

*Status: Point in time view as at 31/12/2020.*

*Changes to legislation: There are outstanding changes not yet made to REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)*

## ANNEX I

### INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLE 4

- (a) Name, address and contact details of the exporter.
- (b) Name, address and contact details of the importer.
- (c) Name and identity of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the State of export.
- (d) Intended date or dates of the transboundary movement, if known.
- (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.
- (i) Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Annex I A, Part 1 of Directive 2001/18/EC.
- (j) Quantity or volume of the GMO to be transferred.
- (k) A previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.
- (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- (m) Regulatory status of the GMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the GMO is banned in the State of export, the reason or reasons for the ban.
- (n) Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.
- (o) A declaration that the abovementioned information is factually correct.

## ANNEX II

### INFORMATION REQUIRED UNDER ARTICLE 9

- (a) The name and contact details of the applicant for a decision for domestic use.
- (b) The name and contact details of the authority responsible for the decision.

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- (c) Name and identity of the GMO.
- (d) Description of the gene modification, the technique used, and the resulting characteristics of the GMO.
- (e) Any unique identification of the GMO.
- (f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (i) Approved uses of the GMO.
- (j) A risk assessment report consistent with Annex II to Directive 2001/18/EC.
- (k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

### ANNEX III

#### INFORMATION REQUIRED UNDER ARTICLE 14

- (a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO.
- (b) Information on the circumstances and estimated date of the release, and on the use of the GMO in the originating Party.
- (c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures.
- (d) Any other relevant information, and
- (e) A contact point for further information.

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