

Genetically Modified Organisms(Control of Release) Ordinance



Briefing on Genetically Modified Organisms (Documentation for Import and Export) Regulation



The Cartagena Protocol on Biosafety to The Convention on Biological Diversity

- **▶** The Convention on Biological Diversity
 - **✓** Conservation of biological diversity.
 - **✓** Sustainable use of the components of biological diversity.
 - ✓ Fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

CARTAGENA

PROTOCOL
ON
BIOSAFETY
TO THE
CONVENTION
ON
BIOLOGICAL
DIVERSITY

TEXT AND ANNEXES

- The Cartagena Protocol on Biosafety
 - ✓ Some GMOs may have adverse effects on conservation and sustainable use of biological diversity.
 - **✓** Provides for the safe transfer, handling and use of those GMOs.
- ➤ The objective of the GMOs (Control of Release) Ordinance is to implement the Cartagena Protocol on Biosafety in Hong Kong.

GMOs (Control of Release) Ordinance

- The Ordinance will control the release into the environment and the transboundary movement of GMOs, and provide for related matters.
- Implementation of the Protocol can
 - **✓** better protect our biological diversity.
 - help you to meet the Protocol's international requirements on import and export of GMOs (most of Hong Kong's trading partners, including China, Japan and EU, are already Parties to the Protocol).
 - **✓** facilitate the identification of GMO in import and export shipments.



Purposes of the Consultation Meeting

- The Administration is preparing the subsidiary GMOs (Documentation for Import and Export) Regulation to the GMOs (Control of Release) Ordinance.
- > Introduce the legislative intent of the Ordinance.
- Explain in detail of the requirements of the subsidiary Regulation.
- Solicit your comments on the Regulation.



GMOs (Control of Release) Ordinance

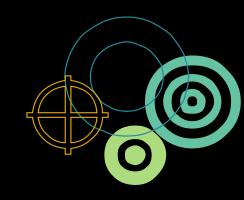
▶ What is GMO?

- possess a novel combination of genetic material obtained through the use of modern biotechnology (e.g. recombinant DNA technology).
- ✓ include a number of GM agricultural produce (e.g. tomato, rice and soybean), seeds, vaccines, cut flowers, animals, etc.

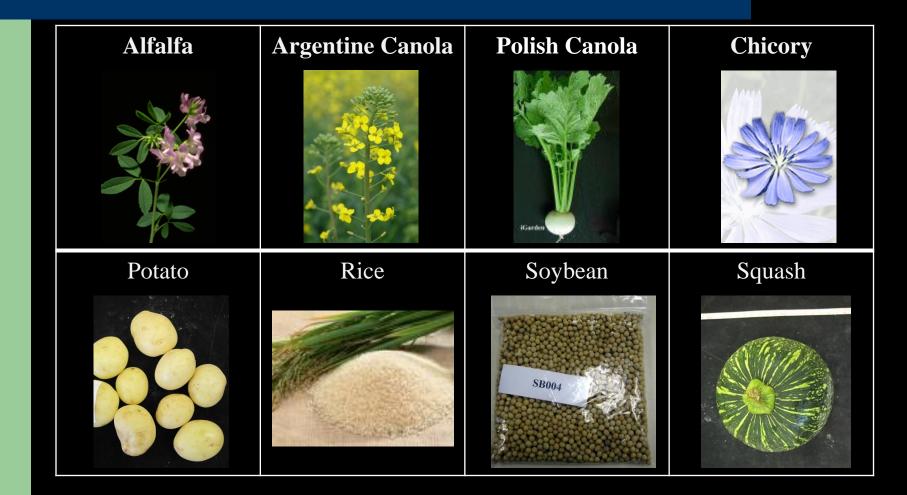


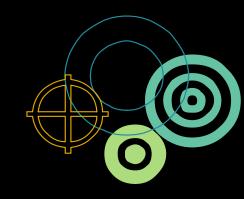
- ✓ do not include non-living agricultural produce, such as cotton fibre and flour.
- ✓ also exclude living organisms with genetic material altered through traditional breeding and selection techniques (e.g. hybrid rice and golden sweet corn).



