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.

Status:
Point in time view as at 04/11/1994.

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