

Guidance for Importers and Producers on the prevention of adventitious GM presence in conventional varieties of Maize seed.

Importers and producers of maize seed should show due diligence before obtaining and supplying seed and steps should be taken to ensure that there is no adventitious GM presence in conventional UK seed. It is the role of the GM Inspectorate to audit seed importers and producers to ensure that appropriate steps (due diligence) have been taken and the appropriate documentation is readily available. The audit may include seed intended for trials purposes. The GM Inspectorate may also take samples for PCR testing where there is uncertainty over the documentation provided (e.g. letters of assurance or PCR testing results) and there is a suspicion of unauthorised adventitious GM presence.

For seed to be marketed as a conventional variety, the types of documentation fulfilling or helping to fulfil these requirements are listed below.

1. **Letters of assurance** from breeder giving assurances that the seed is free from adventitious presence of GM. Details to be provided in the letter 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 appropriate isolation conditions (e.g. following OECD guidelines) and has been isolated from transgenic lines;
 - (ii) details of the systems or protocols in place to prevent contamination during harvesting and processing.

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 (v) below.

And/or,

2. **PCR tests** on individual seed batches or lots. If test results are presented only for batches of seed, additional guarantees should be provided on the separate handling of the seed subsequent to testing (e.g. following the OECD scheme rules). All test certificates should clearly identify the lots or batches to which they refer.

As a minimum, where only PCR tests results are presented with no additional documentation concerning production of seed, the PCR methodology 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). The minimum working sample for analysis should contain no less than 3000 seeds in line with the proposed protocol submitted to the EC Standing Committee on Seeds in 2001;
 - (ii) include appropriate positive and negative controls for performing the PCR test;
 - (iii) indicate testing with commonly used promoters and terminators which could include CaMV p35s (cauliflower mosaic virus promoter), pNos and tNos, followed by the use of primer sets to be able to distinguish authorised GM traits;
 - (iv) in order to address the risk of possible false positives resulting from environmental contamination with DNA (e.g. from cauliflower mosaic virus or soil-borne bacteria), the test methodology should be designed to eliminate this possibility;
 - (v) be conducted to a sensitivity level of at least a 0.1% detection limit. This is in line with the opinion from the EC Scientific Committee on Plants (SCP), 7 March 2001 which indicated that the limit of analytical sensitivity of available detection methods is currently at about 0.1% for routine analysis.
- **Where these PCR test results indicate that no GM events are present then no further documentation is likely to be required.**
 - **Where a PCR test on an individual seed batch or lot indicates the presence of a GM event(s), at any detection level, then none of the seed should be marketed or planted without further reference to the GM Inspectorate. Where a PCR test clearly identifies the adventitious GM event(s) as approved for marketing under Part C of Directive 2001/18/EC (as listed at Annex 1), then there is no legal bar on marketing the seed.***

* However importers should be aware that the European Commission published in October 2000 a set of interim measures on the adventitious presence of authorised GM events in seed of conventional varieties to facilitate harmonised action by EU Member States on a voluntary basis, pending agreement on legislative proposals. The measures set a 0.5% threshold for authorised GM events in Maize seed and companies should be able to demonstrate that any presence of a GM event(s) below this threshold is clearly identified and is listed in Annex 1. For hybrid maize intended for commercial planting, there are no further varietal purity standards.

It should be noted that when you supply seed, your customers may request a covering letter containing assurances that this guidance has been followed and that the CSL GM Inspectorate has audited /will audit your company.

Note. Alternative testing methods may be considered by the GM Inspectorate on the submission of information detailing the type and sensitivity of the method proposed.

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ANNEX 1

MAIZE GM EVENTS APPROVED FOR MARKETING IN EU UNDER DIRECTIVE 2001/18/EC

Company	Reference	GM Event	Scope of consent	Genetic Modification
Syngenta (Ciba-Geigy)	C/F/4/11-3	Bt 176	Cultivation in the EU Approved for animal feed as whole grain, processed products or forage Processed products approved for food uses.	Bt insect resistance and Herbicide tolerance
Monsanto	C/F/95/12/02	MON810	Cultivation in the EU Approved for animal feed as whole grain or processed products. Processed products approved for food uses.	Bt insect resistance
Aventis (AgrEvo)	C/F/95/12/07	T25	Cultivation in the EU Approved for animal feed as whole grain, processed products or forage. Processed products from T25 grain are approved for food uses.	Herbicide tolerance