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## Article 7. Application of the Advance Informed Agreement procedure

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1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.
2. “Intentional introduction into the environment” in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.
3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.
4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

260. *Article 7 identifies those LMOs which will be subject to the advance informed agreement procedure set out in Articles 8–10 and 12. It also identifies a specific category of LMOs which will be subject instead to a separate*

*procedure, set out in Article 11. Finally, it provides a procedure for the possible future exclusion of specific LMOs from the AIA procedure by a decision of the COP/MOP (see commentary on Article 29).*

### Box 23. What is AIA?

Advance informed agreement requires that *before* the first intentional transboundary movement of a specific LMO into its jurisdiction, the Party of import:

- is notified of the proposed transboundary movement;
- receives information about the LMO and its proposed use; and
- is given an opportunity to decide whether or not to allow the import of the LMO, and upon what conditions (if any).

261. While Article 7 is titled “Application of the Advance Informed Agreement Procedure”, it is important to recall that other provisions of the Protocol are also relevant to determining whether or not the AIA procedure in Articles 8–10 and 12 of the Protocol applies to a particular transboundary movement of a LMO. These are:

- Article 4, which determines the scope of the Protocol as a whole;
- Article 5, which excludes the transboundary movement of certain pharmaceutical LMOs from the scope of the Protocol;
- Article 6, which exempts two categories of transboundary movements of LMOs from

the application of the AIA procedure, namely:

- LMOs in transit (Article 6(1)); and
- LMOs destined for contained use undertaken in accordance with the standards of the Party of import (Article 6(2));
- Article 13(1)(b), which allows a Party of import, subject to conditions, to specify that imports of certain LMOs to it will be exempted from the AIA procedure;
- Article 14(3), which exempts from the provisions of the Protocol intentional transboundary movements of LMOs that take place pursuant to bilateral, regional or

multilateral agreements or arrangements (as provided under Article 14), as between Parties to those agreements and arrangements;

- Article 14(4), which allows a Party to determine (and notify to the Biosafety Clearing-House) that its domestic regulations shall apply with respect to specific imports.

262. It should be noted that some of the Articles listed above provide exemptions from the AIA procedure that are applicable as between *all* Parties to the Protocol (Articles 4, 5, 6 and 7), whereas some allow for *potential* exemptions at the discretion of the Party of import, and subject to certain conditions (Articles 13 and 14). More detail on each of these Articles is provided in the relevant sections of this Guide.

### What is the Advance Informed Agreement procedure?

263. The central procedural mechanism set out in the Protocol to regulate transboundary movement of LMOs is the advance informed agreement procedure. Article 7 (taken together with the other Articles listed above) establishes the scope of the application of the AIA procedure – i.e. to which transboundary movements the procedure applies. The AIA procedure itself is then set out in Article 8, 9, 10 and 12. Other provisions of direct relevance to the AIA procedure include:

- Article 15 (Risk Assessment);
- Article 19 (Competent National Authorities and National Focal Points);
- Article 21 (Confidential Information);
- Article 26 (Socio-economic Considerations);
- Annex I (Information Required in Notifications under Articles 8, 10 and 13); and
- Annex III (Risk Assessment).

264. The AIA procedure essentially requires that before the first transboundary movement of a LMO that is subject to the AIA procedure, the Party of import is notified of the proposed transboundary movement and is given an opportunity to decide whether or not the import shall be allowed and upon what conditions. This decision must be based upon a risk assessment. The provisions in Articles 8, 9, 10 and 12 of the Protocol and related provisions in Articles 15, 19, 21 and 26, as well as Annexes I and III to the Protocol attempt to address and clarify a number of important aspects of the AIA procedure.

265. The AIA procedure is modelled loosely on existing mechanisms in international law for the transboundary movement of hazardous substances, for example the prior informed consent (PIC) procedures in the Basel

Convention on the transboundary movement and disposal of hazardous wastes and the Rotterdam Convention on chemicals in international trade. However, the AIA procedure in the Protocol differs from previous models in certain important respects. In addition, as noted in more detail below, the Protocol allows a significant degree of flexibility to Parties as to whether they apply the AIA procedure set out in the Protocol or instead use a different domestic regulatory procedure which must, nonetheless, be consistent with the Protocol (see, for example, Article 9).

