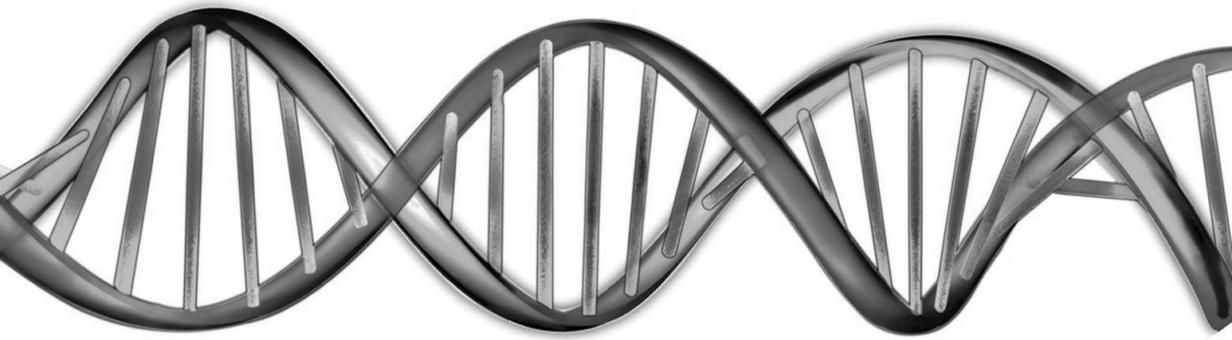


International Conference on

Modern Biotechnologies:
Sustainable Innovation and Regulatory Needs



Penang, Malaysia
7-10 November 2012

Executive Summary



TWN
Third World Network

EXECUTIVE SUMMARY

Reflections from the Organizers

As the developments in modern biotechnology gather pace, so do the challenges for risk assessment, risk management, and policy and regulation related to these technologies. The presentations at the International Conference on Modern Biotechnologies: Sustainable Innovation and Regulatory Needs acknowledged the need to continuously reflect on, update and improve these critical aspects of biosafety, especially given new and emerging applications in diverse fields such as vaccines, insects and microorganisms. It is evident that capacity building and knowledge sharing can play important roles in improving biosafety in all countries, in particular in developing countries.

The issue of sustainability in innovations is also crucial, as the biosafety science and regulatory community needs to collectively take a longer-term and more holistic approach to modern biotechnology development and assessment. Understanding the drivers of research and development, including the current intellectual property system, and re-orienting research and development towards meeting public needs, are important factors to move towards meeting sustainability and public interest goals.

In addition, the presentations at the Conference, in highlighting uncertainties and gaps in scientific knowledge, effectively called for a humbler approach towards science and scientific research, particularly in regard to modern biotechnology. Recognizing the limitations and applying a precautionary approach will help us address the gaps in our scientific knowledge, respect the importance of including traditional knowledge, as well as broaden our options and perspectives. Areas of omitted research should be taken seriously and attention to these gaps can help improve our understanding, assessment and management of genetically modified organisms (GMOs).

Finally, discussing GMOs and modern biotechnology within the wider context of sustainable innovation and sustainable development is absolutely necessary. We believe this should go hand-in-hand with employing a participatory and bottom-up approach towards modern biotechnology and its applications. When these steps are taken, and the full range of alternative options and innovation pathways assessed against a benchmark of meeting needs and for the public good, the choices will become clearer for us all.

Main Recommendations

Setting the Stage: Modern Biotechnology in Context

- There should be recognition by the research community and policy-makers that there are competing frameworks operating in relation to modern biotechnology that are underpinned by different economic and social models. Their different implications should be understood and analyzed, and should inform policy decisions.
- Research and development should be for public needs. There should be an ethical basis for science, innovation and technology development, based on principles of sustainability and the public interest.
- There should be public funding for critical research areas that provide ecological and social solutions, for biosafety research, and for sustainable agriculture. Research outcomes should be made available to the public, e.g., through open licences, without being in private hands, e.g., through patents.
- There should be support for technology assessment as well as for biosafety assessment in the case of modern biotechnologies. The assessment should be from the social, ethical, economic, health and environmental point of view. Regulation of techno-fixes, including genetic engineering, should be enhanced.
- Implementation of the recommendations of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) as well as the outcomes from the Rio+20 conference on agriculture and biodiversity, to operationalize the social and ecological aspects of sustainable development, is needed.
- Governments should use the flexibilities allowed to them under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to not allow for patenting of life forms per se, and still be WTO-consistent. Specifically, as there is no definition of ‘invention’ in the TRIPS Agreement, WTO members can define ‘invention’ such that this would not allow patenting of life forms.
- There should be reform of patent laws in relation to patents on life forms.
- The capacity of patent examiners should be beefed up so that informed decisions on granting patents can be made.
- The implications of free trade agreements (FTAs) which lead to greater restrictions e.g. on farmers’ rights and on transfer of technology should be assessed carefully. Open and transparent policies in relation to these FTAs should be observed.
- Seed and Plant Variety Protection (PVP) laws should recognize the role of farmers in developing seed over millennia.

