STATUTORY RULES OF NORTHERN IRELAND

2019 No. 223

The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 2019

Insertion of Schedule 1A

7. After Schedule 1 insert—

"SCHEDULE 1A Regulation 16

Information to be included in applications for consent to 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 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 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 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 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.—(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,

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

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

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

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

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

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

(j) 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,

(k) 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 14(f)) and which raises a safety concern,

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

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 V

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 microorganisms and the adverse effects arising,

(b) conclusions on the adverse effect of the transfer of newly inserted DNA from the genetically modified plant to microorganisms for 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 effect 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 VI

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.”.