266. The flexibility and discretion accorded to Parties under the Protocol means that the procedure to be followed by the Party of export, the exporter, the importer and the Party of import in any given case may vary significantly depending upon, for example:

- the identity of the countries involved in the transboundary movement (i.e. the importing and exporting countries, as well as any transit countries);
- the LMO in question; and
- the intended use of that LMO in the Party of import.

267. In order to ensure that it is complying with the Protocol and with the relevant national legislation of the Party of import in relation to AIA, the Party of export of a LMO (and indeed a non-Party exporting a LMO) will need to consider (or require the exporter to consider) a number of questions (see Box 24).

268. As noted above, the provisions in Articles 8, 9, 10 and 12 of the Protocol and related provisions in Articles 15, 19, 21 and 26, as well as Annexes I and III to the Protocol, attempt

**Box 24. Is this transboundary movement of this LMO subject to the AIA procedure?**

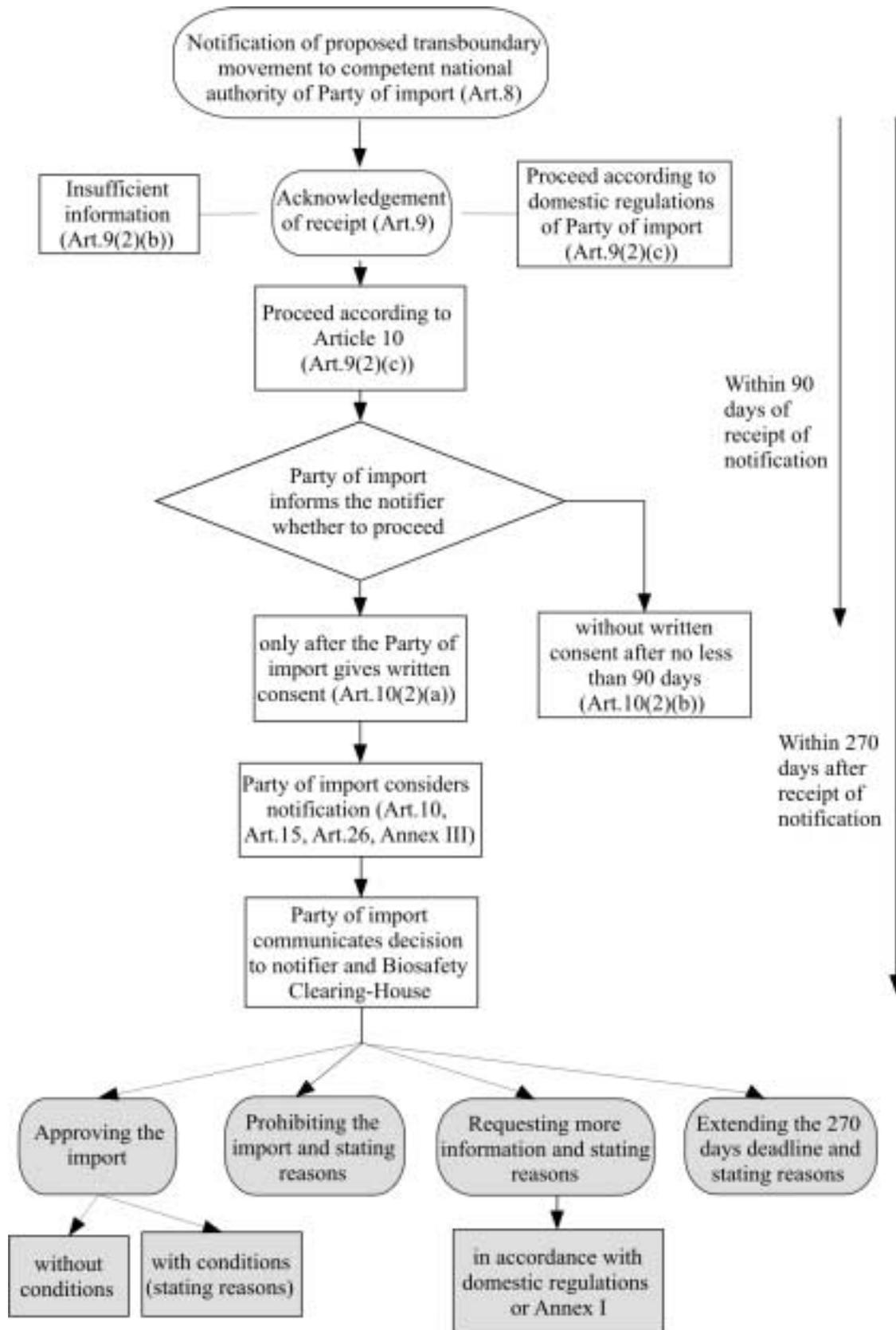
- *What type of LMO is involved?*
  - Is it within the scope of the Protocol (Articles 4 and 5)?
  - Is it within the scope of application of the Protocol’s AIA procedure (Article 7)?
  - Has it subsequently been exempted from AIA by the COP/MOP (Article 7(4))?
  - Is the LMO being imported into the Party of import for the first time (Article 7(1))?
  - Is it a LMO to which the Party of import has decided to apply simplified procedures (Article 13)?
- *What is the country of import?*
  - Is it a Party to the Protocol?
  - Is it a party to a relevant bilateral, regional or multilateral arrangement with the Party of export under Article 14?
  - Has it indicated that it will apply the Protocol’s AIA procedure to potential imports of LMOs, or its own domestic regulatory framework instead?
  - Has it indicated through the Biosafety Clearing-House that it will apply simplified procedures to certain LMOs (Article 13)?

