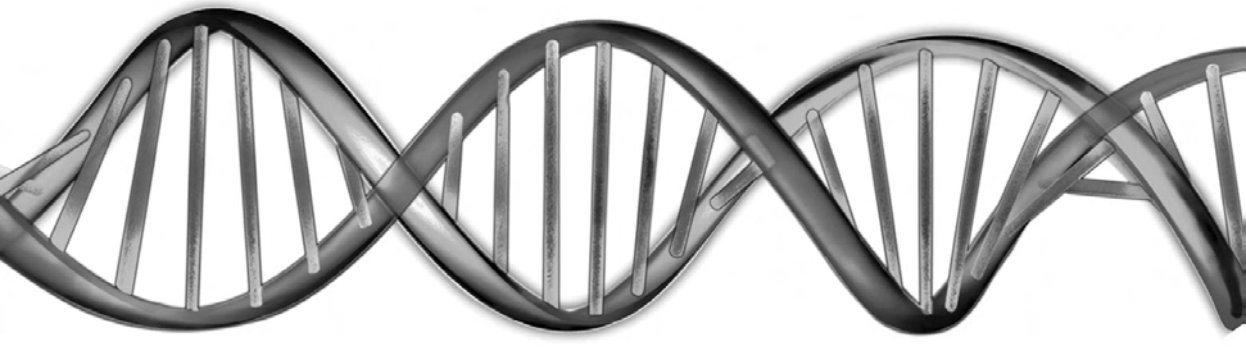
International Conference on

Modern Biotechnologies: Sustainable Innovation and Regulatory Needs



Penang, Malaysia

7-10 November 2012

Conference Proceedings

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TWN
Third World Network

International Conference on Modern Biotechnologies: Sustainable Innovation and Regulatory Needs

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CONFERENCE PROCEEDINGS

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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.

Part One

SUMMARY REPORT

I. INTRODUCTION

The International Conference on Modern Biotechnologies: Sustainable Innovation and Regulatory Needs was held in Penang, Malaysia, from 7 to 10 November 2012. It was co-organized by GenØk–Centre for Biosafety, Norway and Third World Network (TWN) as one of the activities implemented under a collaborative biosafety capacity-building programme funded by the Norwegian Ministry of Foreign Affairs/Norwegian Agency for Developmental Cooperation (Norad).

The strengthening of knowledge of and capacity on biosafety, particularly scientific knowledge and capacity, has been increasingly necessary at national and international levels as genetically modified organisms (GMOs) are being rapidly commercialized. More so for developing countries, as many lack the capacity to monitor research and development activities and trends that may affect their ability to conduct risk assessments and examine the full health, environmental and socio-economic implications of GMOs.

There is an urgent need for biosafety capacity building among policy-makers, regulators, scientists and civil society organizations so that the context, principles and tools for technology assessment and technology choices can be clarified and shared with and among developing countries. Currently, many countries are facing scientific, legal and policy issues in the implementation of the Cartagena Protocol on Biosafety, as well as challenges with assessing applications for research, trials, imports and commercial releases of GMOs.

As such, the Conference focused on building biosafety capacity at both scientific and policy/regulatory levels, for a range of targeted stakeholders. It provided an opportunity for scientists to gather and share their latest research on GMOs and their impacts, as well as a platform to exchange ideas and knowledge on how to deal with the gaps and challenges of biosafety design and implementation.

Part One of this report is the organizers' summary of the proceedings of the Conference. It is structured according to the themes of the Conference: Setting the Stage; Agriculture in Perspective, Agriculture for the Future; GM Innovations and Challenges in Environmental Risk Assessment; and Precautionary Principle as the Basis for Sustainability. Under each theme we explore the background, then summarize the key issues and main recommendations arising from the presentations and discussions. We conclude with some of our reflections. The corresponding abstracts of the presentations discussed under these themes are presented in Part Two.

II. SETTING THE STAGE: MODERN BIOTECHNOLOGY IN CONTEXT

Background

Modern biotechnologies are being developed and used increasingly. Many factors influence these decisions, and many impacts are also experienced as a result of these decisions. As such, it is important to understand the drivers that shape research and innovation, and to scrutinize the policy and regulatory environment that governs these developments, particularly in developing countries where resources and capacities are often low. Understanding this context is essential for sustainable development in developing countries, in order that the right policies, laws and regulatory frameworks are put in place to shape scientific research and development to meet societal needs, and to prevent or minimize any adverse impacts.

There are competing forces that shape scientific research and innovation. The dominant model is economic, largely driven by big companies with profit motives. However, this model has bred growing inequality, depleted the world's resources, and caused many negative social and environmental impacts. Another model is a more balanced sustainable development approach where governments have a critical role to play in balancing competing economic and social goals, and environmental concerns.

Key Issues

In the case of agriculture, the dominant model has led to the use of inputs such as pesticides, synthetic fertilizers and hybrid seeds that allow industrial agriculture to flourish. With the realization that this is reaching its limits, with yields plateauing, loss of biodiversity and decrease in soil fertility, genetic engineering has stepped in with promised solutions. However, there could be further and more serious environmental, health and socio-economic risks.

The emerging view is that in considering agriculture technologies, there is a need to move towards more sustainable forms of agriculture, in particular ecological agriculture, as concluded by the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD).[1] However, the engine to drive this in terms of policy implementation is lacking.

Under the dominant system, commercial companies are driving research and commercialization of modern biotechnologies, aided by the intellectual property (IP) system, which they have shaped. This has led to most of the patents being held by large companies, monopoly profits, and the privatization of research results. This IP system

[1]The IAASTD was a comprehensive assessment of agriculture and was co-sponsored by the World Bank, United Nations Food and Agriculture Organization (FAO), UN Environment Programme (UNEP), UN Development Programme (UNDP), World Health Organization (WHO), UN Educational, Scientific and Cultural Organization (UNESCO) and Global Environment Facility (GEF). Its reports, which drew on the work of over 400 experts, were approved by 58 governments in 2008. IAASTD (2009). *Agriculture at a Crossroads. International Assessment of Agricultural Knowledge, Science and Technology for Development*. Island Press, Washington, DC. http://www.agassessment.org

has spread across the world through the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which has allowed for the patenting of life forms.

The patenting of life forms has implications for research, industry control, health, food security and biodiversity. These implications include increases in the cost of biotechnology research activities, stifling of biotechnology research/downstream research and information, the consolidation of patent ownership over life forms conferring unprecedented economic and market power to a few biotechnology corporations, and adverse impacts on public health because of restrictions on testing and licensing. It also has implications for food security as farmers are prevented from freely exchanging seeds and become licensees of patented products as opposed to owners of their seeds. It affects biodiversity by undermining traditional knowledge and indigenous technologies. There has also been misappropriation of genetic resources located in developing countries, via patenting.

Main Recommendations

- 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 IAASTD recommendations 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 TRIPS Agreement 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.
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- 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.

III. AGRICULTURE IN PERSPECTIVE, AGRICULTURE FOR THE FUTURE

Background

There are many complex and inter-related challenges facing agriculture, such as climate change, biodiversity loss, land degradation, pollution from agricultural chemicals and stagnating yields, which affect whether agriculture can continue to provide food security. Because agriculture is the most important sector in many developing countries and is central to the survival of hundreds of millions of people there, the stakes are higher for developing countries.

Modern biotechnology could potentially provide a tool for increasing productivity in agriculture as well as deliver crops that have enhanced nutritional values, are resistant to different kinds of stresses and can be used as green factories (e.g., to produce pharmaceuticals). However, the introduction of genetically modified (GM) crops for use as food and feed and in industrial use has been very controversial, raising many concerns related to environmental and food safety, implications for small farmers, indigenous peoples, etc.

We need to ask what kind of agricultural system would provide food and nutrition security, meet the needs of farmers and local communities, and safeguard biodiversity and ecosystems, rather than what technology is needed. That is, what are the needs, issues, problems and potential solutions? Asking the right questions would better lead to real options for agriculture that would be more suited to meeting the needs of small farmers in developing countries and contribute to all three dimensions of sustainable development – economic, social and environmental.

Key Issues

Agriculture is at a crossroads and business as usual is not an option. The current model of agricultural production is increasingly acknowledged as inefficient and unsustainable, threatening the resource base of agriculture. On the production side, industrial agriculture, which is highly energy- and input-intensive, has led to environmental, health and social impacts. The contributions of industrial agriculture to climate change are also substantial. Moreover, unless we change consumption patterns, towards more sustainable habits, production patterns will not change either.

The GMOs that are at present introduced in agriculture are an example of linear thinking. A reductionist approach underpins these GM crops and is not likely to advance sustainability and long-term food production. In many countries the main problem for agriculture is abiotic stress such as drought, high temperature, saline soil and/or lack of nutrients. Drought-tolerant crop development especially has been advancing, using traditional breeding approaches, as well as modern biotechnology tools such as marker-assisted breeding and genetic modification. However, serious challenges remain for the use of modern biotechnology in agriculture that need to be addressed, particularly if it is to be applied by small-scale farmers.

A holistic systems approach, such as agroecology, would recognize the

multifunctionality of agriculture and the socio-economic and environmental dimensions of food production. It enables agriculture to work with nature, rather than against it.

There are already many examples of successful ecological agriculture and agroecological practices that provide multiple benefits. These practices are biodiversity-based, are regenerating, promote soil health, reduce reliance on external inputs and make use of natural resources and nature's ecosystem functions, such as ensuring pest-predator balance to enable crop protection. They can be productive, as increasing evidence shows, are more suited to small farmers, and enable both climate adaptation and mitigation.

Farmers have rich traditional knowledge, which is essential capital for sustainable agriculture in the future. The modern tools of science can be used to help build on and improve the field of agroecology.

Main Recommendations

- 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.

IV. GM INNOVATIONS AND CHALLENGES IN ENVIRONMENTAL RISK ASSESSMENT

Background

GM crops have been cultivated in different parts of the globe for just under two decades. Although our knowledge regarding their environmental risks has increased, in particular for the two most prominent traits (herbicide tolerance and insect resistance), we are still facing novel challenges. One problem relates to the sustainability of these traits, in particular regarding the effects that arise after recurrent use of the technology. Cumulative and global risk effects such as insect or weed resistance are now a reality and have shown how, if countries chose to grow GM crops, management strategies need to be applied appropriately and globally.

In future, other challenges for risk assessment and risk management will come not only from novel traits applied to agriculture (abiotic stress, for example), but also from the development of new and emerging applications of modern biotechnology in other fields such as public health and industrial applications, for example, GM vaccines, GM insects and GM microbes. Lessons from our current knowledge can be useful. However, it is inevitable that environmental risk assessment and management related to these upcoming applications will be more challenging, in the face of more scientific uncertainty, complexity, knowledge gaps and issues of omitted research.

Key Issues

Current GM Crops

While some countries have chosen not to grow GM crops, the development of insect resistance to Bt crops is a significant risk for those countries that have. This means that the technology will not be sustainable in the long run, there will be fewer ways to manage insects, and it may ultimately result in increased insecticide use.

Should Bt crops be grown, the scientific consensus is that resistance is inevitable. The goal should therefore be to reduce the evolution of resistance through active management. As a consequence, there are regulatory requirements for resistance management plans.

Bt maize and Bt cotton were designed for US agriculture and cropping systems; resistance management plans include a refuge system. With high-dose events, resistance management has largely worked. However, some low-dose events have failed, as a result of which resistance is increasingly widespread. Some approaches involve the use of novel crops with stacked traits; for example, Bollgard III, which stacks three different toxins, can produce toxins all year round at high concentrations.

Full and global assessment of current insect resistance is, however, difficult because there is a lack of a standardized bioassay for resistance.

The emergence and eventual dominance of secondary pests on Bt crops is another major problem as they can cause significant crop damage and result in increased insecticide use. In the US, the fall armyworm (*Spodoptera frugiperda*) is a key secondary

pest with high potential for resistance development.

In developing countries, the real value of Bt crops needs to be carefully assessed as most Bt crops have been designed to control the major pests in the US and not those of developing countries. The challenges are also likely to be greater as resistance management plans may not be fully implemented or complied with, monitoring may be scarce, and scientific and regulatory capacities are lacking.

Some unique approaches have been taken by certain countries (such as Norway) to include more holistic approaches in their assessment processes, such as the effects on food security, analysis of adjunct technologies (e.g., effects of herbicides used with GM crops), as well as long-term effects on society and the public.

New and Emerging Applications

In the field of GM vaccines, many scientific dogmas, while generally accepted in science, have eventually been demonstrated to not hold true. Another challenge for environmental risk assessment for GM virus vaccines is that the main focus of risk-related research has previously been on the functionality and immunological impacts of GM viruses. On the other hand, work on safety aspects, particularly in relation to ecosystem effects, has been often put off until later in vaccine development. Environmental risk assessment needs to be considered from the very start of a vaccine development project in order to unveil the full spectrum of environmental impacts.

The current thinking on environmental risk assessment for GM insects and GM mosquitoes in particular is insufficient. Models can however provide a pathway and are a starting point. It would be possible to match containment levels to risk categories and community consent, whereby at each stage evidence is collected from the environmental risk assessment to justify progressively lower levels of quarantine. Some of the participants raised the issue of whether there is a need for a moratorium on GM mosquito releases.

Specific guidance for risk assessment of paratransgenesis using GM microbes in insects is currently lacking. Moreover, in this case we are dealing with an application where the mode of action is not very well defined as different applications work to a certain degree but we do not know why they work or how they work.

Main Recommendations

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 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.

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.

V. PRECAUTIONARY PRINCIPLE AS THE BASIS FOR SUSTAINABILITY

Background

Agricultural innovations need to address global food insecurity in ways that are socially, environmentally and economically sustainable. Discussions on modern biotechnology and other technologies however often treat innovation as homogeneous, restricting the scope for debate. Questions over 'Which way?', 'What alternatives?', 'Says who?' and 'Why?' have been missing.

There are branching innovation pathways, i.e., various pathways that could lead to sustainable food futures, for example. As we go down certain decision pathways, other choices will often be closed off. When decisions are made, these can lock in certain technologies, especially when powerful industries come into play and even if they are not the best technologies or if there are better alternatives.

