

Report on the Consultative Follow-up Meeting of the GMO Guidelines Project

Location: ICIPE, Nairobi, Kenya

Date: 29 June 2004-07-05

The morning of the event was dedicated to the opening addresses, presentations and a follow-up on the GMO Guidelines Project and its usefulness and application in on-going biosafety research projects in Kenya (this was underscored by the presentations of Drs. Josephine Songa and Adele Ngi-Song/ Ellie Osir). Lively discussion ensued after each presentation demonstrating that this topic has not lost its actuality in Kenya and people continue to be concerned about these issues. The presentation by Charles Gbedemah of the UNEP GEF Biosafety Project also re-enforced that science needs to have a more active role. As the policy frameworks are being developed and the Cartagena Protocol (CP) on Biosafety is being implemented in more countries, the need for proper scientific methodologies to comply with the legal requirements becomes more urgent. The issues discussed after the presentations touched on concerns for resistance development in *Busseola fusca* and *Helicoverpa armigera* as the efficacy of the Bt-maize tested in Kenya is not sufficiently high for their effective control and the role of wild hosts is still not fully understood. Apparently wild hosts are mainly available before and after the main maize growing seasons. Further, recent work by IRD/ ICIPE scientists has shown that the *B. fusca* larvae found on wild hosts may not be the same species as the *B. fusca* larvae found on maize. Other questions centred around the genetic variability in target pest species from the different agroecological areas of Kenya and the implications that this would have on their susceptibility to the toxins expressed in Bt-maize. The issue of post-commercial monitoring was debated with different views expressed. While the new Biosafety regulations due to be ratified soon by the Kenya government do take care of post-release monitoring, some people stated that the implementation factor is not sufficiently addressed. Other topics discussed included whether and how new the regulations and frameworks developed with the support of the UNEP/ GEF Biosafety Project would apply if something went terribly wrong, and to what degree the biosafety frameworks will differ among countries and create problems in trade and liability between neighbouring countries. We learnt that the GEF Biosafety Project calls for a lot of harmonization but that this is a difficult task and finds its limits with the countries sovereignty. Harmonizing the scientific aspects of Biosafety should be much easier to achieve. It was also noted that building trust in regulations would also depend to a large extent on whether scientists can agree on things and conduct risk assessment with conclusive and convincing outcomes. Issues of mutual interests and benefits should be identified among countries.

After a brief report and presentation by Dr. A. Hilbeck on the topics proposed to Swiss Development Cooperation (SDC) for a phase II of the GMO Guidelines Project, the afternoon was exclusively devoted to a structured discussion on these topics.

I. Develop/establish effective communication tools

Everyone supported the need to develop effective communication among the diverse and growing group of scientists in the GMO Guidelines Project. Finding effective ways to

communicate science to various circles was emphasised as being important. For instance, many people supported the idea of translating technical information to farmers and other stakeholders. Science behind risk assessment must also to be communicated to policy makers and decisions makers. It was proposed that they should actually be involved in the training efforts proposed below.

Also coordination of stakeholders input into the PFOA process should be organized and managed.

II) Capacity and capability building needs:

It was noted that capacity building has several dimensions:

- Hands-on practical training.
- Academic degree training (MSc and PhD levels)
- Group training workshops for regulators and extension workers
- Visiting scientists program (south-south and north-south collaboration)

(a) Science: testing of methodologies and risk assessment concepts developed by the GMO Guidelines Project

All participants essentially agreed that this was one of the most important issues for Kenya.

i) Develop scientific assessment tools along with the training tools (see below) was thought to be a very valuable contribution. When discussing the individual sections of the GMO Guidelines Project, the participants had differing opinions on their importance. So, all wrote down on a piece of paper their personal priority of the sections. The result is quite interesting.

- Problem Formulation and Options Assessment
 - Split opinions: about 40% of the participants assigned it to be a top priority (1) issue, while 60% assigned it the lowest priority (5). Only 2 participants assigned it an intermediate rank.
- Transgene expression and locus structure,
 - Most participants thought this is less important and the majority assigned it lower ranks (4 and 5)
- Non-target and Biodiversity Effects
 - Fairly uniform vote with the majority (>10) assigning rank 2 and 6 participants assigning rank 3
- Gene Flow and its Consequences
 - This section had the most evenly distributed votes across the first 4 ranks, none thought it to be the least important. The majority ranked it among the two top priorities (1 and 2)
- Pest Resistance Evolution & Management Also, here people distributed their ranks evenly across all 5 priorities leading to no clear priority. Largest number assigned it rank 3.