Agriculture in Perspective, Agriculture for the Future

- There needs to be a fundamental transformation of agriculture towards more

sustainable and ecological agriculture. National assessments are needed to determine what policies are required to make this transformation.

- There needs to be investment from the public sector, and support to smallholder farmers and their sustainable practices, and to rural areas. There should be special attention paid to small-scale farmers and family farms, women farmers and indigenous peoples.
- Investments should be made in agriculture management programmes (transition to no-till, organic and agroecological agriculture; training; access to small-scale mechanization); research and development (in soil science and agronomy, crop improvement, orphan crops, appropriate mechanization, etc.); pre-harvest losses (training activities, and effective natural pest and weed management); and food processing (better storage, and processing in rural areas).
- Organic agriculture is knowledge-intensive, and there is a need to invest in this important sector of agriculture research. There should also be more participatory research development – farmers have to be part of the process, women farmers in particular.
- To better support appropriate new agriculture practices, provided by either biotechnology or agroecology, a special focus needs to be put on knowledge transfer and extension services to bridge the gap between research and development, and the farm.

*GM Innovations and Challenges in Environmental Risk Assessment:
Current GM Crops*

- Developing countries need to take insect resistance evolution seriously. If countries decide to use Bt crops, resistance management needs to be mandatory. It is important to understand major pests in developing countries. Low-dose events should be avoided.
- The regulatory system needs to be adaptive and able to respond appropriately to new and emerging challenges, given that the risk identification, risk assessment and risk management of current genetically modified (GM) plants are dynamic and pose challenges in a changing environment.
- If Bt crops are planted, there is a need for adaptive insect resistance management (IRM), that is, an initial management plan, monitoring, and followed by a revised management plan.
- There should be more research on social, environmental and health issues, and capacity building for better assessment of GM technology. Countries also need to be able to monitor and evaluate the possible effects of GM technology and share the data gathered with all stakeholders.

GM Innovations and Challenges in Environmental Risk Assessment: New and Emerging Applications

- For GM vaccines, GM insects and GM microbes, one challenge is to respond to very novel and uncertain applications, as well as to integrate socio-economic and ethical issues in a meaningful way. Robust biosafety frameworks and capacity are needed to respond to these applications.
- Scientific uncertainties, knowledge gaps and areas of omitted research have to be systematically addressed through well-planned research. Research to establish baselines as well as to monitor for non-target effects is also important.
- The use of stakeholder processes to identify harms from new and emerging applications would lead to more robust assessments that may not be achieved by expert processes alone. Transparency in the risk assessment process should be the norm.
- Public consultation, including access to information, on these issues must be meaningful and effective. Risk assessors should pay attention to critical voices, especially those who have little power to influence decisions/outcomes. Obtaining prior informed consent was also raised as an essential, albeit challenging, part of the approvals process.
- There is a need for appropriate guidance addressing specific issues of paratransgenesis in insects at national, regional and international levels. Scientific uncertainty and their mode of action should be taken into account, in order to provide for extra research and data that are currently not asked for by the regulators.

Precautionary Principle as the Basis for Sustainability

- Technology assessment is necessary to assess the potential far-reaching impacts of new and emerging innovations on the environment, health and society.
- Early warnings of hazards need to be heeded and should be followed up with early warnings research.
- There is a need to broaden technology appraisal to include more scientific disciplines, more types of information and knowledge, and more constituencies. Public participation and the involvement of a broad range of stakeholders would lead to more robust risk assessments and a more robust response to uncertainty.
- Blind spots and gaps in scientific knowledge must be identified together with long-term monitoring to detect complex, cumulative, synergistic or indirect and unintended effects.
- Scientific uncertainties, ambiguity and ignorance, as well as the limitations of a risk assessment need to be recognized, communicated and investigated further. There needs to be a more humble science, which is at the same time rigorous, to recognize what we do not know.

- We need to evaluate a range of alternative options and innovation pathways for meeting needs and for the public good, to enable real choices to be made. There is a need to maintain and enhance the diversity of social and technological approaches to challenges and to encourage multiple technology-based strategies in the face of uncertainty and change. Such approaches will also help to intensify innovations in other less risky and alternative areas.
- Reflexivity on contending values and interests in the social choice of technologies is needed. We should be as rigorous about framing assumptions and validating the questions as we are about seeking the answers.
- Transparency and accountability on the part of decision-makers is important. Democratic and participatory processes are needed together with approaches that consider different options in decision-making processes.