



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.4.2005  
COM(2005) 167 final

Proposal for a

**COUNCIL DECISION**

**concerning the provisional restriction of the use and sale in Germany of genetically modified maize (*Zea mays* L. line Bt 176) pursuant to Directive 2001/18/EC**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

1. Concerning the placing on the market of genetically modified maize (*Zea mays* L. line Bt 176), it has been decided by Commission Decision 97/98/EC of 23 January 1997, pursuant to Council Directive 90/220/EEC, that consent shall be given for the placing on the market of the product.
2. On 5 February 1997 the French authorities granted consent for the placing on the market of that product.
3. Pursuant to Article 35(1) of Directive 2001/18/EC which replaced Directive 90/220/EEC procedures in respect of notifications concerning the placing on the market of genetically modified organisms which have not been completed by 17 October 2002 are subject to the provisions of Directive 2001/18/EC.
4. In accordance with Article 16 of Directive 90/220/EEC, the German authorities informed the Commission on 28 February as well as on 2 March and 4 April 2000 of their decision to provisionally restrict the use and sale of the genetically modified maize in question and gave reasons therefore.
5. The Scientific Committee on Plants considered that the information submitted by Germany did not constitute new relevant scientific evidence which had not been taken into account during the original evaluation of the dossier and which would occasion a review of the earlier opinions of the Scientific Committee on Food, the Scientific Committee for Animal Nutrition and the Scientific Committee for Pesticides on this product.
6. On 9 January as well as on 9 and 17 February 2004 Austria submitted to the Commission additional information in support of its national measures concerning maize line Bt 176.
7. The European Food Safety Authority considered that the information submitted by Austria did not constitute new scientific evidence which would invalidate the environmental risk assessment of maize line Bt 176.
8. Under such circumstances Article 23 of Directive 2001/18/EC requires the Commission to take a decision in accordance with the procedures laid down in Article 30(2) of the Directive to which Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
9. Since the Scientific Committee on Food, the Scientific Committee for Animal Nutrition, the Scientific Committee for Pesticides and the Scientific Committee on Plants as well as the EFSA considered that the product did not constitute a risk to human health or the environment the Commission prepared a draft Decision asking Germany to repeal its measures concerning maize line Bt 176.
10. The draft Decision was submitted, in accordance with Article 5(2) of Decision 1999/468/EC, for opinion, to the Committee set up under Article 30 of Directive 2001/18/EC.

11. No opinion was delivered by the Committee, following its consultation, on 29 November 2004, which requires that, the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, shall, without delay, submit to the Council a proposal relating to the measures to be taken and shall inform the European Parliament.
12. Article 5(6) of Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period, the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it; whereas if, on expiry of that period the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act shall be adopted by the Commission.

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**concerning the provisional restriction of the use and sale in Germany of genetically modified maize (*Zea mays L.* line Bt 176) pursuant to Directive 2001/18/EC**

**(Text with EEA relevance)  
(Only the German text is authentic)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC<sup>1</sup>, and in particular Article 23(2) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) 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>2</sup> it has been decided that consent shall be given for the placing on the market of the product.
- (2) On 5 February 1997 the French competent authorities granted consent for the placing on the market of that product.
- (3) Pursuant to Article 35(1) of Directive 2001/18/EC which replaced Directive 90/220/EEC<sup>3</sup> procedures in respect of notifications concerning the placing on the market of genetically modified organisms which have not been completed by 17 October 2002 are subject to the provisions of Directive 2001/18/EC.
- (4) On 28 February as well as on 2 March and 4 April 2000 Germany informed the Commission of its decision to provisionally restrict the use and sale of the genetically modified maize in question and gave reasons therefore in accordance with Article 16(1) of Directive 90/220/EEC.

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<sup>1</sup> OJ L 106, 17.4.2001, p. 1

<sup>2</sup> OJ L 31, 1.2.1997, p. 69

<sup>3</sup> OJ L 117, 8.5.1990, p. 15

- (5) The Scientific Committee on Plants considered that the information submitted by Germany did not constitute new relevant scientific evidence which had not been taken into account during the original evaluation of the dossier and which would occasion a review of the earlier Scientific Committees' opinions on this product.
- (6) On 9 January as well as on 9 and 17 February 2004 Austria submitted to the Commission additional information in support of its national measures concerning maize line Bt 176 having direct implications on the scientific assessment of the current national measures taken by Germany.
- (7) The European Food Safety Authority considered that the information submitted by Austria did not constitute new scientific evidence which would invalidate the environmental risk assessment of maize line Bt 176.
- (8) Under the circumstances there is no reason to consider that the product constitutes a risk to human health or the environment.
- (9) Germany should therefore repeal its measures.
- (10) No opinion was delivered by the Committee established under Article 30 of Directive 2001/18/EC on the measures laid down in a draft Commission Decision, following the Committee's consultation, on 29 November 2004, in accordance with the procedure laid down in Article 30(2) of that Directive,

HAS ADOPTED THIS DECISION:

*Article 1*

The measures taken by Germany to restrict the use and sale of genetically modified maize authorised for placing on the market by Decision 97/98/EC are not justified under the provisions of Article 23 of Directive 2001/18/EC.

*Article 2*

Germany shall take the necessary steps to comply with this Decision at the latest 20 days after its notification.

*Article 3*

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, [...] 2005.

*For the Council  
The President*