



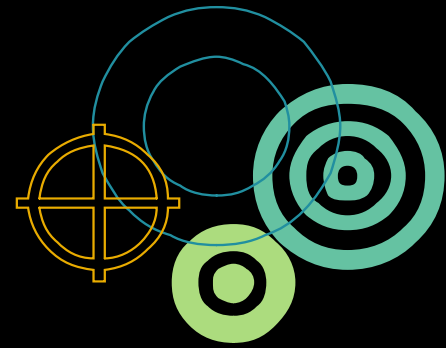
Genetically Modified Organisms (Control of Release) Ordinance



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



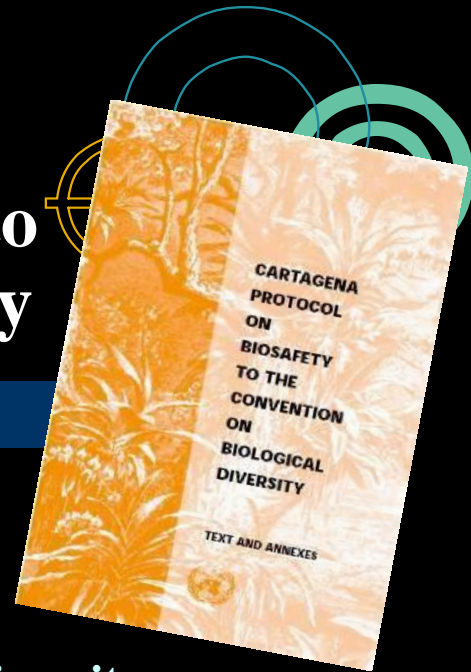
Purposes of the Consultation Meeting



- **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.**



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.**
- **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.**



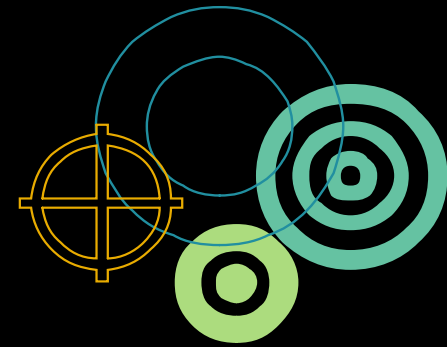
GMOs (Control of Release) Ordinance



➤ 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

Alfalfa



Argentine Canola



Polish Canola



Chicory



Potato



Rice



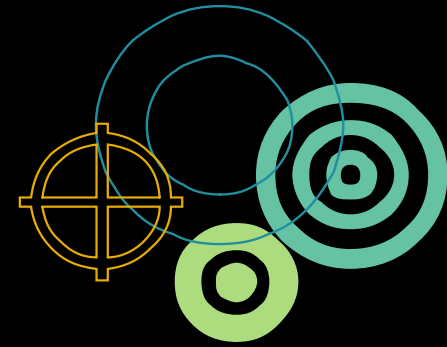
Soybean



Squash



GM Crops Grown Overseas



Maize



Melon



Papaya



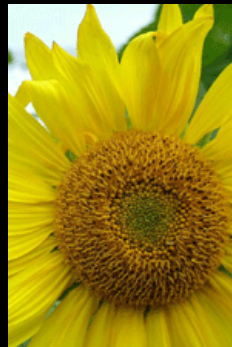
Plum



Sugar Beet



Sunflower



Tomato



Wheat



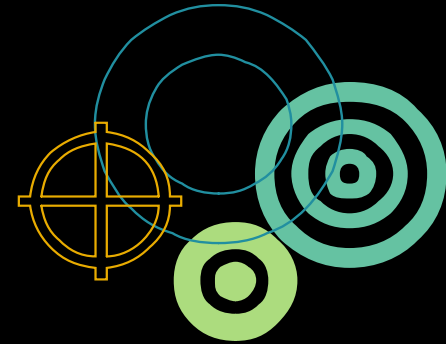
GMOs (Control of Release) Ordinance



- 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.