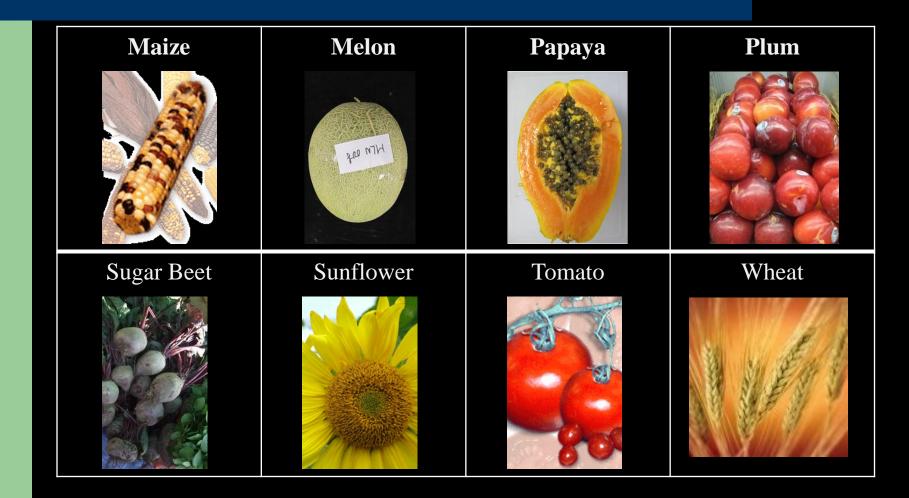


GM Crops Grown Overseas





GM Crops Grown Overseas



GMOs (Control of Release) Ordinance

➤ Prior approval has to be sought from the Director of Agriculture, Fisheries and Conservation before a GMO can be released or imported for release into the environment of Hong Kong.

Subject to the regulatory requirements of the exporting place, prior approval from the competent authority of the place in which a GMO is to be exported for release may be required and a copy of the export notification should be sent to AFCD.



Prescribed Documents

➤ The requirement for provision of prescribed document does NOT apply to the import and export of GMO that is a pharmaceutical product for use by human beings.



- Shipments of the following GMOs should be accompanied by prescribed documents when being imported or exported:
 - **✓** intended for contained use;
 - **✓** intended for release into the environment; and
 - ✓ <u>intended for direct consumption as food or feed, or for processing</u>
- Contravention of the documentation requirements is liable on conviction to a fine at level 3 (i.e. \$10,000)







Definition for Contained Use

- ✓ It is involved in an operation that is undertaken within a facility, installation or other physical barrier; and
- ✓ It is controlled by specific measures that effectively limit its contact with, and its impact on, the environment



Examples

- ✓ Cultivation of GM plants in greenhouse with effective filtering system to restrict the dispersal of pollen to the external environment
- ✓ Keeping knock-out mice inside an escape-proof cage in a laboratory



➤ Prior approval from AFCD is not required for GMO intended for contained use or imported for contained use. Shipment of the GMO should be accompanied by the prescribed documents when being imported or exported.



Release into the Environment

- Definition of release into the environment
 - **✓** The GMO is not in contained use; and
 - **✓** is exposed to a condition in which it may grow or reproduce
- **Examples**
 - ✓ Growing GM papaya in open field, including field trials conducted by laboratories
 - **✓** Use of GM vaccine in animals
 - **✓** Place GM cut flowers at outdoor environment
- Prior approval from AFCD is required for GMO intended for release into the environment or imported for release. Shipment of the GMO should also be accompanied by the prescribed documents when being imported or exported.

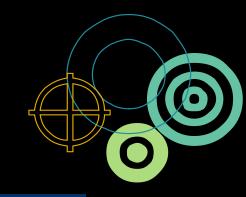




Food, Feed or for Processing

- ➤ Prior approval from AFCD is not required for GMO intended to be used as food, feed or for processing (GMO-FFP). Shipment of the GMO should be accompanied by the prescribed documents when being imported or exported.
- **▶** What is GMO-FFP?
 - ✓ for direct consumption as food, e.g. GM papaya as fruit
 - ✓ as feed, e.g. GM maize for feeding pigs
 - **✓** for processing, e.g. GM soybean for making sauce





Adventitious Threshold

The Ordinance provides an adventitious threshold for the import or export of GMO-FFP

- ✓ The % of the amount of the GMOs to the total amount of living organisms in the lot does not exceed the prescribed % (the suggested % is 5%);
- ✓ The GMOs are imported or exported in a lot together with other living organisms;
- ✓ The GMOs are unintentionally mixed with those other living organisms; and
- **✓** The shipment is not required to be accompanied by the prescribed documents when being imported or exported.



