



PRRI statement on Risk Assessment

Thank you Mme Chair,

I speak on behalf of the Public Research and Regulation Initiative (PRRI).

Madam Chair, one of the key achievements of the Cartagena Protocol is international agreement on the principles and methodology for risk assessment, building on many years of experience.

As Annex III says, risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account guidelines developed by relevant international organizations.

PRRI welcomed the decision of MOP4 to develop a roadmap that would help apply the available guidelines in a way that is consistent with Annex III. PRRI therefore contributed actively to the AHTEG and the online discussions, by making our members' vast collective experience in risk assessment available.

However, after 8 years of online discussions, AHTEGs and testing, PRRI shares the concerns of others about the usefulness of the draft document. As public researchers working on biotechnology for the public good, we are concerned that this guidance, as it is, will confuse rather than help.

With regard to the proposed elements for a draft decision, we offer the following observations.

Regarding the proposed endorsement of the draft guidance, and bearing in mind the different views on the draft guidance, the question arises what 'endorsement' means in procedural terms within the UN system, and even more so in practical terms on the national level.

The question also arises whether the title "reference document" would be more appropriate than "Guidance", given that the document itself explains that it is to provide a reference.

As to the proposed next steps, PRRI believes that while the process of the online forum and AHTEG is a good mechanism to discuss views, it is not suitable for devising guidance on highly specialised areas. Developing guidance and conducting related training is best left to specialised regional and international organizations. It is encouraging to note that several such valuable initiatives in this area are presented at this MOP through flyers and side events.

Thank you Mme Chair,