Technology assessment and risk assessment can help avoid the locking-in of inappropriate innovation pathways and improve the sustainability of innovations. Moreover, applying a precautionary mindset contributes to awareness that there are implications of our lack of knowledge and can also help address scientific uncertainties.

Key Issues

The choice of innovation pathways may shape or affect agriculture development and is driven by certain actors and framings. For example, when obtaining patents is framed as an important outcome, it will affect what one can deliver in terms of R&D and those innovations that are not patentable are not pursued. Science is often used as a justification for policy decisions, but the answer from science also depends on the questions asked. Such framing assumptions determine the answers we would get and also involve values. Public participation in these processes is critical.

There are top-down and bottom-up pathways to agricultural innovation. GMOs were cited as an example of top-down innovation characterized by monocultures and input reliance, with centralized R&D that focuses on technology development, not on their implications. Agroecology was cited as an example of a bottom-up approach that emphasizes farmer participation and systems-based solutions.

New and emerging innovations can have far-reaching impacts on the environment, health and society. While technology transfer to developing countries is desirable, there has to be concomitant emphasis on technology assessment, which can help anticipate costly effects, avoid locking-in of inappropriate innovation pathways and improve sustainability of innovations. Technology assessment can lead to better decision-making, stimulation of more innovation via technological diversity and flexibility, and stimulation of better science oriented to society's needs.

While risk assessment has an important role to play, it is equally important to recognize that where there are open dynamic systems, low frequency events, human factors and changing contexts, such uncertainties make it impossible to identify a single

probability, and hence an estimation of the risk. Risk assessment can also exclude conditions of ignorance.

In the law, the incorporation of the precautionary principle is an attempt to recapture some space in terms of allowing for preventive and anticipatory action. It allows States to take action even if there is some level of uncertainty. The application of the precautionary principle in law requires scientific justification. There have to be reasonable grounds for concern and a risk assessment has to be conducted. If the body of available scientific evidence does not allow the performance of an adequate assessment of risks, the precautionary principle can be applied.

The precautionary principle plays an important role especially in cases of uncertainty. Precaution is about understanding the full implications of our lack of knowledge and about broadening our methods, options and perspectives. Such opening up can inform and catalyze a more mature politics of technology.

Main Recommendations

- 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.

VI. 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 Conference 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 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.

Part Two

ABSTRACTS

I. SETTING THE STAGE: MODERN BIOTECHNOLOGY IN CONTEXT

Research and Innovation for Sustainability: Developing Country Needs and Perspectives

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For research and innovation to be relevant to developing countries, these have to meet their needs for food security, poverty alleviation and sustainable development. Too often, research and innovation are dictated by external forces, rather than by national or local needs and priorities, resulting in research that is of little relevance and, consequently, poor innovation adoption in developing countries. Furthermore, the role of intellectual property is an important one. While it is often argued that IP provides the incentives for particular innovation pathways, the reality in many sectors and experiences is that the wrong IP policy and laws become obstacles for development and transfer of innovation. The need for developing countries to draw up IP policies tailored to their countries' needs and level of development is increasingly important as over the years, the policy space for this has narrowed considerably as a result of binding international rules which impose inappropriate high standards for IP protection.

When it comes to innovation research and development relating to modern biotechnologies, these are fast outpacing the biosafety research that is needed to evaluate the safety of genetically modified organisms. For many developing countries, there are particular contexts and concerns. Most developing countries are neither producers nor exporters of GMOs, and are likely to be importers of GMOs. However, many developing countries still lack biosafety laws and regulations, and have little capacity and resources to carry out risk assessment and monitoring. Many developing countries also have high biodiversity and are centres of origin and diversity for many different food crops and resources for medicinal and industrial uses, so the potential impacts of GMOs that are released in their environments could be great. There are also many socio-economic considerations at stake, for example the nature of agriculture in many developing countries, which is dominated by small farmers who traditionally save and exchange seeds. Developing countries also face capacity constraints, in both institutional and financial terms, in evaluating risks and handling negative effects arising from GMOs.

It has thus been important for developing countries that there is a legally binding international instrument on biosafety which includes the principle of prior informed consent and the precautionary principle. The culmination of these discussions is the Cartagena Protocol on Biosafety, which is to date the only international law specifically regulating GMOs. At the heart of the matter, given that there are concerns over the potential impacts of GMOs, whether from health, environmental or socio-economic perspectives, is the need for technology assessment. Developing countries, in particular, need to be able to ensure that any technology does not impact negatively, as the consequences are likely to be greater for them.

Moreover, there are many scientific uncertainties and gaps in knowledge that are

associated with genetic engineering. For many developing countries, therefore, it is critical to their development interests to get their science policies right and in determining the direction of research and innovation. Choices need to be made not just in terms of whether genetic engineering is needed and what alternatives are available that could be supported, but also in terms of the kind of science and, therefore, the type of capacity-building that are important to ensure biosafety.

All this is set against a backdrop where there has been increasing corporate interest driving science, facilitated by inappropriate IP standards, making independent science even more necessary. The reform of IP policies and their transformation for a development agenda is also critical in addressing the incentive structures for research and innovation. Furthermore, science has impacts on society and there is a need for societal control over decisions related to science and its applications.

Implications of Life Form Patents on Technology Development

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Modern biotechnology uses life organisms to create products. Patents are then claimed for these products on the basis that they are inventions. The law and policy has sought to accommodate this new technology by reshaping its traditional precepts. Concerns have been expressed as to the propriety of such accommodation and its implications for the integrity of the intellectual property system; as well as the impact it has on foreclosing research, preventing access to healthcare and breaching the fundamental basis on which patent law is founded. The presentation discusses these implications on the development of technology.

II. AGRICULTURE IN PERSPECTIVE, AGRICULTURE FOR THE FUTURE

Agriculture: Business as Usual Is Not an Option

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The International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) provides a very good framework for this conference, making the point that a transformation of agriculture and the food systems across the globe is needed to address the issues that the world is facing in terms of long-term food security. It is by far not enough to continue with the reductionist approach championed through the green revolution to assure sufficient and nutritious food for the decades ahead. The existential problems that are affecting agriculture are mostly self-inflicted, this not being restricted to the industrial agriculture model, which is strongly dependent on external inputs, but as well the more traditional practices, which often mine the natural resources and are thus not sustainable either. Part of the problem is short-term thinking, profit orientation, and a technology- and consumer-driven approach. The huge wastage of food in the Western world, added to pre-harvest losses, would more than make up the extra food needed by 2050. Today farmers around the world do produce enough food for some 14 billion people, even as, according to the latest count of some, 850 million go hungry. The one billion obese and over 300 million diabetes type II people are further proof that it is the system that is in need of an overhaul. The recognition that consumer behaviour is closely linked to the production patterns is leading to new measures to tackle that end of the system transformation. Change is now becoming a reality thanks to the wording in the Rio+20 declaration, which makes the case for a transformation of the agriculture and food systems, supported by national multi-stakeholder systemic and holistic assessments that will inform new and transformative policies.

Enhancing Plant Defence Through Sustainable Agriculture

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Ecological farming practices once sustained civilizations for centuries. Within a span of 60 years, high-input agriculture and modern industrial farming have resulted in severe soil depletion and in ecological degradation often beyond repair. Driven by the high buildup of toxicity in soils and water bodies which has affected human and animal health, several communities across the world are now recognizing the need for reverting to more holistic organic farming practices.

Our organic spice farm at Mojo Plantation is located in a high-rainfall zone in Kodagu district in the Western Ghats of Southern India. The farm harbours a rich diversity of plants, small mammals, insects, birds and reptiles. The rich biodiversity

seen on our plantation provides a model system for recognizing the impact of balanced pest-predator relationships on maintaining a healthy agri-ecosystem. Organic farming enables a balance between land use and conservation of biological diversity. Research laboratories in different parts of the world are finally beginning to understand the complexity of the biochemistry involved in plant-insect and plant-plant interactions. This paper highlights some of the recent findings in the field of plant defence systems and discusses how a diversity of plants and insects are required to induce the natural defence-related enzymatic pathways of plants.

Challenges for Biotechnology in Agriculture in Sub-Saharan Africa: Insights from Nigeria

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Agricultural biotechnology is a major tool for promoting the productivity a developing country needs to advance more rapidly to meet growing food demand and raise incomes while protecting the environment for future generations. Investing in agricultural biotechnology can be transformative and more effective in reducing poverty for farmers in sub-Saharan Africa, where the agricultural sector employs nearly two-thirds of the population. The World Bank estimates that growth in the agricultural sector is twice as effective at reducing poverty as growth in other sectors. This investment will help the world's poorest people earn their way out of poverty and withstand future shocks from changing global food prices and climate change. This much-needed biotechnology is restricted by local challenges which must be tackled to meet the need to eradicate poverty, which is a priority in Nigeria, as well to strengthen efforts to achieve the Millennium Development Goals (MDGs) by 2015. This paper discusses the challenges including lack of extension services as a bridge between the laboratory and farmers in the field, poor funding of agricultural biotechnology research and development, inadequate human resources/expertise and policy matters. It concludes that for the sustainability of agricultural biotechnology as an effective tool, these challenges need to be addressed as a regional matter with support from international development organizations that provide and fund these technologies.

Developing Drought-Tolerant Transgenic Maize in Sudan

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In many African countries maize yield is often inadequate due to abiotic stress such as drought, high temperature or scarcity of nutrients. The most significant factor affecting maize production is drought. Most of the area in Sudan has been affected by drought; indeed, all famine and hunger situations experienced are due to drought. Traditional plant breeding methods used to achieve drought tolerance are time-consuming and many unwanted traits are transferred along with the desired ones. Besides, they are limited to the existing narrow gene pool within the maize genotypes. Organisms adjust to abiotic stresses through morphological, physiological and biochemical adaptations. The genes that confer tolerance to drought or diseases can be isolated, cloned and introduced into important crops like maize. Such transformed crops are able to perform well under water defect conditions. Work in development of drought-tolerant transgenic maize for Sudan began in 2005 with training of a research scientist from ARC at Kenyatta University. Under this training important inbred lines in the maize breeding programme in Sudan that are amenable to regeneration were identified. Among them the inbred line IL3 was identified as the most regenerable, averaging a regeneration frequency of 75.833. The identified inbred lines were highly responsive to transformation with a vector harbouring the *npk1* gene for conferring drought tolerance. This initial work formed the foundation for further research in development of drought tolerance in Sudanese maize using a safer gene for identification of transformed maize plants (transgenics). The Sudan biosafety bill was signed into law. This paved the way for the country to engage in GMO at the research and commercialization levels. So far Bt cotton is in the pipeline for commercialization, with field experiments being conducted at ARC.

In 2010, the Annexin P35 gene was isolated and cloned. The gene has been engineered into Sudanese maize germplasm. Other drought tolerance genes introduced to Sudanese maize using *Agrobacterium tumefaciens* method are *Annat1* and *NHX1*. Molecular analyses revealed insertion of the drought tolerance genes in the genome of the transgenic plants. Transformation frequency and efficiency was assessed by using mannose as selectable agent. The transformants were regenerated after selection on mannose and will be evaluated under drought in the glass house and field conditions. Drought-tolerant lines generated will be available to the maize breeders to transfer the trait to lines that have high yield but lack this trait.

Food Security and Future Agriculture in China

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China's population was 1.347 billion in 2011 and is projected to reach 1.4 billion and 1.462 billion in 2020 and 2030 respectively. With the growth of population and income as well as changes in dietary structure, indirect consumption of grain such as through meat and eggs has been increasing, further driving up China's grain demand. There is a big challenge for food security in China.

What is the solution? With a large population but limited land, water resource shortage, complex natural conditions, a big ecological deficit, a fragile environment and underdeveloped rural areas, China is not able to follow the US' and Canada's large-scale operation and machinery farming or Japan's and South Korea's high subsidization to maintain high incomes and high prices for small-scale households. Instead, China must explore a suitable path that is in accordance with China's characteristics for the development of agriculture in the country.

Is GM the future of Chinese agriculture? The development of GM plants is considered as a key special solution of China, into which the government will invest billions of dollars. However, some problems already arose with Bt cotton, a major commercialized GM crop in China. Secondary pests attack cotton more and more seriously, such as mirid bug outbreaks in multiple crops correlated with wide-scale adoption of Bt cotton in China. As a result, the commercialization of GM rice has been postponed.

Ecological agriculture may be a real way to meet the food security challenge in China. With 4,000 years of history, Chinese agriculture has accumulated a lot of farming technologies and experience. The 21st century serves as the critical historical point for China's agriculture to go modern and highly efficient. Ecological agriculture shall be combined with the adjustment of agricultural structure, the improvement of agricultural conditions and ecological environment as well as pollution-free agriculture, so as to enhance the development of ecological agriculture.

III. GM INNOVATIONS AND CHALLENGES IN ENVIRONMENTAL RISK ASSESSMENT

Bt Resistance Evolution: Current Status in the United States

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Transgenic maize and cotton expressing *Bacillus thuringiensis* (Bt) toxins were first commercialized in 1996. By 2009, Bt crops were planted on ca. 47.6 Mha in 22 countries worldwide, with the US and Canada accounting for 54% of this area. Resistance (virulence) development in target insect pests is a major threat to the sustainable use of Bt crops. Four major target pests of Bt crops in the US and Canada – European corn borer (Hübner), southwestern corn borer, *Diatraea grandiosella* Dyar (both Lepidoptera: Crambidae), tobacco budworm, *Heliothis virescens* Fabricius (Lepidoptera: Noctuidae), and pink bollworm, *Pectinophora gossypiella* (Saunders) (Lepidoptera: Gelechiidae) – remain susceptible to Bt toxins after 16 years of intensive use of Bt maize and Bt cotton. The success in sustaining susceptibility in these major pests is associated with successful implementation of the 'high-dose/refuge' insecticide resistance management (IRM) strategy: (i) Bt crop cultivars express a 'high dose', (ii) initial frequency of resistance alleles is very low, and (iii) a refuge is maintained nearby in the environment. Field resistance (including control failure) to a Bt crop has been clearly documented in four situations: fall armyworm (*Spodoptera frugiperda* JE Smith) in Puerto Rico, African stem borer [*Busseola fusca* Fuller (Lepidoptera: Noctuidae)] in South Africa, *P. gossypiella* in Gugarat, India, and western corn rootworm [*Diabrotica virgifera virgifera* LeConte (Coleoptera: Chrysolmelidae)] in the US Corn Belt. Factors associated with these cases of field resistance include: failure to use high-dose Bt cultivars and lack of sufficient refuge. These observations support the claim that implementation of the 'high-dose/refuge' IRM strategy has been successful in substantially delaying field resistance to Bt crops. However, successful IRM for 'low-dose' events has proven elusive. Resistance alleles to Cry1F have been detected in *S. frugiperda* in Louisiana and Florida, and field failures have occurred in two regions of Brazil. Resistance in *D. virgifera virgifera* has proven even more vexed. Standardized discriminating dose assays have not been developed, and the regulatory definition of resistance is so problematic that even though resistance has been widely detected, it is still not possible to confirm it using the regulatory definitions.

