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**WORKING DOCUMENT
DOES NOT NECESSARILY
REPRESENT THE VIEWS
OF THE COMMISSION
SERVICES**



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02.07.2002
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Draft

COMMISSION DIRECTIVE/EC

of [...]

amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC and Decision 95/232/EEC as regards additional conditions and requirements concerning the presence of genetically modified seed in seed lots of non-genetically modified varieties and the details of the information required for labelling in the case of seeds of genetically modified varieties

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 66/400/EEC of 14 June 1966 on the marketing of beet seed¹, as last amended by Directive 98/96/EC², and in particular Article 21a thereof,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed³, as last amended by Directive 2001/64/EC⁴, and in particular Article 21a thereof,

¹ OJ 125, 11.7.1966, p. 2290/66.

² OJ L 25, 1.2.1999, p. 27.

³ OJ 125, 11.7.1966, p. 2298/66.

⁴ OJ L 234, 1.9.2001, p. 60.

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed⁵, as last amended by Directive 2001/64/EC, and in particular Article 21a thereof,

Having regard to Council Directive 66/403/EEC of 14 June 1966 on the marketing of seed potatoes⁶, as last amended by Commission Decision 1999/742/EC⁷, and in particular Article 19a thereof,

Having regard to Council Directive 69/208/EEC of 30 June 1969 on the marketing of seed of oil and fibre plants⁸, as last amended by Directive 98/96/EC, and in particular Articles 2(1b) and 20a thereof,

Having regard to Council Directive 70/458/EEC of 29 September 1970 on the marketing of vegetable seed⁹, as last amended by Directive 98/96/EC, and in particular Article 40a thereof

Whereas:

- (1) Genetically modified plants have been obtained in beet, maize, potato, swede rape, soya bean, cotton, chicory and tomato, all species which are commonly cultivated in the EU. Certain genetically modified organisms belonging to the cited species are authorised to be marketed and cultivated and certain of these genetically modified organisms are in the process of being authorised in the EU or are authorised.
- (2) Directives 66/400/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC and Commission Decision 95/232/EC, lay down minimum conditions in respect of the cultivation conditions of plants in order to obtain seed and the seed harvested and intended to be marketed. These include conditions related to varietal purity, but do not include requirements regarding the presence of genetically modified seed in seed lots of non-genetically modified varieties. Additional conditions and requirements should therefore be included in respect of the presence of genetically modified seed in seed lots of non-genetically modified varieties.
- (3) 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

⁵ OJ 125, 11.7.1966, p. 2309/66.

⁶ OJ 125, 11.7.1966, p. 2320/66 .

⁷ OJ L 297, 18.11.1999, p. 39.

⁸ OJ L 169, 10.7.1969, p. 3.

⁹ OJ L 225, 12.10.1970, p. 7.

and repealing Council Directive 90/220/EEC¹⁰ requires that no genetically modified organism may be placed on the market, unless it has been authorised in accordance with that Directive. The present Directive cannot derogate from these requirements.

- (4) In the case of material derived from genetically modified seed intended to be used as a food or food ingredient, the material must have been authorised in accordance with Regulation (EC) N° 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients¹¹.
- (5) Thresholds for the presence of genetically modified organisms in lots of non-genetically modified seed should be established at levels such that food produced from crops grown from the conventional seed will have a genetically modified organism content not exceeding the 1% threshold provided for by Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC¹², as amended by Commission Regulation (EC) No 49/2000¹³. Above that 1% threshold an indication of the presence in a food of a genetic modification is compulsory.
- (6) The thresholds established for seed should take into account the reproductive system of the plants concerned, the vegetative cycle, as well as the probability of contamination of the crop from which the seed is grown. Different thresholds should therefore be established for different types of plant, depending in particular on whether the plant is self- or cross-pollinated, or propagated vegetatively.
- (7) Good seed production practices designed to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling should be implemented.
- (8) The opinion of the Scientific Committee on Plants (SCP) given on 7 March 2001 concerning the adventitious presence of genetically modified seed in conventional seed confirmed that the proposed measures were necessary and appropriate.

¹⁰ OJ L 106, 17.4.2001, p. 1.

¹¹ OJ L 43, 14.2.97, p. 1.

¹² OJ L 159, 3.6.1998, p. 4.

¹³ OJ L 6, 11.1.2002, p. 13.

