

April 15, 2008

The Honorable Ed Schafer Secretary of Agriculture U.S. Department of Agriculture Washington, DC 20250

Dear Secretary Schafer:

The Biotechnology Industry Organization (BIO) believes it is critical that the U.S. Department of Agriculture (USDA) propose revisions to 7 CFR Part 340 regulations governing oversight of crops produced through modern biotechnology as soon as possible. Issuing a final regulation during the current Administration is essential as the impending change in Administration will lead to further delays to overdue rulemaking. Updating the regulations is needed to help ensure the continued safe development and use of biotechnology-derived crops, minimize trade disruptions, maximize the agricultural and economic benefits of this technology across agricultural, energy and health sectors, and maintain and enhance the U.S. position as the global leader in this technology.

A draft Environmental Impact Statement was published in July, 2007, but the proposed rule has not yet been published, even though 4 ½ years have passed since the Office of Science and Technology Policy first identified that new rules were needed. In that time, the technology has continued to advance; biotechnology industries have grown to become a major force in the U.S. economy; and, hundreds of scientific studies have been published documenting both the safety of the current technologies and the promise of technologies under development to meet increasing global demands for food, fiber, and energy.

Release of a proposed rule is needed as soon as possible to enable the current Administration to finalize the new regulations before the end of this calendar year. Revision of 7 CFR Part 340 regulations is critical for the food and agriculture industry and would enable USDA to:

- Reduce the risk of market and trade disruptions by codifying the U.S. government's response to Low Level Presence, which reduces the risk of market and trade disruptions.
- Institute a fully functional process to bring imported biotechnology-derived crops into the United States when the purpose is for food, feed and processing uses only.
- Create additional permit types so the agency can more easily allocate resources and exercise oversight in proportion to the risks posed by field trials.



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• Impose risk-based regulations that can accommodate the full range of biotechnology products including those intended for non-food as well as food uses. The regulations should ensure the safe development of plant-made biologics for human health, nutrition, and industrial uses under carefully controlled conditions, but should also facilitate production of crops for biofuels production under less restrictive conditions as appropriate to allow the United States to reach its goal of achieving energy independence more quickly.

BIO supports the efforts by USDA to revise its regulations governing biotechnology-derived products. The ability to realize the full benefit of new crops produced through biotechnology will require a regulatory system that continues to be science-based and is rigorous in protecting agriculture, public health, and the environment.

Thank you for your consideration and attention to this important matter.

Sincerely,

Andrew Baum

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