

## LEGISLATIVE COUNCIL BRIEF

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

#### Extension of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to Hong Kong

#### INTRODUCTION

A At the meeting of the Executive Council on 12 May 2009, the Council ADVISED and the Chief Executive ORDERED that the Genetically Modified Organisms (Control of Release) Bill at Annex A should be introduced into the Legislative Council.

#### JUSTIFICATIONS

##### The Convention

2. The Convention was adopted at the 1992 Earth Summit on Sustainable Development and came into operation on 29 December 1993. It provides a comprehensive approach to the conservation of biological diversity, and sets overall goals and general obligations. Conservation of biological diversity can be achieved by various measures by the Parties. There are currently over 190 Parties to the Convention, including China, but the Convention has yet to be extended to Hong Kong.

##### The Protocol

3. The Protocol was adopted under the Convention in 2000 to provide for the safe transfer, handling and use of genetically modified organisms <sup>Note 1</sup> (GMOs) that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The Protocol specifically focuses on transboundary movements of GMOs and seeks to protect individual Parties from potentially adverse impacts of imported GMOs on their biological diversity through the regulation of import and export

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Note 1 Genetically modified organism (GMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. GMOs may cover a variety of food crops (e.g. tomatoes, rice grains and soya beans), seeds, live fish etc. They, however, do not include non-living food products. They also do not include living organisms with genetic material altered through traditional breeding and selection techniques (e.g. Hybrid Rice and Golden Sweet Corn).

of GMOs. The Protocol came into force on 11 September 2003. There are currently over 150 Parties to the Protocol including China. 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 Hong Kong unless the Convention is applicable to Hong Kong.

4. The main objective of the Protocol is to protect biological diversity from possible adverse impacts arising from trans-boundary movement of GMO intended for intentional introduction into the environment, which mainly involves commercial farming or field trials of scientific researches. The Protocol requires Parties to the Protocol to adopt an Advance Informed Agreement (AIA) procedure under which the exporting party needs to have the explicit consent of the importing party before a GMO is to be exported for first intentional introduction into the environment at the importing end. The notification made by the exporting party shall be accompanied by a risk assessment report prepared according to the Protocol's requirements with the objective of assisting the importing party to decide whether the importation should be allowed.

5. The AIA procedure does not apply to any GMO in transit or to any trans-boundary movement of a GMO intended for direct use as food or feed, or for processing (FFP), or for contained use. However, Parties to the Protocol are required to take measures to require documentation accompanying GMO shipments which are intended for FFP to clearly state that they "may contain" GMOs and are not intended for intentional release into the environment. The documentation accompanying GMOs for contained use and GMOs in transit shall clearly identify them as GMOs and specify the requirements for the safe handling, storage, transport and use of the GMOs.

#### Extension of the Convention and Protocol to Hong Kong

6. Our existing nature conservation policy and measures are generally in line with the objectives and requirements of the Convention. The only major area in the Convention on which we need to develop further measures is the regulation, management, and control of the risks associated with the use and release of GMOs into the environment. The Convention and the Protocol cannot be extended to Hong Kong unless we have these measures in place. We need to enact a new piece of legislation to provide the legal basis for the requirements set out in the Protocol in relation to the regulation of GMOs.

7. The Convention and the Protocol are important international agreements on protection of biological diversity and global sustainable development. The extension of the Convention and the Protocol to Hong Kong will demonstrate Hong Kong's commitment in cooperation with the international community to protect the natural environment. Moreover, Hong Kong, as an international city, is expected to share similar international

obligations relating to the protection and sustainable use of biological diversity. We also need to follow the Protocol's requirements where our trading partners have joined the Protocol.

8. According to Article 153 of the Basic Law, the application to the Hong Kong Special Administrative Region (HKSAR) of international agreements to which the People's Republic of China is or becomes a party shall be decided by CPG in accordance with the circumstances and needs of the HKSAR, and after seeking the views of the Government of the HKSAR. We have obtained the agreement-in-principle of CPG to extend the application of both the Convention and the Protocol to Hong Kong. Subject to the passage of the proposed legislation through the Legislative Council, and upon completion of other necessary preparatory work, we will request the CPG to complete the formalities on the extension.

## **THE BILL**

9. The Bill sets out the following main requirements –

- (a) Part 1 contains the preliminary provisions including definitions of terms, and the meanings of “released into the environment” and “contained use”. The meaning of “contained use” is adapted from the Protocol.
- (b) Part 2 deals with the restrictions on release of GMOs into the environment and import of GMOs intended for release. This Part does not apply to GMOs that are pharmaceutical products for human use.
  - (i) A GMO may not be released into the environment and a GMO that is in a state of being released may not be maintained unless it has been approved by the Director of Agriculture, Fisheries and Conservation (DAFC).
  - (ii) A GMO that is intended for release into the environment may not be imported unless it has been approved by DAFC. The restriction does not apply to GMOs in transit or transshipment, and GMOs for FFP.
  - (iii) Applications for approval of a GMO need to be accompanied by a report on a risk assessment carried out on the possible adverse effects of the GMO on the conservation and sustainable use of biological diversity. DAFC must not approve a GMO unless he or she is satisfied that the possible adverse effects are acceptable or manageable.
- (c) Part 3 deals with the restrictions on export of GMOs to places

outside Hong Kong for release into the environment. Exporters are required to send a notification to the authority of the place of import and obtain its approval for exporting a GMO to the place for release into its environment. The notification and approval requirements do not apply to GMOs in transit or transshipment, GMOs for FFP, and GMOs that are pharmaceuticals products for human use. The notification or approval requirement also does not apply if the place of import does not impose such requirement.

- (d) Part 4 establishes a public register containing information on applications for approval of GMOs, decisions made by DAFC, exemptions granted, and any other information relating to the administration of the legislation. Applicants may request DAFC not to enter certain submitted information (particularly confidential commercial and industrial information, including research and development information) in the register. DAFC may decide not to enter the information if he or she is satisfied that not disclosing the information would not be contrary to the public interest.
- (e) Part 5 provides for the enforcement powers of authorized officers. It provides for the circumstances under which an authorized officer may, among other things, search non-military vessels, vehicles, trains and aircraft, enter and inspect non-residential premises, enter any place or premises by force, seize things that appear to contain evidence of commission of offences, take samples of things believed to contain GMOs and carry out tests on the samples.
- (f) Part 6 provides for the disposal and forfeiture of things seized by authorized officers.
- (g) Part 7 contains miscellaneous provisions. It provides for, among other things, appeals to the Administrative Appeals Board against decisions and directions of DAFC, establishment of an expert group, granting of exemptions by the Secretary for the Environment, amendment of schedules and making of regulations for various matters for the implementation of the Bill, including the documents required for the import and export of GMOs.
- (h) Part 8 sets out the transitional arrangements within the 6-month period from the date when the Bill comes into operation. During that period, the maintenance of GMOs that have been released into the environment before the commencement date will not be prohibited. A person who has caused a GMO to be released before that date, or has maintained such a GMO before that date or

during that period, however, must report the release or maintenance to DAFC or submit an application for the approval of the GMO during that period.

- (i) Part 9 makes consequential amendments to the Schedule to the Administrative Appeals Board Ordinance (Cap. 442) so that the Ordinance would apply to the appeals lodged against the decisions and directions of the Director set out in it.
- (j) Schedules 1 and 2 specify the information to be provided in written notices on release of GMOs into the environment and in GMO approval applications;
- (k) Schedule 3 sets out the requirements on risk assessment;
- (l) Schedule 4 specifies the information to be provided in export notifications;
- (m) Schedule 5 specifies the fees payable on various matters provided in the Bill; and
- (n) Schedule 6 specifies the information to be provided in written notices on release or maintenance of GMOs that have been released into the environment before the commencement of the Bill.

## **LEGISLATIVE TIMETABLE**

10. The legislative timetable is –

Publication of the Bill in the Gazette	22 May 2009
First Reading and commencement of Second Reading in LegCo	3 June 2009
Resumption of Second Reading debate, Committee Stage and Third Reading in LegCo	To be notified

## **IMPLICATIONS OF THE PROPOSAL**

11. The proposal has financial, civil service, economic environmental and sustainability implications as set out at Annex B.

12. The proposal is in conformity with the Basic Law, including the provisions concerning human rights. The Bill shall bind the Government, except that any public officer in the officer's capacity will not be liable to be prosecuted for an offence against the Bill, and that no prescribed fee is payable by any Government department that does not operate under a trading fund.

