



GM Inspectorate guidance for processors

SEED PROCESSOR ASSURANCES

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Dear Seed Processor

Seed audit programme 2008 – seed processor assurances.

As you may be aware, before obtaining and supplying seed, importers and producers of seed are under a legal duty to take steps to minimise the risk of adventitious GM presence in conventional seed.

The GM Inspectorate on behalf of Plant Variety Rights Office and Seeds Division of Defra conducts audits of seed merchants & producers within the UK to assist them in meeting their duties under EC Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The GM Inspectorate has authority under Part VI of the Environmental Protection Act 1990 to carry out the necessary inspection and enforcement activities to ensure that the requirements of EC Directive 2001/18/EC are met.

The GM Inspectorate has identified the processing, cleaning and treating stages of seed production as a potential risk area through admixture of GM seed with seed of conventional varieties. It is important therefore that seed companies requesting information from processors are provided with assurances to a suitable standard in order to help them meet the audit requirements.

Although the legal onus regarding marketing of GMOs falls to the marketing company, in order to facilitate improved processor assurances the GM Inspectorate has provided this letter, and the attached guidance documents regarding assurances to seed merchants and producers, for the marketing companies to forward to their processors.

As a licensed seed processor you may wish to consider what further protocols you have in place above those required for normal seed certification: these may be general standards, e.g. ISO or similar accreditation, industry standards, e.g. HVS, or specific standards relating to GMOs. Measures specific to GMOs may be as simple as not deliberately processing GM seed but should ideally take account of the possibility of inadvertently processing GM seed through the adventitious presence of GMOs. Extra measures might, for example, include a requirement that customers provide written assurances or GM test certificates for their seed before it is accepted into your plant.

The GM Inspectorate hopes you will find this guidance useful and that it will aid you in answering questions from your seed company customers regarding adventitious GM presence.

Yours sincerely,

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Guidance for importers and producers on audits for adventitious GM presence in seed of conventional varieties of *BRASSICA NAPUS* (spring and winter oilseed rape, swede and swede forage rape)

Before obtaining and supplying seed, importers and producers should ensure that steps have been taken to minimise the risk of adventitious GM presence in conventional *Brassica napus* crops (spring and winter oilseed rape, swede and swede forage rape) intended for the UK market, in line with their duties under Part VI of the Environmental Protection Act 1990¹.

The GM Inspectorate currently undertakes voluntary audits of seed importers and producers in order to assist them in meeting their duties. The audits are intended to help companies ensure that they have suitable controls in place and that there is appropriate supporting documentation. The audits also include seed intended for private trials purposes. PVS Division of Defra is responsible for seed intended for official trials.

The audit does not relieve companies of their obligations nor should it be seen as an assurance that the GM Inspectorate will not exercise its powers in appropriate cases under Part VI of the Environmental Protection Act 1990.

Detailed information

Companies that have agreed to participate in the audit programme are asked to provide details of seed to be marketed as a conventional variety in the UK or to be placed in private trials. The procedures and types of documentation that will help in demonstrating that suitable controls are in place to minimise the risks of adventitious GM presence are detailed below.

1. Letters of Assurance from the breeder giving assurances that the seed is free from adventitious GM presence. Letters of assurance should include:

- (i) production history of the seed (including, where available, original source and location details), confirmation that seed has been obtained from conventional varieties, maintained under a recognised seed production scheme (e.g. following OECD guidelines) and has been isolated from transgenic lines.

If analytical tests relating to individual lots, batches or parental stock(s) have been performed then information on this testing would improve the documentation. An indication of the sensitivity level of the tests employed should be given - see (2 vi) below.

- (ii) details of the systems or protocols in place to prevent contamination during harvesting, storage and processing.

Letters of assurance may additionally be supported by:

2. Analytical tests on individual seed batches or lots. If test results alone are presented for batches of seed, guarantees should be provided on the separate handling of the seed subsequent to testing (e.g. following OECD scheme rules). All test certificates should clearly identify the seed lots or batches to which they refer. Analytical tests may be protein-based or, more commonly, DNA-based 'PCR' tests. Importers and producers who wish to use an alternative to PCR testing methods should consult the GM Inspectorate with details of the type and sensitivity of the method proposed.

