

## Risk Assessment and Risk Management

### Roadmap and guidance documents prepared by the AHTEG (agenda item 13)

*by Ricarda A. Steinbrecher, Federation of German Scientists*

Building on regional workshops and the experience of parties, it was recognized at the fourth meeting of the parties (MOP4) that there is a need for further guidance on specific aspects on risk assessment of LMOs.

In particular further guidance was required for living modified fish, trees, insects, algae and microorganisms as well as LMOs with particular traits, such as stress tolerance or production of pharmaceuticals, or LMOs with stacked genes.

As mandated by decision BS-IV/11, an open-ended online forum and an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEG) were established for this purpose.

The work of the AHTEG produced four documents, namely the ROADMAP on risk assessment and risk management of LMOs, and three guidance documents covering LM mosquitoes, abiotic stress tolerant LMO plants, and LM plants with stacked genes as presented in document UNEP/CBD/BS/COP-MOP/5/12.

The ROADMAP and a graphic FLOWCHART elaborate on Annex III of the Cartagena Protocol on Biosafety and offers a number of new innovations (see box).

Whilst the AHTEG was able to cover three different categories of LMOs in their work, more time will be required to create the guidance materials for the other LMOs previously identified by parties, as mentioned above.

Additionally, many of these LMOs are capable of spreading across national boundaries and with potentially serious consequences to global forest, water and marine ecosystems. Some of these LMOs are on the verge of commercial production and release, such as LM fish, LM trees and LM algae.

There is urgent need to address the issue of unintentional but unavoidable transboundary movement that have the potential to effect ecosystems way beyond the point of release.

This may not only occur from intentional releases into the environment but also from breach of containment during transit (e.g. eggs, larvae, insects) or from contained use (e.g. fish, alga).

#### Why a ROADMAP?

A ROADMAP, and graphic FLOWCHART, was seen as the best way of presenting the phases and steps to be considered in a risk assessment. Importantly, the ROADMAP shows how the risk assessment relates to other stages in the entire risk appraisal process that leads to decision-making. Further, the ROADMAP can be a navigational tool for training purposes.

- Roadmap innovations:
- Creates a scoping and problem formulation stage prior to the implementation of the risk assessment
- Formalises stakeholder engagement in the framing of relevant questions and needs
- Outlines an iterative approach to evaluating whether the aims of each step have been met
- Formalises definitions of data relevancy
- Defines sound and quality science
- Outlines the systematic treatment of uncertainties
- Provides for an evaluation of new information or management options before risk assessment is finalised (see Step 5 of the Flowchart)

Source: TWN briefing "The Roadmap for risk assessment – The AHTEG answer to the request from Parties for guidance on Annex III" by David Quist and Jack Heineman

These issues need to be addressed at many levels, including at the stage of risk assessment as well as at the level of decision making and should be taken into account when discussing the recommendations of the AHTEG (Annex IV of UNEP/CBD/BS/COP-MOP/5/12) and recommendations to COP.

## Concerning the Recommendations of the AHTEG

To benefit from the work of the AHTEG, the Roadmap and the Guidelines should be made available to all parties and published in all UN languages as outlined in recommendation 3a. It is also evident that further development of guidance is required (3d) as well as the incorporation of relevant background material (3e).

As the development of further guidance materials is still required, this could best be served by an extended Open-ended Online Expert Forum and the continuation of the AHTEG on Risk Assessment and Risk Management, as outlined in recommendation 3g.

## Supplementary Protocol on Liability

Negotiations finally concluded this week on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. Parties resolved two final controversial issues to bring the talks to a close in the early hours of Monday morning.

While the phrase “products thereof” does not appear in the final text, the final report for the meeting contains language noting one understanding held by Parties, that Parties may apply the Supplementary Protocol to damage caused by processed materials that are of LMO-origin, provided that a casual link is established between the damage and the LMO in question.

The second controversial issue to be resolved was that of financial security. Language in the text now enshrines the right of Parties to provide for financial security, to ensure that if a responsible party cannot pay for the damage caused by an LMO, there will be some means available to do so.

---

## GM Fish Without Borders

*by Eric Darier, Greenpeace*

On 21 September 2010, the US Food and Drug Administration (FDA) came close to approving Genetically Modified (GM) salmon for human consumption. AquaBounty Technologies, Inc., a biotech company with a facility in Canada would like to get permission to sell GM salmon to US consumers.