## **PUBLIC CONSULTATION**

13. We have consulted the Legislative Council's Panel on Environmental Affairs on the proposed legislation on 30 March 2009. Members had no objection to the legislative proposal for extending the Convention and Protocol to Hong Kong.

14. On the public front, we have posted the consultation paper on the website of the Agriculture, Fisheries and Conservation Department (AFCD) and the Business Consultation e-Platform under the GovHK website to inform the public on the consultation exercise and to invite comments on the legislative proposal. Letters were also sent to relevant stakeholders (including green groups, relevant academics, biotechnology companies, trade associations, food and beverage traders, local chain stores, seed and vegetable traders, flower and aquarium fish traders, and organic farms) inviting them to join respective focus-group consultation meetings. Relevant overseas authorities were also notified through the World Trade Organization notification system. Copies of the consultation paper had been mailed to some stakeholders as requested. We also consulted the Advisory Council on Food and Environmental Hygiene, the Advisory Council on the Environment (ACE) and its Nature Conservation Subcommittee, and the Advisory Committee on Agriculture and Fisheries.

15. The consulted parties in general supported the extension of the Convention and the Protocol to Hong Kong, and had no objection to the proposed legislation. On the technical issues, some consultees asked about the impact of the legislative proposal on local biotechnology research and development. We have explained that the Protocol and the proposed legislation aim at regulating the release of GMOs into the environment, and not "contained use". Researches using GMOs in laboratories are "contained use" and under the proposed legislation, there is no need to apply for DAFC's approval for the "contained use" of GMOs or the import of GMOs for "contained use". Some members of the trade enquired about the documentation requirements for the import and export of GMOs. We have advised them that we would adopt the relevant Protocol's requirements which equally apply to over 150 parties, including most of our overseas trading partners. 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, with the required information clearly set out, would be acceptable.

Representatives of the organic farms also questioned the possible contamination of organic crops by GMOs growing outside their fields. We have explained that, under the proposed legislation, AFCD would be empowered to regulate the release of GMOs into the environment (including growing GMOs as crops in the fields), and remove unapproved GMOs from the fields. The proposed legislation would help prevent and minimize the possibility of contamination of organic crops by GMOs. Most consulted parties suggested that more public education programmes should be organized to promote public awareness on GMOs. In this connection, AFCD will step up publicity and public education on GMOs following the enactment of the legislation.

### **PUBLICITY**

16. A press release will be issued today (20 May 2009). A spokesman will be available to handle enquires.

### **ENQUIRIES**

17. Any enquiries on this brief may be addressed to Miss Vivien Li, Senior Administrative Officer (Nature Conservation) of the Environmental Protection Department at telephone number 2594 6229.

**Environmental Protection Department**  
**Agriculture, Fisheries and Conservation Department**  
**20 May 2009**

**GENETICALLY MODIFIED ORGANISMS (CONTROL OF  
RELEASE) BILL**

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## A BILL

### To

Give effect to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity; to control the release into the environment, and the import and export, of genetically modified organisms; and to provide for incidental and related matters.

Enacted by the Legislative Council.

## PART 1

### PRELIMINARY

#### **1. Short title and commencement**

(1) This Ordinance may be cited as the Genetically Modified Organisms (Control of Release) Ordinance.

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

#### **2. Interpretation**

(1) In this Ordinance –

“adverse biosafety effect” (生物安全不利影響), in relation to a GMO, means any adverse effect of the GMO on the conservation and sustainable use of biological diversity;

“applicant” (申請人), in relation to a GMO approval application or variation request, means the person in whose name the application or request is made;

“approved GMO” (核准基因改造生物) means a GMO that is approved for release into the environment by –

(a) a decision of the Director under section 10(1)(a), 11(5)(a) or 12(1); or

(b) a decision of the Administrative Appeals Board on an appeal lodged under section 39(1);

“authorized officer” (獲授權人員) means an authorized officer appointed under section 27;

“Biosafety Clearing-House” (生物安全資料交換所) means the clearing-house mechanism established under Article 20 of the Protocol;

“competent authority” (主管當局) –

(a) in relation to a place that is a Party, means the authority designated by the place to perform, on behalf of the place, the administrative functions required of the place under the Protocol;

(b) in relation to a place that is not a Party, means the authority designated by the place to perform, on behalf of the place, the administrative functions that are similar or equivalent to those required of a Party under the Protocol;

“Conference of the Parties” (締約方大會) means the Conference of the Parties established under Article 23 of the Convention;

“confidential information” (機密資料) means any proposed confidential information that is not to be entered in the register according to –

(a) a decision of the Director under section 15(1)(a) or 16(3)(a); or

(b) a decision of the Administrative Appeals Board on an appeal lodged under section 39(1);

“Convention” (《公約》) means the Convention on Biological Diversity done at Rio de Janeiro on 5 June 1992, as amended from time to time;

“Director” (署長) means –

(a) the Director of Agriculture, Fisheries and Conservation;

(b) the Deputy Director of Agriculture, Fisheries and Conservation; or

(c) an Assistant Director of Agriculture, Fisheries and Conservation;

“export” (輸出) means to take, or cause to be taken, out of Hong Kong;

“export notification” (輸出通知書) means a notification sent for the purposes of section 23(1)(a);

“genetically modified organism” and “GMO” (基因改造生物) mean a living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology;

“GMO approval application” (基因改造生物核准申請) means an application made under section 8(1);

“import” (輸入) means to bring, or cause to be brought, into Hong Kong;

“living organism” (活生物體) means a biological entity capable of transferring or replicating genetic materials, including sterile organisms, viruses and viroids, but does not include a human being;

“modern biotechnology” (現代生物技術) means the application of in vitro nucleic acid techniques (including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles), or techniques involving the fusion of cells beyond the taxonomic family, that –

(a) overcome natural physiological reproductive or recombination barriers; and

(b) are not techniques used in traditional breeding and selection;

“non-disclosure request” (不披露要求) means a request made under section 14(1);

“Party” (締約方) means a contracting party to the Protocol and includes a place to which the Protocol applies;

“pharmaceutical product” (藥劑製品) means a pharmaceutical product within the meaning of section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138);

“prescribed fee” (訂明費用), in relation to a matter provided for in this Ordinance, means the fee specified in Schedule 5 in respect of the matter;

“proposed confidential information” (建議機密資料) means any information specified under section 14(2)(b) in a non-disclosure request;

“Protocol” (《議定書》) means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity done at Montreal on 29 January 2000, as amended from time to time;

“Protocol instrument” (《議定書》文書) means –

- (a) a decision adopted by the Conference of the Parties serving as the meeting of the Parties to the Protocol by virtue of Article 29 of the Protocol; or
- (b) a notification made to the Biosafety Clearing-House by a competent authority;

“register” (紀錄冊) means the register established and maintained by the Director under section 25;

“Secretary” (局長) means the Secretary for the Environment;

“specified form” (指明表格) means a form specified under section 44;

“variation request” (更改要求) means a request made under section 11(1) or (2).

- (2) For the purposes of this Ordinance, a GMO is in transit if –
  - (a) it is brought into Hong Kong solely for the purpose of taking it out of Hong Kong; and
  - (b) it remains at all times in or on the vessel, vehicle, train or aircraft in or on which it is brought into Hong Kong.
- (3) For the purposes of this Ordinance, a GMO is in transshipment if –
  - (a) it is brought into Hong Kong solely for the purpose of taking it out of Hong Kong; and



- (b) it is or is to be removed from the vessel, vehicle, train or aircraft in or on which it is brought into Hong Kong and –
  - (i) returned to the same vessel, vehicle, train or aircraft for the purpose of being taken out of Hong Kong; or
  - (ii) transferred to another vessel, vehicle, train or aircraft for the purpose of being taken out of Hong Kong.

### **3. Meanings of “released into environment” and “contained use”**

(1) For the purposes of this Ordinance, a GMO is released into the environment if –

- (a) it is not in contained use; and
- (b) it is exposed to a condition in which it may grow or reproduce.

(2) For the purposes of this Ordinance, a GMO is in contained use if –

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

### **4. Ordinance applies to Government**

(1) Subject to subsections (2) and (3), this Ordinance applies to the Government.

(2) Neither the Government, nor any public officer in the officer’s capacity as such, is liable to be prosecuted for an offence against this Ordinance.

(3) No prescribed fee is payable by any Government department that does not operate under a trading fund within the meaning of the Trading Funds Ordinance (Cap. 430).

## PART 2

### RELEASE OF GMOs INTO ENVIRONMENT AND IMPORT OF GMOs INTENDED FOR RELEASE

#### **Division 1 - Restrictions on Release of GMOs into Environment and Import of GMOs Intended for Release**

##### **5. Restrictions on release into environment and maintenance of lives of GMOs**

(1) This section does not apply to or in relation to a GMO that is a pharmaceutical product for use by human beings.

