SCHEDULE 1

[F2Regulation 12]

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO RELEASE [F1GENETICALLY MODIFIED HIGHER PLANTS FOR NON-MARKETING PURPOSES]

Textual Amendments

F1 Words in Sch. 1 heading substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(2)**

F2 Sch. 1 shoulder note substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(3)**

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 including the distribution in Europe of the compatible 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 (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 **[**F3in Europe**]**.

Textual Amendments

F3 Words in Sch. 1 para. 7 inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(4)**

8. Where the application relates to a plant species which is not normally grown **[**F4in Europe**]**, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

Textual Amendments

F4 Words in Sch. 1 para. 8 substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(5)**

9. 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 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 region or regions,

(c) the copy number of the insert, and

(d) the location or locations of the insert or inserts 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.

[F5 15. Information on parts of the plant where the insert is expressed**]**

Textual Amendments

F5 Sch. 1 para. 15 substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(6)**

[F6 15A. The genetic stability of the insert and phenotypic stability of the genetically modified plant.

Textual Amendments

F6 Sch. 1 paras. 15A, 15B inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(7)**

15B. Conclusions on the molecular characterisation of the genetically modified plant.**]**

Textual Amendments

F6 Sch. 1 paras. 15A, 15B inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(7)**

F7 16. . . . . . .

Textual Amendments

F7 Sch. 1 para. 16 omitted (30.10.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(8)**

F8 17. . . . . . .

Textual Amendments

F8 Sch. 1 para. 17 omitted (30.10.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(8)**

F9 19. . . . . . .

Textual Amendments

F9 Sch. 1 Pt. 4A para. 18 substituted for Sch. 1 paras. 18-23 (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(9)**

F9 20. . . . . . .

Textual Amendments

F9 Sch. 1 Pt. 4A para. 18 substituted for Sch. 1 paras. 18-23 (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(9)**

F9 21. . . . . . .

Textual Amendments

F9 Sch. 1 Pt. 4A para. 18 substituted for Sch. 1 paras. 18-23 (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(9)**

F9 22. . . . . . .

Textual Amendments

F9 Sch. 1 Pt. 4A para. 18 substituted for Sch. 1 paras. 18-23 (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(9)**

F9 23. . . . . . .

Textual Amendments

F9 Sch. 1 Pt. 4A para. 18 substituted for Sch. 1 paras. 18-23 (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(9)**

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.

[F10PART 4A

Information on specific areas of risk

Textual Amendments

F10 Sch. 1 Pt. 4A para. 18 substituted for Sch. 1 paras. 18-23 (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(9)**

18. Information on—

(a) any change to the persistence or invasiveness of the genetically modified plant and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects arising,

(b) any change in the ability of the genetically modified plant to transfer genetic material to micro-organisms and the adverse environmental effects arising,

(c) the mechanism of interaction between the genetically modified plant and target organisms, if applicable, and the adverse environmental effects arising,

(d) potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification and the adverse environmental effects arising,

(e) potential changes in agricultural practices and management of the genetically modified plant resulting from the genetic modification, if applicable, and the adverse environmental effects arising,

(f) potential interactions with the abiotic environment and the adverse environmental effects arising,

(g) any toxic, allergenic or other harmful effects on human health arising from the genetic modification,

(h) conclusions on the specific areas of risk.**]**

Part V

INFORMATION RELATING TO THE SITE OF RELEASE

F11...

Textual Amendments

F11 Words in Sch. 1 Pt. V omitted (30.10.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(10)**

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 sites.

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

Part VI

INFORMATION RELATING TO THE RELEASE

F12...

Textual Amendments

F12 Words in Sch. 1 Pt. VI omitted (30.10.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(11)**

30. The purpose of the release of the genetically modified plant, including its initial use and any intention to use it as or in a product in the future.

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 m^2) to be released.

Part VII

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

F13 …

Textual Amendments

F13 Words in Sch. 1 Pt. VII omitted (30.10.2019) by virtue of The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(12)**

[F14 35.—(1) A description of any precautions to maintain spatial and, as the case may be, temporal separation of the genetically modified plant from sexually compatible plant species.

(2) In sub-paragraph (1) "plant species" means—

(a) wild and weedy relatives, or

(b) crops.**]**

Textual Amendments

F14 Sch. 1 para. 35 substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **6(13)**

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.

[F15SCHEDULE 1A

Regulation 17

Information to be included in applications for consent to market genetically modified higher plants

Textual Amendments

F15 Sch. 1A inserted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **7**

PART 1

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 designation and specification of the genetically modified plant, and the scope of the application, in particular whether the application is in respect of cultivation, for some other use (which must be specified), or both.

PART 2

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 or 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, including the distribution in Europe of the compatible 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 (such as an estimation of how viable pollen or seeds decline with distance where applicable) of dissemination, and

(b) any specific factors affecting dissemination.

7. The geographical distribution of the plant in Europe.

8. Where the application relates to a plant species which is not normally grown in Europe, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

9. 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 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 or organisms of each constituent fragment of the region intended for insertion.

