

Public Research & Regulation

Foundation with the objective to involve the public research sector in regulations and international agreements relevant to modern biotechnology

Second meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (Montreal, Canada, 30 May - 3 June 2005).

Statement on Risk Assessment

Thank you Mr. Co-chair

Mr Co-chair, as is widely accepted, LMOs are neither inherently risky nor inherently safe. Whether or not an LMO can cause damage is determined by scientific risk assessment and depends on the characteristics of the LMO and the way it is applied in the environment.

The general principles and methodology for risk assessment as laid down in Annex III in our view represent an excellent reflection of the effective and consistent practice of risk assessment that started with the 1986 OECD Recombinant DNA Guidelines. We fully endorse the important concepts of science-based, case-by-case, comparative and transparent approach.

Since the adoption of the CBD in 1992, up to 400 million hectares of LMO crops have been planted by millions of farmers in developing and developed countries, consumed in billions of meals, and there have been no verifiable reports of adverse effects to human health or biodiversity. This does not mean that all LMOs by themselves are inherently safe, but it does indicate that the current risk assessment methodology and practice are effective.

The approach toward risk assessment of the Cartagena Protocol is also a pragmatic one. General principles and methodology are laid down in Annex III, and its actual implementation is adapted to local needs on the national level. A wealth of guidance documents is available to assist countries in adapting the general methodology for national use. We commend the secretariat for having produced an excellent compilation of many of those guidance documents.

While Annex III in our view is adequate as it is, we do believe that there is merit in providing additional guidance to public researchers in presenting the risk assessment in notifications that are to be submitted to competent authorities. Such guidance would also be helpful to those same authorities.

For this purpose we have started work on preparing a detailed guide that will take the user step-by-step through the process of risk assessment. This guide will include topics such as a description of the host organism and selected molecular characterisation, followed by a systematic evaluation of the inserted genes in light of the intended application and the potential receiving environment. This guide will be modular in approach and will address genetically modified plants, micro-organisms and animals. An important aspect of the guide will be the need to distinguish between 'need to know' and 'nice to know'. Updates about this initiative will be made available on our web site.

Thank you very much for your attention