(2) A person must not knowingly cause a GMO to be released into the environment, unless each of the conditions specified in subsection (4) is complied with.

(3) A person must not knowingly maintain the life of a GMO that is in a state of being released into the environment, unless each of the conditions specified in subsection (4) is complied with.

(4) The conditions specified for the purposes of subsections (2) and (3) are –

- (a) the GMO is an approved GMO;
- (b) the approval is entered in the register under section 18;
- (c) every condition (if any) for the approval of the GMO, as set out in the register, has been complied with.

(5) A person who contravenes subsection (2) or (3) commits an offence and is liable to a fine at level 6 and to imprisonment for one year.

##### **6. Notification to Director of certain releases of GMOs**

(1) This section applies where a person who has control of a GMO knows that –

- (a) if the GMO is an approved GMO –

- (i) the GMO has been released into the environment;  
and
  - (ii) any condition for the approval of the GMO, as set out in the register, has not been complied with; or
- (b) if the GMO is not an approved GMO –
  - (i) the GMO has been released into the environment;  
and
  - (ii) the GMO is not a pharmaceutical product for use by human beings.
- (2) As soon as practicable after the person knows of the release, the person must, by written notice, inform the Director of the release.
- (3) A person who contravenes subsection (2) commits an offence and is liable to a fine at level 5 and to imprisonment for 6 months.
- (4) A notice under subsection (2) must contain the information set out in Parts 1 and 2 of Schedule 1.
- (5) On receiving a notice under subsection (2), the Director may –
  - (a) direct an authorized officer to enter, during reasonable hours, the place or premises in or on which the GMO was released to dispose of the GMO; or
  - (b) direct the person to dispose of the GMO.

**7. Restrictions on import of GMOs intended for release into environment**

- (1) This section does not apply to or in relation to –
  - (a) a GMO that is in transit or transshipment;
  - (b) a GMO that is intended –
    - (i) for direct consumption as food or feed; or
    - (ii) for processing; or
  - (c) a GMO that is a pharmaceutical product for use by human beings.

(2) A person must not knowingly import a GMO that is intended for release into the environment unless –

- (a) the GMO is an approved GMO;
- (b) the approval is entered in the register under section 18; and
- (c) every condition (if any) for the approval of the GMO, as set out in the register, has been complied with.

(3) A person who contravenes subsection (2) commits an offence and is liable to a fine at level 6 and to imprisonment for one year.

## **Division 2 - Approval of GMOs**

### **8. Application for approval of GMOs for release into environment**

(1) A person may apply to the Director for approval of a GMO for release into the environment.

(2) A GMO approval application must –

- (a) be in the specified form;
- (b) contain the information set out in Part 1 of Schedule 2; and
- (c) be accompanied by –
  - (i) a report on a risk assessment carried out, or caused to be carried out, by the applicant in accordance with Schedule 3, on the possible adverse biosafety effect of the GMO; and
  - (ii) the prescribed fee payable on the application.

(3) If the GMO is to be imported, the GMO approval application must also contain the information set out in Part 2 of Schedule 2.

## **9. Acknowledgement of receipt of GMO approval applications**

(1) Within 90 days after receiving a GMO approval application, the Director must issue a written acknowledgement to the applicant confirming the receipt of the application.

(2) An acknowledgement must state –

- (a) the date on which the Director received the application; and
- (b) whether the application contains, on the face of it, the information set out in Part 1, or Parts 1 and 2, of Schedule 2, as the case requires.

## **10. Approval of GMOs**

(1) Within 270 days after receiving a GMO approval application, the Director must –

- (a) decide whether the GMO is approved for release into the environment; and
- (b) give the applicant a written notice of the decision.

(2) The Director must not approve a GMO for release into the environment unless the Director is satisfied that the possible adverse biosafety effect of the GMO is acceptable or manageable.

(3) On approving a GMO for release into the environment, the Director may attach any condition that the Director thinks fit to the approval.

(4) If the Director refuses to approve a GMO for release into the environment or attaches a condition to an approval, the Director must state the reason for the decision in the notice given under subsection (1).

(5) The Director may, before the expiry of the period within which a decision must be made on a GMO approval application under subsection (1), extend that period by written notice to the applicant.

(6) A notice under subsection (5) must –

- (a) specify the duration of the extended period; and

(b) set out the reason for the extension.

(7) If the Director has, by written notice, required an applicant to provide additional information or supporting documents under section 19(1), the number of days falling within the period specified in subsection (8) must be disregarded in calculating the 270-day period or the extended period for the purposes of subsection (1).

(8) The period is the one –

(a) beginning with the date of the written notice; and

(b) ending with the date on which the additional information or supporting documents required were received by the Director.

#### **11. Request for variation of decisions on GMO approval applications**

(1) If the Director refuses to approve a GMO for release into the environment under section 10(1), the applicant under the GMO approval application may, on any of the grounds specified in subsection (3), request the Director to vary the decision by approving the GMO for such release with or without conditions.

(2) If the Director approves a GMO for release into the environment with conditions under section 10(1), the applicant under the GMO approval application may, on any of the grounds specified in subsection (3), request the Director to vary the decision by cancelling or varying the conditions.

(3) The grounds specified for the purposes of subsections (1) and (2) are –

(a) a change in circumstances that may influence the Director's assessment on the possible adverse biosafety effect of the GMO has occurred;

(b) additional scientific or technical information that may influence the Director's assessment on the possible adverse biosafety effect of the GMO has become available.

- (4) A variation request must –
  - (a) be in the specified form; and
  - (b) be accompanied by –
    - (i) relevant information in support of the request; and
    - (ii) the prescribed fee payable on the request.
- (5) Within 90 days after receiving a variation request, the Director must –
  - (a) decide whether to confirm or vary the decision on the GMO approval application; and
  - (b) give the applicant a written notice of the confirmation or variation and the reason for it.

**12. Variation of decisions on GMO approval applications or variation requests on Director's own initiative**

- (1) The Director may, on his or her own initiative on any of the grounds specified in subsection (2), vary the decision made on a GMO approval application or variation request under section 10(1)(a) or 11(5)(a) by –
  - (a) cancelling or varying any condition attached to, or adding any condition to, the approval of the GMO; or
  - (b) revoking the approval of the GMO.
- (2) The grounds are –
  - (a) a change in circumstances that influences the Director's assessment on the possible adverse biosafety effect of the GMO has occurred;
  - (b) additional scientific or technical information that influences the Director's assessment on the possible adverse biosafety effect of the GMO has become available;
  - (c) the Director considers it in the public interest to do so.

(3) After varying a decision on a GMO approval application or variation request under subsection (1), the Director must give the applicant a written notice of the variation and the reason for it.

(4) If –

(a) the approval of a GMO is revoked under subsection (1)(b);  
and

(b) the GMO has been released into the environment under the approval,

the applicant under the GMO approval application must, within the period specified in the notice of variation under subsection (3), inform the Director of the release by written notice.

(5) A notice under subsection (4) must contain the information set out in Part 1 of Schedule 1.

(6) A person who contravenes subsection (4) commits an offence and is liable to a fine at level 5.

(7) If the approval of a GMO is revoked under subsection (1)(b), the Director may, by the notice of variation under subsection (3), give the applicant under the GMO approval application any direction that the Director thinks fit on the safekeeping or disposal of –

(a) the GMO; or

(b) any container containing the GMO.

(8) A person given a direction under subsection (7) must, subject to section 39(4), carry out the direction at the person's cost within the period specified in the notice.

(9) A person who contravenes subsection (8) commits an offence and is liable to a fine at level 6.



### **Division 3 - Entry of Information and Decisions on GMO Approval Applications and Variation Requests in Register**

#### **13. Entry of information on GMO approval applications and variation requests (other than that specified in non-disclosure requests) in register**

(1) Within 14 days after the Director is satisfied that a GMO approval application contains, on the face of it, the information set out in Part 1, or Parts 1 and 2, of Schedule 2, as the case requires, the Director must enter the information in the register.

(2) If, after entering any information in the register under subsection (1), the Director receives further information from the applicant –

- (a) on the GMO approval application; or
- (b) on a variation request on the Director's decision on that application,

the Director must enter the further information in the register within 14 days after receipt of it.

(3) Subsections (1) and (2) do not apply in relation to any information that is specified in a non-disclosure request.

#### **14. Making of non-disclosure requests**

(1) When providing any information to the Director for the purposes of a GMO approval application or variation request, the applicant may request the Director not to enter the information in the register.