As a minimum PCR tests should:

- (i) be carried out on a representative sample of the seed lot (e.g. systematic sampling to prepare a working sample in accordance with the ISTA rules for seed purity);
- (ii) be carried out on a minimum working sample for analysis that contains no less than 3000 seeds, in line with the proposed protocol submitted to the EC Standing Committee on Seeds in 2001;
- (iii) include appropriate positive and negative controls for performing the PCR test;
- (iv) consist of testing with a combination of commonly used promoter and terminator sequences and antibiotic markers, e.g. CaMV p35S (cauliflower mosaic virus promoter), pNOS, and NptII (the selectable marker for kanamycin resistance). Testing for sequences for specific traits such as PAT/BAR (Liberty link) and GOX (RoundUp Ready) may also be appropriate to strengthen

¹ Under Part VI of the Environmental Protection Act 1990, the importation, acquisition, release or marketing of genetically modified organisms are prohibited unless the requirements for carrying out a risk assessment, giving notification or obtaining a consent are satisfied. In respect of England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) prescribe further matters in relation to Part VI of the Act.

the assurance provided by the testing regime. Where PCR tests are used that span the junctions of genetic elements that are juxtaposed in a specific GM construct/s, the testing laboratory should provide details of the GM lines that are detected by these tests (see point (d) below). It is important to note that the number and type of GM constructs being released both experimentally and commercially is constantly changing and if PCR tests are commissioned they must adequately reflect current risks. Seed companies are therefore requested to ensure that the names of the **specific genetic elements** being tested for are made available. The use of bioassay tests may also be appropriate for certain specific traits;

- (v) address the risk of possible false positives resulting from environmental contamination with DNA (e.g. from cauliflower mosaic virus or soil-borne bacteria);
- (vi) be conducted to a sensitivity level of at least 0.1%, in line with the opinion from the EC Scientific Committee on Plants of 7 March 2001 (indicating that the limit of analytical sensitivity of available detection methods is currently at about 0.1% for routine analysis);
- (vii) provide a clear indication of any standards/accreditation to which the analysis conforms, e.g. UKAS, AFNOR, GLP, ISO17025, etc.;
- (viii) in all cases report the **actual result for the test** with the associated measurement uncertainty for the result (e.g. \pm 95% confidence limits).

The following important points should be noted:

- a) There are currently no Part C authorisations for the use of GM *Brassica napus* seed for cultivation in the EU. Therefore, where a PCR test on an individual batch or seed lot indicates an adventitious GM presence at any detection level none of the seed can be marketed or planted. Further advice should be sought from the GM Inspectorate.
- b) A positive PCR result on one seed lot would not necessarily mean that sister lots from the same crop will be affected. However, this will be explored on a case-by-case basis.
- c) Companies marketing seed are legally responsible for ensuring that they do not market an unauthorised GMO. They should therefore take account of the whole supply chain including processing, i.e. cleaning, treating and bagging, as adventitious GM presence could be introduced at any of these stages through admixture with other seed. Companies should ensure that the processors they employ have appropriate measures in place to minimise the risk of acquiring adventitious GM presence, and that the processors provide written assurances to demonstrate this.
- d) Testing laboratories are increasingly using tests for junctions between two GM elements, in contrast to the former practice of testing for a range of individual GM elements. While junction-spanning tests can increase the specificity of tests and reduce the likelihood of obtaining false positives, companies commissioning such tests should be aware that the increased specificity is gained as a result of detecting only those genetic events where the precise junction between two elements occurs in the transformed line. Therefore, unlike GM tests screening for a range of individual elements, junction-spanning tests will not detect GM lines in which only one of the elements occurs or where no junction between the two specific elements occurs, hence a negative result does not necessarily indicate the absence of adventitious GM presence.

If you have any doubts regarding the suitability of letters of assurance and/or testing, please seek advice from the GM Inspectorate prior to an audit or any subsequent marketing of the seed.

