1995 No. 413

EUROPEAN COMMUNITIES

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995

Made	*1st November 1995*
Coming into operation . .	*8th December 1995*

The Department of the Environment, being a Department designated(**a**) for the purposes of Section 2(2) of the European Communities Act 1972(**b**), in relation to measures relating to the control and regulation of genetically modified organisms, in exercise of the powers conferred by that section and Articles 8(1), (4), (5) and (7) and 19(1) and (4) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**c**), and of all other powers enabling it in that behalf, hereby makes the following regulations:

Citation and commencement

1. These regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995 and shall come into operation on 8th December 1995.

Interpretation

2.—(1) In these regulations "the 1994 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994(**d**).

(2) The Interpretation Act (Northern Ireland) 1954(**e**) shall apply to these regulations as it applies to a Measure of the Northern Ireland Assembly.

*Implementation of Commission Directive 94/15/EC(**f**)*

3.—(1) In regulation 2 of the 1994 regulations (interpretation), there shall be inserted after the definition of "heritable genetic material" the following definition—

" "higher plant" means a plant belonging to the taxonomic group *Gymnospermae* or *Angiospermae*;"

(**a**) S.I. 1991/755
(**b**) 1972 c. 68
(**c**) S.I. 1991/1714 (N.I. 19). *See* Article 2(2) for the definition of "the Department"; *see* Articles 8(11) and 19(4) for the definition of "prescribed" in those Articles
(**d**) S.R. 1994 No. 144
(**e**) 1954 c. 33 (N.I.)
(**f**) O.J. No. L103, 22.04.94, p. 20

(2) For sub-paragraph (*a*) of paragraph (1) of regulation 6 of the 1994 Regulations (information to be contained in an application for consent to release), there shall be substituted the following sub-paragraph—

"(*a*) the information prescribed in—

(i) Schedule 1, where the application is for consent to release any genetically modified higher plant; or

(ii) Schedule 1A, in any other case,

to the extent that such information is appropriate to the proposed release;".

(3) In paragraph (2) of regulation 6 of the 1994 Regulations, after "Schedule 1" there shall be inserted "and Schedule 1A".

(4) Paragraphs (3) and (4) of regulation 6 of the 1994 Regulations shall be deleted.

(5) For sub-paragraph (*a*) of paragraph (1) of regulation 11 of the 1994 Regulations (information to be contained in an application for consent to market), there shall be substituted the following sub-paragraph—

"(*a*) the information prescribed in—

(i) Schedule 1, where the application is for consent to market any genetically modified higher plant; or

(ii) Schedule 1A, in any other case,

to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,"

(6) In paragraph (2) of regulation 11 of the 1994 Regulations, after "Schedule 1" there shall be inserted "and Schedule 1A".

(7) Paragraphs (3) and (4) of regulation 11 of the 1994 Regulations shall be deleted.

(8) For Schedule 1 to the 1994 Regulations there shall be substituted the Schedules set out in the Schedule to these Regulations.

Amendment of the provisions relating to applications for consent to release

4.—(1) In regulation 2 of the 1994 Regulations (interpretation) there shall be inserted—

(*a*) the following definition—

" "application for a consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision and cognate expressions shall be construed accordingly;";

(*b*) after the definition of "the Deliberate Release Directive" the following definition—

" "the First Simplified Procedure (crop plants) Decision" means Commission Decision 94/730/EC(**a**);".

(2) In paragraph (2) of regulation 5 of the 1994 Regulations (consent to release organisms), after the words "the Department, and" there shall be

(a) O.J. No. L292, 12.11.94, p. 31

inserted the words, "unless made under and in accordance with the provisions set out in the First Simplified Procedure (crop plants) Decision,".

(3) In sub-paragraph (*a*) of paragraph (1) of regulation 6 of the 1994 Regulations after the words "appropriate to the proposed release" there shall be inserted the words "or application".

(4) In paragraph (1) of regulation 8 of the 1994 Regulations (advertisement of application for consent to release), for the words "Subject to paragraph (2)", there shall be substituted the words "Subject to paragraphs (1A) and (2)".

(5) After paragraph (1) of regulation 8 of the 1994 Regulations there shall be inserted the following new paragraph—

> "(1A) A notice published under paragraph (1) need not contain the information referred to in sub-paragraphs (*c*) and (*d*) insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application".

(6) In paragraph (3) of regulation 8 of the 1994 Regulations, after the words "the information prescribed in paragraph (1)(*a*) to (*d*)" there shall be inserted the words "save insofar as paragraph (1A) permits such information to be excluded from the notice referred to in paragraph (1)".

Amendment of the requirements for advertising applications for consent to release

5.—(1) In paragraph (1) of regulation 8 of the 1994 Regulations (advertisement of application for consent to release) for the words "not less than 14 days and not more than 28 days after the date of acknowledgement of receipt of that application is sent to him by the Department", there shall be substituted the words "not more than 10 days after he sends that application to the Department,".

(2) In paragraph (3) of regulation 8 of the 1994 Regulations—

(*a*) for the words "not less than 14 days and not more than 28 days after the date of acknowledgement of receipt of that application is sent to him by the Department,", there shall be substituted the words "not more than 10 days after he sends that application to the Department,";

(*b*) in sub-paragraph (*a*), for the words "the site of the proposed release," there shall be substituted the words "any site of a proposed release specified in the application for a consent to release,";

(*c*) sub-paragraphs (*b*), (*c*) and (*d*) shall be deleted.

Amendment of the cases and circumstances in which a marketing consent is required

6.—(1) In regulation 2 of the 1994 Regulations (interpretation), there shall be inserted immediately after the definition of "the Commission" the following definition—

" "the Contained Use Directive" means Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms(**a**);".

(2) In paragraph (1) of regulation 10 of the 1994 Regulations (consent to market products containing genetically modified organisms)—

(*a*) between the words "cases other than" and "the marketing of a product" there shall be inserted "(*a*)";

(*b*) after the words "the Deliberate Release Directive" there shall be inserted the following—

"; (*b*) the marketing of a product containing genetically modified micro-organisms within the meaning of Article 2 of the Contained Use Directive, the conditions of sale for which specify that it is to be used only in conditions of contained use in accordance with the Contained Use Directive; (*c*) the marketing of a medicinal product for human or veterinary use within the meaning of Council Regulation (EEC) No. 2309/93(**b**); (*d*) the marketing of an additive within the meaning of regulation 2(1) of the Feeding Stuffs Regulations (Northern Ireland) 1992(**c**) incorporated in or for incorporation in any feeding stuff within the meaning of that regulation.".

Amendment of provisions relating to keeping of the register

7.—(1) At the end of sub-paragraph (3)(*c*) of regulation 17 of the 1994 Regulations (information to be included in register) there shall be added the words "to the extent that this information is contained in the application for consent".

(2) At the end of sub-paragraph (3)(*e*) of regulation 17 of the 1994 Regulations (information to be included in register) there shall be added the words "to the extent that this information is contained in the application for consent".

(3) In paragraph (2) of regulation 18 of the 1994 Regulations (keeping of the register) for the words "14 days" there shall be substituted the words "12 days".

Sealed with the Official Seal of the Department of the Environment on 1st November 1995.

(L.S.) *John Crother*

Assistant Secretary

(a) O.J. No. L117, 08.05.90, p. 1

(b) O.J. No. L214, 24/08/93, p. 1. A Council Regulation laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. The Regulation provides for the specific risk assessment of medicinal products containing or consisting of genetically modified organisms

(c) S.R. 1992 No. 270, as amended by S.R. 1993 No. 349, S.R. 1994 No. 123 and S.R. 1994 No. 502. These Regulations implement Council Directive 70/524/EEC concerning additives in feeding stuffs (O.J. No. L270, 14.12.70, p. 1), as amended from time to time, in particular by Council Directive 93/114/EC (O.J. No. L334, 31.12.93, p. 24) which provides for the specific risk assessment of additives containing genetically modified organisms

SCHEDULE Regulation 3

"SCHEDULE 1 Regulations 6 and 11

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.

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 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 member State or States, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

9. The potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, 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 regions,

(*c*) the location of the insert 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,

(*d*) the copy number of the insert.

15. The following information on the expression of the insert:

(*a*) information on the expression of the insert 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.

18. The potential for a transfer of genetic material from the genetically modified plants to other organisms.

19. Information on any toxic or harmful effects on human health and the environment arising from the genetic modification.

20. The mechanism of interaction between the genetically modified plants and target organisms.

21. Any potentially significant interactions with non-target organisms.

22. A description of detection and identification techniques for the genetically modified plants.

23. Information about previous releases of the genetically modified plants.

PART V

INFORMATION RELATING TO THE SITE OF RELEASE

(Applications for consent to release only)

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

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

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

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

PART VI

INFORMATION RELATING TO THE RELEASE

(Applications for consent to release only)

28. The purpose of the release.

29. The foreseen dates and duration of the release.

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

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

32. The approximate number of genetically modified plants (or plants per m^2) to be released.

PART VII

INFORMATION ON CONTROL, MONITORING, POST-RELEASE PLANS AND WASTE TREATMENT PLANS

(Applications for consent to release only)

33. A description of any precaution to—

(*a*) maintain the genetically modified plant at a distance from sexually compatible plant species,

(*b*) minimise or prevent pollen or seed dispersal.

34. A description of the methods for post-release treatment of the site or sites.

35. A description of post-release treatment methods for the genetically modified plant material including wastes.

36. A description of monitoring plans and techniques.

37. A description of any emergency plans.

PART VIII

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT OF THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

38. The likelihood of the genetically modified plant becoming more persistent than the recipient or parental plants in agricultural habitats or more evasive in natural habitats.

39. Any selective advantage or disadvantage conferred on other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.

40. The potential environmental impact of the interaction between the genetically modified plant and target organisms.

41. Any possible environmental impact resulting from potential interactions with non-target organisms.

SCHEDULE 1A Regulations 6 and 11

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, 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 ORGANISMS

Characteristics of the 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 the donor and recipient or between parental organisms.

7. The description of identification and detection techniques.

8. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

9. The description of the geographical distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites and competitors, symbionts and hosts.

10. The potential of the organisms for genetic transfer and exchange with other organisms.

11. Verification of the genetic stability of the organisms and factors affecting that stability.

12. The following pathological, ecological and physiological traits—

(*a*) the classification of hazard according to existing Community rules concerning the protection of human health and the environment;

(*b*) the generation time in natural ecosystems, and sexual and asexual reproductive cycle;

(*c*) survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;

(*d*) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

(*e*) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(*f*) involvement in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration.

13. The sequence, frequency of mobilization and specificity of indigenous vectors and the presence in those vectors of genes which confer resistance to environmental stresses.

14. The history of genetic modification.

Characteristics of the vector

15. The nature and source of the vector.

16. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to make the introduced vector and insert function in those organisms.

17. The frequency of mobilisation, genetic transfer capabilities and/or methods of determination of the inserted vector.

18. The degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the modified organisms

19. The methods used for the modification.

20. The methods used—

(*a*) to construct inserts and introduce them into the recipient organism;

(*b*) to delete a sequence.

21. The description of any insert and/or vector construction.

22. The purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.

23. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question and, in particular, any known harmful sequence.

Characteristics of the genetically modified organisms

24. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

25. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.

26. The stability of the organism in terms of genetic traits.

27. The rate and level of expression of the new genetic material in the organisms and the method and sensitivity of measurement of that rate and level.

28. The activity of the gene product.

29. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

30. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

31. The history of previous releases or uses of the organisms.

32. In relation to human health—

(*a*) the toxic or allergenic effects of the non-viable organisms and/or their metabolic products;

(*b*) the product hazards;

(*c*) the comparison of the organisms to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(*d*) the capacity of the organisms for colonization, and

(*e*) if the organisms are pathogenic to humans who are immunocompetent—

(i) diseases caused and mechanisms of pathogenicity including invasiveness and virulence;

(ii) communicability;

(iii) infective dose;

(iv) host range and possibility of alteration;

(v) possibility of survival outside of human host;

(vi) presence of vectors or means of dissemination;

(vii) biological stability;

(viii) antibiotic-resistance patterns;

(ix) allergenicity; and

(x) availability of appropriate therapies.

PART III

INFORMATION RELATING TO CONDITIONS OF RELEASE

The release

33. The description of the proposed deliberate release, including the purpose or purposes and foreseen products of the release.

34. The foreseen dates of the release and time planning of the experiment including frequency and duration of releases.

35. The preparation of the site before the release.

36. The size of the site.

37. The methods to be used for the release.

38. The quantity of organisms to be released.

39. The disturbance of the site, including the type and method of cultivation, mining, irrigation, or other activities.

40. The worker protection measures taken during the release.

41. The post-release treatment of the site.

42. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment.

43 Information on, and the results of, previous releases of the organisms and in particular, releases on a different scale or into different ecosystems.

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

44. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.

45. The physical or biological proximity of the site to humans and other significant biota.

46. The proximity to significant biotopes or protected areas.

47. The size of local human population.

48. The local economic activities which are based on the natural resources of the area.

49. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

50. The climatic characteristics of the region or regions likely to be affected.

51. The geographical, geological and pedological characteristics.

52. The flora and fauna, including crops, livestock and migratory species.

53. The description of target and non-target ecosystems likely to be affected.

54. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.

55. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART IV

INFORMATION RELATING TO THE ORGANISMS AND THE ENVIRONMENT

Characteristics affecting survival etc

56. The biological features which affect survival, multiplication and dispersal.

57. The known or predicted environmental conditions which may affect survival, multiplication and dissemination, including wind, water, soil, temperature, pH.

58. The sensitivity to specific agents.

Interactions with the environment

59. The predicted habitat of the organism.

60. The studies of the behaviour and characteristics of the organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.

61. The capability of post-release transfer of genetic material—

(*a*) from the genetically modified organisms into organisms in affected ecosystems;

(*b*) from indigenous organisms to the genetically modified organisms.

62. The likelihood of post-release selection leading to the expression of unexpected or undesirable traits in the genetically modified organisms.

63. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimize dispersal of genetic material and methods to verify genetic stability.

64. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing.

65. The description of ecosystems to which the organisms could be disseminated.

Potential environmental impact

66. The potential for excessive population increase of the organisms in the environment.

67. The competitive advantage of the organisms in relation to the unmodified recipient or parental organisms.

68. The identification and description of the target organisms.

69. The anticipated mechanism and result of interaction between the released organisms and the target organisms.

70. The identification and description of non-target organisms which may be affected.

71. The likelihood of post-release shifts in biological interactions or in the host range.

72. The known or predicted effects on non-target organisms in the environment and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

73. The known or predicted involvement in biogeochemical processes.

74. Any other potentially significant interactions with the environment.

PART V

INFORMATION RELATING TO MONITORING, CONTROL WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

Monitoring techiques

75. Methods for tracing the organisms and for monitoring their effects.

76. Specificity (to identify the organisms and to distinguish them from the donor, recipient or the parental organisms) sensitivity and reliability of the monitoring techniques.

77. Techniques for detecting transfer of the donated genetic material to other organisms.

78. Duration and frequency of the monitoring.

Control of the release

79. Methods and procedures to avoid and/or minimize the spread of the organisms beyond the site of release or the designated area for use.

80. Methods and procedures to protect the site from intrusion by unauthorised individuals.

81. Methods and procedures to prevent other organisms from entering the site.

Waste treatment

82. Type of waste generated.

83. Expected amount of waste.

84. Possible risks.

85. Description of treatment envisaged.

Emergency response plans

86. Methods and procedures for controlling the organisms in case of unexpected spread.

87. Methods, such as eradication of the organisms, for decontamination of the areas affected.

88. Methods for disposal or sanitation of plants, animals, soils and any other thing exposed during or after the spread.

89. Methods for the isolation of the areas affected by the spread.

90. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.".

EXPLANATORY NOTE

(*This note is not part of the regulations*)

These regulations amend the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994 (S.R. 1994 No. 144) ("the 1994 Regulations") so as to implement Commission Directive 94/15/EC (O.J. No. L103, 22.04.94, p. 20) adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

Regulation 3 and the Schedule make separate provision for information required in relation to applications to release or market higher plants and that required in relation to applications to release or market other organisms.

Regulation 4 amends the provisions relating to applications for consent to release in order to take account of Commission Decision 94/730/EC (O.J. No. L292, 22.11.94, p. 31).

In addition, these Regulations amend the 1994 Regulations with regard to—

(*a*) the requirements for advertising applications for consent to release organisms (regulation 5);

(*b*) the cases and circumstances in which a marketing consent is required (regulation 6);

(*c*) the provisions relating to keeping the public register (regulation 7).

Copies of the Directive and Decision and extracts from the Official Journal of the European Communities may be obtained from Her Majesty's Stationery Office, 16 Arthur Street, Belfast BT1 4GD.