- ➤ The GMOs (Documentation for Import and Export) Regulation specifies the requirements of the prescribed documents.
- ➤ Form of documentation is not specified and the following forms are acceptable:
 - **✓** Commercial invoice
 - **✓** Import / export manifests
 - **✓** Phytosanitary certificates
 - **✓** Animal quarantine certificate
 - **✓** Special permit for importation of animals
- ➤ The required information should be clearly shown to allow for easy identification.



Prescribed Documents — GMO Intended for Contained Use

The prescribed documents for importing or exporting of GMO intended for contained use should contain the following information:

- a) a statement that the shipment in which the GMO is imported or exported contains a GMO and the GMO is intended for contained use;
- b) the common name, scientific name and, where available, commercial name of the GMO;
- c) the name, address and contact details of the consignee and the exporter or importer;



Prescribed Documents — GMO Intended for Contained Use

- d) the requirement, if any, for the safe handling, storage, transport and use of the GMO under applicable existing international instruments, the local legislation of Hong Kong or any agreement entered into by the importer or exporter, as the case may be;
- e) if there is no requirement under paragraph (d), a statement that there is no such requirement; and,
- f) new or modified traits or characteristics of the GMO such as event of transformation, risk class, specification of use, and any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House



Prescribed Documents — Import of Arabidopsis for contained use

Declaration

This shipment contains genetically modified Arabidopsis seeds, which are intended for contained use.

Common Name: Arabidopsis Scientific Name: Arabidopsis thaliana Commercial Name: Not Applicable

Name of Recipient: Peter Chan Address: Room A, 3/F, Hong Kong Court, Hong Kong Street, Hong Kong

Name of Importer: David Chan Address: Room B, 11/F, Kowloon Court, Kowloon Street, Kowloon

The requirement for the safe handling, storage, transport and use of the GMO under applicable legislation of Hong Kong

The Hong Kong Legislation Chapter 207 Plant (Importation and Pest Control) Ordinance Section 4(3):

Subject to section 5, no person shall import any plant other than a plant specified in the First Schedule, unless-

- (a) it is imported subject to the conditions of a plant import licence issued in respect thereof; and
- (b) it is accompanied by a valid phytosanitary certificate.

New or modified traits or characteristics of the GMO

The GM Arabidopsis was created by *Agrobacterium*-mediated transformation to introduce the encoding gene of thioesterase from Laurel *Umbellularia californica* (the Biosafety Clearing-House record identification number 15005), resulting in the accumulation of lauric acid (12:0) and myristic acid (14:0). The purpose of this import is to study the extraction method of myristic acid.

Prescribed Documents — GMO Intended for Release Into Environment

- Prescribed documents for importing or exporting of GMO intended for release into the environment should contain the following information:
 - a) a statement that the shipment in which the GMO is imported or exported contains a GMO;
 - b) the common name, scientific name and commercial name of the GMO;
 - c) the relevant traits and characteristics of the GMO, including transgenic traits and characteristics (such as event of transformation or, where available and applicable, a reference to its system of unique identification code);
 - d) The requirement for the safe handling, storage, transport and use of the GMO under applicable existing international instruments, local legislation or any agreement entered into by the exporter or importer;

Prescribed Documents — GMO Intended for Release Into Environment

- e) if there is no requirement under paragraph (d), a statement that there is no such requirement;
- f) the name and address of the importer and exporter;
- g) the details of the contact point for further information, including an individual or organization in possession of information for safe handling, storage, transport and use of the GMO in case of emergency;
- h) the risk class of the GMO in the exporting country and, the approval for the release of the GMO into the environment granted under this Ordinance; and
- i) a declaration that the movement of the GMO is in conformity with the requirements of the Protocol applicable to the exporter.





Declaration

This shipment contains genetically modified maize.

