July 15, 2013

Low Level Presence for Agricultural Biotechnology

Food and Agriculture Section
Policy Statement

Introduction

Global adoption of biotechnology-derived plant products[i] continues to rise at a rapid rate - with an increasing number of authorizations for new and combined events, as well as the emergence of developing nations creating and commercializing novel products. Expansion of the marketplace elevates the commercial significance of trade in these products for both exporting and importing economies[ii].

A delay between the authorizations of a product in the exporting country and a country of import is termed an "asynchronous authorization[iii]." Such delays increase the potential for situations of low level presence (LLP)[iv] in commercial trade of biotechnology-derived plant products that are permitted in the country of export but not yet authorized in the importing country.

It is well recognized in agriculture and the food industry that 100% product purity is not possible because of the nature of biological systems and the practical limitations of feed and food handling and production systems[v,vi]. The potential for low level presence, combined with importing countries maintaining zero tolerance import policies for biotechnology products not yet authorized, represents a critical trade policy issue. A comprehensive import policy for biotechnology-derived plant products, including a set of commercially viable options for managing LLP instances in the food and feed value chain, would be a significant step towards ensuring trade flows are not unnecessarily interrupted due to LLP. It is critical that countries adopt import policies that facilitate trade without compromising human, animal or plant health. LLP is not a human health or environmental safety concern for products that have undergone a full safety assessment in at least one country. Trade impacts of LLP in seed also exist and are being addressed by the seed industry.

General Policy

BIO supports global adoption of scientifically sound approaches to decision-making that are proportionate to risk and provide for the safety assurance and accommodation of LLP of biotechnology-derived plant material in order to facilitate trade.

LLP Policy and Outreach

The *Coordinated Framework for Regulation of Biotechnology*[vii] (1986), drafted by the Office of Science and Technology Policy (OSTP), outlined a framework for regulatory oversight of biotechnology-derived plant products in the United States. The framework is based on authorities inherent within existing statutes of the U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA). The framework concludes that regulation of biotechnology-derived plant products should be science and risk-based, and should regulate the product, not the process by which the product was made[viii].

While the U.S. remains committed to its current approach of managing instances where LLP occurs on a case-by-case basis, BIO encourages U.S. regulatory agencies to clearly articulate the approaches used for management of LLP in imports that are proportionate to risk. Regulatory agencies also should continue to exercise existing flexibilities within current implementing regulations, and are encouraged to develop additional guidance that articulates a "toolbox" of predictable risk assessment and management options for handling LLP occurrences, which take into account: 1) an unauthorized product's familiarity and

similarity to an authorized product(s); 2) limited exposure and risk; and 3) assessments and authorizations conducted by an exporting country's regulatory authority, either through recognition of and adherence to the Codex Alimentarius Plant Guidelines risk assessment process[ix], or through the recognition of comparability of another country's food safety system to the U.S. system[x].

As agricultural biotechnology continues to rapidly gain acceptance around the world and trade flows increase, the U.S. government will need to apply its LLP policies to imports of biotechnology-derived plant materials, and recognize its trading partners' systems for risk assessment and management. Enhanced communication, data sharing, and recognition of regulatory equivalence between and among global regulators could minimize the differences in approach and reduce the time in making risk assessments and management decisions in countries where an LLP situation could occur.

BIO encourages the U.S. government to conduct outreach and education efforts with trading partners regarding the U.S. approach towards import of biotechnology-derived plant material and essential LLP policy elements; encourage countries developing new products to consult with regulatory agencies for product authorizations in the U.S. to mitigate incidences of LLP; continue to exchange information through international fora and through bilateral discussions on regulatory processes; and identify potential mechanisms for more efficient, coordinated review and authorizations processes.

Specific Policy Objectives:

U.S. Domestic

1. BIO encourages USDA, FDA and EPA to coordinate and articulate a comprehensive and systematic LLP assessment and management process to reduce the trade impacts of instances where LLP occurs. BIO supports LLP policies that are proportionate to risk in order to provide continued food, feed and environmental safety for consumers, farmers, food processors, and grain handlers.

2. BIO supports responsible stewardship of new products entering the marketplace to minimize the potential for occurrences of LLP in trade as outlined in BIO's Food and Agriculture Section Product Launch Stewardship Policy and associated annexes[xi].

International

1. BIO supports U.S. leadership and active participation in coordinated discussions related to LLP and global trade efforts, including the Global LLP Initiative.

