

**Advisory Council on the Environment  
Nature Conservation Subcommittee**

**The Proposed Genetically Modified Organisms  
(Documentation for Import and Export) Regulation**

**Purpose**

This paper briefs Members on the consultation carried out on the subsidiary legislation to the Genetically Modified Organisms (Control of Release) Ordinance for the documentation requirements for the import and export of genetically modified organisms, and invites Members' views on the proposal.

**Background**

2. The Cartagena Protocol on Biosafety (the Protocol) was adopted under the Convention on Biological Diversity (the Convention). The main objective of the Protocol is to protect biological diversity from possible impacts arising from the transboundary movement of living genetically modified organisms (GMOs) on the environment.

3. For the implementation of the Protocol in Hong Kong, a new legislation, the Genetically Modified Organisms (Control of Release) Ordinance (the Ordinance), was enacted on 18 March 2010. The Ordinance gives effect to the Protocol to control the release into the environment, and the import and export, of GMOs. According to the Ordinance, a shipment containing a GMO must be accompanied by prescribed documents when being imported or exported. This documentation requirement applies to the following categories of GMOs:

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

## **Regulation**

4. The detailed documentation requirements will be specified in the Genetically Modified Organisms (Documentation for Import and Export) Regulation (the Regulation) being prepared. The main objective of the Regulation is to provide detailed information on the requirements of documentation accompanying shipment containing GMOs during import or export. The required documentation provides information on the identity of the GMO, and contact details of individuals and institutions responsible for the transboundary movement of the GMO. Besides, the Regulation will specify the percentage prescribed in relation to GMOs-FFP to address the issue of adventitious presence of GMOs in agricultural produces.

## **Public Consultation**

5. Consultation with the relevant stakeholders including traders, food and beverage producers, pharmaceutical manufacturers, academics, biotechnology companies, green groups, organic farms and World Trade Organization etc. was conducted from 1 February to 31 March 2010. The stakeholders were informed through letters and Business Consultation e-Platform, and invited to give their views on the draft Regulation. Two consultation meetings were also held on 26 February 2010 and 5 March 2010 to brief stakeholders on the documentation requirements and collect their views.

6. Most of the participants of the consultation meetings sought clarifications on documentation requirements for particular types of GMOs in order to determine whether their import/export shipments would be affected and how to comply with the documentation requirements. Some participants expressed their concern about the unintentional importation/release of GMOs and suggested that publicity efforts should be stepped up to educate the public about GMOs and the new regulation. Written comments were also received and the Government was urged to strengthen the control of GMOs and further clarifications were sought on the control to be imposed on GMOs for research purposes. The comments received are being taken into account in finalising the Regulation. A copy of the consultation paper is attached

at **Annex**.

### **Advice Sought**

7. Members are invited to note the consultation exercise and express their views on the proposed Regulation.

**Agriculture, Fisheries and Conservation Department**  
**April 2010**

**Consultation Paper**

**Genetically Modified Organisms (Control of Release) Bill**

**Draft Genetically Modified Organisms  
(Documentation for Import and Export) Regulation**

**Purpose**

This paper aims to seek public views on the draft Genetically Modified Organisms (Documentation for Import and Export) Regulation to the Genetically Modified Organisms (Control of Release) Bill.

**Background**

**The Convention and the Protocol**

2. The Convention on Biological Diversity (the Convention) was adopted in the 1992 Earth Summit on Sustainable Development and came into operation in 1993. It provides a comprehensive approach to the conservation of biological diversity, the sustainable use of biological diversity, and the sharing of the benefits arising from the use of genetic resources in a fair and equitable way. There are currently over 190 Parties to the Convention including China, but the Convention has yet to be extended to the Hong Kong Special Administrative Region.

3. Biosafety (i.e. minimizing the risks from the possible adverse effects of modern biotechnology and its products on humans and the environment) is one of the issues addressed by the Convention. In January 2000, Parties to the Convention adopted a Protocol, known as the Cartagena Protocol on Biosafety to the Convention (the Protocol).

4. The Protocol requires Parties to take necessary and appropriate legal, administrative and other measures to ensure that the development, handling, transport, use, transfer and release of any GMO, especially

focusing on transboundary movement, are undertaken in a manner that prevents or reduces the adverse impacts of GMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Protocol came into effect in September 2003. There are currently over 150 Parties to the Protocol including China.

5. The Protocol can better ensure protection of our local biological diversity from possible adverse impacts of imported GMOs. The application of the Protocol to Hong Kong will demonstrate Hong Kong's commitment in cooperating with the international community to protect the natural environment. Hong Kong is expected to share similar international obligations relating to the protection of biological diversity. We also need to follow the Protocol's requirements on import and export of GMOs where our trading partners have joined the Protocol.

