94/730/EC: Commission Decision of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6.5 of Council Directive 90/220/EEC (Only the Spanish, Danish, German, English, French, Italian, Dutch, and Portuguese texts are authentic)

Commission Decision

of 4 November 1994

establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6.5 of Council Directive 90/220/EEC

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(94/730/EC)

COMMISSION DECISION of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC (Only the Danish, Dutch, English, French, German, Italian, Portuguese and Spanish texts are authentic) (94/730/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 [(1)], as last amended by Commission Directive 94/15/EC [(2)], 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;

Whereas such a request has been submitted by the competent authorities of the Member States who consider that sufficient experience has been obtained of releases of certain genetically modified plants;

Whereas Commission Decision 93/584/EEC [(3)] establishes the criteria to enable the Commission to decide on the application of simplified procedures; whereas these criteria are based on safety to human health and the environment and on the evidence available on such safety;

Whereas the Commission has examined the requests submitted by the United Kingdom and France for the application of simplified procedures for certain releases of genetically modified plants and the evidence submitted, and has subsequently evaluated these requests in the light of the criteria already established;

Whereas the Commission has concluded that the requested simplified procedures are in conformity with the established criteria, and that sufficient experience has been obtained of releases of certain GMOs to justify the introduction of the requested simplified procedures;

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; whereas to this effect an appropriate procedure has been established;

Whereas in accordance with that procedure the competent authorities of France, the United Kingdom, Belgium, Italy, Portugal, Ireland, Spain, Denmark, the Netherlands and the Federal Republic of Germany have notified the Commission of their intention to apply the simplified procedures foreseen in this Decision;

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

HAS ADOPTED THIS DECISION:

Article 1 U.K.

The requests submitted by France and the United Kingdom pursuant to Article 6 (5) of Directive 90/220/EEC and concerning the simplified procedures set out in the Annex are approved.

Article 2 U.K.

This Decision is addressed to the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, the Kingdom of Spain, the French Republic, Ireland, the Italian Republic, the Kingdom of the Netherlands, the Portuguese Republic and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 4 November 1994.

For the Commission Yannis PALEOKRASSAS Member of the Commission

ANNEX U.K.

1. *U.K.*

The simplified procedure provides for a single notification dossier to be submitted pursuant to Part B of Directive 90/220/EEC, for more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted/deleted sequences or have the same inserted/deleted sequence but differ in phenotypes.

2. *U.K.*

A notifier can submit in a single notification information on several releases of genetically modified crop plants, to be released on several different sites, on the following conditions:

— the taxononic status and biology of the recipient plants species is well known,

— information is available on the interactions of the recipient plant species in the ecosystems in which the experimental and/or agricultural releases are scheduled,

— scientific data is available on the safety to human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species,

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

— the inserted sequences have been well characterized,

— all the inserted sequences are integrated into the plant nuclear genome,

— all the releases are for an a priori specified programme of work,

— all the releases take place within an a priori specified time period.

3. *U.K.*

The information required in the notification is that indicated in Annex II to Directive 90/220/EEC.

4. *U.K.*

Only one single consent is required for all the releases described in the single notification submitted to the competent authority. The procedure to be used in granting that consent is that outlined in Part B of Directive 90/220/EEC.

5. *U.K.*

In order to obtain one single consent covering several releases, all the necessary information for each release should be indicated in the single notification, including sufficient information on the different sites of the releases and on the experimental design, as well as indication of any conditions for risk management for each different release. Clear reference to each release to be covered should be made in the notification, and the appropriate information should be included to allow completion of the summary notification information format.

6. *U.K.*

A notifier can also submit a single notification covering a whole, a priori specified, programme of development work with a single specific recipient plant species and a specified range of inserts/deletions over several years and on several different sites, and receive a single consent for the whole programme of work.

6.1 In such cases, detailed indications or descriptions of the different sites of the releases, subsequent intra-specific sexual crosses and/or the conditions of release need not be given in

the notification, as would be required under the conditions indicated in paragraph 5. However, the notification must contain sufficient information to enable overall an evaluation of risk, and a detailed risk assessment to be made for at least the first release in the programme of work. The information that need not be given may only relate to the sites of the releases, the description of the sites and their surface area, the number of plants released, and the subsequent sexual crosses of the initially notified plants (including progenies) with themselves and/or with plant lines of the initially notified recipient plant species (including the progenies of these crossings).

7. *U.K.*

In the cases referred to in paragraph 6.1 the notifier will submit to the competent authority the additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation. This information should be sent before the specific release to which it refers is carried out, in the form of a simple additional notice for information only.

7.1 The competent authority will immediately send to the Commission any additional risk assessment associated information received in application of paragraph 7. The Commission will circulate these to the competent authorities of the other Member States for information only.

7.2 The notifier can proceed with the release in question after 15 days from the date of receipt by the competent authority of this additional information, unless he receives written indication from the competent authority.

7.3 If any new information submitted is such that the original consent under simplified procedures is no longer applicable, then it is for the competent authority to indicate to the notifier within 15 days of receipt of the notification that he may only proceed with the intended release if a consent is granted under the standard procedure laid down in the Directive.

8. *U.K.*

When the single consent under simplified procedures is granted, conditions can be attached to each of the releases to which it refers. These conditions can subsequently be altered by the competent authority, as indicated in Article 6 (6) of the Directive.

9. *U.K.*

On completion of one or more of the releases approved within the simplified procedure, the notifier shall submit to the competent authority a report with the results of the release(s) at the time specified in the consent. Such reports may be submitted separately, or as a clearly identifiable section in support of a notification for subsequent releases.

10. *U.K.*

The competent authority may alter the conditions of the original consent or intervene to alter the conditions of specific subsequent releases on the basis of the results indicated in the reports or on the basis of information obtained during inspections.

(**1**) 1
OJ No L 117, 8. 5. 1990, p. 15.

(**2**) 2
OJ No L 103, 22. 4. 1994, p. 20.

(**3**) 3
OJ No L 279, 12. 11. 1993, p. 42.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the 94/730/EC: Commission Decision.