

[F1]SCHEDULE 1A

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

Textual Amendments

F1 Sch. 1A inserted (29.9.2019) by The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 (S.I. 2019/1252), regs. 1(1), 7

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,
- (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—

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- (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.]

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Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

- Blanket amendment words substituted by [S.I. 2011/1043 art. 3-68-10](#)