- (9) Sampling and testing conditions should be specified to ensure seed placed on the market complies with the applicable requirements.
- (10) The examination of the satisfaction of the conditions and requirements related to the seed lot, concerning the presence of genetically modified seed in seed lots of non-genetically modified varieties should not be required under certain conditions.
- (11) Food containing more than 1% authorised genetically modified organisms may lawfully be placed on the market. It is not appropriate to prohibit the marketing of non-genetically modified seed with a content of genetically modified organisms such that the 1% limit would be exceeded. However, without prejudice to the other conditions to be satisfied by the seed in respect of varietal purity, where the thresholds for genetically modified seeds are exceeded, the label or document which is affixed to or accompanies a seed lot of non-genetically modified seed containing genetically modified organisms in excess of the thresholds provided for should state that that lot contains genetically modified seeds in excess of the applicable threshold.
- (12) Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC provide that the fact that seed is of a genetically modified variety must be clearly indicated in any label or document, official or otherwise, which is affixed to or accompanies the seed lot. It is appropriate to establish the details of the information required for labelling in this case
- (13) Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC, and Decision 95/232/EC should therefore be amended accordingly.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I, III and IV to Directive 66/400/EEC are amended in accordance with Annex I to this Directive.

Article 2

Annexes IV and V to Directive 66/401/EEC are amended in accordance with Annex II to this Directive.

Article 3

Annexes I, II, IV and V to Directive 66/402/EEC are amended in accordance with Annex III to this Directive.

Article 4

Annexes I and III to Directive 66/403/EEC are amended in accordance with Annex IV to this Directive.

Article 5

Annexes I, II, IV and V to Directive 69/208/EEC are amended in accordance with Annex V to this Directive.

Article 6

Article 3 of Decision 95/232/EC is amended in accordance with Annex VI to this Directive.

Article 7

Annexes I, II, IV and V to Directive 70/458/EEC are amended in accordance with Annex VII to this Directive.

Article 8

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2002 at the latest. They shall forthwith inform the Commission thereof. They shall apply them from 1 January 2003.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 9

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 10

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission

Member of the Commission

ANNEX I

Annexes I, III and IV to Directive 66/400/EEC are amended as follows:

(1) Annex I, Part A is amended as follows:

(a) The following section 6 is added:

“6. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented through the whole production chain.”

(2) In Annex I, part B the following sections are inserted after section 1:

“1a Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I Part A and B section 1, seed of a non-genetically modified variety may contain not more than 0.5% of genetically modified seeds.

The presence of such seed must however be adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid the presence of genetically modified organisms.

The placing on the market of such seed must have been authorised for cultivation in accordance with Community legislation for the placing on the market of genetically modified organisms. Furthermore, in the case of a non-genetically modified variety intended to be used as a food or food ingredient, material derived from such genetically modified seed must have already been authorised pursuant to Regulation (EC) N° 258/97/EC.

1b Member States shall ensure compliance with section 1a and the requirement of Directive 2001/18/EC (in so far as it relates to seed) that no genetically modified organism be deliberately released or placed on the market unless it has been authorised in accordance with that Directive as well as where appropriate the requirement of Regulation (EC) 258/97/EC that no novel food or novel food ingredient be placed on the market unless it has been authorised in accordance with that Regulation, by seed testing carried out in accordance with Commission Regulation (EC) N° ../... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.

1c In respect of the conditions under section 1a and seed testing pursuant to section 1b, the certification authority

– notwithstanding the obligation to carry out the official examination or where appropriate the examination under official supervision in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic basis where it is reasonable to believe

that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,

- shall carry out such examinations in all cases when there is reason to believe that the requirements may not have been satisfied.

1d Notwithstanding the conditions laid down in section 1a, Member States shall permit the marketing of seed of a non-genetically modified variety in which more than 0.5% genetically modified seeds authorised as described in section 1a are present, provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states the seed contains more than 0.5% genetically modified seed together with information that specifies the original transformation event(s) of such genetically modified seeds."

(3) Annex III is amended as follows:

(a) In part A I the following points 5a and 5 b are inserted:

“5a For seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seed” together with information that specifies the original transformation event(s) of such genetically modified seeds.

5b In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) In part B the following points 7 a and 7 b are inserted:

“7a For seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

7b In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(4) Annex IV is amended as follows:

(a) In part A the following indents are inserted after the fourth indent:

“- for seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1 a, the following notice must be included:

“the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- in the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event. "

(b) In part C the following indents are inserted after the third indent:

- “- for seed of non-genetically modified varieties which do not meet the condition laid down in Annex I, part B, section 1a, the following notice must be included:

“the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- in the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event."

