

Item 4.2: Expert advice and the role of risk assessors

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Assessment of Living Modified Organisms

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Expert advice and the role of risk assessors (1)

How to guarantee the best possible expertise and knowledge for risk assessment?

- Internal/in house expertise in regulatory agencies or government institutes
- Consulting university researchers
- Expert panels, advisory boards
 - To provide specific expertise or to carry out the risk assessment
- Research related to risk assessment
 - Examples from Finland, Norway, Estonia

Expert advice and the role of risk assessors (2)

What are the main responsibilities of the risk assessor(s)?

- Review the information provided
- Identify additional scientific information, new information, previous risk assessments
- Consider information gaps, scientific uncertainties
- Additional tasks:
 - How to deal with lack of data and scientific uncertainties?
 - Prepare good notes, good summaries to get ready for the risk assessment
 - Compile information in a logic and organized manner

Expert advice and the role of risk assessors (3)

- Conduct the risk assessment
 - Request additional information if needed
 - Involve new experts if needed
 - Reserve enough time
 - Iterative, step-wise process
- Prepare a report
 - Describe the process
 - Identify people involved
 - Summarize conclusions
 - Identify problems, gaps in data, uncertainties
 - Present conclusions and justify them

Expert advice and the role of risk assessors (4)

Some other issues to remember and consider

- Some information is/may be confidential
- Experience from Finland:
 - Risk assessors cannot have conflict of interest to a particular notification/risk assessment
 - There maybe cases where a risk assessor must recuse oneself

Expert advice and the role of risk assessors (5)

Final points

- Roster of Experts on Biosafety
 - International experts available
- Stakeholder participation
 - In Advisory Boards
- Public participation
 - Usually in decision making, a possible channel to provide new information to the risk assessment
 - E.g. in the EU the risk assessments of product applications are open for public consultation in a centralized manner
 - Public participation in risk assessments of field trials is done at national level