

[^{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****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;

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- (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.]