COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20.05.1996
COM(96) 206 final

Proposal for a

COUNCIL DECISION

concerning the placing on the market of genetically modified maize (*Zea mays L.*) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In accordance with Article 11 of Directive 90/220/EEC, the French authorities received a notification (ref. C/F/94/11-03) concerning the placing on the market of maize (*Zea mays L.*) which has been genetically modified to include pesticide properties (conferred by the Bt-endotoxin gene) and improved tolerance of the herbicide glufosinate ammonium.

2. In accordance with Article 12 of the Directive, the competent French authority forwarded the dossier to the Commission with a favourable opinion.

3. The competent authorities of certain other Member States (A, B, D, DK, I, S and UK) raised objections regarding specific points, including labelling, the effects on human health of the non-expressed β-lactamase gene, the environmental impact of using herbicides on plants and the possible development of resistance to the Bt-toxin. The Commission must therefore take a decision in accordance with the procedure laid down in Article 21 of Directive 90/220/EEC.

4. A proposal for a decision on the measures to be taken was sent for opinion to the Committee set up by Article 21 of the Directive.

5. The Committee has not delivered an opinion, which means that, in accordance with Article 21 of Directive 90/220/EEC, the Commission must, without delay, submit to the Council a proposal relating to the measures to be taken. The Council must act by a qualified majority.

6. The same Article stipulates that if, on the expiry of a period of three months from the date of referral to the Council, the latter has not acted, the proposed measures must be adopted by the Commission.

THE COUNCIL OF THE EUROPEAN UNION,

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] and in particular Article 13 thereof,

Having regard to the proposal from the Commission,

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 consisting of genetically modified organisms;

Whereas a notification concerning the placing on the market of such a product has been submitted to the competent authority of a Member State (France);

Whereas the competent authority of France subsequently forwarded the dossier to the Commission with a favourable opinion; whereas the competent authorities of other Member States raised objections to the said dossier;

Whereas, therefore, pursuant to Article 13(3), the Commission had to take a decision in accordance with the procedure laid down in Article 21 of the Directive;

Whereas, having examined each objection in light of the provisions of Directive 90/220/EEC and analyzed the information supplied in the dossier, the Commission reached the following conclusions:

- The applicant provided information on all the newly introduced genes, and not only those expressed.

- The risk assessment took account of all the introduced genes whether expressed or not. Assessment was also made in this case of the risks from the presence of the non-expressed β-lactamase gene with a bacterial promoter.

- In the case of products intended for use as human food or animal feed, risk assessment under Directive 90/220/EEC determines whether the genetic modification is liable to result in any toxic or harmful effects for human health and the environment.

- There is no reason to believe that the introduction of these genes into maize will have any adverse effects on human health or the environment.

- Possible development of resistance to the truncated CryIA(b) protein in insects cannot be considered an adverse environmental effect, as existing agricultural means of controlling such resistant species of insects will still be available.

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[1] OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 94/15/EC (OJ L 103, 22.5.1994, p. 20).

- There are no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques.

- The label should indicate that the plants have increased tolerance to the herbicide glufosinate ammonium;

Whereas authorization of chemical herbicides and assessment of how their use impacts on human health and the environment are governed by Council Directive 91/414/EEC of July 1991 concerning the placing of plant protection products on the market,[2] and not by Council Directive 90/220/EEC;

Whereas the product under consideration has been notified for unrestricted use, including human food and animal feed;

Whereas this decision does not exclude the application, in compliance with Community law, of Member State provisions on human food or animal feed safety to the extent that they are not specifically related to the genetic modification of the product or its components;

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 Committee set up by Article 21 of Directive 90/220/EEC and consulted by written procedure on 8 March 1996 has not delivered an opinion on the measures laid down in a draft Commission decision,

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2 OJ L 230, 19.08.1991, p. 1. Directive as last amended by Directive 93/43/EC (OJ L 227, p. 31).

HAS ADOPTED THIS DECISION:

Article 1

1. Without prejudice to other Community legislation and subject to the conditions set out in paragraphs 2 and 3, the French authorities shall give consent to the placing on the market of the following product, notified by Ciba-Geigy Limited (Ref. C/F/94/11-03), in accordance with Article 13 of Directive 90/220/EEC.

   The product consists of inbred lines and hybrids derived from a maize (*Zea mays L.*) line (CG 00256-176) which has been transformed using plasmids containing:

   (i) one copy of the *bar* gene, from *Streptomyces hygroscopisus,* (encoding a phosphinothricin acetyltransferase), under the regulation of the 35S promoter and the 35S terminator from the cauliflower mosaic virus (CaMV);

   (ii) two copies of a synthetic truncated gene encoding an insect control protein representing the active portion of the CryIA(b) δ-endotoxin, from *Bacillus thuringiensis subsp. kurstaki* strain HD1-9 and containing intron # 9 from the maize phosphoenolpyruvate carboxylase gene;

   the first copy is under the regulation of a promoter from the maize phosphoenolpyruvate carboxylase gene and the CaMV 35S terminator, and the second copy under the regulation of a promoter derived from a maize calcium-dependent protein kinase gene and the CaMV 35S terminator;

   (iii) the prokaryotic gene *bla* (coding for a β-lactamase conferring resistance to ampicillin) under prokaryotic promoter.

2. This consent covers any progeny derived from crosses of this product with any traditionally bred maize.

3. Without prejudice to other labelling required by Community legislation, the label of each package of seeds shall indicate that the product:

   - protects itself against corn borers and,
   - has increased tolerance to the herbicide glufosinate-ammonium.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

For the Council

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DOCUMENTS

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