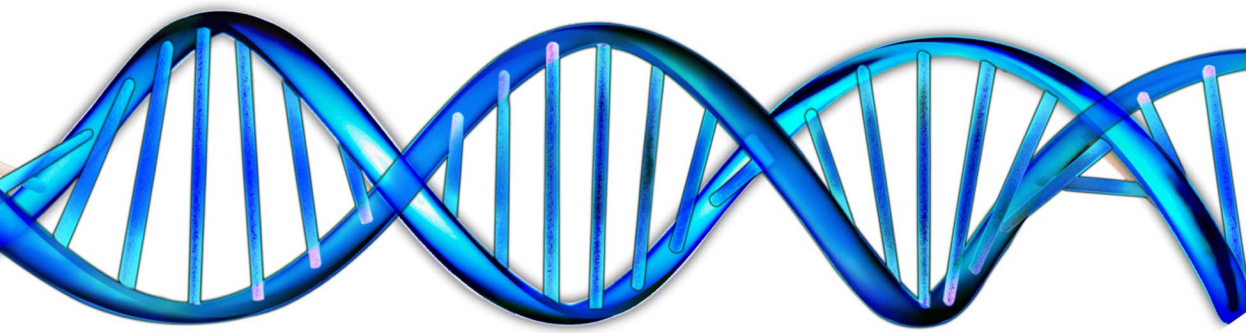
International Conference on

Modern Biotechnologies:
Sustainable Innovation and Regulatory Needs



Penang, Malaysia

7-10 November 2012

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ABSTRACTS

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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 (IP) 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 (GMOs). 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, both in institutional and financial terms, for 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 what 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 its 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.

Enhancing Plant Defense 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 severely depleting the soils and in ecological degradation often beyond repair. Driven by the high buildup of toxicity in soils and water bodies which have affected human and animal health, several communities across the world are now recognizing the need for reverting back 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 labs 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 defense systems and discusses how a diversity of plants and insects are required to induce the natural defense-related enzymatic pathways of plants.

Socio-Economic Considerations in the Indian Context

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RESEARCH and Information System for Developing Countries (RIS) is a think tank with the government of India. We work very closely with Ministry of Environment and Forests (MoEF), the nodal Ministry for the regulation of LMOs in India. An important work of RIS with MoEF, has been the pioneering study on the environmental risk assessment, socio-economic considerations and decision making support for LMOs in India. RIS has also organized international conferences on the same topics. We are now doing a study involving MoEF and all the scholars who have been recommended by MoEF as subject experts to participate in the online discussion forum on socio-economic considerations organized by the CBD to identify relevant socio-economic factors in the Indian contexts which are to be included in the decision making process and to identify the gaps in the capacity. The study is expected to give a clear idea on what are the relevant socio-economic considerations in the Indian contexts as well as what capacity building assistance would India require and what capacity building assistance India would be in a position to offer to its neighbouring counties.

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

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AGRICULTURE biotechnology is a major tool to the productivity a developing countries needs to advance more rapidly to meet growing food demands 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 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. These 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 to include 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. However the most significant factor affecting maize production is drought. However most of the area in Sudan has been affected by drought, indeed, all famine and hunger situation 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 e.g. 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 program 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 haboring 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). Sudan Biosafety bill was signed into law. This paved way for the country to engage in GMO at the research and commercialization levels. So far Bt-cotton is in pipeline for commercialization with field experiments being conducted at Agricultural Research Corporation (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. The drought tolerance genes were introduced to Sudanese maize using *Agrobacterium tumefaciens* method. 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 at glass house and field condition. 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.

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 USA 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 USA 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 D 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 virgifiera 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 D 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.

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

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BT cotton has been cultivated in China for more than 15 years. Aiming to the impacts of multiple years' plantation of *Bt* cotton, the field surveys and interviews were conducted in the six provinces of Hubei, Anhui, Jiangsu, Henan, Shangdong and Hebei in China. The investigation revealed that the *Bt* cotton is generally effective to cotton bollworm (*Helicoverpa armigera*) and pink bollworm (*Pectinophora gossypiella*), but, in many places, the *Bt* cotton has resulted in the outbreak of the secondary pests as well as several cotton diseases, after 5-8 years' plantation. 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 haven't 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 become the new dominating cotton pests in recent years. For example, the *Bt* cotton in Hubei and Anhui province of Yangtze River Valley area are threatened by the cotton leaf worms and the beet armyworms; while in Hebei and Shangdong provinces of Yellow River Valley area, the beet armyworms and cotton thrips are the main pests; however in Henan Province the whitefly became the main insect 3-5 years ago.

