[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.

I.INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLES 6 AND 7

A. **General information**

1. Name and address of the notifier (company or institute)

2. Name, qualifications and experience of the responsible scientist(s)

3. Title of the project

4. Information relating to the release

(a) Purpose of the release

(b) Foreseen date(s) and duration of the release

(c) Method by which the GMHP will be released

(d) Method for preparing and managing the release site, prior to, during and post release, including cultivation practices and harvesting methods

(e) Approximate number of plants (or plants per m^2).

5. Information relating to the site of release

(a) Location and size of the release site(s).

(b) Description of the release site ecosystem, including climate, flora and fauna.

(c) Presence of sexually compatible wild relatives or cultivated plant species.

(d) Proximity to officially recognised biotopes or protected areas which may be affected.

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.

(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.

II. INFORMATION REQUIRED IN NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 13

A. **General information**

1. Name and address of the notifier (company or institute).

2. Name, qualifications and experience of the responsible scientist(s).

3. Designation and specification of the GMHP.

4. Scope of the notification.

(a) Cultivation

(b) Other uses (to be specified in the notification).

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/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 the Union 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.

(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 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 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

3. Comparative analysis of agronomic and phenotypic characteristics and of composition

(a) Choice of conventional counterpart and additional comparators.

(b) Choice of sites for field studies.

(c) Experimental design and statistical analysis of data from field trials for comparative analysis:

(i) Description of field studies design

(ii) Description of relevant aspect of the receiving environments

(iii) Statistical analysis.

(d) Selection of plant material for analysis, if relevant.

(e) Comparative analysis of agronomic and phenotypic characteristics.

(f) Comparative analysis of composition, if relevant.

(g) Conclusions of comparative analysis.

4. Specific information for each area of risk

For each of the seven areas of risk referred to in Section D.2 of Annex II the notifier shall first describe the pathway to harm explaining in a chain of cause and effect how the release of the GMHP could lead to harm, taking into account both hazard and exposure.

The notifier shall submit the following information, except where it is not relevant in view of the intended uses of the GMO:

(a) Persistence and invasiveness including plant to plant gene transfer

(i) Assessment of the potential for the GMHP to become more persistent or invasive and the adverse environmental effects thereof;

(ii) Assessment of the potential for the GMHP to transmit transgene(s) to sexually compatible relatives and the adverse environmental effects thereof;

(iii) Conclusions on the adverse environmental effect(s) of persistence and invasiveness of the GMHP including the adverse environmental effect(s) of plant-to-plant gene transfer.

(b) Plant to micro-organism gene transfer

(i) Assessment of the potential for transfer of newly inserted DNA from the GMHP to microorganisms and the adverse effects thereof;

(ii) Conclusions on the adverse effect(s) of the transfer of newly inserted DNA from the GMHP to microorganisms for human and animal health and the environment;

(c) Interactions of the GMHP with target organisms, if relevant

(i) Assessment of the potential for changes in the direct and indirect interactions between the GMHP and target organisms and the adverse environmental effect(s);

(ii) 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(s) thereof;

(iii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with target organisms.

(d) Interactions of the GMHP with non-target organisms.

(i) Assessment of the potential for direct and indirect interactions of the GMHP with non-target organisms, including protected species, and the adverse effect(s) thereof.

The assessment shall also take into account the potential adverse effect(s) on relevant ecosystem services and on the species providing those services.

(ii) Conclusions on adverse environmental effect(s) of interactions of the GMHP with non-target organisms.

(e) Impacts of the specific cultivation, management and harvesting techniques

(i) For GMHPs for cultivation, assessment of the changes in the specific cultivation, management and harvesting techniques used for the GMHP and the adverse environmental effect(s) thereof;

(ii) Conclusions on adverse environmental effect(s) of the specific cultivation, management and harvesting techniques.

(f) Effects on biogeochemical processes

(i) Assessment of the changes in the biogeochemical processes within the area in which the GMHP is to be grown and in the wider environment, and the adverse effects thereof;

(ii) Conclusions on adverse effects on biogeochemical processes.

(g) Effects on human and animal health

(i) Assessment of potential direct and indirect interactions between the GMHP and persons working with or coming into contact with the GMHPs, including through pollen or dust from a processed GMHP, and assessment of the adverse effects of those interactions on human health;

(ii) For GMHPs not destined for human consumption, but where the recipient or parental organism(s) may be considered for human consumption, assessment of the likelihood of and possible adverse effects on human health due to accidental intake;

(iii) Assessment of the potential adverse effects on animal health due to accidental consumption of the GMHP or of material from that plant by animals;

(iv) Conclusions on the effects on human and animal health.

(h) Overall risk evaluation and conclusions.

A summary of all the conclusions under each area of risk shall be provided.

The summary shall take into account the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II and the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II.

5. Description of detection and identification techniques for the GMHP.

6. Information about previous releases of the GMHP, if applicable.**]**