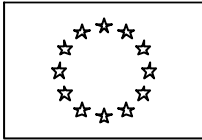


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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2003)

Final

Draft

COMMISSION DIRECTIVE

of

amending Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC in particular as regards additional conditions and requirements concerning the adventitious or technically unavoidable presence of genetically modified seeds 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)

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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 Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed¹, as last amended by Directive 2003/61/EC², and in particular Article 21a thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed³, as last amended by Directive 2003/61/EC, and in particular Article 21a thereof,

Having regard to Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed⁴, as last amended by Directive 2003/61/EC, and in particular Article 27 thereof,

Having regard to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed⁵, as last amended by Directive 2003/61/EC, and in particular Article 45 thereof,

Having regard to Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes⁶, as last amended by Directive 2003/61/EC, and in particular Article 24 thereof,

Having regard to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants⁷, and last amended by Directive 2003/61/EC, and in particular Article 24 thereof;

Whereas:

¹ OJ 125, 11.7.1966, p. 2298/66.

² OJ L165, 3.7.2003, p. 23.

³ OJ 125, 11.7.1966, p. 2309/66.

⁴ OJ L 193, 20.7.2002, p. 12.

⁵ OJ L 193, 20.7.2002, p. 33.

⁶ OJ L 193, 20.7.2002, p. 60.

⁷ OJ L 193, 20.7.2002, p. 74.

- (1) Genetic modifications have been introduced in beet, maize, potato, swede rape, soya bean, cotton, chicory and tomato. All of these species are cultivated in the Community. Certain genetically modified organisms belonging to the cited species have been authorised for marketing and for use in cultivation in the Community or in third Countries, and certain others are in the process of being authorised in the Community.
- (2) Directives 66/402/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC lay down minimum conditions in respect of the seed harvested and intended to be marketed, in particular in respect of varietal purity, but do not include specific requirements regarding the presence of genetically modified seeds in seed lots of non-genetically modified varieties. Additional conditions and requirements should therefore be included in respect of the adventitious or technically unavoidable presence of genetically modified seeds in seed lots of non-genetically modified varieties of the plant species cited above. Conditions and requirements could also be included for other plant species, if appropriate, in the future.
- (3) The above mentioned Directives provide conditions as regards previous cropping, except in the case of Directive 2002/55/EC for vegetable seed crops and Directive 2002/56/EC for seed potato crops; requirements should therefore be established in these cases.
- (4) In order to be placed on the market, genetically modified organisms for the use in cultivation or genetically modified organisms for food or feed use to be used as seeds must either be authorised in accordance with 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/EEC⁸, as amended by Regulation (EC) No .../2003 of the European Parliament and of the Council of ...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/EC⁹ or be authorised in accordance with Regulation (EC) No .../2003 of the European Parliament and of the Council of 2003 on genetically modified food and feed¹⁰. Such authorisations are without prejudice to the provisions of Directives 2002/53/EC and 2002/55/EC, which provide in particular for the rules and the criteria for the acceptance of varieties and their official acceptance for inclusion in common catalogues.
- (5) In the case of the presence of traces of genetically modified seeds in seeds of a non-genetically modified variety to be used in food or feed, the genetically modified material derived from such genetically modified seeds used in food or feed must be authorised under Regulation (EC) No .../2003 (*genetically modified food and feed*).

⁸ OJ L 106, 17.4.2001, p. 1.

