

# Enhancing Biosafety and Reducing Risks

National Workshop on Sustainable Rice Production: Re-visiting IPM  
12-13 September 2012, UKM

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# Genetic engineering

- Definitions in the Cartagena Protocol on Biosafety:
  - “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
  - “Modern biotechnology” means the application of:
    - a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
    - b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

# GE rice research

- Herbicide tolerance
  - Glufosinate tolerance: Liberty Link
  - Glyphosate tolerance: Roundup Ready
  - Use of human cytochrome genes for tolerance to sulphonylurea and triazine herbicides (atrazine, simazine)
- Insect resistance
  - Bt rice (Cry genes): Lepidopterans
  - Cowpea trypsin inhibitor (CpTI): stem borers
  - Snowdrop lectin: sap-sucking insects, BPH

# GE rice research

- Disease resistance
  - Bacterial blight resistance (Xa21 gene)
  - Rice blast resistance
  - Virus resistance
- Tolerance to abiotic stresses
  - Low iron availability in alkaline soils
  - Salt tolerance
  - Drought tolerance

# GE rice research

- Nutritional enhancement
  - Pro-vitamin A ('Golden Rice')
  - Iron
- Production of pharmaceuticals
  - Human milk proteins (lactoferrin, lysozyme)
- **No commercial production yet of GE rice anywhere in the world**

# Potential environmental impacts

- **Gene flow**
  - Interbreeding with wild or weedy relatives could lead to greater invasiveness or loss of biodiversity
  - Horizontal gene flow
- **Examples**
- Transgenic contamination of Mexican maize landraces (Quist and Chapela 2001, Dyer et al. 2009)
  - Mexico centre of origin and diversity of maize -> biodiversity and socio-economic implications
- Gene flow to wild relatives from GE rice in China (Lu and Yang 2009)
- Gene flow from GE canola in Canada - triple herbicide resistance (Hall et al. 2000)
  - Agronomic/weed problems

# Potential environmental impacts

- **Non-target and indirect effects**
  - Impact on beneficial insects e.g. predators and parasitoids
  - Loss of biodiversity, altered community or ecosystem function e.g. reduced pollination, secondary pest outbreaks
- **Examples**
  - 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 non-target organisms e.g. worms (Zwalhen 2005)
  - Surge in secondary pests in Bt cotton fields in China (Lu et al. 2010)

# Potential environmental impacts: Examples

- **Evolution of resistance in pests**
  - Insect resistance with insect resistant crops
- **Example**
- Rapid evolution of Bt-resistant target pests in S. Africa, leading to more insecticide use (van den Berg 2010)
- “Mounting evidence” of resistance development in corn rootworm (US EPA, 2012)
- **Effects on agricultural practices**
  - Herbicide resistance in weeds
- **Example**
- Evolution of weed resistance with herbicide tolerant crops, leading to increased use of more toxic herbicides in North and South America (e.g. Benbrook 2009)



# Potential health impacts: Concerns

- Transgenic or altered host cell proteins - toxic or allergenic?
- Transgene DNA sequences in notifications not the same as the inserts found in the GMO (Windels et al. 2001, Holck et al. 2002, Herdendez et al. 2003, Collonier et al. 2003, Ronning et al. 2003)
  - Unpredictable effects on long-term genetic stability, as well as on nutritional value, allergenicity and toxicity
- Use of antibiotic resistance marker genes

# Potential health impacts: Concerns

- Impact of products used with GMO e.g. herbicides
  - Glyphosate is toxic and an endocrine disrupter in human cell lines (Gasnier et al. 2009); induces cell death in human umbilical, embryonic and placental cells (Benachour and Seralini 2009)
- Chemical- and pharmaceutical-producing plants
  - Biologically active chemicals that are potentially toxic
  - Risk of contamination: gene flow, grain admixture, human error

# 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 GE potatoes with the snowdrop lectin gene (GNA) showed changes in stomach and gastrointestinal tract (Ewen and Pusztai 1998)
- GE 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)

# Early warnings

- Signs of hepatorenal toxicity linked with GE maize (MON 810, NK 603, MON 863) consumption (de Vendomois et al. 2009)
- Effects on liver of mice fed RR soya (Malatesta et al. 2008)
- Mice fed GE maize MON 810 x NK603 showed significant negative reproductive effects (Velimirov et al. 2008)
- MON 810 maize induced alterations in intestinal and peripheral immune response of weaning and old mice (Finamore et al. 2008)

# Socio-economic considerations

- Rice is culturally, religiously and socially embedded
  - Potential contamination of traditional varieties of rice with transgenes
- Contamination of non-GE rice with transgenes
  - Gene flow through cross pollination, seed exchange, spillage during transport, etc.
  - Affects export markets, especially for organic rice
  - Unapproved GE rice has entered food chain: LL601, Bt63
- Intellectual property issues
  - Broad patents that extend scope to other major cereals: E.g. Syngenta patent on basic gene sequences that regulate flowering development, flower formation, whole plant architecture and flower timing in rice

# Precaution as the basis for regulation

- Lack of scientific certainty does not prevent one from taking action to prevent or mitigate potential adverse impacts
- Scientific uncertainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects

# International biosafety regulation

- **Cartagena Protocol on Biosafety**
  - **Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress**
- Codex Alimentarius principles and guidelines
- International Plant Protection Convention
- World Organization on Animal Health
- WTO Agreements



# Biosafety regulation in Malaysia

- Party to the Cartagena Protocol
- Biosafety Act 2007
  - Case-by-case approvals system based on risk assessment, decision making based on precaution, allows inclusion of socio-economic considerations, public participation
- Implementing regulations
  - Approval for release activities
  - Notification for contained use, import for contained use, export
  - GM food labelling regulation (under MOH)

# Alternative approaches

- **Do we need GE rice, especially with the potential risks it poses? What should countries prioritize for resource mobilization and research?**
- Agroecology/ecological agriculture
- Integrated pest and disease management
- Use of beneficial insects
- Conservation and sustainable use of agricultural biodiversity
- Use of different varieties (Zhu et al. 2000)
- Seed saving, exchange
- Farmers to farmer learning and networks

# Thank you!

[www.biosafety-info.net](http://www.biosafety-info.net)