#### SCHEDULE 1

[F2Regulation 11]

# Information to be included in applications for consent to release [FI genetically modified higher plants for non-marketing purposes]

- F1 Words in Sch. 1 heading substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(2)
- F2 Sch. 1 shoulder note substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(3)

# **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.

1

- 7. The geographical distribution of the plant [F3 in Europe].
- **F3** Words in Sch. 1 para. 7 inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **6(4)**
- **8.** Where the application relates to a plant species which is not normally grown [<sup>F4</sup>in Europe], a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
  - **F4** Words in Sch. 1 para. 8 substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **6(5)**
- **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.
  - [F515. Information on parts of the plant where the insert is expressed.]
  - F5 Sch. 1 para. 15 substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(6)
- [<sup>F6</sup>15A. The genetic stability of the insert and phenotypic stability of the genetically modified plant.

Document Generated: 2024-01-19

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- F6 Sch. 1 paras. 15A, 15B inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(7)
- **15B.** Conclusions on the molecular characterisation of the genetically modified plant.
- **F6** Sch. 1 paras. 15A, 15B inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **6(7)**
- F7 Sch. 1 para. 16 omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(8)
- F8 Sch. 1 para. 17 omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(8)

# [F9PART 4A

# Information on specific areas of risk

F9 Sch. 1 Pt. 4A heading and para. 18 substituted for Sch. 1 paras. 18-23 (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(9)

#### **18.** Information on—

- (a) any change to the persistence or invasiveness of the genetically modified plant and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects arising,
- (b) any change in the ability of the genetically modified plant to transfer genetic material to microorganisms and the adverse environmental effects arising,
- (c) the mechanism of interaction between the genetically modified plant and target organisms, if applicable, and the adverse environmental effects arising,
- (d) potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification and the adverse environmental effects arising,
- (e) potential changes in agricultural practices and management of the genetically modified plant resulting from the genetic modification, if applicable, and the adverse environmental effects arising,
- (f) potential interactions with the abiotic environment and the adverse environmental effects arising,
- (g) any toxic, allergenic or other harmful effects on human health arising from the genetic modification,
- (h) conclusions on the specific areas of risk.]

<sup>F9</sup> 19.																

<sup>9</sup> 20.																
<sup>9</sup> 21.																
<sup>9</sup> 22.																
923																

- 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

F10

- **F10** Words in Sch. 1 Pt. 5 omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), **6(10)**
- **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

F11

- F11 Words in Sch. 1 Pt. 6 omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(11)
- **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

F12...

- F12 Words in Sch. 1 Pt. 7 omitted (29.9.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(12)
- [F1335.—(1) A description of any precautions to maintain spatial and, as the case may be, temporal separation of the genetically modified plant from sexually compatible plant species.
  - (2) In sub-paragraph (1) "plant species" means—
    - (a) wild and weedy relatives, or
    - (b) crops.]
  - F13 Sch. 1 para. 35 substituted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 6(13)
  - **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.

# **Changes to legislation:**

There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations. View outstanding changes

# Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Blanket amendment words substituted by S.I. 2011/1043 art. 3-68-10