GMO concerns: Global issues and implications

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Overview

- Potential environmental impacts
- Issues around potential health impacts
- Context and significance of international regulation
  - Convention on Biological Diversity
  - Cartagena Protocol on Biosafety
    - AHTEG on Risk Assessment
    - AHTEG on Socio-economic Considerations
    - AHTEG on Synthetic Biology
  - Codex Alimentarius (FAO-WHO)
  - International Plant Protection Convention (FAO)
- Trans-Pacific Partnership Agreement

GM applications

- Agriculture: Plants/crops & animals (e.g. fish – food and pets)
- Medicine: e.g. insulin & vaccines
- Industrial applications: e.g. enzymes for food processing & microorganisms for environmental remediation
- Trees & horticulture
- Insects: e.g. mosquitoes
- Biological weapons/ Biodefence

GM crops globally

- 181 million hectares in 2014 (ISAAA, 2015)
- Approximately 77 per cent of global GM crop area is confined to just three countries (USA, Brazil, Argentina)
- The USA has 40 per cent of global GM crop area
- Commercially available GM crops almost exclusively limited to soy, maize, cotton, canola
- Two traits dominate – herbicide resistance and insect resistance (either singly or stacked)

Examples of potential environmental impacts

- **Gene flow**
  - Transgenic contamination of Mexican maize landraces (Quist & Chapela 2001, Dyer et al. 2009)
    - Mexico centre of origin and diversity of maize -> biodiversity and socio-economic implications
  - Gene flow from GM canola in Canada - triple herbicide resistance (Hall et al. 2000)
    - Agronomic/weed problems
  - Gene flow to wild relatives from GM rice in China (Lu & Yang 2009)

Examples of potential environmental impacts

- **Non-target and indirect effects**
  - Potential harm of Bt corn to aquatic ecosystems, increased mortality and reduced growth in caddisflies, which are food for higher organisms (Royer et al. 2007)
  - Reduced fitness and survival of *Daphnia* when fed Bt corn (Bohn et al. 2008)
  - Effect of Bt toxins on beneficial non-target organisms e.g. worms (Zwalhen 2005), lady beetle (Schmidt et al. 2009), lacewings (Hilbeck et al. 1998)
  - Surge in secondary pests in Bt cotton fields in China (Wu et al. 2002, Lu et al. 2010)

Examples of potential environmental impacts

- **Evolution of resistance in pests**
  - Insect resistance with insect resistant crops
  - Rapid evolvement of Bt-resistant target pests (van den Berg 2010)

- **Effects on agricultural practices**
  - Herbicide resistance in weeds with the use of herbicide resistant crops
  - Increased use of herbicides in US with herbicide resistant crops due to evolution of weed resistance (Benbrook 2003, 2004, 2009, 2012).
  - Global agricultural use of glyphosate rose 14.6-fold, from 51 m kg in 1995 to 747 m kg in 2014 (Benbrook 2016)

Concerns with studies on potential health impacts

- Lack of relevant and independent scientific research
- Early warnings
- Scientific uncertainties

Lack of relevant scientific research

- The few studies that have been designed to reveal physiological or pathological differences are extremely few, and they demonstrate quite a worrisome trend (Pryme and Lembecke, 2003):
  - studies performed by the industry find no differences
  - studies from independent research groups reveal differences that should have merited immediate follow-up, confirmation and extension, which has not been the case

Early warnings

- Rats fed GM potatoes showed changes in **stomach and gastrointestinal tract** (Ewen and Pusztai 1998)
- GM pea fed to mice elicited **immune response**, characterised by inflammation of the lungs (Prescott et al. 2005)
- Reanalysis of Monsanto data showed indications of **liver/kidney toxicity** in rats fed Bt corn MON863 (Seralini et al. 2007)
- Effects on **liver** of mice fed RR soya (Malatesta et al. 2008)

Early warnings

- Signs of **hepatorenal toxicity** linked with GM maize (MON 810, NK 603, MON 863) consumption (de Vendomois et al. 2009)
- MON 810 maize induced alterations in intestinal and peripheral **immune response** of weaning and old mice (Finamore et al. 2008)
- NK603 maize and Roundup: 2 year study found female **mortality** 2–3 times higher mostly due to **large mammary tumors** and **disabled pituitary function**. Males suffer **liver congestion and necrosis, severe kidney nephropathies and large palpable tumors** (Séralini et al, 2012)

Early warnings

- Review of 19 studies of mammals fed with commercialized GMOs: Meta-analysis of all biochemical disruptions indicated signs of **liver and kidney** toxicity (Séralini, et al., 2011)
- Review of toxicity studies concerning GM foods: Results of most studies with GM foods indicate that they may cause some common toxic effects such as **hepatic, pancreatic, renal, or reproductive effects**, and might alter the **hematological, biochemical, and immunologic parameters** (Dona and Arvanitoyannis, 2009)

Scientific uncertainties

- Little known about the long-term effects of consuming GM food and foods derived from GMOs
  - ‘Many opinions but few data’, *Science*, June 2000
- Gaps in scientific knowledge regarding long-term environmental impacts
- Very little independent biosafety research has been conducted, while commercialization is increasing
- Early warnings are emerging – what is the appropriate scientific, policy and regulatory response?

