II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 26 March 2007

concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium

(notified under document number C(2007) 1234)

(Only the Dutch and French texts are authentic)

(2007/232/EC)

THE COMMISSION OF THE EUROPEAN UNION,

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/EEC [1], and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority concerned, in accordance with the procedure laid down in that Directive.

(2) A notification concerning the placing on the market of genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) was submitted by Bayer BioScience nv to the competent authority of Belgium.

(3) The notification covered cultivation and import of the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) for all uses as for any other oilseed rape including use as or in feed, but with the exception of uses as or in food, in the Community.

(4) In accordance with the procedure provided for in Article 14 of Directive 2001/18/EC, the competent authority of Belgium prepared an assessment report, which was submitted to the Commission and the competent authorities of other Member States; whereby the assessment report concluded that the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) should be placed on the market for import and processing and for use as any other oilseed rape but not for the requested use of cultivation.

(5) The competent authorities of certain Member States raised objections to the placing on the market of the products.

(6) In view of the objections raised by the competent authority of Belgium and other Member States concerning cultivation of the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3), the opinion of EFSA is restricted to import and processing, including use in feed.

[1] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

(7) The opinion adopted in September 2005 by the European Food Safety Authority, concluded that the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) are as safe as conventional oilseed rape for humans and animals, and in the context of the intended uses, for the environment. The European Food Safety Authority also concluded that the monitoring plan provided in the notification was acceptable in view of the intended uses.

(8) An examination of each of the objections in the light of Directive 2001/18/EC, of the information submitted in the notification and of the opinion of the European Food Safety Authority, discloses no reason to believe that the placing on the market of the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) will adversely affect human or animal health or the environment.

(9) Processed oil from genetically modified oilseed rape derived from (a) the Ms8 oilseed rape line and all conventional crosses, (b) the Rf3 oilseed rape line and all conventional crosses and (c) the hybrid combination Ms8xRf3 has been placed on the market in accordance with Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1]. As a consequence, it is subject to the requirements provided for in Article 8 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2] and may be placed on the market and used in accordance with the conditions mentioned in the Community register of genetically modified food and feed.

(10) Unique identifiers should be assigned to the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) for the purposes of Regulation (EC) No 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/EC [3] and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms [4].

(11) Adventitious or technically unavoidable traces of genetically modified organisms in products are exempted from labelling and traceability requirements in accordance with thresholds established under Directive 2001/18/EC and Regulation (EC) No 1829/2003.

(12) In the light of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended uses with regard to the handling or packaging of the products and the protection of particular ecosystems, environments or geographical areas.

(13) In the light of the opinion of the European Food Safety Authority, an appropriate management system should be in place to prevent grains of the genetically modified oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) entering cultivation.

(14) Prior to the placing on the market of the products, the necessary measures to ensure its labelling and traceability at all stages of its placing on the market, including verification by appropriate validated detection methodology, should be applicable.

(15) The measures provided for in this Decision are not in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC and the Commission therefore submitted to the Council a proposal relating to these measures. Since on the expiry of the period laid down in Article 30(2) of Directive 2001/18/EC the Council had neither adopted the proposed measures nor indicated its opposition to them in accordance with Article 5(6) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [5] the measures should be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Consent

Without prejudice to other Community legislation, in particular Regulation (EC) No 258/97 and Regulation (EC) No 1829/2003, written consent shall be granted by the competent authority of Belgium to the placing on the market, in accordance with this Decision, of the products identified in Article 2, as notified by Bayer BioScience nv (Reference C/BE/96/01).

[1] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
[2] OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).
[3] OJ L 268, 18.10.2003, p. 24.
[4] OJ L 10, 16.1.2004, p. 5.
[5] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

Article 2

Products

1. The genetically modified organisms to be placed on the market as or in products, hereinafter 'the products', are grains of oilseed rape (*Brassica napus* L.) from the individual female and male lines containing events Ms8 and Rf3 respectively as well grains obtained from traditional crossings (Ms8xRf3 hybrid) between these female and male parental lines, which contain the following inserted DNA:

Female line (Ms8)

1. PTA29-*barnase*-3'nos:

— the tapetum cell-specific promoter PTA29 from *Nicotiana tabacum*,

— the *barnase* gene from *Bacillus amyloliquefaciens* to engineer male sterility,

— part of the 3' non-coding region (3' nos) of the nopaline synthase gene of *Agrobacterium tumefaciens*;

2. PssuAra-*bar*-3'g7:

— the PssuAra promoter from *Arabidopsis thaliana*,

— the *bar* gene isolated from *Streptomyces hygroscopicus* conferring tolerance to the herbicide glufosinate-ammonium,

— the 3' untranslated sequence of the TL-DNA gene 7 of *Agrobacterium tumefaciens*;

Male line (Rf3)

3. PTA29-*barstar*-3'nos:

— the tapetum cell-specific promoter PTA29 from *Nicotiana tabacum*,

— the *barstar* gene from *Bacillus amyloliquefaciens* to engineer fertility restoration,

— part of the 3' non-coding region (3' nos) of the nopaline synthase gene of *Agrobacterium tumefaciens*;

4. PssuAra-*bar*-3'g7:

— the PssuAra promoter from *Arabidopsis thaliana*,

— the *bar* gene isolated from *Streptomyces hygroscopicus* conferring tolerance to the herbicide glufosinate-ammonium,

— the 3' untranslated sequence of the TL-DNA gene 7 of *Agrobacterium tumefaciens*.