AquaBounty’s plan is to produce GM salmon eggs in Canada, raise them in Panama and then, sell GM salmon to US consumers.

The Atlantic salmon of AquaBounty Technologies is genetically modified with a growth hormone gene from a Chinook salmon and an antifreeze gene from an ocean pout. As a result, the GM salmon grows faster.

Concerns over the human welfare and environmental impact of intensive fish farming include:

- Frequent escape of fish from aquaculture facilities leading to interbreeding or displacing of native fish populations;
- High potential for ecological disturbance if GM fish escape from either land-based or container aquaculture facilities;
- Competition from fast-growing GM fish for food for wild fish;

- Disruption of aquatic food webs and ecosystems;
- Lack of certainty that sterilization of GM fish will be 100% effective in preventing cross-breeding with wild fish.

It is only a matter of time before GM fish would find their way into aquatic ecosystems across borders. GM salmon in Panama: environmental dumping

Canadian and US authorities – usually supportive of biotechnology - have not yet approved the growing of GM salmon. Many organizations have expressed deep concerns about the hazards of commercialization of GM fish including the Royal Society of Canada and the US National Academy of Science. All the credible scientific evidence leans toward extreme caution on the commercialization of GM fish.

Plan to grow GM salmon in Panama is a way to get around the concerns of US and Canadian scientists and would constitute environmental dumping on Panama from Canada and the US. Parties to the Protocol on Biosafety must immediately prohibit GM fish for commercial use.

Greenpeace report

<http://www.greenpeace.org/international/en/publications/reports/genetically-engineered-fish/>

---

# "We are all the public"

## Reflections on the Joint Aarhus Convention/Cartagena Protocol on Biosafety Workshop on public awareness, access to information and public participation regarding living modified organisms/genetically modified organisms, 8-9 October 2010 in Nagoya

*by Antje Lorch, ECOROPA*

The Aarhus Convention can be seen as a complementary international instrument on public awareness, access to information and public participation under Article 23 of the Cartagena Protocol. The connection between the two of them was highlighted by a second joint workshop prior to COP-MOP 5. The first one was held in Cologne close to COP-MOP 4 in Bonn.

When the text of the Cartagena Protocol was negotiated and signed, the general assumption was that the public needs to be educated about LMOs and modern biotechnology and their awareness would need to be promoted and facilitated. Ten years later it is obvious that "the public" is not a homogenous un-educated mass but that in fact "the public" includes very diverse actors and groups. Amongst them are of course the farmers, producers and consumers, but also such distinct groups as journalists, scientists, parliamentarians and (local) policy makers.

This becomes more obvious if you look at it from the angle of the Aarhus Convention. You may be registered for the COP-MOP in a specific role be it as an official delegate representing a Party, an observer from civil society, academia or the business sector or as staff member, but in terms of your access to information and participation you are 'just' a member of "the public".

So, "the public" includes not only the so-called "uninformed" man/woman on the street but also brilliant scientists, high ranking policy makers or editors that have been following a topic for the last 20 years.

This situation was summarized very appropriately by Helmut Gaugitsch, chair of the Joint Workshop: "We are all the public."

Access to information and public participation, therefore, needs to be addressed with the understanding that it is not automatically necessary for authorities and companies to process and simplify the information so that an uneducated public can understand it. On the contrary: when it comes to members of the public such as scientists at universities and research institutes then the full scientific data is what they need. Journalist also require the full original sources of information in order to substantiate their articles. Access to

the right kind of information allows them to participate on their level, bringing in their own expertise.

And that is where we are heading: Public participation is more than being given information which enable people to arrive at informed personal opinions, but also have an influence on the opinion. It is more than being given the opportunity to go to a public consultation and being told in the end what the outcome of the official decision-making was. Public participation is also about contributing valuable information and aspects.

One form of such contribution by the public is research on specific LMOs in particular and on modern biotechnology in general, done by scientists who are neither involved with the companies producing LMOs nor with the decision-making regulatory authorities. The Pre-MOP Scientific Conference on "Advancing the Understanding of Biosafety" and the following Public Forum at the University of Nagoya can serve as an example. It was organised and supported by Organisations of Scientists and by NGOs. Scientists reported on their research, thereby giving additional input to information and the decision making process.

