IPQA

IOWA QUALITY PRODUCERS ALLIANCE, L.L.C.
A Producer-Owned *Opportunity Search & Development Services* Company
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Documents Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

January 6, 2003

Re: Docket No. 02-D-0324: Draft Guidance for Industry -- Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals

Dear Sir/Madam:

These comments are submitted on behalf of the 83 independent corn and soybean crop producer-members of the Iowa Quality Producers Alliance, L.L.C. ("IQPA"). The Board of Managers of IQPA has been studying potential biotech corn growing opportunities and processing-plant investment opportunities for the past two years, based on our members' strong belief in the need to diversify their income sources through innovative approaches and technological advances. During the past year the Board also has participated with other Iowa producer groups such as the Iowa Cooperative and various other public agencies and private groups in an effort to create the state-wide "infrastructure" needed for Iowa producers to take advantage of advancements in agricultural biotechnology. IQPA, for example, has been working with the Iowa Grain Quality Initiative and Iowa State University to develop advanced producer training and certification programs that are essential if the promise of higher-income-generating crop production is to be realized in Iowa.

As an alliance of independent corn and soybean growers, IQPA obviously is not in a position to comment in any detail on many of the technical and legal aspects of the draft guidance document. IQPA's views and comments are limited at this time to the following broad policy considerations and related issues.

A Strong and Enforceable But Reasonable Regulatory System is Needed

IQPA supports the adoption of a rigorous regulatory system related to the use of corn and other food/feed crops to produce substances that are not intended for use as food or feed, including plant-manufactured pharmaceuticals. We agree with recent policy statements of the Biotechnology Industry Organization and the Center for Science in the Public Interest that the regulatory system should include rigorous requirements for grower training and certification, documentation and self-audits, third-party inspections, mandatory minimum "confinement" standards,

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and strict penalties for violations of regulations and permit requirements. We also agree with the need for USDA permits that include environmental assessments and FDA premarket approvals that include food safety assessments for products derived from bioengineered plants.

100% Containment Is Not Feasible and Thus "Zero Tolerance" Is Not Practicable

We understand the National Food Processors Association supports FDA's "zero tolerance" policy with respect to commingling "any" non-food substance or material with food or feed crops, because of their inflexible interpretation of the "adulteration" standard contained in the FDA law and, perhaps more importantly, a "public perception" that any commingling of non-food material with a food/feed crop renders the food or feed "unsafe. " We do not believe this is a workable or "practicable" regulatory system in the case of open-field-grown agricultural crops, no matter how stringent and enforceable the regulatory requirements may be. Even if producers comply perfectly with every imaginable requirement contained in the applicable rules and permits, acts of nature and human error cannot be avoided in every case. We understand that federal agencies have the power to create "de minimis exemptions" from regulatory requirements when it is shown that they will not undermine the goals/purposes of the law being administered. Thus, in addition to conducting environmental and food safety risk assessments, we urge FDA and USDA to create a "practicable" regulatory system by, for example, exercising their authority to exempt from broad regulatory prohibitions a specified de minimis level of transgenic plant material that (similar to "naturally-occurring materials" such as rocks, rodent feces, etc.) might be present in food or feed crops.

Proposed Blanket Restrictions Based on Geographic Location or the Type of Host Plant Are Inherently Arbitrary and Unreasonable

As Iowa corn growers interested in producing higher-value crops that will benefit Iowa's rural economy and help sustain Iowa's rural communities, we oppose any "blanket" restriction on the use of corn as a host plant for producing non-food substances, as well as any blanket restriction on growing in Iowa any corn that is genetically-modified to produce non-food substances. The National Food Processors Association has opposed the use of environmental and food safety assessments and proposed instead an outright ban on the use of food and feed crops to produce non-food substances --unless there are in place "100% effective" procedures to prevent commingling. In light of the practical reality that no plant or regulatory system is or can be made 100% effective, such an outright ban would be inherently arbitrary and unreasonable.

Respectfully submitted,

David Denne, President

Dave Denne (by MKH)