(2) A non-disclosure request must –

- (a) be in the specified form;
- (b) specify the information that the Director is requested not to enter in the register; and
- (c) set out the justifications for the request.

(3) Subsection (1) does not apply in relation to the following information –

- (a) the name and address of the applicant;
- (b) a general description of the GMO;
- (c) a summary of the risk assessment on the possible adverse biosafety effect of the GMO; and
- (d) any proposed methods and plans for dealing with the possible adverse biosafety effect of the GMO in emergency circumstances.

**15. Director's decisions on non-disclosure requests**

(1) Within 30 days after receiving a non-disclosure request on a GMO approval application or variation request, the Director must –

- (a) decide –
  - (i) that none of the proposed confidential information is to be entered in the register;
  - (ii) that only some of the proposed confidential information is to be entered in the register; or
  - (iii) that all of the proposed confidential information is to be entered in the register; and
- (b) give the applicant a written notice of the decision and the reason for it.

(2) The Director may decide not to enter certain proposed confidential information in the register if the Director is satisfied that non-disclosure of the information would not be contrary to the public interest.

**16. Review of Director's decisions on non-disclosure requests**

(1) An applicant under a GMO approval application or variation request who is aggrieved by a decision of the Director under section 15(1)(a)(ii) or (iii) may, within 14 days after receiving notice of the decision, request the Director to review the decision.

- (2) A request for review must –
  - (a) be in the specified form;
  - (b) set out the justifications for the request; and
  - (c) be accompanied by the prescribed fee payable on the request.
- (3) Within 30 days after receiving a request for review, the Director must –
  - (a) decide on the request; and
  - (b) give the applicant a written notice of the decision and the reason for it.

**17. Entry of non-confidential information in register**

(1) Subject to subsection (4), if no request has been made under section 16(1) within the 14-day period for reviewing the Director's decision on a non-disclosure request, the Director must, as soon as practicable after the expiry of that period, enter the non-confidential information in the register.

- (2) Subject to subsection (4), if –
  - (a) a request has been made under section 16(1) for reviewing the Director's decision on a non-disclosure request; and
  - (b) no appeal has been lodged under section 39(1) within the 28-day period against the Director's decision on the request for review, or an appeal so lodged has been withdrawn or abandoned,

the Director must, as soon as practicable after the expiry of that period, or after the appeal has been withdrawn or abandoned, as the case may be, enter the non-confidential information in the register.

(3) Subject to subsection (4), if an appeal has been lodged under section 39(1) against the Director's decision on a request for review under section 16(1) and the appeal has not been withdrawn or abandoned, the Director

must, as soon as practicable after the appeal has been decided, enter the non-confidential information in the register.

(4) The Director must not, in relation to a GMO approval application, enter any non-confidential information in the register before other information received for the purposes of the application has been so entered under section 13(1).

(5) In this section –  
 “non-confidential information” (非機密資料), in relation to a GMO approval application or variation request, means any proposed confidential information specified in the non-disclosure request that is to be entered in the register –

- (a) in the case of subsection (1), according to the decision of the Director under section 15(1)(a)(ii) or (iii);
- (b) in the case of subsection (2), according to the decision of the Director under section 16(3)(a);
- (c) in the case of subsection (3), according to the decision of the Administrative Appeals Board.

### **18. Entry of decisions on GMO approval applications and variation requests in register**

(1) If no appeal has been lodged under section 39(1) within the 28-day period against the Director’s decision under section 10(1)(a), 11(5)(a) or 12(1), the Director must, as soon as practicable after the expiry of that period, enter that decision in the register.

(2) If an appeal has been lodged under section 39(1) within the 28-day period against the Director’s decision under section 10(1)(a), 11(5)(a) or 12(1), the Director must –

- (a) as soon as practicable after the appeal has been withdrawn or abandoned, enter that decision in the register; or

- (b) as soon as practicable after the appeal has been decided, enter the Director's decision as confirmed, varied or reversed by the Administrative Appeals Board in the register.

#### **Division 4 - Provisions Supplementary to Divisions 2 and 3**

##### **19. Provision of additional information or supporting documents on GMO approval applications and variation requests**

(1) For the purpose of determining a GMO approval application or variation request, the Director may, by written notice, require the applicant –

- (a) to provide additional information or supporting documents on the application or request; and
- (b) to appear before the Director to answer any question raised, or provide any clarification required, by the Director.

(2) The Director may require an applicant under a GMO approval application to provide additional information or supporting documents under subsection (1) even though the acknowledgment under section 9(1) states that the application contains, on the face of it, the information set out in Part 1, or Parts 1 and 2, of Schedule 2, as the case requires.

##### **20. Withdrawal of GMO approval applications or variation requests**

(1) An applicant under a GMO approval application or variation request may, in writing, withdraw the application or request at any time before the Director makes a decision on the application or request.

(2) If a GMO approval application or variation request is withdrawn under subsection (1), the Director must –

- (a) cease to process the application or request; and

- (b) return to the applicant any record or document, or part of the record or document, containing any confidential information in relation to the application or request.

## **21. Withdrawal of information or document provided**

(1) An applicant under a GMO approval application or variation request may, in writing, withdraw any information or document provided for the purposes of the application or request at any time before the Director makes a decision on the application or request.

(2) Where any information or document provided for the purposes of a GMO approval application or variation request is withdrawn under subsection (1), the Director must –

- (a) continue to process the application or request as if the information or document had not been provided; and
- (b) if the information withdrawn is confidential information, return to the applicant any record or document, or part of the record or document, containing the information.

## **PART 3**

### **EXPORT OF GMOs INTENDED FOR RELEASE INTO ENVIRONMENT**

## **22. Application of this Part**

This Part does not apply to or in relation to –

- (a) a GMO that is in transit or transshipment;
- (b) a GMO that is intended –
  - (i) for direct consumption as food or feed; or
  - (ii) for processing; or
- (c) a GMO that is a pharmaceutical product for use by human beings.

### **23. Restrictions on export of GMOs intended for release into environment**

(1) A person must not knowingly export a GMO that is intended for release into the environment unless –

(a) the person has sent to the competent authority of the place to which the GMO is to be exported a notification of the export; and

(b) the person has received from that authority the approval (whether or not with conditions attached) for that export.

(2) Subsection (1)(a) does not apply if prior notification to the competent authority for exporting the GMO to the place is not required under the legal or regulatory requirements of that place.

(3) Subsection (1)(b) does not apply if prior approval from the competent authority for exporting the GMO to the place is not required under the legal or regulatory requirements of that place.

(4) An export notification must contain the information set out in Schedule 4.

(5) A person who contravenes subsection (1) commits an offence and is liable to a fine at level 6 and to imprisonment for one year.

(6) In any proceedings for an offence under subsection (5), a certificate purporting to be issued by or on behalf of the competent authority of a place outside Hong Kong certifying that prior notification to, or approval from, as the case requires, that authority for exporting the GMO to the place is, or is not, required under the legal or regulatory requirements of that place is admissible as evidence of the matters stated in the certificate.

### **24. Copies of export notifications and approvals to be sent to Director**

(1) Within 14 days after sending an export notification, a person must send to the Director –

(a) a copy of the notification; and

- (b) a declaration by the person that –
  - (i) the copy is a true copy of the notification; and
  - (ii) the information contained in the notification is true and correct to the best of the person's knowledge and belief.

(2) Within 14 days after receiving from the competent authority of a place outside Hong Kong an approval mentioned in section 23(1)(b), a person must send to the Director –

- (a) a copy of the approval; and
- (b) a declaration by the person that the copy is a true copy of the approval.

(3) A declaration under subsection (1)(b) or (2)(b) must be in the specified form.

(4) A person who contravenes subsection (1) or (2) commits an offence and is liable to a fine at level 5.

## PART 4

### REGISTER

#### **25. Director must establish and maintain register**

(1) The Director must establish and maintain a register for the purposes of this Ordinance.

(2) The Director may keep the register in such form as the Director considers appropriate, including in a form other than a documentary form.

(3) The register must be available for inspection by members of the public at the office of the Agriculture, Fisheries and Conservation Department during normal business hours, free of charge.

#### **26. Contents of register**

- (1) The register must contain –



- (a) subject to subsection (3) –
    - (i) every GMO approval application, and any information received by the Director for the purposes of the application; and
    - (ii) every variation request, and any information received by the Director for the purposes of the request;
  - (b) every decision of the Director made under section 10(1)(a), 11(5)(a) or 12(1);
  - (c) every decision of the Administrative Appeals Board on any appeal lodged against a decision of the Director made under section 10(1)(a), 11(5)(a) or 12(1); and
  - (d) every exemption granted by the Secretary under section 42.
- (2) The register may also contain any other information relating to the administration of this Ordinance or implementation of the Protocol that the Director considers appropriate.
- (3) The register must not contain any confidential information in relation to a GMO approval application or variation request.

