

[^{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.](#)

**II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO
ARTICLE 13****B. Scientific information****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 genetically modified plant

- (i) Description of the trait(s) and characteristics which have been introduced or modified.
- (ii) Information on the sequences actually inserted or deleted:
 - size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,
 - the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format,
 - in case of deletion, size and function of the deleted region(s),
 - subcellular location(s) of the insert(s) (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination,
 - in the case of modifications other than insertion or deletion, 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,
 - sequence information in a standardised electronic format for both 5' and 3' flanking regions at each insertion site,
 - bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,
 - all Open Reading Frames, (hereafter referred to as '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. ORF is defined as a nucleotide sequence that contains a

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- string of codons that is uninterrupted by the presence of a stop codon in the same reading frame,
 - bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,
 - primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein,
 - 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.
- (iii) Information on the expression of the insert:
- method(s) used for expression analysis together with their performance characteristics,
 - information on the developmental expression of the insert during the life cycle of the plant,
 - parts of the plant where the insert/modified sequence is expressed,
 - potential unintended expression of new ORFs identified under the seventh indent of point (ii), which raise a safety concern,
 - protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown.
- (iv) Genetic stability of the insert and phenotypic stability of the GMHP.
- (c) Conclusions of molecular characterisation]