Insect Resistance and Bt Cotton in Australia

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The longevity of transgenic crops expressing insecticidal proteins from *Bacillus thuringiensis* (Bt) is likely to depend on the rate at which pests evolve resistance to the

toxins. The Australian cotton industry has developed a comprehensive management plan to impede the development of resistance by the major cotton pests *Helicoverpa armigera* and *H. punctigera*. Prior to the widespread deployment of cotton expressing Cry2Ab toxin, 'resistance alleles' were found in both species at frequencies well above mutation rates. More recently, both *Helicoverpa* species have been shown to harbour alleles that confer resistance to Vip3A. This toxin will be included in Monsanto's Bollgard III which is under development but to date has not been grown on more than an experimental scale. Bollgard III will also express two other toxins, Cry1Ac and Cry2Ab, so insects should be exposed to all three toxins simultaneously. As there is no evidence of cross-resistance, and known forms of resistance to both Cry2Ab and Vip3A encountered are recessive, opportunities for selection for resistant phenotypes should be extremely rare. However, in plants of current varieties of Bollgard II cotton expressing both Cry1Ac and Cry2Ab, variability in toxin titre occasionally allows susceptible *Helicoverpa spp*. to survive. Expression variability has also been observed in cotton expressing the single toxin Vip3A. Such variability may allow opportunities for selection of single-toxin resistance even when the three-toxin Bollgard III is grown. From a resistance management perspective, Bollgard III represents a significant improvement over the two-toxin Bollgard II and a vast improvement over single-toxin constructs. Nevertheless, an effective resistance management plan will remain necessary for the three-toxin Bollgard III.

The Impacts of Bt Transgenic Cotton on Secondary Pests in Six Provinces of China

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Bt cotton has been cultivated in China for more than 15 years. Seeking to examine the impacts of multiple years' planting of Bt cotton, field surveys and interviews were conducted in the six provinces of Hubei, Anhui, Jiangsu, Henan, Shandong and Hebei in China. The investigation revealed that the Bt cotton is generally effective against cotton bollworm (*Helicoverpa armigera*) and pink bollworm (*Pectinophora gossypiella*), but, in many places, the Bt cotton has resulted in the outbreak of secondary pests as well as several cotton diseases after 5-8 years' planting. It has plagued cotton farmers as a serious problem. Based on the survey, it is found that the target pests of Bt cotton like cotton bollworm have not developed significant resistance to *Bacillus thuringiensis* because there exist a lot of natural sanctuaries around Bt cotton fields, but some non-target piercing-sucking insects such as cotton aphid (*Aphis gossypii*), mirids (*Hemiptera miridae*) and cotton thrips have become the new dominating cotton pests in recent years. For example, the Bt cotton in Hubei and Anhui provinces in the Yangtze River Valley area is threatened by the cotton leaf worm and the beet armyworm; in Hebei and Shandong provinces in the Yellow River Valley area, the beet armyworm and cotton thrips are the main pests; in Henan Province the whitefly became the main insect 3-5 years ago.

Wild Rice and Lepidopteran Diversity in Vietnam

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Wild rice, *Oryza rufipogon* Griff., is found in and around cultivated rice fields throughout the Mekong Delta of Vietnam. Bt rice may threaten wild arthropod biodiversity if the Bt gene enters and is fixed in *O. rufipogon* populations. Relatively little is known about arthropod biodiversity and community structure in wild rice. Here, we proposed to document the diversity and abundance of non-target Lepidoptera and their natural enemies in wild rice ecosystems, and assess variation in non-target lepidopteran susceptibility to Bt toxins. Although it is challenging to predict the ecological consequences of transgene flow, this study offers empirical evidence and a framework for determining how transgene flow may affect non-target lepidopteran food webs.

We sampled arthropods during wet and dry seasons for two years at three wild rice fields in the Mekong Delta of Vietnam in order to determine lepidopteran diversity in wild rice *O. rufipogon*. All arthropod samples were examined under dissecting microscopes for sorting, counting and taxonomic identification up to species level, when possible. The susceptibility of the four common lepidopteran species against two forms of Bt toxins, Cry1Ac (MVP II) and Cry1Ab (purified), was studied using a leaf section bioassay method.

A total of 1,178 Lepidoptera individuals from 45 unique species and morphospecies belonging to 12 families of order Lepidoptera were collected on wild rice. Of these, 26 species belonging to eight families equalled 90.75% of the lepidopteran individuals; seven of the species were more abundant and well distributed, contributing 86% of total lepidopteran individuals: *Cnaphalocrocis medinalis* Guenée (Lepidoptera: Pyralidae), *Nola taeniata* Snellen (Lepidoptera: Noctuidae), *Orgyia postica* Walker (Lepidoptera: Lymantriidae), *Scirpophaga nivella* Fabricius (Lepidoptera: Pyralidae), *Creatonotis gangis* Linnaeus (Lepidoptera: Arctiidae), *Mocis frugalis* Fabricius (Lepidoptera: Noctuidae), and *Pelopidas mathias* Fabricius (Lepidoptera: Hesperiidae).

Leaf section bioassays with four lepidopteran species, *C. medinalis, M. frugalis, S. novella* and *S. incertulas*, exposed to different concentrations of Cry1Ac (MVP II) and purified Cry1Ab showed these lepidopteran species were highly susceptible to both toxins with different susceptibility levels.

The Cry1Ab and Cry1Ac Bt toxins that are commonly expressed in transgenic Bt rice are widely known to affect many Lepidoptera species. The wild rice, *O. rufipogon,* is widely distributed throughout the Mekong Delta of Vietnam and can naturally interbreed with cultivated rice. Our surveys on *O. rufipogon* wild rice areas of the Mekong Delta indicate that several lepidopteran species frequently occur on *O. rufipogon,* suggesting that outcrossing of Bt genes to *O. rufipogon* wild rice might strongly affect their distribution or abundance.

Our results indicate that arthropod diversity generally appears to be greater in wild systems than in cultivated systems. Some target and non-target lepidopteran species commonly found in wild rice are found to be highly affected by Cry1Ab and Cry1Ac toxins. Of these lepidopteran species, leaf folder *C. medinalis* appears to dominate the food webs and provide good food sources for predators to feed on. This indicates that the diversity of trophic linkages could buffer taxa at higher trophic levels from the loss of *C. medinalis* from the wild rice food web.

Can Herbicide-Resistant GMOs Contribute to Sustainable Development?

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The Norwegian Gene Technology Act states that living genetically modified organisms, in order to be approved for import to Norway or cultivation within Norway, must not be detrimental to health and the environment. Also, considerable weight should be given to whether the use of the GMO contributes to sustainable development, is beneficial to society and is ethically acceptable.

The Norwegian Biotechnology Advisory Board (NBAB) gives advice to the authorities on GMOs. In an ongoing project we aim at further concretizing the sustainability criterion in the Gene Technology Act. We have considered what criteria must be met before the use of herbicide-resistant genetically modified plants can be seen as a contribution to sustainable development, within the areas of environment, economy and society. This includes long-term as well as global impacts. When assessing the sustainability of imports to Norway, impacts in the producing country should also be taken into account.

Among the environmental issues to be considered are gene flow, and impacts on non-target organisms, soil, water, energy and climate. Not only the genetically modified plant itself but also impacts of altered herbicide use should be evaluated. Within the categories of economy and society, we have identified criteria concerning food security, animal health, living conditions and profitability for farmers and for other people in the production area, farmers' rights, duties, health and safety, protection of biodiversity and choice of future agricultural system. Finally, NBAB and the authorities should make an overall evaluation based on the criteria of health, environment, sustainability, ethics and benefit to society.

Detection of Traces of GM Rice with PAT Protein

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Recently there have been claims of introduction of GM rice in West Africa. This study was conducted to assess the presence of GM rice among rice brands in the West African region. Seventeen brands of rice were purchased from markets in three West African countries of Nigeria, Ghana and Sierra Leone. Of the 17 brands purchased, six brands were from the open market in Sierra Leone, three from Ghana and eight from Nigeria. They were tested for traces of Liberty Link rice (event LLRice62 expressing the PAT protein) in 2,000 non-transgenic seeds and Liberty Link rice (event LLRice601 expressing the PAT protein) in 50 non-transgenic seeds using Strategic Diagnostic Inc. Trait LL Bulk rice test kit.

All the rice samples from Sierra Leone were negative, one of the three from Ghana was positive while six out of the eight tested from Nigeria were positive. In all, seven of the 17 rice brands purchased from the open market in the countries were positive with PAT protein.

This indicates that there are genetically modified imported rice brands in West Africa. Since these brands were not labelled as GM, consumers may be unaware that they are GM. This has implications for biosafety and calls for biosafety laws to be put in place and enforced in these three Anglophone West African countries.

Biosafety Research Relevant to Risk Assessment of Poxvirus Vectored Vaccines: An Example with Modified Vaccinia Virus Ankara (MVA)

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Poxvirus vectored vaccines against infectious diseases and cancers are in development and some are already licensed for veterinary applications. Modified vaccinia virus Ankara (MVA) is a highly promising poxvirus vector because of its host restriction *in vitro* and immunogenicity *in vivo*. Using *in vitro* infection models, molecular biology

and proteomic techniques, we have examined the potential risk issues associated with the use of genetically modified poxviruses as vaccines. We have demonstrated that MVA multiplies in some mammalian cell lines and limited production of mature virions occurs in supposedly non-permissive cell lines. We have also shown that naturally occurring orthopoxviruses (OPVs) are common in the Scandinavian ecosystem and hypothesized that these naturally occurring OPVs could form partners for recombination with poxvirus vectored vaccines. We have confirmed the hypothesis *in vitro* by generating recombinants between MVA vectored influenza vaccine and a naturally occurring cowpox virus (CPXV). Some of the recombinant viruses displayed loss of transgene on passage in cell culture and the phenotypic/genotypic stability of the transgenic viruses is dependent on the cell line used for virus propagation. In addition, we have demonstrated recombination in the wild by isolating a naturally occurring CPXV that is a recombinant between CPXV and ectromelia virus. To examine the consequence of genetic modification of the virus vector on a global scale, we profiled cells infected with MVA and MVA vectored influenza vaccine and there was significant difference in the protein profiles of cells infected with the respective viruses. These results are relevant to risk assessment of poxvirus vectored vaccines and the implication of these findings for current laboratory protocols for biological risk assessment of poxvirus vectored vaccines will be discussed.

GM Vaccines and Ethical Challenges in Environmental Risk Assessment

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Genetically engineered or modified viruses (GMVs) are being increasingly used as live vaccine vectors and their applications may have environmental implications that must be taken into account in risk assessment and management processes. In most legislative frameworks GMVs are treated as GMOs, which require environmental risk assessment (ERA) in addition to the evaluation of the quality, safety and efficacy of the product before marketing authorization or clinical trial applications are submitted. The ERA is performed in order to identify the potential risks for public health and the environment that may arise due to the use and release of GMVs.

We will in our presentation discuss the relevance and shortcomings of the present risk assessment framework. For example, there are important distinctions between chemicals and organisms and between viruses and organisms that need to be taken into account. One important challenge for ERA is that the main focus of risk-related research has previously been on the functionality and the intended immunological impacts of GMVs, while work on safety aspects, particularly in relation to ecosystem effects, has often been put off until later in vaccine development.

Traditionally, risk assessment has been considered as a 'scientific' process, while risk management and communication has included value judgments with regard to acceptability, the trade-off criteria and the adaptation of strategies for coping with

uncertainty. However, risk assessments are influenced by scientific, ethical, economic, social and political information. For instance, risk assessments include value judgments with regard to the consequences that should be avoided and to the process of risk characterization. Consequently, risk assessment and management strategies need to be connected from the very start of a vaccine development project in order to unveil the full spectrum of environmental impacts.

Endpoints of any risk assessment and risk management are always connected to the regulative framework. Article 1 of the Cartagena Protocol specifies that the entire objective of the document is to protect and conserve biodiversity according to a precautionary approach. In the EU directive 2001/18/EC, it is stated that the applicant must submit a notification including an environmental risk assessment that considers direct and indirect effects, immediate and delayed effects, as well as potential cumulative and long-term effects due to interaction with other GMOs and the environment.

We will discuss concepts and definitions related to harms and hazards in the context of legislative frameworks, and we will argue that for descriptive as well as for normative purposes biological, ecological and ethical terms are needed for identification of unwanted harm and unwanted ecological consequences. In this context it is important to be aware that the way we approach the environment and the values we put on the environment may also affect the frames and approaches chosen in environmental risk assessment and management.

Finally, we will elaborate on how precautionary motivated research involves the need to advance hypotheses about GMV specific harm and hazard endpoints and that such endpoints are dependent on the objectives of ERA and of the management strategies.

