Article 11. Procedure for living modified organisms intended for direct use as food or feed, or for processing

1. **A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.**
2. **The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.**
3. **Any Party may request additional information from the authority identified in paragraph (b) of Annex II.**
4. **A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.**
5. **Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.**
6. **A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:**
   (a) **A risk assessment undertaken in accordance with Annex III; and**
   (b) **A decision made within a predictable timeframe, not exceeding two hundred and seventy days.**
7. **Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.**
8. **Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.**

9. A Party may indicate its needs for financial and technical assistance and capacity- building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

344. *As noted under Article 7, while they fulfil the definition of "living modified organism" in Article 3 of the Protocol, living modified organisms for direct use as food or feed or for processing (LMO-FFPs) are not intended to be introduced into the environment. They are intended to be used directly as food for humans, as animal feed, or processed. Examples of LMO-FFPs are genetically modified fruits or vegetables for human consumption (i.e. for direct use as food) or genetically modified soya or corn intended for processing into edible oils. Non-food examples include genetically modified grain intended for feeding to animals. LMOs may also be used in industrial processing, for example in the production of plastics and oils.*

345. *During the negotiations, arguments centred first on whether LMO-FFPs should be within the scope of the Protocol at all. Once it was agreed that they would be, debate focused on whether they should be subject to the Protocol's AIA procedure. Those in favour of subjecting LMO-FFPs to the AIA procedure, along with other LMOs, argued that notwithstanding their intended use in the Party of import, in practice, such LMOs may end up being released in the environment of the Party of import either accidentally, for example where there is spillage during a shipment or in processing operations, or deliberately, where the LMO in question is planted in the environment. They also noted that the objective of the Protocol refers to risks to human health. Most developing countries argued in favour of subjecting transboundary movements of LMO-FFPs to AIA. Those who opposed the application of AIA to LMO-FFPs argued that since they were intended for direct consumption by humans or animals or for processing use, LMO-FFPs posed no threat to the biological diversity in the Party of import, and thus were properly outside the scope of Protocol. They also argued that subjecting LMO-FFPs to AIA would subject trade in agricultural commodities to prohibitive delays and expense.*

346. *Negotiations and consultations in the period between the Cartagena session of the ExCOP in February 1999 and the resumed ExCOP in Montreal in January 2000 focused on finding a solution to differences over LMO-FFPs. In the end, LMO-FFPs were exempted from the Protocol's AIA procedure (see commentary on Article 7). But the provisions of Article 11 in effect provide a special, and in principle simpler, procedure for transboundary movements of LMO-FFPs. Essentially, in contrast to the "bilateral" AIA procedure, Article 11 establishes a multilateral information exchange mechanism for LMO-FFPs, centred around the Biosafety Clearing-House. It places the onus on an importing Party to check the Biosafety Clearing-House for information on new LMO-FFPs which may enter international trade, and, if it wishes, to subject such imports to domestic regulation. Article 11 explicitly permits Parties to subject first imports of LMO-FFPs to prior risk assessment and approval.*

347. *It is important to note that Article 11 applies to LMO-FFPs, and not to all foods and feeds derived from LMOs. Thus, while Article 11 is* ***relevant*** *to regulation of transboundary movement of what are commonly referred to as "genetically modified foods", it is* ***applicable*** *only where the product being exported and imported fulfils the definition of "living modified organism" in Article 3 of the Protocol. Article 11 does not apply directly to processed food products derived from, but not consisting of or containing a LMO (e.g. a refined processed oil derived from genetically modified soya). It* ***does*** *however apply to transboundary movement of LMOs destined for use in the production of processed foods, as well as to LMOs for direct use as food or animal feed. Issues related to the safety assessment and labelling of foods derived from modern biotechnology are being addressed in another intergovernmental forum, the Codex Alimentarius (see Box 12).*

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

348. Under Article 11(1), where a Party makes a final decision regarding the commercial growing or placing on the market of a LMO at the domestic level, and that LMO may be exported for direct use as food or feed, or for processing, then that Party must notify the Biosafety Clearing-House (and thereby other Parties) within 15 days of reaching the decision. In some cases, the Party may have to inform competent national authorities of other Parties directly, as well as the Biosafety Clearing-House.