2. BIO encourages U.S. leadership to strongly advocate for predictable and transparent approaches to improve synchrony of global regulatory authorizations as the most effective way to minimize or eliminate LLP situations for grain, food and feed. These approaches should include bilateral or multilateral trade agreements that incorporate commitments to allow trade to continue in the instance of an LLP situation.

3. BIO encourages U.S. regulators, trade agencies and industry collaborators to strongly advocate for the recognition of risk assessments consistent with Codex Alimentarius Commission's *Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Plants*[xii] and for the global adoption of trade facilitative policies that result in internationally harmonized LLP standards for grain, food and feed.

4. BIO actively participates in the Global Alliance for Agricultural Biotechnology Trade (GAABT) to provide input and assistance to global LLP initiatives in order to develop solutions for the issues of asynchronous approvals and LLP.

5. BIO supports and encourages seed industry efforts to develop a science-based, internationally harmonized standard for low level presence of biotechnology-derived plant material in seed through appropriate international fora.

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Notes

[i] Biotechnology-derived plant products means those derived by the application of 1) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or 2) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection. This definition of modern biotechnology has been adopted by the Cartagena Biosafety Protocol under the Convention on Biological Diversity and by the Codex Alimentarius Commission.

[ii] For example, in 2012, the U.S. exported approximately $11.240B in corn, $24.503B in soybeans, meal and oil, and $6.553B in cotton. GM crops are planted on the majority of commodity crops acreage in the U.S.: 88% corn, 93% soybeans, and 94% cotton. (http://usda01.library.cornell.edu/usda/ers/AES//2010s/2012/AES-11-29-2012.pdf; http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us.aspx)

[iii] Authorizations in importing countries vary depending on the timing of submissions for import authorization as well as the duration of the authorization process in each country.

[iv] Low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined. This is in contrast to adventitious presence (AP), which is the accidental or unintentional appearance of foreign material in a product. Or, the presence of biotechnology-derived material that is an experimental trait not yet authorized for commercial use in any country (e.g. field trials). AP is not within the purview of this policy.

[v] "Given the vast infrastructure dedicated to moving grain from farms to consumers around the world, adventitious commingling is virtually guaranteed, even in the most stringent identity preservation system." Thus, a zero tolerance for LLP is unachievable, despite the use of good agricultural and manufacturing practices to minimize its occurrence during production, handling, processing and transport. *International Policy Council, Food & Agriculture Trade. Upcoming Decisions on the Biosafety Protocol Could Sharply Increase Food Costs: IPC Urges Governments to Weight Costs before Taking Decisions. Study Highlights, Jan. 10, 2005.*

[vi] In order to address issues in production and manufacturing practices yet still facilitate product flow in the marketplace, FDA has established Food Defect Action Levels, which "allows…maximum levels of natural or unavoidable defects in foods for human use that present no health hazard… The FDA set these action levels because it is economically impractical to grow, harvest, or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects."
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm
To date, authorized biotech products have no known health effects, and in the instance of an LLP situation, have already been deemed by a competent regulatory authority not to pose a food or feed safety risk when consumed at the same level as a non-biotech crop.

[vii] http://usbiotechreg.epa.gov/usbiotechreg/

[viii] In 2002, OSTP coordinated an effort with FDA, EPA, and USDA's Animal Plant Health Inspection Service to update its existing regulatory authority for plant biotechnology to address instances of adventitious and low level presence. These actions were aimed to account for increased research and development and field trials, and were intended to minimize the chances of a regulated product from entering commerce. *Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants: Notice*. (Office of Science and Technology Policy, 2002) FR 67:50578

[ix] www.codexalimentarius.org/input/download/standards/10021/CXG_045e.pdf

[x] A recent example includes FDA's recognition of New Zealand's food safety system as comparable to the U.S. "Once assessments (of a trading partner's system) are complete, systems recognition arrangements will lead the way to a new level of regulatory cooperation between FDA and our regulatory partners in other countries, allowing us to avoid duplication of effort while leveraging the high quality work done by regulatory authorities in each country."
http://www.fda.gov/Food/InternationalInteragencyCoordination/ucm103013.htm

[xi] \\Bioapp4.ad.bio.org\food_ag\Policy Papers - Final\Product Launch Stewardship 11272012 (with new bio logo).pdf

[xii] www.codexalimentarius.org/input/download/standards/10021/CXG_045e.pdf