

MANAGEMENT OF THE RISKS OF ADVENTITIOUS GM PRESENCE IN CONVENTIONAL SEEDS:

GM INSPECTORATE AUDIT PROGRAMME

GUIDANCE TO ALL IMPORTERS AND PRODUCERS OF SEEDS OF: *Brassica napus, Brassica rapa, Glycine max and Zea mays*

Dated: July 2009. This guidance replaces all previously issued guidance

Purpose and legal status of this guidance

Before obtaining and supplying seed, importers and producers should ensure that steps have been taken to minimise the risk of adventitious GM presence in seed of conventional crops that are intended for the UK market and which are assessed to be at risk of adventitious GM presence. This is in line with their duties under Part VI of the Environmental Protection Act 1990¹ (EPA).

The GM Inspectorate undertakes voluntary audits of seed importers and producers 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 include seed intended for official trials and for private trials. This guidance provides advice on actions companies can take to demonstrate they have taken appropriate steps to meet the requirements of the EPA.

Participation in 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 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 official trials and/or 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 maintained isolated from transgenic lines.
 - (ii) Details of the systems or protocols in place to prevent contamination during harvesting, storage and processing.

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

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.

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 appropriate to the crop in question. These could include CaMV p35S (cauliflower mosaic virus promoter), the common terminator tNOS, 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 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 (c) 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; see http://ec.europa.eu/food/fs/sc/scp/out93_gmo_en.pdf);
- (vii) provide a clear indication of any standards or accreditation to which the analysis conforms, e.g. UKAS, AFNOR, GLP, ISO17025, etc.;
- (viii) 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) 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.
- b) Companies marketing seed are legally responsible for ensuring that they do not market an unauthorised GMO. They are therefore advised to 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.

- c) Analytical 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.

CROP SPECIFIC INFORMATION

In the 2009-10 audit programme the following crops have been identified as being at risk of containing adventitious GM presence and are included in the audit programme:

- *Brassica napus*: winter and spring oilseed rape, swede and swede forage rape
- *Brassica rapa*: turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc.
- *Glycine max*: soya
- *Zea mays*: maize including sweetcorn

At-risk crops were identified by the GM Inspectorate through quantitative risk assessment modelling, and have been included in the audit programme with the agreement of the Plant Varieties and Seeds team. Further details of the modelling approach are available at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/>

- ***Brassica napus* (winter and spring oilseed rape, swede and swede forage rape)**

There are currently no 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 and further advice should be sought from the GM Inspectorate.

- ***Brassica rapa* (turnip, turnip fodder rape, stubble turnips, pak choi, Chinese cabbage, etc.)**

There are currently no 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 and further advice should be sought from the GM Inspectorate.

- ***Glycine max* (soya)**

There are currently no 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 and further advice should be sought from the GM Inspectorate.

- ***Zea mays* (maize including sweetcorn)**

There are currently two consents authorising cultivation of GM maize in the EU, these are MON810 (C/F/95/12/02, Monsanto) and T25 (C/F/95/12/07, Bayer CropScience). As of 1st July 2009 there were more than 70 varieties of MON810 listed in the EC Common Catalogue of Varieties.

There is no marketing restriction on approved GMOs which have been cleared as presenting no risk to human health or to the environment. Similarly, maize seed certified in other EU Member States may be freely marketed throughout the EU as we would expect all such seed to meet EU legal requirements.

In 2001, the UK adopted the European Commission's 0.5% interim voluntary labelling threshold for the adventitious presence of approved GMOs in conventional seed of maize. This legacy remains while Government waits for the Commission to come forward with proposals for evidence-based legislative

thresholds. However, there is a widely held view that, in the absence of legislative thresholds, the *de facto* legal threshold for labelling purposes should be the level of detection (currently 0.1%). This has never been tested in the courts because industry has chosen to adopt a precautionary approach and operates to the level of detection.

Due to the continuing absence of specific legislative seed thresholds, it is strongly recommended that any company contemplating marketing maize seed in the UK with a detectable level of approved GM should declare that level on the seed label.

Fera GM Inspectorate:

8 July 2009

Contacting the GM Inspectorate:

Email: gm-inspectorate@fera.gsi.gov.uk

Web: <http://www.gm-inspectorate.gov.uk/>

Ged Kerins (Seed Audit Programme Manager)

Tel: 01904 462342

Mob 07730 049671

ged.kerins@fera.gsi.gov.uk

Sarah Hugo (Head of GM Inspectorate)

Tel: 01904 462223

Mob 07795 122313

sarah.hugo@fera.gsi.gov.uk

James Blackburn (GM Inspector & auditor)

Tel: 01904 462055

Mob 07764 594458

james.blackburn@fera.gsi.gov.uk

Justin Dixon (GM Inspector & auditor)

01904 462744

Mob 07764 442406

justin.dixon@fera.gsi.gov.uk