



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.4.2005  
COM(2005) 166 final

Proposal for a

**COUNCIL DECISION**

**concerning the provisional prohibition of the use and sale in France of genetically modified spring swede rape (*Brassica napus* L. ssp. *oleifera*) derived from transformation event Topas 19/2, pursuant to Directive 2001/18/EC**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

1. Concerning the placing on the market of genetically modified spring swede rape (*Brassica napus* L. ssp. *oleifera*) derived from transformation event Topas 19/2, it has been decided by Commission Decision 98/291/EC of 22 April 1998, pursuant to Council Directive 90/220/EEC, that consent shall be given for the placing on the market of the product.
2. On 9 June 1998 the authorities of the United Kingdom 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 French authorities informed the Commission on 20 November 1998 of their decision to provisionally prohibit the use and sale of the genetically modified spring swede rape in question for two years and gave reasons therefore. This measure has been renewed on 26 July 2001.
5. The Scientific Committee on Plants considered that the information submitted by France 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 its original opinion on this product.
6. On 6 October 2003 and 27 August 2004 France informed the Commission of its decision to renew the above mentioned prohibition measure for one year and until 17 October 2006 respectively and of reasons therefore with reference to Article 23 of Directive 2001/18/EC.
7. On 5 March 2004 Greece submitted to the Commission additional information in support of its national measures concerning spring swede rape derived from transformation event Topas 19/2 having direct implications on the scientific assessment of the current national measures taken by France.
8. The European Food Safety Authority considered that the information submitted by Greece did not constitute new scientific evidence which would invalidate the environmental risk assessment of spring swede rape derived from transformation event Topas 19/2.
9. 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.
10. Since both 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 France to repeal its measures concerning spring swede rape derived from transformation event Topas 19/2.

11. 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.
12. 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.
13. 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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**(Text with EEA relevance)  
(Only the French 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 98/291/EC of 22 April 1998 concerning the placing on the market of genetically modified spring swede rape (*Brassica napus* L. ssp. *oleifera*), 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 9 June 1998 the competent authorities of the United Kingdom 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 20 November 1998 France informed the Commission of its decision to provisionally prohibit the use and sale of the genetically modified spring swede rape in question for two years and gave reasons therefore in accordance with Article 16(1) of Directive 90/220/EEC. This measure has been renewed on 26 July 2001.

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

<sup>2</sup> OJ L 131, 5.5.1998, p. 26

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

- (5) The Scientific Committee on Plants considered that the information submitted by France 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 its original opinion on this product.
- (6) On 6 October 2003 and 27 August 2004 France informed the Commission of its decision to renew the above mentioned prohibition measure for one year and until 17 October 2006 respectively<sup>4,5</sup> and of reasons therefore with reference to Article 23 of Directive 2001/18/EC.
- (7) On 5 March 2004 Greece submitted to the Commission additional information in support of its national measures concerning spring swede rape derived from transformation event Topas 19/2 having direct implications on the scientific assessment of the current national measures taken by France.
- (8) The European Food Safety Authority considered that the information submitted by Greece did not constitute new scientific evidence which would invalidate the environmental risk assessment of spring swede rape derived from transformation event Topas 19/2.
- (9) Under the circumstances there is no reason to consider that the product constitutes a risk to human health or the environment.
- (10) France should therefore repeal its measures.
- (11) 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 France to prohibit the use and sale of genetically modified spring swede rape authorised for placing on the market by Decision 98/291/EC are not justified under the provisions of Article 23 of Directive 2001/18/EC.

#### *Article 2*

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

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<sup>4</sup> Arrêté du 25 juillet 2003 portant suspension de la mise sur le marché de colza génétiquement modifié au titre de l'article 23 de la directive 2001/18/CE, J.O. de la République française n° 187 du 14 août 2003, p. 14061

<sup>5</sup> Arrêté du 19 juillet 2004 portant suspension de la mise sur le marché de colza génétiquement modifié au titre de l'article 23 de la directive 2001/18/CE, J.O. de la République française n° 194 du 21 août 2004, p. 28

*Article 3*

This Decision is addressed to the French Republic.

Done at Brussels, [...] 2005.

*For the Council  
The President*