to address and clarify a number of aspects of the AIA procedure. For example:

- Who initiates the AIA procedure – i.e. who notifies the Party of import of the proposed import of a LMO (Article 8)?
- What information must be provided with the notification (Article 8; Annex I)?
- Is the Party of import under any obligation to keep information received in the AIA procedure confidential (Article 21)?
- How long does the Party of import have to make a decision whether to allow or to prohibit the import of the LMO (Articles 9 and 10)?
- On what basis must the decision be made (Articles 10 and 15; Annex III)?
- Who is responsible for undertaking the risk assessment? And who will pay for it (Articles 10 and 15)?
- What factors should be taken into account in the risk assessment process (Article 15; Annex III)?
- What happens if the Party of import fails to respond to a notification, or fails to make a decision on import within the time period allowed in the Protocol (Articles 9 and 10)?
- Under what circumstances can import decisions be reviewed (Article 12)?

269. However, the flexibility accorded to Parties under the Protocol, and the terms of the AIA provisions of the Protocol themselves, may give rise to some ambiguity and uncertainties in practice. Parties to the Protocol will need to implement the AIA provisions, or similar, in their domestic laws and regulations in order to give effect to them. In this respect, transparent and comprehensive domestic regulations and procedures can assist in clarifying some of the areas left unclear in the Protocol.

