

## COMMISSION DECISION

of 22 April 1998

concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC

(Text with EEA relevance)

(98/294/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 authority 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 France;

Whereas the competent authorities of France 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 the notifier subsequently modified the proposed labelling in the original dossier as follows:

- to state on all the seed bags that they contain seeds of maize obtained by genetic modification in order to render the maize resistant through the expression of a toxin from *bacillus thuringiensis*,
- to provide all purchasers of such seeds with a technical guide containing comprehensive information on the development, mode of action and use of the seeds, including the use of biotechnology in their development and the necessity for prescribed insect-resistance-management practices,
- to inform European grain traders of the authorisation of maize line MON 810 and to provide them with full product information,

— to inform international maize traders in those countries where maize line MON 810 is authorised for production, that this maize has been authorised for production, that it has been developed using genetic modification techniques and that shipments of grains may contain genetically modified grains,

— to inform international traders and the appropriate authorities of countries exporting maize that any statements accompanying international shipments must be in compliance with the requirements of Directive 90/220/EEC,

— to recommend that statements accompanying international shipments include the wording 'may contain genetically modified grains';

Whereas, the notifier has defined a management strategy in order to minimise the development of insect resistance and has offered to inform the Commission and/or the Competent Authorities of Member States of the results of monitoring of this aspect;

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 placing on the market of the product would have any adverse 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 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 gene *cryIA* (b) coding for insect protection;

<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.

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,

HAS ADOPTED THIS DECISION:

*Article 1*

1. Without prejudice to other Community legislation, in particular Council Directives 66/402/EEC<sup>(1)</sup> and 70/457/EEC<sup>(2)</sup> and Regulation (EC) No 258/97 of the European Parliament and the Council<sup>(3)</sup>, and subject to paragraph 2 of this Article, consent shall be given by the competent authorities of France to the placing on the market of the following product, notified by Monsanto Europe SA (Ref. C/F/95/12-02):

inbred lines and hybrids derived from maize line MON 810 containing the *cryIA* (b) gene from *Bacillus thuringiensis* subsp. *kurstaki* under the control of the enhanced 35S promoter from cauliflower mosaic virus and an intron from the gene coding for the heat shock protein 70 from maize.

2. The consent shall cover any progeny derived from crosses of the product with any traditionally bred maize.

*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*

<sup>(1)</sup> OJ 125, 11. 7. 1966, p. 2309/66.

<sup>(2)</sup> OJ L 225, 12. 10. 1970, p. 1.

<sup>(3)</sup> OJ L 43, 14. 2. 1997, p. 1.