SCHEDULE 1

Regulation 2(1)

DEFINITION OF REGULATION 2309/93

"Regulation 2309/93" means Council Regulation (EEC) No. 2309/1993(**1**) 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 as amended by–

Community Instrument	*Reference*
Commission Regulation 1995/542/EC	O.J. No. L 55, 11.3.95, p.15
Commission Regulation 1995/540/EC	O.J. No. L 55, 11.3.95, p.5
Commission Regulation 1996/2141/EC	O.J. No. L 286, 8.11.96, p.6
Commission Regulation 1998/1069/EC	O.J. No. L 153, 27.5.98, p.11
Commission Regulation 1998/649/EC	O.J. No. L 88, 24.3.98, p.7

SCHEDULE 2

Regulations 11(1) and 16(2)

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, 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, that is–

(a) family name;

(b) genus;

(c) species;

(d) subspecies;

(e) cultivar/breeding line; and

(f) common name.

4. Information concerning–

(a) the reproduction of the plant, that is–

(**1**) O.J. No. L 214, 24.8.93, p.1.

(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, that is–

(a) its ability to form structures for survival or dormancy; and

(b) any specific factors affecting survivability.

6. Information concerning the dissemination of the plant, that is–

(a) the means and extent (such as an estimation of how viable pollen and/or seeds declines with distance where applicable) 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 United Kingdom, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

9. Information concerning 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 source (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 higher plant or any carrier or foreign DNA remaining in the genetically modified higher plant;

(b) the size and function of the deleted region or regions;

(c) the copy number of the insert; and

(d) 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.

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

(a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterisation; and

(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 recipient plant in the following respects:–

(a) mode or modes and/or the rate of reproduction;

(b) dissemination; and

(c) survivability.

17. The genetic stability of the insert and phenotypic stability of the genetically modified higher plant.

18. Any change to the ability of the genetically modified higher plant to transfer genetic material to other organisms.

19. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.

20. Information on the safety of the genetically modified higher plant to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the genetically modified higher plant is intended to be used in animal feedstuffs.

21. The mechanism of interaction between the genetically modified plant and target organisms, if applicable.

22. The potential changes in the interactions of the genetically modified higher plant with non-target organisms resulting from the genetic modification.

23. The potential interactions with the abiotic environment.

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

(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 and fauna.

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

29. The proximity of the release site or sites to officially recognised biotopes or protected areas which may be affected.

PART VI

INFORMATION RELATING TO THE RELEASE

(Applications for consent to release only)

30. The purpose of the release.

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

(Applications for consent to release only)

35. A description of–

(a) any precautions taken to maintain the genetically modified plant at a distance from sexually compatible plant species, both wild relatives and crops; and

(b) any measures to minimise or prevent dispersal of any reproductive organ of the genetically modified higher plant (such as pollen, seeds, tuber).

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.

SCHEDULE 3 Regulations 11(1) and 16(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, 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 donor, parental and recipient organisms

1

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 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 geographic distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites and competitors, symbionts and hosts.

10. The organisms with which transfer of genetic material is known to occur under natural conditions.

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, sexual and asexual reproductive cycle;

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

(d) pathogencity, 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 colonise other organisms;

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

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

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

14. The history of genetic modifications.

Characteristics of the vector

2

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. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the modified organisms

3

19. The methods used for the modification.

20. The methods used–

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

(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 methods and criteria used for selection.

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

Characteristics of the genetically modified organisms in their final form

4

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

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

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

28. The rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level.

29. The activity of the expressed protein.

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

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

32. The history of previous releases or uses of the genetically modified organisms.

33. In relation to human health, animal health and plant health–

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

(b) the comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(c) the capacity of the organisms for colonisation;

(d) if the organism is pathogenic to humans who are immunocompetent–

(i) diseases caused and mechanism 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; and

(e) the other product hazards.

PART III

INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

The release

5

34. The description of the proposed deliberate release, including the purpose of the release and the foreseen products of the release.