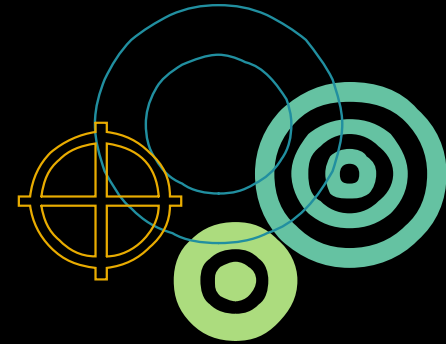
Prescribed Documents



- 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
 - ✓ intended for direct consumption as food or feed, or for processing
- Contravention of the documentation requirements is liable on conviction to a fine at level 3 (i.e. \$10,000)



Contained Use



➤ 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**

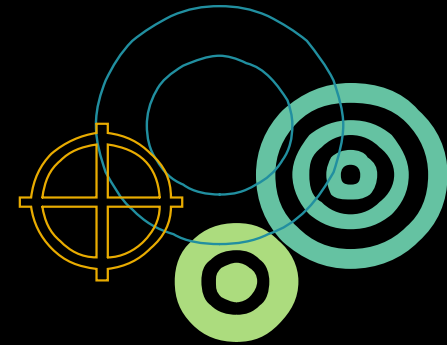


➤ Examples

- ✓ 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.

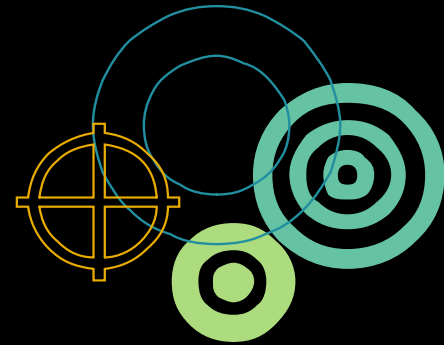


Release into the Environment

- **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.



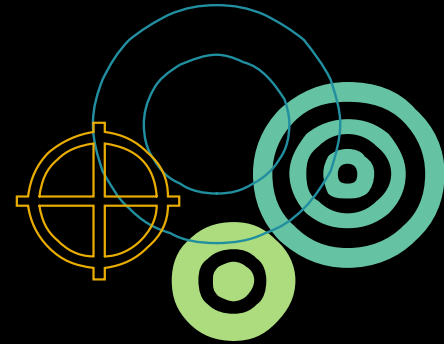
Food, Feed or for Processing



- 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
- Prior approval from AFCD **is not required** for GMO intended for direct consumption as food or feed or for processing (GMO-FFP). Shipment of the GMO should be accompanied by the prescribed documents when being imported or exported.

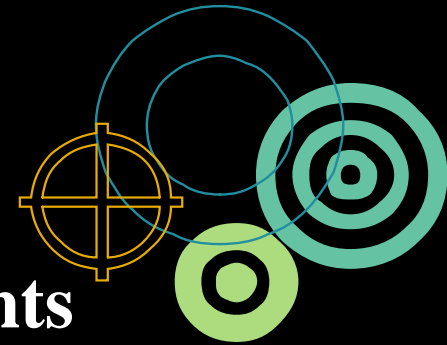


Adventitious Threshold



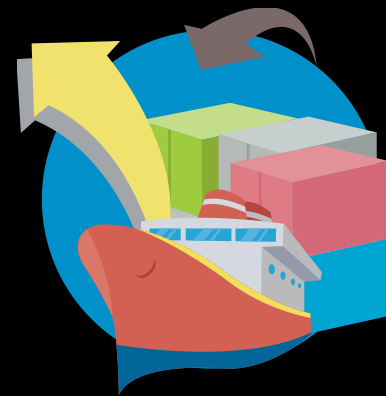
The Ordinance provides an **adventitious threshold** for the import or export of GMO-FFP

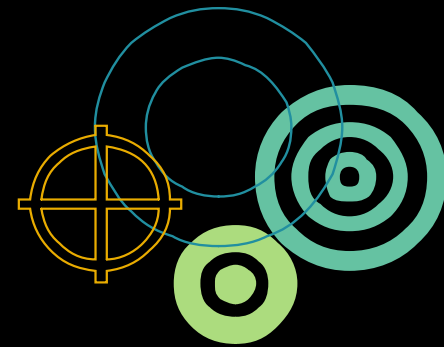
- ✓ The % of the amount of the GMOs to the total amount of living organisms in the lot does not exceed the prescribed % (the suggested % is **5%**);
- ✓ The GMOs are imported or exported **in a lot together** with other living organisms;
- ✓ The GMOs are **unintentionally** mixed with those other living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



