

Draft
COMMISSION DECISION (EC) No .../..

of[...]

**establishing minimum thresholds for adventitious or technically unavoidable traces of
genetically modified seeds in other products**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC¹ of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and in particular Article 21(2) thereof,

Whereas:

(1) Labelling and traceability of genetically modified seeds, authorised for the placing on the market for uses to include cultivation in accordance with Community legislation, is provided for under Article 21(1) of Directive 2001/18/EC and Article 4 of Regulation (EC) N° 1830/2003² of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

(2) Traces of genetically modified seeds in a conventional seed lot or genetically modified seed lot product derived from a different transformation event may be adventitious or technically unavoidable.

(3) Minimum threshold values may be established, in accordance with Article 21(2) of Directive 2001/18/EC, below which adventitious or technically unavoidable traces of genetically modified seeds, authorised for the placing on the market for uses including cultivation, in other products should be exempted from labelling and traceability requirements.

(4) Threshold values for genetically modified seeds should be scientifically sound, operational, such that they can be met by appropriate management practices, as well as enforceable.

(5) Thresholds for the adventitious or technically unavoidable presence of genetically modified seeds in a conventional seed lot or genetically modified seed lot product derived from a different transformation event should be established at levels such that the level of genetically modified organisms in harvested material from the resultant crops, intended for direct use as food, feed or for direct processing, does not exceed the relevant Community thresholds established under Articles 12(2) and 24(2) of Regulation (EC) N° 1829/2003³ on genetically modified food and feed, Article 21(3) of Directive 2001/18/EC and under other Community legislation.

(6) The threshold level established for a genetically modified seed variety should take account of its reproductive mechanism, namely whether reproduction is vegetative or by self and/or cross-pollination, of the species in question, and the likelihood of its presence from other sources during cultivation, harvest and subsequent storage and handling,

(7) The Opinion of the Scientific Committee on Plants, of 7 March 2001 (and as confirmed by the Committee in April 2002 and January 2003), concluded that proposed thresholds of 0.3% for genetically modified seeds from cross-pollinating species and 0.5% for genetically modified seeds from self-pollinating species to be met under ideal seed production conditions, would allow the 0.9% threshold for harvested material from the resultant crops, intended for direct use as food, feed or for direct processing, established under Regulation (EC) N° 1829/2003 and Directive 2001/18/EC.

(8) Thresholds should be established for genetically modified seed varieties, on the basis of their species and taking account of the Opinion of the Scientific Committee on Plants, and applied on authorisation of these varieties for the placing on the market for uses including cultivation under Community legislation.

(9) Thresholds should be established for genetically modified seed varieties which completed a comprehensive environmental risk assessment according to the procedure as referred to in Directive 2001/18/EC.

(10) The European Commission adopted a Recommendation⁴ on 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, the principles of which also apply for seed production.

(11) Member States may, under Article 26(a) of Directive 2001/18/EC, take appropriate measures to avoid the unintended presence of genetically modified organisms, including genetically modified seeds, in other products.

(12) In the case where seed producers find it workable to produce conventional seed lots with an admixture level of genetically modified seeds below the mandatory labelling thresholds, they shall be free to either indicate on the label the exact admixture level, or ascertain that the admixture level remains below a certain voluntary threshold, which shall then be lower than the mandatory labelling threshold. The availability of such seed lots may benefit farmers who would like to supply to certain markets

products with a lower than the legally acceptable admixture of genetically modified organisms.

(13) The establishment of thresholds and threshold values for the adventitious or technically unavoidable presence of genetically modified seeds under other Community legislation should be consistent with those established under this Decision.

(14) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

Article 1

The threshold values as laid down in the Annex to this Decision shall, according to the species in question, apply to adventitious or technically unavoidable traces of a genetically modified organisms, authorised for the placing on the market under Community legislation for uses to include cultivation, in other products (seed lots) intended for cultivation.

Article 2

Products, where adventitious or technically unavoidable traces of authorised genetically modified organisms are present below the threshold values as laid down in the Annex, shall not have to be labelled according to Article 21(1) of Directive 2001/18/EC.

Article 3

In order to establish that the presence of genetically modified organisms, referred to in Article 1 is adventitious or technically unavoidable, operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate measures to avoid the presence of such material.

Article 4

Member States may provide for the possibility that seed producers could label conventional seed lots on a voluntary basis by indicating on the label either the exact value of admixture of GM seeds or a guaranteed content of GM seeds below a threshold chosen by the seed producer, which has to lie below the mandatory threshold as provided for in this Decision.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, [...]

For the Commission
Margot Wallstrom

ANNEX

The following threshold values are applicable to adventitious or technically unavoidable traces of genetically modified seeds, of the species denoted, authorised for the placing on the market under Community legislation for uses including cultivation where present in other products for cultivation.

Species of genetically modified organism	Threshold value (Percentage modified DNA/total genomic DNA of the species)
Oilseed rape (<i>Brassica napus</i>)	0.3%
Maize (<i>Zea mays</i>)	0.3%
Sugar beet (<i>Beta vulgaris</i>)	0.5%
Fodder beet (<i>Beta vulgaris</i>)	0.5%
Potato (<i>Solanum tuberosum</i>)	0.5%
Cotton (<i>Gossypium spp</i>)	0.5%