ANNEX II

Annexes IV and V to Directive 66/401/EEC are amended as follows :

(1) Annex IV is amended as follows:

(a) Part A(1) is amended as follows:

(i) In point (a) the following point 5a is inserted:

“5a. In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(ii) In point (c) (4) the following subparagraph is added:

“In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) Part B is amended as follows:

(i) In point (a) the following point 7a is inserted:

“7a. In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(ii) In point (c)(11) the following subparagraph is added:

“In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(2) Annex V is amended as follows:

(a) In part A the following indent is inserted after the third indent:

“- in the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) In part C the following indent is inserted after the third indent:

“- in the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

ANNEX III

Annexes I, II, IV and V to Directive 66/402/EEC are amended as follows:

- (1) Annex I is amended as follows:

The following section 6 is added:

"6. Good practices for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented through the whole production chain."

- (2) In Annex II the following sections are inserted after section 1:

"1a Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I section 3 and Annex II section 1, seed of a non-genetically modified variety of *Zea mays* may contain not more than 0.5% of genetically modified seeds.

The presence of such seed must however be adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid the presence of genetically modified organisms.

The placing on the market of such seed of *Zea mays* must have been authorised for cultivation in accordance with Community legislation for the placing on the market of genetically modified organisms. Furthermore, in the case of a non-genetically modified variety of maize intended to be used as a food or food ingredient, material derived from such genetically modified seed must have already been authorised pursuant to Regulation (EC) N° 258/97/EC.

- 1b Member States shall ensure compliance with section 1a and the requirement of Directive 2001/18/EC (in so far as it relates to seed) that no genetically modified organism be deliberately released or placed on the market unless it has been authorised in accordance with that Directive as well as where appropriate the requirement of Regulation (EC) 258/97/EC that no novel food or novel food ingredient be placed on the market unless it has been authorised in accordance with that Regulation, by seed testing carried out in accordance with Commission Regulation (EC) N° ../... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.

- 1c In respect of the conditions under section 1a and seed testing pursuant to section 1b, the certification authority

– notwithstanding the obligation to carry out the official examination or where appropriate the examination under official supervision in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic basis where it is reasonable to believe that the

requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,

- shall carry out such examinations in all cases when there is reason to believe that the requirements may not have been satisfied.

1d Notwithstanding the conditions laid down in section 1a, Member States shall permit the marketing of seed of a non-genetically modified variety of *Zea mays* in which more than 0.5% genetically modified seeds authorised in the Community are present, provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states the seed contains more than 0.5% genetically modified seed together with information that specifies the original transformation event(s) of such genetically modified seeds.”

(3) Annex IV is amended as follows:

(a) Part A is amended as follows:

(i) In point (a) the following points 5a and 5 b are inserted:

“5a For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

5b In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(ii) In point (b)(4) the following subparagraphs are added:

“For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a:

- - “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(4) Annex V is amended as follows:

(a) In part A the following indents are inserted after the third indent:

- “- For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

“the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) In part C the following indents are inserted after the third indent:

- “- For seed of non-genetically modified varieties of maize which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

“the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

ANNEX IV

Annexes I and III to Directive 66/403/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) the following section 01 is inserted before section 1:

“01. The previous cropping of the field shall not have been incompatible with the production of seed potatoes of the variety of the crop, and the field shall be sufficiently free from plants which are volunteers from previous cropping. ”

(b) The following section 7 and 8 are added:

"7. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented through the whole production chain.

8. Presence of genetically modified seed potatoes:

8a Without prejudice to the conditions to be satisfied by the seed potatoes in respect of the varietal purity in accordance with Annex I sections 1b and 2b, seed potatoes of a non-genetically modified variety may contain not more than 0.5% of genetically modified seed potatoes.

The presence of such seed potatoes must however be adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid the presence of genetically modified organisms.

The placing on the market of such seed potatoes must have been authorised for cultivation in accordance with Community legislation for the placing on the market of genetically modified organisms. Furthermore, in the case of a non-genetically modified variety of seed potato intended to be used as a food or food ingredient, material derived from such genetically modified seed potato must have already been authorised pursuant to Regulation (EC) N° 258/97/EC.

8b Member States shall ensure compliance with section 8a and the requirement of Directive 2001/18/EC (in so far as it relates to seed) that no genetically modified organism be deliberately released or placed on the market unless it has been authorised in accordance with that Directive as well as where appropriate the requirement of Regulation (EC) 258/97/EC that no novel food or novel food ingredient be placed on the market unless it has been authorised in accordance with that Regulation, by seed testing carried out in accordance with Commission Regulation (EC) N°/.... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.

