STATUTORY RULES OF NORTHERN IRELAND

2003 No. 167

EUROPEAN COMMUNITIES ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

Made - - - - 12th March 2003

Coming into operation 15th April 2003

THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) REGULATIONS (NORTHERN IRELAND) 2003

PART I

GENERAL

1. Citation and commencement
2. Interpretation
3. Purpose of the Order and meaning of expressions used
4. Meaning of “damage to the environment” etc
5. Techniques of genetic modification
6. Environmental risk assessment
7. Communication with applicant for consent

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8. Requirement for consent to release
9. Exempt activities
10. Applications for consent to release genetically modified organisms – general provisions
11. Information to be contained in applications for consent to release
12. Advertisement of applications for consent to release
13. Transitional provisions for release

PART III

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16. Applications for consent to market
17. Transitional provision of marketing
18. Applications for renewal of consent to market

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20. Duties of the Department in relation to applications for consent to release
21. Decisions by the Department on applications for consent to release
22. Variation or revocation of a consent to release genetically modified organisms
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25. Duties of the Department on receiving applications for renewal of consent to market
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28. General provisions of consents to market genetically modified organisms
29. General conditions in consents to release or market genetically modified organisms
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31. New information on risks of damage from marketing genetically modified organisms

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32. Safeguard

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34. Information to be included in the register
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SCHEDULE 1 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,...
2. The title of the project.
PART II — INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT
3. The full name of the plant –
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.
8. Where the application relates to a plant species which is...
9. Any other potential interactions, relevant to the genetically modified organism,...
PART III — INFORMATION RELATING TO 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 IV — INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT
13. A description of the trait or traits and characteristics of...
14. The following information on the sequences actually inserted or deleted...
15. The following information on the expression of the insert –...
16. Information on how the genetically modified plant differs from the...
17. The genetic stability of the insert and phenotypic stability of...
18. Any change to the ability of the genetically modified plant...
19. Information on any toxic, allergenic or other harmful effects on...
20. Information on the safety of the genetically modified plant to...
21. The mechanism of interaction between the genetically modified plant and...
22. The potential changes in the interactions of the genetically modified...
23. The potential interactions with the abiotic environment.
24. A description of detection and identification techniques for the genetically...

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

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...
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

(Applications for consent to release only)

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

(Applications for consent to release only)

35. A description of any precautions to –
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 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 ORGANISMS

3. Characteristics of donor, parental and recipient organisms
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.
15. Characteristics 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...
19. Characteristics of the modified organisms
20. The methods used – (a) to construct the insert or...
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,...
25. Characteristics of the genetically modified organisms in their final form
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

34. The release
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...
45. The environment (both on the site and in the wider environment)
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

54. Characteristics affecting survival, multiplication and dissemination

55. The known or predicted environmental conditions which may affect survival,...
56. The sensitivity to specific agents.
57. Interactions with the environment
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 potentially significant interactions of the organisms with the...

PART V — INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

73. Monitoring techniques
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.
77. Control of the release
78. Methods and procedures to protect the site from intrusion by...
79. Methods and procedures to prevent other organisms from entering the...
80. Waste treatment
81. Expected amount of waste.
82. Description of treatment envisaged.
83. Emergency response plans
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

SCHEDULE 3 INFORMATION TO BE INCLUDED IN AN APPLICATION 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. Information on the genetic modification for the purposes of placing...
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 product in and/or imports to the Community.
15. Any proposed additional labelling, which may include, at least in...

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