

CropLife International Product Launch Stewardship Guidance

Introduction

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. As a beginning, work in Codex is underway to develop an international food safety standard for the low level presence of recombinant-DNA plant material in food. Such an international standard will help address the problem when completed, 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 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.

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.

CropLife International establishes the following guideline 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 a market and 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 market and trade assessment to identify key import markets, including those with functioning regulatory systems, 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 (i.e., facilitate 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 prior to commercialization of a new biotechnology product intended for international commodity trade unless determined otherwise in the consultation with the value chain for the crop.
3. 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.
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.
5. 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 keep this guideline current.

Updated July 2008

² Commercialization for this document is defined as the first planting of seed sold into commerce for the production of a crop.

³ 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 and decision-making processes must be predictable, completed in a timely manner, and not subject to undue political influence.