Reasons developing countries pushed for international regulation

- No national biosafety laws or regulation
- No / little capacity to do risk assessment and monitoring
- Concern about becoming a ‘dumping / testing ground’
- Most biodiversity hotspots / centres of origin / ecologically sensitive areas
- Agriculture mostly in the hands of small farmers
- Concern about loss of markets
- Staple foods and food consumption patterns

Convention on Biological Diversity

- Parent treaty to the Cartagena Protocol on Biosafety
- Adopted in 1992, with Article 19.3 requiring Parties to "consider the need for and modalities of a protocol setting out appropriate procedures … in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology…"

Cartagena Protocol on Biosafety

- Negotiations began in 1996
- Adopted: 29 January 2000 in Montreal, after negotiations collapsed in Cartagena in 1999
- Entered into force: 11 September 2003
- 170 Parties currently
- Primary international law on genetic engineering/genetically modified organisms

Significance of the Cartagena Protocol

- For the 1st time in international law there is a recognition that **GMOs are different from other naturally occurring organisms** and may carry special risks and hazards and therefore need to be regulated internationally
- Recognises that GMOs may have **biodiversity, human health, and socio-economic impacts**; and that these impacts must be risk assessed or taken into account when making decisions
- Scope covers **all** GMOs

Significance of the Cartagena Protocol

- Operationalises the **Precautionary Principle**
- Operationalises the principle of **prior informed consent** (Advance Informed Agreement procedure)
  - Decision making based on **risk assessment** and precaution
  - Risk assessment in a “scientifically sound manner”, in accordance with the annex on RA, and taking into account recognised RA techniques

Risk assessment guidance under the Cartagena Protocol

Ad Hoc Technical Experts Group (AHTEG) on Risk Assessment:

- Roadmap on risk assessment
- Specific guidance - GM trees, GM insects, GM plants with stacked genes, GM abiotic stress tolerant plants
- Guidance on monitoring of GMOs released into the environment

Further risk assessment guidance

- Work to integrate relevant information into the Roadmap on

  (i) centres of origin, genetic diversity and unmanaged ecosystems

  (ii) human health

  (iii) RNAi and dsRNA

  (iv) synergistic effects of herbicides part of LMO technology packages

- Possible additional guidance: synthetic biology and GM fish

Socio-economic considerations under the Cartagena Protocol

- Ad Hoc Technical Experts Group (AHTEG) on socio-economic considerations
  - Revised Framework for Conceptual Clarity
    - Comprises of Operational Definition, Objective and General Aspects.
- Possible guidance on socio-economic considerations

Operational definition

- Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may cover **economic, social, cultural/traditional/religious/ethical aspects, as well as health and ecological aspects, if they are not already covered by risk assessment procedures** under Article 15 of the Protocol.

Synthetic biology and the CBD

- “Living organisms developed through current and near future applications of synthetic biology are similar to LMOs as defined in the Cartagena Protocol.”

- Decision X/13 (COP 10, 2010)
- Decision XI/11 (COP11, 2012)
- Decision XII/24 (COP 12, 2014)
  - apply the **precautionary approach**

Synthetic biology and the CBD

- Decision XII/24 (COP 12, 2014) also recommended
  - effective **risk assessment and management procedures** and/or **regulatory systems** to regulate environmental release
  - to only approve for field trials after **appropriate risk assessments** have been carried out
  - to carry out scientific assessments that consider risks to biodiversity, human health, food security and **socio-economic considerations,** which should be done with the full **participation of indigenous and local communities**

AHTEG on Synthetic Biology under the CBD

Draft terms of reference:

- (a) Review recent technological developments within the field of synthetic biology to assess if could lead to impacts on biodiversity and the three objectives of the Convention, including unexpected and significant impacts;
- (b) Identify any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of LMOs under the Cartagena Protocol;
- (c) Further analyse evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention, and gather information on risk management measures, safe use and best practices for safe handling;

