Crop Life International Detection Methods Project Team & ABLE - AG

Detection Methods Website www.detection-methods.com

November 22nd, New Delhi



Detection Methods

CropLife International (CLI)

- Global federation representing the plant science industry and a network of regional and national associations in 91 countries
- Acts as an ambassador for the plant science industry, based in Brussels
- Biotech Members: BASF, Bayer, Dow AgroSciences, DuPont, Monsanto, and Syngenta

CLI Detection Methods Project Team

 Implementation of harmonized and practical laws, regulations or policies for the development, validation, and utilization of detection methods for plant biotechnology products



Detection Methods

- 1. Provide a forum for seed technology registrants to address industry-wide regulatory applications of detection methods and reference materials.
- 2. Work towards global harmonization of standards and requirements:
 - development, validation and utilization of GMO <u>detection methods</u>.
 - production, distribution and use of related reference materials.
- 3. Assess intellectual property issues associated with methods and reference materials.



CropLife International (CLI) Position

CLI member companies:

- Recognize the need for reference materials for use in calibration, validation and proficiency testing of detection methods.
- Seek to provide those materials to government agencies in globally harmonized approach.
- Seek to provide materials under principles for transfer in order to control the distribution and use of intellectual property.



Situation Analysis

- ➤ Crop Life International (CLI) Companies have committed to make our detection methods and reference materials available for regulatory requirements, consumer preference and stewardship of our products
- Currently, event specific detection methods are initially made public under the name of JRC (EURL – European Union Reference Laboratories) as a requirement of registration
- ➤ Other than commercial fee for service testing agreements, CLI Companies are not using our IP to restrict use of the methods



Recommendation

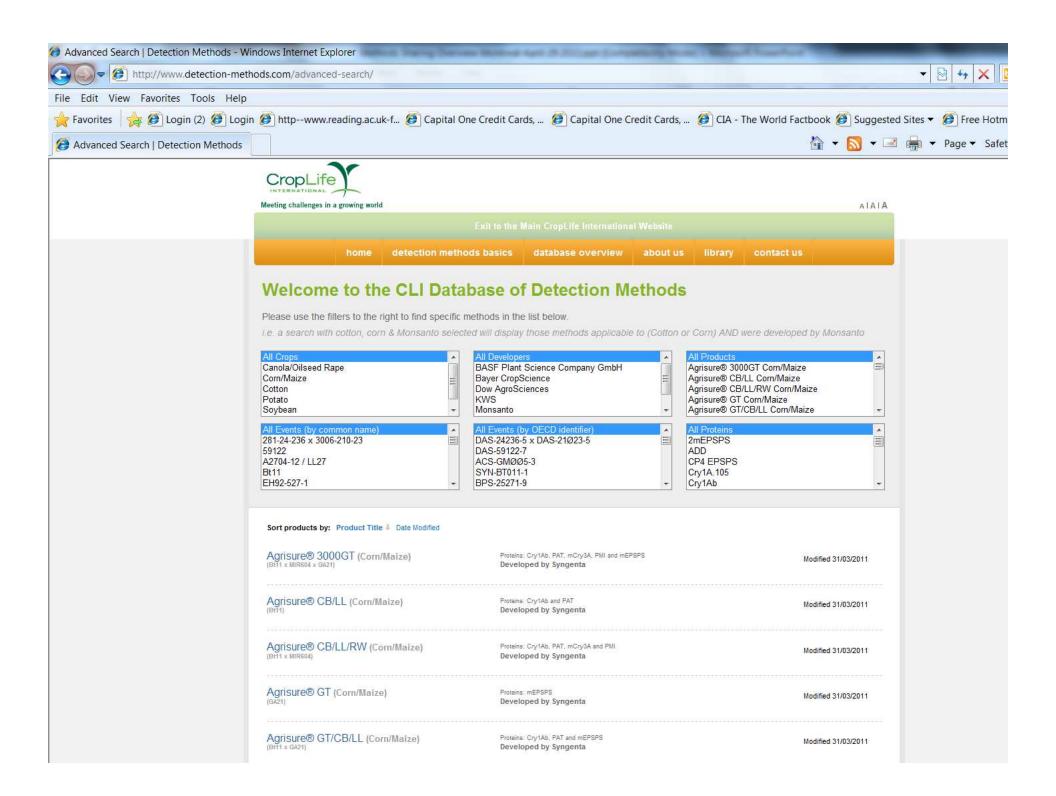
- CLI Companies <u>publish</u> detection methods, associated information and link to sources of reference material (AOCS) on CLI web site
- Timing would be after approval but upon commercial sales
- ➤ In order to access/download the information, requestor must agree to <u>terms</u> in drop down box
 - > Only restriction would be to prohibit fee for service testing (unless covered under a separate license agreement)
 - Terms would allow other companies to use the method for AP testing of seed for quality and product stewardship
 - Provide contact information of party making request



Benefits

- ➤ Enables other companies to test for AP in their seeds without additional legal agreements
- Clearly asserts CLI company methods, reference materials, etc. as the only methods that CLI companies support
- Might limit proliferation of other methods and reference materials which could otherwise slow down harmonization of test results
- > Transparency, stewardship and goodwill
- Questions, inquiries come directly to trait provider
- Open to others willing to post detection methods www.detection-methods.com





http://www.detection-methods.com/wpcontent/themes/detectionmethods/private_file.php?key=13218048970927
(Valid for 14 days)

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Monsanto Company Standard Operating Procedure BQ-QC-10030-02 Page 1 of 5

Corn MON88017 Event Specific EndPoint TaqMan PCR with PUB-pea ubiquitin Internal Control for 1:200 Seed Pools

RESTRICTED USE Downloaded and used subject to and under license from Monsanto Company Controlled Document/Distribution The distribution of this SOP is controlled by the Proficiency Testing Team Lead. A matrix/database controls the distribution of the SOP and revision levels.

Overview Purpose & Scope This SOP describes the method used by Seed Quality Technology at Monsanto to confirm the presence of the corn MON88017 transformation event in genomic DNA extracted from seed tissue. This method will also confirm the integrity of the template DNA by amplification of PUB-pea



Thank you

For more details,
 please contact
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