Bills Committee on
Genetically Modified Organisms (Control of Release) Bill

Administration's Response to the
List of follow-up actions arising from the discussion at the meeting on 27 October 2009

This paper seeks to respond to the issues raised at the meeting of the Bills Committee on Genetically Modified Organisms (Control of Release) Bill (the Bill) held on 27 October 2009, which are listed at Appendix I of the letter dated 28 Oct 2009 from the Bills Committee Secretariat –

(1) To refine the Chinese rendition of Clause 3(2)(a)

(2) To advise whether the exemptions granted by Secretary for the Environment (SEN) under Clause 42 are subsidiary legislation, and whether consultation with the expert group and the public would be conducted in advance. To also explain the legal and practical effects of the other provisions of the Bills on the person(s), groups(s) or genetically modified organism (GMO)(s) which are exempted from the application of Clauses 5, 7 and 23 of the Bill.

(3) To advise the specific subsidiary legislation to be made under the Bill, and provide the relevant drafts to the Bills Committee, where available.

(4) To consider including in Clause 43 the possible sectors from which members to the expert group might be appointed.

(5) To consider the need for a new clause to provide for the requirement under Clause 46 for documentation in relation to the import and export of a GMO intended for direct consumption as food or feed or for processing, which is not a subject of control under the Bill according to Clause 7(1)(b).

(6) To include in the speech to be delivered by SEN at the Resumption of Second Reading debate on the Bill the policy intent that enforcement would mainly focus on the control of import of GMOs and target a large enterprises producing or using GMOs, and that members of the public (such as schools and hospitals) who might have inadvertently grown or kept GMOs would not be the target group of enforcement. To also include in the speech an undertaking that the gist of the operation manual for enforcement officers will be made available for public enforcement officers will be made available for public

inspection, as well as clarification on the powers of entry and inspection in relation to premises used exclusively as a dwelling house.

Chinese rendition of Clause 3(2)(a)

2. We have considered the suggestion and propose to amend the Chinese rendition of Clause 3(2)(a) as follows -

" (a) 該生物屬在某一設施、裝置或其他實體屏障內進行的作業所涉及者該生物; 及"。

For easy reference, the English version of Clause 3(2)(a) is as follows –

"(a) it is involved in an operation that is undertaken within a facility, installation or other physical barrier; and".

The Expert group and exemption under Clause 42 of the Bill

3. An exemption granted by the Secretary for the Environment (SEN) under Clause 42 will be a piece of subsidiary legislation, and consultation with the expert group will be conducted before SEN grants such an exemption. We have also considered the suggestion of including in Clause 43 the possible sectors from which members to the expert group might be appointed. We now propose to amend Clause 43 along the following lines –

> "(1) The Secretary must establish an expert group consisting of members appointed by the Secretary from different sectors including the farming, biotechnology, environmental protection, academic and trading sectors.
> (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, and granting of exemptions, to the expert group, or individual members of the group, for advice."

4. Clause 42 of the Bill provides that SEN may, by notice published in the Gazette, exempt any person, any group or description of persons, or any GMO from the application of Clauses 5, 7 or 23. An exemption may take effect generally or for any purposes or by reference to any circumstances, and either conditionally or unconditionally. This provision allows SEN to exempt, for example, any GMO that is identified in a decision of the Conference of the Parties to the Cartagena Protocol on Biosafety (the Protocol) as being not likely to have adverse effects on the conservation and sustainable use of biological diversity[1], or any GMO that the Administration, after consultation with the expert group, considers as being unlikely to have adverse effects on local biological diversity when being released into the environment. Exemption for a particular person/a group of persons may also be given under special circumstances. The following paragraphs provide examples on exemptions under Clause 42 and highlight the legal and practical effects on the person/group of persons or the GMOs exempted from the application of Clauses 5, 7 and 23 of the Bill.

5. As an example, a particular type of GM papaya is considered as being unlikely to have any adverse effects on local biological diversity after risk assessment and consultation with the expert group, and is granted an exemption from the application of Clauses 5 and 7 without any condition attached. The exemption is also entered in the register under Clause 26. A person may then release the GM papaya into the environment (for example, by planting the GM papaya in the field) or import the GM papaya for release into the environment even though the GM papaya has not been approved. As an application for approval is not required, the provisions in Clauses 8 to 21 relating to applications for approval would not be relevant. The reporting requirement in Clause 6 also would not be relevant in this case and we propose to introduce Committee Stage Amendments to Clause 6 to clarify this. On the other hand, if the GM papaya is not exempted from the application of Clause 23, a person who wants to export the GM papaya for release into the environment must still comply with the requirements in Clause 23(1) (i.e. the person has to send an export notification to the competent authority of the place to which the GM papaya is to be exported and obtain approval for the export).

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[1] Article 7(3) of the Protocol provides that "*The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.*"

6. If a particular GM potato is identified in a decision of the Conference of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, consideration would be given by SEN to exempt the GM potato from the application of Clauses 5, 7 and 23. Once exempted, a person may import the GM potato and release it into the environment (for example, by planting the GM potato in the field). The person may also export the GM potato without complying with the requirements in Clause 23(1). Similar to the scenario of the GM papaya above, the provisions in Clause 6 and Clauses 8 to 21 relating to applications for approval would not be relevant to the GM potato.

