purpose is to promote and sustain the development of commercial export grain and oilseed trade from the United States. Chartered in 1912 and incorporated in 1920, NAEGA is a not-for-profit organization, whose members are privately and publicly owned companies and cooperatives.

We agree that the Cry9C protein has been sufficiently removed from the human food supply to render the theoretical level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added public health protection. Further we believe this has been the case for several years and the action is long overdue.

Our concurrence with the conclusion of the draft is based on the following considerations:

- Exposure to Cry9C was low in 2001, and by agency calculations is now 8,000-200,000 times lower.
- The method used to detect Cry9C is capable of detecting the protein in single parts per billion levels (1 part per billion is equivalent to 1 second in 32 years). The US Department of Agriculture has tested more than 450,000 corn samples since 2000, and even with such highly sensitive testing, has not found Cry9C since one sample tested positive in April 2005.
- The industry has voluntarily tested more than three million corn samples since 2000, and has not found Cry9C since one sample tested positive in October 2004.
- Analyses of corn grown between 1974-1980, years before StarLink corn was developed, showed positive results for the presence of Cry9C, suggesting some or all of those few

samples testing positive may have, in fact, contained other naturally occurring detectable proteins and not Cry9C.

- According to the Agency, between 2001 and 2007 there have been no reports reliably linking allergic reactions to exposure to Cry9C.
- Since the last StarLink corn was grown in 2000, the US has produced and utilized 6 complete crops and more than 75 billion bushels of corn. Production and handling (in the absence of Starlink propagation) of grain in just a few annual crop cycles – let alone 7 – was effective to ensure that no relevant trace of StarLink corn grain existed.

In conclusion, we agree with and support EPA's recommendation that the FDA withdraw its guidance for dry milling facilities and masa operations that recommends sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues. The safety and wholesomeness of foods containing dry milled corn ingredients would not be increased by continued testing, and such testing is therefore not supported by sound science or good public policy.

The EPA recommendation should be implemented at the earliest possible time. Such a testing and clearance requirement sends an incorrect signal to our international customers and acts a barrier to trade by promoting an unsound, non-science based policy.

Thank you for the opportunity to submit these comments. We appreciate your consideration and any further opportunity to address them.

Sincerely,

A handwritten signature in black ink that reads "Gary C. Martin". The signature is written in a cursive style with a large initial "G" and "M".

Gary C. Martin
President and CEO

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December 17, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration

Via <http://www.fda.gov/dockets/ecomments>

Attention: Docket No. 2001D-0025

Dear Madam/Sir:

This letter is submitted in response to FDA's October 17, 2007 Federal Register notice, page 58980. That notice solicited comments on whether the Food and Drug Administration (agency) should withdraw its guidance document entitled "FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues."

The North American Export Grain Association (NAEGA) is comprised of grain and oilseed exporters and interested parties, whose purpose is to promote and sustain the development of commercial export grain and oilseed trade from the United States. Chartered in 1912 and incorporated in 1920, NAEGA is a not-for-profit organization, whose members are privately and publicly owned companies and cooperatives.

We agree that the Cry9C protein has been sufficiently removed from the human food supply to render the theoretical level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added public health protection. Further we believe this has been the case for several years and the action is long overdue.

Our concurrence with the conclusion of the draft is based on the following considerations:

- Exposure to Cry9C was low in 2001, and by agency calculations is now 8,000-200,000 times lower.
- The method used to detect Cry9C is capable of detecting the protein in single parts per billion levels (1 part per billion is equivalent to 1 second in 32 years). The US Department of Agriculture has tested more than 450,000 corn samples since 2000, and even with such highly sensitive testing, has not found Cry9C since one sample tested positive in April 2005.
- The industry has voluntarily tested more than three million corn samples since 2000, and has not found Cry9C since one sample tested positive in October 2004.
- Analyses of corn grown between 1974-1980, years before StarLink corn was developed, showed positive results for the presence of Cry9C, suggesting some or all of those few

samples testing positive may have, in fact, contained other naturally occurring detectable proteins and not Cry9C.