349. The minimum information to be provided to the Biosafety Clearing-House at this stage is set out in Annex II, and corresponds in large part to the information required in notifications made under Article 8 of the Protocol, although there are some significant differences.

350. The obligation to notify the Biosafety Clearing-House in Article 11(1) will apply where, for example, a Party decides to permit the commercial growing or marketing of a genetically modified corn, soya or oilseed rape within its territory which may subsequently be exported for animal feed or for processing for food or other use. It would also apply to a decision permitting the growing and/or marketing of genetically modified tomatoes, which may be exported for direct use as food, or for processing.

351. The requirement to inform other Parties through the Biosafety Clearing-House does not apply where the Party concerned has approved the LMO in question only for field trials – i.e. for research and development purposes. However, if the same LMO were to be sent to *another* Party for field trials then, subject to the provisions of Article 7, it would likely be subject to the Protocol's AIA procedure (since it would be then intended for introduction into the environment of the Party of import).

352. The reference to "direct" use in Article 11(1) suggests that Article 11 will only apply where there is no intermediate use of the LMO in question in a Party of import.

353. During the negotiations, the controversy over Article 11 centred on agricultural commodities. However, Article 11 as adopted also applies to LMOs for direct use for processing. Examples of such LMOs may include those used in industrial processes for the production of plastics or oils.

354. The purposes of the notification to the Biosafety Clearing-House under Article 11(1) are:

- to put other Parties "on notice" that the LMO in question may be exported for food, feed or processing use; and
- to provide relevant information on that LMO that another Party can use when deciding whether or not to allow the import of that LMO for food, feed or for processing in its territory.

355. It is therefore essential that all Parties have access to this information. It was recognized during the negotiation of Article 11 that for some Parties access to the Biosafety Clearing-House may be problematic, particularly where it depends upon regular and reliable internet access (see commentary on Article 20). Thus, if the national focal point (see commentary on Article 19) of a Party does not have access to the Biosafety Clearing-House it should inform the Secretariat of this fact. It should then receive instead a written copy of the information on any new LMO-FFP direct from the Party which has approved that LMO for domestic use. Although Article 11(1) states that this facility is available to a Party that "does not have access to the Biosafety Clearing-House", it presumably extends beyond those that have *no* access to those Parties that have limited or unreliable access to the Biosafety Clearing-House. It may therefore be prudent for any Party which may experience difficulties accessing the Biosafety Clearing-House through the internet on a regular and reliable basis to notify the Secretariat upon entry into force of the Protocol, so that it will receive hard copies of any information on new LMO-FFPs.

356. In contrast to the AIA procedure, Article 11 of the Protocol does not require a Party exporting a LMO-FFP, or an exporter of a LMO-FFP, to provide any notification or information *directly* to the importing Party. Any such obligation needs to be triggered by the domestic regulations of the *importing* Party (see commentary on Article 11(4) and (6)). In practice, however, in some instances the domestic requirements of the importing Party may result in first imports of a LMO-FFP being subject to procedures similar to AIA – e.g. the importing country may well require prior notification of a first import of a LMO-FFP, as well as a risk assessment, and explicit approval.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

357. As in Article 8(2) of the Protocol, Parties are required to ensure that under their domestic law there is a requirement for accuracy of information provided in relation to the LMO-FFP. The "applicant" is not defined in the Protocol, but will presumably be the person or entity which submits the application relating to the domestic use of the LMO-FFP in the Party that makes the final decision on such use.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

358. Once the Annex II information has been conveyed to the Biosafety Clearing-House by the Party which has made a final decision regarding domestic use of a LMO-FFP, any Party may request additional information from the national authority responsible for taking that decision.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

359. Article 11(4) asserts the right of Parties to require prior approval of imports of LMO-FFPs. Thus although LMO-FFPs are outside the scope of application of the Protocol's AIA procedure, in their domestic regulatory framework Parties may still choose to require advance notification and approval of a proposed transboundary movement of a LMO-FFP. The domestic regulatory framework must be consistent with the objective of the Protocol. As discussed in relation to Article 9, on the basis of Article 1, consistency with the *objective* of the Protocol might be considered in terms of the following kinds of issues:

- Avoidance of adverse effects on the conservation and sustainable use of biological diversity;
- Risks to human health;
- Provision of an adequate level of protection in the field of the safe transfer, handling and use of LMOs;
- Reference to the precautionary approach referred to in Article 1.

