

COMMISSION DECISION

of 22 October 1993

establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC

(93/584/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ⁽¹⁾, and in particular Article 6 (5) thereof,

Whereas, where a competent authority considers that sufficient experience has been obtained of releases of certain genetically modified organisms (GMOs), it may submit to the Commission a request for the application of simplified procedures for the release for such types of GMOs, and whereas the Commission is required to establish criteria based on safety to human health and the environment and on the evidence available on such safety, to enable the Commission to decide whether a specific simplified procedure should be approved;

Whereas there is now accumulated knowledge and data available concerning the necessary prerequisites for safety to human health and the environment for the release of certain types of GMOs;

Whereas it is considered appropriate that given the different safety concerns for different types of organisms, separate criteria should be established for plants, animals and micro-organisms and that accordingly, the criteria established by this Decision are applicable only in relation to genetically modified plants, which is the group of GMOs with which most of the experience has been acquired to date;

Whereas evidence from releases of genetically modified plants has indicated that the safety of releases of such plants depends on the characteristics of the recipient plant species, on the characteristics of the inserted sequences and their products, and on the receiving ecosystems, and whereas the criteria to be established should be aimed specifically at the evaluation of these characteristics;

Whereas these criteria form an objective and harmonized basis for decisions on the requests for application of simplified procedures;

Whereas it is appropriate, in the interest of transparency, to establish a uniform procedure for the making of a request for simplified procedures;

Whereas, such a request should be based on experience with the GMOs under consideration and on the evidence of safety for human health and the environment and whereas, to these ends, it is appropriate that this experience may include the competent authority's own experience with releases of the same GMOs and the experience in similar ecosystems whether within the Community or internationally, of the GMOs under consideration;

Whereas it is important, in the interests of the greatest possible applicability of uniform procedures, compatible with considerations of safety to human health and the environment, that all Member States should have the opportunity to join in any request for the application of simplified procedures and whereas to this effect an appropriate procedure should be established;

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

HAS ADOPTED THIS DECISION:

Article 1

1. The Commission shall take a decision on the application for simplified procedures for the deliberate release of genetically modified plants, as required under Article 6 (5) of Directive 90/220/EEC, by reference to the criteria set out in paragraphs 2, 3 and 4 and by reference to the sufficient experience and evidence thereof referred to in Article 2.

2. The criteria relating to the characteristics of the recipient plant species shall be as follows:

- (a) the taxonomic status and the biology (mode of reproduction and pollination, ability to cross with related species), should be well-known,

⁽¹⁾ OJ No L 117, 8. 5. 1990, p. 15.

and

- (b) information should be available on any interactions of particular relevance for the evaluation of risk, involving the recipient plant species and other organisms in agricultural ecosystems or in the experimental release ecosystem,

and

- (c) scientific data should be available on the safety for human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species.

3. The criteria relating to the characteristics of the inserted sequences and their expression products shall be as follows:

- (a) the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release,

and

- (b) the inserted sequences should be:

- well characterized, and
- integrated into the plant nuclear genome.

4. The criterion relating to the characteristics of the field release experiments shall be that whenever necessary, the appropriate practices for the management of risks will be applied during or after the experimental release, to ensure the protection of human health and the environment.

5. The criteria set out in paragraphs 2 and 3 should be applied in every case whereas the criterion set out in paragraph 4 should be taken into account when examining a proposed simplified procedure and applied as appropriate.

Article 2

1. A request for the application of simplified procedures shall be made in accordance with the procedures laid down in paragraphs 2 and 3 and Article 3.

2. The request shall be submitted to the Commission in writing and shall be accompanied by a dossier which shall include a description of the proposed simplified procedures, the conditions (if any) under which they are to be applied and information and data on the sufficient experience which has been obtained of releases of the GMOs under consideration.

3. Sufficient experience shall show that the GMOs under consideration are safe for human health and the environment and may be based on the competent authority's own experience with release of the same GMOs, experience with releases of the GMOs under consideration in similar ecosystems and international experience.

Article 3

1. On receipt of the request and the accompanying dossier, the Commission shall immediately forward to the competent authorities of the other Member States a copy of the said request and accompanying dossier.

2. Within 45 days following the dispatch of the request and accompanying dossier, any other competent authority may notify the Commission in writing of its intention to join in the request. To that end, the competent authority may submit any further or additional evidence in support of the original request.

3. Upon expiry of the time limit specified in paragraph 2, the Commission shall forthwith take a decision on the request in accordance with the procedure laid down in Article 21 of Directive 90/220/EEC.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 22 October 1993.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission