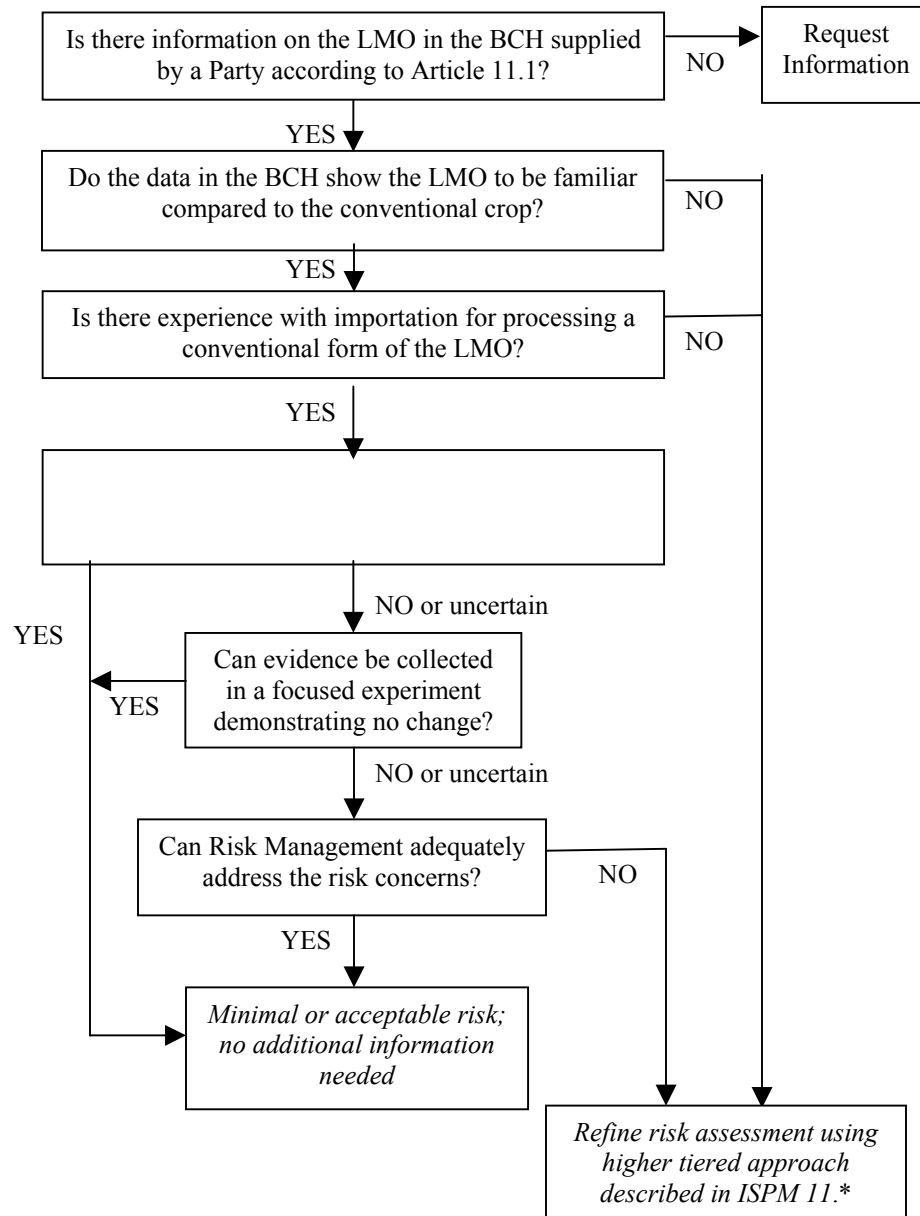


An Assessment Procedure for Plant-derived Living Modified Organisms Imported for Direct Use in Foods and Feeds, or for Processing (LMO-FFP)

- Article 11 of the Cartagena Protocol on Biosafety (BSP) applies to the first transboundary movement of a LMO-FFP. Parties importing a LMO-FFP that will not be subject to further transboundary movement have the flexibility under Article 11 to accept the risk assessment conducted by the exporting party rather than conducting a separate risk assessment for that importation.
- International trade of agricultural commodities defined as LMOs under both the Convention on Biological Diversity and the International Plant Protection Convention should be protected as regulatory and phytosanitary obligations are being clarified. Specifically, a party's obligations regarding LMO-FFPs under these conventions are currently subject to various interpretations.
- International Standard of Phytosanitary Measure (ISPM) 11(*) applies to LMOs. Countries choosing to apply a phytosanitary measure (PM) to a LMO-FFP may use ISPM 11 or an equivalent locally developed PM. ISPM 11 describes a three step process where the first step involves making a determination whether a LMO poses a potential phytosanitary risk or not. (* see footnote on p. 2)
- Information should be available from technology providers or the Biosafety Clearing House (BCH) to enable importing countries to understand how the risks of a LMO were assessed. In many cases the existing information will be adequate to assess the environmental risks associated with a LMO-FFP.
- Many countries will determine that they do not need to conduct a specific risk assessment for a LMO-FFP. However, countries choosing to examine the environmental and phytosanitary risks associated with a LMO-FFP can use a science-based, decision tree process consistent with the initiation step in ISPM 11 (Figure 1) and the principles outlined in Annex III of the BSP.
- The decision tree presented in Figure 1 is science-based, and leverages the use of existing information and experience with the traditional crop, as a comparator, to make a determination of the pest potential of a LMO-FFP. For GM crops that have been assessed and shown to pose no greater risk to the environment and human health compared to the conventional crop, the focus of the assessment becomes the experience with importing the conventional crop, and how the GM trait could meaningfully change the impact of the crop in the likely receiving environment.
- In cases where there is sufficient scientifically-based uncertainty about the environmental risks associated with the GM trait, the decision tree allows for conducting targeted experiments and information collection. These experiments will enable regulators to evaluate whether the GM plant is potentially more persistent and invasive than its conventional counterpart. The information also enables decision-making regarding risk management, when determined to be necessary.
- The proposed decision tree is intended to facilitate the evaluation of LMO-FFPs by countries choosing to formally decide whether a LMO-FFP poses a potential pest concern and avoid undue hindrance of trade. It is based on the risk assessment principles in Annex III of the BSP and is compliant with ISPM 11. The proposed process enables regulators to make appropriate data-driven decisions, proportionate to the probable risks.

Figure 1. Decision Tree for determining the appropriate data and environmental risk assessment process for a Plant-derived LMO-FFP.



* Available at:
www.ippc.int/servlet/BinaryDownloaderServlet/ISPM_11_2004_E.pdf?filename=1107531644613_ISPM_11_2004_A5.pdf