Requirement of the Prescribed Documents

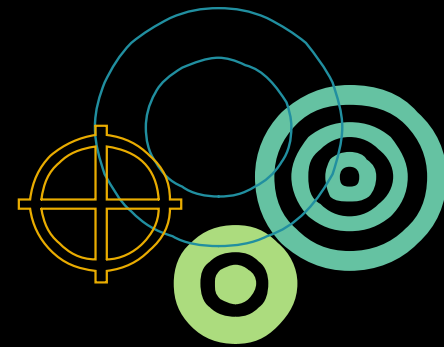
- **The GMOs (Documentation for Import and Export) Regulation specifies the requirements of the prescribed documents.**
- **Form of documentation is not specified and the following forms are acceptable:**
 - ✓ **Commercial invoice**
 - ✓ **Import / export manifests**
 - ✓ **Phytosanitary certificates**
 - ✓ **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 **contains** a GMO that is **intended for contained use**;
 - b) the common **name**, scientific name and, if 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 any applicable existing international instruments, the local legislation of Hong Kong or any agreement entered into by the importer and exporter;
- 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 (including specification of use of the GMO and, if available, the transformation event code, unique identifier code and risk class of the GMO)

Prescribed Documents — Import of GM carnation for contained use



This shipment contains genetically modified carnation cut flowers intended for contained use.

Common name: genetically modified carnation

Scientific name: *Dianthus caryophyllus*

Commercial name: Moonshadow™

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

Tel: 2234 5678

Fax: 2234 5679

Email: efgh@abcd.com

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

Tel: 2234 5678

Fax: 1234 5679

Email: abcd@abcd.com

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):

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

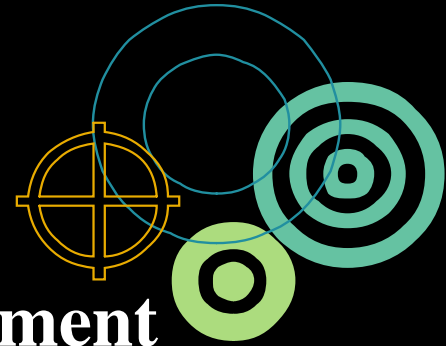
The GM carnation (transformation event code: 11363; unique identifier code: FLO-11363-1) was created by the introduction of the encoding gene of dihydroflavonol 4-reductase (DFR) from *Petunia hybrida* and flavonoid 3'5' hydroxylase from *Viola*. The GMO will be used as indoor ornamental plant.

Signature of Importer:.....

Company Chop

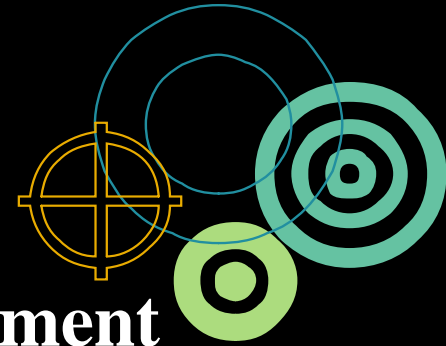
Date:

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 **contains** a GMO that is intended for **release into the environment**;
 - b) the name, address and **contact details** of the importer and exporter;
 - c) the name, address and contact details of any person who is able to provide information relating to the safe handling, storage, transport or use of the GMO in case of emergency;
 - d) the common name, scientific **name** and commercial name of the GMO;

Prescribed Documents — GMO Intended for Release Into Environment



- e) the **traits and characteristics** of the GMO, including the transgenic traits and characteristics of the GMO (including the transformation event code of the GMO and, if available, the unique identifier code and risk class of the GMO;
- f) The requirement for the **safe handling, storage, transport and use** of the GMO under any applicable existing international instruments, local legislation or any agreement entered into by the exporter and importer;
- g) if there is no requirement under paragraph (d), a statement that there is no such requirement;
- h) the **approval number** assigned to the approval under the Ordinance and the conditions attached to the approval, if any; and
- i) **a declaration** that the movement of the GMO is in conformity with the requirements of the Protocol applicable to the exporter.