## PART 5

### ENFORCEMENT

#### **27. Appointment of authorized officers**

The Director may, in writing, appoint any public officer or class of public officer to be an authorized officer for the purposes of this Ordinance.

#### **28. Powers to search vessels, detain persons, etc.**

(1) An authorized officer may stop, board and search any vessel, vehicle, train or aircraft (other than a ship of war, military vehicle or military aircraft) if the officer has reason to suspect that an offence under section 5, 7 or

23 has been, is being or is to be committed in or on the vessel, vehicle, train or aircraft.

(2) If an authorized officer has reason to suspect that a person has committed, is committing or is to commit an offence under section 5, 7 or 23, the officer may without warrant –

- (a) stop and search the person, and search the property of the person, for anything that is likely to be relevant (whether by itself or together with anything else) to the investigation of the offence; and
- (b) detain the person for a reasonable period while the officer inquires about the suspected commission of the offence.

**29. Powers to inspect place or premises, take copies of documents, etc. for verifying compliance with this Ordinance**

(1) If an authorized officer has reason to suspect that a GMO is being kept in any place or premises, the officer may, for the purpose of verifying compliance with this Ordinance, without notice –

- (a) enter and inspect the place or premises during reasonable hours;
- (b) require the production of, inspect and examine any thing that the officer has reason to believe to be, or to contain, a GMO; and
- (c) require the production of, inspect, examine and take copies of any document that is related to compliance with this Ordinance, or any document that relates to the nature or origin of the GMO.

(2) Subsection (1) does not empower an authorized officer to enter –

- (a) any premises that are used exclusively as a dwelling house;
- or

- (b) any part of any premises that is used exclusively as a dwelling house.

**30. Powers to enter and search place or premises on issue of warrant**

(1) A magistrate may issue a warrant authorizing an authorized officer to enter and search any place or premises if satisfied by information on oath that there are reasonable grounds to suspect that –

- (a) an offence under this Ordinance has been, is being or is to be committed in or on the place or premises; or
- (b) there is in or on the place or premises any thing that is or contains evidence of the commission of an offence under this Ordinance.

(2) A warrant continues in force until the purposes for which the entry is necessary have been satisfied.

(3) An authorized officer authorized by such a warrant to enter and search any place or premises –

- (a) may at any time enter and search the place or premises, using necessary force; and
- (b) may remove any thing that obstructs the entry and search.

(4) An authorized officer may also detain any person found in or on the place or premises, for such period as is reasonably required to permit the search to be carried out, where the person might prejudice the purpose of the search if not so detained.

(5) An authorized officer entering any place or premises under a warrant may take with the officer such persons as may be necessary.

(6) This section does not prejudice any powers of entry and search conferred on police officers under any other law.

### **31. Powers to seize, remove and detain things**

(1) An authorized officer may seize, remove and detain any thing that appears to the officer to be or to contain evidence of the commission of an offence under this Ordinance.

(2) An authorized officer does not incur any civil liability in respect of anything done or omitted to be done by the officer in good faith in the exercise or purported exercise of any power under this section.

### **32. Powers to take samples and carry out tests**

(1) An authorized officer may, for the purpose of verifying compliance with this Ordinance or obtaining evidence of the commission of an offence under this Ordinance –

- (a) take a sample of any thing that the officer has reason to believe to be, or to contain, a GMO;
- (b) require any person in control of such thing to provide a sample of it; and
- (c) take any photographs of the thing.

(2) An authorized officer who takes a sample under subsection (1) must issue a receipt for the sample, but is not required –

- (a) to pay for it; or
- (b) to return it to the person from whom it was taken.

(3) An authorized officer may arrange to carry out any necessary test in respect of a sample taken under subsection (1) to ascertain –

- (a) whether the sample is or contains a GMO;
- (b) if the sample is or contains a GMO –
  - (i) the identity of the GMO; and
  - (ii) the quantity and percentage of the GMO in the sample.

(4) A certificate of analysis issued by an accredited laboratory on a sample taken under subsection (1) may be tendered in evidence in any

proceedings under this Ordinance and is evidence of the facts stated in it unless the contrary is proved.

(5) In this section, “accredited laboratory” (獲認可實驗室) means a laboratory accredited under the Hong Kong Laboratory Accreditation Scheme managed by the Commissioner for Innovation and Technology on behalf of the Government.

### **33. Power to require identification**

(1) If an authorized officer has reason to suspect that a person has committed, is committing or is to commit an offence under this Ordinance, the officer may without warrant stop the person or, where the person is in or on a vessel, vehicle, train or aircraft (other than a ship of war, military vehicle or military aircraft), stop and board the vessel, vehicle, train or aircraft for the purposes of requiring that person –

- (a) to state the person’s name and address; and
- (b) to produce the person’s proof of identity for inspection.

(2) In this section, “proof of identity” (身分證明文件) means proof of identity within the meaning of section 17B of the Immigration Ordinance (Cap. 115).

## **PART 6**

### **DISPOSAL AND FORFEITURE OF THINGS SEIZED**

#### **34. Director’s power to sell or dispose of certain things immediately after seizure**

(1) If any of the things specified in subsection (2) has been seized under section 31, the Director may, immediately after the seizure, sell the thing or disposed of it in any other way.

- (2) The things are –
- (a) any live animal –

- (i) that, for any reason, it is not practicable for the Director to keep in captivity; or
- (ii) that is likely to die or to be subject to unnecessary suffering if it is kept in captivity;
- (b) any live plant that, for any reason, it is not practicable for the Director to keep; and
- (c) any thing –
  - (i) that, for any reason, it is not practicable for the Director to keep; or
  - (ii) that is perishable.
- (3) Subject to sections 35, 36 and 37, the proceeds of sale of any thing sold under subsection (1) must be paid into the general revenue.

**35. Return and forfeiture of things seized in respect of offences under section 5, 7 or 23**

(1) If a person is convicted of an offence under section 5, 7 or 23, any thing seized under section 31 in connection with the offence that is a GMO or contains a GMO is, or any proceeds of sale of that thing are, to be forfeited to the Government.

(2) If a person is convicted of an offence under section 5, 7 or 23, the court or magistrate may order any thing seized under section 31 in connection with the offence that is not a GMO or does not contain a GMO, or any proceeds of sale of that thing –

- (a) to be returned to the person from whom it was seized or to its owner; or
- (b) to be forfeited to the Government.

(3) If an offence is prosecuted under section 5, 7 or 23 and no defendant in the proceedings is convicted of the offence, the court or magistrate may order any thing seized under section 31 in respect of which the prosecution is brought, or any proceeds of sale of that thing –

- (a) to be returned to the person from whom it was seized or to its owner; or
- (b) to be forfeited to the Government.

**36. Return and forfeiture of things seized in respect of offences under other sections**

If an offence is prosecuted under a provision of this Ordinance other than section 5, 7 or 23, the court or magistrate may, whether or not any defendant in the proceedings is convicted of the offence, order any thing seized under section 31 in respect of which the prosecution is brought, or any proceeds of sale of that thing –

- (a) to be returned to the person from whom it was seized or to its owner; or
- (b) to be forfeited to the Government.

**37. Return and forfeiture of things seized if no prosecution for offences**

(1) If a thing has been seized under section 31 but no prosecution has been brought in respect of that thing under this Ordinance, an authorized officer may apply to the court or magistrate for an order in respect of that thing or any proceeds of sale of that thing.

(2) On an application under subsection (1), the court or magistrate may, subject to subsection (3), order the thing concerned or any proceeds of sale of that thing –

- (a) to be returned to the person from whom it was seized or to its owner; or
- (b) to be forfeited to the Government.

(3) The court or magistrate must, if satisfied that the owner of the thing concerned is unknown or cannot be found, order the thing concerned or any proceeds of sale of that thing to be forfeited to the Government.

(4) If a thing forfeited to the Government pursuant to an order under subsection (3) is sold or disposed of under section 38(1), a person who considers that he, she or it is aggrieved by the sale or disposal may complain to the court or magistrate within 6 months after the sale or disposal.

(5) On a complaint under subsection (4), the court or magistrate may, if satisfied as to the complainant's title to the thing concerned, order such amount of compensation to be paid to the complainant as the court or magistrate considers just.