PART 4

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.—(1) The following information on the sequences 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 region or regions, where appropriate,

(c) the copy number of the insert,

(d) the subcellular location of any insert in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form) and methods for its determination,

(e) the organisation and sequence of the genetic material at each insertion site in a standardised electronic format,

(f) the sequence of genomic DNA flanking each insertion site in a standardised electronic format,

(g) bioinformatic analysis to identify interruptions of known genes,

(h) information on Open Reading Frames ("ORFs") within the insert and ORFs created at the junction of the insert and genomic DNA,

(i) bioinformatic analysis to identify similarities between any ORFs generated by the genetic modification and known genes that may have adverse effects,

(j) the amino acid sequence and if necessary, other structures of proteins produced as a results of the genetic modification,

(k) bioinformatic analysis to identify sequence homologies, and if necessary, structural similarities, between proteins produced as a result of the genetic modification and known proteins and peptides with potential adverse effects,

(l) in the case of genetic modifications other than insertion or deletion, information on the function of the genetic material targeted by the genetic modification before and after modification, as well as direct changes in the expression of genes as result of the modification.

(2) In this paragraph, an ORF is a nucleotide sequence that contains a string of codons uninterrupted by the presence of a stop codon in the same reading frame.

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

(a) information on the developmental expression of the inserted or modified DNA during the lifecycle of the plant and methods used for its characterisation,

(b) the parts of the plant where the insert is expressed, such as roots, stem or pollen,

(c) the potential unintended expression of a new ORF (which has the meaning given in paragraph 14(2)), which has resulted from the insertion or deletion of genetic material into a known gene (as identified under paragraph **[**F16 14(1)(g)**]**) and which raises a safety concern,

(d) protein expression data from genetically modified plants grown under field conditions.

Textual Amendments

F16 Words in Sch. 1A para. 15(c) substituted by S.I. 2019/1316, reg. 7 (as amended) (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) (Amendment) Regulations 2019 (S.I. 2019/1407), regs. 1(2), **4(b)**

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

17. Conclusions on the molecular characterisation of the genetically modified plant.

18. The following information on the comparative analysis of agronomic and phenotypic characteristics and of composition—

(a) choice of a conventional counterpart and any additional comparators used in comparative analyses,

(b) choice of field site location for producing plant material for comparative analyses,

(c) experimental design including statistical analysis,

(d) selection of plant material for analysis, where relevant,

(e) comparative analysis of agronomic and phenotypic characteristics,

(f) comparative analysis of composition, if relevant,

(g) conclusions of comparative analysis.

PART 5

Information on specific areas of risk

19. For each of the areas of risk listed in section D.2 of Annex 2 to the Deliberate Release Directive the applicant must describe each pathway through which harm could occur in respect of the release of a genetically modified plant, taking hazard and exposure into account.

20. The applicant must provide—

(a) the information described in paragraphs 21 to 27, and

(b) the overall risk evaluation and conclusions described in paragraph 28,

except where the applicant considers it is not relevant in view of the intended use of the genetically modified plant.

21. Information relating to the persistence and invasiveness including plant to plant gene transfer including—

(a) an assessment of the potential for the genetically modified plant to become more persistent or invasive and the adverse environmental effects arising,

(b) an assessment of the potential for the genetically modified plant to transmit transgenes to sexually compatible relatives and the adverse environmental effects arising,

(c) conclusions on the adverse environmental effect of persistence and invasiveness of the genetically modified plant including the adverse environmental effect of plant to plant gene transfer.

22. Information relating to plant to micro-organism gene transfer including—

(a) an assessment of the potential for transfer of newly inserted DNA from the genetically modified plant to micro-organisms and the adverse effects arising,

(b) conclusions on the adverse effect of the transfer of newly inserted DNA from the genetically modified plant to micro-organisms on human and animal health and the environment.

23. Information relating to the interactions of the genetically modified plant, if relevant, with target organisms including—

(a) an assessment of the potential for changes in the direct and indirect interactions between the genetically modified plant and target organisms and the adverse environmental effects arising,

(b) an assessment of the potential for evolution of resistance of the target organism to the expressed protein based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits, and any adverse environmental effects arising,

(c) conclusions on adverse environmental effects of interactions of the genetically modified plant with target organisms.

24.—(1) Information on the interactions of the genetically modified plant with non-target organisms including—

(a) an assessment of the potential for direct and indirect interactions of the genetically modified plant with non-target organisms, including protected species, and the adverse effect arising,

(b) conclusions on adverse environmental effects of interactions of the genetically modified plant with non-target organisms.

(2) The assessment described in sub-paragraph (1) must take into account the potential adverse effect on relevant ecosystem services and on the species providing those services.

25. Information on the impacts of the specific cultivation, management and harvesting techniques including—

(a) in respect of genetically modified plants for cultivation, an assessment of the changes in the specific cultivation, management and harvesting techniques used for the genetically modified plant and the adverse environmental effects arising,

(b) conclusions on adverse environmental effects of the specific cultivation, management and harvesting techniques.

