



National Grain and Feed
Association



North American Export
Grain Association

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Biotechnology Regulatory Services
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U.S. Department of Agriculture
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Dear Dr. Dunahay:

The National Grain and Feed Association (NGFA) and North American Export Grain Association (NAEGA) appreciate the opportunity to provide input on the North American Plant Protection Organization's (NAPPO) discussion paper entitled, "Development of Module 4 of the NAPPO Standard for Importation of Transgenic Plants into NAPPO Member Countries: Importation for Non-Propagative Use Only." Importantly, we urge NAPPO to move forward with finalizing Module 4 and favor Option 3 as the basis for such a standard. Our responses to the specific questions raised in the discussion paper follow.

The NGFA consists of 1,000 grain, feed, processing and grain-related companies that operate about 5,000 facilities that store, handle, merchandise, mill, process and export more than two-thirds of all U.S. grains and oilseeds. Also affiliated with the NGFA are 36 state and regional grain and feed associations.

NAEGA, established in 1912, is comprised of private and publicly-owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States.

Responses to the Specific Questions Raised in the Discussion Paper

- Question 1: Do you believe that Module 4, which will provide guidelines on pest risk assessment criteria for importation of transgenic plants for non-propagative use only,

would provide useful guidance for NAPPO countries and stakeholders, or for other Parties to the IPPC and the Biosafety Protocol?

Answer: Yes. Completion of Module 4 would fill the gap that exists in NAPPO and IPPC standards for objective guidelines for determining what, if any, significant phytosanitary risks may be present when importing transgenic plants for food, feed or further processing purposes. As noted in the discussion paper, “none of the three [NAPPO] countries have regulations in place or specific guidance to address the specific question of what type of pest risk assessment should be required for importation of transgenic plants intended solely for non-propagative purposes.” We agree that treating all imports the same regardless of intended use is illogical because “the level of risk posed by crops imported for non-propagative use only is expected to differ significantly from the level of risk posed by crops intended for environmental release...”

Completion of Module 4 could help non-NAPPO countries as well because NAPPO Module 4 can be adopted as an IPPC standard. As such, Module 4 would help countries and parties to the Biosafety Protocol in making an objective decision on the importation of transgenic crops for food, feed or processing purposes.

- Question 2: If you agree that Module 4 would be useful, please provide comments on the proposed options for regulatory approaches. Do you support developing of NAPPO Module 4 according to Option 3, which provides for the establishment of a set of criteria that would facilitate a case-by-case assessment of the need for, and extent of, pest risk assessment for transgenic plants not intended for environmental release, or do you prefer regulatory framework outlined in Options 1 or 2 [in the discussion paper]? Is there another alternative or option that is not considered in the discussion paper?

Answer: We support Option 3 – **A Case-by-Case Determination of the Level of Risk for Identification of Appropriate Date Elements** – as the framework on which to build Module 4.

We do not believe that Option 1 – **Maintaining the Status Quo** – serves the long-term interests of U.S. exporters because it would not promote harmonization of science-based procedures on a global basis. On the other hand, Option 2 – **Full Evaluation of Phytosanitary Risks** -- would be excessive and unnecessarily costly in the case of importation of transgenic plants for non-propagative purposes, e.g., for food, feed and processing.

- Question 3: What is the appropriate scope of Module 4? Should the standard address all transgenic plant products that could pose a plant pest risk, including material such as cut flowers (that may have viable pollen)? Or should the standard be limited to viable plant products such as grains, oilseeds, pulses and fresh fruits and vegetables?

Are there other examples of transgenic plant products that should be specifically considered in this standard?

Answer: We favor limiting the scope of Module 4 to viable plant products such as grains, oilseeds, pulses and fresh fruits and vegetables because international rules being developed under the Biosafety Protocol are focused solely on living transgenic material.

- Question 4: Should the standard include guidelines for transgenic plant products not intended for direct use as food, feed or processing into food or feed material, such as plants engineered to produce pharmaceutical or industrial products? Or do the concerns and potential additional risks posed by these products warrant the development of a separate standard?

Answer: No. Module 4 should focus exclusively on crops destined for food, feed or further processing. If deemed warranted by NAPPO, pharmaceutical and industrial crops should be covered by a separate standard because such crops present their own unique set of concerns and potential additional risks.

- Question 5: Is exempting of certain transgenic products from the need for an environmental risk assessment a viable regulatory alternative? Would complete exemption from regulatory review be acceptable for any transgenic products, or only with mandatory notification of the regulatory agency? What criteria would define transgenic plant products that could be exempted from environmental review?

Answer: Yes, provided that the criteria used to exempt a transgenic products from an environmental assessment are transparent and science-based.

Furthermore, exempting crops from regulatory review based on the availability of an acceptable existing pest risk assessment performed by the exporting country could encourage other regional plant protection organizations to adopt similar criteria and promote a solution to the asynchronous approval problem (i.e., lagging approvals of biotech crops between exporting and importing countries).

- Question 6: Do you agree with the proposed criteria that could be used to determine whether a transgenic plant product should be subject to environmental review, and the extent of the assessments and data requirements necessary (in section 4.3.3.3)? Are there additional criteria that should be included?


Answer: In general, we agree with the proposed criteria. We recommend that criterion 2 also include an analysis of the probability that an unintended release could occur and, if so, the likely extent of the release (e.g., a few kernels falling off the back of a truck).

Thank you for allowing us to comment on the discussion paper. If we can be of further assistance, please contact Mr. Thomas C. O'Connor, Director of Technical Services, National Grain and Feed Association, at 202-289-0873.

Sincerely,



Arvid Hawk, Chairman
NGFA Food Safety Committee



Paul Green, Chairman
NAEGA Biotechnology Committee