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

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 of cultivation, mining, irrigation or other activities.

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 modified organisms at the end of the experiment or other purpose of the release.

44. 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)

6

45. The geographical location and national grid reference of the site onto which the release will be made, or in the case of applications for consent to market or renewed consent to market the foreseen areas of use of the product.

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

47. The proximity to significant biotopes, protected areas or drinking water supplies.

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

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 be affected.

52. A comparison of the natural habitat of the recipient organism with the proposed site or sites of release.

53. 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 INTERACTIONS BETWEEN THE GENETICALLY MODIFIED ORGANISMS AND THE ENVIRONMENT

Characteristics affecting survival, multiplication and dissemination

7

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

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

56. The sensitivity to specific agents.

Interactions with the environment

8

57. The predicted habitat of the genetically modified organisms.

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

59. 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.

60. The likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organism.

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

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

63. The description of ecosystems to which the genetically modified organisms could be disseminated.

64. The potential for excessive population increase of the genetically modified organisms in the environment.

65. The competitive advantage of the genetically modified organisms in relation to the unmodified recipient or parental organisms.

66. The identification and description of the target organisms if applicable.

67. The anticipated mechanism and result of interaction between the released genetically modified organisms and the target organisms, if applicable.

68. The identification and description of non-target organisms which may be adversely affected by the release of the genetically modified organism, and the anticipated mechanisms of any identified adverse interaction.

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

70. The known or predicted interactions with non-target organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens.

71. The known or predicted involvement of the genetically modified organisms in biogeochemical processes.

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

9

73. Methods for tracing the genetically modified organisms and for monitoring their effects.

74. Specificity (to identify the genetically modified organisms, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.

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

76. Duration and frequency of the monitoring.

Control of the release

10

77. Methods and procedures to avoid and/or minimise the spread of the genetically modified organisms beyond the site of release or the designated area for use.

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

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

Waste treatment

11

80. Type of waste generated.

81. Expected amount of waste.

82. Description of treatment envisaged.

Emergency response plans

12

83. Methods and procedures for controlling the genetically modified organisms in case of unexpected spread.

84. Methods, such as eradication of the genetically modified organisms, for decontamination of the areas affected.

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

86. Methods for the isolation of the area affected by the spread.

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

PART VI

INFORMATION ON METHODOLOGY

88. 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.

SCHEDULE 4 Regulations 16(2), 16(5) and 28

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 the genetically modified organisms in the product, and any specific identification, name or code used by the applicant to identify the genetically modified organism.

2. The name and address in the Community of the person who is responsible for the placing on the market, whether it be the manufacturer, importer or distributor.

3. The name and address of the supplier of control samples.

4. A description of how the product and the genetically modified organism as or in the product are intended to be used, highlighting any differences in use or management of the genetically modified organism compared to similar non-genetically modified products.

5. A description of the geographical area and types of environment where the product is intended to be used within the Community, including, where possible, an estimate of the scale of use in each area.

6. A description of the intended categories of users of the product, such as industry, agriculture, skilled trades or consumer use by the public at large.

7. Information on the genetic modification for the purposes of placing on one or several registers modifications in organisms, which can be used for the detection and identification of particular genetically modified organism products to facilitate post marketing control and inspection. This information should include where appropriate the lodging of samples of the genetically modified organism or its genetic material with the Scottish Ministers, and details of nucleotide sequences or other type of information which is necessary to identify the genetically modified organism product and its progeny, for example the methodology for detecting and identifying the genetically modified organism product, including experimental data demonstrating the specificity of the methodology. Information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register should be identified.

8. Information regarding proposed labelling, which must include, in a label or an accompanying document, at least in summarised form, a commercial name of the product, a statement that "This product contains genetically modified organisms", the name of the genetically modified organism and the name and address of the person established in the Community who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

PART II

ADDITIONAL RELEVANT INFORMATION

9. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

10. Specific instructions or recommendations for storage and handling of the product.

11. Specific instructions for carrying out monitoring and reporting to the applicant and, if required, the Scottish Ministers, which are consistent with Part C of Annex VII of the Deliberate Release Directive, so that the Scottish Ministers can be effectively informed of any adverse effect.