- 8c In respect of the conditions under section 8a and seed testing pursuant to section 8b, the certification authority
- notwithstanding the obligation to carry out the official examination or where appropriate the examination under official supervision in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic basis where it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - shall carry out such examinations in all cases when there is reason to believe that the requirements may not have been satisfied.
- 8d Notwithstanding the conditions laid down in section 8a, Member States shall permit the marketing of seed potatoes of a non-genetically modified variety in which more than 0.5% genetically modified seed potatoes authorised in the Community are present, provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states that the seed potato lot contains more than 0.5% genetically modified seed potatoes together with information that specifies the original transformation event(s) of such genetically modified seeds.”

(2) In Annex III, part A, the following points 4a and 4 b are inserted:

“(4a) For seed potatoes of non-genetically modified varieties which do not meet the condition laid down in Annex I point 8 a, the following notice must be included:

“the seed potato lot contains more than 0.5% genetically modified seed potatoes” together with information that specifies the original transformation event(s) of such genetically modified seeds.

(4b) In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

ANNEX V

Annexes I, II, IV and V to Directive 69/208/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) The following section 6 is added:

"6. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented through the whole production chain."

(2) Annex II is amended as follows:

In Part I the following sections are inserted after section 1a:

"1b Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I section 3 and Annex II section 1 or in the case of hybrids of *Brassica napus* with points 2, 3 and 5 of the annex to Commission Directive 95/232/EEC, seed of a non-genetically modified variety of *Brassica napus*, of *Glycine max* or of *Gossypium spp.*, may contain not more than 0,3 % of genetically modified seeds for *Brassica napus*, not more than 0,7 % of genetically modified seeds for *Glycine max* and not more than 0.5% of genetically modified seeds for *Gossypium spp.*

The presence of such seed must however be adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid the presence of genetically modified organisms.

The placing on the market of such seed must have been authorised for cultivation in accordance with Community legislation for the placing on the market of genetically modified organisms. Furthermore, in the case of a non-genetically modified variety intended to be used as a food or food ingredient, material derived from such genetically modified seed must have already been authorised pursuant to Regulation (EC) N° 258/97/EC.

1c Member States shall ensure compliance with section 1b and the requirement of Directive 2001/18/EC (in so far as it relates to seed) that no genetically modified organism be deliberately released or placed on the market unless it has been authorised in accordance with that Directive as well as where appropriate the requirement of Regulation (EC) 258/97/EC that no novel food or novel food ingredient be placed on the market unless it has been authorised in accordance with that Regulation, by seed testing carried out in accordance with Commission Regulation (EC) N°/... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.

- 1d In respect of the conditions under section 1b and seed testing pursuant to section 1c, the certification authority
- notwithstanding the obligation to carry out the official examination or where appropriate the examination under official supervision in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic basis where it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - shall carry out such examinations in all cases when there is reason to believe that the requirements may not have been satisfied.
- 1e Notwithstanding the conditions laid down in section 1b, Member States shall permit the marketing of seed of a non-genetically modified variety of *Brassica napus* in which more than 0.3% genetically modified seeds authorised in the Community are present, seed of a non-genetically modified variety of *Glycine max* in which more than 0.7% genetically modified seeds authorised in the Community are present, seed of a non-genetically modified variety of *Gossypium spp* in which more than 0.5% genetically modified seeds authorised in the Community are present, provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states the seed contains more than 0.3% genetically modified seed in the case of *Brassica napus*, more than 0.7% genetically modified seed in the case of *Glycine max*, more than 0.5% genetically modified seed in the case of *Gossypium spp*, together with information that specifies the original transformation event(s) of such genetically modified seeds.”

(3) Annex IV is amended as follows:

(a) Part A is amended as follows:

In point (a) the following points 6a and 6 b are inserted:

“6a For seed of non-genetically modified varieties of *Brassica napus*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:

- “the seed lot contains more than 0.3% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

For seed of non-genetically modified varieties of *Glycine max*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:

- “the seed lot contains more than 0.7% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

For seed of non-genetically modified varieties of *Gossypium spp*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.
- 6b In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(4) Annex V is amended as follows:

(a) In part A the following indents are inserted after the third indent:

- For seed of non-genetically modified varieties of *Brassica napus*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:
 - “the seed lot contains more than 0.3% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.
- For seed of non-genetically modified varieties of *Glycine max*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:
 - “the seed lot contains more than 0.7% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.
- For seed of non-genetically modified varieties of *Gossypium spp*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:
 - “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.
- In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) In part C the following indents are inserted after the third indent:

For seed of non-genetically modified varieties of *Gossypium spp*, which do not meet the conditions laid down in Annex II, Part I, section 1b, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.
- In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

ANNEX VI

Decision 95/232/EC is amended as follows:

Article 3 is replaced by the following:

“Seed of hybrids and varietal associations of swede rape and turnip rape may be marketed within the Community provided that the conditions and requirements in the Annex are satisfied, without prejudice to the conditions laid down in Council Directive 69/208/EEC in respect of the seed crops, the seed lots and the labels of non-genetically modified varieties of swede rape”.

