

Chapter Bioethic and B



Outline:

- 9.1 Bioethic
- 9.2 Biosafety

Learning outcomes:

- Describe some bioethical issues in biotechnology.
- List biosafety regulations in Malaysia

9.1 Bioethic

- Ethics identifies a code of values for our actions
- Bioethics – area of ethics that deals with the **implications** of biological research and biotechnological applications, especially regarding medicine
 - Ask “**Should this be done?**” not “Can this be done?”



9.1 Bioethic

- GM Crops: Are You What You Eat?
- Several areas of concern
 - **The plant itself (species integrity)**
 - **Possible effect of altered plants on the ecosystem and on overall biodiversity**
 - **How will the crop be used? Is it safe to feed to animals? Is it safe for humans?**
 - **Consideration of other genes or products present in the GM crop.**



Would you accept GM food?

9.1 Bioethic

- The Human Question
 - Informed consent – patients have the right to be informed fully of the potential effects of the experimental treatment, both good and bad
 - **Placebos** – a safe but non-effective treatment
 - **Double-blind trials**

9.1 Bioethic

- Your Genes, Your Self
 - Concern over the **privacy** of DNA information
 - **How genetic information could be used negatively by employers, insurance companies, governmental agencies, or through perceptions by the general public**

9.2 Biosafety

- There are various pieces of legislation that are relevant to the biotechnology industry in Malaysia.
- Biosafety Act of Malaysia
 - to govern and regulate the release and import of **living modified organisms** (LMOs) and products of such organisms in Malaysia.
 - to ensure safety and prevent unforeseen consequences as a result of the release or import of LMOs.



9.2 Biosafety

- Biosafety Act of Malaysia
 - the only LMOs that have been released in Malaysia were genetically **modified mosquitoEs** to suppress the *Aedes aegypti* population for a mark-release-recapture field test in Bentong, Pahang.



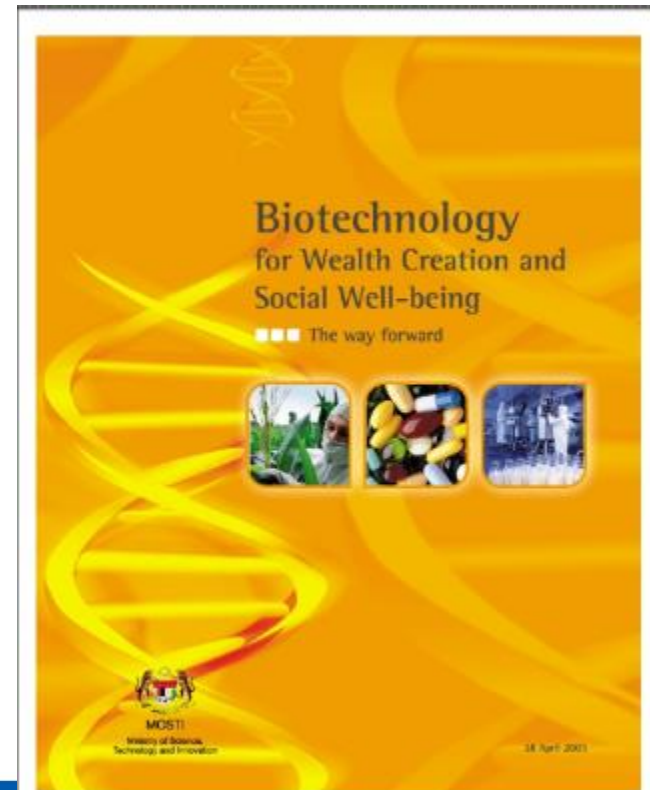
9.2 Biosafety

- Malaysia's National Biodiversity Policy
 - to **conserve** Malaysia's biological diversity
 - to ensure that its components are utilised in a **sustainable** manner for the continued progress and socio-economic development of the nation



9.2 Biosafety

- National Biotechnology Policy
- Trust 7: Legislative and Regulatory Framework Development



9.2 Biosafety

- Good manufacturing practices (GMPs)
 - a **production and testing practice** that helps to ensure a quality product.
 - Many countries have legislated that pharmaceutical and medical device companies must follow GMP procedures,



9.2 Biosafety

- Good clinical practices (GCPs)
 - is an international quality standard that is provided by International Conference on Harmonisation (ICH), an international body that defines standards, which governments can transpose into regulations for **clinical trials** involving **human subjects**.



9.2 Biosafety

- Good laboratory practices (GLPs)
 - a quality system of management controls for **research laboratories and organizations**
 - try to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.



THANK YOU