References: Myhr, A.I. and Traavik, T. (2012). Genetically Engineered Virus Vaccine Vectors: Environmental Risk Management Challenges. In: Genetic Engineering*, InTech publishers, ISBN 978-953-307-671-3, and references therein.*

Release of Genetically Engineered Insects: A Framework to Identify Potential Adverse Ecological Effects

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Genetically engineered (GE) insects have the potential to radically change pest management worldwide. With recent approvals of GE insect releases, and the promise of GE technology to combat devastating insect-vectored diseases such as malaria, there is a need for a synthesized framework to evaluate potential adverse ecological effects of these novel tools. We propose that the adverse ecological effects associated with GE insect release may occur in two phases: a transitory phase during which the focal population briefly increases in density and a steady-state phase where the population stays at a constant low density. Within this framework, we review potential adverse effects of organism release stemming from gene flow, changes in ecological relationships, and evolutionary-mediated changes of perturbed natural and released populations of a wide

diversity of organisms. We apply this framework to the *Anopheles gambiae* mosquito – the predominant vector of malaria currently being engineered to suppress the mosquito population – to identify the kinds of adverse effects that may occur during transitory and steady-state phases of its release.

Risk Assessment of Paratransgenesis Applications in Insects – The Challenges Ahead

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The environmental release of genetically modified insects is currently receiving a lot of attention from technology developers, regulators and the general public. However, in parallel another type of biotech application is being developed to suppress or modify certain insect species: paratransgenesis – the use of GM microorganisms (GMMs) to fight insect pests or to reduce the capacity of their arthropod hosts to transmit infectious diseases.

A wide range of arthropod species may be targeted by paratransgenesis: research and development involves various microorganisms associated with insect vectors of human pathogens, e.g., mosquitoes, tsetse flies or kissing bugs. These insects transmit diseases of major importance like malaria and dengue, sleeping sickness and Chagas disease, respectively. Other applications target relevant agricultural insect pests like fruit flies, tephrid flies, locusts and termites or arthropod vectors of plant diseases, e.g., leafhoppers transmitting Pierces crop disease. Further arthropod species are currently screened for the occurrence of viruses or bacterial and fungal symbionts or pathogens that could be genetically modified and used for paratransgenesis. Different paratransgenesis strategies are explored to limit survival or reproduction of the target insects, to decrease the pathogen vectoring capacity of certain insect species, or to increase the efficacy of biological control agents.

In most cases the GMMs used in paratransgenesis would be able to persist and spread in the environment. In applications targeting population replacement, the respective GMMs should become stably associated with whole populations of their arthropod hosts. This is a significant difference to GM insect applications which are currently developed for population suppression of the respective species and thus regarded to be self-limiting.

Most national legislations mandate a risk assessment (RA) to be conducted prior to the release of GMMs into the environment. However, the RA of paratransgenesis applications will be particularly complex and challenging due to a number of reasons, including the following:

1) As indicated, a diverse range of viruses, bacteria and (entomopathic) fungi is used for paratransgenesis. The biological characteristics and interactions of such GMMs with the target arthropods and the environment are very different. However, the current knowledge on some of the (parental) species is limited at best.

2) The degree of association of certain GMMs with their hosts can be very different. For example, intracellular bacterial symbionts, like *Wolbachia*, are very closely associated with the target arthropods and their pattern of vertical transmission would resemble the reproduction of GM insects from the same species. Other microbes are less closely associated and/or less specific for a particular host. Thus horizontal transmission within host populations or even infection of different species may result.
3) The specific ability of GMMs to spread in host populations is different: viruses and pathogens are infectious to different degrees. On the other hand, paratransgenesis applications are designed to take advantage of genetic drive mechanisms which are naturally present in microbes, like *Wolbachia* bacteria.
4) There is only limited knowledge on some of the transgenic traits explored for paratransgenesis.
5) Knowledge is also limited concerning the interactions of the specific GMM x host arthropod combinations with the environment. In this respect the influence of the amounts of released paratransgenic animals or GMMs needs to be considered, mindful of respective knowledge gaps.

Other than comparable applications of non-GM microorganisms, e.g., release of *Wolbachia*-bearing mosquitoes, the release of GMMs for paratransgenesis would certainly be subject to regulation according to existing biosafety frameworks. While this precludes uncertainties as to who shall regulate such applications, specific guidance adequately and comprehensively addressing the RA for paratransgenesis needs to be developed urgently.

In the EU the available guidance for RA of GMMs is primarily concerned with applications of GMMs for food and feed use. While some of the principles of the respective EFSA (European Food Safety Authority) guidance documents will apply for paratransgenesis, the specifics of such applications demand further urgent attention. Clearly some of the issues encountered with ERA of GM insects will also apply for paratransgenesis. However, the recent consultation on draft guidance for ERA of GM insects indicated that most of these issues are far from being resolved.

Recommendations:

1) The existing biosafety frameworks should be reviewed to ensure that a thorough RA for paratransgenesis applications as well as for comparable applications of non-GM microbes is conducted prior to environmental release.
2) This RA needs to take into account the specific characteristics of: (i) the biological agent used for paratransgenesis (virus, bacteria or other microorganisms like fungi), (ii) the incorporated transgenic traits, (iii) the target arthropod species, (iv) the receiving environments which would be intentionally or unintentionally exposed to the paratransgenic arthropods or the used GMMs, and (v) impacts of paratransgenesis applications on other insect management activities, e.g., with

pesticides, applications of GM insects or sterile insect technology as well as approaches to engage residents in pest control.

3) A comprehensive monitoring plan should be designed for paratransgenesis applications to address impacts on the environment and health issues, as well as to monitor efficacy of the application and human and environmental exposure.
4) Guidance for RA and monitoring needs to be developed, ensuring that these complex subjects are addressed adequately and comprehensively, involving multidisciplinary expertise and all relevant stakeholders, including the general public.
5) Similar to certain applications of GM insects, (inter)national public institutions will bear responsibility for the implementation of particular (large-scale) paratransgenesis applications. Conflicts of interests during RA resulting from the involvement of these institutions need to be avoided.
6) Since transboundary movement of paratransgenic arthropods in some cases would be possible or likely, the guidance for RA of paratransgenesis should also be discussed at an international level and harmonized, if necessary. Respective expert working groups established under the Cartagena Protocol on Biosafety or by the Organization for Economic Cooperation and Development (OECD) should further address relevant questions. The OECD working group on harmonization of regulatory oversight in biotechnology recently considered further activities to address paratransgenesis.

The Release of GM Insects: Is Criticism of Regulators for Lack of Transparency Fair?

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Since 2006 genetically modified insects (mosquitoes and moths) have been released into the environment in open field trials in four countries: Malaysia, the United States, the Cayman Islands and Brazil. The regulatory authorities responsible for approving these releases have received some criticism from both sceptics and proponents of the field testing of this transgenic technology. For example, some scientists and members of the public have voiced concern about the extent to which it is possible to assess the scientific quality of regulatory decisions. Equally, some proponents of field testing argue that regulations are unnecessarily onerous and result in excessive delays.

Starting from the assumption that regulators have a self-interest in advertising to their citizens the scientific rigour of their regulatory decisions (this is sometimes a statutory obligation), I will attempt to identify factors that can restrict their capacity to do this effectively. Using examples drawn from the four countries that have permitted open field trials of genetically modified insects, I will attempt to determine how permit applicants facilitated transparent scientific evaluation of reasonable environmental and

human health concerns by regulators prior to granting approval.

The positive role that regulators can play in communicating with the public about complex scientific techniques, without appearing to become advocates for them, will also be briefly considered.

Hidden Pitfalls: How Much Information Does a Biotechnology Regulator Need?

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Regulators, in most cases, act as an intermediate between the developers of technology and the public. However, limited legislative frameworks, lack of available information and minor intricacies of a technology can hinder the task of protecting the public interest and maintaining public confidence. These factors, coupled with poor public confidence, can also hinder regulators as developers and evaluators of valuable new technologies.

Currently, regulators around the world are evaluating new technologies for the control of mosquito-vectored disease. Included amongst these technologies are both genetically modified *Aedes aegypti* and *Wolbachia*-infected *Aedes aegypti*.

Here we examine the breadth of the scientific information required to answer the question 'Can I be bitten by a transgenic insect during experimental releases of genetically modified mosquitoes?'. Using a *Drosophila melanogaster* (fruit fly) sterile insect model, of a tetracycline-based sterilization system, we find that answering this question is deceptively complex and requires the consideration of both environmental and strain-specific data.

The progeny survival rate differed in response to (1) tetracycline concentration, (2) the specific tetracyclines (tetracycline, oxytetracycline, etc.) and (3) genetic background of the fruit fly. This suggests that to determine the answer to the aforementioned question the presence and concentration and type of tetracycline at release sites need to be considered. Moreover, survival rates of the specific stock to be released should be determined.

GM Mosquitoes: Survival in the Presence of Tetracycline

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With over 50 million infections every year, the fight against dengue fever is one of the most important priorities for societies not only in the developing world but also in some regions of the developed world. Strategies range from vector management to early and accurate diagnosis, and while the research on vaccines and viral drugs is under

development, no commercial vaccine is available for the moment. *Aedes aegypti* is the principal, but not only, species of mosquito capable of transmitting the dengue fever virus through bites from the female to humans. A novel technological strategy has been developed around the release of genetically engineered *Ae. aegypti* mosquitoes. This technology is called RIDL – Release with a Dominant Lethal – where the insects carry a genetic regulation that, in the absence of the antibiotic tetracycline, causes death at the larval stage of the offspring. This application aims to reduce the incidence of dengue fever by suppressing the mosquito population.

This work presents novel considerations for risk assessors considering the open field release of these organisms. These considerations are based in the recent review of new scientific findings and information, particularly related to the associated technology of the genetic switch, the antibiotic tetracycline. Survival of transgenic mosquito larvae to adulthood, due to unintended presence of tetracycline in the environment, could limit the technology's potential for effective population suppression, posing unknown risks due to the presence of increased numbers of biting females expressing the transgenic trait. This work proposes to look over unanswered questions and underestimated risk scenarios in the communities where these mosquitoes are more likely to be released.

Tetracycline is one of the major antibiotics used in agriculture and farming, therefore its presence in the receiving environment should be considered a major risk factor. The fate of released GM mosquitoes that are likely to encounter antibiotics-exposed animals and soil/water containing manure from these animals or residues of agricultural practices must be assessed based on the appropriate analysis of the heterogeneity of the receiving environment. It has been well documented that tetracycline is also one of the major antibiotics used for humans, and can be found in the sewage system due to its presence in urine after treatment or consumption of meat treated with tetracycline or from direct disposal of drugs. Based on the growing number of publications showing observational and experimental evidence that sewage-contaminated breeding may be significant, this type of tetracycline-contaminated environment should now be considered by risk assessors of GM mosquitoes.

Malaysian Biosafety Act 2007 and Its Application

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The issue of biosafety arises due to concerns surrounding the development of modern biotechnology, especially technological systems of genetic engineering. The genetic engineering technique is an application that has been used to produce genetically modified organisms. GMO refers to an organism whose natural genetic material has been altered, removed or added by genetic engineering techniques in order to give it characteristics that it does not have naturally. Modern biotechnology can not only produce great social and economic benefits, but can also do harm to the environment and human health and result in many socio-economic problems. One of the major environmental risks is the novel varieties which may replace some of the existing varieties, which

can affect the conservation of biodiversity and genetic diversity. In order to enable biotechnology to contribute major benefits to human beings and at the same time to ensure their security, great attention has been paid to biosafety. Thus, biosafety refers to efforts to reduce and eliminate the potential risks resulting from this technology and its products, focusing on both the environment and human health.

Responding to this issue, Malaysia as a Party to the Cartagena Protocol on Biosafety has enacted its Biosafety Act 2007. A central aim of biosafety legislation is that it would strike a balance between protecting against the adverse effects of GMOs and promoting modern biotechnology. However, the extent to which the Act achieves this balance is yet to be determined.

This research examined the adequacy and the applicability of the Biosafety Act 2007 in balancing the role of protecting the environment from the adverse effects of GMOs and, at the same time, promoting modern biotechnology in Malaysia. Apart from that, this research also seeks to propose recommendations for amending the Act to do enough to protect biological diversity as well as avoiding any hindrances to biotechnology development in Malaysia.

The objective of this research is to create a legal mechanism in order to improve the current legal framework in dealing with GMOs. It is hoped that the findings of this research could assist the industry in guiding them with best practices for themselves and the policy-makers in formulating and implementing the relevant regulations and policies on issues relating to GMOs.

GM Probiotics and Risk Issues

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Intestinal bacteria protect the animal by the anticipation of colonization by pathogens and other unfavourable microbes.

Aim: The main aim of this study was comparative characterization of growth peculiarities of buffalo gut *Lactobacillus* and *Bifidobacterium* isolates after different probiotic treatments.

Methods: We used logistic differential equation of Verhulst for the characterization of growth of *Lactobacillus* and *Bifidobacterium* buffalo fecal isolates after different probiotic treatments. Seventy healthy buffalo were involved in these studies, and at least 10 randomly selected gut isolates from each animal were investigated.

Results: The obtained results show differences in growth parameters of predominant randomly selected gut *Lactobacillus* and *Bifidobacterium* isolates after probiotic treatment and demonstrate a possibility of use of mathematical models for the probiotic recommendations.

According to information from EU nutrition and health claims, due to insufficient

research data the most rejected applications during the last years by the European Food Safety Authority are related to probiotics. The application of genetically modified probiotics in foodstuffs, the progress in nanobiotechnology and the use of transgenic bacteria for environmental bioremediation aims increase the caution against the probiotics' use. Despite this, the market for probiotics continues to rapidly grow in developing countries and there is a need for information exchange and discussion on probiotic production at the international level.

Development of Microorganisms Important in Agriculture, Environment, Medicine and Food Production and Security Through Biotechnology

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Biotechnology, the exploitation of biological components for the production of useful products, has been used in various sectors of a nation's development. The involvement of genetics and molecular biology to develop some microorganisms for use in various sectors in Nigeria is the main focus of this report. Conventional microbiological methods and genetic and molecular biology techniques were used to screen and identify the best oil-degrading microorganisms, and sequence and clone the gene encoding oil degradation in the bacteria. We determined biocontrol of mosquitoes using some microbes with microbiological methods. The cowpea (*Vigna unguiculata* var. 'Oloyin') compatible *Rhizobium* was genetically modified and tested to grow at 60°C. *Saccharomyces cerevisiae* and *Micrococcus luteus* were genetically modified and assayed for protein and glucose production using biochemical method. The antimicrobial property of certain Nigerian plants including peppers and folkloric plants was tested. The structures of some of the bioactive components of these plants were also determined by chemical techniques. In addition, we initiated the use of non-pathogenic microbes in industrial processing of fruits for juice production.

