ANNEX U.K.

1. *U.K.*

The simplified procedure provides for a single **[**F1application**]** to be submitted F2..., 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

F1 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)

F2 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.*

[F3An 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

F3 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)

*I*F4*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

F4 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 **[**F5application **]** submitted to the competent authority. F6...

Textual Amendments

F5 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)

F6 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 **[**F7application**]**, 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 **[**F7application**]**F8....

Textual Amendments

F7 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)

F8 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.*

[F9An applicant**]** can also submit a single **[**F10application**]** 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 **[**F11application**]**, as would be required under the conditions indicated in paragraph 5. However, the **[**F11application**]** 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 **[**F12plants contained in the initial application **]** (including progenies) with themselves and/or with plant lines of the **[**F13recipient plant species contained in the initial application**]** (including the progenies of these crossings).

Textual Amendments

F9 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)

F10 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)

F11 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)

F12 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)

F13 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 **[**F14applicant**]** 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.

F15 7.1 . . . . . .

7.2 The **[**F16applicant**]** 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 **[**F17consent holder**]** within 15 days of receipt of the **[**F18application**]** that he may only proceed with the intended release if a **[**F19new consent is applied for and granted that does not rely on the simplified procedures provided for in this Decision**]**.

Textual Amendments

F14 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)

F15 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)

F16 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)

F17 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)

F18 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)

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)(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. [F20]...

Textual Amendments

F20 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 **[**[F21]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 **[**[F22]an application**]** for subsequent releases.

Textual Amendments

F21 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)

F22 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.

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