DRAFT SCOTTISH STATUTORY INSTRUMENTS

2019 No.

The Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019

Amendment to the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

18. For schedule 2 (information to be included in applications for consent to release or market genetically modified higher plants) substitute—

"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 1

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO RELEASE FOR ANY OTHER PURPOSE THAN FOR PLACING ON THE MARKET

A. 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.

B. Information relating to the release

3. The purpose of the release.

4. The foreseen date or dates and duration of the release.

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

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

7. The approximate number of genetically modified plants (or plants per square metre) to be released.

C. Information relating to the site of release

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

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

10. The details of any sexually compatible wild relatives or cultivated plant species site or sites.

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

D. Information relating to the recipient plant or, where appropriate, to the parental plants

12. The full name of the plant, that is—

(a) family name,

(b) genus,

(c) species,

(d) subspecies,

(e) cultivar or breeding line, and

(f) common name.

13. The geographical distribution and cultivation of the plant within the EU.

14. Information concerning—

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

(i) the mode or modes of reproduction,

(ii) any specific factors affecting reproduction,

(iii) the 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.

15. 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.

16. Information concerning the dissemination of the plant, that is—

(a) the ways and extent of dissemination, and

(b) any specific factors affecting dissemination.

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

18. 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.

E. Molecular characterisation

19. Information relating to the genetic modification, that is—

(a) a description of the methods used for the genetic modification,

(b) the nature and source of the vector used, and

(c) the source of the nucleic acid or acids used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

20. Information relating to the genetically modified higher plant, that is—

(a) a general description of the trait or traits and characteristics which have been introduced or modified,

(b) information on the sequences actually inserted or deleted, namely—

(i) the size and copy number of all insert or inserts and methods used for its or their characterisation,

(ii) in case of deletion, size and function of the deleted region or regions,

(iii) the subcellular location or locations of the insert or inserts in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination,

(c) parts of the plant where the insert is expressed, and

(d) the genetic stability of the insert and phenotypic stability of the genetically modified higher plant.

21. Conclusions of the molecular characterisation

F. Information on specific areas of risk

22. Any change to the persistence or invasiveness of the genetically modified higher plant, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.

23. Any change to the ability of the genetically modified higher plant to transfer genetic material to microorganisms and the adverse environmental effects thereof.

24. Information on the mechanism of interaction between the genetically modified higher plant and target organisms (if applicable) and the adverse environmental effects thereof.

25. Information on the potential changes in the interactions of the genetically modified higher plant with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.

26. Information on the potential changes in agricultural practices and management of the genetically modified higher plant resulting from the genetic modification and the adverse environmental effects thereof.

27. Information on the potential interactions with the abiotic environment and the adverse environmental effects thereof.

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

29. Conclusions on the specific areas of risk.

G. Information on control, monitoring, post-release and waste treatment plans

30. Any measures taken, including—

(a) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops, and

(b) any measures to minimise or prevent the dispersal of any reproductive part of the genetically modified higher plant.

31. A description of methods for post-release treatment of the site.

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

33. A description of monitoring plans and techniques.

34. A description of any emergency plans.

35. A description of the methods and procedures to,—

(a) avoid or minimise the spread of the genetically modified higher plants beyond the site of release,

(b) protect the site from intrusion by unauthorised individuals, and

(c) prevent other organisms from entering the site or minimise such entries.

H. Other

36. A description of detection and identification techniques for the genetically modified higher plant**.**

37. Information about previous releases of the genetically modified higher plant, if applicable.

PART 2

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO PLACE ON MARKET

A. General information

38. 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.

39. The designation and specification of the genetically modified higher plant.

40. The **s**cope of the notification including—

(a) cultivation

(b) any other use.

B. Information relating to the recipient plant or, where appropriate, to the parental plants

41. The complete name of the plant, that is—

(a) family name,

(b) genus,

(c) species,

(d) subspecies,

(e) cultivar/breeding line, and

(f) common name.

42. The geographical distribution and cultivation of the plant within the EU.

43. The reproduction of the plant, that is—

(a) the mode or modes of reproduction,

(b) any specific factors affecting reproduction,

(c) generation time, and

(d) the sexual compatibility of the plant with other cultivated or wild plant species including the distribution in the EU of the compatible species.

44. 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.

45. Information concerning the dissemination: of the plant, that is—

(a) the ways and extent of dissemination, and

(b) any specific factors affecting dissemination.

46. Where a plant species is not normally grown in the EU, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

47. Information concerning any other potential interactions, relevant to the genetically modified higher plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. Molecular Characterisation

48. Information relating to the genetic modification including—

(a) a description of the methods used for the genetic modification,

(b) the nature and source of the vector used, and

(c) the source of the nucleic acid or acids used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.