7. Under certain circumstances, it might also be necessary to grant exemptions to a person or group/description of persons from the application of Clauses 5, 7 or 23. For example, a GM veterinary vaccine would be considered as being released into the environment if the vaccine is applied to animals. To cater for the genuine need of application of veterinary vaccines, in particular in emergency situation or under special circumstances, if the Director is satisfied that the possible adverse biosafety effect of the concerned GM vaccines is acceptable, an exemption may be granted to veterinary surgeons from the restrictions imposed on the import and use (release) of a GM veterinary vaccine under Clauses 5 and 7 of the Bill on certain conditions (for example, that the use complies with the relevant legislative requirements and that copies of the relevant documents required for the import of GMOs intended for release into environment have to be submitted to AFCD for record purpose prior to its use). With this exemption, a registered veterinary surgeon could, on meeting all the relevant conditions, import and use a GM veterinary vaccine for the purpose of treatment of a particular animal even though the vaccine has not been approved under the Bill. If any of the relevant conditions is not being complied with, the surgeon would have contravened the requirements under Clauses 5 and 7 (as the exemption is subject to conditions). The surgeon also has to comply with the relevant reporting requirements in Clause 6. In this case, it should also be noted that the surgeon is not allowed to export the vaccine for release into the environment as exemption is not given for Clause 23.

Documentation requirements in relation to import and export of GMOs for different purposes

8. According to Article 18 of the Protocol, each contracting party shall take measures to require documentation to accompany import and export of GMOs intended for food, feed or processing (FFP), GMOs intended for contained use, and GMOs intended for release into the environment. The purposes of the requirement are to enable easy identification of their GMO status; to facilitate tracing of GMO shipments if necessary; and to provide information which may help to contain the damage to the environment in the event of an accidental release during shipment.

9. In the light of Members' comments, we have considered the need for a new clause to provide for the requirement pursuant to Article 18 of the Protocol that GMOs intended for FFP, GMOs intended for contained use and GMOs intended for release into the environment are to be accompanied by specified documentation when being imported and exported. We now propose to add a new clause to provide for this requirement in the Bill, instead of in a piece of subsidiary legislation to be made under the Bill. The new clause will set out the following –

(a) GMOs intended for FFP, GMOs intended for contained use and GMOs intended for release into the environmentare to be accompanied by specified documentation when being imported and exported.

(b) The importer or exporter (as the case may be) of the GMOs commits an offence if the requirement is not complied with.

(c) The documentation requirements in relation to GMOs intended for FFP and for contained use do not apply if the quantity of the GMOs falls below a specified percentage of the shipment in which the GMOs are contained.

For GMOs intended for FFP and GMOs intended for contained use, it is worthwhile to note that a failure to comply with the documentation requirements will not lead to a prohibition of import / export of the shipment concerned. For GMOs intended for release into the environment, a mere

failure to comply with the documentation requirements also will not lead to a prohibition of the import / export. However, import / export would be prohibited if the import / export restrictions set out in clauses 7 or 23 are not complied with.

10. The detailed requirements on the documentation to accompany GMOs intended for FFP, GMOs intended for contained use and GMOs intended for release will be set out in a piece of subsidiary legislation under the Bill. The subsidiary legislation is to be made by SEN and will be laid before the Legislative Council for negative vetting. It is now being prepared and will have regard to our further consultation with the stakeholders, and the draft is not yet available for inspection. The major contents of the subsidiary legislation are set out in the following paragraphs –

(a) For GMOs intended for FFP, the documentation should clearly indicate that the shipment "contains" or "may contain" GMOs that are for direct use as FFP, and are not intended for release into the environment. The documentation should also contain other information including the name and address of the exporter / importer. Where available, the documentation should also contain other information including the common name, scientific name, commercial name and unique identifier code of the GMO;

(b) For GMOs intended for contained use, the documentation should clearly indicate that the shipment contains GMOs "destined for contained use". The documentation should also contain other information including the name and address of the consignee and exporter / importer, any requirements for the safe handling, storage, transport and use of the GMOs. Where available, the commercial name, modified traits (e.g. transformation event, risk class), specification of use and any unique identifier code; and

(c) For GMOs intended for release into the environment, the documentation should clearly indicate that the shipment contains GMOs intended for release into the environment. The documentation should also contain other information including a brief description of the GMOs, the name and address of the exporter or importer, any requirement for the safe handling,

storage, transport and use of the GMOs, a declaration that the movement of the GMOs is in conformity with the requirements of the Protocol applicable to the exporter. Where available, the commercial name and risk class, and import approval for the first transboundary movement, of the GMOs.

(d) The subsidiary legislation will also provide for the "specified percentage" referred to in paragraph 9(c) above.

Points to be covered by SEN in the speech to be delivered at the Resumption of Second Reading

11. We confirm that the points raised by the Bills Committee will be included in the Resumption of Second Reading debate on the Bill to be delivered by SEN.

Agriculture, Fisheries and Conservation Department
Environmental Protection Department
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