BEST PRACTICE GUIDELINES

Australian Seed Federation
SOWING SEEDS

FOR THE MANAGEMENT OF GM TRAITS IN CANOLA SEED

Developed by the Australian Seed Federation Biotechnology Committee

August 2015

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1. *Purpose and Aims of this Manual:*

The purpose of this manual is to describe the process and protocols to be followed by members of the Australian Seed Federation for all non-GM canola seed sold for sowing in Australia in relation to the unintended or low level presence of Genetically Modified (GM) material. This is to ensure that members of the Australian Seed Federation comply with Australian regulatory requirements and/or industry standards without losing the benefits of international collaborations or imposing a significant cost burden on the organization.

The focus of these procedures is where the consequences of unintended or low level presence (LLP) are greatest rather than where the likelihood of such presence is greatest. A very high level of confidence is demanded that a commercially sold variety is free of non-approved GM seed. A lesser, but still stringent level of confidence is similarly demanded that a commercially sold non-GM canola variety is free of GM events approved for commercial release in Australia by the OGTR. .

The aim is that all seed released into the environment has a risk assessment and that where an identified risk exists, varieties will have been through a rigorous screen to provide a high level of confidence that they do not contain either OGTR-approved events or non-approved GM seed, and that where appropriate seed lots are screened to ensure that the presence of any GM events, if any, is below generally accepted levels of detection or regulatory and/or industry requirements. Any seed lot produced in an area where GM crops of that species are grown will be tested to a level of scrutiny consistent with any regulatory requirements.

2. *Scope:*

This guide applies to members of the Australian Seed Federation selling canola seed for sowing in Australia..

3. *Definitions*

GM Event: Refers to each instance of a genetic modification of a GMO. For example, the same gene inserted by man into a given plant genome at two different locations along that plant's DNA would be considered two different "events".

GMO: Genetically Modified Organism. An organism such as a plant that has undergone specific genetic manipulation techniques defined by the OGTR.

Seed Low Level Presence: The unintended low level presence of a GM Event in seed that has been approved for unrestricted cultivation in at least one other country but not in the country of import.

Non-approved GM Seed: Seed that has tested positive for the presence of a GM event that has not been approved by the OGTR for commercial release in Australia.

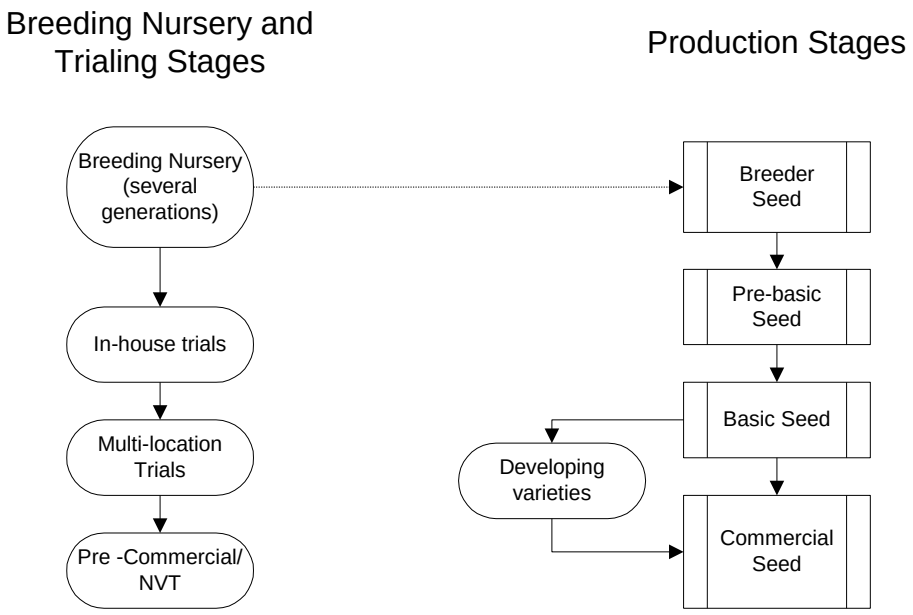
OGTR: The Office of the Gene Technology Regulator provides administrative support to the Gene Technology Regulator in the performance of his functions under the *Gene Technology Act 2000 (Cth)*. Under the Act, there is a national scheme for the regulation of GMOs in Australia.

PCR: Polymerase Chain Reaction: A laboratory test that amplifies (makes millions of copies of) DNA sequences present in the sample. Without amplification, the sequence could not be detected or studied. This enables the detection of trace amounts of the DNA sequence of interest. Where PCR's are used to check for low level presence, the DNA sequences amplified are chosen to indicate the presence of a specific GM event. The test is reliable provided the testing laboratories techniques are sound and the sequence being tested reliably identifies the GM event.

