

LEGISLATIVE COUNCIL BRIEF

Genetically Modified Organisms (Control of Release) Ordinance

GENETICALLY MODIFIED ORGANISMS (DOCUMENTATION FOR IMPORT AND EXPORT) REGULATION

INTRODUCTION

By virtue of section 50(1) of the Genetically Modified Organisms (Control of Release) Ordinance (the Ordinance), the Secretary for the Environment (the Secretary) has made the Genetically Modified Organisms (Documentation for Import and Export) Regulation (the Regulation) (at **Annex A**) on 5 July 2010.

JUSTIFICATIONS

2. The Ordinance was enacted on 18 March 2010 after being passed by the Legislative Council (LegCo). It seeks to implement the relevant requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Protocol). The Protocol is an international agreement adopted under the Convention on Biological Diversity (the Convention) in 2000. It aims to ensure the safe transfer, handling and use of genetically modified organisms (GMOs) produced from modern biotechnology, as the GMOs concerned may have adverse impacts on the conservation and sustainable development of biological diversity.

3. The existing nature conservation policy of Hong Kong and our conservation measures are generally in line with the objectives and requirements of the Convention. The only area that further works are required in order to comply with the Convention is the regulation, management, and control of the risks associated with the use and release of GMOs into the environment, as stipulated under the Protocol. To this end, the Ordinance was drawn up and then enacted in March 2010 to provide for the legal basis to implement the relevant requirements set out in the Protocol for the regulation of GMOs.

4. Section 26 of the Ordinance (at **Annex B**) provides that GMOs that are intended for direct consumption as food or feed, or for processing (GMOs-FFP),

or which are intended for contained use or for release into the environment must be accompanied by specified documents when being imported into or exported from Hong Kong. This section has also provided exceptions to the requirements if certain conditions are met. Details of the exceptions are set out in paragraphs 7 to 9 below. The Regulation seeks to set out the detailed documentation requirements under the framework prescribed in section 26 of the Ordinance.

Documentation requirements

5. To ensure safe handling and movement of GMOs and to provide information to those handling GMOs, Article 18.2 of the Protocol (at **Annex C**) requires the Parties to the Protocol to provide documentations with required information when conducting transboundary movements of GMOs. Under Article 18.2 of the Protocol, the documentation requirements vary for GMOs-FFP; GMOs that are intended for contained use; and GMOs that are intended for release into the environment.

6. In addition, Parties to the Protocol meet every two years to review the implementation of the Protocol and make decisions necessary to promote its effective implementation. Detailed requirements on the information to be provided in the documentations are drawn up by the Parties to the Protocol in their conferences. The documentation requirements set out in the Regulation closely follow Article 18.2 of the Protocol and the decisions made by the Parties to the Protocol in their conferences.

Prescribed percentage for exception (Adventitious Threshold)

7. Section 26 of the Ordinance provides that documentation requirements would not be required for GMOs-FFP or GMOs that are intended for contained use, if (a) where the GMOs concerned are imported or exported in a lot together with other living organisms; (b) the GMOs are unintentionally mixed with those other living organisms; and (c) the percentage of the quantity of the GMOs to the total quantity of living organisms in the lot does not exceed the prescribed percentage. The prescribed percentage is to be prescribed by regulations made under section 50(1) of the Ordinance by the Secretary, and if no percentage is prescribed, it will be 0%. The Regulation proposes to prescribe the percentage for GMOs-FFP at 5%, but has not prescribed any percentage for GMOs for contained use.

8. The reason is that the mixing of products from different sources, including genetically modified varieties, is inevitable in commercial agricultural production, storage and transportation of agricultural products. Some Parties to the Protocol, such as Japan, Indonesia, Philippines and Thailand have adopted thresholds at 5% under their domestic regulatory framework for the adventitious presence of GMOs for triggering the documentation requirements. Taking into account the small scale of local agricultural industry in Hong Kong and the fact that most GMOs-FFP are in fact not grown in Hong Kong, it is recommended that Hong Kong follows the practice of such Parties to the Protocol in adopting adventitious threshold for GMOs-FFP at 5% for triggering the need for documentation requirements. In other words, if the percentage of GMOs in a shipment of living organisms for FFP does not exceed 5%, the shipment is not required to be accompanied by documentation identifying the presence of GMOs. We consider that the proposed threshold reflects a pragmatic and realistic level for the Government to manage the possible risks to our biological diversity, and for the trade to comply with.

