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

(Only the Spanish, Danish, German, English, French, Italian, Dutch, and Portuguese texts are authentic)

(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:

[F1 Article 1 U.K.

1. Applications for consent to release genetically modified plants for any other purpose than marketing may be made in accordance with the simplified procedures set out in the Annex.**]**

Textual Amendments

F1 Art. 1 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Article 2 U.K.

. . . . . .

Textual Amendments

F2 Art. 2 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(3)**; 2020 c. 1, Sch. 5 para. 1(1)

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 **[**F3application**]** to be submitted F4..., 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.

Textual Amendments

F3 Word in Annex para. 1 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Annex para. 1 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

2. *U.K.*

[F5An applicant**]** 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.

Textual Amendments

F5 Words in Annex para. 2 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(6)**; 2020 c. 1, Sch. 5 para. 1(1)

[F6 3. *U.K.*

The information required in the application is that specified in—

(1) in the case of an application to release in England, Schedule 1 to the Genetically Modified Organisms (Deliberate Release) Regulations 2002;

(2) in the case of an application to release in Wales, Schedule 1 to the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;

(3) in the case of an application to release in Scotland, Schedule 2 to the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;

(4) in the case of an application to release in Northern Ireland, Schedule 1 to the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.**]**

Textual Amendments

F6 Annex para. 3 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(7)**; 2020 c. 1, Sch. 5 para. 1(1)

4. *U.K.*

Only one single consent is required for all the releases described in the single **[**F7application **]** submitted to the competent authority. F8...

Textual Amendments

F7 Word in Annex para. 4 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(8)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in Annex para. 4 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(8)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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 **[**F9application**]**, 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 **[**F9application**]**F10....

Textual Amendments

F9 Word in Annex para. 5 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Annex para. 5 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

6. *U.K.*

[F11An applicant**]** can also submit a single **[**F12application**]** 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 **[**F13application**]**, as would be required under the conditions indicated in paragraph 5. However, the **[**F13application**]** 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 **[**[F14]plants contained in the initial application **]** (including progenies) with themselves and/or with plant lines of the **[**[F15]recipient plant species contained in the initial application**]** (including the progenies of these crossings).

Textual Amendments

F11 Words in Annex para. 6 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(10)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Word in Annex para. 6 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(10)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Word in Annex para. 6.1 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(11)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in Annex para. 6.1 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(11)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in Annex para. 6.1 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(11)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

7. *U.K.*

In the cases referred to in paragraph 6.1 the **[**[F16]applicant**]** 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.

[F17]7.1 . . . . . .

7.2 The **[**[F18]applicant**]** 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 **[**[F19]consent holder**]** within 15 days of receipt of the **[**[F20]application**]** that he may only proceed with the intended release if a **[**[F21]new consent is applied for and granted that does not rely on the simplified procedures provided for in this Decision**]**.

Textual Amendments

F16 Word in Annex para. 7 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(12)**; 2020 c. 1, Sch. 5 para. 1(1)

F17 Annex para. 7.1 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(13)**; 2020 c. 1, Sch. 5 para. 1(1)

F18 Word in Annex para. 7.2 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(14)**; 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in Annex para. 7.3 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(15)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F20 Word in Annex para. 7.3 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(15)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F21 Words in Annex para. 7.3 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(15)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

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. [F22]...

Textual Amendments

F22 Words in Annex para. 8 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(16)**; 2020 c. 1, Sch. 5 para. 1(1)

9. U.K.

On completion of one or more of the releases approved within the simplified procedure, the **[**[F23]consent holder**]** 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 **[**[F24]an application**]** for subsequent releases.

Textual Amendments

F23 Words in Annex para. 9 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(17)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F24 Words in Annex para. 9 substituted (31.12.2020) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90), regs. 1(2)(b), **7(17)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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 31/12/2020.

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