

Public Research & Regulation

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

MOP3 - PRRI STATEMENT ON RISK ASSESSMENT

Thank you Mr. Chairman,

I speak on behalf of the Foundation for Public Research and Regulation.

Mr. Chairman, as scientists the topic of risk assessment is close to our hearts.

As a starting point in this debate it is important to keep reminding ourselves of some very important considerations that are relevant to risk assessment in the field of biosafety.

- Risk assessment has to be based on sound science – i.e. based on scientific reasoning, verifiable and replicable;
- Risk assessment is comparative – i.e. any risks identified in the risk assessment have to be compared with the risks of using the non modified recipient organism;
- Information should only be requested if it is clear how it will be used in the risk assessment
- The precautionary approach does not mean ‘zero risk’

Having said this, we can also conclude that the methodology in Annex III is an adequate reflection of over 20 years of practice and that at this point there is no need for further generic guidance.

With this introduction, Mr. Chairman, we can only say that we are very pleased with the outcome of the Ad Hoc Technical Expert Group on Risk Assessment, in which PRRI participated with great pleasure. We like to use this opportunity to thank the Italian Government for their warm hospitality and efficient organizations and we wish to extend a special thanks to the chairman of the meeting, Dr. Nelson Marmioli, who chaired the meeting very capably.

Back to the question of what to do next, Mr Chairman, in our view it is time follow a two-track approach: First, it is important to provide specific guidance on how the methodology of Annex III is applied in concrete cases, for example in the case of the release of insect resistant crop plants. At MOP2, the Foundation for Public Research and Regulation announced that it was preparing such guidance and we are pleased to announce that we have completed the first module of such guidance on genetically modified crop plants. That Guide is on our web site and, encouraged by the feedback, we are working on the next version. Second, there is an urgent need for repeated and continued ‘hands-on’ training workshops in risk assessment, using ‘real-life’ cases, which are introduced by ‘real-life’ applicants, where ‘real-life’ interest groups participate in the discussions and where the trainers have substantial experience in risk assessments.

Mr. Chairman, the Foundation for Public Research and Regulation remains available if you wish to explore these issues further.

Thank you very much for your attention