Common Name: BT maize Scientific Name: Zea mays L. Commercial Name: NaturGardTM KnockOutTM

Transformation Event Code: 176 **Unique Identifier Code:** SYN-EV176-9

Website of the Biosafety Clearing-House: http://bch.cbd.int/

The BT maize was produced by biolistic transformation to introduce the truncated cry1Ab gene of *Bacillus thuringiensis subsp. Kurstak* to provide resistance to European corn borer. The bar gene of *Streptomyces hygroscopicus* was also introduced to provide resistance to the glufosinate herbicide.

The requirement for the safe handling, storage, transport and use of the GMO under applicable legislation of Hong Kong

The Hong Kong Legislation Chapter 207 Plant (Importation and Pest Control) Ordinance Section 4(3):

Subject to section 5, no person shall import any plant other than a plant specified in the First Schedule, unless-

- (a) it is imported subject to the conditions of a plant import licence issued in respect thereof; and
- (b) it is accompanied by a valid phytosanitary certificate.

Name of Exporter: David Ng Address: Room A, 3/F, Hong Kong Court, Hong Kong Street, USA

Name of Importer: Peter Chan Address: Room A, 3/F, Hong Kong Court, Hong Kong Street, Hong Kong

Details of Contact Point: Syngenta Seeds, Inc. **Address:** 7500 Olson Memorial Highway, Golden Valley, MN, USA

Approval No. under the GMO (Control of Release) Ordinance: 20100226-01

Declaration

The movement of the GMO is in conformity with the requirements of the Protocol applicable to the exporter.

Signature of Importer: Company Chop Date::





- Prescribed documents for importing or exporting of GMO-FFP should contain the following information:
 - a) A statement that the shipment in which the GMO is imported or exported contains or may contain GMO and that the GMO is not intended for release into the environment;
 - b) The common name, scientific name and, where available, commercial name of the GMO;
 - c) The transformation event code of the GMO or, where available, its unique identifier code;
 - d) the Internet address of the Biosafety Clearing-House of the GMO; and
 - e) the name, address and contact details of the importer, or exporter or, where an authority designated by the government of a place is able to provide further information relating to the GMO, the authority.

Prescribed Documents — Import of GM Papaya as Food



Declaration

The shipment contains genetically modified papaya intended to be used as food and is not intended for release into the environment.

Common Name: Hawaii Papaya Scientific Name: Carica papaya

Commercial Name: Sunset Papaya

Transformation Event Code: 55-1 **Unique Identifier Code:** CUH-CP551-8

The Internet Address of the Biosafety Clearing House of the GMO

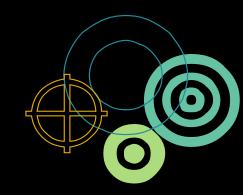
http://bch.cbd.int/database/record-v4.shtml?documentid=40294

Name of the Importer: David Chan

Address: Room A, 3/F, Hong Kong Court, Hong Kong Street, Hong Kong

Signature of Importer: Company Chop Date:





- ➤ The following websites contain the relevant information for most of the commercialized GMO produce
 - ✓ The Biosafety Clearing-House http://bch.cbd.int/
 - ✓ AGBIOS http://www.agbios.com/dbase.php
- ➤ There are over 150 Parties to the Protocol, including most of the trading partners of Hong Kong. The producers and traders of these Parties have been following the same requirements of the Protocol for many years. Such information should be readily available from them.
- ➤ The Genetically Modified Organisms Register of AFCD contains relevant information on the approved GMO and other GMOs. The Register will be updated on a regular basis. You can browse the Register at http://www.afcd.gov.hk/GMO or contact AFCD for more information

GMO (Control of Release) Ordinance GMO (Documentation for Import and Export) Regulation



- ➤ The Ordinance and the Regulation will be gazetted in mid of March and mid of May 2010 respectively and expected to commence by late 2010 / early 2011.
- > Detailed information about the Ordinance and the Regulation can be obtained from:

Biodiversity Conservation Division
Agriculture, Fisheries and Conservation Department
Government of Hong Kong Special Administrative Region
Address: 6/F, Cheung Sha Wan Government Offices
303 Cheung Sha Wan Road, Kowloon, Hong Kong

Tel: 2150 6918 Fax: 2314 2802

Website: http://www.afcd.gov.hk/GMO

Email: biosafety@afcd.gov.hk