2. The consent shall cover grains from progeny derived from crosses of oilseed rape line Ms8, Rf3 and Ms8xRf3 with any traditionally bred oilseed rape as or in products.

Article 3

Conditions for placing on the market

The products may be put to the same uses as any other oilseed rape, with the exception of cultivation and uses as or in food, and may be placed on the market subject to the following conditions:

(a) the period of validity of the consent shall be for a period of 10 years starting from the date on which the consent is issued;

(b) the unique identifiers of the products shall be:

— ACS-BNØØ5-8 for lines containing the Ms8 event alone;

— ACS-BNØØ3-6 for lines containing the Rf3 event alone, and;

— ACS-BNØØ5-8 x ACS-BNØØ3-6 for hybrid lines containing both the Ms8 and Rf3 events;

(c) without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall, whenever requested to do so, make positive and negative control samples of the products, or their genetic material, or reference materials available to the competent authorities;

(d) without prejudice to specific labelling requirements provided by Regulation (EC) No 1829/2003, the words 'This product contains genetically modified oilseed rape' or 'This product contains genetically modified Ms8 oilseed rape' or 'This product contains genetically modified Rf3 oilseed rape' or 'This product contains genetically modified Ms8xRf3 oilseed rape', as appropriate, shall appear either on a label or in a document accompanying the product, except where other Community legislation sets a threshold below which such information is not required; and

(e) as long as the products have not been authorised for the placing on the market for the purpose of cultivation, the words 'not for cultivation' shall appear either on a label or in a document accompanying the products.

Article 4

Monitoring

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan, to check for any adverse effects on human and animal health or the environment arising from handling or use of the products, is put in place and implemented.

2. The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the products and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental grain spillage. Technical guidelines for the implementation of this Article are provided in the Annex to this Decision.

3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.

4. Without prejudice to Article 20 of Directive 2001/18/EC the monitoring plan as notified shall, where appropriate and subject to the agreement of the Commission and the competent authority of the Member State which received the original notification, be revised by the consent holder, and/or by the competent authority of the Member State which received the original notification, in the light of the results of the monitoring activities. Proposals for a revised monitoring plan shall be submitted to the competent authorities of the Member States.

5. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

(a) that the existing monitoring networks, as specified in the monitoring plan contained in the notification, gathers the information relevant for the monitoring of the products; and

(b) that these existing monitoring networks have agreed to make available that information to the consent holder before the date of submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

Article 5

Applicability

This Decision shall apply from the date on which detection methods specific to the Ms8 and Rf3 events and the Ms8xRf3 hybrid oilseed rape are validated by the Community Reference Laboratory as referred to in the Annex of Regulation (EC) No 1829/2003, and as specified in Commission Regulation (EC) No 641/2004 [1] on detailed rules for the implementation of Regulation (EC) No 1829/2003.

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 26 March 2007.

For the Commission
Stavros DIMAS
Member of the Commission

[1] OJ L 102, 7.4.2004, p. 14.

ANNEX

Technical guidelines for the implementation of Article 4(2)

1. The consent holder should inform operators in the Community who handle and process bulk mixtures of imported oilseed rape grains which may contain Ms8, Rf3 and Ms8xRf3 oilseed rape that:

   (a) Ms8, Rf3 and Ms8xRf3 oilseed rape has received consent for import and use, in accordance with the definition given in Article 3 of the Decision, in the Community;

   (b) the establishment of a general surveillance plan for any unanticipated adverse effects arising from the placing on the market of Ms8, Rf3 and Ms8xRf3 oilseed rape for the above uses is a condition of consent.

2. The consent holder should provide operators with a national contact person for the reporting of any unanticipated adverse effects.

3. The consent holder should inform operators that the possibility of and consequences arising from accidental spillage of Ms8, Rf3 and Ms8xRf3 oilseed rape have been evaluated by the European Food Safety Authority (EFSA) in the context of its intended uses. The consent holder should maintain regular contact with operators to ensure that they are informed of any changes to current practice which may change the conclusions of the environmental risk assessment.

4. The consent holder should ensure that operators are alert to the possibility that accidental spillage of imported oilseed rape grains in ports and crushing facilities may result in the germination and establishment of volunteer plants, including Ms8, Rf3 and Ms8xRf3 oilseed rape.

5. In the event that volunteer oilseed rape plants include Ms8, Rf3 and Ms8xRf3 oilseed rape, the consent holder should:

   (a) inform operators that these plants should be eradicated to minimise the potential for unanticipated adverse effects arising from the Ms8, Rf3 and Ms8xRf3 oilseed rape;

   (b) provide operators with appropriate plans for eradicating volunteer oilseed rape plants that include Ms8, Rf3 and Ms8xRf3 oilseed rape.

6. Under Article 4(5) of Directive 2001/18/EC and section C.1.6 of the Annex to Council Decision 2002/811/EC [1] establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, Member States may carry out checks and/or additional monitoring with respect to accidental spillage of Ms8, Rf3 and Ms8xRf3 oilseed rape grains and identification of potential unanticipated adverse effects arising from such spillage.

[1] OJ L 280, 18.10.2002, p. 27.