



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION DECISION .../.../EC

of [...]

establishing, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, thresholds for adventitious or technically unavoidable traces of genetically modified seeds in other products

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC 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/EEC¹ and in particular Article 21(2) thereof,

After consulting the Scientific Committee on Plants,

Whereas:

- (1) Directive 2001/18/EC and of Regulation (EC) N° 1830/2003 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/EC² provide for the labelling and the traceability of genetically modified seeds, authorised for the placing on the market for uses to include cultivation in accordance with Community legislation.
- (2) Experience shows that conventional seed lots may contain traces of genetically modified seeds which may be adventitious or technically unavoidable.
- (3) In order to establish that the presence of those traces is adventitious or technically unavoidable, operators must be in a position to demonstrate to the competent authorities that they have taken appropriate steps to avoid the presence of the genetically modified seeds.
- (4) Labelling thresholds for the adventitious or technically unavoidable presence of genetically modified seeds in a conventional seed lot or in a genetically modified seed

¹ OJ L 106, 17.04.2001, p.1-38.

² OJ L 268, 18.10.2003, p.24-28.

lot derived from a different transformation event should be established at levels to help ensure 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 in Article 12(2) and Article 24(2) of Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed³, in Article 21(3) of Directive 2001/18/EC and under other Community legislation.

- (5) The labelling threshold level established for a genetically modified seed variety should take account, among other things, 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.
- (6) Labelling 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 upon authorisation of these varieties for the placing on the market for uses including cultivation under Community legislation.
- (7) Labelling 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.
- (8) Labelling thresholds should be established for traces of genetically modified seeds derived from crop species which have already been authorized for the placing on the market for uses including cultivation under Directive 90/220/EEC.
- (9) Labelling threshold values for genetically modified seeds should be science based, practical, such that they can be met by appropriate management practices, proportional, as well as enforceable.
- (10) According to the Opinion of the Scientific Committee on Plants, labelling 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 to respect the 0.9% labelling threshold for harvested material from the resultant crops, intended for direct use as food, feed or for direct processing, established by Regulation (EC) N° 1829/2003 and Directive 2001/18/EC. However, the opinion of the SCP stressed that those thresholds will be achieved under ideal seed production conditions and will become increasingly difficult to meet as GM crop production increases.
- (11) 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 should 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 should then be lower than the mandatory labelling threshold. The availability of such seed lots should be able to benefit farmers who would like to supply to certain markets products with an admixture of genetically modified organisms below the thresholds.

³ OJ L 268, 18.10.2003, p.1-23.

(12) 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

Products (seed lots) intended for cultivation, in which adventitious or technically unavoidable traces of genetically modified organisms authorised for the placing on the market under Community legislation for uses to include cultivation are present in proportions below the labelling threshold value laid down in Article 2, shall not have to be labelled according to Article 21(1) of Directive 2001/18/EC.

Article 2

The labelling threshold value of 0.3% shall be applicable for the adventitious or technically unavoidable presence of traces of genetically modified maize (*Zea mays*) or oilseed rape (*Brassica napus*), authorised for the placing on the market under Community legislation for uses including cultivation, where present in other products for cultivation.

Article 3

In order to establish that the presence of genetically modified organisms, referred to in Article 1 is adventitious or technically unavoidable, Member States shall ensure that operators are 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 relevant threshold provided for in Article 2.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, [...]

For the Commission
Margot Wallström
Member of the Commission