- According to the Agency, between 2001 and 2007 there have been no reports reliably linking allergic reactions to exposure to Cry9C.
- Since the last StarLink corn was grown in 2000, the US has produced and utilized 6 complete crops and more than 75 billion bushels of corn. Production and handling (in the absence of Starlink propagation) of grain in just a few annual crop cycles – let alone 7 – was effective to ensure that no relevant trace of StarLink corn grain existed.

In conclusion, we agree with and support EPA's recommendation that the FDA withdraw its guidance for dry milling facilities and masa operations that recommends sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues. The safety and wholesomeness of foods containing dry milled corn ingredients would not be increased by continued testing, and such testing is therefore not supported by sound science or good public policy.

The EPA recommendation should be implemented at the earliest possible time. Such a testing and clearance requirement sends an incorrect signal to our international customers and acts a barrier to trade by promoting an unsound, non-science based policy.

Thank you for the opportunity to submit these comments. We appreciate your consideration and any further opportunity to address them.

Sincerely,

A handwritten signature in black ink that reads "Gary C. Martin". The signature is written in a cursive style with a large initial "G" and "M".

Gary C. Martin
President and CEO

December 17, 2007

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Attention: Docket No. 2001D-0025

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These comments are submitted on behalf of a coalition of the vertically integrated food corn industry.

The Environmental Protection Agency (EPA) recently published its "White Paper Concerning Dietary Exposure to Cry9C Protein Produced by STARLINK Corn and the Potential Risks Associated with Such Exposure." We agree with the white paper's conclusion, namely that the Cry9C protein from StarLink corn has been sufficiently removed from the human food supply to render the theoretical level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added public health protection. We base our position on the following:

- Exposure to Cry9C was low in 2001, and by EPA calculations is now 8,000-200,000 times lower.
- The method used to detect Cry9C is capable of detecting the protein in single parts per billion levels (1 part per billion is equivalent to 1 second in 32 years). The US Department of Agriculture has tested more than 450,000 corn samples since 2000, and even with such highly sensitive testing, has not found Cry9C since one sample tested positive in April 2005.
- The industry began voluntarily testing for Cry9C protein prior to the issuance of the FDA guidance, and with more than three million corn samples since 2000, has not found Cry9C since one sample tested positive in October 2004.
- Analyses of corn grown between 1974-1980, years before StarLink corn was developed, showed positive results for the presence of Cry9C, suggesting some or all of those few samples testing positive may have, in fact, contained other naturally occurring detectable proteins and not Cry9C.
- Since the last StarLink corn was grown in 2000, the US has produced and utilized more than 75 billion bushels of corn. If loaded into trucks and lined up bumper to bumper, the line of trucks would stretch more than 1.09 million miles, equal to 43.9 trips around Earth. Said another way, following the end of StarLink's cultivation in 2000, the entire

corn storage system, both on-farm and commercial, has been effectively emptied and refilled 5-6 times. This massive quantity of grain has effectively ensured that any relevant trace of StarLink corn grain no longer exists in the US corn supply.

- According to the EPA, between 2001 and 2007 there have been no reports reliably linking allergic reactions to exposure to Cry9C.

In conclusion, the safety and wholesomeness of foods containing dry milled corn ingredients would not be increased by continued testing, and such testing is therefore not supported by sound science or good public policy. Therefore, we agree with and support EPA's recommendation that FDA withdraw its guidance for dry milling facilities and masa operations that recommends sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues. We encourage FDA to implement that recommendation at the earliest possible time.

Thank you for the opportunity to offer these comments. We appreciate any consideration you may give them.

Sincerely,

American Seed Trade Association
Biotechnology Industry Association
Corn Refiners Association
Grocery Manufacturers Association
National Corn Growers Association
National Grain and Feed Association
North American Export Grain Association
North American Millers' Association
US Grains Council