



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

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OUTLINE

Biosafety Laws

Regulatory Authorities

Regulatory Status of GE Plants

Conclusion



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.

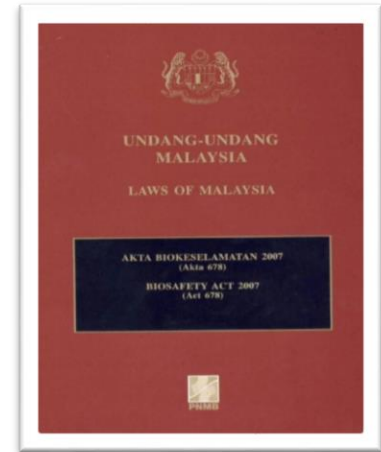
Biosafety Laws and Regulations

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

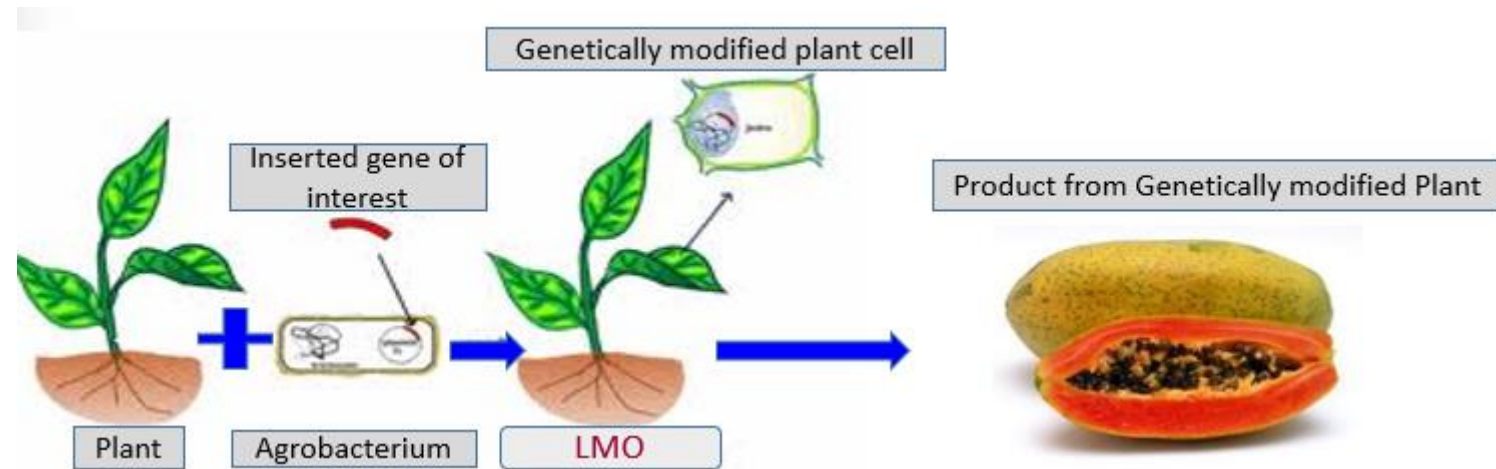


*The term LMO is used interchangeably with GMO

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’)





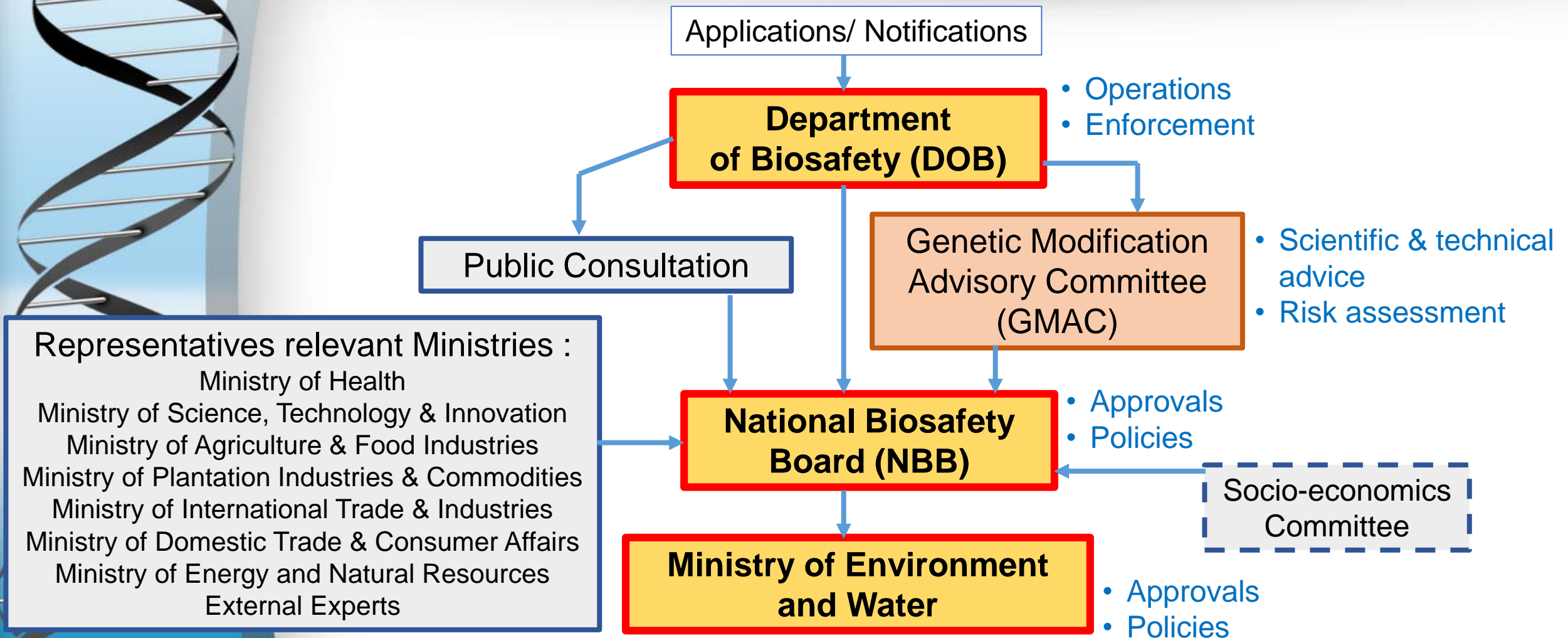
“Modern Biotechnology”