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- (6) Thresholds for the adventitious or technically unavoidable presence of genetically modified organisms, authorised either under Directive 2001/18/EC or under Regulation (EC) No .../2003 for the use in cultivation, in seed lots of non-genetically modified varieties should be established at levels such that food, feed or products intended for direct processing produced from crops grown from the non-genetically modified seed should have a genetically modified organism content not exceeding the 0.9% threshold provided for by Regulation (EC) No .../2003 (*genetically modified food and feed*) and by Regulation (EC) No .../2003 (*traceability and labelling*).
- (7) The thresholds established for seed should be adapted to the reproductive system of the plants concerned, the vegetative cycle, as well as the probability of adventitious or technically unavoidable presence of genetically modified organisms in 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.
- (8) The opinion of the Scientific Committee on Plants given on 7 March 2001, reviewed on 24 April 2002 and 30 January 2003, concerning the adventitious presence of genetically modified seed in conventional seed has been considered for setting the thresholds proposed.
- (9) Sampling and testing conditions should be specified to ensure seed placed on the market complies with the applicable requirements. Seed testing shall be carried out in accordance with Commission Regulation (EC) No .../... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.
- (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) 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 or where the presence of genetically modified seeds is not adventitious or technically unavoidable, the label or document which is affixed to or accompanies a seed lot of a non-genetically modified variety should state that the lot contains genetically modified seeds and should specify the unique identifier(s) established under Regulation (EC) No .../2003 of 2003 (*traceability and labelling*).
- (12) Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC provide that if seed is of a genetically modified variety, this 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, in particular as regards the indication of the unique identifier established under Regulation (EC) No .../2003 (*traceability and labelling*).
- (13) Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/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 IV and V to Directive 66/401/EEC are amended in accordance with Annex I to this Directive.

Article 2

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

Article 3

Annexes I, III and IV to Directive 2002/54/EC are amended in accordance with Annex III to this Directive.

Article 4

Annexes I, II, IV and V to Directive 2002/55/EC are amended in accordance with Annex IV to this Directive.

Article 5

Annexes I and III to Directive 2002/56/EC are amended in accordance with Annex V to this Directive.

Article 6

Annexes II, IV and V to Directive 2002/57/EC are amended in accordance with Annex VI to this Directive.

Article 7

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [day before the application of Regulation on genetically modified food and feed and Regulation on traceability and labelling of genetically modified organisms] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [day of application of Regulation on genetically modified food and feed and Regulation on traceability and labelling of genetically modified organisms].

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.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 8

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

Article 9

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
David BYRNE
Member of the Commission

ANNEX I

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'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

“In the case of a genetically modified variety: the words 'genetically modified variety. In addition, the unique identifier assigned to the transformation event must be provided.”

(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'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

“In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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. In addition, the unique identifier assigned to the transformation event must be provided.”

(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'. In addition, the unique identifier assigned to the transformation event must be provided.”

ANNEX II

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

1. In Annex II the following points are inserted after point 1:

"1a. Adventitious or technically unavoidable presence of genetically modified seeds:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I point 3 and point 1 of this Annex, seed of a non-genetically modified variety of *Zea mays* may contain up to 0.5% of genetically modified seeds.

The presence of such seeds 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 certification authority that they have taken appropriate steps to avoid the presence of genetically modified organisms. The certification authority shall on request make available this evidence to any other certification authority in whose territory the seed is marketed.

Further, the genetically modified organisms present in seeds of a non-genetically modified variety of *Zea mays*, must either (a) be authorised under Directive 2001/18/EC for the placing on the market, in which case the authorisation must permit the use of the genetically modified organisms in cultivation, or (b) be authorised under Regulation (EC) No ... of ...2003 on genetically modified food and feed for the placing on the market of genetically modified organisms for food or feed use to be used as seeds.

Additionally, in the case of presence of genetically modified seeds in seeds of a non-genetically modified variety of *Zea mays* intended to be used in food or feed, the genetically modified material derived from such genetically modified seeds must be authorised to be used in food or feed under Regulation (EC) No ...2003 on genetically modified food or feed.

1b. Member States shall ensure compliance with point 1a, and with the requirements of Directive 2001/18/EC and of Regulation (EC) No ... 2003 on genetically modified food and feed by seed testing carried out in accordance with Commission Regulation (EC) No/... *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 point 1a and seed testing pursuant to point 1b, the certification authority
- (a) 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 way where, on the basis of a comprehensive analysis, it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - (b) shall carry out such examinations in all cases when there is reason to believe that the requirements have not been satisfied.
- 1d. For seed of a non-genetically modified variety of *Zea mays* in which genetically modified seeds satisfying the conditions set out in point 1a, third paragraph and, if appropriate fourth paragraph, are present, but for which a condition laid down in point 1a, first or second paragraph, is not fulfilled, any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive must state that the seed lot contains genetically modified seeds, and specify the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds.”