4. *Procedures:*

For consistency, the names of the various stages involved in the breeding, trialing and production of seed in Australia will be referred to as per the following diagram. Decisions to commercialize a variety and begin the parent seed bulk up phase may be taken at different stages in the breeding and trialing process, depending on varietal performance and market influences. It is therefore possible to have production or bulk up of parent seed and trialing occurring simultaneously.

Figure1:- Diagram of Breeding, Trialing and Production Stages



4.1. Breeding Nurseries

Definition:
Nurseries are under the direct supervision of the breeder or researcher. The primary purpose of the nursery is for preliminary evaluation, comparison, observation and crossing of genotypes as part of the development and selection of new varieties.

Requirements:
The actual area of any one genotype in a nursery is below 0.01 ha and seed produced in the nursery is not harvested for inclusion in the commercial grain crop. Seed from a nursery would not be used for production of commercial seed without further seed increase generations in isolation from other varieties. Testing of this material is not mandatory provided the breeder has in place procedures to manage the risk of GMOs in imported material.

Responsibilities reporting and recording:

Breeder or relevant manager must have documentary evidence of the GM free status of all material in their program.

4.2. Multi Location Field Trials

Definition:
Research trials where varieties are tested in small plots, in multiple locations across the growing areas.

Requirements:
The actual area of any one genotype in a trial is usually below 0.01 ha. Seed from a trial would not be used for production of commercial seed without further seed increase generations in isolation from other varieties. Testing of this material is not mandatory provided breeder has in place procedures to manage the risk of GMOs in imported material.

Responsibilities reporting and recording:
Relevant manager must have documentary evidence of the GM status of all material being used in these trials.

4.3. Pre-Commercial Strip Trial Entries:

Definition:
Varieties that are in the final stages of evaluation: seed will be distributed to farmers for on farm evaluation, grown in commercial situations, or grown in national variety trials (NVTs). The produce from the crop may be used for food or feed, and it may be commingled with commercially produced product.

Requirements for testing canola seed imported for pre-commercial strip trials in Australia for low level presence:
The sowing seed should be tested to give 99% confidence that no unapproved events are present in a test of at least 4600 seeds. This requirement would be negated if the variety had passed the requirements for variety commercialisation as described in 4.5.

Requirements for testing of seed produced in Australia for the presence of OGTR approved GM events:
As the areas of each variety grown are larger than in-nursery or multi-location trials, seed should be tested to give 95% confidence that the presence of OGTR approved GM events is less than the accepted tolerance (as well as ensuring that no low level presence of non approved GM seed is detected. This requirement would be negated if the variety has passed the tests required for variety commercialisation in 4.5.

Responsibilities reporting and recording:
Pre-Commercial Strip Trials Entries: Relevant Manager is responsible for ensuring all entries into these trials meet the requirements listed above.

4.4. Contract Production

Definition:
Production of seed of varieties not commercialized in Australia intended for export to off shore clients. Production in Australia is restricted to seed production sites under the supervision of the Production Company. (If contracted production is performed on behalf of 3rd parties for sale into the domestic market, then same rules as in 4.5 below are applicable).

Requirements for testing for low level presence:
The sowing seed should be tested to give 99% confidence that no unapproved events are present in a test of at least 4600 seeds. This requirement would be negated if the variety had passed the requirements for commercialisation as described in 4.5.

Responsibilities reporting and recording:
Contract Production:
The Relevant Manager is responsible for ensuring that supplied seed has either a declaration from the supplying party or is tested prior to use.

Reporting and recording:
Test results and declarations should be recorded and maintained by the responsible manager.

4.5. Variety Commercialisation

Definition:
The breeder intends to progress the variety for commercial sale, releasing breeder seed for increase by the commercial department or marketer.
(Note : This can occur before, or at the same time as trialing in commercial strip trials, NVTs, etc).

Requirements:
Unless there is documentary evidence that provides a high level of confidence that there is no GM material within the breeding program, the following criteria must be met for each variety leaving the breeding program.

1. An absolute test (tissue sample) where all plants producing seed intended to form the new variety are tissue sampled and tested for the presence of unintended GM events. Pollination of these plants must be controlled by ensuring physical or temporal isolation from other sexually compatible plants. The number of plants pooled for this test must be limited to a level where a single GM plant can still be reliably detected. The primer set or type of testing chosen must be reasonably capable of detecting all relevant commercialized GMOs, those that have been in extensive field trials globally plus those that have been in the program of the breeding organizations or its associated programs identified through an appropriate risk assessment.