- 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



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
	50

- **Non-FFPs**

Enzyme	1
Larvicide	1
Cut flowers	1
Single Cell Protein	1
TMOF_yeast	1
	5

- **Field Trials**

Mosquito	1
Papaya	2
Rubber	1
	4

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



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



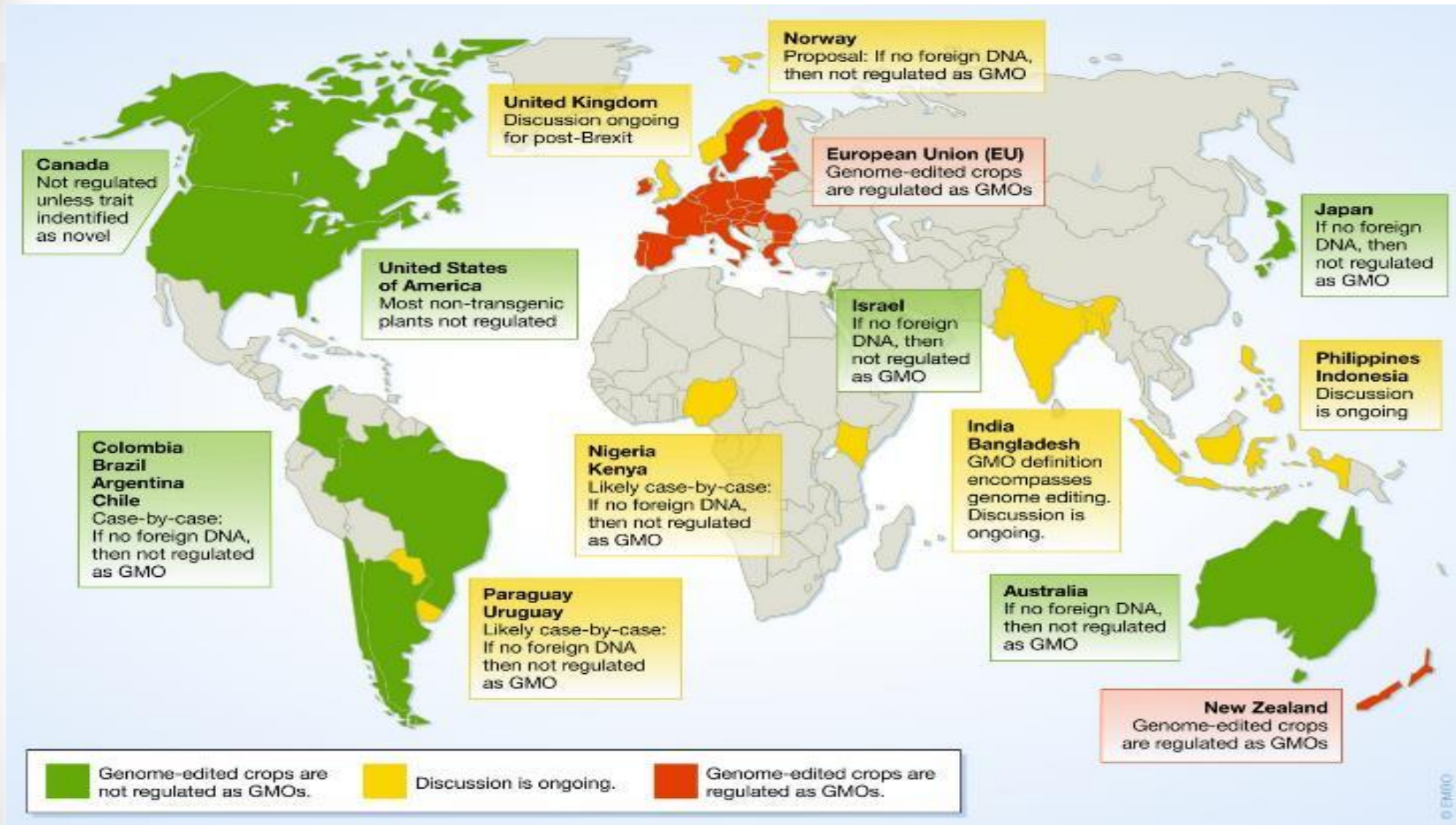
Regulatory approach for NBT/ GE plants

UNDER DISCUSSION :

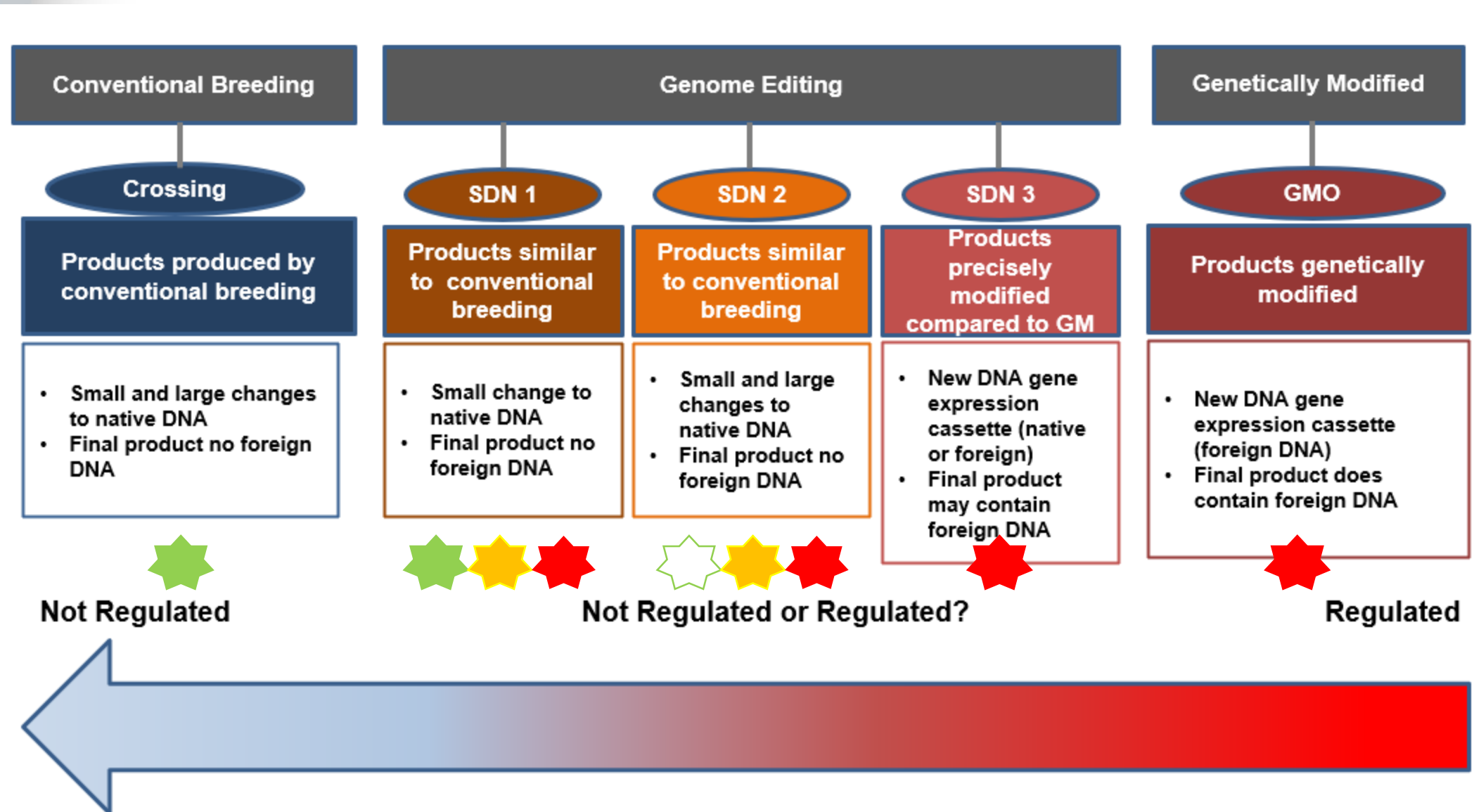
- Ambiguity in regulatory scope of specific GE plants
 - similar changes that can occur naturally
 - combination of modern biotechnology & natural crossing
- GE techniques that do not result in integration of foreign DNA
- Detectability and monitoring of products from gene editing
- Transient RNA-delivered-RNAi

- 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





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

THANK YOU

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