**38. Director's powers to sell or dispose of and to give directions on disposal of forfeited things**

(1) The Director may sell, or dispose of in any other way, any thing that is forfeited to the Government under this Part in such manner as the Director thinks fit.

(2) The proceeds of sale of any thing sold under subsection (1) must be paid into the general revenue.

(3) If –

(a) a person has been convicted of an offence under section 5, 7 or 23; and

(b) a thing in connection with the offence has been forfeited to the Government under section 35(1) or (2),

the Director may, by written notice, direct the person to dispose of the thing through repatriation or destruction.

(4) A person given a direction under subsection (3) must, subject to section 39(4), carry out the direction at the person's cost within the period specified in the notice.

(5) A person who contravenes subsection (4) commits an offence and is liable to a fine at level 6.



## PART 7

### MISCELLANEOUS PROVISIONS

#### **39. Appeals**

(1) If a person is aggrieved by a decision under section 10(1)(a), 11(5)(a), 12(1) or 16(3)(a), or a direction under section 12(7) or 38(3), the person may, within 28 days after receiving notice of the decision or direction, appeal to the Administrative Appeals Board against that decision or direction.

(2) After lodging an appeal under subsection (1), the person must, pending the Administrative Appeals Board's decision on the appeal, cause the GMO that is the subject of the appeal to be kept in a manner that effectively limits its contact with, and its impact on, the environment.

(3) Subsection (2) does not apply if the GMO has already been released into the environment.

(4) If an appeal is lodged against a direction referred to in subsection (1), the person is not required to carry out the direction pending the Administrative Appeals Board's decision on the appeal.

#### **40. Offences on obstruction and failure to comply with requirements**

(1) On performing any function or duty, or exercising any power, under this Ordinance, an authorized officer must produce written evidence of the officer's identity.

(2) A person commits an offence if the person –

(a) wilfully obstructs an authorized officer from performing any function or duty, or exercising any power, under this Ordinance; or

(b) without reasonable excuse, fails to comply with any requirement imposed by an authorized officer under this Ordinance.

(3) A person who commits an offence under subsection (2) is liable to a fine at level 6 and to imprisonment for 6 months.

#### **41. Provision of false information**

(1) A person commits an offence if the person, in respect of a GMO approval application or variation request, or in purported compliance with this Ordinance, produces any document, furnishes any information or makes any statement that the person –

- (a) knows or believes to be false;
- (b) does not believe to be true; or
- (c) knows or believes to be misleading in a material particular.

(2) A person who commits an offence under subsection (1) is liable to a fine at level 6 and to imprisonment for 6 months.

#### **42. Secretary's power to grant exemptions**

(1) The Secretary may, by notice published in the Gazette, exempt any person, any group or description of persons, or any GMO from the application of section 5, 7 or 23.

(2) An exemption may take effect generally or for any purposes or by reference to any circumstances, and either conditionally or unconditionally.

#### **43. Expert group**

(1) The Secretary may establish an expert group consisting of members appointed by the Secretary.

(2) The Director may refer any question in connection with the administration of this Ordinance, including the processing of individual GMO approval applications, variation requests and non-disclosure requests, to the expert group, or individual members of the group, for advice.

#### **44. Director's power to specify forms**

The Director may specify any form to be used for the purposes of any matter provided for in this Ordinance.

**45. Secretary's power to amend Schedules**

The Secretary may, by order published in the Gazette, amend Schedule 1, 2, 3, 4, 5 or 6.

**46. Secretary's power to make regulations**

(1) The Secretary may make regulations for all or any of the following purposes –

- (a) to provide for the requirements relating to the documents to be furnished for the import and export of –
  - (i) a GMO intended for direct consumption as food or feed, or for processing;
  - (ii) a GMO intended for contained use; or
  - (iii) a GMO intended for release into the environment;
- (b) to enable any part of a Protocol instrument to have the force of law in Hong Kong with or without modification;
- (c) to provide generally for the better carrying out of the purposes of this Ordinance.

(2) A regulation under subsection (1) may –

- (a) make different provisions for different circumstances and provide for a particular case or class of case;
- (b) be made so as to apply only in specified circumstances; and
- (c) contain such incidental, supplementary, consequential, transitional or saving provision as may be necessary or expedient in consequence of the regulation.

(3) A regulation under subsection (1) may provide –

- (a) that it is an offence for a person to contravene a provision of the regulation; and

- (b) that such an offence is punishable by a fine not exceeding level 6 and imprisonment for a term not exceeding 6 months.

**47. Prescribed fees paid not refundable**

Any prescribed fee paid under this Ordinance is not refundable.

**PART 8**

**TRANSITIONAL PROVISIONS**

**48. Interpretation**

In this Part –

“commencement date” (生效日期) means the date on which this Ordinance comes into operation;

“released GMO” (已釋出的基因改造生物) means a GMO that was released into the environment before the commencement date;

“transitional period” (過渡期) means the 6-month period beginning on the commencement date.

**49. Maintenance of lives of released GMOs during transitional period**

During the transitional period, section 5 does not prohibit a person from knowingly maintaining the life of a released GMO that is in a state of being released into the environment.

**50. Notification of or application for approval of released GMOs during transitional period**

- (1) This section applies if a person knows that –
- (a) the person caused a released GMO to be so released;
  - (b) the person, before the commencement date, maintained the life of a released GMO that was in a state of being released into the environment; or

- (c) the person, during the transitional period, maintains the life of a released GMO that is in a state of being released into the environment.
- (2) The person must, during the transitional period –
  - (a) inform the Director of the release or maintenance by written notice; or
  - (b) submit a GMO approval application in accordance with section 8 in respect of the released GMO.
- (3) On receiving a notice under subsection (2)(a), the Director may –
  - (a) direct an authorized officer to enter the place or premises in or on which the released GMO was released or maintained during reasonable hours to dispose of the GMO; or
  - (b) direct the person to dispose of the released GMO.
- (4) Section 5 does not prohibit a person who has informed the Director of the release or maintenance of a released GMO under subsection (2)(a) from knowingly maintaining the life of the GMO that is in a state of being released into the environment, during the period from the date of the notice to the date when the GMO is disposed of.
- (5) Section 5 does not prohibit a person who has submitted a GMO approval application under subsection (2)(b) from knowingly maintaining the life of the released GMO that is in a state of being released into the environment, during the period from the date of the application to the date when the decision on the application is entered in the register under section 18.
- (6) A notice under subsection (2)(a) must contain the information set out in Schedule 6.

## PART 9

## CONSEQUENTIAL AMENDMENT

**Administrative Appeals Board Ordinance****51. Schedule amended**

The Schedule to the Administrative Appeals Board Ordinance (Cap. 442) is amended by adding –

- “67. Genetically Modified Organisms (Control of Release) Ordinance ( of 2009)
- (a) A decision of the Director of Agriculture, Fisheries and Conservation, the Deputy Director of Agriculture, Fisheries and Conservation or an Assistant Director of Agriculture, Fisheries and Conservation –
- (i) under section 10(1)(a) on an application for approval of a genetically modified organism;
  - (ii) under section 11(5)(a) on a request to vary a prior decision on an application for approval of a genetically modified organism;
  - (iii) under section 12(1) to vary a prior decision on an application for approval of a genetically modified organism or on a request to vary such a prior decision.

- (b) A direction of the Director of Agriculture, Fisheries and Conservation, the Deputy Director of Agriculture, Fisheries and Conservation or an Assistant Director of Agriculture, Fisheries and Conservation –
- (i) under section 12(7) on the safekeeping or disposal of a genetically modified organism or a container containing the organism;
  - (ii) under section 38(3) to dispose of a forfeited thing through repatriation or destruction.
- (c) A decision of the Director of Agriculture, Fisheries and Conservation, the Deputy Director of Agriculture, Fisheries and Conservation or an Assistant Director of Agriculture, Fisheries and Conservation under section 16(3)(a) to enter certain information submitted for the approval of a genetically modified organism in the register.”.

## SCHEDULE 1

[ss. 6, 12 &amp; 45]

INFORMATION TO BE CONTAINED IN WRITTEN NOTICES ON  
RELEASE OF GMOs

## PART 1

1. The name and identity of the GMO.
2. The location, date and time of release into the environment of the GMO.
3. The circumstances under which the GMO was released.
4. The use of the GMO.
5. The quantity or volume of the GMO released.
6. Any other available information relating to the release of the GMO.
7. The name, address and contact details of the person making the notification.

## PART 2

8. The taxonomic status of the GMO.
9. The characteristics and traits of the GMO.
10. Any available information on the possible adverse biosafety effect of the GMO.
11. Any possible risk management measures on the release of the GMO into the environment.



