COMMISSION

COMMISSION DECISION

of 18 July 1994

amending the Decision of 18 December 1992 concerning the placing on the market of a GMO containing product, the vaccine Nobi-Porvac Aujeszky live (gI⁻, tk⁻), pursuant to Article 13 of Council Directive 90/220/EEC

(94/505/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), 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 a product containing GMOs;

Whereas, according to this procedure, and in particular with regard to Article 13, a Commission Decision was taken on 18 December 1992 [1] enabling the Competent Authority of the Federal Republic of Germany to give consent for the placing on the market of the following product, notified by Vemie Veterinär Chemie GmbH (Ref. C/D/92/I-1):

Nobi-Porvac Aujeszky live (gI⁻, tk⁻) (with Diluvac forte) Pseudorabies virus (strain Begonia)
(for intra-muscular application only);

Whereas, subsequent to that Decision, a further notification has been received by the Competent Authority of the Federal Republic of Germany from the same notifier, requesting that consent be given for extending the use to intra-dermal application as well; 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, the Commission is required to take a further decision, according to the procedures established under Article 21 of Directive 90/220/EEC;

Whereas, the Commission, having examined the dossier and compared it to the elements contained in the dossier considered for the previous decision, and having taken into account all the information submitted by the authorities of the Member States, including extensive evidence of testing, has found that any potential risks for human health and the environment by placing on the market of the product Nobi-Porvac Aujeszky live for intra-dermal use are no different from those presented by the intra-muscular use of the same product;

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 Pseudovaries virus (Strain Begonia) to recombine with other related viruses;

Whereas, consequently, the information contained in the dossier is sufficient to enable the Commission to take a favourable decision on the placing on the market of the product Nobi-Porvac Aujeszky live, extending its use to intra-dermal application, as well as intra-muscular application as permitted by the previous Commission Decision;

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,

[1] C (92) 3215 final.

HAS ADOPTED THIS DECISION:

Article 1

A favourable decision is hereby taken, according to which, the product Nobi-Porvac Aujeszky live, containing a genetically modified pseudorabies virus (strain Begonia) (gI^-, tk^-) in a preparation with Diluvac Forte, modified by Vemie Veterinär Chemie GmbH (Ref. C/D/92/I-1) and for which consent has been given by a Commission Decision of 18 December 1992 for the placing on the market as a live vaccine for Aujeszky disease to be administered by intra-muscular application only, shall now also be given consent for intra-dermal application as well.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 18 July 1994.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission