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Paper for the House Committee meeting on 5 November 2010

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

Purpose

This paper reports on the deliberations of the Subcommittee on Genetically Modified Organisms (Documentation for Import and Export) Regulation.

Background

2. Genetically modified organism (GMO) refers to any living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology. The Cartagena Protocol on Biosafety (the Protocol) under the Convention on Biological Diversity (the Convention) was adopted in 2000 to provide for the safe transfer, handling, storage and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health. 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 (HKSAR). According to the Convention, a party may not participate in a protocol unless it is, or becomes at the same time, a party to the Convention. Hence, the Protocol cannot be extended to HKSAR unless the Convention is applicable to HKSAR.

3. According to Article 153 of the Basic Law, the application of international agreements, to which the People's Republic of China is or becomes a party, to HKSAR shall be decided by the Central People's Government (CPG) in accordance with the circumstances and needs of HKSAR, and after seeking the views of the HKSAR Government. The Convention and the Protocol are important international agreements on protection of biological diversity and global sustainable development. Their extension to HKSAR can reinforce its commitment in cooperating with the international community to protect the natural environment. Moreover, as an international city, HKSAR is expected to share similar international obligations relating to the protection and sustainable use of biological diversity. It also needs to

follow the Protocol's requirements where its trading partners have joined the Protocol. Hence, the Administration has obtained the agreement-in-principle of CPG to extend the application of both the Convention and the Protocol to HKSAR, subject to the passage of the necessary local legislation.

4. The Genetically Modified Organisms (Control of Release) Ordinance (Cap. 607) (the Ordinance) was enacted in March 2010 to give effect to the Protocol to ensure the safe transfer, handling, storage and use of GMOs. The Ordinance has yet to come into operation pending the enactment of the subsidiary regulation on documentation for import and export of GMOs.

The Regulation

5. Section 26(1) of the Ordinance provides that GMOs that are intended for direct consumption as food or feed or for processing (FFP), contained use, and release into the environment must be accompanied by prescribed documents when being imported into or exported from Hong Kong. The Regulation seeks to provide for the detailed documentation requirements in relation to GMOs intended to be used for the described purposes. The Regulation also specifies the prescribed percentage of unintentional mixing of GMO-FFP to be 5%.

The Subcommittee

6. At the House Committee meeting held on 8 October 2010, Members agreed to form a Subcommittee to study the Regulation. Under the chairmanship of Hon Audrey EU Yuet-mee, the Subcommittee has held one meeting. The membership list of the Subcommittee is in **Appendix I**. Apart from examining the Regulation with the Administration, the Subcommittee has also invited views from interested parties, including green groups and related sectors. A list of organizations which have provided written submissions to the Subcommittee is in **Appendix II**.

Deliberations of the Subcommittee

7. In the course of deliberation of the Regulation, members have examined a number of issues relating to documentation requirements, interpretation, and legislative time-table.

<u>Documentation requirements</u>

8. Under Article 18.2 of the Protocol, Parties to the Protocol are required to provide documentation with required information when conducting trans-boundary movements of GMOs. The documentation requirements vary for GMOs-FFP, GMOs that are intended for contained use, and GMOs that are intended for release into the

environment. The documentation requirements set out in the Regulation closely follow Article 18.2 of the Protocol and the two decisions made by the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (MOP). Article 18.2 of the Protocol and the two relevant decisions are given in Annex C to the Legislative Council Brief issued by the Environmental Protection Department and Agriculture, Fisheries and Conservation Department in July 2010 (Ref: EPD CR 9/15/26 Pt.5) and LC Paper No. CB(1) 166/10-11(04) respectively.

9. Subcommittee members have enquired whether the Administration will set out the information requirements in specified forms to facilitate compliance by importers and exporters of GMOs. According to the Administration, specified forms for documentation are not mandatory under the Protocol. Exporters/importers of GMOs are only required to produce any document, say an invoice, which could satisfy the documentation requirements in relation to GMOs intended to be used for different described purposes. Nevertheless, the Administration is prepared to provide sample forms for the reference of importers and exporters of GMOs. Copies of the sample forms are given in **Appendix III**.

Interpretation

Definition of "safety requirement"

10. "Safety requirement" 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 any applicable existing international instrument, the Ordinance, or any agreement entered into by the importer and exporter of the GMO.

11. The Subcommittee has sought clarification on the meaning of "applicable international instrument". According to the Administration, the term refers to the relevant international rules and standards covering safe handling, storage, , transport or use of GMOs and might extend to general international rules and standards governing health, safety and environment of international trades. At present, specific GMOs may be covered by relevant international rules and standards on the basis of their characteristics rather than just because they are GMOs. Examples of such relevant international instruments include the International Plant Protection Convention by the World Health Organization, and the United Nations Recommendations on the Transport of Dangerous Goods.

12. Subcommittee members have enquired whether examples of relevant international instruments can be included in the Regulation to facilitate understanding of importers and exporters of GMOs. Given the wide range of applicable international instruments, and the fact that MOP may develop relevant rules and standards in accordance with Article 18(3) of the Protocol in future, the Administration has considered it appropriate to make a general reference to "any applicable existing international instrument" in the Regulation, rather than to any

specific international instrument. Administrative guidelines will be prepared for the documentation requirements and examples of international instruments will be given for the reference of importers and exporters of GMOs. The guidelines will be uploaded to the online GMO Register for public viewing. Some members have suggested that the Administration should integrate, as far as practicable, all the information requirements under relevant international instruments in the sample forms referred to in paragraph 9 to minimize the need for cross-referencing.

Legislative time-table

13. The Subcommittee has enquired about the legislative time-table for the Ordinance and the Regulation. The Administration has advised that the initial plan is to bring the Ordinance and the Regulation into operation on the same date around March 2011 by which the Convention and the Protocol should have been extended to HKSAR.

Amendments to the Regulation

14. The Administration and the Subcommittee have not proposed any amendment to the Regulation.

Advice sought

15. Members are requested to note the deliberations of the Subcommittee.

Council Business Division 1
Legislative Council Secretariat
3 November 2010

Appendix I

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

Membership list

Chairman	Hon Audrey EU Yuet-mee, SC, JP
Members	Hon WONG Ting-kwong, BBS, JP Hon KAM Nai-wai, MH Hon Cyd HO Sau-lan Hon CHAN Hak-kan Hon Tanya CHAN (up to 26 October 2010) (Total : 5 Members)
Clerk	Miss Becky YU
Legal Adviser	Mr Bonny LOO
Date	26 October 2010

Appendix II

List of organizations which have made written submissions to the Subcommittee

1. CropLife Asia
2. CropLife International
3. Biotechnology Industry Organization
4. Dr M MACKETT, The University of Hong Kong
5. Produce Green Foundation

Appendix III(A)

Sample Form for Prescribed Document Accompanying GMOs Intended for Direct Consumption as Food or Feed, or for Processing with Unknown Identity

(Specified forms for documentation are not mandatory. Any documents, such as commercial invoices or import/export manifests, which contain the required information, could satisfy the documentation requirements under the Regulation)

This shipment **may contain** a GMO that is intended for direct consumption as food. [Note 1] The GMO is not intended for release into the environment.

Exporter	**Importer**
Name: ABC Company Ltd. Address: 12345 ABC Road Cambridge, MA USA Phone: (314) 987-6543	Name: XYZ Company Ltd. Address: 98765 XYZ Road, Sham Shui Po, Hong Kong Phone: (852) 1233-4567

Designated Authority in relation to the GMO [Note 2]	**The Internet Address of the Biosafety Clearing-House**
Name: - Address: - Email: -	http://bch.cbd.int

Identity of the GMO [Note 3]
Common name: - Scientific name: - Commercial name: - Transformation event code: - Unique identifier code: -

Note:

1. If the identity of the GMO is not known, a statement to the effect that 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 should be provided.
2. This information is not required if there is no designated authority in relation to the GMO or the identity of the GMO is not known.
3. This part of information is not required if the identity of the GMO is not known.

Sample Form for Prescribed Document Accompanying GMOs Intended for Direct Consumption as Food or Feed, or for Processing with Known Identity

(Specified forms for documentation are not mandatory. Any documents, such as commercial invoices or import/export manifests, which contain the required information, could satisfy the documentation requirements under the Regulation)

This shipment **contains** a GMO that is intended for direct consumption as food. [Note 1] The GMO is not intended for release into the environment.

Exporter	**Importer**
Name: ABC Company Ltd. Address: 12345 ABC Road Barcelona Spain Phone: (314) 987-6543	Name: XYZ Company Ltd. Address: 98765 XYZ Road, Sham Shui Po, Hong Kong Phone: (852) 1233-4567

Designated Authority in relation to the GMO [Note 2]	**The Internet Address of the Biosafety Clearing-House**
Name: European Commission Directorate General Environment Address: Office BU 9-5/172 Brussels Belgium, 1049 Email: hugo-maria.schally@ec.europa.eu	http://bch.cbd.int

Identity of the GMO
Common name: Papaya
Scientific name: *Carica papaya*
Commercial name [Note 3]: Sunset Papaya
Transformation event code: 55-1
Unique identifier code [Note 4]: CUH-CP551-8

Note:

1. If the identity of the GMO is known, a statement to the effect that 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 should be provided.
2. This information is not required if there is no designated authority in relation to the GMO or the identity of the GMO is not known..
3. This information is not required if the GMO's commercial name is not available.
4. This information is not required if the GMO's unique identifier code is not available.

Appendix III(B)

Sample Form for Prescribed Document Accompanying GMOs Intended for Contained Use

(Specified forms for documentation are not mandatory. Any documents, such as commercial invoices or import/export manifests, which contain the required information, could satisfy the documentation requirements under the Regulation)

This shipment contains a GMO that is intended for contained use.

Exporter [Note 1]	**Importer** [Note 2]
Name: ABC Company Ltd. Address: 12345 ABC Road Cambridge, MA USA Phone: (314) 987-6543	Name: Professor Paul Chan Address: GMO Lab, Science Building XYZ University Hong Kong Phone: (852) 2233-4567

Consignee	**Identity of the GMO**
Name: David Lee Address: Departmental Office of Biology XYZ University, Hong Kong Phone: (852) 123-4567	Common name: Arabidopsis Scientific name: *Arabidopsis thaliana* Commercial name [Note 3]: -

New or Modified Traits and Characteristics of the GMO

Transformation event code [Note 4]: RE-01

Unique identifier code [Note 5]: -

Risk class [Note 6]: -

Specification of Use: The GMO will be used to study the extraction method of myristic acid.

Safety Requirements Applicable to the GMO

(a) Applicable existing international instrument [Note 7]:

International Plant Protection Convention

International Standards for Phytosanitary Measures (ISPM No. 11)

Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms.

No significant risk was observed according to the pest risk analysis undertaken for the

GMO.

(b) Ordinance [Note 7]**:**

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.

Plant import license and phytosanitary certificates for the GMO are attached.

(c) Agreement entered into by the importer and exporter of the GMO

Not to be used for human consumption or animal feed, commercial sale or unauthorized transfers.

Note:

1 This information is not required if the GMO is imported into Hong Kong and the details of the overseas exporter is not available.
2 This information is not required if the GMO is exported from Hong Kong and the details of the overseas importer is not available.
3 This information is not required if the GMO's commercial name is not available.
4 This information is not required if the GMO's transformation event code is not available.
5 This information is not required if the GMO's unique identifier code is not available.
6 This information is not required if the GMO's risk class is not available.
7 If there is no such requirement, then provide a statement to that effect.
Information on existing international instruments and local legislation applicable to various varieties of GMOs is provided in the online Genetically Modified Organisms Register. Please refer to <http://www.afcd.gov.hk/english/conservation/con_gmo/con_gmo.html> for details.

Appendix III(C)

Sample Form for Prescribed Document Accompanying GMOs Intended for Release into Environment

(Specified forms for documentation are not mandatory. Any documents, such as commercial invoices or import/export manifests, which contain the required information, could satisfy the documentation requirements under the Regulation)

This shipment contains a GMO that is intended for release into environment.

Exporter	**Importer**
Name: ABC Company Ltd. Address: 12345 ABC Road Cambridge, MA USA Phone: (314) 987-6543	Name: XYZ Company Ltd. Address: 98765 XYZ Road, Sham Shui Po, Hong Kong Phone: (852) 1233-4567

Person who can provide information relating to the safe handling, storage, transport or use of the GMO in case of emergency

Name: Professor David Chan
Address: Equine Protection Laboratory, XYZ University, Iowa, USA
Phone: (210) 123-4567

Identity of the GMO

Common name: Equine strangles vaccine
Scientific name: *Streptococcus equi*
Commercial name [Note 1]: Equilis StrepE
Approval granted under the Genetically Modified Organisms (Control of Release) Ordinance [Note 2]: 20110301-1
Condition attached to the approval [Note 3]: The GM horse vaccines shall only be administered by a registered veterinary surgeon.

Traits and Characteristics of the GMO

Transformation event code: TW928
Unique identifier code [Note 4]: -
Risk class [Note 5]: EEC Class 1 (according to EU Guideline 2000/54/EC)

Safety Requirements Applicable to the GMO

(a) Applicable existing international instrument [Note 6]**:**

UN Recommendations on the Transport of Dangerous Goods - Model Regulations - Sixteenth Revised Edition

Provision 2.9.2 Assignment to Class 9: GMMOs or GMOs which do not meet the definition of toxic substances or infectious substances shall be assigned to UN 3245.

Provision 4.1.4.1 (P904 - Packing Instruction Applicable for UN3245):

The following packagings are authorized:

(1) Packagings meeting the provisions of 4.1.1.1, 4.1.1.2, 4.1.1.4, 4.1.1.8 and 4.1.3 and so designed that they meet the construction requirements of 6.1.4. Outer packagings constructed of suitable material of adequate strength and designed in relation to the packaging capacity and its intended use shall be used. Where this packing instruction is used for the transport of inner packagings of combination packagings, the packaging shall be designed and constructed to prevent inadvertent discharge during normal conditions of transport.

(2) Packagings, which need not conform to the packaging test requirements of Part 6, but conforming to the following:

(a) An inner packaging comprising:

(i) primary receptacle(s) and a secondary packaging, the primary receptacle(s) or the secondary packaging shall be leak-proof for liquids or sift-proof for solids;

(ii) for liquids, absorbent material placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in a quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

(iii) if multiple fragile primary receptacles are placed in a single secondary packaging they shall be individually wrapped or separated to prevent contact between them;

(b) An outer packaging which shall be strong enough for its capacity, mass and intended use, and with a smallest external dimension of at least 100 mm.

The GM vaccine is packaged in accordance with the requirements laid down by the UN Recommendations on the Transport of Dangerous Goods above.

(b) Ordinance [Note 6]**:**

The Hong Kong Legislation Chapter 138A Pharmacy and Poisons Regulations Section 36(1) states that:

No person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product or substance unless the product or substance is registered with the Board-

(a) by the manufacturer, if the pharmaceutical product or substance is manufactured in Hong Kong;

(b) by the importer, if the pharmaceutical product or substance is manufactured outside Hong Kong; or

(c) by the local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong.

A copy of the certificate of registration for the GM vaccine issued by the Pharmacy and Poisons Regulations is attached.

(c) Agreement entered into by the importer and exporter of the GMO:

Nil.

Declaration

The transboundary movement of the GMO is in conformity with the requirements of the Cartagena Protocol on Biosafety that are applicable to the exporter.

Signature of the Exporter	**Date**

Note:

1 This information is not required if the GMO's commercial name is not available.

2 This information should be provided if the GMO has been approved for release into the environment under section 10 of the Genetically Modified Organisms (Control of Release) Ordinance.

3 This information is not required if there is no condition attached to the approval.

4 This information is not required if the GMO's unique identifier code is not available.

5 This information is not required if the GMO's risk class is not available.

6 If there is no such requirement, then provide a statement to that effect.
Information on existing international instruments and local legislation applicable to various varieties of GMOs is provided in the online Genetically Modified Organisms Register. Please refer to <http://www.afcd.gov.hk/english/conservation/con_gmo/con_gmo.html> for details.