

CropLife International
Product Launch Stewardship Guideline
Updated September 2012

An increasing number of biotechnology-derived plant products¹ 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 were international governmental consensus eliminating zero tolerance policies.

CropLife International 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. Codex has developed and approved an international food safety standard for the low-level presence of recombinant-DNA plant material in food. Such an international standard helps to address the problem of asynchronous authorizations. Another pragmatic approach is to minimize the number of asynchronous authorizations in key markets. This can be achieved by CropLife International member 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.

CropLife International establishes the following guidelines to address these matters.

General Guideline

CropLife International believes in access to the shared benefits of crop biotechnology.

To help ensure the continued adoption of agricultural biotechnology globally and to continue to have products of agricultural biotechnology bring value to the marketplace, CropLife International supports actions that facilitate the flow of goods in commerce and minimize trade disruptions. CropLife International believes that henceforth individual member companies should, prior to commercialization,² meet applicable regulatory requirements in key countries identified in the trade assessment that have functioning regulatory systems³ and are likely to import the new biotechnology-derived plant products.

Specific Guideline Objectives

Consistent with this general guideline, CropLife International believes that henceforth individual member companies commercializing biotechnology-derived plant products should, and encourages them to:

1. Conduct a trade assessment to identify key countries of production and import (herein referred to as “key countries”), prior to the commercialization of any new biotechnology product (crop by event) in any country of commercial launch. In preparing the 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 and purpose or use (e.g., specialty, identity preservation, and global) for that crop are available and preserved.
2. Meet applicable regulatory requirements in key countries for imports for each country of production prior to commercialization of a new biotechnology product in commodity corn, soybeans, and canola, unless determined otherwise in consultation with the value chain for the crop.
 3. Conditions within the value chain can change, e.g. countries may become key importing markets or become functioning regulatory systems. Therefore, the determination of which regulatory systems are functioning, as well as assessments, need to be regularly re-evaluated by a company in consultation with the value chain as circumstances change. As a result of any significant change in circumstances the company needs to properly steward the planned and ongoing product launches to minimize the potential for trade disruption. Given production country approval, meaning that there are no environmental, health or safety concerns associated with the product, the company should consider, and the value chain support, a full complement of regulatory alternatives (e.g. low-level presence thresholds, waivers, changes in or acceleration of the authorization process) in importing countries which become key countries.
 4. Follow generally accepted best seed quality practices designed to prevent adventitious 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[®].
 5. 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.
 6. Promptly communicate broadly and in a transparent manner with stakeholders as to its company-specific product launch stewardship policies and their implementation.

In light of the constantly changing regulatory and trade environment, CropLife International will undertake regular reviews of these guidelines.

Footnotes

1 Biotechnology-derived plant products or plant products derived from modern biotechnology means 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 the Codex Alimentarius Commission.

2 Commercialization for this document is defined as the transfer of title and control of seed to the purchaser for the planting and production of a crop or crop product that will be placed into general commerce.

3 A "functioning" regulatory system is science-based, with clearly defined timelines and processes for regulatory review and decision-making, and for appropriate protection for proprietary information and data. In a "functioning" regulatory system, the regulatory and decision-making processes must be predictable and not subject to undue political influence. The term "predictable" includes, without limiting the definition, that the regulatory system accepts submissions in the ordinary course without preconditions related to the regulatory status in other countries, and the regulatory process for import authorization is completed routinely within 30 months or less. Since regulatory systems continue to evolve and change globally, countries' systems may become functional or dysfunctional. Over time, a country should develop a track record of systematic authorizations with consistent and predictable timelines and processes.