(See commentary on Article 9, paragraph 302).

360. A number of countries already have in place domestic regulatory frameworks which require prior approval for the import or placing on the market for the first time of a LMO for food, feed or processing use, or for some such uses. In general terms, these frameworks provide for the risk assessment of the LMO-FFP in question, taking into account the characteristics of the LMO, and its intended use.

361. Beyond consistency with the objective of the Protocol, Article 11 does not specify any particular procedural requirements to be reflected in domestic regulatory frameworks applicable to imports of LMO-FFPs. Of course, a Party may also be subject to other relevant international obligations, including those under the WTO Agreements (see Appendix). In addition, a Party may decide to take action that is more protective of the conservation and sustainable use of bioogical diversity than that called for in the Protocol, subject to the proviso set out in Article 2(4).

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

362. Article 11(5) is intended to promote transparency and predictability, by requiring Parties to notify through the Biosafety Clearing-House relevant national frameworks that they will apply to imports of LMO-FFPs. Thus domestic regulatory frameworks under Article 11(4) should be notified to the Biosafety Clearing-House under Article 11(5). In this way, a Party or person who intends to export a LMO-FFP to a Party to the Protocol should be able to find out through the Biosafety Clearing-House what national regulations of the importing Party will apply to the proposed export.

363. The Protocol does not specify in which language or format the information on relevant national regulations is to be made available. This is an issue which will need to be resolved by the COP/MOP if the system envisaged in Article 11 is to be workable, and it is currently being addressed in discussions on the operation of the Biosafety Clearing-House (see commentary on Article 20).

364. Similar notification requirements apply under WTO agreements, for example in relation to notification of sanitary and phytosanitary measures and technical regulations.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

365. Article 11(6) was intended to ensure that developing country Parties and Parties with economies in transition which do not yet have in place a domestic regulatory framework addressing imports of LMO-FFPs could nonetheless subject such imports to prior notification and approval procedures in a manner consistent with the Protocol's objective.

366. Any such Party which does not have a domestic regulatory framework for LMO-FFP imports in place, but which wishes to subject such imports to prior assessment and approval, should indicate this to the BCH. In practice, any Party which does not have such a framework in place upon entry into force of the Protocol for it, may wish to consider making such a declaration. For practical purposes, a Party making such a declaration should also indicate the national authority to which notification of any proposed import should be made – this will be the competent national authority of the importing Party under Article 19 (or one of them).

367. One question which arises here is whether the "domestic regulatory framework" referred to here must be a national biosafety framework or a framework specifically designed to address LMO-FFPs, or whether it could also include more general import procedures, such as existing quarantine measures. The better view would appear to be that where a Party does not have a comprehensive domestic framework addressing LMO-FFPs, then it may make a declaration under Article 11(6).

Risk assessment and predictable time frame

368. Article 11(6) provides that decisions on imports are to be undertaken in accordance with a risk assessment under Annex III of the Protocol, and within a predictable timeframe not exceeding 270 days. In effect this provision allows an importing Party to utilize an AIA-type procedure for reaching a decision on the first import of a LMO-FFP. However,

some potential difficulties might be noted here:

- First, Annex III addresses risk assessment guidelines for LMOs intended for intentional introduction into the environment. Since the Protocol itself differentiates between LMOs and LMO-FFPs one might expect certain different or supplementary criteria to be applicable for risk assessment for LMO-FFPs. For example, while Annex III sets out primarily an environmental risk assessment rather than addressing food safety and related issues, risk assessment for LMO-FFPs, in addition to potential risks associated with their introduction into the environment, might address in more detail human health aspects of the food, feed and processing use of the LMO in question. In this regard, principles and methodologies such as those adopted under the *Codex Alimentarius* may be of relevance (see Box 12) In addition, the reference in Annex III to risks associated with products of LMOs ("products thereof") may be of particular relevance to risk assessment for LMO-FFPs.
- Second, in relation to the time frame for decision-making, unlike Article 10, Article 11(6) does not explicitly allow for an extension of the 270-day time period where the importing Party has either requested additional information about the LMO-FFP or where it simply requires additional time in order to reach a decision. This might create difficulties for an importing Party which does not have a full domestic regulatory framework in place within which to reach its decision. In particular, the lack of a provision to extend the time period for decision-making may be problematic given the language of Article 11(7). On the other hand, there is also nothing in Article 11 which indicates when the 270-day period *begins* in relation to decision-making on imports of LMO- FFPs.

369. Although Article 11(6) is intended as a proective measure for developing country Parties and Parties with economies in transition, it may be challenging in practice for a country which does not have a domestic regulatory framework in place to take a decision on the potential import of a LMO-FFP based on a risk assessment in accordance with Annex III and within a predictable time frame of not more than 270 days. It is perhaps feasible that interim guidelines and procedures could be applied. However, in practical terms, it may make sense for a Party developing a national biosafety framework to deal with LMO-FFP imports within the same framework as LMOs, while taking into account that different or supplementary considerations relating to food safety may need to be taken into account in relation to LMO-FFPs. As in the case of the AIA procedure, gaps and ambiguities in the Protocol may best be resolved through clear national regulations.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

370. Article 11(7) reflects the approach taken in Articles 9 and 10 of the Protocol in relation to AIA, that consent to a transboundary movement of a LMO cannot be implied.

371. Article 9(4) and Article 10(5) provide that failure by a Party of import to acknowledge receipt of a notification or to communicate a decision respectively "shall not imply its consent" to an intentional transboundary movement of a LMO. In contrast to Article 9(4) and Article 10(5), Article 11(7) states that failure by a Party to communicate a decision shall not imply its consent *or refusal* to the import of the LMO-FFP. Since this additional wording was added intentionally, it is to be presumed that the negotiators intended the consequences of a failure to communicate a decision under Article 11 to be different to a failure under Article 9 or Article 10. It cannot be presumed that the words "or refusal" are simply redundant.

372. Nonetheless, the practical implication of the additional wording remains unclear. In these circumstances, for practical purposes and to enhance certainty and predictability, a Party may wish to put in place a domestic regulatory framework for imports of LMO-FFPs under Article 11(4) rather than rely on Article 11(6) and (7). This domestic regulatory framework could then set out the procedure and time frame by which an import decision on LMO-FFPs would be reached, and specify

whether explicit written consent is required prior to the first import of a LMO-FFP.

373. In the event that a Party of import has difficulties in assessing potential imports of LMO-FFPs, it may be that some assistance would be available through the procedures and mechanisms to facilitate decision-making adopted by the COP/MOP under Article 10(7).[83] Strictly speaking, it would appear that Article 10, and hence Article 10(7), is not applicable to LMO-FFPs as it relates to the Protocol's AIA procedure. Nonetheless, it seems likely that similar types of assistance may be required in relation to LMO-FFPs.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

374. Like Article 10(6), Article 11(8) allows Parties of import to take a precautionary approach to decision-making on imports. While the debate over the inclusion of precautionary language in Article 10 was protracted, once the language of Article 10(6) was agreed it was also included in Article 11 without additional debate.

9. A Party may indicate its needs for financial and technical assistance and capacity- building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

375. Article 11(9) appears to recognize that there may be additional specific capacity-building needs in Parties regarding LMO-FFPs – for example regarding risk assessments. Although Parties may "indicate" these needs, Article 11(9) does not specify to whom such needs should be indicated. The reference to Article 22 and Article 28 would appear to suggest that such capacity-building needs should be addressed through the COP/MOP and the financial mechanism as well as through bilateral, regional and multilateral channels.

[83] ICCP Recommendation 2/7, UNEP/CBD/ICCP/2/15, Annex I.