12. Any other available information relating to the GMO.

## SCHEDULE 2

[ss. 8, 9, 13, 19 & 45]

### INFORMATION TO BE CONTAINED IN GMO APPROVAL APPLICATIONS

#### PART 1

1. The name, address and contact details of the applicant.
2. The name and identity of the GMO.
3. The intended date of release into the environment of the GMO.
4. The taxonomic status, common name and point of collection or acquisition of the recipient organism or parental organism of the GMO, and characteristics of that recipient organism or parental organism related to possible adverse biosafety effect.
5. The centre of origin and centre of genetic diversity, if known, of the recipient organism of and, if applicable, the parental organism of the GMO and a description of the habitats where that recipient organism and parental organism may persist or proliferate.
6. The taxonomic status, common name and point of collection or acquisition of the donor organism of the GMO, and characteristics of that donor organism related to possible adverse biosafety effect.
7. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.
8. Intended use of the GMO or products from the GMO, namely, processed materials that are of genetically modified organism origin and that contain

detectable novel combinations of replicable genetic materials obtained through the use of modern biotechnology.

9. The quantity or volume of the GMO to be released and, if applicable, imported.
10. Suggested methods for the safe handling, storage, transport and use of the GMO, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

## PART 2

11. The place from which the GMO is to be imported into Hong Kong.
12. The name, address and contact details of the exporter in that place.
13. The intended date of export of the GMO from that place, if known.
14. The domestic classification of the biosafety level of the GMO in that place, if any.
15. The regulatory status of the GMO in that place and, if the GMO is banned in that place, the reason for the ban.
16. The result and purpose of any notification made to competent authorities of other places regarding the export of the GMO to those other places.

## SCHEDULE 3

[ss. 8 & 45]

### REQUIREMENTS ON RISK ASSESSMENT ON POSSIBLE ADVERSE BIOSAFETY EFFECTS OF GMOS

1. Risk assessment must be carried out in a scientifically sound and transparent manner, and may take into account expert advice of, and guidelines developed by, relevant international organizations.

2. Risks associated with the GMO or products from the GMO, namely, processed materials that are of genetically modified organism origin and that contain detectable novel combinations of replicable genetic materials obtained through the use of modern biotechnology, must be considered in the context of the risks posed by the non-modified recipient or parental organism in the likely potential receiving environment.
  
3. Risk assessment must entail, as appropriate, the following steps –
  - (a) an identification of any novel genotypic and phenotypic characteristics associated with the GMO that may have an adverse effect on biological diversity in the likely potential receiving environment;
  - (b) an evaluation of the likelihood of the adverse effect being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO;
  - (c) an evaluation of the consequences should the adverse effect be realized;
  - (d) an estimation of the overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the adverse effect being realized;
  - (e) a recommendation as to whether or not the risks are acceptable or manageable, including, if necessary, identification of strategies to manage those risks;
  - (f) where there is uncertainty regarding the level of risk, obtaining further information on the specific issues of concern or implementing appropriate risk management strategies or monitoring the GMO in the likely potential receiving environment.

4. Risk assessment must take into account the relevant technical and scientific details regarding the characteristics of the following subjects –

- (a) recipient organism or parental organism: biological characteristics of the recipient organism or parental organism, including information on taxonomic status, common name, origin, centre of origin and centre of genetic diversity, if known, and a description of the habitat where that recipient organism or parental organism may persist or proliferate;
- (b) donor organism: the taxonomic status, common name, source, and other relevant biological characteristics of the donor organism;
- (c) vector: characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- (d) insert and modification –
  - (i) if modification was introduced through the application of in vitro nucleic acid techniques: genetic characteristics of the inserted nucleic acid and the function it specifies, and characteristics of the modification introduced;
  - (ii) if modification was introduced through the application of techniques involving the fusion of cells: characteristics of the modification introduced;
- (e) GMO: identity of the GMO, and the differences between the biological characteristics of the GMO and those of the recipient organism or parental organism;
- (f) detection and identification of the GMO: suggested detection and identification methods and their specificity, sensitivity and reliability;

- (g) information relating to the intended use of the GMO: information relating to the intended use of the GMO, including new or changed use compared to the recipient organism or parental organism;
- (h) likely potential receiving environment: information on the location, and geographical, climatic and ecological characteristics, including relevant information on biological diversity and centre of origin of the likely potential receiving environment.

#### SCHEDULE 4

[ss. 23 & 45]

#### INFORMATION TO BE CONTAINED IN EXPORT NOTIFICATIONS

1. The name, address and contact details of the exporter in Hong Kong.
2. The place to which the GMO is to be exported from Hong Kong.
3. The name, address and contact details of the importer in that place.
4. The name and identity of the GMO.
5. The intended date of export and release into the environment of the GMO, if known.
6. The taxonomic status, common name and point of collection or acquisition of the recipient organism or parental organism of the GMO, and characteristics of that recipient organism or parental organism related to possible adverse biosafety effect.
7. The centre of origin and centre of genetic diversity, if known, of the recipient organism of and, if applicable, the parental organism of the

- GMO and a description of the habitats where that recipient organism and parental organism may persist or proliferate.
8. The taxonomic status, common name and point of collection or acquisition of the donor organism of the GMO, and characteristics of that donor organism related to possible adverse biosafety effect.
  9. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.
  10. Intended use of the GMO or products from the GMO, namely, processed materials that are of genetically modified organism origin and that contain detectable novel combinations of replicable genetic materials obtained through the use of modern biotechnology.
  11. The quantity or volume of the GMO to be exported and released.
  12. A current risk assessment report regarding the proposed release of the GMO into the environment in that place.
  13. Suggested methods for the safe handling, storage, transport and use of the GMO, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
  14. The regulatory status of the GMO in Hong Kong and, if a GMO approval application has been submitted in respect of the GMO and approval of the GMO is refused, the reason for the refusal.
  15. The result and purpose of any notification made by the exporter to other places regarding the export of the GMO.

## SCHEDULE 5

[ss. 2 &amp; 45]

## PRESCRIBED FEES

Item	Description	Amount
1.	Prescribed fee payable on a GMO approval application	\$14,250
2.	Prescribed fee payable on a variation request	\$1,890
3.	Prescribed fee payable on a request for review on a non-disclosure request	\$1,010

## SCHEDULE 6

[ss. 45 &amp; 50]

INFORMATION TO BE CONTAINED IN WRITTEN NOTICES ON  
RELEASE OR MAINTENANCE OF RELEASED GMOS

1. The name and identity of the GMO.
2. The location, date and time of release into the environment or maintenance of the GMO.
3. The circumstances under which the GMO was released or maintained.
4. The use of the GMO.
5. The quantity or volume of the GMO released or maintained.
6. Any other available information relating to the release or maintenance of the GMO.
7. The name, address and contact details of the person making the notification.

## **Explanatory Memorandum**

The object of this Bill is to implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (“Protocol”). The Protocol aims to protect biological diversity from possible adverse impacts arising from the transfer, handling and use of genetically modified organisms (“GMOs”). The Bill controls the release of GMOs into the environment and the import and export of GMOs, and provides for related matters.

### Part 1 – Preliminary

2. Clause 1 provides for the short title and commencement of the Bill (when enacted).
3. Clause 2 contains definitions that are necessary for the interpretation of the Bill.
4. Clause 3 sets out the meanings of “released into environment” and “contained use”. A GMO is released into the environment if it is not in contained use and it is exposed to a condition in which it may grow or reproduce.
5. Clause 4 provides that the Bill (when enacted) applies to the Government.

### Part 2 – Release of GMOs into environment and import of GMOs intended for release

6. Clause 5 contains provisions regulating the release into the environment of GMOs and the maintenance of lives of GMOs that are in a state of being released. It sets out the conditions that must be met before a GMO may be released or the life of a GMO that is in a state of being released may be maintained. Some of the conditions are that there is a valid approval in respect of the GMO and the approval is entered in the register (“register”) to be established for the implementation of the Bill (when enacted). The restrictions



in clause 5, however, do not apply to or in relation to GMOs that are pharmaceutical products for use by human beings.

7. Clause 6 requires a person who has control of an approved GMO to report to the Director of Agriculture, Fisheries and Conservation, the Deputy Director of Agriculture, Fisheries and Conservation, or an Assistant Director of Agriculture, Fisheries and Conservation (“Director”) if the person knows that the GMO has been released into the environment but a condition for the approval has not been complied with. The clause also requires a person who has control of an unapproved GMO (other than one that is a pharmaceutical product for use by human beings) to report to the Director if the person knows that the GMO has been released into the environment.

