

## COMMISSION DECISION

of 22 April 1998

concerning the placing on the market of genetically modified spring swede rape  
(*Brassica napus* L. ssp. *oleifera*), pursuant to Council Directive 90/220/EEC

(Text with EEA relevance)

(98/291/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms <sup>(1)</sup>, as last amended by Commission Directive 97/35/EC <sup>(2)</sup>, and in particular Article 13 thereof,

Whereas Articles 10 to 18 of Directive 90/220/EEC lay down a Community procedure enabling the competent authorities of a Member State to give consent to the placing on the market of products containing, or consisting of, genetically modified organisms;

Whereas a notification concerning the placing on the market of such a product has been submitted to the competent authorities of the United Kingdom;

Whereas the competent authorities of the United Kingdom have subsequently forwarded the dossier thereon to the Commission with a favourable opinion;

Whereas the competent authorities of other Member States raised objections to the said dossier;

Whereas subsequently the notifier formally requested that the scope of the notification be limited to 'handling of the product during import and before and during storage and processing';

Whereas the notifier subsequently modified the proposed labelling in the original dossier as follows:

- those companies which are known to import for processing the product into the Community will be provided with product documentation informing them of the possibility that the product covered by the notification and produced outside the Community by or under licence from Hoechst Schering AgrEvo

GmbH, may be present in bulk swede rape consignments,

- the product documentation to be provided will include, among others, information that the product has been produced by genetic modification as well as information on the potential uses of the product,
- the product documentation will also indicate that specific labelling requirements may be applicable in the Community for products derived from genetically modified swede rape;

Whereas, therefore, in accordance with Article 13(3) of Directive 90/220/EEC, the Commission is required to take a decision in accordance with the procedure laid down in Article 21 of that Directive;

Whereas the Commission sought the opinion of the relevant Scientific Committees established by Commission Decision 97/579/EC <sup>(3)</sup> on this dossier; whereas the opinion was delivered on 10 February 1998 by the Scientific Committee on Plants which concluded that there is no reason to believe that the import of the product with the aim of processing would have any effects on human health or the environment;

Whereas the Commission, having examined each of the objections raised in the light of Directive 90/220/EEC, the information submitted in the dossier and the opinion of the Scientific Committee on Plants, has reached the conclusion that there is no reason to believe that there will be any adverse effects on human health or the environment from the handling of the product in the environment during import and before and during storage and processing;

Whereas, Article 11(6) and Article 16(1) of Directive 90/220/EEC provide additional safeguards if new information on risks of the product becomes available;

Whereas the measures provided for in this Decision are in accordance with the opinion of the committee established under Article 21 of Directive 90/220/EEC,

<sup>(1)</sup> OJ L 117, 8. 5. 1990, p. 15.

<sup>(2)</sup> OJ L 169, 27. 6. 1997, p. 72.

<sup>(3)</sup> OJ L 237, 28. 8. 1997, p. 18.

HAS ADOPTED THIS REGULATION:

*Article 1*

1. Without prejudice to other Community legislation, in particular Regulation (EC) No 258/97 of the European Parliament and the Council <sup>(1)</sup>, and subject to paragraph 2 of this Article, consent shall be given by the competent authorities of the United Kingdom to the placing on the market of the following product, notified by AgrEvo UK Crop Protection (Ref. C/UK/95/M5/1):

seeds of spring swede rape (*Brassica napus* L. spp. *oleifera*) derived from traditional breeding crosses between non-genetically modified swede rape and a line resulting from transformation event Topas 19/2 which has been transformed using plasmid pOCA/AC containing:

- (a) a synthetic *pat* gene coding for phosphinothricin acetyltransferase under the regulation of 35S promoter and terminator sequences from cauliflower mosaic virus, and

- (b) an *npt II* gene coding for neomycin phosphotransferase II under the regulation of the nopaline synthase promoter and on actopine synthase terminator sequence.

2. The consent shall cover the placing on the market of the product or handling in the environment during import and before and during storage and processing.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 22 April 1998.

*For the Commission*

Ritt BJERREGAARD

*Member of the Commission*

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<sup>(1)</sup> OJ L 43, 14. 2. 1997, p. 1.