



“Working Together to Make Trade Work”

March 12, 2007

Docket No. APHIS-2006-0157
Regulatory Analysis and Development
PPD APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Subject: Petition for the Determination of Non-Regulated Status: Corn Rootworm Protected Transformation Event MIR604 – Revised (Petition Application Number 04-362-01p)

This is in response to your request for comments regarding the petition of Syngenta Seeds, Inc. – Field Crops – NAFTA (Syngenta) for determination of non-regulated status for corn plants, developed through the use of genetic engineering, producing a modified Cry3A protein that protects the corn from damage associated with feeding by corn rootworm larvae (Coleoptera, Diabrotica sp.). In that petition we understand Syngenta requests that USDA-APHIS/BRS make a determination of non-regulated status for Corn Rootworm Protected Transformation Event MIR604, any progeny derived from crosses between MIR604 and other corn varieties, and progeny derived from crosses of MIR604 with other transgenic corn varieties that have received non-regulated status under 7 CFR Part 340.

These comments are based on the input and consideration of the membership of the North American Export Grain Association (NAEGA). NAEGA is a not for profit trade association, established in 1912, whose membership consists of private and publicly owned companies and farmer-owned cooperatives that are involved in and provide services to the bulk grain and oilseed exporting industry. NAEGA members are responsible for the vast majority of US exports grain, oilseeds and their products. NAEGA’s mission is to promote and sustain the development of commercial export of grain and oilseed trade. NAEGA acts to accomplish this mission from its office in Washington D.C. and in markets throughout the world.

Through its submissions Syngenta has certified that to the best of its knowledge and belief the petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner that are unfavorable to the petition.

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We take no exception to the information provided by Syngenta. However we do encourage you to take into context additional economic impact information in consideration of this petition.

Syngenta AG has indicated and appears already to be in the process of placing on the market hybrid corn seed containing the modified protein (MIR604). Thus, the modified protein will be essentially in the food and feed corn supply effective with corn harvested from that seed this Fall. Syngenta is marketing these “Agrisure RW” seeds in advance of critical international authorizations. As such the commercialization plans of Syngenta for MIR604 are of great concern for US exports of grains and oilseeds – indeed all crops - that are exposed to crops produced using modern biotechnology.

As background, US farmers and the grain export industry have relied on the commercial responsibility of technology providers to maintain access to major export markets as new biotechnology derived events become commercialized. One of the principle measures of maintaining access has included the voluntary restriction of commercialization until such time as the technology provider has obtained export market authorizations that are adequate to avoid significant disruption of markets. Over the last several years, we believe this process has eroded and subsequently failed US agriculture several times. This erosion of corporate responsibility to maintain major export markets has reached a point where now the provider of the MIR604 technology has indicated it will disregard the single largest market for US corn, Japan. The unknown status of authorization in Japan is already adding risk mitigation costs, reducing competitiveness and posing a threat to sales of corn to a reliable, stable, and highest of value export market. This is a development that can and should be addressed promptly.

In this case before you, Syngenta has indicated to several stakeholders it intends to distribute to US farmers for planting products containing MIR 604 (“Agrisure RW” brand) despite the fact that MIR604 has not received approval in major export markets for US corn and corn products. We further understand the products will be distributed in widespread and “significant” amount as soon as MIR604 is deregulated by USDA. Syngenta has also indicated it is certain US deregulation will occur before this coming planting season, allowing it to release this event for planting with the full knowledge that requisite approvals or authorizations in most corn and corn product importing countries (including Japan) are not assured prior to the upcoming harvest. Based on Syngenta’s recent experience with the BT10 event, we also believe it is well aware of the fact that producers and the export industry will be required to test all US corn destined for export. Such testing would occur at high costs and, we understand, with access to methods that are not commercially-viable for first point of sale segregation (in



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this case PCR testing only). This testing obligation will be triggered if approvals are not achieved before harvest and will be based on commercial needs as well as international regulatory requirements to address concerns about what will be considered an illegal trans-boundary movement.

To the best of our knowledge, it remains uncertain when a critical comment period for health safety assessment will start in Japan for MIR604. Based on our own experience, it is very difficult to determine when and if Japan might provide for approvals sufficient to overcome what is now a zero tolerance for such illegal presence.

We emphasize that for the grains and oilseeds and the primary products whose export NAEGA works to support and sustain, the evidence is overwhelming that no program of controls (stewardship, channeling etc.) can adequately meet the zero tolerance requirements that result when events unapproved in country of import are entered into the supply in the US. We are convinced that with a zero tolerance requirement, grain channeling is not a commercially viable option to prevent the presence of such events at low levels in commodity grain shipments. Syngenta has suggested to some that they intend to place the Agrisure RW products in existing programs of controls that are designed to meet the requirements of the European Union’s approach to unauthorized events. Such programs are not sufficient to meet Japanese requirements for the illegal presence of a biotechnology in imported agricultural products.

As an example of the growing international concern, please find the attached letter the Japan Feed Trade Association (corn importers) sent to Syngenta Japan recently.

Because of our serious concerns, we offer the following specific suggestions for APHIS to consider imposing on any decision to deregulate MIR604:

1. APHIS should require that Syngenta provide, before any deregulation, a sample of the product and a full description of the analytical method that should be used to determine the presence or absence of the genetically modified protein in products. Such information would be available to mitigate some of the market and legal risk for producers and handlers associated with Syngenta’s apparent commercialization plan should approvals in international markets not occur prior to harvest. Provision of such information to APHIS would presumably make the same information available to all qualified laboratories in the event testing to determine the presence of the event is needed. Ultimately Syngenta should be required by APHIS to provide, 45 days prior to harvest in the year of commercialization, a commercially viable test for point of sale identification of



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MIR604. In the past technology providers have provided for lateral flow devices to accomplish this need for tools to assist in the management of their technology in the agricultural product supply chain. A “PCR” only test as we understand is now contemplated is not commercially viable.

2. APHIS should require Syngenta to label its products with a prominent message such as the following: *“This product has not been approved for distribution or sale in numerous countries, and the purchaser acknowledges that use of this product before widespread approval around the world could result in rejection of shipments, which could in turn result in allegations that the user of this product has misrepresented the merchantability of corn or other grains grown utilizing this product.”* Such a label is necessary to ensure that the product is marketed with sufficient and full disclosure of information related to the potential implications of deregulation, including likely or at least potential rejection of product shipments overseas, which could in turn result in the non-payment of farmers. We believe that a failure to provide a warning of this sort could be considered to be a fraudulent omission in the sale of corn seeds by Syngenta because it failed to inform the buyer of facts significant to a decision to purchase.

3. To further meet the need to ensure that the product is marketed with sufficient and full disclosure of information, it would also be appropriate for APHIS to require Syngenta to have the buyer of seeds containing MIR604 sign a document acknowledging that it has read and understands the warning contained in the label (2 above).

We are looking forward to the opportunity to discuss this matter with you or others at USDA and greatly appreciate your willingness to consider and utilize the recommendations.

Thank you.

Gary C. Martin
President and CEO