Or

2. At least 7 seeds from each individual plant that will form the variety are sampled bulked and without subdividing the bulk seed sample before grinding, the sample is tested using a primer set as specified in 1. (Provides 99.9% confidence that there is no unintended presence).

Alternatively, where neither 1 nor 2 is possible,

3. A sample based test of the variety using a primer set as in 1 above. The testing plan must give at least 99% confidence that any unintended presence is below 0.01%.

A sample based test (Option 3) at this level is a compromise that recognises that in some instances an absolute test is not possible, or practical. However, as all seed cannot be tested, either the population must be small, or the sample size needs to be large, to give a very high level of confidence.

Responsibilities reporting and recording:
Test results and declarations should be recorded and maintained by the Relevant Manager.

4.6. Pre Basic, Basic (Foundation) Seed

Definition:
Seed produced or used to produce seed for sowing for commercial production.

Requirements:
An assurance that the variety has been variety tested as described in section 3.4 above, is a pre-requisite for seed reaching this level. Thereafter, no additional testing is required unless the seed line has been produced in a field, or directly adjacent to a field, where GMOs are being grown, or have been grown in the previous 12 months, or where planting/ harvesting/ processing equipment has been used for OGTR approved GM canola in the previous 12 months. In these instances the grower line should be tested for the particular GMOs potentially present.

The level of testing should be sufficient to give 95% confidence that any presence of OGTR-approved GM events is less than the agreed tolerance. Commercial lots should not be grown in fields or directly adjacent to fields where GMOs not approved for commercial release by the OGTR are being grown, or have been grown in the previous 12 months. In addition, handling / processing equipment should not have been used for GMOs not approved for commercial release by the OGTR in the previous 12 months. (This is consistent with OGTR rules for field trials of such GM events).

Where testing is required the sowing seed should be tested to give 99% confidence that no **non-approved GM seed** is detected in a test of 4600 seeds.

4.7. Commercial Seed Lots:

Definition:
Seed being sown for commercial grain production.

Requirement:
An assurance that the variety has been variety tested as described in section 3.4 above, is a pre-requisite for seed reaching this level. Thereafter, no additional testing is required unless the seed line has been produced in a field, or directly adjacent to a field, where GMOs are being grown, or have been grown in the previous 12 months, or where planting/ harvesting/ processing equipment has been used for OGTR approved GM canola in the previous 12 months. In these instances the grower line should be tested for the particular GMOs potentially present.

The level of testing should be sufficient to give 95% confidence that any presence of OGTR-approved GM events is less than the agreed tolerance. Commercial lots should not be grown in fields or directly adjacent to fields where GMOs not approved for commercial release by the OGTR are being grown, or have been grown in the previous 12 months. In addition, handling / processing equipment should not have been used for GMOs not approved for commercial release by the OGTR in the previous 12 months. (This is consistent with OGTR rules for field trials of such GM events).

Where testing is required the sowing seed should be tested to give 99% confidence that no **non-approved GM seed** is detected in a test of 4600 seeds.

Responsibilities reporting and recording: Relevant manager must have documentary evidence of the GM status of all material being used in this production.

4.8. Seed Imports:

4.8.1. Germplasm and Breeding Lines:

Definition:
Seed material to be used in Australia under the direct supervision of the breeder, in breeding nurseries or controlled pollination environments. It would not be used in multi location trials or for commercial demonstration plots, or for open field seed increases.

Requirements:
Supplier Declaration:
The supplier of the seed should provide a declaration that the GM status of the seeds is as described, that the supplier has in place QA procedures that minimize the risk of low level presence of GM events and that to the best of the supplier's knowledge no low level presence is present (Appendix 1). In the absence of a suitable supplier declaration, the breeder must apply appropriate risk management procedures such as testing or physical isolation during production.

Responsibilities reporting and recording:

Relevant manager must have documentary evidence of the GM status of all material entering their program or take appropriate risk management actions.

4.8.2. Commercial Seed, Parent Seed, Pre-commercial trials and NVT trials:

Definition:

This is seed intended for use to produce either seed or grain in a commercial open field environment.

Requirements:

The variety must comply with the requirements set out in section 4.4 and each seed lot or the consignment must be tested for the presence of all OGTR-approved GM events, and any that have been in, or are believed to have been in, extensive field trials. The testing level must be sufficient to give 95% confidence that any OGTR approved GM events, if present, are at levels below the accepted tolerance, and that no non-approved GM seed is detected.

Commercial lots should not be grown in fields or directly adjacent to fields where GMOs not approved for commercial release by the OGTR are being grown, or have been grown in the previous 12 months. In addition, handling / processing equipment should not have been used for GMOs not approved for commercial release by the OGTR in the previous 12 months. (This is consistent with OGTR rules for field trials of such GM events).

