STATUTORY INSTRUMENTS

2002 No. 2443

ENVIRONMENTAL PROTECTION

Genetically Modified Organisms (Deliberate Release) Regulations 2002

Made - - - -	*25th September 2002*
Laid before Parliament	*26th September 2002*
Coming into force	*17th October 2002*

GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS 2002

PART I

GENERAL

PART II

RELEASING ORGANISMS FOR ANY OTHER PURPOSE THAN MARKETING

PART III

MARKETING ORGANISMS

PART IV

DUTIES AFTER THE MAKING OF APPLICATIONS

PART V

GENERAL PROVISIONS FOR CONSENTS

PART VI

SAFEGUARD

PART VII

CONFIDENTIALITY

PART VIII

REGISTER OF INFORMATION

...

27. A description of the release site ecosystem, including climate, flora...
28. Details of any sexually compatible wild relatives or cultivated plant...
29. The proximity of the release sites to officially recognised biotopes...

PART VI — Information relating to the release

...

30. The purpose of the release of the genetically modified plant,...
31. The foreseen date or dates and duration of the release....
32. The method by which the genetically modified plants will be...
33. The method for preparing and managing the release site, prior...
34. The approximate number of genetically modified plants (or plants per...

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

...

35. (1) A description of any precautions to maintain spatial and,...
36. A description of the methods for post-release treatment of the...
37. A description of the post-release treatment methods for the genetically...
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...

SCHEDULE 1A — Information to be included in applications for consent to market genetically modified higher plants

PART 1 — General information

1. The name and address of the applicant, and the name,...
2. The designation and specification of the genetically modified plant, and...

PART 2 — Information relating to the parental or recipient plant

3. The full name of the plant— (a) family name,
4. Information concerning— (a) the reproduction of the plant—
5. Information concerning the survivability of the plant—
6. Information concerning the dissemination of the plant—
7. The geographical distribution of the plant in Europe.
8. Where the application relates to a plant species which is...
9. Any other potential interactions, relevant to the genetically modified organism,...

PART 3 — 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...

PART 4 — Information relating to the genetically modified plant

13. A description of the trait or traits and characteristics of...
14. (1) The following information on the sequences inserted or deleted—...
15. The following information on the expression of the insert—
16. The genetic stability of the insert and phenotypic stability of...
17. Conclusions on the molecular characterisation of the genetically modified plant....
18. The following information on the comparative analysis of agronomic and...

PART 5 — Information on specific areas of risk

19. For each of the areas of risk listed in section...

20. The applicant must provide— (a) the information described in paragraphs...
21. Information relating to the persistence and invasiveness including plant to...
22. Information relating to plant to micro-organism gene transfer including—
23. Information relating to the interactions of the genetically modified plant,...
24. (1) Information on the interactions of the genetically modified plant...
25. Information on the impacts of the specific cultivation, management and...
26. Information on biogeochemical processes including— (a) an assessment of the...
27. Information on the effects on human and animal health including—...
28. (1) The overall risk evaluation and conclusions must include a...

PART 6 — Information about the detection, identification and previous releases of the genetically modified plant

30. A description of detection and identification techniques for the genetically...
31. Information about previous releases of the genetically modified plant, if...

SCHEDULE 2 — Information to be included in applications for consent to release or market organisms other than genetically modified higher plants

PART I — General information

1. The name and address of the applicant, and the name,...
2. The title of the project.

PART II — Information relating to the organisms

Characteristics of donor, parental and recipient organisms

3. Scientific name and taxonomy.
4. Usual strain, cultivar or other name.
5. Phenotypic and genetic markers.
6. The degree of relatedness between donor and recipient or between...
7. The description of identification and detection techniques.
8. The sensitivity, reliability (in quantitative terms) and specificity of detection...
9. The description of the geographic distribution and of the natural...
10. The organisms with which transfer of genetic material is known...
11. Verification of the genetic stability of the organisms and factors...
12. The following pathological, ecological and physiological traits—
13. The sequence, frequency of mobilisation and specificity of indigenous vectors,...
14. The history of previous genetic modifications.

Characteristics of the vector

15. The nature and source of the vector.
16. The sequence of transposons, vectors and other non-coding genetic segments...
17. The frequency of mobilisation, genetic transfer capabilities and/or methods of...
18. The degree to which the vector is limited to the...

Characteristics of the modified organisms

19. The methods used for the modification.
20. The methods used— (a) to construct the insert or inserts...
21. The description of any insert and/or vector construction.

22. The purity of the insert from any unknown sequence and...
23. The methods and criteria used for selection;
24. The sequence, functional identity and location of the altered, inserted...

Characteristics of the genetically modified organisms in their final form

25. The description of genetic trait or traits or phenotypic characteristics...
26. The structure and amount of any vector or donor nucleic...
27. The stability of the organisms in terms of genetic traits....
28. The rate and level of expression of the new genetic...
29. The activity of the gene product.
30. The description of identification and detection techniques, including techniques for...
31. The sensitivity, reliability (in quantitative terms), and specificity of detection...
32. The history of previous releases or uses of the organisms....
33. In relation to human health, animal health and plant health—...

PART III — **Information relating to the conditions of release**

The release

34. The description of the proposed deliberate release, including the initial...
35. The intended dates of the release and time planning of...
36. The preparation of the site before the release.
37. The size of the site.
38. The method or methods to be used for the release....
39. The quantity of organisms to be released.
40. The disturbance on the site, including the type and method...
41. The worker protection measures taken during the release.
42. The post-release treatment of the site.
43. The techniques foreseen for elimination or inactivation of the organisms...
44. Information on, and the results of, previous releases of the...

