CropLife International A.I.S.B.L.
Avenue Louise 326, box 35 - B-1050 - Brussels – Belgium
TEL +32 2 542 04 10 FAX +32 2 542 04 19 www.croplife.org

CropLife International

Detection Methods Project Team

Summary

The production and global trade of grain from genetically modified (GM) crops is increasing. Companies are required to provide validated diagnostic methods as a condition of the regulatory approval process in some jurisdictions. Numerous governmental agencies and industry organizations are attempting to develop standardization guidelines independently. Global harmonization of these efforts is necessary to ensure a consistent standard. CropLife International (CLI) supports international coordination of detection methods for plant biotechnology products and the proper development of guidelines for their use.

Background

While certain global regulatory bodies require development of DNA detection methods that allow for unique identification of commercial transgenic events, harmonised guidelines for the validation and use of these methods are not yet in place. As a result, numerous governmental agencies, global standards organizations (e.g. Codex, ISO) and industry organisations are attempting to develop their own independent standardisation guidelines for testing methodologies. Further complexity exists as a result of modifications made to registrant methods by regulatory officials. Screening methods are employed by some jurisdictions that add an even greater level of complexity and potentially misleading test results.

Reference Materials

CropLife International recognizes the need for materials for use in calibration and validation of detection methods as well as proficiency testing of laboratories. CropLife seeks to provide those materials to government agencies in a globally harmonized approach and provide them under principles for transfer in order to control the distribution and use of intellectual property.

Reference Materials are required as reference standards in method calibration and must be produced according to international standards and guidelines and may be certified. Reference materials will be made available for all products which are commercially available. These reference materials will be made available globally and on a single event basis by each company through a designated third-party source. The third-party source will be selected by each company based upon factors such as the following:

- Global presence
- Operational independence
- Dependability of supplier
- Experience in working with such materials under ISO standards

Polymerase Chain Reaction Technology as a Detection Method

The primary use of polymerase chain reaction (PCR) technology is to verify the presence or absence of a particular GM material in a product, or to quantify the amount of GM material present in a product. There are many areas to which attention must be paid in order to produce reliable test results. Because of the very high degree

of amplification of trace amounts of genetic material, PCR is prone to false positives and misleading results unless scrupulous attention is paid to avoiding sample contamination. It is critical that such methods are reliable and give the same results in laboratories across the world. This can only be achieved by proper validation of the methods.

As a tool to assist governments and others in addressing this issue, a group of seven authors from biotechnology companies, grain traders and private testing laboratories published a peer-reviewed document describing in detail the needs and requirements for successful application of PCR-based detection methods. This publication can be found at www.croplife.org.

Principles for the Transfer and Use of Intellectual Property

CLI member companies provide proprietary intellectual property, which includes reference materials and PCR methodology, to regulatory authorities as a condition of regulatory approval for GM traits. There are some basic principles of intellectual property rights that must apply to these materials:

- Non-commercial use: The regulatory authority's use of a registrant's proprietary intellectual property is solely for the purpose of fulfilling its regulatory obligations pursuant to the applicable laws and regulations. No commercial uses are authorized.
- Commercial use: Certain uses of a registrant's proprietary intellectual property may constitute an unauthorized commercial use and may require an agreement with the registrant. Examples might include the distribution of materials to labs

conducting fee-for-service activities or for the purpose of developing or selling kits.

- Method and material validation: A registrant should be involved in and review the data from the exercises conducted to validate detection methods.
- Analysis and derivation: A regulatory authority should not analyze, characterize, or develop derivative analytical protocols from the materials and protocols provided.
- Publication: A registrant should review and/or approve the draft of any manuscript resulting from the regulatory authority's use of a registrant's materials and protocols
- Duration of Supply: Conditions of maintenance and use should anticipate that the registered trait and products may be discontinued at a future time.

For more information on CropLife International's position on reference materials please see *"CropLife International Global Position On Materials for Use with Detection Methods"*

Crop Life International

CropLife International (CLI) is a global federation representing the plant science industry and a network of regional and national associations in 91 countries. As a global network that is based in Brussels, CropLife International acts as an ambassador for the plant science industry, encouraging understanding and dialogue whilst promoting agricultural technology in the context of sustainable development. Our members include BASF, Bayer, Dow AgroSciences, DuPont, Monsanto, and Syngenta.

The Detection Methods Project Team operates under the auspices of the CLI Regulatory Committee. The Team's objectives are the implementation of harmonised and practical laws, regulations or policies for the development, validation, and utilization of detection methods for plant biotechnology products, including the production, distribution, and use of rigorously defined and standardized reference materials by regulatory authorities globally.

CLI Detection Methods Project Team

Objectives:

1. Provide a forum for seed technology registrants to address industry-wide regulatory applications of detection methods and reference materials for GM crops.

2. Work towards global harmonization of standards and requirements:

    - Development, validation and utilization of GM detection methods
    - Production, distribution and use of related reference materials

3. Identify and resolve intellectual property issues associated with the possible misappropriation and unintended use of methods and reference materials.

Positions

CropLife believes that the global harmonisation of detection methods and reference materials for GM crops is necessary to ensure a

consistent standard. The absence of such standardised tests can result in inaccurate claims and enforcement actions being taken without a means to referee the results. Development of reliable, validated, internationally-accepted methods is necessary to avoid negative economic impacts on trade due to incorrect or inaccurate test results.

CropLife supports efforts towards global standardisation, such as the work being undertaken in the Codex Committee on Methods of Analysis and Sampling (CCMAS) to achieve consensus criteria for developing methods for detecting GM material in food. Global compatibility of test results is needed to facilitate international trade.

CropLife member companies are working with the global grain handling and processing value chain to provide access to seed specific diagnostic methods appropriate to their needs, and to encourage international coordination of existing test proficiency and validation efforts.