The best oil-degrading microorganisms (*Rhizobium* species CWP G34A and a new bacterium) were identified. The gene encoding oil degradation (Catechol-2,3-dioxygenase) in the bacteria was sequenced and cloned. Pilot experiments using maize and cowpeas with the bacteria in cleaning oil-polluted soil and water bodies are in progress. A *Bacillus* species different from *B. thuringiensis* israelensis was isolated in Nigeria. It was able to kill mosquitoes.

The cowpea is one of the highly consumed protein-rich food crops in Nigeria, but the crop is available only at a high price in the off-season. In order to encourage farmers to cultivate the plant throughout the year, we have genetically modified a compatible *Rhizobium* to fix nitrogen at high temperature (60°C).

Rice grains are generally low in protein content relative to legumes. Rice is widely eaten in Nigeria. Biotechnologically improved strains of *Saccharomyces cerevisiae* and *Micrococcus luteus* individually increased the protein and glucose concentrations of the

rice during fermentation by more than fourfold.

Many natural plants in Nigeria are medicinal. Certain plants including peppers and folkloric plants screened showed good antimicrobial property which could potentially be utilized given the drug resistance of some pathogenic microbes. The structures of some of the bioactive components of these plants have been determined. The genes encoding these bioactives are considered for mass expression through microbes.

We have identified a bacterium for the peeling of fruits for industrial production of fruit juices. The organism showed a good fruit peel degradative potential with high enzymes (pectinases) activities.

The biotechnology works reported here are considered for adoption for Nigerian growth if appropriate biosafety measures are taken.

Handling Omitted Research and Knowledge Gaps in Risk Assessment: How We Interpret and Handle Public Hearings on GMOs

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As a designated National Competence Centre for Biosafety, GenØk provides independent, holistic and useful analysis of technical and scientific information in order to assist Norwegian authorities in the safety evaluation of GMOs and future biotechnologies.

The Norwegian Directorate for Nature Management (DN) is one of five government agencies under the Ministry of the Environment and serves as an executive and advisory body for the Ministry. One of their areas of management is evaluation on GMO legislation in Norway. GenØk provides analysis to DN on GMO applications with relevant questions or topics that we consider are important when assessing applications for marketing of GMOs.

GMO legislation in Norway is closely linked to that of the EU through the Agreement on the European Economic Area (EEA). There are many similarities both regulatory and in practice between Norway and the EU in GMO assessments. However, in addition to the EU regulatory framework for GMO assessment, an impact assessment in Norway follows the Norwegian Gene Technology Act. In accordance with the aim of the Act, production and use of the GMO shall, besides avoiding risks to health and the environment, take place in an ethically and socially justifiable way, under the principle of sustainable development.

Based on a detailed assessment, our evaluation of GMOs and their derived products is focused on:

- Potentially adverse effects on the environment and health
- Other consequences of the proposed release
- Aspects related to social utility and the potential contribution to sustainable development.

In practical terms, this means that some standard issues like molecular characterization (stability of the insert, potential fusions, sequence analysis, etc.),

physiological/agronomic parameters (mainly field trial data), composition [nutritional parameters compared to the (near-)isogenic parent], allergenicity/toxicity (feeding studies, digestibility, etc.), claims of safe use, social utility and contribution to sustainable development are to be considered.

We therefore go through the technical data available to analyze whether the applicant behind the public hearing has covered each area of research in a good scientific way. If there are uncertainties within the technical data or in relevant scientific literature, we acknowledge a precautionary approach and advise that more research is needed to assure the safety by use or introduction of the GMO in question.

For more information and overview of GMO assessments, see http://www.genok.com/reports

IV. PRECAUTIONARY PRINCIPLE AS THE BASIS FOR SUSTAINABILITY

Reconciling Science and Precaution in Biotechnology Regulation

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Worldwide policy debates over biotechnology regulation are pervaded by apparent tensions. Emotive 'public perceptions' are repeatedly portrayed in beleaguered government and business circles to be in conflict with 'sound scientific' realities. In this view, moves towards more 'precautionary' and 'participatory' approaches are feared to open the door to 'irrational anxieties', helping foster an apparently indiscriminate 'anti-technology' climate. The fear is that such trends threaten somehow generally to 'suppress innovation', detract from competitiveness in an apparently one-track global 'race to advance technology' and obstruct crucial Sustainability aims. The widely advocated alternative is 'science-based' decision-making, protecting incumbent patterns and directions for innovation from spurious interference by politics. This talk will argue that each of these understandings is not only mistaken, but intrinsically unscientific. Even more important, they are fundamentally undermining of the progressive values and qualities shared between science and democracy. Nowhere is this dissonance more stark than where policy ostensibly aims at Sustainability.

The argument will begin by examining the ways these tensions are highlighted in high-level biotechnology policy. It will compare these representations with well-established understandings of the real nature of scientific and technological change. Far from being a 'one-track race', research and innovation in any specific area can typically evolve in a radical diversity of directions. And both research and innovation are far wider than science and technology alone, including practices, organizations, institutions, cultures and discourses. This compounds uncertainties and ambiguities over what constitute the 'best' or 'most viable' directions for progress. Yet the realities of constrained resources, market dynamics and institutional power mean that not all feasible or desirable innovation trajectories can – or will or should – be pursued to their full potential. The apparent single tracks highlighted in policy are not given by Nature, but all-too-human artefacts of different kinds of power.

Likewise, conventional high-level policy representations of public understandings of science and technology are also well documented to be persistently deficient. Contrary to expedient caricatures, publics are actually highly discerning between contrasting aims, pathways and contexts for research and innovation. Mischaracterized 'zero tolerance' of risk is actually better understood as an aversion to disingenuous denial of uncertainty, ambiguity and ignorance. There is widespread public appreciation for qualities of independence and scepticism in science. Indeed, public criticism of technology is a means to robust quality control, much like the role of scepticism in science itself.

On this basis, the paper will conclude that there are in fact no necessary tensions between imperatives for rationality, progress, precaution and democracy in biotechnology regulation. Any reasoned understanding of scientific and technological progress must

acknowledge the intrinsic plurality of possible pathways. When we escape from 'science-based', 'one-track', 'race to the future' rhetoric, it follows rationally that questions of scientific and technological progress are pervaded by social values, economic interests and political aspirations. This expands regulatory attention away from polarized questions over 'how safe?', 'yes or no?', 'how much?', 'how fast?' and 'who leads?'. Instead, more searching and explicitly political queries are raised over 'which way?', 'who says?' and 'why?'. As restricted notions of risk regulation thus progress towards more enlightened understandings of innovation governance, we face the prospect of reconciling apparently contending pressures for scientific rigour, technological robustness and democratic legitimacy. There exists a variety of concrete appraisal methods, institutional practices and political procedures that can help practically in realizing this potential. But it is only by understanding the open and plural social dimensions of science, technology and innovation – and the essential synergies between science and democracy – that we can hope truly to realize the full diversity and promise of human ingenuity in the life sciences as in other areas.

Precaution in the Design of International and National Biosafety and Technology Regulations

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This presentation highlights the evolution of the precautionary principle in international law with a special focus on the tough negotiations preceding its inclusion in the Cartagena Protocol on Biosafety. The various facets of this principle are explored to provide a clearer understanding of its fundamental precepts. There is also an examination of the case law in the context of the WTO international trade jurisprudence which demonstrates the role of the precautionary principle when trade clashes with environmental concerns. The presentation highlights the relevance and adaptation of the principles of the Cartagena Protocol to national law-making with regard to biotechnology, and concludes by noting the applicability of the principle in new and emerging technologies, such as synthetic biology and geoengineering.

Science, Policy and Democracy in Argentina: The Case of the National Commission on Agricultural Biotechnology (CONABIA)

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The CONABIA (in Spanish) was created in 1991. This state commission is in charge of the release of GMOs for research, production and commercialization, and creates the national policies that regulate the safety of these organisms, including transgenic seeds.

The commission is composed of experts in biological and agronomical disciplines, and although this public organization has been constituted as a consultative arena, the commission has a strategic role in promoting GMO crops, releasing and regulating these products.

In this paper, we identify the main characteristics of this commission, its composition and the ideas that have been expressed within the regulation, in order to analyze the primary consequences of their activity. This mode of action and its specific view of biotechnologies avoid and restrict public participation, impose one way to see the complex problem of GMOs and ignore the necessity of a social debate with multiple approaches. As a result, policies implemented by the national government are not democratic enough in relation to these topics.

Analyzing interviews and current regulatory frameworks, we will identify notions of 'uncertainty', 'biotechnology', 'risk', 'biosafety', 'expert' and 'democracy'. Then, we will analyze critically the relationship between science and policy, and the particular consequences that this mode to build knowledge has in the contribution towards the construction of a participatory democracy over biotechnology issues.

Technology Assessment for New and Emerging Innovations

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Technologies can play an important role in development. However, new and emerging innovations include powerful technologies such as modern biotechnology, nanotechnology, geoengineering and synthetic biology which could have far-reaching impacts on the environment, health and society.

While developing countries in particular are looking for facilitated access to useful technologies that can contribute to sustainable development, there is a need to ensure that the right technologies are transferred to the right places in the right way. The best way to do so is to subject them to meaningful and holistic technology assessment. Therefore, any emphasis on the positive potentials of new technologies requires a concomitant emphasis on a strengthened global, regional and national capacity to monitor and assess technologies.

At the international level, the need for technology assessment was recognized 20 years ago at the UN Conference on Environment and Development ('Earth Summit') in Rio in 1992. Chapter 34 of Agenda 21 recognizes that technology assessment and the need for capacity building in this area is an important component of the transfer and management of environmentally sound technology. Post-Rio, technology assessment was discussed at the first meeting of the Commission on Sustainable Development (CSD-1) in 1993. It laid the foundations for the principle that technologies have impacts, and these need to be assessed, prior to technology transfer, in terms of their environmental, health, safety and social impacts. The outcomes on technology assessment at CSD-1 were used as a basis for arguing the need for a biosafety protocol and for technology assessment of genetic engineering.

Thus, the Cartagena Protocol on Biosafety, the only international law that

specifically regulates GMOs (or living modified organisms, LMOs, as they are known in the Protocol), is the embodiment of the principles of technology assessment that were envisioned at the CSD. In the Cartagena Protocol, technology assessment for LMOs is operationalized via the risk assessment provisions and an annex providing general guidance on risk assessment. Further guidance on specific aspects has been developed under the Cartagena Protocol with the 'Guidance on Risk Assessment of LMOs'.

Lessons from modern biotechnology and technology assessment thereof can be applied to other new and emerging innovations. At the UN Conference on Sustainable Development ('Rio+20') in June 2012, governments agreed at the highest level to 'recognize the importance of strengthening international, regional and national capacities in research and technology assessment, especially in view of the rapid development and possible deployment of new technologies that may also have unintended negative impacts, in particular on biodiversity and health, or other unforeseen consequences'.

The need to make technology assessment concrete and to take action early enough to prevent harm is never more urgent than now, as the history of development of new and emerging technologies is littered with late lessons from early warnings. If technology assessment is deemed too costly or time-consuming, the cost of *not* assessing technologies is likely even greater. A strong scientific and socio-economic basis is necessary for technology assessment, which would include addressing gaps in scientific knowledge and long-term environmental and health monitoring and research into early warnings. The application of the precautionary principle as the overarching framework is particularly relevant in situations characterized by uncertainty and ignorance. Meaningful and effective public participation, democratic governance of technologies and a multilateral mechanism for information sharing and assessment will greatly contribute to more sustainable innovations, as would an evaluation of a range of alternative options for meeting needs alongside the option under appraisal.

The Cartagena Protocol on Biosafety's Guidance for Risk Assessment

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The Cartagena Protocol on Biosafety is the first international law to specifically regulate modern biotechnology. It recognizes that GMOs may have biodiversity, human health and socio-economic impacts, and that these impacts should be risk-assessed or taken into account when making decisions on GMOs.

Under the Protocol, risk assessments must be carried out in a scientifically sound and transparent manner, and on a case-by-case basis. The Protocol states general principles to be taken into account when conducting a risk assessment. These are: (i) lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk; and (ii) risks of LMOs or products thereof should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving

environment. Individual Parties use these general principles to guide the development and implementation of their own national risk assessment process.

In setting the stage for risk assessment, countries' overarching environmental and public health strategies as well as national and international obligations provide the broad context within which the risk assessment of GMOs is carried out. Protection goals are often relevant for the identification and selection of appropriate assessment endpoints and for determining which methodology will be used in the risk assessment process. After consideration of the protection goals, the risk assessment of a particular LMO proceeds to the scoping phase in order to define the extent and the limits of the risk assessment process. This phase usually consists of at least three main actions: (i) selecting relevant assessment endpoints or representative species on which to assess potential adverse effects; (ii) establishing baseline information; and (iii) when possible, establishing the appropriate comparator(s). Conducting the risk assessment involves synthesizing what is known about the LMO, its intended use and the likely potential receiving environment to establish the likelihood and consequences of potential adverse effects to biodiversity and human health resulting from the introduction of the LMO.

Steps of the risk assessment methodology are described in Annex III to the Protocol. These include identifying potential adverse effects, assessing the likelihood that the adverse effect may occur, and evaluating the magnitude of the consequences should the potential adverse effect occur. These steps describe a structured and integrated process, whereby the results of one step are relevant to subsequent steps. The risk assessment process may also need to be conducted in an iterative manner, where certain steps may be repeated or re-examined to increase or re-evaluate the reliability of the risk assessment.

As uncertainty is inherent in the concept of risk, it is important to consider and analyze, in a systematic manner, the various forms of uncertainty that can arise at each step of the risk assessment process. Ultimately, it is the responsibility of the decision-makers to decide how to take into account the precautionary approach when making a decision on an LMO. Precaution is the basis for the Protocol itself, and is operationalized in risk assessment and decision-making.