Guidance for importers and producers on audits for adventitious GM presence in seed of conventional varieties of *BRASSICA RAPA*

Before obtaining and supplying seed, importers and producers should ensure that steps have been taken to minimise the risk of adventitious GM presence in conventional *Brassica rapa* (**turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc.**) intended for the UK market, in line with their duties under Part VI of the Environmental Protection Act 1990².

The GM Inspectorate currently undertakes voluntary audits of seed importers and producers in order to assist them in meeting their duties. The audits are intended to help companies ensure that they have suitable controls in place and that there is appropriate supporting documentation. The audits also include seed intended for private trials purposes. PVS Division of Defra is responsible for seed intended for official trials.

The audit does not relieve companies of their obligations nor should it be seen as an assurance that the GM Inspectorate will not exercise its powers in appropriate cases under Part VI of the Environmental Protection Act 1990.

Detailed information

Companies that have agreed to participate in the audit programme are asked to provide details of seed to be marketed as a conventional variety in the UK or to be placed in private trials. The procedures and types of documentation that will help in demonstrating that suitable controls are in place to minimise the risks of adventitious GM presence are detailed below.

3. Letters of Assurance from the breeder giving assurances that the seed is free from adventitious GM presence. Letters of assurance should include:

- (iii) production history of the seed (including, where available, original source and location details), confirmation that seed has been obtained from conventional varieties, maintained under a recognised seed production scheme (e.g. following OECD guidelines) and has been isolated from transgenic lines.

If analytical tests relating to individual lots, batches or parental stock(s) have been performed then information on this testing would improve the documentation. An indication of the sensitivity level of the tests employed should be given - see (2 vi) below.

- (iv) details of the systems or protocols in place to prevent contamination during harvesting, storage and processing.

Letters of assurance may additionally be supported by:

4. Analytical tests on individual seed batches or lots. If test results alone are presented for batches of seed, guarantees should be provided on the separate handling of the seed subsequent to testing (e.g. following OECD scheme rules). All test certificates should clearly identify the seed lots or batches to which they refer. Analytical tests may be protein-based or, more commonly, DNA-based 'PCR' tests. Importers and producers who wish to use an alternative to PCR testing methods should consult the GM Inspectorate with details of the type and sensitivity of the method proposed.

As a minimum PCR tests should:

- (ix) be carried out on a representative sample of the seed lot (e.g. systematic sampling to prepare a working sample in accordance with the ISTA rules for seed purity);
- (x) be carried out on a minimum working sample for analysis that contains no less than 3000 seeds, in line with the proposed protocol submitted to the EC Standing Committee on Seeds in 2001;
- (xi) include appropriate positive and negative controls for performing the PCR test;
- (xii) consist of testing with a combination of commonly used promoter and terminator sequences and antibiotic markers, e.g. CaMV p35S (cauliflower mosaic virus promoter), pNOS, and NptII (the selectable marker for kanamycin resistance). Testing for sequences for specific traits such as PAT/BAR (Liberty link) and GOX (RoundUp Ready) may also be appropriate to strengthen the assurance provided by the testing regime. Where PCR tests are used that span the junctions

² Under Part VI of the Environmental Protection Act 1990, the importation, acquisition, release or marketing of genetically modified organisms are prohibited unless the requirements for carrying out a risk assessment, giving notification or obtaining a consent are satisfied. In respect of England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) prescribe further matters in relation to Part VI of the Act.

of genetic elements that are juxtaposed in a specific GM construct/s, the testing laboratory should provide details of the GM lines that are detected by these tests (see point (d) below). It is important to note that the number and type of GM constructs being released both experimentally and commercially is constantly changing and if PCR tests are commissioned they must adequately reflect current risks. Seed companies are therefore requested to ensure that the names of the **specific genetic elements** being tested for are made available. The use of bioassay tests may also be appropriate for certain specific traits;

- (xiii) address the risk of possible false positives resulting from environmental contamination with DNA (e.g. from cauliflower mosaic virus or soil-borne bacteria);
- (xiv) be conducted to a sensitivity level of at least 0.1%, in line with the opinion from the EC Scientific Committee on Plants of 7 March 2001 (indicating that the limit of analytical sensitivity of available detection methods is currently at about 0.1% for routine analysis);
- (xv) provide a clear indication of any standards/accreditation to which the analysis conforms, e.g. UKAS, AFNOR, GLP, ISO17025, etc.;
- (xvi) in all cases report the **actual result for the test** with the associated measurement uncertainty for the result (e.g. \pm 95% confidence limits).

