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ANNEX II

PRINCIPLES FOR THE ENVIRONMENTAL RISK ASSESSMENT

[F1D.Conclusions on the specific areas of risk of the e.r.a.

Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of GMOs shall be drawn for each relevant area of risk listed in Section D1 for GMOs other than higher plants or Section D2 for genetically modified higher plants, on the basis of an e.r.a. carried out in accordance with the principles outlined in Section B and following the methodology described in Section C, and on the basis of the information required pursuant to Annex III.]

- D.1. In the case of GMOs other than higher plants
- 1. Likelihood of the GMO to become persistent and invasive in natural habitats under the conditions of the proposed release(s).
- 2. Any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised under the conditions of the proposed release(s).
- 3. Potential for gene transfer to other species under conditions of the proposed release of the GMO and any selective advantage or disadvantage conferred to those species.
- 4. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO and target organisms (if applicable).
- 5. Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.
- 6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s).
- 7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed.
- 8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).
- 9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the GMO where these are different from those used for non-GMOs.

[F1D.2. In the case of genetically modified higher plants (GMHP)

'Higher plants' shall mean plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae).

- 1. Persistence and invasiveness of the GMHP, including plant to plant gene transfer
- 2. Plant to micro-organisms gene transfer
- 3. Interactions of the GMHP with target organisms

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- 4. Interactions of the GMHP with non-target organisms
- 5. Impacts of the specific cultivation, management and harvesting techniques
- 6. Effects on biogeochemical processes
- 7. Effects on human and animal health.]