Comprehensive Parliamentary Committee Report on Cultivation of GM Crops in India: Prospects and Effects

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Bt cotton was introduced in India in the year 2002 for large-scale cultivation despite strong protests by the farmers' unions and civil society activists against its release. The Genetic Engineering Approval Committee working under the Ministry of Environment and Forests recommended the first GM food crop, Bt brinjal, for field cultivation in October 2009. Once again there was a lot of opposition to its introduction. Finally the government was forced to withdraw its decision and declared a moratorium on

the release of Bt brinjal 'till such time independent scientific studies establish to the satisfaction of both the public and professionals the safety of the product from the point of view of its long-term impact on human health and environment including the rich genetic wealth existing in brinjal in India'. Ten years after the introduction of the first genetically modified crop, Bt cotton, on a commercial scale, the Government of India constituted a high-level 31-member committee under the chairmanship of Sri Basudeb Acharia, Member of Parliament to study Cultivation of GM Food Crops – Prospects and Effects. The committee submitted a comprehensive report to the Ministry of Agriculture (Department of Agriculture and Cooperation) to Parliament on 9 August 2012.

Some of the major recommendations of the committee are as follows. The committee after critically analyzing the evidence placed before them, both for and against the transgenic agricultural crops, have – in view of the compelling concerns regarding India being one of the richest centres of biodiversity; agriculture providing sustenance to almost 70% of the rural populace; more than 70% of India's farmers being small and marginal for whom agriculture is not a commercial venture but a way of life and means of survival; food security and safety; the manpower-intensive nature of agriculture in India; the severe agrarian crisis afflicting the country for years now; 60% of cultivated area still being rained; the irretrievability of GM crops once released in the environment; effects on environment, human, livestock and animal health; the gross inadequacy of the regulatory mechanism, the total absence of post-release surveillance and monitoring, the absence of chronic toxicology studies and long-term environmental impact assessment of GM crops; the virtual non-existent nature of the oversight bodies like National Biodiversity Authority, Protection of Plant Varieties and Farmers' Right Authority, Food Safety and Standards Authority of India, etc. – recommended that till all the concerns voiced in their report are fully addressed and decisive action is taken by the government with utmost promptitude, to put in place all regulatory, monitoring, surveillance and other structures, further research and development on transgenics in agricultural crops should only be done in strict containment and field trials under any garb should be discontinued forthwith.

Hungry for Innovation in a World of Food: Pathways from GM Crops to Agroecology

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The central focus of this presentation deals with the idea of 'innovation', and how the choice of innovation pathways shapes the direction and diversity of options and the distribution of benefits for agricultural development to address global food insecurity and malnutrition in ways that are socially, environmentally and economically sustainable.

We first set out to look at the following: What framings and incentives currently drive innovation and innovation policy? How do we conceive agriculture and its role? What kinds of agricultural innovations support this role?

We contrast two innovation pathways to agriculture that we term 'top-down' and

'bottom-up' approaches and weigh their relative opportunities and costs for agricultural development, particularly to address issues of food security for the world's poor and undernourished.

Top-down innovation tends to centralize research and development and reduces choice, where the focus is to increase economic competitiveness through commodifiable products, which benefits certain actors by granting intellectual property rights to those products. This often shuts down innovation by creating technological lock-ins and path dependence to specific research choices at the expense of others. Further, top-down innovation produces black-box products that are resistant to further innovation either because of their technologic complexity or due to legal restrictions. Innovation here aims at products for those in the wealthiest markets, bypassing innovations for those most in need.

In contrast, the bottom-up approach tends to produce innovations that utilize ecosystem management innovations that fit into the social and cultural practices and context of local farming systems. The main feature of the bottom-up approach is that it decentralizes solution providers and their solutions, thereby facilitating the transfer of products, services or information that allows continued innovation at the hands, skills and knowledge of the local user. By their very distributive and participatory nature, bottom-up innovation strategies do not tend to concentrate power.

The bottom-up approach also may involve the public as a key actor in decisions in the design of food systems, particularly as it relates to food quality, health and environmental sustainability. Here the real innovation potential starts by augmenting existing knowledge of the local system with the aim of addressing problems that are relevant to the local ecological and sociocultural context through experimentation and education. These practices support agrobiodiversity, which contributes to sustained productivity by creating resilience to unpredictable changes at the local level, such as to resource availability or climate, and have been shown to work on a large scale.

Both top-down and bottom-up approaches will have their roles to play, but getting them in the right mix and order is critical to ensure their benefits and risks are more evenly distributed if we are to produce the kinds of innovations capable of achieving the Millennium Development Goals. This will require a radical shift on how we think about and perform innovations in the future, where business as usual is no longer an option.

V. POSTER PRESENTATIONS

Comparison of Different DNA Extraction Methods for Plant Oils Used in Production of Fish Feed

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GenØk–Centre for Biosafety, Tromsø, Norway

The composition of plant oils consists mainly of phospholipids with no or little DNA and may contain genetically modified components. However, DNA-based methods regarding these plant oils are still limited. Therefore the aim of this study was to determine which DNA extraction method is most appropriate for plant oils used in production of fish feed. Four refined plant oils – maize, cold press canola, soy and rape seed – were used for DNA extraction. The DNA extraction consisted of the CTAB method and three commercial kits (NucleoSpin Plant II, NucleoSpin Food and Fast ID). Results showed that the NucleoSpin Plant II kit had the highest yield of DNA compared to the CTAB and two other commercial kits. In conclusion, so far only the NucleoSpin Plant II kit showed high DNA yield and further optimalization of the DNA extraction methods is necessary.

Comparative Proteomic Analysis of MON810 Revealing Differences in Cellular Energy Homeostasis, Redox State and Possible New Allergen Isoform

Sarah Zanon Agapito-Tenfen[1,2], Miguel Pedro Guerra[1], Rubens Onofre Nodari[1] and Odd-Gunnar Wikmark[2]
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Biosafety-related science is demanded by different domestic and international treaties to which nearly the whole world subscribes. Up to now, despite the fact that confidence in the safety and reliability of crop species depends significantly on their genetic integrity, the frequency of transformation-induced mutations and their importance as potential biohazards are poorly understood. In order to assess the risks of genetically modified organisms related to both health and the environment, different challenges have been faced by regulators. Profiling technologies allow the simultaneous measurement and comparison of thousands of plant components without prior knowledge of their identity. The combination of these non-targeted approaches is considered to facilitate a more comprehensive approach than the targeted methods and thus provide additional opportunities to identify unintended effects. In our investigation, 2-D Fluorescence Difference Gel Electrophoresis combined with mass spectrometry was first used as a semi-targeted profiling approach in order to assess protein product differences between MON810 and its non-GM near-isogenic variety in plants grown under farm conditions.

Protein contents of leaf samples from each variety were extracted and analyzed by bidimensional gel electrophoresis using fluorescent dyes. Protein profiles were then compared using specific software and statistically significant expressed spots were analyzed by mass spectrometry. These proteins reveal many isoforms, mainly related to cellular energy homeostasis and reduction-oxidation (redox) state. The majority of these proteins were newly expressed/overexpressed in the GM plant. A newly expressed protein isoform with potential allergenic effect has been also identified. Although the presence of such truncated form is evidence of possible pleotropic effects due to transgene insertion, these should be further investigated in order to determine their biological relevance.

Development and Use of Cotransformation Techniques to Recover Biosafe Drought-Tolerant Maize Plants

J.M. Matheka[1], S. Anami[2], J. Gethi[3], C. Mugoya[4], S. Runo[1], J. Machuka[1] and C. Masiga[4]
[1]Kenyatta University, Kenya
[2]Mombasa Polytechnique University College, Kenya
[3]Kenya Agricultural Research Institute, Kenya
[4]ASARECA, Uganda

Biosafety has become a key requirement for approval of genetically modified organisms by many biosafety regulatory authorities globally. This is because of the potential environmental and health effects posed by genetic elements [such as selectable marker (SM) genes] that accompany genes of interest (GOI) delivered into the modified organism. Removal of such genetic sequences is a challenging objective, with very few GM products reported to be free of these SM genes such as herbicide or antibiotic resistance genes. Part of the problem is because of the difficulty in obtaining marker gene-removal systems as well as in the development of such systems. We explored the hypothesis that it is possible to develop a system of cotransformation vectors that can separate an SM gene from a GOI when used in *A. tumefaciens* mediated transformation of plants. We further hypothesized that the developed system can be as efficient as ordinary binary vector systems when used in maize transformation. Finally we tested the hypothesis that the system will help recover SM-free maize plants possessing a gene for drought tolerance (amiRNA3-PARP1). We have successfully developed and tested a cotransformation technique for routine insertion of drought tolerance genes into maize. The technique is a series of new binary vectors (including pMarkfree5, pMarkfree3.1 and pMarkfree4) possessing two T-DNA, one for the selectable marker (*nptII*) and the other for the bar gene representing the gene of interest. In tobacco, this vector system enabled the generation of tobacco cotransformants at the rate of 66.67%. Six out of 10 cotransformed lines produced progenies that were segregating the *nptII* gene. These lines produced marker-free tobacco progeny plants. In maize, cotransformation vectors transformed maize as efficiently as an ordinary single T-DNA binary vector. Taken together, our results indicate that using a GOI in combination with cotransformation vectors is a workable approach for production of marker-free plants.

Development of Recombinant Vaccine for Rift Valley Fever: Pox Virus Vectored Vaccine

Willis A. Adero, A. Wambugu, M. Mwirigi and R. Soi
Kenya Agricultural Research Institute (KARI)

Rift Valley fever (RVF) virus (RVFV) is a mosquito-borne member of the genus *Phlebovirus*, family *Bunyaviridae*. It is widely distributed in Africa, causing endemic and epidemic disease in both humans and livestock, including sheep, cattle and goats. RVF was first described in Kenya and was shown to be caused by a filterable virus transmissible via blood. Acute RVF in lambs is characterized by fever and death within 24 to 48 hours of being detected. Signs in adult sheep include fever, mucopurulent nasal discharge, haemorrhagic diarrhoea and abortion in pregnant ewes. While attenuated live RVF vaccine is available, documented studies have shown that it causes teratogenic effects in lambs when vaccinated, and the inactivated vaccine requires three doses and is expensive to produce.

Capripoxvirus strain KSI was used for vector construction, the strain of the virus used was the smith burn strain currently used as animal vaccine. The CPV virus was propagated in primary lamb testicle cells passaged 12 or less. RVF was propagated in BHK21 ATCC-10 using RPMI 1640media (CPV) recombinant virus (rKS1/RVFV) was developed, which expressed the Rift Valley fever virus Gn and Gc glycoproteins. These expressed glycoproteins had the correct size and reacted with monoclonal antibodies (MAb) to native glycoproteins. Mice vaccinated with rKS1/RVFV were protected against RVFV challenge. Sheep vaccinated with rKS1/RVFV twice developed neutralizing antibodies and were significantly protected against RVFV and sheep poxvirus challenge. The most important evidence of protection was the absence of viremia following RVFV challenge in rKS1/RVFV-inoculated group 1 sheep compared to the number of viremic sheep in control group 2 ($P < 0.05$), and this was supported by a significant difference between the number of febrile sheep in group 1 compared to that in group 2 ($P < 0.01$). The inoculation of sheep with rKS1/RVFV induced significant protective immunity against challenge with SPV, evidenced by a significant absence of fever and skin lesions compared with the control group which could not be evaluated with the recombinant LSD vaccine. The bivalent protection against both RVFV and SPV challenge in rKS1/RVFV-vaccinated sheep was associated with the presence of SN antibodies, although this was the only potentially protective immune response that was measured. Vaccination of sheep with rKS1/RVFV would avoid the abortigenic complications of live attenuated RVFV vaccines. Furthermore, the RVFV glycoproteins expressed by rKS1/RVFV have the potential to induce protective immunity against most field isolates in Africa. This assumption is based on observations that minimal genetic variance has occurred in the RVFV glycoprotein-encoding region of 22 African isolates collected over a period of 34 years.

Ecological Impacts of Transgenic Crops Released in Tropical Ecosystems: The Andean Countries as a Model

Ivan R. Artunduaga
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New agro-biotechnology products are being pioneered, financed, commercialized, regulated and (strongly) debated mostly in the rich industrial world. Yet it is precisely in the non-industrialized tropical world where a comprehensive analysis of the agricultural promises and environmental risk analysis of these new technologies are scarce and where governments should strongly provide all levels of society with timely, balanced information and technical capacity to analyze implementation.

In contrast, consumers in the industrial world have a higher per capita income, more complete technological information and a relatively wide range of alternative products available, so they can select the product they buy, which is a strong and effective instrument of civilian control over the market.

The Andean region (Bolivia, Colombia, Ecuador, Peru and Venezuela) gave rise among others to potato, peanut, tomato, pumpkin, pepper, cassava, papaya, cocoa and pineapple.

The discussion of opportunities and environmental and health risks and concerns is of particular importance and should be set in the context of a number of distinct characteristics of the region's agricultural sector as well as its science and technology systems and political and economic institutions. However, other factors must be considered in context: poor farmers of the region suffer low average crop yields due to abiotic stress (such as salt or drought) and insect and pathogen pests, so developing plants for very specific resistances and better adapted to such stresses may be a part of the solution.

Implementing Biosafety Principles to Achieve Sustainable Innovation Arising from Modern Biotechnologies in Moldova and CEE/NIS Countries

Angela Lozan
Ministry of Environment Moldova, Biosafety Office

In countries of the CEE/NIS (Central and Eastern Europe and Newly Independent States) sub-region with economies in transition, economic growth and sustainability depend on the strong performance of the agricultural sector. Today the countries successfully develop various classical biotechnologies and their applications in agriculture. Access to modern biotechnology generally is limited due to lack of a rational and predictable biosafety framework that facilitates access to products and plant varieties produced using biotechnology.

The agriculture conditions in the countries involved have many similarities, having

in the past been part of a common USSR agriculture system. The best quality of soils and appropriate climatic conditions are basically good preconditions for efficient agriculture in the sub-region. Land privatization reform conducted by parcellation of the agricultural lands became one of the factors of inefficient agriculture, providing difficulties in applying progressive technologies. Countries, however, have not integrated biotechnology into their agricultural systems. Corn, soybean, sugar beet, potato, tobacco, wheat, grapes, and various fruits and legumes are the main agricultural crops in the region.