9. However, a zero tolerance of adventitious presence of GMOs is recommended for GMOs intended to be released to the environment as well as for contained use. This is because if GMOs are mixed with non-GMOs and the whole lot is released into the environment, the GMOs concerned may have adverse impacts on local biodiversity. The zero tolerance level for GMOs intended for release into the environment has therefore been adopted by many Parties to the Protocol, such as the Mainland, the European Union and the South Korea. As organisms for contained use are generally for scientific research purposes, it is reasonable to expect that these organisms would unlikely be mixed with GMOs unintentionally and their identities should also be known, hence no adventitious presence of GMOs is proposed.

THE REGULATION

10. The Regulation provides for the detailed documentation requirements in relation to GMOs-FFP, GMOs that are intended for contained use and GMOs that are intended for release into the environment. This Regulation also provides the prescribed percentage of the unintentional mixing of GMOs-FFPs to be 5%.

11. Meanwhile, we are seeking the Central People's Government's agreement

to initiate the required procedures to extend the application of the Convention and the Protocol to Hong Kong. The Ordinance, together with the Regulation, are intended to commence operation upon the extension of the Convention and the Protocol to Hong Kong.

LEGISLATIVE TIMETABLE

12. The legislative timetable is as follows –

Gazettal of the Regulation	9 July 2010
Tabling at the Legislative Council	14 July 2010
Commencement	On a date to be separately appointed by SEN (upon the extension of the Convention and the Protocol to Hong Kong)

IMPLICATIONS OF THE REGULATION

13. The Regulation is in conformity with the Basic Law, including the provisions concerning human rights. The Regulation does not affect the current binding effect of the Ordinance. Any additional workload and recurrent cost arising from the implementation of the proposed Regulation will be absorbed within the existing resources of the Agriculture, Fisheries and Conservation Department (AFCD).

14. The economic, environmental and sustainability implications of the Regulation are set out at **Annex D**.

PUBLIC CONSULTATION

15. We have consulted the Legislative Council Panel on Environmental Affairs in March 2009 in relation to the legislative proposal to implement the requirements of the Protocol in Hong Kong. Consultation on the proposed Regulation with the relevant stakeholders including traders, food and beverage producers, medicine manufacturers, academics, biotechnology companies, green groups, organic farms and World Trade Organization had been conducted from 1 February to 31 March 2010. They were invited to give views on the proposed Regulation. Two consultation meetings were held on 26 February 2010 and 5

March 2010 to brief stakeholders on the documentation requirements and to collect their views.

16. During consultation, many respondents had raised questions relating to the documentation requirements so as to determine whether their import or export of shipments would be affected by this proposed Regulation, and if so, how to comply with the documentation requirements. Some participants had expressed concerns over the unintentional importation or release of GMOs and suggested that the Government should step up the publicity to educate the public about GMOs and the Regulation. Written comments were also received highlighting similar concerns and the Government was urged to strengthen its control over GMOs and further clarifications were sought on the control to be imposed on GMOs for research purposes. The comments so received had been taken into account in finalising the Regulation.

PUBLICITY

17. A spokesman will be available to handle media enquiries. The AFCD will step up publicity and public awareness programme before the commencement of the Regulation. Pamphlets will be distributed to stakeholders to introduce the new Regulation and notify them of the commencement date. Such information will also be made available to the public on the AFCD's website at www.afcd.gov.hk/GMO.

ENQUIRY

18. Any enquiry of this brief should be directed to Miss Vivien LI, Senior Administrative Officer (Nature Conservation) on telephone 2594 6229 or fax 2136 3304.

Environmental Protection Department
Agriculture, Fisheries and Conservation Department
July 2010

**GENETICALLY MODIFIED ORGANISMS
(DOCUMENTATION FOR IMPORT AND EXPORT)
REGULATION**

(Made by the Secretary for the Environment under section 50 of the
Genetically Modified Organisms (Control of Release) Ordinance (7 of
2010))

1. Commencement

This Regulation comes into operation on a day to be appointed by the Secretary for the Environment by notice published in the Gazette.