In summary, the following overall priorities can be derived:

1. Gene Flow and its consequences
2. Non-target and biodiversity issues
3. Resistance development and management
4. Transgene and locus structure

PFOA could not be really assigned any rank as the votes indicated a strong split in opinions.

ii) Facilitate grant writing and provide international back-up for submission of proposals. Incorporating and applying developed protocols in on-going programs was felt to be another important undertaking as developing countries scientists often lacked experience and the necessary leverage for doing so. It was pointed out that some grant agencies required that a scientist from the developing country must be principal investigator to be eligible for funding but that external collaboration and co-investigators would be welcome and strengthen a case.

Perceived existing important gaps in capacity in East Africa included:

- The capacity and capability to detect GMOs in the environment
- Repeated strong votes were made on the importance of IPR issues. If phase II could not be able to incorporate it, it was stated that at least the awareness for its importance must be addressed. Otherwise, as one person said: ‘This is like playing football without knowing the rules!’
- Socio-economic issues were also repeatedly stated as issues of great importance.

(b) *Teaching: Training Trainers program.*

It was widely agreed that this was a very important issue. A local network of experts able to conduct assessment workshops and use the developed training tools would be very important. Developing tool kits (manuals, protocols) would be very useful. It was interesting to note that the GEF Biosafety Project has also taken a similar route and produced tool kits for developing a national biosafety policy framework. The idea was put forward to use such new tools and make them available electronically for rapid update and dissemination.

The idea to do practical training within the existing conditions of the country was felt to be a good idea and a useful complementation of the on-going teaching efforts with UNEP facilitation in Norway (under the leadership of Prof. Terje Traavik, Tromsø), where participants are being trained in the Tromsø lab learning methodologies and techniques relevant for scientific risk assessment. Participants felt that both approaches would be necessary.

(i) Concern was raised that a number of biosafety students have been trained in Kenya now with the help of international programs and that it is unclear what further opportunities would be open to them. Much of the country’s knowledge on biosafety rests with them. Either they would have to leave Kenya to pursue further training overseas (and probably never return) or simply stay in Kenya but leave the research field to do something else. Either way, the expertise would be lost for Kenya. So, the idea was raised whether or not these students, some of who were present at the meeting (namely James Kanya and Elijah Lelmen and Dennis Ochieno) could become constitute the nucleus of students to be involved phase II. Phase II should be about developing human resources for biosafety in East Africa. Focal points for different training needs should be identified and universities should play a pivotal role in capacity building. It was also emphasized that the NARIs (national agricultural research institutes) and IARCs (international agriculture research centers) should work closely together. The objective should be create models that can be replicated in different parts of the continent. It was felt that the above mentioned young students might benefit most if they could participate in both an in-country training program as proposed by the GMO Guidelines Project as well as visiting a developed country laboratory for further training.

(ii) Participants pointed out repeatedly that they feel the project must include a strong element of raising awareness on IPR issues. Some felt very strongly about this and thought even that it would be for developing countries the issue of greatest concern and connected to

biosafety at large. It was proposed to reach out or include external experts or link up with projects that have expertise in this field for teaching purposes and develop a teaching tool for that issue!

iii) Complimentarity with existing capacity building programs on Biosafety was emphasized. These include BIOEARN, the Program for Biosafety Systems (PBS) funded by USAID and a training program coordinated jointly by Michigan State and Kenyatta Universities.

III) Expansion of the project to different regions of Africa was generally supported welcomed but people felt that this would only be possible if organisations sub-regional organizations (SROs) such as like ASARECA, CORAF and SACCAR are involved. Others thought that availability of resources would be an important consideration. Alternatively, it was suggested that complimentary proposals could be developed for different regions of the continent.

Appended:

- Program
- List of participants
- Speech by Svein Tveitdal, Director UNEP/DEC/DEPI, opening our event on behalf of Klaus Töpfer, Executive Director of UNEP based in Nairobi

Consultative Meeting of GMO Guidelines Project

- 0900 – 0910 Introduction of participants
- 0910 – 0920 Welcome remarks
Dr. Hans R. Herren, Director General ICIPE, Nairobi, Kenya
- 0920 – 0950 Opening address
Dr. Klaus Toepfer, Executive Director UNEP, Nairobi, Kenya

