

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 8 June 1994

concerning the placing on the market of a product consisting of a genetically modified organism, seeds of herbicide-resistant tobacco variety ITB 1000 OX, pursuant to Article 13 of Council Directive 90/220/EEC

(94/385/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 (GMOs)⁽¹⁾, and in particular Article 13 thereof,

Whereas, in accordance with Part C of Council Directive 90/220/EEC, there is a Community procedure enabling the competent authority of a Member State to give consent to the placing on the market of products consisting of GMOs;

Whereas, a notification concerning the placing on the market of such a product (a herbicide-resistant tobacco variety) has been submitted to the competent authorities of a Member State;

Whereas, in consequence, the competent authority has subsequently forwarded the dossier thereon to the Commission with a favourable opinion;

Whereas the Commission has forwarded the dossier to the competent authorities of all Member States; whereas the competent authorities of some Member States have raised an objection to the said dossier;

Whereas, therefore, in accordance with Article 13 (3), the Commission is required to take a decision in accordance with the procedure provided for in Article 21 of Directive 90/220/EEC;

Whereas under Directive 90/220/EEC only the risks related to the release of the genetically modified tobacco plant itself are evaluated;

Whereas, furthermore, authorization of the chemical herbicides applied to plants and assessment of the impact of their use on 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⁽²⁾ and not within the scope of Council Directive 90/220/EEC;

Whereas the Commission having examined the dossier and having taken into account all the information submitted by the authorities of the Member States, including extensive evidence of testing, has found that the potential risks for human health and the environment presented by the placing on the market and cultivation of the tobacco variety resistant to the herbicide bromoxynil, are not expected to be significant, as regards the aspects covered under Directive 90/220/EEC;

Whereas, consequently, the Commission can take a favourable decision on the placing on the market of the said product under Directive 90/220/EEC;

Whereas this Decision is in accordance with the opinion of the Committee of Member States Representatives established under Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DECISION:

Article 1

A favourable decision is hereby taken, according to which, consent shall be given under Article 13 of Directive 90/220/EEC by the authorities of France for the placing on the market of the following product, notified by the

⁽¹⁾ OJ No L 117, 8. 5. 1990, p. 15.

⁽²⁾ OJ No L 230, 19. 8. 1991, p. 1.

Société nationale d'exploitation industrielle des tabacs et allumettes (Seita) (Notification number: C/F/93/08-02):

Seeds of the genetically modified *Nicotiana tabacum* (common name: Tobacco), variety ITB 1000 OX, male sterile hybrid, resistant to the herbicide bromoxynil and containing the nitrilase gene from *Klebsiella ozaenae*, the promoter RuBisCo SSU from *Helianthus annuus* and the nopaline synthase gene terminator from *Agrobacterium tumefaciens* pTiA6.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 8 June 1994.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission