

MANAGEMENT OF THE RISKS OF ADVENTITIOUS PRESENCE OF GENETICALLY MODIFIED ORGANISMS 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: November 2011. This guidance replaces all previously issued GM Inspectorate seed audit guidance

Purpose and legal status of this guidance

Before obtaining and supplying seed, importers and producers should ensure that appropriate steps have been taken to minimise the risk of adventitious GM presence (AGMP) in seed of conventional, i.e. not genetically modified, crops that are intended for sowing or marketing in the UK. This is in line with their responsibilities under Part VI of the Environmental Protection Act 1990¹ (EPA).

The GM Inspectorate undertakes audits of importers and producers of seed of species which are assessed to be at risk of AGMP to assist importers and producers in meeting their EPA responsibilities. The audits are voluntary and are intended to help companies ensure that they have suitable controls in place to minimise the risk of AGMP, and that there is appropriate supporting documentation. The audits include seed intended for official and/or 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.

Note: participation in the audit does not relieve companies of their legal 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.

Definitions

Genetically modified organisms (GMOs) and genetic modification (GM) are as defined in European Directive 2001/18 EC. Adventitious GM presence (AGMP) is the accidental or technically unavoidable presence of GMOs in a conventional commodity, in this case seed.

Detailed information requirements

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 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/producer 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 OECD² guidelines) and has been maintained in isolation from transgenic lines.
- (ii) Details of the systems or protocols in place to prevent contamination during harvesting, storage, processing and transport.

¹ Under Part VI of the Environmental Protection Act 1990, the importation, acquisition, release or marketing of genetically modified organisms (GMOs) 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 Organisation for Economic Co-operation and Development

If analytical tests relating to individual lots, batches or parental stock(s) have been performed then information on this testing would support the documentation.

2. Analytical tests on individual seed batches or lots. Test results should not be presented alone, but should be provided as evidence that quality assurance measures to manage AGMP risk are effective. Guarantees should be provided on the separate handling of the seed subsequent to any testing. All test certificates should clearly identify the seed lots or batches to which they refer. Analytical tests may be spray tests (e.g. for herbicide resistance), protein based or, more commonly, DNA tests based on the polymerase chain reaction (PCR).

As a minimum, analytical 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 International Seed Testing Association (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 test;
- (iv) address the risk of possible false positives, e.g., for PCR tests, those resulting from environmental contamination with DNA from cauliflower mosaic virus and/or soil-borne bacteria;
- (v) 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);
- (vi) provide a clear indication of any standards or accreditation to which the analysis conforms, e.g. UKAS, AFNOR, GLP, ISO17025, etc.;
- (vii) report the **actual result for the test** with the associated measurement uncertainty for the result (e.g. \pm 95% confidence limits).
- (viii) **for PCR tests**, 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;

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 the analysis 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 (see contact details, below).

CROP SPECIFIC INFORMATION

For the 2011-12 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, etc.
- *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 Fera Varieties and Seeds team. Further details of the risk assessment modelling approach are available at <http://www.gm-inspectorate.gov.uk/seedAuditProgramme/>

- ***Brassica napus*, *Brassica rapa* and *Glycine max*:**

There are currently no authorisations for the use of GM *Brassica napus*, *B. rapa* or *Glycine max* 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.

- ***Zea mays*:**

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 01 November 2011 there were over 200 varieties of maize containing 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 (labelling requirements as described in Regulation (EC) 1830/2003 apply).

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 an approved GMO should declare that level on the seed label.

Fera GM Inspectorate:

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Contacting the GM Inspectorate:

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