

SCHEDULE 1

Regulations 11 and 16

Information to be included in applications for consent to release or market genetically modified higher plants

PART I

General Information

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.
2. The title of the project.

PART II

Information relating to the parental or recipient plant

3. The full name of the plant—
 - (a) family name,
 - (b) genus,
 - (c) species,
 - (d) subspecies,
 - (e) cultivar/breeding line,
 - (f) common name.
4. Information concerning—
 - (a) the reproduction of the plant:
 - (i) the mode or modes of reproduction,
 - (ii) any specific factors affecting reproduction,
 - (iii) generation time; and
 - (b) the sexual compatibility of the plant with other cultivated or wild plant species, including the distribution in Europe of the compatible species.
5. Information concerning the survivability of the plant:
 - (a) its ability to form structures for survival or dormancy,
 - (b) any specific factors affecting survivability.
6. Information concerning the dissemination of the plant:
 - (a) the means and extent (such as an estimation of how viable pollen and/or seeds decline with distance where applicable) of dissemination; and
 - (b) any specific factors affecting dissemination.
7. The geographical distribution of the plant.
8. Where the application relates to a plant species which is not normally grown in the United Kingdom, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

Status: This is the original version (as it was originally made).

9. Any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

PART III

Information relating to the genetic modification

10. A description of the methods used for the genetic modification.
11. The nature and source of the vector used.
12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

Information relating to the genetically modified plant

13. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.
14. The following information on the sequences actually inserted or deleted:
 - (a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant or any carrier or foreign DNA remaining in the genetically modified plant,
 - (b) the size and function of the deleted region or regions,
 - (c) the copy number of the insert, and
 - (d) the location or locations of the insert or inserts in the plant cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.
15. The following information on the expression of the insert—
 - (a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation,
 - (b) the parts of the plant where the insert is expressed, such as roots, stem or pollen.
16. Information on how the genetically modified plant differs from the parental or recipient plant in the following respects—
 - (a) mode or modes and/or the rate of reproduction,
 - (b) dissemination,
 - (c) survivability.
17. The genetic stability of the insert and phenotypic stability of the genetically modified plant.
18. Any change to the ability of the genetically modified plant to transfer genetic material to other organisms.
19. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

20. Information on the safety of the genetically modified plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified plant is intended to be used in animal feeding stuffs.

21. The mechanism of interaction between the genetically modified plant and target organisms, if applicable.

22. The potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification.

23. The potential interactions with the abiotic environment.

24. A description of detection and identification techniques for the genetically modified plant.

25. Information about previous releases of the genetically modified plant, if applicable.

PART V

Information relating to the site of release

(Applications for consent to release only)

26. The location and size of the release site or sites.

27. A description of the release site ecosystem, including climate, flora and fauna.

28. Details of any sexually compatible wild relatives or cultivated plant species present at the release sites.

29. The proximity of the release sites to officially recognised biotopes or protected areas which may be affected.

PART VI

Information relating to the release

(Applications for consent to release only)

30. The purpose of the release of the genetically modified plant, including its initial use and any intention to use it as or in a product in the future.

31. The foreseen date or dates and duration of the release.

32. The method by which the genetically modified plants will be released.

33. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.

34. The approximate number of genetically modified plants (or plants per square metre) to be released.

PART VII

Information on control, monitoring, post-release and waste treatment plans

(Applications for consent to release only)

- 35.** A description of any precautions to—
 - (a) maintain the genetically modified plant at a distance from sexually compatible plant species, both wild relatives and crops.
 - (b) any measures to minimise or prevent dispersal of any reproductive organ of the genetically modified plant (such as pollen, seeds, tuber).
- 36.** A description of the methods for post-release treatment of the site or sites.
- 37.** A description of the post-release treatment methods for the genetically modified plant material including wastes.
- 38.** A description of monitoring plans and techniques.
- 39.** A description of any emergency plans.
- 40.** Methods and procedures to protect the site.

PART VIII

Information on methodology

- 41.** A description of the methods used or a reference to standardised or internationally recognised methods used to compile the information required by this Schedule, and the name of the body or bodies responsible for carrying out the studies.