

**PROJECT DOCUMENT****Annex to the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* on Low-level Presence of Recombinant-DNA Plant Material****1. Purpose and scope of the proposed work**

The goal of the project will be to develop recommendations to the Task Force on performing a safety assessment in situations of low-level presence (to be referred to as “low-level situations” in this document) in which the recombinant-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Codex Plant Guideline, but the importing country has not determined its food safety, and on the requisite data and information sharing systems to facilitate this process.<sup>1</sup>

With this in mind, the objectives of the project will be to:

- Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in low-level situations, and
- Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country.

The project would not:

- Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate.
- Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.
- Eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries’ relevant import requirements, including in relation to unapproved recombinant-DNA material.

**2. Relevance and timeliness**

An increasing number of recombinant-DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant-DNA plant materials that have passed a food safety assessment in one or more countries may on occasion be present in food in countries in which the food safety of the relevant recombinant-DNA plants has not been determined. This Annex is intended to aid countries that want to determine the food safety of a recombinant-DNA plant under such circumstances or in advance preparation for such potential circumstances.

**3. The main aspects to be covered**

- Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in low-level situations, and
- Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country.

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<sup>1</sup> The guidance would not be intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.