COMMISSION DECISION

of 19 October 1993

concerning the placing on the market of a product containing genetically modified organisms pursuant to Article 13 of Council Directive 90/220/EEC

(93/572/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to 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 containing GMOs;

Whereas, a notification concerning the placing on the market of such a product (a live vaccine) has been submitted to the competent authorities of a Member State; whereas, in consequence, the competent authority has 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 authority of another Member State has 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 use of the genetically modified organism are evaluated; whereas other aspects of the vaccine are evaluated under specific Community product legislation;

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 use of the genetically modified virus contained in Raboral V-RG (Vaccinia virus, Copenhagen strain, tk-phenotype, expressing glycoprotein G of the rabies virus, ERA strain) when used as an oral live anti-rabies vaccine for foxes and administered in bait, are not expected to be significant;

Whereas, the information submitted and the evidence from testing indicate in particular that the genetic modification of the virus is not expected to result in any post-release shift in biological interactions or host range or in any known or predictable effects on non-target organisms in the environment or other potentially significant interaction with the environment or in any increase in pathogenicity as compared to the parental virus strain and/or in any increase in the capacity of the Raboral V-RG virus to recombine with other related viruses;

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

1. A favourable decision is hereby taken, according to which, consent, subject to paragraph 2 below, shall be given under Article 13 of Directive 90/220/EEC by the authorities of Belgium for the placing on the market of the following product, notified by Rhône Mérieux (Ref. C/B/92/B28 and C/F/93/03-02):

— Raboral V-RG

(Vaccinia virus, Copenhagen strain, tk-phenotype, expressing glycoprotein G of the rabies virus, ERA strain)

— Oral live anti-rabies vaccine for foxes, to be administered in bait.

2. The conditions of use and labelling shall be as follows:

(i) Raboral is an oral vaccine against rabies administered in bait to foxes and shall not be used for human vaccination;

(ii) Raboral shall only be made available to and used by duly designated competent administrative authorities or their authorized agents;

[1] OJ No L 117, 8. 5. 1990, p. 15.

(iii) Raboral baits shall be distributed manually or by low-altitude aerial drops, at approximately 15 vaccine-baits per square kilometre, and shall not be distributed in inhabited areas, roads, rivers or other bodies of water;

(iv) Raboral shall only be made available to the third parties indicated in (ii) above in the form indicated in the notification, that is, in liquid form, as a viral suspension in a polyethylene sachet, itself enclosed in a bait for foxes, which is resistant to temperature variation and shock. The packaging shall be sealed bags or cases of 200 vaccine-baits contained in secondary packaging (carton). The labelling on each vaccine-bait shall be 'vaccine — do not touch'. On the packaging the labelling shall be in conformity with the veterinary legislation in force;

(v) Raboral vaccine and vaccine-baits shall be destroyed by Rhône-Mêrieux or the duly designated competent administrative authorities, by incineration, when the vaccine-baits are out of date or are otherwise rendered unsuitable for use due to, for example, accidents during the production, storage, delivery or distribution of the vaccine or vaccine-baits.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 19 October 1993.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission