

COMMISSION DECISION

of 22 April 1998

concerning the placing on the market of genetically modified maize (*Zea mays* L. T25), pursuant to Council Directive 90/220/EEC

(Text with EEA relevance)

(98/293/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⁽¹⁾, as last amended by Commission Directive 97/35/EC⁽²⁾, 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 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 mention on the seed bags to be sold to farmers that the product has been genetically modified to make it tolerant to the herbicide glufosinate ammonium,
- to indicate either on the label of seed bags to be sold to farmers or in the accompanying documentation that because of the original genetic modification specific labelling requirements may be applicable for the harvested material, and
- to provide information relating to the genetically modified crops subject to this notification produced by or under licence from Hoechst Schering AgrEvo GmbH outside the Community, to those companies which are known to import the crops concerned into the Community for processing;

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

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⁽³⁾ 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 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 introduction into maize of the gene coding for phosphinotricine-acetyl-transferase and the truncated gene coding for beta-lactamase;

Whereas the authorisation of chemical herbicides applied to plants and the assessment of the impact of their use on human health and the environment falls within the scope of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽⁴⁾, as last amended by Commission Directive 97/73/EC⁽⁵⁾, and not within the scope of Directive 90/220/EEC;

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,

⁽¹⁾ OJ L 117, 8. 5. 1990, p. 15.

⁽²⁾ OJ L 169, 27. 6. 1997, p. 72.

⁽³⁾ OJ L 237, 28. 8. 1997, p. 18.

⁽⁴⁾ OJ L 230, 19. 8. 1991, p. 1.

⁽⁵⁾ OJ L 353, 24. 12. 1997, p. 26.

HAS ADOPTED THIS DECISION:

Article 1

1. Without prejudice to other Community legislation, in particular Council Directives 66/402/EEC⁽¹⁾ and 70/457/EEC⁽²⁾ and Regulation (EC) No 258/97 of the European Parliament and the Council⁽³⁾, 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 AgrEvo France (Ref. C/F/95/12/07):

seeds and grains of genetically modified maize (*Zea mays* L.) with increased glufosinate ammonium tolerance derived from the maize line HE/89 transformation event T25 which has been transformed using plasmid pUC/Ac containing:

(a) a synthetic *pat* gene coding for phosphinothricine acetyl transferase under the regulation of a 35S promoter and terminator sequences from Cauliflower Mosaic Virus, and

(b) a truncated beta-lactamase gene missing about 25 % of the gene from the 5' end, which when complete, codes for betalactam antibiotic resistance and the Col E1 origin of replication of pUC.

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

⁽¹⁾ OJ 125, 11. 7. 1966, p. 2309/66.

⁽²⁾ OJ L 225, 12. 10. 1970, p. 1.

⁽³⁾ OJ L 43, 14. 2. 1997, p. 1.