12. The proposed restrictions in the approved use of the genetically modified organism, such as where the product may be used and for what purposes.

13. The proposed packaging.

14. The estimated production in and/or imports to the Community.

15. Any proposed additional labelling, which may include, at least in summarised form, the information referred to in paragraphs 4 and 5 of Part I of this Schedule, or paragraphs 9 to 12 of this Part.

SCHEDULE 5

Regulations 23(1), 25(1) and 31(3)

INFORMATION TO BE INCLUDED IN AN ASSESSMENT REPORT

1. An identification of the characteristics of the recipient organism which are relevant to the assessment of the relevant genetically modified organisms.

2. An identification of any known risks to human health and the environment resulting from the release into the environment of the recipient non-modified organism.

3. A description of the result of the genetic modification in the modified organism.

4. An assessment of whether the genetic modification has been characterised sufficiently for the purpose of evaluating any risks to human health and the environment.

5. An identification of any new risks to human health and the environment that may arise from the release of the relevant genetically modified organisms as compared to the release of the corresponding non-modified organism, based on the environmental risk assessment carried out in accordance with regulation 6.

6. A conclusion which addresses the proposed use of the product, risk management and the proposed monitoring plan, and states whether the relevant genetically modified organisms should be placed on the market on its own or in a product and under which conditions, or not placed on the market for reasons which are specified, or whether the views of other competent authorities and the Commission are sought for on specified aspects of the environmental risk assessment carried out in accordance with regulation 6. Where it is concluded that the genetically modified organisms should not be placed on the market the Scottish Ministers shall give reasons for their conclusion.

SCHEDULE 6

Regulation 37

AMENDMENT TO THE SCOTLAND ACT 1998 (AGENCY ARRANGEMENTS) (SPECIFICATION) (NO. 2) ORDER 2002

For paragraphs (d) and (e) of the Schedule to the Scotland Act 1998 (Agency Arrangements) (Specification) (No. 2) Order 2002(**2**) substitute–

"(ca) Section 126(5)(b) of the Environmental Protection Act 1990 (function of consulting the Food Standards Agency).

(**2**) S.I. 2002/800.

(cb) Regulation 16(5) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of consideration whether applicant may omit certain information from an application for consent to market genetically modified organisms).

(cc) Regulation 20 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (functions on receiving applications for consent to release genetically modified organisms).

(cd) Regulation 23(1) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (functions on receipt of applications for consent to market genetically modified organisms).

(ce) Regulations 23(4) and 31(4) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of consulting the Health and Safety Executive).

(cf) Regulation 27(2) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of evaluating information in environmental risk assessments).

(cg) Regulation 35 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (function of maintaining the register).".

SCHEDULE 7

Regulation 38

REVOCATIONS

Regulations revoked	*References*	*Extent*
The Genetically Modified Organisms (Deliberate Release) Regulations 1992	S.I.1992/3280 as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993 (S.I. 1993/152), the Genetically Modified Organisms (Deliberate Release) Regulations 1995 (S.I. 1995/304), the Genetically Modified Organisms (Deliberate Release) and Risk Assessment–Amendment) Regulations 1997 (S.I. 1997/1900) and the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831)	The whole Regulations other than for the purposes of regulations 9 and 13 of those Regulations
The Genetically Modified Organisms (Deliberate Release) Regulations 1993	S.I. 1993/152	The whole Regulations

Regulations revoked	*References*	*Extent*
The Genetically Modified Organisms (Deliberate Release) Regulations 1995	S.I. 1995/304	The whole Regulations
The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997	S.I. 1997/1900	Regulation 2
The Genetically Modified Organisms (Contained Use) Regulations 2000	S.I. 2000/2831	Regulation 31(2)