The newly independent countries in East Europe and Central Asia such as Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan (11 countries) have similarities mainly in their political developments, agricultural systems and the state of biosafety.

It is worth noting that there have been some successes in the development of national biosafety frameworks during the last period. A general decision-making system in accordance with the Cartagena Protocol principles is in place in many countries in the sub-region. Based on the information available via the Biosafety Clearing House system and national websites, we may conclude the following:

Nine of the countries have nominated their National Biosafety Authority, which in the majority of cases is the governmental body in the field of environmental protection, with only one from healthcare. There are three countries that have established a National Biosafety Commission to conduct advisory work during the decision-making process to the National Authority. From one to three National Focal Points are nominated per country. Five countries have drafted their National Biosafety Framework concept paper, with the assistance of the UNEP/GEF NBF Biosafety projects. Three countries have laws on biosafety approved (Belarus, Republic of Moldova and Ukraine). Azerbaijan has updated the Law on Seeds with provisions on biosafety, and Armenia has drafted the Law on Living Modified Organisms.

At present, no decision for authorization of LMO imports, deliberate release into the environment or food, feed or processing (FFP) use of LMOs has been informed by the countries. Belarus has notified several field trials for transgenic plants, specifically sugar beet Edda variety, virus-resistant GM potato variety, tobacco, linen and alfalfa, by several national academic institutions.

However, the differences in biosafety regulations and institutional systems, which vary from country to country, insufficient capacities for informed decision-making on LMOs, limited abilities for scientific risk assessment and risk management, generally inefficient customs controls and monitoring services due to the lack of experience with LMOs, as well as poor awareness and understanding by the public provide general limitation for biotechnologies and uncertainty in decision-making.

Following the decision of the recent Meeting of the Parties to the Cartagena Protocol on Biosafety (in Hyderabad) that recommends Parties to provide the testing of the Roadmap on Risk Assessment of LMOs, a sub-regional approach and collaboration in risk assessment and risk management, laboratory detection of LMOs and information exchange in the CEE/NIS countries are important issues to be addressed.

Legal Constraints on Field Trials of GM Crops in Thailand

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Although the biosafety guideline for field work and genetically modified organisms was approved in June 1992, there was no enforcement regulation on the import and field trials of GM crops prior to June 1994 in Thailand. As a result, the field trial of Flavr Savr tomato was conducted in 1993. From June 1994 to October 2003, imports of 40 and 49 known GM crops were prohibited except for research by the Department of Agriculture. Small- and large-scale field trials were then allowed until 3 April 2001 when GM crop field trials were banned pending an enactment of the biosafety law. However, imports of GMOs for food, feed or processing, derived from these GM crops, especially soybean and corn, were allowed but labelling was made mandatory by the Food and Drug Administration in March 2000. The April 2001 ban was partially lifted in December 2007 such that the field trials would be allowed when conducted within government premises. The proposals to carry out field trials of GM papaya and tomato that are developed domestically and imported GM corn are currently in the preparation process. Ironically, it is to be noted also that GM cotton is now unofficially cultivated and GM papaya has been detected in several locations in the country.

Molecular Diagnostics for Risk Assessment and Management of Genetically Modified Organisms

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As acreage of GM crops grows, the likelihood that transgenes will find their way into non-GM crops also emerges very fast. GM material finds its way into non-GM material in different ways. This raises the question of how growers of GM and non-GM crops can peacefully coexist. Many countries have already made rules on acceptable threshold levels on the adventitious presence of GM material and have then developed protocols to achieve these levels. In this context several major issues will need to be resolved and one of them is to detect the presence of unauthorized GMOs. The presence of unauthorized GMOs is by definition illegal. This requires detection of a GMO or a derivative of a GMO, which can be done by detecting a molecule (DNA, RNA or protein) that is specifically associated with or derived from the genetic modification of interest. The majority of the methods hitherto developed for detection of GMOs and GMO derivatives focus on detecting DNA, while only a few methods have been developed for detecting proteins or RNA. Different methods and their advantages and disadvantages will be discussed here. As the number of GMOs on the global market has increased rapidly,

the ability to perform comprehensive GMO testing has been challenged, because identification (and possibly quantification) for each individual GMO will require the use of a large number of detection methods for each sample. International collaboration to facilitate information and material exchange and to harmonize analytical approaches and traceability could have great positive impacts on the ability to cope with some of the major challenges.

Rapid Detection of Contagious Bovine Pleuropneumonia by a *Mycoplasma capricolum* subsp. *capripneumoniae* Capsular Polysaccharide-Specific Antigen Detection. Latex Agglutination Test

Willis A. Adero, A. Wambugu, M. Mwirigi and R. Soi
Kenya Agricultural Research Institute (KARI)

Mycoplasma capricolum subspecies *capripneumoniae* is the causative agent of contagious caprine pleuropneumonia (CCPP), a significant disease of goats in Africa, the Middle East and western Asia, with mortality rates being up to 80% in susceptible herds. While clinical disease has so far been reported in 38 countries, only 11 countries have isolated the causative organism, principally because *M. capricolum* subsp. *capripneumoniae* is difficult to culture. A number of serological tests currently exist, but most are difficult to use *in situ*, lack specificity or require resources unavailable in many countries affected by the disease. These include the complement fixation test (CFT); the prescribed test for international trade, passive hemagglutination and competitive enzyme-linked immunosorbent assay (ELISA). However, all these tests exhibit certain limitations in specificity, sensitivity, ease of application, cost, or the requirement for specialist equipment and expertise. A latex agglutination test (LAT) was developed for the diagnosis of CCPP. The latex microspheres were coated with anti-*Mycoplasma capricolum* subsp. *capripneumoniae* polyclonal immunoglobulin G (IgG) antiserum (anti-F38 biotype). The coated microspheres were then used in a LAT, and the test detected *M. capricolum* subsp. *capripneumoniae* antigen in the serum of goats with CCPP. Coated sensitive beads also agglutinated strongly in the presence of purified *M. capricolum* subsp. *capripneumoniae* capsular polysaccharide (CPS). Pre-absorption of CPS-specific antibodies prior to coating of the beads removed agglutinating activity in the presence of *M. capricolum* subsp. *capripneumoniae*, strongly suggesting that CPS is the likely soluble antigen recognized by the test. In addition, the specificity of the LAT exactly mirrored that of an *M. capricolum* subsp. *capripneumoniae* CPS-specific monoclonal antibody (WM25): of the eight other mycoplasma species tested, agglutination was observed only with bovine serogroup. The LAT detected all 11 strains of *M. capricolum* subsp. *capripneumoniae* examined in this study, with a sensitivity level of 2 ng of CPS, or the equivalent of 1.7×10^4 CFU, in a reaction volume of 0.03 ml of serum. With field sera from goats with CCPP, the results of the LAT exhibited a 67% correlation with the results of the currently used complement fixation test, with the main discrepancy in diagnosis resulting from the increased sensitivity of the LAT compared

to that of CFT. This antigen detection proved particularly useful in identifying animals in the earliest stages of infection and combines sensitivity and low cost with ease of application in the field, without the need for any specialist training or equipment.

Scrutinizing the Safety Assessment of the Brazilian Genetically Modified Bean EMBRAPA 5.1

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Just before the 20th anniversary of the Rio Declaration, Brazil approved its first homemade transgenic food crop amid an intense scientific debate and legal battle. The GM common bean (*Phaseolus vulgaris*) from the Brazilian Agricultural Research Corporation (EMBRAPA) has been genetically modified through introduction of the anti-sense viral replication gene to silence the expression of the Bean Golden Mosaic Virus replication gene by RNA interference. However, not much about this GM event is known. In the risk analysis dossier provided by EMBRAPA to the regulator, the National Technical Biosafety Commission (CTNBio), sweeping commercial-in-confidence protection has been granted to genetic information on the insert. The handling of confidential business information (CBI) in the Brazilian biosafety framework is controversial. While operating in blatant disregard of its own rules, CTNBio was ordered by the court to rewrite its CBI policies, currently under appeal (Normative 373/ June 2011). Remarkably, 15 of CTNBio's own 22-strong decision-making committee posted an online petition (http://www.petitiononline.com/dy8lhUaz/petition.html) to the Presidency and other authorities in support of the GM common bean approval, drawing rebuke from the Public Prosecutor's Office. The National Food and Nutritional Security Council officially expressed concern to the Presidency over human safety, finding deficits in feeding and gene flow studies. Despite these credible grounds for concern and within the CBI framework under legal dispute, the GM common bean has been approved for cultivation and human consumption. Transparency is essential both to good science and to good governance, something reflected in the Rio Declaration, in the Convention on Biological Diversity and the Cartagena Protocol on Biosafety that followed in its footsteps. Biotechnology may indeed have much to offer Brazil, but today, 20 years on from Rio, it seems the same battle must be fought yet again.

Part Three

ANNEXES

ANNEX 1: CONFERENCE PROGRAMME

Wednesday, 7 November 2012

08.30-09.00	Registration
09.00-09.30	CONFERENCE OPENING **S.M. Mohd. Idris**, Third World Network & **Anne Myhr**, GenØk

THEME: SETTING THE STAGE

Moderator:	*Lim Li Lin*
09.30-10.10	KEYNOTE **Martin Khor**: Research and innovation for sustainability – Developing country needs and perspectives
10.10-10.50	KEYNOTE **Gurdial Singh Nijar**: Implications of life form patents on technology development
10.50-11.20	Coffee/Tea
11.20-11.50	Plenary discussion
11.50-12.30	*POSTER SESSION I*
12.30-14.00	Lunch

THEME: AGRICULTURE IN PERSPECTIVE, AGRICULTURE FOR THE FUTURE

Moderator:	*Lim Li Ching*
14.00-14.40	KEYNOTE **Hans Herren**: Agriculture – Business as usual is not an option
14.40-15.00	**Sujata Lakhani**: Enhancing plant defence through sustainable agriculture
15.00-15.20	**Afusat T. Jagun**: Challenges for biotechnology in agriculture in Sub-Saharan Africa – Insights from Nigeria
15.20-15.50	Coffee/Tea
15.50-16.10	**Rasha Adam Omer**: Developing drought-tolerant transgenic maize in Sudan
16.10-16.30	**Xue Dayuan**: Food security and future agriculture in China
16.30-17.15	Plenary discussion
19.30	CONFERENCE DINNER

Thursday, 8 November 2012

THEME: GM INNOVATIONS AND CHALLENGES IN ENVIRONMENTAL RISK ASSESSMENT

Moderator:	*Camilo Rodriguez-Beltrán*
09.00-09.40	KEYNOTE **David Andow:** Bt resistance evolution – Current status in the United States
09.40-10.20	KEYNOTE **Rod Mahon**: Resistance management for Bt cotton in Australia
10.20-10.50	Coffee/Tea
10.50-11.10	**Chen Chen:** The impacts of Bt transgenic cotton on secondary pests in six provinces of China
11.10-11.30	**Ngo Luc Cuong**: Wild rice and lepidopteran diversity in Vietnam
11.30-12.15	Plenary discussion
12.15-13.00	*POSTER SESSION II*
13.00-14.30	Lunch
Moderator:	*Idun Grønsberg*
14.30-14.50	**Audrun Utskarpen:** Can herbicide-resistant GMOs contribute to sustainable development?
14.50-15.10	**Joshua O. Odewale:** Detection of traces of GM rice with PAT protein
15.10-15.40	Coffee/Tea
15.40-16.20	KEYNOTE **Malachy Okeke:** Biosafety research relevant to risk assessment of poxvirus vectored vaccines: an example with modified vaccinia virus Ankara (MVA)
16.20-16.40	**Anne Myhr:** GM vaccines and ethical challenges in environmental risk assessment
16.40-17.20	KEYNOTE **Ørjan Olsvik:** Bioeconomy terrorism
17.20-18.00	Plenary discussion

THEME: GM INNOVATIONS AND CHALLENGES IN ENVIRONMENTAL RISK ASSESSMENT (continued)

Moderator:	*Hans Herren*
09.00-09.40	KEYNOTE **David Andow:** Release of genetically engineered insects – A framework to identify potential adverse ecological effects
09.40-10.20	KEYNOTE **Michael Eckerstorfer:** Risk assessment of paratransgenesis in GM insects – The challenges ahead
10.20-10.40	**Guy Reeves:** The release of GM insects – Is criticism of regulators for lack of transparency fair?
10.40-11.10	Coffee/Tea
11.10-11.30	**Jai Denton:** Hidden pitfalls – How much information does a biotechnology regulator need?
11.30-11.50	**Camilo Rodriguez-Beltrán:** GM mosquitoes – Survival in the presence of tetracycline
11.50-12.10	**Siti Hafsyah Idris:** Malaysian Biosafety Act 2007 and its application
12.10-12.45	Plenary discussion
12.45-14.45	Lunch
14.45-15.30	*POSTER SESSION III*
Moderator:	*Malachy Okeke*
15.30-15.50	**Astghik Pepoyan:** GM probiotics and risk issues
15.50-16.10	**Bolatito Boboye:** Development of microorganisms important in agriculture, environment, medicine and food production and security through biotechnology
16.10-16.40	Coffee/Tea
16.40-17.20	KEYNOTE **Idun Grønsberg:** Handling omitted research and knowledge gaps in risk assessment
17.20-18.00	Plenary discussion

Saturday, 10 November 2012

THEME: PRECAUTIONARY PRINCIPLE AS THE BASIS FOR SUSTAINABILITY

Moderator:	*Anne Myhr*
09.00-09.40	KEYNOTE **Andy Stirling:** Reconciling science and precaution in biotechnology regulation
09.40-10.20	KEYNOTE **Gurdial Singh Nijar:** Precaution in the design of international and national biosafety and technology regulations
10.20-10.40	**Carla Poth:** Science, policy and democracy in Argentina – The case of the National Commission on Agricultural Biotechnology (CONABIA)
10.40-11.10	Coffee/Tea
11.10-11.50	KEYNOTE **Lim Li Ching:** Technology assessment for new and emerging innovations
11.50-12.10	**Ossama A. El-Kawy:** The Cartagena Protocol on Biosafety's guidance for risk assessment
12.10-12.30	Plenary discussion
12.30-14.00	Lunch
Moderator:	*Lim Li Ching*
14.00-14.20	**B.N. Reddy:** Comprehensive recommendations of Parliament Standing Committee report on cultivation of GM crops in India – Challenges and risks
14.20-15.00	KEYNOTE **Anne Myhr:** Hungry for innovation in a world of food – Pathways from GM crops to agroecology
15.00-16.30	Plenary discussion with invited panel: Way forward for implementing sustainable innovation and regulatory needs
16.30-16.45	Conference closure
16.45	Coffee/Tea

ANNEX 2: LIST OF SPEAKERS

Martin Khor, formerly Director of the Third World Network, is Executive Director of the South Centre, an intergovernmental body with 50 member states from the developing world. He was educated as an economist in the University of Cambridge (United Kingdom) and Universiti Sains Malaysia. He is the author of several books and papers on issues relating to trade and development, environment and sustainable development.

