



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02.06.1998  
COM(1998) 339 final

Proposal for a  
COUNCIL DECISION

**concerning the provisional prohibition of the sale in  
Austria 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**

(presented by the Commission)



## EXPLANATORY MEMORANDUM

1. In accordance with Article 21 of Directive 90/220/EEC, the Commission adopted a Decision on the placing on the market of genetically modified maize notified by Ciba-Geigy on 23 January 1997. The Decision was taken following the opinions of the Scientific Committee for Pesticides (SCP), the Scientific Committee for Animal Nutrition (SCAN) and the Scientific Committee for Food (SCF).
2. In accordance with Article 13 of the Directive, the Competent Authorities of France granted the necessary consent on 5 February 1997.
3. On 17 February 1997 Austria informed the Commission that it had banned the sale of the Bt-maize in its territory with a Decree signed on 14 February.
4. On 28 February 1997 the arguments of the Austrian Authorities which concerned potential adverse effects for human health and the environment from transfer of the antibiotic resistance gene as well as the possible development of insect resistance to Bt-toxin were submitted to the three relevant Scientific Committees which had originally examined the dossier with the following questions:
  - a) Does the information submitted by Austria constitute new relevant scientific evidence which was not taken into account by the Committees at the time their Opinions were delivered?
  - b) Would this information thus cause the Committees to consider that this product constitutes a risk to human health or the environment?
5. The three Scientific Committees gave their Opinions on the information submitted on 21 March 1997 (SCF), 10 April 1997 (SCAN) and 12 May 1997 (SCP). According to these Opinions, the information submitted by Austria does not constitute new evidence which would occasion a review of the Opinions of the Scientific Committees.

6. As a consequence, on 10 September 1997 the Commission adopted a draft Decision requesting Austria to repeal its national provision prohibiting the sale of the Bt-maize in its territory. This draft measure was then submitted to the Regulatory Committee under Article 21 of the Directive.
7. On 13 April 1998 the Regulatory Committee, which was consulted by written procedure, failed to deliver an opinion on the Draft Commission Decision. According to Article 21 of the Directive, the Commission must therefore, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by qualified majority.
8. The same Article stipulates that if, on the expiry of a period of three months from the date of the referral to the Council, the latter has not acted, the proposed measures shall be adopted by the Commission.
9. In the framework of the adoption of its Decision on the placing on the market, the Commission decided on 18 December 1996 to launch a programme for monitoring insect resistance to Bt-maize. The Expert Group on monitoring insect resistance to Bt, established by the Competent Authorities under Directive 90/220/EEC, has developed a draft monitoring protocol intended to be applied when cultivation of Bt plants commences in the EC. The relevant Scientific Committees are fully involved in the preparation of this monitoring programme.
10. At the same time a subgroup of the Competent Authorities under Directive 90/220/EEC has been set up to assess the general issue of any potential adverse effects for human health and the environment on the transfer of antibiotic resistance genes from plants to micro organisms. The relevant Scientific Committees are fully involved in this work.

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## **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<sup>(1)</sup>, as last amended by Commission Directive 97/35/EC<sup>(2)</sup>, and in particular Article 16 (2) thereof;**

**Having regard to the Proposal from the Commission,**

**Whereas by Commission Decision 97/98/EC of 23 January 1997 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<sup>(3)</sup> it has been decided that consent shall be given for the placing on the market of the product;**

**Whereas on 5 February 1997 the French authorities granted such consent;**

**Whereas pursuant to Article 13 (5) of Directive 90/220/EEC, the product may be used throughout the Community;**

**Whereas Austria provisionally prohibited the sale of genetically modified maize in question by a measure which entered into force on 14 February 1997;**

**Whereas, on 17 February 1997 Austria informed the Commission and the other Member States of such action and gave reasons for its decision relying on Article 16 (1) of Directive 90/220/EEC ;**

**Whereas the Commission must take a decision on the matter pursuant to Article 16 (2) of that Directive;**

**Whereas the Commission sought the opinions of the Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC<sup>(4)</sup>, of the Scientific Committee for Food established by Commission Decision 95/273/EEC<sup>(5)</sup>, and of the Scientific Committee for Pesticides established by Commission Decision 78/436/EEC<sup>(6)</sup> on the information submitted by Austria;**

**Whereas the Scientific Committees did not consider that the information submitted by Austria constituted new relevant scientific evidence which was not taken into account during the**

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(1) OJ N° L117, 8.5.1990, p.15.

(2) OJ N° L169, 27.6.1997, p.72.

(3) OJ N° L31, 1.2.1997, p.69.

(4) OJ N° L279, 9.10.1976, p.35.

(5) OJ N° L167, 18.7.1995, p.22.

(6) OJ N° L124, 12.5.1978, p.16

original evaluation of the dossier and which would occasion a review of their original opinions on this product;

Whereas the Austrian authorities submitted on 9 May 1997 additional information concerning the likely rate of development of insect-resistance to the Bt-toxin;

Whereas the aspect of the environmental effects of the development of insect resistance to the Bt-maize had already been fully considered by the Scientific Committee for Pesticides;

Whereas under the circumstances there is no reason to consider that the product constitutes a risk to human health or the environment;

Whereas the Austrian measures must therefore be repealed;

Whereas the Committee set up by Article 21 of Directive 90/220/EEC and consulted by written procedure on 16 March 1998 has not delivered an opinion on the measures laid down in a draft Commission decision,

**HAS ADOPTED THIS DECISION:**

**Article 1**

Austria shall repeal at the latest 20 days after notification of this Decision its national provisions which prohibit the placing on the market of the genetically modified maize covered by Commission Decision 97/98/EC, to which the French authorities gave their consent on 5 February 1997.

**Article 2**

This Decision is addressed to Austria.

Done at Brussels,

**For the Council**



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# DOCUMENTS

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