Prescribed Documents — Import of GM maize for Release into Environment



This shipment contains genetically modified maize seeds intended for release into the environment.

Common name: BT maize **Scientific name:** *Zea mays* **Commercial name:** NaturGard™ KnockOut™

Transgenic traits and characteristics: The BT maize (**transformation event code:** 176 ; **unique identifier code:** SYN-EV176-9) was produced by the introduction of 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):

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, ABC Court, ABC Street, USA **Tel:** 1234 5678

Name of importer: Sue Chan **Address:** Room A, 3/F, ABC Court, ABC Street, Hong Kong **Tel:** 2234 5678

The person who is able to provide information relating to the safe handling, storage, transport or use of the GMO in case of emergency

Name: Sam Cheung **Address:** Room B, 3/F, ABC Court, ABC Street, Hong Kong **Tel:** 2234 5679

Approval No. under the GMO (Control of Release) Ordinance: 20120226-01

Declaration

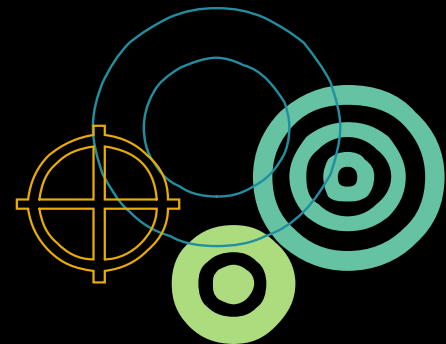
The movement of the GMO is in conformity with the requirements of the Protocol applicable to the exporter.

Signature of Importer:.....

Company Chop

Date::

Prescribed Documents — GMO-FFP



- Prescribed documents for importing or exporting of **GMO-FFP** should contain the following information:
 - a) A statement that the shipment **contains** or **may contain** GMO that is intended for direct consumption as **food or feed or for processing** and a statement to the effect that the GMO is **not intended for release** into the environment;
 - b) **the Internet address of the Biosafety Clearing-House**; and
 - c) the name, address and **contact details** of the importer, exporter and each designated authority in relation to the GMO, if any.
 - d) The common **name**, scientific name and, if available, commercial name of the GMO;
 - e) The transformation event code of the GMO and, if available, its unique identifier **code**;

Prescribed Documents — Import of GM **Papaya** as Food



The shipment contains genetically modified papaya intended to be used as food for direct consumption. The GM papaya 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: <http://bch.cbd.int/>

Name of exporter: David Ng **Address:** Room A, 3/F, ABC Court, ABC Street, USA **Tel:** 1234 5678

Name of importer: Sue Chan **Address:** Room A, 3/F, ABC Court, ABC Street, Hong Kong **Tel:** 2234 5678

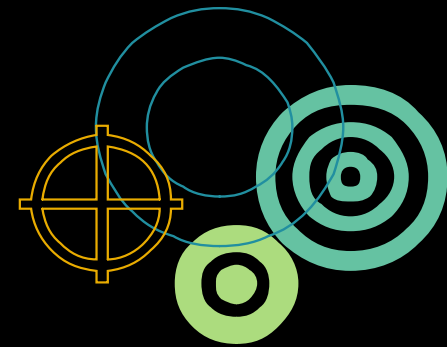
Name of the designated authority: Food and Drug Administration (USA) **Tel:** 800-216-7331

Address: 10903 New Hampshire Ave, Silver Spring, MD 20993-0002

Signature of Importer:.....

Company Chop

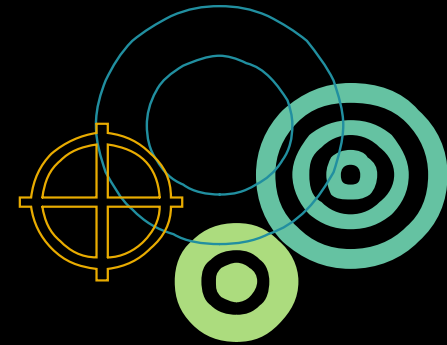
Date:



How to Find the Information for the Prescribed Documents ?

- 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 are expected to **commence by 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**