Gurdial Singh Nijar is Director of the Centre of Excellence for Biodiversity Law (Faculty of Law, University of Malaya, Malaysia). He has been actively involved in the processes of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity as one of the lead negotiators of developing countries.

Hans Rudolf Herren's (M.Sc. Agronomy, Ph.D. Biological Control from the ETH-Zurich, postdoc UC-Berkeley) main interests and experience are in agriculture and food, and ecologically, socially and economically sustainable development. He has hands-on experience in research, capacity development and management of international research organizations [the International Institute of Tropical Agriculture in Nigeria and Benin, where he was the Director of the Africa Center for Biological Control and Head of the Plant Health Division (1979 to 1994); and the International Center of Insect Physiology and Ecology in Nairobi, Kenya, where he was Director General (1994-2005)]. He is presently President of the Millennium Institute in Washington, working at the policy level to ensure that knowledge, science and technology do contribute effectively to sustainable and equitable development as well as to peace and security. He is also the founder and President of the Biovision Foundation for ecological development, based in Zurich. He is Co-Chair of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), member NAS and TWAS, laureate World Food Prize 1995, Kilby Award 1995, Brandenberger Prize 2003, Tyler Prize (2003), among others.

Sujata Lakhani is a plant biochemist and research scientist turned organic farmer. She was formerly working with the International Centre for Genetic Engineering and Biotechnology (ICGEB) in New Delhi, India. Together with her husband Anurag Goel, she now runs an ecological farm in the rainforests of the Western Ghats in South India.

Afusat T. Jagun holds a Doctor of Veterinary Medicine degree and a Masters of Veterinary Science in Veterinary Pathology, and is a Ph.D. candidate in Veterinary Pathology. She is currently a junior faculty member at the University of Ibadan in Nigeria. Her current research interest is on the impact of environmental toxicity on organ pathologies in animals (investigating gene toxicity).

Rasha Adam Omer Abdalla is a scientist from the Biosafety and Biotechnology Research Centre at the Agricultural Research Corporation of Sudan. She obtained her B.Sc. (Honours) in Agricultural Biotechnology from the University of Khartoum, and her M.Sc. in genetic engineering of maize from Kenyatta University, Kenya. She is the first scientist to transform Sudanese maize and has been focusing on genetic engineering of maize for drought tolerance.

Xue Dayuan is a Professor at the College of Life and Environmental Science, Minzu University of China, in Beijing, and Chief Scientist on Biodiversity at the Nanjing Institute of Environmental Science, Ministry of Environmental Protection of China. For many years, he has been focusing on research on biodiversity conservation, especially on biosafety for genetically modified organisms and benefit sharing of genetic resources and associated traditional knowledge. As a representative assigned by the Chinese government, he has been involved in negotiations of the Convention on Biological Diversity, Cartagena Protocol on Biosafety and Nagoya Protocol on

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization.

David Andow is Distinguished McKnight University Professor of Insect Ecology at the University of Minnesota. He has been working on environmental risks associated with GMOs since the early 1980s and has consulted with FAO, WHO, WTO, NAFTA-CEC, US-NAS, USDA, US-EPA and many other international and national organizations. His broader interests coalesce around sustainability issues, where he is studying ecological pest control and human interactions with invasive species.

Rod Mahon is an honorary fellow, CSIRO Ecosystem Sciences. As an entomologist he has worked in various parts of the world (including six years in Johor, Malaysia) on malaria vectors and myiases flies. His present interests and research concern the evolution of resistance to Bt toxins by pests of cotton.

Chen Chen is a Masters student at Minzu University of China. Her area of research is Bt cotton in China, focusing on the impacts on secondary pests and the economic benefits.

Ngo Luc Cuong is Principal Researcher, Head of Entomology Department at Cuu Long Delta Rice Research Institute (CLRRI), Vietnam. He was a Post-Doctoral Fellow (Biosafety) at the United Nations University/Institute of Advanced Studies (UNU/IAS) in Tokyo, Japan, from 2002 to 2003. He has a Ph.D. (Entomology) from IRRI-University of the Philippines Los Banos, Philippines (1997-2001); M.Sc. (Entomology) from Govind Ballabh Pant University of Agriculture & Technology, Pantnagar, UP, India (1991-93); and B.Sc. from University of Agriculture No. 4, Ho Chi Minh City, Vietnam (1976-81). His research interests are in integrated pest management of rice insect pests, host plant resistance, resistance management, risk assessments of GMOs, and biodiversity.

Audrun Utskarpen works as a senior advisor at the Norwegian Biotechnology Advisory Board that gives advice on ethical and sustainable use of biotechnology. She holds a Ph.D. in molecular biology and has previously worked in cancer research and molecular plant biology.

Joshua O. Odewale is a Nigerian born on 22 August 1952. He has a B.Sc. (Hons.) Genetics (1975), M.Sc. Genetics (1979), Ph.D. Genetics & Tissue Culture (Jan. 1984), all from the University of Ife (now Obafemi Awolowo University), Ile-Ife, Osun State, Nigeria. He is Assistant Director (Research) Breeding and Biotechnology of Palms at the Nigerian Institute for Oil Palm Research (NIFOR) (1976-present).

Malachy Okeke is a scientist at GenØk–Centre for Biosafety in Tromsø, Norway. He received a First Class Honours degree in Microbiology from the University of Nigeria, Nsukka and was the University of Nigeria valedictorian for the 1992 graduating class. He received his Ph.D. from the University of Tromsø, Norway in 2007, where he characterized recombinant viruses obtained from recombination *in vitro* between a poxvirus vectored vaccine and naturally occurring orthopoxviruses. He did his postdoctoral work (2008-10) in the laboratory of Professor Terje Traavik at GenØk mapping naturally occurring recombinant and non-recombinant orthopoxviruses. Presently he is the project coordinator of the Poxvirus Research Group at GenØk and an advisor to relevant government agencies on the biosafety of genetically modified virus vaccines and virus vectored gene therapies. His current research interests focus on the molecular/cellular basis of host restriction of poxvirus vectors, virus-virus interaction between transgenic and naturally occurring orthopoxviruses, virus-host interaction between transgenic or naturally occurring orthopoxviruses and their mammalian host or cells, and exploring the biosafety implications of these interactions with respect to the environment and human and animal health.

Anne Ingeborg Myhr is the Acting Director of GenØk–Centre for Biosafety in Tromsø, Norway. She holds a Master's degree in Biotechnology from NTNU, Trondheim, and a Ph.D. from the University of Tromsø. Her present research involves the use of emergent technologies, such as GMOs and nanobiotechnology, and capacity building in risk assessment and management of GMO use and release in developing countries. She has been a member of the Norwegian Scientific Committee for Food Safety (VKM) and has internationally been involved in various issues related to GMOs including socio-economic impacts under the Cartagena Protocol on Biosafety.

Ørjan Olsvik has 10 years of service in the US government at the Centers for Disease Control in Atlanta, including studies at Stanford, California. His specialization is outbreak epidemiology and antibiotic resistance. In 1990, he was appointed Professor in Veterinary Medicine, and in 1995 Professor in Medical and Clinical Microbiology. He co-founded GenØk with Professor Terje Traavik in 1998, and served as Chairman of the Board for the first five years. He was formerly Acting Director of GenØk. He has a special interest in Africa and has worked in most countries of this continent. He has served as an expert for the World Bank, World Health Organization and several other international organizations.

Michael Eckerstorfer holds a Ph.D. in molecular genetics from the University of Vienna and works as a Scientific Officer in the department of Landuse & Biosafety at Environment Agency Austria (Umweltbundesamt). His work focuses on issues relevant for risk management of GMOs released to the environment, specifically environmental risk assessment (ERA) and monitoring. In 2010 he coordinated an EU project assessing the information base for ERA of GM insects. He is a member of the Austrian Gentechnikkommission (National Advisory Body on Genetic Engineering) and head of the Austrian delegation to the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology.

Guy Reeves is an evolutionary biologist who did his Ph.D. at the Smithsonian in Panama on evolution of Central American fish. He remains interested in evolution, but in recent years has become interested in exploring the possibility of using GM insects to reduce the reliance of insect control on pesticides. He currently works at the Max Planck Institute for Evolutionary Biology in Germany.

Jai Denton has a Ph.D. in genetics (fungal biotechnology) from the University of Adelaide and is currently working as a post-doctoral researcher at the Max Planck Institute for Evolutionary Biology. His current research relates to the development and evaluation of methods for vector control. He has a strong interest in the application of biology to solve real world problems but is also interested in the ethical and legal issues that surround such applications of these new technologies.

Camilo Rodriguez-Beltrán is a researcher and head of applied innovation at the Engineering Department of the Universidad del Desarrollo, Chile. He is also a biosafety consultant and member of the Centre for Integrated Research in Biosafety (INBI), University of Canterbury, New Zealand.

Siti Hafsyah Idris is a Ph.D. Researcher at the Faculty of Law, Universiti Teknologi MARA, Malaysia. Her research areas are in Environmental Law, Biosafety Law, and Bioethics (Human Rights).

Astghik Pepoyan is the Principal Scientist and Head of the Food Safety and Biotechnology Department, Armenian National Agrarian University. She is also President of the International Association for Human and Animals Health Improvement and a Board Member at Science and Technology in the Prevention of Biological Threats Targeted Initiative, International Science

and Technology Centre (ISTC). She has a Ph.D. in Molecular Biology and Genetics (Candidate of Sciences) (1990) and an M.Sc. in Biophysics (1987). Her main field is microbiology, and her other fields of interest are biotechnology and food safety.

Bolatito Boboye (Professorial cadre) is a lecturer in microbial genetics in the Department of Microbiology at the Federal University of Technology, Akure, Ondo State, Nigeria. She has done research on some microorganisms with the application of genetics for use in Nigerian agriculture, environment, medicine and food production.

Idun Grønsberg is currently working as a scientist at GenØk–Centre for Biosafety in Tromsø, Norway. She was previously the laboratory manager of GenØk (2003-04, 2006-10). She holds a Ph.D. from the University of Tromsø (UIT, 1997-2001) working with colon carcinoma cells and differentiation. She worked at the Paediatric Department, UIT (2001-03) analyzing TRAIL induced apoptosis in neuroblastoma and osteosarcoma cell lines. Her work at GenØk has been centred on uptake (and mechanisms of uptake) of foreign DNA in cells and tissues during feeding experiments and cell culture experiments and analysis of potential antibody reaction specific proteins in animal sera.

Andy Stirling is Research Director at the Science Policy Research Unit at the University of Sussex. With a background in natural science and the environment and peace movements, he is an interdisciplinary social scientist who has also served on many policy advisory committees.

Carla Poth is a Researcher at the Programme of Agrarian and Globalization Studies at the National University of General Sarmiento, Argentina. She is writing her doctoral thesis about institutions and regulation frames of the agrarian model in Argentina. She is part of a political movement called the Environmental Assemblies Union.

Lim Li Ching has a B.Sc. in Ecology and an M.Phil. in Development Studies. She works with the Third World Network and helps coordinate its biosafety and sustainable agriculture work. She has been actively participating at the UN Cartagena Protocol on Biosafety negotiations, its related experts' meetings and other international, regional and national biosafety meetings. She was a lead author in the East and South Asia and the Pacific (ESAP) sub-global report of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD).

Ossama A. El-Kawy (Ph.D.) is Senior Scientist, Atomic Energy Commission, Egypt and Regional Advisor on Cartagena Protocol, Division of Environmental Law and Conventions, United Nations Environment Programme. He is an interdisciplinary researcher and lecturer with a background in microbiology and biosafety. He has represented Egypt and the scientific profession at numerous international forums and meetings. He also serves as an expert advisor in international capacity-building projects related to biosafety (e.g., in the framework of the Cartagena Protocol on Biosafety, UNEP GEF).

B.N. Reddy has been teaching and carrying out research at Osmania University, Hyderabad, India for the last 30 years. He has published 60 and presented 50 research papers in national and international journals and conferences respectively in India and abroad. He has guided 10 students for the award of Ph.D. degrees. He has organized 15 conferences/seminars and is a Member of the Roster Committee of the UN Food and Agriculture Organization (FAO). He is a recipient of the Government of India's highest award for science and technology communication, and has interacted with 10 Nobel laureates and visited 15 countries. His areas of interest are mycotoxins, mycorrhiza and science communication among the general public.

The International Conference on Modern Biotechnologies: Sustainable Innovation and Regulatory Needs took place in Penang, Malaysia, on 7-10 November 2012. It was co-organized by GenØk-Centre for Biosafety, Norway and Third World Network.

With the increasing development and use of modern biotechnologies in agriculture, public health and industrial applications, the strengthening of knowledge of and capacity on biosafety is becoming ever more crucial. In light of this urgent need, the Conference was held to build biosafety capacity at both scientific and policy/regulatory levels with a view to improving risk assessment, risk management and policy and regulation related to these technologies, especially in developing countries where resources and capacities are often low.

This report comprises the organizers' summary of the proceedings of the Conference as well as abstracts of the presentations delivered. It examines the key issues and main recommendations put forward, within the context of the need to shape scientific research and innovation on modern biotechnologies to prevent or minimize any adverse impacts and to advance the societal interest.

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