

## COMMISSION DECISION

of 22 April 1998

concerning the placing on the market of genetically modified maize (*Zea mays*  
L. line Bt-11), pursuant to Council Directive 90/220/EEC

(Text with EEA relevance)

(98/292/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 product has been notified for handling in the environment during import and storage consistent with its use as an animal feed and the production of industrial and food products but not for further grain production;

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 have raised objections to the said dossier;

Whereas, as the product will enter the market of the Community mixed with other maize grain, including non-genetically modified maize grain, the notifier subsequently modified the proposed labelling in the original dossier as follows:

- exporters from countries where the product is grown, importers into the Community as well as the food and feed processing industry in the Community will be provided with product documentation informing them the possibility that the product may be present in bulk maize 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 maize line Bt-11;

Whereas, the notifier subsequently supplemented the original dossier with further information;

Whereas, 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 this product with the aim of use as any other maize grain is likely to cause any adverse effects on human health and 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 concluded that there is no reason to believe that there will be any adverse effects on human health or the environment from the introduction into maize of the synthetic *cryIA* (b) gene expressing resistance to certain lepidopteran pests and the synthetic *pat* gene expressing increased tolerance to glufosinate ammonium herbicides;

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 DECISION:

*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 paragraphs 2 and 3 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 Novartis Seeds Inc. (Ref. C/GB/96/M4/1):

grains of genetically modified maize line Bt-11 containing:

(a) a synthetic version of the *cryIA* (b) gene derived from *Bacillus thuringiensis* subsp. *kurstaki* strain HD1 under the control of a 35S promoter from Cauliflower Mosaic Virus, and IVS 6 intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of *Agrobacterium tumefaciens*, and

(b) a synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes* under the control of a 35S promoter from Cauliflower Mosaic Virus, an IVS 2 intron from the maize alcohol dehydrogenase gene and the nopaline synthase terminator sequence of *Agrobacterium tumefaciens*.

2. The consent shall cover grains from progenies derived from crosses of maize line Bt-11 with any traditionally bred maize imported into the Community.

3. The consent shall cover the placing on the market of the product to be used as any other maize grain but not for cultivation.

*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.