Food and Agriculture Section December 10, 2009

Product Launch Stewardship

Introduction

Through its advocacy efforts, BIO's Food and Agriculture Section supports a regulatory framework that facilitates and enables the development and commercialization of new biotechnology-derived plant products[1]. Therefore, BIO's Food and Agriculture Section is committed to supporting appropriate regulatory and complementary stewardship efforts, in coordination with the relevant stakeholders in the value chain, to advocate globally for synchronous authorizations and elimination of non-science-based zero-tolerance regulatory approaches and to facilitate the introduction of new biotechnology-derived plant products in such a manner as to facilitate the flow of goods in commerce and minimize trade disruptions.

New product introduction can more effectively be achieved by companies, in part through the use of market and trade assessments prior to commercialization that anticipate and consider the potential impacts within the value chain. The engagement with various stakeholders in the value chain is important to the success of these assessments (e.g., identifying conditions related to handling, distributing, processing and testing the products). Because of the differences in crops, products, product uses and applications, each new biotechnology-derived plant product should undergo a case-by-case assessment by the company introducing that product.

This policy, through its annexes[2], sets forth general policy statements and recommended processes for such assessments as guidance for companies engaged in the launch of a new biotechnology-derived plant product and as a basis for BIO's Food and Agriculture Section's advocacy.

[1] 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 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.

[2] Under BIO's bylaws and applicable antitrust law, individual member companies are not bound by this Association policy or its annexes.

BIO's Food and Agriculture Section believes that member companies should develop and implement company product launch stewardship policies consistent with the general policy statements and the guidance set forth in the annexes to this policy.

General Policy Statement

To encourage the continued adoption of agricultural biotechnology globally and to continue to have products of agricultural biotechnology bring value to the marketplace, BIO's Food and Agriculture Section supports actions that facilitate the flow of goods in commerce, minimize trade disruptions, and facilitate the availability of crops and products with the appropriate function and composition for intended uses. BIO's Food and Agriculture Section believes that henceforth and pursuant to the specific policy statements set forth in the annexes to this policy, individual companies should determine whether biotechnology-derived plant products, which a company intends to commercialize, are intended for commodity use or special use, and then conduct a market and trade assessment appropriate to the biotechnology-derived plant product, develop management plans appropriate to the product and the market and trade assessment, and undertake early, regular and mutual consultations with relevant stakeholders during the assessment and management plan development process. Companies should communicate promptly, broadly and in a transparent manner with stakeholders regarding company-specific product launch stewardship policies and their implementation.

In light of the constantly changing regulatory and trade environment, the Food and Agriculture Section Governing Board will keep this policy and its annexes current and adopt additional annexes, as appropriate.

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Annex 1: Commodity Crops[3] (and Their By-Products) Intended for Food and Feed

Introduction

Since the commercial introduction of biotechnology-derived plant products in 1996, an increasing number of biotechnology-derived plant products intended for food or feed use are authorized for commercial production in many countries throughout the world; however, 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. As a consequence of these asynchronous authorizations, low levels of recombinant-DNA plant materials that have completed full safety assessments in accordance with national and international standards in one or more countries may, on occasion, be present in food or feed in countries in which the authorization process of the relevant recombinant-DNA plant material has not been completed.

Asynchronous authorizations combined with importing countries maintaining "zero tolerance" for recombinant-DNA products not yet authorized results in the potential for major trade disruptions. The potential occurrences of trade disruptions will only increase given the substantial amount of research that will bring many new products and combinations of products to market. The problem could be further compounded as countries that currently have no regulatory authorization systems for biotechnology-derived plant products establish them in the future. The potential for trade disruption could be significantly reduced if all countries provided authorizations simultaneously or if there was international governmental consensus to eliminate zero tolerance policies. BIO's Food and Agriculture Section is committed and seeks the commitment of the value chain to continue to actively engage in ongoing concerted efforts to harmonize science-based agricultural biotechnology regulatory approaches to achieve synchronous authorizations and to eliminate zero tolerance policies. As a beginning, the Codex Alimentarius Commission has developed an international food safety standard for the low level presence of recombinant-DNA plant material in food. With national adoption, this international standard will help address the problem, but it is not a substitute for full safety authorizations. In the interim, one pragmatic approach is to minimize the number of asynchronous authorizations in key markets. This can be achieved by companies commercializing their new biotechnology-derived plant products after meeting applicable regulatory requirements from the key countries most likely to produce or import the seed or products derived from those new biotechnology-derived plant products.

[3] A "Commodity Crop" is a crop which in the ordinary course is grown using common agricultural practices and is commingled and not segregated for special handling or use when it enters the chain of commerce. For purposes of this policy, Commodity Crops are generally grain and oilseed crops traded on commodity exchanges.

BIO's Food and Agriculture Section establishes the following policy statement to address these matters.

Specific Policy Statement

To encourage the continued adoption of agricultural biotechnology globally and to continue to have products of agricultural biotechnology bring value to the marketplace, BIO's Food and Agriculture Section believes that individual companies, prior to commercialization[4] of a new biotechnology-derived plant product in a Commodity Crop intended for food and feed, should meet applicable regulatory requirements in key countries, identified in a market and trade assessment, that have functioning regulatory systems and are likely to import commodities including the new biotechnology-derived plant products.

Policy Guidance

In implementing this policy statement, BIO's Food and Agriculture Section encourages the following process for assessing and launching Commodity Crop products to guide a company in its development and commercialization of these products globally. This guidance does not limit the implementation of additional measures designed to facilitate adoption and use of those products and to prevent disruption of the production and use of or the trading of the commodity.

