CropLife Australia Policy Statement on Product Launch Stewardship for Crop Biotechnology Products

Key Points

An increasing number of crop biotechnology-derived plant products[i] for food, feed and fibre are approved for commercial[ii] cultivation in many countries around the world; however, approval in some importing countries varies depending on the timing of submissions for import approval as well as the duration of the approval process in each country.

CropLife Australia is committed to continuing, and seeks the commitment of the value chain to continue to actively engage in, ongoing concerted efforts to harmonise science-based crop biotechnology regulatory approaches to achieve synchronous approvals and to eliminate zero tolerance policies.

Asynchronous authorisation, combined with importing countries maintaining a 'zero tolerance' for unapproved crop biotechnology products, has the potential to result in major trade disruptions.

The potential for trade disruption could be significantly reduced if all countries provided authorisation simultaneously, or if there was international government consensus eliminating 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 approvals.

Another pragmatic approach is to minimise the number of asynchronous approvals in key markets. This can be addressed by CropLife Australia member companies commercialising their new crop biotechnology products in Australia only after meeting applicable regulatory requirements from the key countries most likely to import those seeds or products.

General Policy – Promoting access to the shared benefits of crop biotechnology

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

To help ensure the continued adoption of crop biotechnology globally; and to continue to have products of crop biotechnology bring value to the marketplace, CropLife Australia supports actions that facilitate trade and minimise disruptions.

CropLife Australia member companies should, prior to commercialisation in Australia, meet applicable regulatory requirements in key countries identified in a market and trade assessment that have functioning regulatory systems[iii] and are likely to import the new crop biotechnology product.

Specific Policy Objectives

Consistent with the General Policy, CropLife Australia encourages member companies commercialising crop biotechnology-derived products in Australia to:

- Conduct a market and trade assessment to identify key import markets, including those with functioning regulatory systems, prior to the commercialisation in Australia of any new crop biotechnology product. 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. coexistence) and markets (i.e. speciality, identity preservation and global) for that crop are available and preserved.
- Meet applicable regulatory requirements in key markets prior to commercialisation of a new biotechnology product in Australia intended for international commodity trade unless determined otherwise in the consultation with the value chain for the crop.
- Follow generally accepted best seed quality practices designed to prevent adventitious presence[iv] of unapproved products and minimise unintended low level presence[v] of products approved in the country of production.
- Make available prior to commercialisation in Australia a reliable detection method or test for use by growers, processors and buyers that enables crop identity verification for intended use.
- Promptly communicate broadly and in a transparent manner with stakeholders as to company-specific product launch stewardship policies and their implementation.

[i] Crop 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.

[ii] Commercialisation for this document is defined as the first planting of seed sold into commerce for the production of a crop.

[iii] 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.

[iv] 'Adventitious presence' (AP) refers to trace amounts of a genetically modified (GM) product that has not been approved for commercial use by any competent government authority.

[v] 'Low Level Presence' (LLP) refers to the unintended presence, at low levels, of minute amounts of GM plant material that has been approved in at least one country but not necessarily in the importing country.