The following important points should be noted:

- There are currently no Part C authorisations for the use of GM *Brassica rapa* seed for cultivation in the EU. Therefore, where a PCR test on an individual batch or seed lot indicates an adventitious GM presence at any detection level none of the seed can be marketed or planted. Further advice should be sought from the GM Inspectorate.
- A positive PCR result on one seed lot would not necessarily mean that sister lots from the same crop will be affected. However, this will be explored on a case-by-case basis.
- Companies marketing seed are legally responsible for ensuring that they do not market an unauthorised GMO. They should therefore take account of the whole supply chain including processing, i.e. cleaning, treating and bagging, as adventitious GM presence could be introduced at any of these stages through admixture with other seed. Companies should ensure that the processors they employ have appropriate measures in place to minimise the risk of acquiring adventitious GM presence, and that the processors provide written assurances to demonstrate this.
- Testing laboratories are increasingly using tests for junctions between two GM elements, in contrast to the former practice of testing for a range of individual GM elements. While junction-spanning tests can increase the specificity of tests and reduce the likelihood of obtaining false positives, companies commissioning such tests should be aware that the increased specificity is gained as a result of detecting only those genetic events where the precise junction between two elements occurs in the transformed line. Therefore, unlike GM tests screening for a range of individual elements, junction-spanning tests will not detect GM lines in which only one of the elements occurs or where no junction between the two specific elements occurs, hence a negative result does not necessarily indicate the absence of adventitious GM presence.

If you have any doubts regarding the suitability of letters of assurance and/or testing, please seek advice from the GM Inspectorate prior to an audit or any subsequent marketing of the seed.

CSL GM Inspectorate (2nd June 2008)

Guidance for importers and producers on audits for adventitious GM presence in seed of conventional varieties of SOYA.

Before obtaining and supplying seed, importers and producers should ensure that steps have been taken to minimise the risk of adventitious GM presence in conventional **soya** seed intended for the UK market, in line with their duties under Part VI of the Environmental Protection Act 1990³.

The GM Inspectorate currently undertakes voluntary audits of seed importers and producers in order to assist them in meeting their duties. The audits are intended to help companies ensure that they have suitable controls in place and that there is appropriate supporting documentation. The audits also include seed intended for private trials purposes. PVS Division of Defra is responsible for seed intended for official trials.

The audit does not relieve companies of their obligations nor should it be seen as an assurance that the GM Inspectorate will not exercise its powers in appropriate cases under Part VI of the Environmental Protection Act 1990.

Detailed information

Companies that have agreed to participate in the audit programme are asked to provide details of seed to be marketed as a conventional variety in the UK or to be placed in private trials. The procedures and types of documentation that will help you in demonstrating that appropriate steps have been taken to minimise the risks of adventitious GM presence are detailed below.

5. Letters of Assurance from the breeder giving assurances that the seed is free from adventitious GM presence. Letters of assurance should include:

- (v) production history of the seed (including, where available, original source and location details), confirmation that seed has been obtained from conventional varieties, maintained under a recognised seed production scheme (e.g. following OECD guidelines) and has been isolated from transgenic lines.

If PCR tests relating to individual lots, batches or parental stock(s) have been performed then information on this testing would improve the documentation. An indication of the sensitivity level of the PCR tests employed should be given - see (2 vi) below.

- (vi) details of the systems or protocols in place to prevent contamination during harvesting, storage and processing.