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 that 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.

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 access 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 seventeen (17) brands of rice purchased six (6) brands were from open market in Sierra Leone, three (3) from Ghana and eight (8) 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 seventeen 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 labeled as GMs, 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.

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) were conducted 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 the 26 species belonging to 8 families equaled 90.75% of the Lepidopteran individuals; seven of the species were more abundant and well distributed, contributed 86% of total lepidopteran individuals such as: *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*, appear 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.

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 licenced 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 (OPV) 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 were 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 to 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 (genetically modified organisms), which require ERA (environmental risk assessment) 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 present risk assessment framework. For example there are important distinctions between chemicals and organisms and between viruses and organisms that needs 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, often have 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 both 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 of 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 both the objectives of ERA and of the management strategies.

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Myhr, A.I. and Traavik, T. (2012). Genetically Engineered Virus Vaccine Vectors: Environmental Risk Management Challenges. In: Genetic Engineering, InTech publishers, 20 pages, 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.

The Release of GM Insects: Is Criticism of Regulators for the 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, USA, 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 identify factors that can restrict their capacity to do this effectively. Using examples drawn from the 4 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 frame works, 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 mosquitos?*'. 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 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 needs 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 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 propose to look over unanswered questions and underestimated risks 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 the concern on 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 Organism (GMO). 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 cannot only produce great social and economic benefits, but can also do harm to the environment, human health, and results in many socioeconomic problems. One of the major environmental risks is the novel varieties which may replace some of the existing varieties that 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 the biosafety GMOs. Thus, biosafety is efforts to reduce and eliminate the potential risks resulting from this technology and its products, focusing both on 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 to create biosafety legislation is that it would strike a balance between protecting against the adverse effects of GMOs and promoting modern biotechnology. However, how far does the extent of the Act in balancing this role is yet to be determined.

This research examined the adequacy and the applicability of the Biosafety Act 2007 in balancing the role of protecting environment from the adverse effects of the GMOs and at the same time, promoting modern biotechnology in Malaysia. Apart from that, this research also seeks to propose recommendations for the amendment to the Biosafety Act 2007 to do enough to protect biological diversity as well as avoiding any hindrances in the country's biotechnology development in Malaysia. Based on a qualitative research method, this research employed a case study research design in order to examine the applicability of the Biosafety Act 2007 in balancing the role of protecting the environment and promoting modern biotechnology in Malaysia.

The outcome 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 Probiotic and Risk Issues

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

Aim: Main aim of this study was comparative characterization of growth peculiarities of buffalos gut *Lactobacillus* and *Bifidobacterium* isolates after different probiotics' treatment.

Methods: We used logistic differential equation of Verhulst for the characterization of growth of *Lactobacillus* and *Bifidobacterium* buffalos fecal isolates after different probiotics' treatment. Seventy healthy buffalo were involved in these studies, and at least, ten 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 probiotics treatment and demonstrate a possibility of use of mathematical models for the probiotics' recommendations.

According to information from EU nutrition and health claims, due to insufficient research data the most rejected applications during the last years by European Food Safety Authority are related to probiotics. The applications of genetically modified probiotics in foodstuffs, the progress in nanobiotechnology and the use of transgenic bacteria for the environmental bioremediation aims increase the caution against the probiotics' use. Despite this, the market of probiotics continues to rapidly grow in developing countries and there is a need for information exchange and discussion on probiotics' 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 severally in various sectors of a nation's development. The involvement of genetics and molecular biology to develop some microorganisms for use in various sectors of Nigeria is the main objective of this report. Conventional microbiological methods, genetic and molecular biology techniques were used to screen and identify the best oil degrading microorganisms, 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^{o}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 (*Vigna unguiculata* var. "Oloyin") is one of the highly consumed protein-rich food crops in Nigeria, but the crop is available at a high price in 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^{o}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 4 folds.

Many natural plants in Nigeria are medicinal. Due to drug resistance of some pathogenic microbes, certain plants including peppers and folkloric plants screened showed good antimicrobial property. The structures of some of the bioactive components

of these plants have been determined. The genes encoding these bio-actives 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.