2. 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 *Zea mays* under Annex II, point 1d, the following information must be included :

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

5b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

“For seed of non-genetically modified varieties of *Zea mays* under Annex II, point 1d, the following information must be included:

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided

In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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 *Zea mays* under Annex II, point 1d, the following information must be included:

“the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

– In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

“? For seed of non-genetically modified varieties of *Zea mays* under Annex II, point 1d, the following information must be included:

“the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

– In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

ANNEX III

Annexes I, III and IV to Directive 2002/54/EC are amended as follows:

1. In Annex I, part B the following points are inserted after point 1:

“1a. Adventitious or technically unavoidable presence of genetically modified seeds:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I Part A point 1, and point 1 of this Part, seed of a non-genetically modified variety may contain up to 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 certification authority that they have taken appropriate steps to avoid the presence of genetically modified organisms. The certification authority shall on request make available this evidence to any other certification authority in whose territory the seed is marketed.

Further, the genetically modified organisms present in seeds of a non-genetically modified variety, must either (a) be authorised under Directive 2001/18/EC for the placing on the market, in which case the authorisation must permit the use of the genetically modified organisms in cultivation, or (b) be authorised under Regulation (EC) No ... of ...2003 on genetically modified food and feed for the placing on the market of genetically modified organisms for food or feed use to be used as seeds.

Additionally, in the case of presence of genetically modified seeds in seeds of a non-genetically modified variety intended to be used in food or feed, the genetically modified material derived from such genetically modified seeds must be authorised to be used in food or feed under Regulation (EC) No .../2003 on genetically modified food and feed.

1b. Member States shall ensure compliance with point 1a, and with the requirements of Directive 2001/18/EC and of Regulation (EC) No .../2003 on genetically modified food and feed by seed testing carried out in accordance with Commission Regulation (EC) No/... *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 point 1a and seed testing pursuant to point 1b, the certification authority
- (a) 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 way where, on the basis of a comprehensive analysis, it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - (b) shall carry out such examinations in all cases when there is reason to believe that the requirements have not been satisfied.
- 1d. For seed of a non-genetically modified variety in which genetically modified seeds satisfying the conditions set out in point 1a, third paragraph and, if appropriate fourth paragraph, are present, but for which a condition laid down in point 1a, first or second paragraph, is not fulfilled, any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive must state that the seed lot contains genetically modified seeds, and specify the unique identifier(s) of the transformation event(s) of such genetically modified seeds.”

2. Annex III is amended as follows:

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

“6a. For seed of non-genetically modified varieties under Annex I, part B, point 1d, the following information must be included:

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

6b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

“7a. For seed of non-genetically modified varieties under Annex I, part B, point 1d, the following information must be included:

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

7b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

3. Annex IV is amended as follows:

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

“? for seed of non-genetically modified varieties under Annex I, part B, point 1d, the following information must be included:

“the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

– In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided."

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

“? for seed of non-genetically modified varieties under Annex I, part B, point 1d, the following information must be included:

“the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

– In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided."

ANNEX IV

Annexes I, II, IV and V to Directive 2002/55/EC are amended as follows:

1. Annex I is amended as follows:

The following point 01 is inserted before point 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.”

2. In Annex II the following points are inserted after point 1:

“1a. Adventitious or technically unavoidable presence of genetically modified seeds:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I, point 1 where applicable and point 1 of this Annex, seed of a non-genetically modified variety of *Cichorium intybus* or *Lycopersicon lycopersicum* may contain up to 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 certification authority that they have taken appropriate steps to avoid the presence of genetically modified organisms. The certification authority shall on request make available this evidence to any other certification authority in whose territory the seed is marketed.

Further, the genetically modified organisms present in seeds of a non-genetically modified variety, must either (a) be authorised under Directive 2001/18/EC for the placing on the market, in which case the authorisation must permit the use of the genetically modified organisms in cultivation, or (b) be authorised under Regulation (EC) No ... of ...2003 on genetically modified food and feed for the placing on the market of genetically modified organisms for food or feed use to be used as seeds.