2. Interpretation

In this Regulation –

“exporter” (輸出者) –

- (a) in relation to a GMO imported into Hong Kong from another place, means the person who exports the GMO from that other place; or
- (b) in relation to a GMO exported from Hong Kong to another place, means the person who exports the GMO from Hong Kong;

“importer” (輸入者) –

- (a) in relation to a GMO imported into Hong Kong from another place, means the person who imports the GMO into Hong Kong; or
- (b) in relation to a GMO exported from Hong Kong to another place, means the person who imports the GMO into that other place;

“safety requirement” (安全規定), in relation to a GMO imported into or exported from Hong Kong, means any requirement for the safe handling, storage, transport or use of the GMO under –

- (a) any applicable existing international instrument;
- (b) any Ordinance; or
- (c) any agreement entered into by the importer and exporter of the GMO;

“transformation event code” (轉基因事件編碼), in relation to a GMO, means the code given to the GMO by the person who develops the GMO on the integration of a transgene into the cell of the GMO;

“unique identifier code” (獨特標識編碼), in relation to a GMO, means the unique code that is –

- (a) assigned to the GMO in accordance with the Organisation for Economic Co-operation and Development Guidance for the Designation of a Unique Identifier for Transgenic Plants; and
- (b) entered into the Biosafety Clearing-House or other unique identification systems adopted by the Conference of the Parties.

3. Documentation required for GMOs intended for direct consumption as food or feed or for processing

(1) For the purposes of section 26(1) of the Ordinance, a GMO that is intended for direct consumption as food or feed or for processing must, when being imported into or exported from Hong Kong, be accompanied by a document that contains –

- (a) the statements specified in subsection (2); and
- (b) the particulars specified in subsection (3).

(2) The statements are –

- (a) a statement to the effect that –
 - (i) if the identity of the GMO is not known, the shipment in which the GMO is imported or exported may contain a GMO that is intended for

direct consumption as food or feed or for processing; or

- (ii) if the identity of the GMO is known, the shipment in which the GMO is imported or exported contains a GMO that is intended for direct consumption as food or feed or for processing; and

- (b) a statement to the effect that the GMO is not intended for release into the environment.

(3) The particulars are –

- (a) the Internet address of the Biosafety Clearing-House;
- (b) the name, address and contact details of –
 - (i) the importer and exporter of the GMO; and
 - (ii) each designated authority in relation to the GMO, if any; and
- (c) if the identity of the GMO is known –
 - (i) its common name and scientific name and, if available, its commercial name; and
 - (ii) its transformation event code and, if available, its unique identifier code.

(4) In this section –

“designated authority” (指定當局), in relation to a GMO imported into Hong Kong from another place or exported from Hong Kong to another place, means an authority designated as the contact point to provide information relating to the GMO by –

- (a) the Director; or
- (b) the government of that other place.

4. Documentation required for GMOs intended for contained use

- (1) For the purposes of section 26(1) of the Ordinance, a GMO that is intended for contained use must, when being imported into or exported from Hong Kong, be accompanied by a document that contains –
- (a) a statement to the effect that the shipment in which the GMO is imported or exported contains a GMO that is intended for contained use;
 - (b) the safety requirements applicable to the GMO or, if there is no such requirement, a statement to that effect; and
 - (c) the particulars specified in subsection (2).
- (2) The particulars are –
- (a) the name, address and contact details of the consignee;
 - (b) the name, address and contact details of –
 - (i) if the GMO is imported into Hong Kong from another place, the importer of the GMO; or
 - (ii) if the GMO is exported from Hong Kong to another place, the exporter of the GMO;
 - (c) if available, the name, address and contact details of –
 - (i) if the GMO is imported into Hong Kong from another place, the exporter of the GMO; or
 - (ii) if the GMO is exported from Hong Kong to another place, the importer of the GMO;
 - (d) the common name and scientific name of the GMO and, if available, the commercial name of the GMO; and
 - (e) new or modified traits and 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).

5. Documentation for GMOs intended for release into environment

(1) For the purposes of section 26(1) of the Ordinance, a GMO that is intended for release into the environment must, when being imported into or exported from Hong Kong, be accompanied by a document that contains –

- (a) a statement to the effect that the shipment in which the GMO is imported or exported contains a GMO that is intended for release into the environment;
- (b) the safety requirements applicable to the GMO or, if there is no such requirement, a statement to that effect;
- (c) the particulars specified in subsection (2); and
- (d) a declaration by the exporter of the GMO that the transboundary movement of the GMO is in conformity with the requirements of the Protocol that are applicable to the exporter.