**Box 25. Advance Informed Agreement Procedure**



**1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.**

**First intentional transboundary movement**

270. During the negotiation of the Protocol, there was some debate as to whether the AIA procedure should apply to *every* transboundary movement of a LMO into a Party or only to the *first* transboundary movement of a specific LMO into a Party of import. Article 7(1) appears to resolve this issue, providing that AIA shall only apply to the “first intentional transboundary movement of LMOs into the environment of the Party of import”. However, on the face of Article 7(1), it may be somewhat unclear whether AIA will be required each time a particular LMO is imported into a Party for the first time from a “new” Party of export, or whether it only applies the first time a particular LMO is imported into the Party of import from *any* Party – after which, assuming the first import is allowed, imports of the same LMO should be allowed under the same conditions from all Parties. The former interpretation could be supported by a strict reading of the definition of “transboundary movement” in Article 3(k) which indicates that this term means the “movement of a LMO from *one* Party to *another* Party”. In this interpretation, “one Party” in Article 3(k) refers to a specific Party of export – so each time a new Party of export is involved in a transaction with the Party of import, it would constitute the “first” transboundary movement for the purposes of Article 7.
271. A plain reading of Article 7(1) may provide more support for the interpretation that the AIA procedure applies where a particular LMO is to be introduced into the Party of import for the first time from any other Party to the Protocol, and that AIA does not apply automatically each time the same LMO is subsequently imported from other Parties. However, such an interpretation may give rise to some difficulties for the Party of import. If it approves the first import of a specific LMO from another Party, then for subsequent imports from that Party or from other Parties, the Party of import will need to be sure that what is being imported is in fact the “same” LMO that has already been approved under the AIA procedure. In the absence of unique identification mechanisms (see Box 34) this may not be a simple matter. The Party of import will need to be aware of subsequent imports, which suggests a need for some notification procedure so that the Party of import can confirm that the LMO to be imported is the same as that which has been approved. This issue may be appropriately addressed under the provision in Article 10(3)(a) for conditions to be attached to import approvals, or by the provision in Article 12(4) which allows a Party of import to require a risk assessment for subsequent imports. In these provisions, the Protocol provides a “safety net” for Parties of import in that they may require approvals for subsequent imports of LMOs.
272. The use of the word “intentional” in Article 7(1) also raises certain interpretative difficulties.
- First, in the phrase “intentional transboundary movement of LMOs”, the word “intentional” might be interpreted as referring *either* to the transboundary movement *or* to the LMOs, or to *both*. By way of practical example, suppose an exporter intends to make a shipment not of LMOs but of conventional (non-modified) seeds, but knows or suspects that the shipment may have unintentionally become contaminated with a small percentage of LMOs. Would this constitute an intentional transboundary movement of LMOs for the purpose of triggering the Protocol’s AIA procedure?
  - Second, Article 7(1) and 7(2) refer to “intentional introduction into the environment”, but do not specify whose intention is relevant here: for example the exporter, the importer or the Party of import. In this regard, it is significant that it is the exporter or Party of export which triggers the AIA procedure by making the notification of the proposed transboundary movement to the Party of import. However, the exporter and Party of export are unlikely to be involved in the final use of the LMO in the Party of import (see further paragraph 275 below).

## Intentional introduction into the environment of the Party of import

273. This phrase further limits the application of the Protocol's AIA procedure. Article 7(1) removes from the AIA provisions of the Protocol any LMO which is not destined for *intentional introduction into the environment* of the Party of import.
274. The phrase "intentional introduction into the environment" is not defined. However, paragraph 2 of Article 7 makes it clear that it excludes LMOs which are intended for direct use as human food or animal feed, or for

processing (see commentary on Article 11). Intentional introduction into the environment may include for example: the use of the LMO in question in field trials in the Party of import; the commercial scale growing of agricultural LMOs; the release of transgenic fish; or the deliberate release of genetically modified micro-organisms into the environment. In general, the term "introduction into the environment" may be contrasted with "contained use" in Article 3(b).

### Box 26. Intentional introduction into the environment of a LMO

As noted above, this phrase is not defined in the Protocol. Some examples of national legislation or regulations on biosafety incorporate similar terms, but tend to use the word "release". For example:

- EU Directive 2001/18 on the deliberate release into the environment of GMOs defines "deliberate release" as "any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment".
- Australia's 2000 Gene Technology Act provides that "a dealing with a GMO involves the intentional release of the GMO into the environment if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment".
- Colombia's Resolution 3492 of 22 December 1998 regulating and establishing a procedure for the introduction, production, release and commercialization of genetically modified organisms uses the term "release into the environment" defined as "the use of a product manipulated outside the limits of a normal physical confinement in a closed area, laboratory, greenhouse, fermented, or any other closed structure under established biosafety conditions".
- Norway's Gene Technology Act No. 38 of 2 April 1993 goes into more detail. It provides that "deliberate release" means any production and use of genetically modified organisms that is not considered to be contained use [as defined in the Act].