AHTEG on Synthetic Biology under the CBD

- (d) In order to avoid or minimize any potential negative effects on the conservation and sustainable use of biodiversity, evaluate the availability of tools to detect and monitor the organisms, components and products of synthetic biology;
- (e) [Propose elements to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol to facilitate the clarification of, if and how, the use of digital sequence information on genetic resources relates to access and benefit-sharing;]
- (f) Provide, for consideration by SBSTTA, recommendations to facilitate future discussions and actions on synthetic biology under the Convention, as well as a robust analysis to decide whether or not this is a new and emerging issue related to conservation and sustainable use of biodiversity;

International standards, guidelines & recommendations

- Codex Alimentarius Commission
  - For food safety
- International Plant Protection Convention (IPPC)
  - For plant health
- World Organisation for Animal Health (OIE)
  - For animal health and zoonoses

=> Explicitly recognized in the World Trade Organisation SPS Agreement

  - WTO consistency presumed

Codex Alimentarius

- Ad-hoc Intergovernmental Task Force on Foods derived from Biotechnology
- Adopted in 2003:
  - Principles for the risk analysis of foods derived from modern biotechnology
  - Guideline for the conduct of food safety assessment of foods derived from r-DNA plants, including an annex on the assessment of possible allergenicity
  - Guideline for the conduct of food safety assessment on foods produced using r-DNA microorganisms

Codex Alimentarius

- Adopted in 2008:
  - Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals
  - Annex on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits
  - Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food

Significant elements of Codex Principles and Guidelines

- Recognized that they may be uncertainties and unintended effects that have to be assessed
- Safety assessments should be conducted on all GM foods prior to their market approval
- Clarified that ‘substantial equivalence’ is only a starting point for any GMO risk assessment
- Consideration of indirect effects on human health e.g. herbicide residues from GM herbicide resistant crops or potential risks associated with out-crossing

Significant elements of Codex Principles and Guidelines

- Called for moving away from the use of antibiotic resistance marker genes
- Foods derived from GM plants or produced using GM organisms that have been intentionally modified to alter their nutritional quality or functionality should be subjected to additional nutritional assessment and may require additional testing
- Risk management measures could include food labelling conditions for marketing approvals and post-market monitoring

Codex Alimentarius

- Committee on Food Labelling (CCFL)
  - Guidelines adopted in July 2011: ‘Compilation of Codex texts relevant to the labelling of foods derived from modern biotechnology’
    - Acknowledges that different approaches to labelling GM food are used
    - Any approaches by Codex members should be consistent with already adopted Codex provisions
    - Sets out relevant Codex Standards, Guidelines, Principles

International Plant Protection Convention (IPPC)

- Pest Risk Analysis for Quarantine Pests including Analysis of Environmental Risks and LMOs
  - Covers GM plants, GMOs that may be harmful to plants such as GM insects, fungi and bacteria
  - GMOs considered potential phytosanitary risk/quarantine pest until decided otherwise
  - Consideration of intentional and unintentional pathways of introduction
  - Assessment of potential economic consequences
  - If no satisfactory measure available to reduce risk to acceptable level, importation may be prohibited

Trans Pacific Partnership Agreement Article 2.29: Trade in Products of Modern Biotechnology

- The main aim of the Article is to circumscribe what importing Parties can do when arriving commodity shipments (e.g. soya, corn) and shipments of other plants and plant products (e.g. vegetables, crops for planting) for food or animal feed are contaminated with GMOs that are not approved by them

- In most cases, shipments of grains are an inadvertent mixture of non-GM and GM due to the lack of segregation in storage and transportation. In some cases, the GMOs may not be approved in the country of export or in the country of import, or both.

GMO trade

- There have been a number of cases where countries have rejected shipments because they contain GMOs that have not been approved by them

- A number of TPPA member countries (e.g. US, Canada, Australia and Chile) are growers and exporters of GMOs. The rest of the TPPA member countries, including Malaysia, are essentially importers of GMOs.

TPPA and zero tolerance?

- Most countries, including Malaysia, have implicit ‘zero tolerance’ policies that require all GMOs entering the country to be subject to a prior risk assessment and approvals procedure.
- As such, most countries do not have laws, regulations or policies on LLP occurrence as this would circumvent their zero tolerance policy and allow shipments contaminated with illegal and unapproved GMOs to enter the country.
- The TPPA, by establishing a protocol for Parties to follow when there is an LLP occurrence, effectively undermines a Party’s ability in practice to subject all GMOs to a prior risk assessment procedure, before that GMO is released into the environment or is placed on the market, and to reject GMOs that they have not approved, and which are illegal in their countries.