Biotechnology, the exploitation of biological components for the production of useful products has been used severally in various sectors of a nation's development. The works reported here are considered for adoption for Nigerian growth if appropriate bio-safety measures are taken.

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 ethically acceptable.

The Norwegian Biotechnology Advisory Board (NBAB) gives advise to the authorities on GMOs. In an on-going 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 environment, economy and society. This includes long-term as well as global impacts. When assessing the sustainability of import to Norway, also impacts in the producing country should 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 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 health, environment, sustainability, ethics and benefit to society.

Food Security and Future Agriculture in China

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CHINA'S population in 2011 is 1.347 billion, based on which, the population will reach 1.4 billion and 1.462 billion in 2020 and 2030 respectively. With the growth of population and income as well as dietary structure change, indirect consumption of grain such as meat and eggs has been increasing, further driving up China's grain demand. There is big challenge for food security in China.

What is the solution of Chinese food security? With a large population while limited land, water resource shortage, complex natural conditions, big ecological deficit, fragile environment and underdeveloped rural area, China is not able to follow the US and Canada's large-scale operation and machinery farming or Japan and South Korea's high subsidy to maintain high income and high price for small-scale households. Instead, China must explore a most suitable road that is in accordance with China's characteristics for the development of future agriculture in China.

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 US dollars for GM varieties development. However, some problems already happened on *Bt* cotton, a main commercialized GM crop in China. The secondary pests attack cotton more and more seriously, such as mired bug outbreaks in multiple crops correlated with wide-scale adoption of *Bt* cotton in China. As a result, GM rice has been postponed for its commercialization.

Ecological agriculture may be a real way to resolve food security 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. The ecological agriculture shall be combined with the adjustment of agricultural structure, the improvement of agricultural conditions and ecological environment as well as the pollution-free agriculture, so as to enhance the development of ecological agriculture.

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 Center 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 Norwegian Gene Technology 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 theirs 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 term 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 advice 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

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 are 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, organisations, institutions, cultures and discourses. This compounds uncertainties and ambiguities over what constitutes 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. Mischaracterised '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' rhetorics, 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 polarised questions over: "how safe?", "yes or no?"; "how much?"; "how fast?" and "who leads?" Instead are raised more searching and explicitly political queries 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 realising 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 realise 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 (CPB). 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 CPB 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 of 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 regulates the safety of these organisms, including transgenic seeds.

This commission is composed by experts in biological and agronomical disciplines and, although this public organism has been constituted as a consultive arena, this comission has an strategical role in promoting the GMO crops, releasing and regulating these productions.

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 ignores the necessity of a social debate with multiple approaches. As a result, policies implemented by the national government are not democratic enough in regards with these topics.

Analizing 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-plus 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 analyse, 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 lots of protests by the farmers' unions and civil society activists against its release. The Genetically Engineering Approval Committee working under the Ministry of Environment and Forests, Govt. of India has recommended the first GM food crop, Bt brinjal for field cultivation in October 2009. Once again there was a lot of opposition for its introduction. Finally the government has 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 first genetically modified crop, Bt cotton on commercial scale, the Govt. of India constituted a high level 31 member committee under the chairmanship of Sri Basudeb Acharia, Member of Parliament to study on Cultivation of GM Food Crops-Prospects and Effects. The committee has submitted a comprehensive report to the Ministry of Agriculture (Department of Agriculture and Cooperation) to Lok Sabha on August 9, 2012.

Some of the Major Recommendations of the Committee are as under:

The committee after critically analyzing the evidence placed before them, both for against the transgenic agricultural crops have, in view of the compelling concerns regarding India being one of the richest centers of biodiversity, agriculture providing sustenance to almost 70% of 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; 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 a be done in strict containment and field trials under and 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 shape the directions 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 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 weight 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 centralise research and development and reduces choice, where the focus is to increase economic competitiveness through commodiable products, which benefit certain actors by granting intellectual property (IP) rights to those products. This often shut downs 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 legal restrictions. Innovation here aims at products for those in the wealthiest markets, by passing innovations for those most in need.

In contrast, the bottom-up approaches tend to produce innovations that utilize ecosystem management innovations that are fit intothe social and cultural practices and context of local farming systems. The main feature of the bottom up approach is that it decentralises 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 augumenting existing knowledge of the local system with the aim to address 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 changes to 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.