

[^{F1}ANNEX III B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) (GYMNOSPERMAE AND ANGIOSPERMAE)

Textual Amendments

- F1** Substituted by [Commission Directive \(EU\) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms.](#)

INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7

B. Scientific information

1. Information relating to the recipient plant or, where appropriate, to the parental plants
 - (a) Complete name:
 - (i) family name
 - (ii) genus
 - (iii) species
 - (iv) subspecies
 - (v) cultivar or breeding line
 - (vi) common name.
 - (b) Geographical distribution and cultivation of the plant within the Union.
 - (c) Information concerning reproduction:
 - (i) mode(s) of reproduction
 - (ii) specific factors affecting reproduction, if any
 - (iii) generation time.
 - (d) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.
 - (e) Survivability:
 - (i) ability to form structures for survival or dormancy
 - (ii) specific factors affecting survivability, if any.
 - (f) Dissemination:
 - (i) ways and extent of dissemination
 - (ii) specific factors affecting dissemination, if any.

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (g) Where a plant species is not normally grown in the Union, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
 - (h) Potential interactions of the plant, that are relevant to the GMHP, with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.
2. Molecular characterisation
- (a) Information relating to the genetic modification
 - (i) Description of the methods used for the genetic modification.
 - (ii) Nature and source of the vector used.
 - (iii) Source of the nucleic acid(s) used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.
 - (b) Information relating to the GMHP
 - (i) General description of the trait(s) and characteristics which have been introduced or modified.
 - (ii) Information on the sequences actually inserted/deleted:
 - size and copy number of all insert(s) and methods used for its/their characterisation,
 - in case of deletion, size and function of the deleted region(s),
 - subcellular location(s) of the insert(s) in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination.
 - (iii) Parts of the plant where the insert is expressed.
 - (iv) Genetic stability of the insert and phenotypic stability of the GMHP.
 - (c) Conclusions of the molecular characterisation
3. Information on specific areas of risk
- (a) Any change to the persistence or invasiveness of the GMHP, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.
 - (b) Any change to the ability of the GMHP to transfer genetic material to microorganisms and the adverse environmental effects thereof.
 - (c) Mechanism of interaction between the GMHP and target organisms (if applicable) and the adverse environmental effects thereof.
 - (d) Potential changes in the interactions of the GMHP with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.
 - (e) Potential changes in agricultural practices and management of the GMHP resulting from the genetic modification and the adverse environmental effects thereof.
 - (f) Potential interactions with the abiotic environment and the adverse environmental effects thereof.

- (g) Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.
- (h) Conclusions on the specific areas of risk.
- 4. Information on control, monitoring, post-release and waste treatment plans
 - (a) Any measures taken, including:
 - (i) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops;
 - (ii) any measures to minimise or prevent the dispersal of any reproductive part of the GMHP.
 - (b) Description of methods for post-release treatment of the site.
 - (c) Description of post-release treatment methods for the genetically modified plant material including wastes.
 - (d) Description of monitoring plans and techniques.
 - (e) Description of any emergency plans.
 - (f) Description of the methods and procedures to:
 - (i) avoid or minimise the spread of the GMHPs beyond the site of release;
 - (ii) protect the site from intrusion by unauthorised individuals;
 - (iii) prevent other organisms from entering the site or minimise such entries.
- 5. Description of detection and identification techniques for the GMHP.
- 6. Information about previous releases of the GMHP, if applicable.]