Policy approaches in NBT and implications for market and trade in Malaysia

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New Breeding Technologies (NBT)

1. Gene/ genome editing (GE)
2. Gene silencing /RNA inhibition (RNAi)
3. Synthetic biology
4. Grafting on GM stocks
5. Agro-infiltration
6. Intragenesis
7. Cisgenesis
8. Epigenetics/ RNA-directed DNA methylation
9. Other emerging technologies etc.
The Biosafety Act 2007 (Act 678)

- regulate living modified organisms (LMOs*) & the release of products of such organisms
  + Biosafety (Approval and Notification) Regulations 2010
  + Biosafety (Compounding of Offences) Regulations 2018
  + Biosafety (Sampling Procedures) Regulations 2018

The Cartagena Protocol on Biosafety

The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

*The term LMO is used interchangeably with GMO
Living Modified Organisms (LMOs)

“Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”

Regulatory trigger is process-based (‘modern biotechnology’)
“Modern Biotechnology”

a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the 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.
Regulating Authorities

**Representatives relevant Ministries:**
- Ministry of Health
- Ministry of Science, Technology & Innovation
- Ministry of Agriculture & Food Industries
- Ministry of Plantation Industries & Commodities
- Ministry of International Trade & Industries
- Ministry of Domestic Trade & Consumer Affairs
- Ministry of Energy and Natural Resources
- External Experts

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**Applications/ Notifications**

- **Department of Biosafety (DOB)**
  - Operations
  - Enforcement

- **Genetic Modification Advisory Committee (GMAC)**
  - Scientific & technical advice
  - Risk assessment

- **National Biosafety Board (NBB)**
  - Approvals
  - Policies

- **Ministry of Environment and Water**
  - Approvals
  - Policies

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**Socio-economics Committee**
Current status - GMO for open release

- No applications for commercial planting of GM crops
- FFPs
  - Corn/Maize: 22
  - Soybean: 16
  - Cotton: 6
  - Canola/oilseed rape: 3
  - Potato: 3
- Non-FFPs
  - Enzyme: 1
  - Larvicide: 1
  - Cut flowers: 1
  - Single Cell Protein: 1
  - TMOF_yeast: 1
- Field Trials
  - Mosquito: 1
  - Papaya: 2
  - Rubber: 1
  - Total: 5

- No applications for open release of GE crops
- No commercialization/ FFP of GE crops
- Some activities on contained use R & D of GE crops

Info Updated June 2021
GE contained use activities in Malaysia

- Involves innovative work by research institutes and universities
- Mostly in R&D stage
- Crop improvement using CRISPR/Cas9
- Research on some diseases (human and animal) using CRISPR/Cas9
Regulatory approach for NBT/GE plants

FOR NOW:

• No specific policy for gene/genome editing
• Regulated under the Biosafety Act 2007 as ‘modern biotechnology’
  • Process-based regulatory trigger – modern biotechnology
  • *in vitro* techniques which involves the manipulation of genes
  • Involvement of exogenous DNA
  • Novel genetic combination that results in LMO

• Case-by-case basis but defined by the regulatory scope
Regulatory approach for NBT/GE plants

UNDER DISCUSSION:

- Ambiguity in regulatory scope of specific GE plants
  - similar changes that can occur naturally
  - combination of modern biotechnology & natural crossing
- GE techniques that do not result in integration of foreign DNA
- Detectability and monitoring of products from gene editing
- Transient RNA-delivered-RNAi

- Risk factor varies according to the event to be introduced and evaluated
- Science based regulation- commensurate with actual risk
Malaysia – “Discussion is ongoing”
Conventional, GM and GE

Conventional Breeding
- Crossing
- Products produced by conventional breeding
  - Small and large changes to native DNA
  - Final product no foreign DNA
- Not Regulated

Genome Editing
- SDN 1
- Products similar to conventional breeding
  - Small change to native DNA
  - Final product no foreign DNA
- Not Regulated or Regulated?

- SDN 2
- Products similar to conventional breeding
  - Small and large changes to native DNA
  - Final product no foreign DNA
- Not Regulated or Regulated?

- SDN 3
- Products precisely modified compared to GM
  - New DNA gene expression cassette (native or foreign)
  - Final product may contain foreign DNA
- Regulated

Genetically Modified
- GMO
- Products genetically modified
  - New DNA gene expression cassette (foreign DNA)
  - Final product does contain foreign DNA
- Regulated

Lisa Zanni: https://www.liebertpub.com/doi/10.1089/crispr.2018.00
Conclusion

• Open release and contained use activities for genome/ gene editing activities is regulated by the existing regulatory framework
• GE crops will be regulated as LMOs if they fall under the definitions of the current regulations
• Possible that simplified procedures may be developed in near future for NBT, and applied on a case-by-case basis
• Discussions have started at the scientific/ technical level
• Wider consultation and inputs will be obtained to have an enabling framework that is ready to process future release
• Outlook – biosafety regulation framework in Malaysia has thus far been facilitative and responsible – likely to maintain this direction