

Proposed Legislation for the Implementation of the Biosafety Protocol



The Convention on Biological Diversity

- ★ Came into operation in 1993
- ★ Main objectives
 - conservation of biological diversity
 - sustainable use of biological diversity
 - sharing of the benefit arising from the use of genetic resources
- ★ Over 190 Parties, including mainland China (but not applicable to HKSAR)

Cartagena Protocol on Biosafety

- ★ Adopted under the Convention and came into effect in Sept 2003
- ★ Over 140 Parties including mainland China (but not applicable to HKSAR)
- ★ Regulate transboundary movement and release of Living Modified Organisms (LMO)
- ★ Prevent or reduce the adverse impacts of LMOs on the conservation and sustainable use of biodiversity, taking also into account risks to human health

Cartagena Protocol on Biosafety



- ★ "LMO" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology
- ★ "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids
- ★ "Modern biotechnology" means the application of
 - *in vitro* nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
 - 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***

Cartagena Protocol on Biosafety



- ★ Advance Informed Agreement procedure
 - transboundary movement for the first intentional introduction into the environment
 - importing party to consider whether to approve the import / release before shipment
- ★ Shipment documentation
 - to identify LMO shipment
 - contact point for further information
- ★ Biosafety Clearing House
 - information exchange

Biosafety Bill

- ❖ To implement the Biosafety Protocol in Hong Kong
- ❖ To discharge obligations of the Protocol with penalties for violations

Biosafety Bill – Legislative Framework

- ❖ Define terms
- ❖ Restrict LMO release / import for releasing
- ❖ Establish application mechanism
- ❖ Require export notification to the authority of the place of import and its prior consent before the shipment
- ❖ Provide penalties for violation
- ❖ Establish a public register
- ❖ Secretary to specify shipment documentation requirements / to grant exemptions

Operation – Release into the Environment

- ❖ Defined as “release into the environment” if LMO is not in “contained use”
- ❖ Contained use – any operation, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific manner to *effectively limit their contact with, and their impact on, the external environment*

Operation – Decision Making Process



- ❖ Approval application to AFCD for release of an LMO into the environment
- ❖ Information received (excluding confidential information) will be posted to a public register
- ❖ Seek Expert Group's comments
- ❖ Director to take into account the findings of the risk assessment and comments from the Expert Group in decision making
- ❖ Approved LMOs entered in the register, no applications are needed for subsequent releases

Operation – Risk Assessment

- ❖ On a case-by-case basis
- ❖ Identify novel genotypic and phenotypic characteristics of the LMO that may have adverse effects on biodiversity
- ❖ Identify likelihood of the adverse effects being realized
- ❖ Evaluate consequences / estimate overall risks
- ❖ Evaluate whether the risks are *acceptable* / *manageable*
- ❖ uncertainty of the risks → request further information

Operation – Risks to be Assessed

- ❖ Adverse effects on the conservation and sustainable use of biodiversity
- ❖ Effects on other components of the environment (e.g. air, water, noise, etc) excluded
- ❖ Risks on human health resulted through the effects on biodiversity only
- ❖ Not dealing with food safety / GM food labelling issues

Operation – Expert Group

- ❖ To advise the Director on LMO approval applications and other matters related to operation of the proposed legislation
- ❖ Consist of experts from academics, industry, NGOs in the fields of agriculture, biodiversity, biotechnology, risk assessment and management, etc.
- ❖ Director to take into account comments from the Expert Group in decision making

Operation – Register

- ❖ A centralized source of information
- ❖ The Biosafety Clearing House of HK
- ❖ In digital format and accessible by the public through the internet
- ❖ Contain
 - applications / supporting information
 - exemptions granted by the Secretary
 - other relevant information on the legislation, the Protocol and biosafety
- ❖ Exclude confidential information

Operation – Shipment Documentation (1)

- ❖ Three categories of documentation accompanying import / export
 - LMO for release into the environment
 - LMO for direct use as food, feed or processing
 - LMO for contained use



Operation – Shipment Documentation (2)

❖ LMO for release into the environment

- Should indicate that the shipment contains LMOs for intentional introduction into the environment
- A brief description of the LMOs
- Any requirement for the safe handling, storage, transport and use of the LMOs
- The name and address of the exporter and importer
- The details of the contact point for further information
- A declaration that the movement of the LMOs is in conformity with the requirements of the Protocol applicable to the exporter
- The commercial name, where available, risk class and import approval for the first transboundary movement

Operation – Shipment Documentation (3)

❖ LMO for food, feed or processing

- Should indicate that the shipment “contains” / “may contain” LMOs that are intended for direct use as food or feed or for processing
- The LMOs are not intended for introduction into the environment
- The common name, scientific name and, where available, the commercial name of the LMOs
- The transformation event code of the LMOs
- The internet address of the Biosafety Clearing-House for further information
- The details of a contact point for further information

Operation – Shipment Documentation (4)

❖ LMO for contained use

- Should indicate that the shipment contains LMOs “destined for contained use”
- The name and address of the consignee & exporter / importer
- Any requirements for the safe handling, storage, transport and use of the LMOs
- the commercial name, if available, new or modified traits and characteristics such as event(s) of transformation, risk class, specification of use and any unique identification, where available.

Operation – Shipment Documentation (5)

❖ Form of documentation

- No specific requirement
- The use of a commercial invoice or other documents required by other documentation systems is acceptable
- Should include the information specified above and allow for easy recognition

Operation – Sampling and Testing

- ❖ Random inspections and samplings
- ❖ Tested by accredited laboratories
- ❖ Results may be used for law enforcement and prosecution purposes

Operation – Adventitious Threshold

- ❖ Contamination inevitable in commercial production, storage, transportation of agricultural products
- ❖ Traditional varieties for food, feed or processing with an adventitious present of < 5% LMO varieties are exempted from the documentation requirements
- ❖ No exemption for “release into the environment” or “contained use”



Operation – Transitional Arrangement

- ❖ To apply for approval of an LMO for release into the environment
- ❖ To report to the Director for disposal directions
- ❖ No requirements for LMO shipment documentation
- ❖ No notification requirements for LMO export





Your Advice, please!