More and more, participation of "the public" is even explicitly required. Post-market monitoring plans for GM crops in the European Union generally rely on farmers and others to report unexpected effects and on environmental monitoring programmes run by third parties.

The CBD and its Cartagena Protocol are already very inclusive to "the public" in its different manifestations, in the text of their articles and decisions as well as in the practicalities of actual public participation in the negotiations. It can be hoped that a continuous and close cooperation between the Aarhus Convention and the Cartagena Protocol will pave the way to go beyond some of the still existing realities of one-directional top-down approaches of "having your awareness built" or "getting educated" or "accessing only shortened or watered down information" or "being consulted only formally without the actual will to listen to and to learn from the public".

Real access to information and public participation lead to mutual learning based on a two-way communication and will enhance real biosafety.

---

# "Advancing the Understanding of Biosafety"

## Scientific Conference & Citizens Forum in Nagoya

by Dr. Denis W. Aheto, University of Cape Coast, Ghana

As pre-events to MOP5, the *European Network of Scientists for Social and Environmental Responsibility (ENSSER)* in conjunction with the *Third World Network (TWN)* and the *Federation of German Scientists (VDW)* from the 7-9 October 2010, provided a platform for independent scientists from across the world to contribute their most recent findings on biosafety research and to share and debate knowledge with a wider audience of Japanese stakeholders and media. The Scientific Conference and Citizens Forum "Advancing the Understanding of Biosafety" presented a broad range of topics and research results amongst them

- In the current GMO controversy, only a very small part of research and public information deals with independent analysis taking into account the socio-cultural, economic and environmental conditions in developing countries and other countries in development transition. The presenters therefore concentrated on result from research in the specific receiving environment rather than presenting extrapolations from foreign data.
- The meetings introduced relevant dimensions of GMO risk assessment from the developed and developing country contexts with a focus on the receiving environments, agro-structure and agroecology. Scientific studies on gene flow impacts, spatial and temporal isolation distance implications and insect pest resistance issues were discussed.
- It stressed that a large body of scientific knowledge is required in order to make informed decisions about GMOs. From the level of molecular studies through individual populations to landscape contexts would be necessary. Such a large body of knowledge allows to evaluate the completeness of risk assessment studies.
- It indicated that regulators not only have a huge task to predict the benefits of GMOs but also to anticipate the relevant country-specific problems that could emerge in accordance with the precautionary principle and country's biosafety laws.
- There was the call for the promotion of independent, transparent and reproducible studies for new commercial products due to the controversies

surrounding the science of risk assessments and divergent biological interpretations.

- The issue to grant legitimacy to public sector scientists independence to conduct research on transgenic varieties was strongly advocated, and the call for fundamental reform to global IPRs framework and patenting system that ensures that living organisms are not patentable and permissions for disclosure agreements was discussed to be implemented.
- The issue of unjustified secrecy about risk assessment reports and data was highlighted in the case of Bt binjal/eggplants of India. Through a Supreme Court case, the authorities were forced to make public the risk assessment files. That allowed civil society organisation to engage independent scientists to scrutinise the data and provide the Ministry with a critical view on the shortcomings of the risk assessment performed by the applicant and accepted by the authorities.
- Unintended dispersal from GM feral oil seed rape populations to wild natural relatives can not be avoided due to gene flow with consequences of persistence in the environment and potentially higher costs of removal.
- The unintentional spread of GMOs has already caused scientific and societal debate and concern. GM contamination of maize in Mexico lead to cultural conflicts fearing threats for food security in that country. Widespread deforestation in Argentina due to the expansion of GE soya agriculture is documented to be 0.85% annually, greater than those of Africa at 0.78% and much greater than the world average.

Full documentation: <http://www.ensser.org/activities/events/advancing-the-understanding-of-biosafety/>

*ECO is currently being published at Fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP5) in Nagoya, Japan and coordinated by the CBD Alliance. The opinions, commentaries, and articles printed in ECO are the sole opinion of the individual authors or organisations, unless otherwise expressed.*  
SUBMISSIONS: Welcome from all civil society groups.  
Email: lorch@ifrik.org or jdempsey@interchange.ubc.ca