6. The Protocol concerns GMOs (referred as LMO or living modified organism in the Protocol). A "living organism" is defined as any biological entity capable of transferring or replicating genetic material, and GMOs are living organisms that possess new combination of genetic material obtained through the use of modern biotechnology that overcomes natural reproductive barriers. Living organisms with genetic material altered through traditional breeding and selection techniques (e.g. Hybrid Rice and Golden Sweet Corn) are not GMOs. Non-living products (e.g. cotton fibre) or processed food (e.g. milled maize, canned bean, soy milk) also are not GMOs. Besides, GMO that is a pharmaceutical product for human use is outside the scope of the Protocol.

7. The enactment of the Genetically Modified Organisms (Control of Release) Bill will give effect to the implementation of the Protocol. According to the Bill, prior approval has to be sought from the Director of Agriculture, Fisheries and Conservation (DAFC) before a GMO can be released or imported into Hong Kong for release into the environment. The Bill would be enacted in 2010.

8. According to the draft Regulation, a shipment containing a GMO

must be accompanied by relevant documentation during the import or export of the shipment. Documentation is required for the following categories of GMOs:

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

### **The Regulation**

9. The draft Regulation details the documentation requirements for shipments containing GMOs. The following paragraphs summarize the main aspects of the draft Regulation.

#### Objective

10. The main objective of the Regulation is to provide detailed information on the requirements of documentation accompanying shipment containing GMOs during import or export. The required documentation provides information on the identity of the GMO, and provides contact details for individuals and institutions responsible for the transboundary movement of the GMO.

#### Documentation Requirement

11. According to the draft Regulation, a shipment containing GMO would need to be accompanied by documentation containing the following information:

- a) For GMOs-FFP -
  - i) If the identity of the GMO is known, the shipment contains such a GMO; if the identity of the GMO is not known, the shipment may contain such a GMO;
  - ii) The GMO is not intended for release into the environment;

- iii) The common name, scientific name and, where available, commercial name of the GMO;
  - iv) The transformation event code of the GMO or, where available, its unique identifier code; and,
  - v) The details of the importer or exporter (such as name, address and contact information) for further information.
- b) For GMOs intended for contained use -
- i) The shipment contains a GMO which is intended for contained use;
  - ii) The common name, scientific name and, where available, commercial name of the GMO;
  - iii) The name, address and contact details of the consignee and the exporter or importer;
  - iv) The requirement, if any, for the safe handling, storage, transport and use of the GMO. If there is no requirement as stated above, a statement that there is no such requirement; and,
  - v) 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.
- c) For GMO intended for release into environment -
- i) The shipment contains a GMO;
  - ii) The common name, scientific name and, where available, commercial name of the GMO;
  - iii) The traits and characteristics of the GMO, including transgenic traits and characteristics such as event of transformation or, where available, a reference to a system of unique identification;
  - iv) 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;

- vi) If there is no requirement as stated above, a statement that there is no such requirement;
- vii) The name, address and contact details of the exporter or importer;
- viii) The details of contact point for further information, including an individual or organization in possession of information, in case of emergency;
- ix) The risk class and import approval for the first transboundary movements of the GMO; and,
- x) A declaration that the movement of the GMO is in conformity with the requirements of the Protocol and which is applicable to the exporter.

#### Adventitious Presence

12. In commercial production and transportation of agriculture products, mixing from different sources is inevitable. GMO varieties may contaminate adventitiously the traditional varieties and shipped as non-GMO products. It is proposed that the above documentation requirements do not apply 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 amount of the GMOs to the total amount of living organisms in the lot does not exceed the prescribed percentage.

13. The prescribed percentages were proposed as follows:

- a) 5% for GMOs-FFP;
- b) 0% for GMOs intended for contained use; and,

- c) 0% for GMOs intended for release into the environment.

### Form of Documentation

14. There is no specific requirement regarding the form of documentation accompanying GMO shipments. The use of a commercial invoice or other documents required or utilized by existing documentation systems, or documentation as required by other local legislation and / or administrative frameworks is acceptable as documentation that should accompany the GMO shipments. Such documentation should include the information specified in the paragraphs above (as the case may be) and allow for easy recognition, transmission and effective integration of the information requirements. In addition to commercial invoices, other forms of documentation that are acceptable include import / export manifests, licences or certificates issued or required under other legislation e.g. phytosanitary certificates.

### **Implementation Plan**

15. The consultation is being announced on AFCD's website for consultation with the public and the Business Consultation e-Platform under the GovHK website for the business sectors. Overseas trading partners are being informed through the channel of World Trade Organization. The consultation document has also been mailed to stakeholders known to AFCD. Taking into account comments received from the consultation, we will finalize the draft Regulation before the commencement of the Bill.

### **Advice Sought**

16. You are invited to send your views on the draft Regulation by letter, facsimile or e-mail to the Agriculture, Fisheries and Conservation Department at the following address on or before 31 March 2010:

Biodiversity Conservation Division  
Agriculture, Fisheries and Conservation Department  
Address: 6/F, Cheung Sha Wan Government Offices,  
303 Cheung Sha Wan Road, Kowloon

Fax: 2314 2802  
E-mail: [biosafety@afcd.gov.hk](mailto:biosafety@afcd.gov.hk)

Agriculture, Fisheries and Conservation Department  
January 2010