1. Conduct a market and trade assessment to identify key import markets, including those with functioning regulatory systems[5], prior to the commercialization of any new biotechnology product (crop by event) in any country of commercial launch. In that market and trade assessment, consult at an early stage with the value chain for the specific crop. Manage the product's introductions so that choice of production methods (coexistence) and markets (e.g., specialty, identity preservation, and global) for that crop are available and preserved.

2. Meet applicable regulatory requirements in key markets (which at a minimum shall include the United States, Canada, and Japan[6]) prior to commercialization of a new

[4] Commercialization for purposes of this annex is defined as the first planting of seed for the production of a crop or crop product that will be placed into general commerce.

[5] A "functioning" regulatory system is science-based, with clearly defined timelines and processes for regulatory review and decision-making, and appropriate protection for proprietary information and data. The regulatory decision-making processes must be predictable, completed in a timely manner, and not subject to undue political influence.

[6] After stakeholder consultation, Mexico or other countries will be added to this list after the country has developed, over time, a track record of systematic authorizations with consistent and predictable timelines and processes.

biotechnology product in commodity corn, soybeans, and canola in the United States or Canada[7], unless determined otherwise in consultation with the value chain for the crop.

3. Follow generally accepted best seed quality practices designed to prevent low level presence of unauthorized products and minimize unintended incidental presence of products authorized in the country of production pending full implementation of the company's program under Excellence Through Stewardship®.

4. Make available prior to commercialization a reliable detection method or test for use by growers, processors and buyers that enables crop identity verification for intended use.

[7] For commercialization outside of the United States and Canada of biotechnology-derived seeds of Commodity Crops intended for food and feed use, BIO supports that each company individually meet its applicable regulatory requirements in key export markets for the country of production prior to commercialization, unless determined otherwise through the company's consultation with the value chain for the crop in the exporting country.

Annex 2: Special Use Traits[8] in Commodity Crops

Introduction

This policy statement addresses the unique and evolving area of food and feed Commodity Crops with one or more special use biotechnology-derived traits and provides guidance for companies in the development and commercialization[9] of these special use traits.

Specific Policy Statement

To encourage the continued adoption of agricultural biotechnology globally and to continue to have products of agricultural biotechnology bring value to the marketplace, BIO's Food and Agriculture Section encourages individual companies to conduct market and trade assessments for special use traits in Commodity Crops prior to their commercialization to anticipate, consider, and develop approaches to help manage and mitigate any potential significant, unintended processing, product functional or compositional negative effects in crop use or processing streams.

Policy Guidance

In implementing this policy statement, BIO's Food and Agriculture Section encourages the following process for assessing and managing special use traits to guide a company in its development and commercialization of these products globally. This guidance does not limit the implementation of additional or alternative measures designed to facilitate adoption and use of those products and to prevent disruption of the production and use of or the trading of the commodity.

1. Identify relevant stakeholders for the trait and crop, and:

    a. Communicate with those stakeholders and other relevant stakeholders identified to the company on the function of the trait, and the benefits, properties, uses and the company's understanding of the potential for significant unintended processing, product functional or compositional negative effects of the plant product on other processes or products; and,

    b. While protecting the confidential business information and intellectual property of all participants, engage relevant stakeholders in early, regular and mutual dialogue

[8] A special use trait is a value-added, quality or other specialty biotechnology-derived trait resulting in functional or compositional change that may have significant, unintended processing or product functional or compositional effects in crops, crop uses and/or processing streams. Plant-made pharmaceuticals are outside the scope of this policy and are separately addressed by BIO's Containment Analysis and Critical Control Point Plan.

[9] "Commercialization" for the purposes of this annex is defined as the first planting of a crop which will be placed into commerce to be processed into a crop product with or utilizing a special use trait, or the first production of a crop product with a special use trait that will be sold into general commerce.

during the development of the market and trade assessment and of any product management plans prior to the issuance of a proposed regulatory authorization of the plant product.

2. In the development of plans for product commercialization, conduct a market and trade assessment of the trait and of the crop. The assessment may include:

    a. The types and nature of the special use trait use(s);

    b. Whether the plant product or byproduct with the special use trait has multiple uses, including commodity uses and what types of downstream products or processes will likely be negatively affected;

    c. Whether these alternate uses require unique handling, distribution or other operational conditions;

    d. To the extent possible, based on publicly available information, information provided to the company, and company-developed information, map or otherwise characterize those product process/ingredient flows (to include by-product streams) that would likely be significantly and negatively affected;

    e. To the extent possible, based on publicly available information, information provided to the company and company-developed information, assess whether special use trait presence is likely to cause significant, unintended processing, product functional or compositional negative effects, the types of downstream products that are likely to be so affected, and what levels of trait presence, if any, would cause those significant, unintended processing, product functional or compositional negative effects;

    f. Whether the special use trait in a Commodity Crop will be exported as grain, processed fractions or food/feed end products; and

    g. As relevant, assess whether the value chains in countries of import have similar or different uses for the plant products or byproducts.

3. On a case-by-case basis and as relevant, develop management, mitigation and incident response plans appropriate to the significant, unintended processing, product functional or compositional negative effects, if any, of the special use trait in a Commodity Crop or crop product processing stream, and appropriate to the likelihood of presence of the special use trait, including:

    a. The identification and management of critical control points.

    b. The development of plans to address potential escape or unintended presence of the trait such as:

- Meet applicable regulatory requirements in key countries of production and import with functioning regulatory systems;

- Develop production, handling and use systems designed to control, contain or manage the intended use of the trait; and

- Develop plans and tools (e.g., reliable detection methods or tests) to enable the technology provider and stakeholders to manage, mitigate or abate any significant, unintended processing, product functional or compositional negative effects of the presence of the special use trait in crop use and processing streams.

4. Undertake appropriate outreach, communications and education necessary to effectively implement the management, mitigation and incident response plans, including identifying the risks and providing the information necessary to implement the management plans.