The environment (both on the site and in the wider environment)

45. The geographical location and national grid reference of the site...
46. The physical or biological proximity of the site of the...
47. The proximity to significant biotopes, protected areas or drinking water...
48. The climatic characteristics of the region or regions likely to...
49. The geographical, geological and pedological characteristics.
50. The flora and fauna, including crops, livestock and migratory species....
51. The description of the target and non-target ecosystems likely to...
52. The comparison of the natural habitat of the recipient organisms...
53. Any known planned developments or changes in land use in...

PART IV — **Information relating to the interactions between the organisms and the environment**

Characteristics affecting survival, multiplication and dissemination

54. The biological features which affect survival, multiplication and dispersal.
55. The known or predicted environmental conditions which may affect survival,...
56. The sensitivity to specific agents.

Interactions with the environment

57. The predicted habitat of the organisms.
58. The studies on the behaviour and characteristics of the organisms...
59. The capability of post-release transfer of genetic material—
60. The likelihood of post-release selection leading to the expression of...
61. The measures employed to ensure and to verify genetic stability,...
62. The routes of biological dispersal, known or potential modes of...
63. The description of ecosystems to which the organisms could be...
64. The potential for excessive population increase of the organisms in...
65. The competitive advantage of the organisms in relation to the...
66. The identification and description of the target organisms if applicable....
67. The anticipated mechanism and result of interaction between the released...
68. The identification and description of non-target organisms which may be...
69. The likelihood of post release shifts in biological interactions or...
70. The known or predicted interactions with non-target organisms in the...
71. The known or predicted involvement of the organisms in biogeochemical...
72. Any other potential interactions of the organisms with the environment....

PART V — **Information on monitoring, control, waste treatment and emergency response plans**

Monitoring techniques

73. Methods for tracing the organisms and for monitoring their effects....
74. Specificity (to identify the organisms, and to distinguish them from...
75. Techniques for detecting transfer of the donated genetic material to...
76. Duration and frequency of the monitoring.

Control of the release

77. Methods and procedures to avoid and/or minimise the spread of...
78. Methods and procedures to protect the site from intrusion by...
79. Methods and procedures to prevent other organisms from entering the...

Waste treatment

80. Type of waste generated.
81. Expected amount of waste.
82. Description of treatment envisaged.

Emergency response plans

83. Methods and procedures for controlling the organisms in case of...
84. Methods, such as eradication of the organisms, for decontamination of...
85. Methods for disposal or sanitation of plants, animals, soils, and...
86. Methods for the isolation of the areas affected by the...
87. Plans for protecting human health and the environment in case...

PART VI — **Information on methodology**

A description of the methods used or a reference to...

SCHEDULE 3 — **Information to be included in applications for consent to market genetically modified organisms**

PART I — General information

1. The proposed commercial name of the product and names of...
2. The name and address in the Community of the person...

3. The name and address of the supplier or suppliers of...
4. A description of how the product and the genetically modified...
5. A description of the geographical area or areas and types...
6. A description of the intended categories of users of the...
7. (1) Information on— (a) methods for the detection, identification and,...
8. The proposed labelling, which must include, in a label or...

PART II — **Additional relevant information**

9. The measures to be taken in the event of the...
10. Specific instructions or recommendations for storage and handling of the...
11. Specific instructions for carrying out monitoring and reporting to the...
12. The proposed restrictions in the approved use of the genetically...
13. The proposed packaging.
14. The estimated production in and/or imports to England.
15. Any proposed additional labelling, which may include, at least in...

SCHEDULE 3A — Information to be provided to the Secretary of State alongside a notice of intention to release a qualifying higher plant

1. The title of the project under which the qualifying higher...
2. The aim of the project (including any matters being investigated...
3. The name, address, telephone number and email address of the...
4. The name, qualifications and experience of every person responsible for...
5. The name, qualifications and experience of every person responsible for...
6. The full name of the qualifying higher plant to be...
7. The expected date on which the project will start.
8. The expected duration of the project.

SCHEDULE 4 — **Information to be included in an assessment report**

1. An identification of the characteristics of the recipient organism which...
2. A description of the way in which the characteristics of...
3. An identification of any known risks of damage to the...
4. An assessment of whether the genetic modification has been characterised...
5. An identification of any new risks of damage to the...
6. A conclusion which addresses the proposed use of the product,...

SCHEDULE 5 — REVOCATIONS

Explanatory Note

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 :

- Sch. 3 para. 7 words omitted by S.I. 2019/88 reg. 3(18)(c) (This amendment not applied to legislation.gov.uk. Reg. 3(18)(c) omitted (29.9.2019) by virtue of S.I. 2019/1252, regs. 1(1), 9)
- reg. 23(1)(b) substituted by S.I. 2019/88 reg. 3(9)(a)(i) (This amendment not applied to legislation.gov.uk. Reg. 3(9)(a) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)
- reg. 23(1)(e) substituted by S.I. 2019/88 reg. 3(9)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 3(9)(a) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)
- reg. 23(4) omitted by S.I. 2019/88 reg. 3(9)(d) (This amendment not applied to legislation.gov.uk. Reg. 3(9)(d) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)
- reg. 24(1)-(4) substituted by S.I. 2019/88 reg. 3(10)(a) (This amendment not applied to legislation.gov.uk. Reg. 3(10)(a) omitted immediately before IP completion day by virtue of S.I. 2019/759, regs. 1(a), 11)

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