

## 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 DNA 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.

## References

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# Detection Methods in Plant Biotechnology

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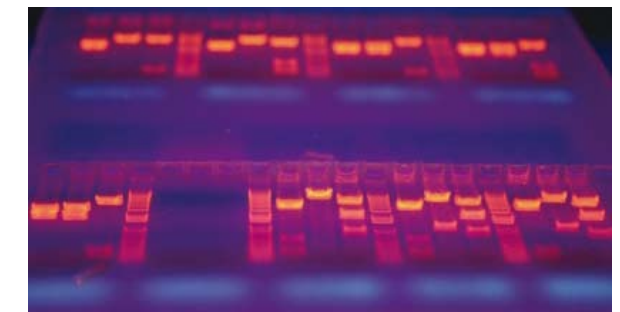
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## Summary

The production and global trade of products 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 organisations are attempting to develop standardisation guidelines independently. Global harmonisation of these efforts is necessary to ensure a consistent standard. CropLife International supports international coordination of detection methods for plant biotechnology products and the proper development of guidelines for their use.

## Global Methods Harmonisation

While certain global regulatory bodies require submission to them of detection methods that allow for identification of commercial transgenic events, global agreement on how to validate and use these methods is not yet in place. Numerous governmental agencies, global standards organisations (e.g. Codex, ISO) and industry organisations are attempting to develop standardisation guidelines for testing methodologies. Further complexity exists as a result of modifications made to the methods that are submitted, and due to regulatory agencies and other stakeholders developing their own methods. Screening methods are employed extensively, and add an even greater level of complexity and potential for misleading test results. The CropLife Detection Methods Project team works with governments, standardisation bodies and other stakeholders to increase the harmonisation of method use worldwide.



## Reference Materials

CropLife International recognises the need for standardised materials for 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 harmonised approach and provide them under principles for transfer that manage the distribution and use of intellectual property, as explained below.

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, and to the interpretation of results. 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 (Lipp et al., 2005).

## Protein-based Detection Methods

Protein-based detection methods are used extensively in the trade of commodities, as well as seed purity testing. These methods are robust and well-adapted to field use, as well as being suitable for laboratory use. Peer-reviewed documents describing in detail the needs and requirements for successful application of protein-based detection methods have been published by Grothaus et al. (2006) and Lipton et al. (2000).



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## Principles for the Transfer and Use of Intellectual Property

CropLife International 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 authorised.
- **Commercial use:** Certain uses of a registrant's proprietary intellectual property may constitute an unauthorised 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 third-party authority should not analyse, characterise, 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.

## CropLife International

CropLife International 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 CropLife International Regulatory Committee. The Team's objectives are the implementation of harmonised and practical laws, regulations or policies for the development, validation, and utilisation of detection methods for plant biotechnology products, including the production, distribution, and use of rigorously defined and standardised reference materials by regulatory authorities globally.

## CropLife International 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 harmonisation of standards and requirements:
  - Development, validation and utilisation 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.