ANNEX VII

Annexes I, II, IV and V to Directive 70/458/EEC are amended as follows:

(1) Annex I is amended as follows:

(a) The following section 01 is inserted before section 1:

“01. The previous cropping of the field shall not have been incompatible with the production of seed of the species and variety of the crop, and the field shall be sufficiently free from plants which are volunteers from previous cropping.”

(b) The following section 6 is added:

“6. Good practice for seed production to minimise admixtures and undesirable gene flow throughout crop growth and post-harvest handling shall be implemented through the whole production chain.”

(2) In Annex II the following sections are inserted after section 1:

“1a Presence of genetically modified seed:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I section 1 where applicable and Annex II section 1, seed of a non-genetically modified variety of *Cichorium intybus* or of *Lycopersicon lycopersicum* may contain not more than 0.5% of genetically modified seeds.

The presence of such seed must however be adventitious or technically unavoidable. In order to establish that the presence of this material is adventitious or technically unavoidable, producers must be in a position to supply evidence to satisfy the Member State that they have taken appropriate steps to avoid the presence of genetically modified organisms.

The placing on the market of such seed must have been authorised for cultivation in accordance with Community legislation for the placing on the market of genetically modified organisms. Furthermore, in the case of a non-genetically modified variety intended to be used as a food or food ingredient, material derived from such genetically modified seed must have already been authorised pursuant to Regulation (EC) N° 258/97/EC.

1b Member States shall ensure compliance with section 1a and the requirement of Directive 2001/18/EC (in so far as it relates to seed) that no genetically modified organism be deliberately released or placed on the market unless it has been authorised in accordance with that Directive as well as where appropriate the requirement of Regulation (EC) 258/97/EC that no novel food or novel food ingredient be placed on the market unless it has been authorised in accordance with that Regulation, by seed testing carried out in accordance with Commission Regulation (EC) N°/... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.

- 1c In respect of the conditions under section 1a and seed testing pursuant to section 1b, the certification authority
- notwithstanding the obligation to carry out the official examination or where appropriate the examination under official supervision in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic basis where it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - shall carry out such examinations in all cases when there is reason to believe that the requirements may not have been satisfied.
- 1d Notwithstanding the conditions laid down in section 1a, Member States shall permit the marketing of seed of a non-genetically modified variety of *Cichorium intybus* or of *Lycopersicon lycopersicum* in which more than 0.5% genetically modified seeds authorised in the Community are present, provided that any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive states the seed contains more than 0.5% genetically modified seed in the case of *Cichorium intybus* or of *Lycopersicon lycopersicum*, together with information that specifies the original transformation event(s) of such genetically modified seeds.”

(3) Annex IV is amended as follows:

(a) In Part A (a) the following points 6a and 6b are inserted:

“6a For seed of non-genetically modified varieties of *Cichorium intybus* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

“the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

For seed of non-genetically modified varieties of *Lycopersicon lycopersicum* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

– “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

6b In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) In Part B (a) the following points 5a and 5b are inserted:

“5a For seed of non-genetically modified varieties of *Cichorium intybus* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

For seed of non-genetically modified varieties of *Lycopersicon lycopersicum* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

5b In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(4) Annex V is amended as follows:

(a) In Part A the following indents are inserted after the third indent:

“- For seed of non-genetically modified varieties of *Cichorium intybus* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- For seed of non-genetically modified varieties of *Lycopersicon lycopersicum* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”

(b) In Part C the following indents are inserted after the third indent:

“- For seed of non-genetically modified varieties of *Cichorium intybus* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.

- For seed of non-genetically modified varieties of *Lycopersicon lycopersicum* which do not meet the condition laid down in Annex II, section 1a, the following notice must be included:

- “the seed lot contains more than 0.5% genetically modified seeds” together with information that specifies the original transformation event(s) of such genetically modified seeds.
- In the case of a genetically modified variety: the words 'genetically modified variety' together with information that specifies the original transformation event.”