

Prepared by:	CropLife America Detection Methods Project Team
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Approved by:	CropLife International Detection Methods Project Team, CropLife International Biotech Committee

Position Paper

Consensus Position on Diagnostic Test Methods for Agricultural Biotechnology Products

We recognize that:

- Current global regulatory requirements for labelling of agricultural biotechnology products derived through the use of recombinant DNA technologies necessitate the development and validation of diagnostic methods for detection of protein and DNA associated with the introduced trait(s).
- Diagnostic methods are an integral part of proper product development, quality control, and regulatory data gathering for agricultural biotechnology products.
- Validation of methods designed to detect recombinant DNA and proteins expressed from the inserted DNA in seeds, plants, grain and processed fractions (where appropriate) is an integral step to implement and fulfil international regulatory requirements.
- Performance verified methodologies are needed in order to implement the use of accurate and precise methods for quantification of agricultural biotechnology products.
- While global regulatory bodies require development of DNA detection methods that allow for unique identification of commercial transgenic events, harmonized guidelines for the validation and use of diagnostic methods are not yet in place. As a result, numerous governmental agencies and industry organizations are attempting to develop and initiate standardization guidelines for testing methodologies. Global

harmonization of these efforts is necessary to ensure a consistent standard.

- Testing for agricultural biotechnology products is being performed on many grain and food products. The absence of standardization tests is resulting in inaccurate claims and enforcement actions being taken without a means to challenge the results. Development of reliable, validated methods is necessary to avoid negative economic impacts on trade due in incorrect or inaccurate test results.

Therefore, we support the following policy regarding diagnostic tests for agricultural biotechnology products. We will:

- Work with our direct customers and end users to provide access to diagnostic methods appropriate to their needs and to encourage international coordination of existing test proficiency and validation efforts.
- Work collaboratively to identify the analytical needs, relevant solutions and, as appropriate, provide access to consultation, diagnostic methodology and reference materials for globally approved agricultural biotechnology products to:
 1. Licensees of traits and products containing traits derived through recombinant DNA technology
 2. Developers and distributors of seed products containing the biotechnology derived traits
 3. Members of the commodities industry
 4. Members of the processed food and feed industries
 5. Government agencies involved in the regulation of biotechnology derived crops
 6. Government agencies and supra-governmental organizations (e.g. CODEX) involved in validation of diagnostic methods
 7. Accredited laboratories that support the above industries.
- Support activities of industry associations and governmental agencies to develop and adopt guidelines for proper development, validation and use of diagnostic methods and associated reference materials; and
- Cooperate in initiatives on laboratory certification.