Additionally, in the case of presence of genetically modified seeds in seeds of a non-genetically modified variety intended to be used in food or feed, the genetically modified material derived from such genetically modified seeds must be authorised to be used in food or feed under Regulation (EC) N° .../2003 on genetically modified food and feed.

- 1b. Member States shall ensure compliance with point 1a, and with the requirements of Directive 2001/18/EC and of Regulation (EC) No .../2003 [on genetically modified food and feed], by seed testing carried out in accordance with Commission Regulation (EC) No ... 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 point 1a and seed testing pursuant to point 1b, the certification authority
- (a) notwithstanding the obligation to carry out the official examination, except in the case of the category of standard seed, in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic way where, on the basis of a comprehensive analysis, it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - (b) shall carry out such examinations in all cases when there is reason to believe that the requirements have not been satisfied.
- 1d. For seed of a non-genetically modified variety of *Cichorium intybus* or *Lycopersicon lycopersicum*, in which genetically modified seeds satisfying the conditions set out in point 1a, third paragraph and, if appropriate fourth paragraph, are present, but for which a condition laid down in point 1a, first or second paragraph, is not fulfilled, any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive must state that the seed lot contains genetically modified seeds, and specify the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds.”

3. Annex IV is amended as follows:

- (a) In Part A, section I, the following points 6a and 6b are inserted:

“6a. For seed of non-genetically modified varieties of *Cichorium intybus* or *Lycopersicon lycopersicum* under Annex II, point 1d, the following information must be included:

“the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

6b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

- (b) In Part B, section I, the following points 5a and 5b are inserted:

“5a. For seed of non-genetically modified varieties of *Cichorium intybus* or *Lycopersicon lycopersicum* under Annex II, point 1d, the following information must be included:

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

5b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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* or *Lycopersicon lycopersicum* under Annex II, point 1d, the following information must be included:

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

– In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

“? For seed of non-genetically modified varieties of *Cichorium intybus* or *Lycopersicon lycopersicum* under Annex II, point 1d, the following information must be included:

– “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

– In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

ANNEX V

Annexes I and III to Directive 2002/56/EC are amended as follows:

1. Annex I is amended as follows:

(a) the following point 01 is inserted before point 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 text is added:

"7. Adventitious or technically unavoidable presence of genetically modified seed potatoes:

7a. Without prejudice to the conditions to be satisfied by the seed potatoes in respect of the varietal purity in accordance with points 1(b) and 2(b) of this Annex, seed potatoes of a non-genetically modified variety may contain up to 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 certification authority that they have taken appropriate steps to avoid the presence of genetically modified organisms. The certification authority shall on request make available this evidence to any other certification authority in whose territory the seed is marketed.

Further, the genetically modified organisms present in seed potatoes of a non-genetically modified variety, must either (a) be authorised under Directive 2001/18/EC for the placing on the market, in which case the authorisation must permit the use of the genetically modified organisms in cultivation, or (b) be authorised under Regulation (EC) No ... of ...2003 on genetically modified food and feed for the placing on the market of genetically modified organisms for food or feed use to be used as seeds.

Additionally, in the case of presence of genetically modified seed potatoes in seed potatoes of a non-genetically modified variety intended to be used in food or feed, the genetically modified material derived from such genetically modified seed potatoes must be authorised to be used in food or feed under Regulation (EC) No .../2003 on genetically modified food and feed.

- 7b. Member States shall ensure compliance with point 7a, and with the requirements of Directive 2001/18/EC and of Regulation (EC) No .../2003 on genetically modified food and feed, by seed potato testing carried out in accordance with Commission Regulation (EC) No ./.... *on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.*
- 7c. In respect of the conditions under point 7a and seed testing pursuant to point 7b, the certification authority
- (a) notwithstanding the obligation to carry out the official examination in order to examine the satisfaction of the above conditions, need not to carry out such examinations on a systematic way, where, on the basis of a comprehensive analysis, it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - (b) shall carry out such examinations in all cases when there is reason to believe that the requirements have not been satisfied.
- 7d. For seed potato of a non-genetically modified variety in which genetically modified seed potatoes satisfying the conditions set out in point 7a, third paragraph and, if appropriate fourth paragraph, are present, but for which a condition laid down in point 7a, first or second paragraph, is not fulfilled, any label or document, official or otherwise, which is affixed to or accompanies the seed potato lot under the provisions of this Directive must state that the seed potato lot contains genetically modified seed potatoes, and specify the unique identifier(s) assigned to the transformation event(s) of such genetically modified seed potatoes.”