CHAIRPERSON: Dr. Gilbert Kibata

- 1020 – 1050 Update of GMO Guidelines Project and Recommendations for Kenya. Introduction to the project, scientific products, current status and planned phase II of the project
Dr. Angelika Hilbeck, ETH Zurich, Switzerland
- 1050 – 1100 Discussion
- 1100 – 1130 Update on KARI – CIMMYT Impact Assessment Project
Dr. Josephine Songa, KARI Biotechnology Centre, Nairobi, Kenya
- 1130 – 1140 Discussion
- 1140 - 1210 Update on USAID funded project on Impact Assessment
Dr. Adele Ngi-Song, ICIPE, Nairobi, Kenya
- 1210 – 1220 Discussion
- 1220 – 1250 UNEP Biosafety Capacity Building Activities
Dr. Charles Gbedemah, UNEP, Nairobi, Kenya
- 1250 – 1300 Discussion

CHAIRPERSON: Dr. Angelika Hilbeck

- 1400 - 1430 The way forward – what are the most pressing needs for biosafety assessment in East Africa?
Drs. Angelika Hilbeck, Hans Herren, Ellie O. Osir
- 1430 – 1530 Structured discussion on proposed topics:
- Capacity building needs for the testing of methodologies and risk assessment concepts developed by the GMO Guidelines Project.
 - Collaborative linkages in biosafety research projects.
 - Brainstorming on next steps regarding research and implementation of recommended actions.
- 1550 – 1630 Conclusions

List of participants

Name	Organization
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Opening Address to the follow-up Meeting of the GMO Guidelines Project held at the International Centre for Insect Physiology and Ecology (ICIPE)

Headquarters, 30 June 2004

By. Mr. Svein Tveitdal, Director Division for Environmental Conventions and Division for Policy Implementation, UNEP

Dr, Herren, Distinguished Guests, Ladies and Gentlemen,

1. It is a great honor for me to be here at ICIPE this morning on behalf of the Executive Director of UNEP, Dr. Klaus Toepfer, for the opening of this Follow-up Meeting of the GMO Guidelines Project.
2. I am grateful to ICIPE and the organizers of this workshop, and wish to pay particular tribute to the Swiss Development Cooperation (SDC) for funding the project. Such North/South and South/South international cooperation is critical to the successful intervention in this crucial emerging global issue of GMOs. I also wish to congratulate the Group of Scientists under the umbrella of the **International Organization for Biological Control (IOBC)** for their excellent job with the concept and in their articulation of the key project elements, in particular:
 - to develop scientific methodologies and protocols for pre-release biosafety, testing of GM plants that are in the agreement with the requirements of the Cartagena Protocol on Biosafety of which Kenya is a signatory, and
 - to build capacity on conducting scientific risk assessment to test the developed guidelines in real case examples in three focal countries.
3. Developing countries, who are primarily importers of GMOs, are also most vulnerable to the socio-economic and ecological impacts of genetic engineering and its products. Although many of these countries are also the main centres of genetic diversity and crop origin, most of them have yet to formulate or implement biosafety regulations domestically. There is an urgent need to strengthen the capacities of countries, in particular developing countries and countries with economies in transition to effectively implement provisions of the Cartagena Protocol on Biosafety. This is needed to meet obligations as stipulated in the protocol, which requires, among others, scientific and technical capacity for biosafety assessment and regulation.
4. The gaps in scientific knowledge and the scientific uncertainty regarding the impacts of GMOs require urgent recognition. With the strong economic forces involved, strong science is also needed for sound decision making. Science that is independent and holistic so that truly informed decisions can be made. Countries need the ability to monitor and regulate at the national level based on the best available scientific biosafety information.

Ladies and Gentlemen,

5. Indeed, it is not surprising to note, that biotechnology has become polarized and controversial when it takes on an environmental as well as a socio-economic and developmental angle. This is so, because, as some argue, it is precisely the poor and lower income majority in the developing world who stand to gain the most from successful biotechnology innovation, and conversely, the ones who could ultimately be hard-hit by, and suffer the most, from any adverse impacts which may be brought about by the unregulated introduction of genetically modified crops. This issue poses a major dilemma to policy makers. Strong stakeholder involvement, transparency and good governance is needed if the envisaged food security and farming futures in developing countries are to be truly beneficial and pro-poor as well as pro-South in terms of food sufficiency, national food security and fair benefit sharing
6. Decisions about the future of biotechnology and GMOs cannot be decided on the basis of simple cost-benefit analyses, law or 'sound science' alone. It is essential to find ways of bringing together the different dimensions of GM debates, and the multi-faceted health, environmental, ecological, social, ethical and cultural perspectives they generate.
7. This project assumes great significance when viewed in the above context, as well as the historical biotechnology landscape, and the global road map being chartered by the international community for the twin areas of biotechnology and biosafety over the past 2 decades. The following are a few of the milestones on the road map that may be highlighted:
 - ◆ The Earth Summit at Rio in 1992 adopted **Agenda 21**, which observes in Chapter 16 that the potential of biotechnology to contribute to sustainable food production, health care and improved environmental protection, can only be exploited maximally if adequate national biosafety frameworks are set in place. Countries and organizations were called upon to collaborate in capacity building in this field.
 - ◆ The Earth Summit also adopted the **Convention on Biological Diversity (CBD)** which in Article 19 requires the Parties to consider, in addition to technology transfer, the need for and modalities of a Protocol on Biosafety.
 - ◆ The Convention on Biological Diversity (CBD) entered into force in 1993.
 - ◆ In 1995, the UNEP Guidelines for Safety in Biotechnology were adopted at a global Conference in Cairo, paving the way for the protocol, called for in Article 19, of the CBD.
 - ◆ **The Cartagena Protocol on Biosafety** was adopted in January 2000. The Protocol contains, among others, provisions on advanced informed agreement for transboundary movement of Living Modified Organisms (LMOs) and risk