26. Information on biogeochemical processes including—

(a) an assessment of the potential changes in the biogeochemical processes within the area in which the genetically modified plant is to be grown and in the wider environment, and the adverse effects arising,

(b) conclusions on adverse effects on biogeochemical processes.

27. Information on the effects on human and animal health including—

(a) an assessment of potential direct and indirect interactions between the genetically modified plant and persons working with or coming into contact with the genetically modified plant, including through pollen or dust from a processed genetically modified plant, and assessment of the adverse effects of those interactions on human health,

(b) for a genetically modified plant not destined for human consumption, but where the recipient or parental organisms may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake,

(c) an assessment of the potential adverse effects on animal health due to accidental consumption of the genetically modified plant or of material from that plant by animals,

(d) conclusions on the effects on human and animal health.

28.—(1) The overall risk evaluation and conclusions must include a summary of each of the conclusions specified in paragraphs 21 to 27.

(2) The summary referred to in sub-paragraph (1) must take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex 2 and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex 2 to the Deliberate Release Directive.

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 modified plant.

31. Information about previous releases of the genetically modified plant, if applicable.**]**

SCHEDULE 2

Regulations 12 and 17

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, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the genetically modified organisms, and for the supervision, monitoring and safety of the release.

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 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;

(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 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 used to construct the genetically modified organisms and to make the introduced vector and insert functions 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 genetically modified organisms

19. The methods used for the modification.

20. The methods used—

(a) to construct inserts and to introduce it or 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 methods and criteria used for selection.

24. 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

25. The description of genetic trait or 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 organisms.

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

28. 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.

29. The activity of the gene product.

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 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 organisms to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity,

(c) the capacity of the organisms for colonisation,

(d) if the organisms are 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

The release

34. The description of the proposed deliberate release, including the purpose or purposes of the release and any intention to use the genetically modified organism as or in a product in the future.

35. The intended 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, and 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 genetically modified organisms, and in particular, releases on a different scale or into different ecosystems.

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

45. 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.

46. The physical or biological proximity of the site of the genetically modified 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. The comparison of the natural habitat of the recipient organisms 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

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

57. The predicted habitat of the genetically modified organisms.

58. The studies on the behaviour and characteristics of the 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 organisms.

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 organisms in relation to the unmodified recipient or parental organism or organisms.

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

67. The anticipated mechanism and result of interaction between the released 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 organisms, 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 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

73. Methods for tracing the 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

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

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 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 areas 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 3

Regulation 17(2)(d) and (h) and (6)

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 the genetically modified organisms in the product, **[**F17the unique identifier assigned in accordance with Regulation 65/2004, and any other**]**, name or code used by the applicant to identify the genetically modified organism.

Textual Amendments

F17 Words in Sch. 3 para. 1 substituted (20.3.2019) by The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/379), regs. 1(2), **2(4)**

2. The name and address [F18]... of the person who is responsible for the placing on the market, whether it be the manufacturer, importer or distributor.

Textual Amendments

F18 Words in Sch. 3 para. 2 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/1492), regs. 1(3), **2(18)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

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

4. A description of how the product and the genetically modified organism 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 or areas and types of environment where the product is intended to be used [F19]... including, where possible, an estimate of the scale of use in each area.

Textual Amendments

F19 Words in Sch. 3 para. 5 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/1492), regs. 1(3), **2(18)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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

[[F20]**7.**—(1) Information on—

(a) methods for the detection, identification and, where appropriate, quantification of the transformation event,

(b) samples of the genetically modified organisms and their control samples,

(c) the place where the reference material can be accessed.

(2) Information under sub-paragraph (1) that cannot be placed on the register for confidentiality reasons, must be identified.**]**

Textual Amendments

F20 Sch. 3 para. 7 substituted (30.10.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019 (S.I. 2019/1316), regs. 1(2), **8**

8. The 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 [F21]... who is responsible for the placing on the market, and how to access the information in the publicly accessible part of the register.

Textual Amendments

F21 Words in Sch. 3 para. 8 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/1492), regs. 1(3), **2(18)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

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 National Assembly for Wales, which are consistent with Part C of Annex VII of the Deliberate Release Directive.

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 product in and/or imports to **[**[F22]Wales**]**.

Textual Amendments

F22 Word in Sch. 3 para. 14 substituted (31.12.2020) by The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/1492), regs. 1(3), **2(18)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

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 4

Regulations 24, 26 and 32

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. A description of the way in which the characteristics of the organisms have been affected by genetic modification.

3. An identification of any known risks of change to the environment resulting from the release into the environment of the recipient non-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.

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 marketed and under which conditions, or should not be marketed, including reasons for that conclusion[F23]...

Textual Amendments

F23 Words in Sch. 4 para. 6 omitted (31.12.2020) by virtue of The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019 (S.I. 2019/1492), regs. 1(3), **2(19)**; 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 5

Regulation 39

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
The Genetically Modified Organisms (Deliberate Release) Regulations 1993	S.I. 1993/152	The whole Regulations
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)

Changes to legislation:
There are currently no known outstanding effects for the The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002.