2. In Annex III, part A, the following points 5a and 5 b are inserted:

“5a. For seed potatoes of non-genetically modified varieties under Annex I, point 7d, the following information must be included:

“the seed potato lot contains genetically modified seed potatoes”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seed potatoes must be provided.

5b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

ANNEX VI

Annexes II, IV and V to Directive 2002/57/EC are amended as follows:

1. Annex II is amended as follows:

In Part I the following points are inserted after point 2:

- “2a. Adventitious or technically unavoidable presence of genetically modified seeds:

Without prejudice to the conditions to be satisfied by the seed in respect of the varietal purity in accordance with Annex I point 3, and points 1 and 1a of this Part, seed of a non-genetically modified variety of *Brassica napus* may contain up to 0.3% of genetically modified seeds, seed of a non-genetically modified variety of *Glycine max* may contain up to 0.7% of genetically modified seeds, seed of a non-genetically modified variety of *Gossypium spp.* may contain up to 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 certification authority that they have taken appropriate steps to avoid the presence of genetically modified organisms. The certification authority shall on request make available this evidence to any other certification authority in whose territory the seed is marketed.

Further, the genetically modified organisms present in seeds of a non-genetically modified variety, must either (a) be authorised under Directive 2001/18/EC for the placing on the market, in which case the authorisation must permit the use of the genetically modified organisms in cultivation, or (b) be authorised under Regulation (EC) No ... of ...2003 on genetically modified food and feed for the placing on the market of genetically modified organisms for food or feed use to be used as seeds.

Additionally, in the case of presence of genetically modified seeds in seeds of a non-genetically modified variety intended to be used in food or feed, the genetically modified material derived from such genetically modified seeds must be authorised to be used in food or feed under Regulation (EC) No/2003 on genetically modified food and feed.

- 2b. Member States shall ensure compliance with point 2a, and with the requirements of Directive 2001/18/EC and of Regulation (EC) No/2003 on genetically modified food and feed, by seed testing carried out in accordance with Commission Regulation (EC) No/... on a protocol for sampling and testing of seed lots of non-genetically modified varieties for the presence of genetically modified seed.

- 2c. In respect of the conditions under point 2a and seed testing pursuant to point 2b, the certification authority
- (a) 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 way where, on the basis of a comprehensive analysis, it is reasonable to believe that the requirements are satisfied, provided that the examinations are nonetheless carried out on a targeted basis,
 - (b) shall carry out such examinations in all cases when there is reason to believe that the requirements have not been satisfied.
- 2d. For seed of a non-genetically modified variety of *Brassica napus*, or *Glycine max* or *Gossypium spp*, in which genetically modified seeds satisfying the conditions set out in point 2a, third paragraph and, if appropriate fourth paragraph, are present, but for which a condition laid down in point 2a, first or second paragraph, is not fulfilled, any label or document, official or otherwise, which is affixed to or accompanies the seed lot under the provisions of this Directive must state that the seed lot contains genetically modified seeds, and specify the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds.”

2. Annex IV is amended as follows:

- (a) Part A is amended as follows:

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

“6a. For seed of non-genetically modified varieties of *Brassica napus*, or *Glycine max*, or *Gossypium spp*, under Annex II, Part I, point 2d, the following information must be included:

- “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

6b. In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

3. 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*, or *Glycine max*, or *Gossypium spp*, under Annex II, Part I, point 2d, the following information must be included:

- “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

- In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”

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

- For seed of non-genetically modified varieties of *Brassica napus*, or *Glycine max*, or *Gossypium spp*, under Annex II, Part I, point 2d, the following information must be included:

- “the seed lot contains genetically modified seeds”

In addition, the unique identifier(s) assigned to the transformation event(s) of such genetically modified seeds must be provided.

- In the case of a genetically modified variety: the words 'genetically modified variety'. In addition, the unique identifier assigned to the transformation event must be provided.”