assessment.

- ◆ In November 2000, the GEF Council adopted the **GEF Initial Strategy on Biosafety**, to assist countries to prepare themselves for the entry into force of the Biosafety Protocol.
 - ◆ The Cartagena Protocol on Biosafety came into force on 11th September 2003 and the 1st MOP was held in Malaysia in February this year. With the ratification on 9 June 2004 by Gambia, this brings the number of parties to 100.
8. UNEP is dedicated to support capacity building at the national level to ensure that biotechnology becomes an asset to support sustainable development. UNEP/GEF is currently implementing a biosafety project that is helping to develop national biosafety frameworks in 127 countries and implementing them in 8 countries. These national biosafety frameworks will establish a combination of policy, legal, administrative and technical instruments aimed at addressing safety for the environment and human health in relation to modern biotechnology.
 9. Furthermore, UNEP is supporting national biosafety information systems within the context of the **Biosafety Clearing House (BCH)** in collaboration with the CBD Secretariat through additional GEF funding. The aim is to assist countries to promote information sharing and collaboration at regional and sub-regional levels. Country-based demonstration projects are critical in this regard.
 10. There is no question whatsoever that biotechnology has the great potential to bring about dramatic changes to our lives and livelihoods as well as the health and well being of our human environment. Through biotechnology, we have the tool by which to address our global needs for food, feeds, pharmaceutical fibers and fuel. In addition, certain biotechnology applications will provide solutions for phasing out persistent pollutants and toxic chemicals from both the sea and the atmosphere. However, the protection of the environment and effective management of its ecosystems to ensure their smooth functioning is of paramount importance, for the survival of not only humankind but also our Planets' overall biological diversity with which particularly developing countries are endowed.
 11. The Cartagena Protocol is the principal global instrument that specifically focuses on the transboundary movement of GMOs. Accordingly, the provisions of the Protocol should be domesticated and fully internalized in these, or indeed any other GMO Guidelines being developed if they are meant to give countries the necessary technical and scientific advice in their efforts to tap into the immense potential benefits of biotechnology.

12. In particular, these GMO Guidelines must embrace the relevant provisions of the Protocol especially Articles 8-10, 12 and 15 and Annexes I and III, in which the Protocol stipulates legal and administrative systems and various sets of procedures for GMOs: those that are destined for contained use; those for introduction/release into the environment, or those to be used directly as food or feed or for processing. Such a set of Guidelines encompassing the critical provisions elaborated in the protocol would greatly assist Parties to the Protocol in meeting their obligations, for example, in respect of their Environmental Impact Assessments (EIAs) and the Advance Informed Agreement (AIAs) processes, to name a few areas.
13. In other words, Parties to the Protocol need to have systems in place that allow them to handle and process notifications, carry out risk assessments of the GMOs in question, and develop appropriate systems for monitoring and evaluations of the GMOs performance and impacts. In this respect, they need Guidelines that are workable, well thought through, transparent and consistent with the Protocol in the context of other Agreements.
14. It is important to ensure that the help the countries receive through the Guidelines is seen as credible, transparent and inclusive of the views of the major stakeholders at national level particularly the local communities and resource poor farmers.
15. This project is an important contribution to developing countries to develop their capacity to use biotechnology in support to sustainable development of their countries, and in implementing biosafety regulations and provisions of the Cartagena Protocol on Biosafety. I congratulate you with your achievements so far and wish you fruitful deliberations and a successful meeting as you chart the way forward for phase 2 of the project. With these remarks I declare the GMO guidelines workshop officially opened.