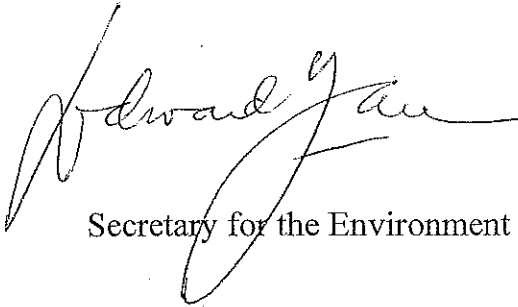
(2) The particulars are –

- (a) the name, address and contact details of the importer and exporter of the GMO;
- (b) 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;
- (c) the common name and scientific name of the GMO and, if available, the commercial name of the GMO;
- (d) 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); and
- (e) if the GMO has been approved for release into the environment under section 10 of the Ordinance –

- (i) the approval number assigned to the approval; and
- (ii) the conditions attached to the approval, if any.

6. Prescribed percentage

For the purposes of section 26(2)(c) of the Ordinance, the prescribed percentage in relation to GMOs intended for direct consumption as food or feed or for processing is 5%.


Secretary for the Environment

5 July

2010

Explanatory Note

Section 26(1) of the Genetically Modified Organisms (Control of Release) Ordinance (7 of 2010) provides that genetically modified organisms (“GMOs”) that are intended for direct consumption as food or feed or for processing, GMOs that are intended for contained use and GMOs that are intended for release into the environment must be accompanied by prescribed documents when being imported into or exported from Hong Kong. The requirement, however, does not apply if certain conditions are met. Two of the conditions are that the GMOs are imported or exported in a lot together with other living organisms, and that the percentage of the quantity of the GMOs to the total quantity of living organisms in the lot does not exceed the prescribed percentage.

2. The purpose of this Regulation is to provide for the detailed documentation requirements in relation to GMOs intended to be used for the purposes described

above. The Regulation also provides that the prescribed percentage in relation to GMOs intended for direct consumption as food or feed or for processing is 5%.

**Genetically Modified Organisms
(Control of Release) Ordinance (7 of 2010)**

Part 4

Documentation Requirements for Import and Export of GMOs

26. Documentation requirements for import and export of GMOs

(1) When being imported or exported –

- (a) GMOs that are intended for direct consumption as food or feed, or for processing;
- (b) GMOs that are intended for contained use; and
- (c) GMOs that are intended for release into the environment,

must be accompanied by the documents prescribed by regulations made under section 50(1).

(2) Subsection (1) does not require GMOs falling within paragraph (a) or (b) of that subsection to be accompanied by the prescribed documents if –

- (a) the GMOs are imported or exported in a lot together with other living organisms;
- (b) the GMOs are unintentionally mixed with those other living organisms; and
- (c) the percentage of the quantity of the GMOs to the total quantity of living organisms in the lot does not exceed the prescribed percentage.

(3) If subsection (1) is not complied with, the person who imports or exports the GMOs commits an offence and is liable to a fine at level 3.

(4) In any proceedings for an offence under subsection (3), it is a defence for the person charged to establish that the person did not know and could not with reasonable diligence have known that GMOs falling within subsection (1)(a), (b) or (c) were being imported or exported.

(5) In subsection (2)(c) –

“prescribed percentage” (訂明百分比) means –

- (a) the percentage prescribed by regulations made under section 50(1) for the purposes of that subsection in relation to GMOs falling within subsection (1)(a) or (b); or
- (b) if no percentage is prescribed, 0%.”.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Article 18. Handling, transport, packaging and identification

2. Each Party shall take measures to require that documentation accompanying:
 - (a) Living modified organisms^(Note) that are intended for direct use as food or feed, or for processing, clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;
 - (b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and
 - (c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

^(Note) Under the Ordinance, the term genetically modified organism (GMOs) is used to denote living modified organisms (LMOs) as covered by the Protocol. The two terms have the same definition.

ECONOMIC IMPLICATIONS

The documentation requirements should not pose significant burden on local traders since there is no need for a stand-alone document and the use of a commercial invoice or a document required by other existing documentation systems that clearly sets out the required information, would be acceptable. Against this, there will be benefit in terms of better protection of the environment.

ENVIRONMENTAL IMPLICATIONS

2. Application of the Convention and the Protocol to Hong Kong would reinforce our existing efforts to protect biodiversity. The regulatory controls provided under the Protocol would help to safeguard Hong Kong against possible adverse impacts on biodiversity arising from trans-boundary movement of GMOs.

SUSTAINABILITY IMPLICATIONS

3. The Convention and the Protocol would enhance the conservation of biodiversity in Hong Kong and hence contribute to the sustainability principle of maintaining the biodiversity of Hong Kong. The adoption of the regulatory framework under the Protocol would in principle harmonise trading requirements over GMOs in transboundary movements and thereby facilitate trade.