

## COMMISSION RECOMMENDATION

of 16 August 2005

**concerning the measures to be taken by the consent holder to prevent any damage to health and the environment in the event of the accidental spillage of an oilseed rape (*Brassica napus* L., GT73 line — MON-00073-7) genetically modified for tolerance to the herbicide glyphosate**

(notified under document number C(2005) 3073)

(Only the Dutch text is authentic)

(2005/637/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the second indent of Article 211 thereof,

Whereas:

- (1) On 16 January 2003, the Commission received a dossier, in accordance with the third subparagraph of Article 13(1) and the second indent of Article 14(2) of 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 <sup>(1)</sup> requesting authorisation to place on the market a product based on a genetically modified oilseed rape (*Brassica napus* L., GT73 line — MON-00073-7), together with a favourable assessment report from the competent authority of the Kingdom of the Netherlands.
- (2) The Commission has sent the assessment report to all the other Member States and some of them have expressed and maintained objections to the said report concerning the molecular characterisation, allergenic potential, monitoring, labelling and detection of the product. In such a case, the Commission, in accordance with the first subparagraph of Article 18(1) of Directive 2001/18/EC, must take a decision pursuant to the procedure provided for in Article 30(2) of the Directive, to which Articles 5 and 7 of Council Decision 1999/468/EC <sup>(2)</sup> apply, having regard to the provisions of Article 8 thereof.
- (3) In February 2005, the Japanese Environmental Studies Institute published a report referring to the accidental presence of oilseed rape genetically modified for tolerance to a herbicide around five of the six port facilities where sampling had been carried out.
- (4) It seems necessary to prevent the same situation arising in the European Union, and in particular to prevent any

damage to health and the environment in the event of accidental spillage of the oilseed rape MON-00073-7 during transportation, storage, handling in the environment and processing into derived products.

- (5) In this framework the consent holder is best placed to inform operators and users directly about the safety and general characteristics of the product and the monitoring conditions, in particular the appropriate management measures to be taken in the event of accidental grain spillage.
- (6) The Commission therefore considers it preferable for specific technical guidelines to be added to the decision to place the oilseed rape MON-00073-7 on the market to prevent any damage to health and the environment in case of accidental spillage of this product,

HEREBY RECOMMENDS:

*Article 1*

When applying the provisions of Article 4(2) of the decision to place on the market an oilseed rape (*Brassica napus* L., GT73 line — MON-00073-7) genetically modified for tolerance to the herbicide glyphosate, the measures listed in the Annex shall be taken into account.

*Article 2*

This Recommendation is addressed to the Kingdom of the Netherlands.

Done at Brussels, 16 August 2005.

*For the Commission*

Stavros DIMAS

*Member of the Commission*

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 184, 17.7.1999, p. 23.

## ANNEX

1. The consent holder must inform operators in the Community who handle and process bulk mixtures of imported oilseed rape grains which may contain MON-00073-7 oilseed rape that:
  - (a) MON-00073-7 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 MON-00073-7 oilseed rape for the above uses is a condition of consent.
2. The consent holder must provide operators with a national contact person for the reporting of any unanticipated adverse effects.
3. The consent holder must inform operators that the possibility of and consequences arising from accidental spillage of MON-00073-7 oilseed rape have been evaluated by the European Food Safety Authority (EFSA) in the context of its intended uses. The consent holder must 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 must 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 MON-00073-7 oilseed rape.
5. In the event that volunteer oilseed rape plants include MON-00073-7 oilseed rape, the consent holder must:
  - (a) inform operators that these plants should be eradicated to minimise the potential for unanticipated adverse effects arising from the MON-00073-7 oilseed rape;
  - (b) provide operators with appropriate plans for eradicating volunteer oilseed rape plants that include MON-00073-7 oilseed rape.
6. Under Article 4(5) of Directive 2001/18/EC and section C.1.6 of Council Decision 2002/811/EC <sup>(1)</sup>, Member States may carry out checks and/or additional monitoring with respect to accidental spillage of MON-00073-7 oilseed rape grains and identification of potential unanticipated adverse effects arising from such spillage.

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<sup>(1)</sup> OJ L 280, 18.10.2002, p. 27.