Letters of assurance may additionally be supported by:

6. Analytical tests on individual seed batches or lots. If test results alone are presented for batches of seed, guarantees should be provided on the separate handling of the seed subsequent to testing (e.g. following OECD scheme rules). All test certificates should clearly identify the seed lots or batches to which they refer. Analytical tests may be protein-based or, more commonly, DNA-based 'PCR' tests. Importers and producers who wish to use an alternative to PCR testing methods should consult the GM Inspectorate with details of the type and sensitivity of the method proposed.

As a minimum PCR tests should:

- (xvii) be carried out on a representative sample of the seed lot (e.g. systematic sampling to prepare a working sample in accordance with the ISTA rules for seed purity);
- (xviii) be carried out on a minimum working sample for analysis that contains no less than 3000 seeds, in line with the proposed protocol submitted to the EC Standing Committee on Seeds in 2001;
- (xix) include appropriate positive and negative controls for performing the PCR test;
- (xx) consist of a general screen, e.g. using the promoter CaMV p35S (cauliflower mosaic virus promoter). Testing for common terminators, e.g. tNOS, or sequences for specific traits such as PAT/BAR (Liberty Link) and GOX (RoundUp Ready) may also be appropriate to strengthen the assurance provided by the testing regime. Where PCR tests are used that span the junctions of genetic elements that are juxtaposed in a specific GM construct, the testing laboratory

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should provide details of the GM lines that are detected by these tests (see point (d) below). It is important to note that the number and type of GM constructs being released both experimentally and commercially is constantly changing and if PCR tests are commissioned they must adequately reflect current risks. Seed companies are therefore requested to ensure that the names of the **specific genetic elements** being tested for are made available. The use of bioassay tests may also be appropriate for certain specific traits;

- (xxi) address the risk of possible false positives resulting from environmental contamination with DNA (e.g. from soil-borne bacteria);
- (xxii) be conducted to a sensitivity level of at least 0.1%, in line with the opinion from the EC Scientific Committee on Plants of 7 March 2001 (indicating that the limit of analytical sensitivity of available detection methods is currently at about 0.1% for routine analysis);
- (xxiii) provide a clear indication of any standards/accreditation to which the analysis conforms, e.g. UKAS, AFNOR, GLP, ISO17025, etc.;
- (xxiv) in all cases report the **actual result for the test** with **either** the associated measurement uncertainty for the result (e.g. \pm 95% confidence limits).

The following important points should be noted:

- There are currently no Part C authorisations for the use of GM soya seed for cultivation in Europe. Therefore, where a PCR test on an individual batch or seed lot indicates an adventitious GM presence at any detection level none of the seed can be marketed or planted. Further advice should be sought from the GM Inspectorate.
- A positive PCR result on one seed lot would not necessarily mean that sister lots from the same crop will be affected. However, this will be explored on a case-by-case basis.
- Companies marketing seed are legally responsible for ensuring that they do not market an unauthorised GMO. They should therefore take account of the whole supply chain including processing, i.e. cleaning, treating and bagging, as adventitious GM presence could be introduced at any of these stages through admixture with other seed. Companies should ensure that the processors they employ have appropriate measures in place to minimise the risk of acquiring adventitious GM presence, and that the processors provide written assurances to demonstrate this.
- Testing laboratories are increasingly using tests for junctions between two GM elements, in contrast to the former practice of testing for a range of individual GM elements. While junction-spanning tests can increase the specificity of tests and reduce the likelihood of obtaining false positives, companies commissioning such tests should be aware that the increased specificity is gained as a result of detecting only those genetic events where the precise junction between two elements occurs in the transformed line. Therefore, unlike GM tests screening for a range of individual elements, junction-spanning tests will not detect GM lines in which only one of the elements occurs or where no junction between the two specific elements occurs, hence a negative result does not necessarily indicate the absence of adventitious GM presence.

If you have any doubts regarding the suitability of letters of assurance and/or testing, please seek advice from the GM Inspectorate prior to an audit or any subsequent marketing of the seed.

CSL GM Inspectorate (2nd June 2008)