The following are among the activities that are considered to be deliberate release under the Act:

- a) deliberate release of genetically modified organisms for research purposes (field experiments);
- b) deliberate release of genetically modified organisms for commercial purposes, for remedial purposes and the like;
- c) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation and the like, unless the facility in question is approved for contained use as part of an approved laboratory or other installation;
- d) routine release of genetically modified organisms from contained use;
- e) disposal of waste containing living genetically modified organisms;
- f) placing on the market of a product consisting of or containing genetically modified organisms;
- g) import of genetically modified organisms;
- h) transport of genetically modified organisms.

275. It is notable that the Protocol does not expressly require the exporter or the Party of export to seek confirmation that exported LMOs are or will only be used only for their

intended purpose once in the Party of import. This may be contrasted with, for example, the Basel Convention on the Transboundary Movement of Hazardous Wastes and their

Disposal which contains provisions designed to ensure, before any transboundary movement of hazardous wastes takes place, that arrangements are in place for environmentally sound management in the State of import. However, it might be argued that both Parties of export and Parties of import are bound in this respect to take into account the objective of the Protocol, in Article 1, and

their general obligation in Article 2(2) to ensure that activities involving LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking into account risks to human health. The obligations of the Party of import under Article 8(g) of the CBD and Article 16 of the Protocol are also relevant here.

**2. “Intentional introduction into the environment” in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.**

**3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.**

276. The treatment of LMOs intended for direct use as food or feed, or for processing, or “LMO-FFPs”, was the subject of intense debate during the Protocol negotiations. The debate centred on potential exports of agricultural commodities (e.g. grains from genetically modified crops) which, while fulfilling the legal definition of LMO in Article 3 of the Protocol, are intended to be used directly for food, feed or processing use and are not intended to be introduced into the environment of the Party of import.

the Party of import, in practice LMO-FFPs might in fact end up being released into the environment, particularly in developing countries, and thus should be equally subject to AIA and risk assessment if adequate safeguards for biological diversity were to be put in place. It was also noted that LMO-FFPs might accidentally be introduced into the environment of the Party of import during shipment and processing.

277. During the negotiation of the Protocol, some argued that to include LMO-FFPs within the scope of the Protocol’s AIA provisions could be unworkable and have severe implications for trade in agricultural commodities. They argued that since LMO-FFPs were not intended to be introduced into the environment they were not properly within the remit of the Protocol which was intended primarily to address potential risks to biological diversity. On the other side, it was argued that, whatever the *intended* use of a LMO shipment in

278. The differences of view on the treatment of LMO-FFPs threatened the conclusion of the Protocol as a whole. The resolution found was to include LMO-FFPs within the scope of the Protocol, but to subject transboundary movements of LMO-FFPs to a separate and less onerous procedure in the Protocol, which is set out in Article 11. Articles 8-10 and 12 do not therefore apply to LMO-FFPs. Shipments of LMO-FFPs are also subject to different documentation and identification requirements under the Protocol than those of other LMOs (see commentary on Article 18).

**4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.**

279. Article 7(4) allows the COP/MOP (see commentary on Article 29), at a later date, to decide collectively to exclude additional LMOs or categories of LMOs from the application of the AIA procedure. This will require a decision of the COP/MOP, taken in accordance with its rules of procedure. Any such LMOs must first be identified as being not likely to have adverse effects on the conservation and sustainable use

of biological diversity, taking also into account risks to human health. The Protocol gives no guidance as to what information or evidence might be required to support such a conclusion. Nonetheless, any such decision would need to be taken in the light of the precautionary approach in Principle 15 of the Rio Declaration which is referred to in the Protocol’s objective in Article 1 (see Introduction).

280. This provision for the “collective” exclusion of additional LMOs from the AIA procedure is distinct from the provision in Article 13 which allows individual Parties to exempt imports of particular LMOs from AIA at domestic level,

provided that adequate measures are applied to ensure the safe intentional transboundary movement of LMOs in accordance with the objective of the Protocol (see commentary on Article 13).