

February 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Rockville, MD 20852

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RE: Docket No. 02D-0324

To Whom It May Concern:

Thank you for considering this response to Food and Drug Administration's (FDA) request in the September 12, 2002 Federal Register (FR) for comments on a draft document, developed in conjunction with the U.S. Department of Agriculture (USDA), entitled "Guidance for Industry: Drugs, Biologics and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals."

The North American Export Grain Association 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. The introduction and rapid expansion of agricultural crops produced via modern biotechnology has created new opportunities and challenges that impact US grain and oilseed trade. NAEGA is working with its members, their customers, government officials and other stakeholders here and abroad to address the commercial and regulatory challenges created by the rapid introduction and expansion of biotechnology.

The principle that commercial solutions are the most effective and preferable means to meet customer needs for unique commodities, including those intended to be free of any genetically modified products, remains fundamental to our approach to crop biotechnology. However, knowledge and experience with respect to the realities of the production and marketing of grain and oilseed crops leads us to conclude that the use of crops as suggested by your draft guidance is entirely inappropriate at this time. Hence we have adopted the following statement as policy:

"NAEGA believes that all modifications to crops commercially used for food or feed must have complete regulatory approval for use as food and feed."

Given current regulatory and consumer standards in the international markets served by our membership, production of these and other types of bioengineered products in food crops without approval for use as food will lead to further deterioration of markets for US exports. As a prerequisite to production of these and other types of bioengineered plants, two fundamental issues must be satisfactorily addressed: First is the lack of international consensus on regulations that apply to bioengineered plants and their impact on the human health, plant health, animal health and the environment. Second is the misconception that, as one might conclude from your draft guidance, a regulatory scheme

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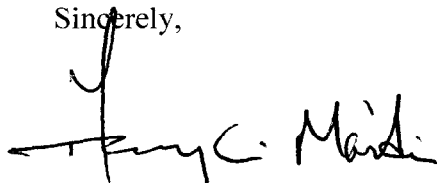
can be implemented that will satisfy these effectively "zero tolerance" standards. Until some level, other than zero, of acceptance for non-food approved genetic material can be established in key international markets, production of non-food use approved seeds or plant material in crops normally and commercially grown for food will inevitably result in lack of confidence in the regulatory system and a prohibition of access for large amounts of US production to important international markets.

Thus, it is imperative that industry and US government (FDA and USDA especially) work first to develop international agreement on standards that acknowledge the potential for trace amounts of genetic material not approved for food prior to continuing to allow the production of such crops that might inadvertently contaminate food and feed crops. Until such international agreement can be reached we suggest that all modifications to crops commercially used for food or feed must have complete regulatory approval for use as food and feed.

This is a critical matter with regard to maintaining access to international markets and the US role in providing for human nutrition around the world. Your consideration of the necessary prerequisite for your guidance is most appreciated.

We look forward to your response. If you have questions or we can be of further assistance in this matter, please contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary C. Martin". The signature is written in a cursive style with a large initial "G" and "M".

Gary C. Martin
President and CEO

CC: USDA