8. Clause 7 contains provisions regulating the import of GMOs that are intended for release into the environment. It sets out the conditions that must be met before such a GMO may be imported. Some of the conditions are that there is a valid approval in respect of the GMO and the approval is entered in the register. The restriction in clause 7, however, does not apply to or in relation to GMOs that are in transit or transshipment, intended for direct consumption as food or feed, or for processing, or pharmaceutical products for use by human beings.

9. Clauses 8, 9 and 10 set out the procedures relating to an application for approval of a GMO for release into the environment (“GMO approval application”). In particular, clause 10(2) provides that the Director must not approve the GMO unless the Director is satisfied that the possible adverse biosafety effect of the GMO is acceptable or manageable.

10. Clause 11 provides that an applicant under a GMO approval application may submit a request (“variation request”) asking the Director to vary his or her prior decision on the application if there is a change in circumstances, or additional scientific or technical information, that may influence the Director’s assessment on the possible adverse biosafety effect of the GMO.

11. Clause 12 empowers the Director to vary his or her prior decision on a GMO approval application or variation request if there is a change in circumstances, or additional scientific or technical information, that influences the Director's assessment on the possible adverse biosafety effect of the GMO, or if the Director considers it in the public interest to do so. If the approval of a GMO has been revoked and the GMO has been released under the approval, the applicant under the GMO approval application must inform the Director of the release. The clause also empowers the Director to give directions on the safekeeping or disposal of a GMO the approval of which has been revoked.

12. Clauses 13, 17 and 18 provide for the time frame within which the Director has to enter the information received on a GMO approval application or variation request, and to enter the Director's decision on the application or request, in the register.

13. Clauses 14 to 16 provide for a mechanism under which an applicant under a GMO approval application or variation request may request ("non-disclosure request") the Director not to enter certain information on the application or request in the register. The Director may decide not to enter the information if the Director is satisfied that non-disclosure of the information would not be contrary to the public interest. The applicant may ask the Director to review the original decision.

14. Clause 19 empowers the Director to require an applicant under a GMO approval application or variation request to provide additional information or supporting documents and to appear before the Director to provide clarification on the application or request.

15. Clauses 20 and 21 provide for the cases in which an applicant under a GMO approval application or variation request may withdraw the application or request, or withdraw certain information or documents provided on the application or request.

### Part 3 – Export of GMOs intended for release into environment

16. Clause 22 provides that Part 3, which contains provisions regulating the export of GMOs that are intended for release into the environment, does not apply to or in relation to GMOs that are in transit or transshipment, intended for direct consumption as food or feed, or for processing, or pharmaceutical products for use by human beings.

17. Clause 23 requires a person who wants to export to a place a GMO that is intended for release into the environment to send a notification on the export (“export notification”) to, and to obtain the approval (“export approval”) from, the competent authority of the place before the export. The requirements, however, do not apply if such notification and approval on the export are not required under the legal or regulatory requirements of the place. The clause also provides that a certificate from the authority certifying whether such notification or approval is required for the export of the GMO is admissible as evidence of the matters stated in the certificate.

18. Clause 24 requires a person who has sent an export notification or received an export approval to send a copy of the notification or approval to the Director.

### Part 4 – Register

19. Clauses 25 and 26 provide for the establishment and contents of the register. The register must contain, among other things, every GMO approval application and variation request, every decision made by the Director regarding the application or request, and every decision made by the Administrative Appeals Board on the appeals lodged against the Director’s decisions.

### Part 5 – Enforcement

20. Clause 27 empowers the Director to authorize public officers to enforce the Bill (when enacted). Clauses 28, 29, 30 and 33 provide for the circumstances under which an authorized officer may board and search vessels,

vehicles, trains or aircraft, search persons, inspect and search places or premises, and require persons to produce proof of identity.

21. Clauses 31 and 32 provide for the powers of seizure and taking samples. Clause 32 also provides for the circumstances under which a certificate of analysis on a sample may be tendered in evidence in proceedings under the Bill.

#### Part 6 – Disposal and forfeiture of things seized

22. Clause 34 provides for the circumstances under which the Director may sell or dispose of things seized immediately after their seizure.

23. Clauses 35 to 37 provide for the different circumstances under which seized things or proceeds of sale of those things are to be forfeited to the Government or to be returned to the owner or the person from whom the things were seized.

24. Clause 38 empowers the Director to sell or dispose of the things that have been forfeited to the Government, and provides for the circumstances under which a person may be directed to dispose of those things through repatriation or destruction.

#### Part 7 – Miscellaneous provisions

25. Clause 39 provides that a person may appeal to the Administrative Appeals Board against decisions made by the Director regarding a GMO approval application, a variation request or a review on a non-disclosure request, and directions given by the Director regarding the safekeeping or disposal of GMOs or containers containing GMOs, or disposal of forfeited things through repatriation or destruction.

26. Clause 40 requires an authorized officer to produce written evidence of the officer's identity before performing any function or duty, or exercising any power. It also provides that a person who obstructs the officer from performing any function or duty, or exercising any power, or fails to comply with the officer's requirements, commits an offence.

27. Clause 41 creates an offence regarding provision of false or misleading information and making of false or misleading statement.

28. Clause 42 empowers the Secretary for the Environment (“Secretary”) to make notices to provide for exemptions from the provisions regulating the release of GMOs into the environment, the maintenance of lives of GMOs that are in a state of being released, and the import and export of GMOs that are intended for release into the environment.

29. Clause 43 provides for the establishment of an expert group. The Director may refer questions in connection with the administration of the Bill (when enacted) to the group for advice.

30. Clause 44 empowers the Director to specify forms.

31. Clause 45 empowers the Secretary to amend the Schedules to the Bill.

32. Clause 46 empowers the Secretary to make regulations on various matters for the purposes of the Bill.

33. Clause 47 provides that prescribed fees paid are not refundable.

#### Part 8 – Transitional provisions

34. Clauses 48 to 50 set out the transitional arrangements during the 6-month period from the date when the Bill (when enacted) comes into operation. During that period, the restriction on the maintenance of lives of GMOs will not apply to a GMO that was released into the environment before that date. However, a person who knows that he, she or it caused such a GMO to be released or maintained the life of the GMO before that date, or maintains the life of the GMO during the transitional period, is required to report the release or maintenance or to submit a GMO approval application in respect of the GMO during that period.

#### Part 9 – Consequential amendment

35. Clause 51 makes a consequential amendment to the Schedule to the Administrative Appeals Board Ordinance (Cap. 442) so that the Ordinance will

apply to the appeals lodged against the decisions and directions of the Director set out in the clause.

### Schedules

36. Schedule 1 sets out the information to be provided to the Director regarding the release of GMOs into the environment under different circumstances.

37. Schedule 2 sets out the information to be contained in GMO approval applications.

38. Schedule 3 sets out the requirements on a risk assessment to be carried out on the possible adverse biosafety effect of a GMO. An applicant under a GMO approval application is required to submit the risk assessment when making the application.

39. Schedule 4 sets out the information to be contained in export notifications.

40. Schedule 5 specifies the prescribed fees payable on various matters provided under the Bill.

41. Schedule 6 sets out the information to be provided to the Director regarding the release or maintenance of GMOs released into the environment before the Bill (when enacted) comes into operation.

**Implications of the Proposal**

**FINANCIAL AND CIVIL SERVICE IMPLICATIONS**

Any additional workload and recurrent cost arising from the implementation of the proposal will be absorbed within the existing resources of AFCD.

2. It is proposed that all prescribed fees payable under the proposed legislation are to be set at levels to recover the full costs. Further, since most existing GMOs are those developed to enhance agricultural productivity, and commercial farming of GMOs and field trials of scientific researches are limited in Hong Kong, we do not expect there will be many GMO approval applications. In view of the above, we expect that the revenues to be generated from the proposed legislation would be insignificant.

**ECONOMIC IMPLICATIONS**

3. The intended regulatory and control measures are likely to pose certain compliance burden on the trades and activities concerned, but it would not be too onerous. As both commercial farming and field trials of scientific researches are limited in Hong Kong, we do not expect much importation of GMOs that would be subject to the proposed approval system for release into the environment of Hong Kong. Moreover, the documentation requirements on GMOs imported for food or feed, or for processing 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 the above, there will be benefit in terms of better protection of the environment.

**ENVIRONMENTAL IMPLICATIONS**

4. 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**

5. 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 harmonize trading requirements over GMOs in trans-boundary movements and thereby facilitate trade.