WELSH STATUTORY INSTRUMENTS

# 2002 No. 3188 (W.304)

# ENVIRONMENTAL PROTECTION, WALES

## The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

*Made - - - - 18th December 2002*

*Coming into force 31st December 2002*

## THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (WALES) REGULATIONS 2002

Part I

**General**



Part II

**DELIBERATE RELEASE OF ORGANISMS FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET**

Part III

**PLACING ON THE MARKET OF ORGANISMS AS OR IN PRODUCTS**



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**



Part IX

**MISCELLANEOUS**



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SCHEDULE 1 **INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO RELEASE OR MARKET GENETICALLY MODIFIED HIGHER PLANTS**

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— (a) maintain the genetically...
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 GENETICALLY MODIFIED 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 GENETICALLY MODIFIED 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 genetically modified organisms*

19. The methods used for the modification.
20. The methods used— (a) to construct inserts and to introduce...
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*

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 purpose...
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 methods to be used for the release.
39. The quantity of organisms to be released.
40. The disturbance of 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 genetically...
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 GENETICALLY MODIFIED 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 genetically modified 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 genetically modified organisms...
64. The potential for excessive population increase of the genetically modified...
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 genetically modified organisms, and to distinguish...
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 genetically modified organisms in...
84. Methods, such as eradication of the genetically modified organisms, for...
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**

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

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...