The testing level must be sufficient to give 99% confidence there is no low level presence of non-approved GM seed in a test of at least 4600 seeds.

Responsibilities reporting and recording:

The Relevant Manager is responsible for ensuring all seed is compliant prior to sowing and for maintaining records of documentary evidence

5. *Seed Purchases:*

Where seed is purchased from other suppliers a declaration, including any documentary evidence of its GM event status, should be requested and be a condition of purchase (Appendix 1).

6. *Review:*

These procedures will be reviewed annually under the guidance of the Australian Seed Federation.

7. *Links:*

The OGTR maintain a Record of all GM Events approved in Australia. This includes information specific to approvals for limited and controlled field trials and for commercial releases, as listed under "Dealings Involving Intentional Release (DIR)".
Information relating to the global status of GMOs can be found using the following links:

- CERA website: http://cera-gmc.org/index.php?action=gm_crop_database .
- CropLife International website: www.BIOTradeStatus.com.

Other sites to consider are:

- Agrilife
- The Global Pipeline of New GM Crops
- Biosafety Clearing House - Living Modified Organism (LMO) Registry http://bch.cbd.int/database/lmo-registry/

Appendix 1

Declarations:

To be provided to customers / cooperators requesting a declaration and as a pro-forma for suppliers declarations.

A general statement is needed to explain the reasons behind the request and to provide a link to further information on the detail of the requirements that it is expected they will meet. This would accompany the purchase contract/ order, production contractor, MTA etc. For example:

["The XYZ Seed Company"] takes its responsibility to comply with its legal and commercial obligations seriously. Consistent with these obligations and the Industry wide recognition that we have shared Genetically Modified Organisms (GMOs) stewardship obligations the Company has introduced procedures throughout its operations to minimize the risk of adventitious presence of GMOs. We are requesting suppliers to examine their procedures to ensure they are following good industry practices to minimize the risk of adventitious presence of GMOs.

Seed Supplier Declaration:

The seeds, which are supplied with this delivery, are conventional varieties bred from parent plants that have not been genetically modified. Where Genetically Modified Organisms (GMOs) technology is applied in the species methods and procedures are used in the breeding and development of these varieties aimed at minimising the likelihood of the presence of Genetically Modified Organisms ('GMO')..... (The supplier) does not have in its possession any evidence that the seeds in this consignment contain GMOs.

……(the supplier) gives no guarantee that the seed is GMO free and can accept no liability for any damage whatsoever arising from the possible occurrence of adventitious traces of GMO.

Standard Sale Condition

The seeds, which are supplied with this delivery, are conventional varieties bred from parent plants that have not been genetically modified. Where Genetically Modified Organisms (GMOs) technology is applied in the species methods and procedures are used in the breeding and development of these varieties aimed at minimising the likelihood of the presence of Genetically Modified Organisms ('GMO'). The ("XYZ Seed Company") has no evidence in its possession that the seed in this consignment contains levels of approved GMOs above the Industry accepted thresholds and we have no evidence of the presence of unapproved GMOs.

("XYZ Seeds") gives no guarantee that the seed is GMO free and can accept no liability for any damage whatsoever arising from the possible occurrence of adventitious traces of GMOs. (as above comment)

Germplasm Supplier Declaration

The varieties (Insert Variety name), which are supplied with this delivery, are conventional varieties bred from parent plants which have not been genetically modified. Where Genetically Modified Organisms (GMOs) technology is applied in the species methods and procedures are used in the breeding and development of these varieties aimed at minimising the likelihood of the presence of Genetically Modified Organisms (GMOs). Where the variety or seeds of this consignment have been tested for the presence of GMOs, no evidence of GMOs has been found. ..... (The supplier) does not have in its possession any evidence that the seeds in this consignment contain GMOs.

Appendix 2

Variety GM Status record

Species……..
Variety……..
Breeder……..
GM status of Species……
Review date……..
By Whom……
References - Office of the Gene Technology Regulator or www.ogtr.gov.au
ISAAA http://www.isaaa.org/gmapprovaldatabase/default.asp

The relevant manager maintains a database of the GM status of all varieties

Appendix 3

Sample Size

The sample size affects the confidence levels and accuracy of the tests.

Some relevant tolerances and test numbers (with no deviants) are shown in the following table reproduced from The American Seed Trade Association (ASTA) paper “Standardization of Seed Testing Protocols for Adventitious Presence”:

Confidence Level (%)	AP Purity Standard	No. Seeds to be tested
95	1.0	300
	0.5	600
	0.1	3000
	0.01	30000
99	1.0	460
	0.5	1000
	0.1	4600
	0.01	46000
100	0.0	All Seed