49.—(1) Information relating to the genetically modified plant, that is—

(a) a description of the trait or traits and characteristics which have been introduced or modified,

(b) information on the sequences actually inserted or deleted namely—

(i) the size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,

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

(iii) in case of deletion, the size and function of the deleted region or regions,

(iv) the subcellular location or locations of the insert or inserts (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its or their determination,

(v) in the case of modifications other than insertion or deletion, the function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification,

(vi) the sequence information in a standardised electronic format for both 5′ and 3′ flanking regions at each insertion site,

(vii) the bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,

(viii) all Open Reading Frames, ('ORFs') within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA,

(ix) the bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,

(x) the primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein, and

(xi) the bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.

(2) An 'ORF' is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame.

50. Information on the expression of the insert that is—

(a) the method or methods used for expression analysis together with their performance characteristics,

(b) any information on the developmental expression of the insert during the life cycle of the plant,

(c) the parts of the plant where the insert or modified sequence is expressed,

(d) the potential unintended expression of new ORFs identified under regulation 49(b)(vii), which raise a safety concern,

(e) the protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown and,

(f) the genetic stability of the insert and phenotypic stability of the genetically modified higher plant.

52. The conclusions of molecular characterisation.

D. Comparative analysis of agronomic and phenotypic characteristics and of composition of the genetically modified higher plant.

53. The comparative analysis of agronomic and phenotypic characteristics and of composition that is—

(a) the choice of conventional counterpart and additional comparators,

(b) the choice of sites for field studies,

(c) the experimental design and statistical analysis of data from field trials for comparative analysis namely—

(i) a description of field studies design

(ii) a description of the relevant aspect of the receiving environments,

(iii) the statistical analysis,

(d) the selection of plant material for analysis, if relevant,

(e) the comparative analysis of agronomic and phenotypic characteristics,

(f) the comparative analysis of composition, if relevant, and

(g) the conclusions of the comparative analysis.

54. For each of the seven areas of risk referred to in Section D.2 of Annex II of the Deliberate Release Directive, a description of the pathway to harm explaining in a chain of cause and effect how the release of the genetically modified higher plant could lead to harm, taking into account both hazard and exposure.

55. The following information is required, except where it is not relevant in view of the intended uses of the genetically modified organism—

(a) in respect of persistence and invasiveness including plant to plant gene transfer—

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

(ii) an assessment of the potential for the genetically modified higher plant to transmit transgene or transgenes to sexually compatible relatives and the adverse environmental effects thereof, and

(iii) conclusions on the adverse environmental effect of persistence and invasiveness of the genetically modified higher plant including the adverse environmental effect of plant-to-plant gene transfer,

(b) in respect of plant to micro-organism gene transfer—

(i) an assessment of the potential for transfer of newly inserted DNA from the genetically modified higher plant to microorganisms and the adverse effect or effects thereof, and

(ii) the conclusions on the adverse effect or effects of the transfer of newly inserted DNA from the genetically modified higher plant to microorganisms for human and animal health and the environment,

(c) in respect of interactions of the genetically modified higher plant with target organisms, if relevant—

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

(ii) 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 effect or effects thereof, and

(iii) the conclusions on adverse environmental effect or effects of interactions of the genetically modified higher plant with target organisms,

(d) the interactions of the genetically modified higher plant with non-target organisms namely—

(i) an assessment of the potential for direct and indirect interactions of the genetically modified higher plant with non-target organisms, including protected species, and the adverse effect or effects thereof,

(ii) an assessment of the potential adverse effect or effects on relevant ecosystem services and on the species providing those services,

(iii) the conclusions on adverse environmental effect or effects of the interactions of the genetically modified higher plant with non-target organisms,

(e) the impacts of the specific cultivation, management and harvesting techniques, namely—

(i) for genetically modified higher plants for cultivation, an assessment of the changes in the specific cultivation, management and harvesting techniques used

for the genetically modified higher plant and the adverse environmental effect or effects thereof, and

(ii) the conclusions on the adverse environmental effect or effects of the specific cultivation, management and harvesting techniques,

(f) the effects on biogeochemical processes, namely—

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

(ii) the conclusions on adverse effects on biogeochemical processes,

(g) the effects on human and animal health, namely—

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

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

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

(iv) the conclusions on the effects on human and animal health, and

(h) an overall risk evaluation and conclusions, namely a summary of all the conclusions under each area of risk taking into account—

(i) the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II of the Deliberate Release Directive, and

(ii) the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II of the Deliberate Release Directive.

56. A description of detection and identification techniques for the genetically modified higher plant.

57. Information about previous releases of the genetically modified higher plant, if applicable.”.