

YOUR LETTER OF

YOUR REF

OUR REF (98.914/L460/MD: NL version)

DATE (25 MAY 2007: NL VERSION)

ENCL(S) DECISION 2007/232/EC

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SUBJECT Notification C/BE/96/01 (English translation of document 98.914/L460/MD of 25 May 2007)

The Minister of Public Health and Social Affairs,
The Minister of Environment and Pensions,

Having regard to the request made by Plant Genetic Systems N.V. (later known as Aventis CropScience N.V. and today as Bayer BioScience N.V.), located in Ghent (Belgium), on 30 September 1996, about the placing on the market of oilseed rape lines (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3), and to the supplementary information relating to it, within the framework of Directive 90/220/EEC¹ (reference No C/BE/96/01);

Having regard to the request updated by Bayer BioScience N.V. on 14 January 2003 in accordance with Article 35 of Directive 2001/18/EC² repealing Council Directive 90/220/EEC, and to the supplementary information relating to it;

Having regard to the Royal Decree of 21 February 2005 regulating the deliberate release into the environment and/or marketing of GMOs or products that contain GMOs ("Arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant" - Belgian Official Gazette of 24 February 2005), replacing the Royal Decree of 18 December 1998 concerning the regulation on the deliberate release in the environment and on the putting on the market of genetically modified organisms or products which contain them ("Arrêté royal du 18 décembre 1998 réglementant la dissémination volontaire dans l'environnement ainsi que la mise sur le marché d'organismes génétiquement modifiés ou de produits en contenant" - Belgian Official Gazette of 31 December 1998);

Having regard to Decision 2007/232/EC of the European Commission (hereinafter referred to as "the Commission") of 26 March 2007 (Official Journal of the European Union L 100/20 of 17 April 2007) concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council (hereinafter referred to as "the Directive"), of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium;

Having regard to the validation of event-specific methods for the detection of Ms8 and Rf3 transformation events and the hybrid oilseed rape line Ms8xRf3 by the Community Reference Laboratory on 29 January 2007³;

¹ Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

² 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

Hereby decree the following:

Article 1

Consent

1. 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 Belgian Minister of Public Health and Social Affairs and the Belgian Minister of Environment and Pensions to the placing on the market, in accordance with this Decision, of the products identified in Article 2, as notified by Bayer BioScience N.V. (reference No C/BE/96/01).
2. In accordance with Article 19(3) of Directive 2001/18/EC, the consent shall specify the conditions as 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 (Ms 8)

(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 glufosinateammonium,
- the 3' untranslated sequence of the TL-DNA gene 7 of *Agrobacterium tumefaciens*;

- Male line (Rf 3)

(1) 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*;

(2) PssuAra-*bar*-3'g7:

- the PssuAra promoter from *Arabidopsis thaliana*,
- the *bar* gene isolated from *Streptomyces hygroscopicus* conferring tolerance to the herbicide glufosinateammonium,
- 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

³ <http://gmo-crl.jrc.it/statusofdoss.htm>

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 authorized 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 below.
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.

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 of 3 October 2002⁴ 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.

Article 5

Entry into force

This decision shall be effective from the date of signature.

APPLICABLE LEGAL AND REGULATORY PROVISIONS

⁴ OJ L 280, 18.10.2002, p. 27

1. Royal Decree of 21 February 2005 regulating the deliberate release into the environment and/or marketing of GMOs or products that contain GMOs (“Arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l’environnement ainsi que la mise sur le marché d’organismes génétiquement modifiés ou de produits en contenant”)
2. 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, part C “Placing on the market of GMOs as or in products”

THE PROCEDURE FOLLOWED

1. Pursuant to Directive 90/220/EEC, the Belgian authorities received a notification (reference No C/BE/96/01) concerning the placing on the market of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium.
2. The notification covered cultivation and import of the above-mentioned genetically modified oilseed rape products (*Brassica napus* L. lines Ms8, Rf3 en 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.
3. Pursuant to Article 14 of Directive 2001/18/EC (hereinafter referred to as “the Directive”), the competent authority of Belgium submitted an assessment report to the Commission on 2 February 2004. The assessment report concluded that the genetically modified oilseed rape products (*Brassica napus* L. lines Ms8, Rf3 en 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. The Commission forwarded the assessment report to all other Member States.
4. In accordance with the standard procedure as laid down in Article 15 of the Directive, a competent authority or the Commission could ask for further information, make comments or present reasoned objections to the placing on the market of the GMO(s) in question within a period of 60 days from the date of circulation of the assessment report. There were comments, objections and requests for information by Member States, some of which raised and maintained objections to the placing on the market of the products in terms of allergenicity, toxicity, monitoring plan, pollen dispersal, accidental spillage and detection of the product.
5. Pursuant to Article 28 of the Directive, the Commission consulted the European Food Safety Authority (EFSA) on the request in question.
6. The EFSA Opinion of 14 September 2005 concluded that the placing on the market of Ms8, Rf3 and Ms8 x Rf3 oilseed rape for import and processing for feed and industrial purposes is unlikely to have an adverse effect on human or animal health or, in the context of its proposed uses, on the environment. The EFSA also advised that appropriate management systems are in place to minimize accidental loss and spillage of transgenic oilseed rape during transportation, storage, handling in the environment and processing into derived products.
7. Based on an examination of each of the objections in the light of the Directive, of the information submitted in the request and of the opinion of the EFSA, and in accordance with the procedure used in case of objections and laid down in Article 18 and 30(2) of the Directive, the Commission concluded that there is no reason to believe that the placing on the market of Ms8, Rf3 and Ms8xRf3 oilseed rape products will adversely affect human or animal health or the environment.
8. The Commission therefore drew up, in accordance with Article 19 of the Directive, a draft decision concerning the placing on the market of Ms8, Rf3 and Ms8xRf3 oilseed rape products. On 5 December 2005, the draft decision was examined and put to the vote in the Committee provided for in Article 30 of the Directive.

9. The Committee has not delivered any opinion, which required that the Commission, in accordance with Article 5(4) of Decision 1999/468/EC⁵, should, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament (informed on 6 December 2005). The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above-mentioned Decision.
10. The draft decision was put on the agenda of the Agriculture Council of 18 September 2006. The meeting could not decide by qualified majority to adopt or oppose the proposal of decision.
11. Pursuant to Decision 1999/468/EC, the Commission then adopted the decision as sent to the Agriculture Council. On 17 April 2007, the positive decision of the Commission was published in the Official Journal of the European Union (OJ L 100/20) under No 2007/232/EC. The decision in question is addressed to the Kingdom of Belgium and aims at authorizing Bayer BioScience N.V. to market Ms8, Rf3 and Ms8xRf3 lines of oilseed rape (*Brassica napus* L.).
12. The decision specifies which conditions are attached to this authorization, in accordance with article 19(3) of the Directive.

Done at Brussels,

The Minister of Public Health
and Social Affairs,

The Minister of Environment
and Pensions,

[signed]

[signed]

R. DEMOTTE

B. TOBBACK

⁵ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission