

立法會
Legislative Council

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**Paper for the House Committee Meeting
on 5 June 2009**

**Legal Service Division Report on
Genetically Modified Organisms (Control of Release) Bill**

I. SUMMARY

- 1. Object of the Bill** To give effect to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Protocol), and for the control of the release of genetically modified organisms (GMO) into the environment and the import and export of GMO.
- 2. Comments** The Bill seeks to implement a new policy, that is, a regulatory scheme with respect to the control of release of GMO into the environment and the import and export of GMO. Certain legal and policy aspects of the Bill may warrant a detailed examination (e.g. the serious criminal sanctions against non-compliance with the provisions of the Bill, the various enforcement powers, the powers for disposal and forfeiture of things seized by the Director of Agriculture, Fisheries and Conservation and the referral of questions in connection with the administration of the Bill to the expert group appointed by the Secretary for the Environment).
- 3. Public Consultation** According to the Administration, relevant stakeholders, overseas authorities, the Advisory Council on Food and Environmental Hygiene, the Advisory Council on the Environment and its Nature Conservation Subcommittee, and the Advisory Committee on Agriculture and Fisheries were consulted. The consulted parties in general supported the extension of the Protocol to Hong Kong.
- 4. Consultation with LegCo Panel** The proposed extension of the Protocol to Hong Kong was discussed by the Panel on Environmental Affairs at its meeting on 30 March 2009. The Administration informed the Panel that accidental release would not be an offence under the proposed legislation. Members of Panel were also advised by the Administration that 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, had been consulted. Members did not raise any objection to the legislative proposal for extending the Protocol to Hong Kong.
- 5. Conclusion** The Bill seeks to impose a regulatory scheme over genetically modified organisms. Members may wish to examine the policy perspective and operational aspects of the new regulatory scheme.

II. REPORT

Object of the Bill

To give effect to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the Protocol), and for the control of the release of genetically modified organisms (GMO) into the environment and the import and export of GMO.

LegCo Brief Reference

2. EP/86/21/25(09) Pt. 8 issued by the Environmental Protection Department and the Agriculture, Fisheries and Conservation Department on 20 May 2009.

Date of First Reading

3. 3 June 2009.

Comments

4. The Convention on Biological Diversity done at Rio de Janeiro (the Convention) provides for a comprehensive approach to the conservation of biological diversity and sets overall goals and general obligations. The Convention came into operation in December 1993. There are over 190 Parties including China to the Convention, but the Convention has yet to be extended to Hong Kong. The Protocol was adopted under the Convention in 2000 to provide for safe transfer, handling and use of living modified organisms (LMO) that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, with specific focus on trans-boundary movements of LMO. The Convention and the Protocol cannot be extended to Hong Kong unless appropriate measures are put in place to meet the requirements of the Protocol.

5. The provisions in the Bill seek to give effect to the Protocol and aim to protect biological diversity from possible adverse impacts arising from the transfer, handling and use of GMO. The key provisions of the Bill are set out below -

(a) Definition and Application

The definition of "genetically modified organism" and GMO is same as that of LMO as contained in Article 3(g) of the Protocol, which means a living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology. 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.

Although the Bill applies to the Government, neither the Government nor any public officer in the officer's capacity as such is liable to be prosecuted for an offence against the Bill. 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).

(b) *Release of GMO into the environment*

The requirements which 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 are that the GMO is an approved GMO and approval in respect of the GMO is entered in the register (the register) established under the Bill, but GMO that is a pharmaceutical product for use by human beings is excepted.

A person who has control of an approved GMO must inform the Director, Deputy Director or Assistant Director of Agriculture, Fisheries and Conservation (the Director) if he knows that the GMO has been released into the environment and any condition for the approval of the GMO as set out in the register has not been complied with. A person who has control of a GMO which is not an approved GMO and is not a pharmaceutical product for use by human being is also required to inform the Director if he knows that the GMO has been released into the environment.

(c) *Import of GMO intended for release*

A person must not knowingly import a GMO that is intended for release into the environment unless the GMO is an approved GMO and the approval is entered in the register, except 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.

(d) *Approval of GMO*

Under the procedure with regard to an application for approval of a GMO for release into the environment (GMO approval application), the Director must not approve the GMO for release into the environment unless the Director is satisfied that the possible adverse biosafety effect of the GMO is "acceptable or manageable".

The Director may vary his decision on a GMO approval application or variation request if there is a change in circumstances, or additional scientific or technical information that influences his 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 GMO approval application must inform the Director of the release.

The Director may also give directions on the safekeeping or disposal of a GMO where approval of which has been revoked.

(e) *Export of GMOs intended for release into environment*

A person must not knowingly export a GMO that is intended for release into the environment unless he has sent to the competent authority of the place to which the GMO is to be exported a notification of the export and that he has received from that authority the approval for that export. GMO 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 are excepted. Notification of the export is not required if prior notification to the competent authority from that place is not legally required in that place. A certificate purported to be issued by the competent authority certifying that prior notification to, or approval from, that authority for exporting the GMO to that place is or is not legally required is admissible as evidence of the matters stated in the certificate.

(f) *Register*

The Director must establish and maintain a register for the purposes of the Bill and the register must be available for inspection by members of the public free of charge. The register must contain, amongst 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.

(g) *Enforcement*

The Director may appoint any public officer to be an authorized officer for the purposes of the Bill.

An authorized officer may stop, board and search vessels, vehicles, trains or aircraft, stop, search and detain persons, enter and inspect places or premises and require persons to produce proof of identity.

An authorized officer may also seize, remove and detain any thing that appears to the officer to be or to contain evidence of the commission of an offence under the Bill. The 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 of these particular powers.

An authorized officer may also take samples for the purpose of verifying compliance with Bill.

(h) *Disposal and forfeiture of thing seized*

Powers of seizure and disposal of seized items are provided and the Director is empowered to sell or dispose of certain things immediately after seizure, for example, any live animal that, for any reason, it is not practicable for the Director to keep in captivity.

(i) *Offences on obstruction and failure to comply with requirements*

A person commits an offence if he wilfully obstructs an authorized officer from performing any duty or exercising any power under the Bill or if he without reasonable excuse fails to comply with any requirement imposed by an authorized officer under the Bill.

It is also an offence if a person, in respect of a GMO approval application or variation request, or in purported compliance with the Bill, produces any document, furnishes any information or makes any statement that he knows or believes to be false, does not believe to be true, or know or believe to be misleading in a material particular.

(j) *Appointment of expert group*

The Secretary may establish an expert group consisting of members appointed by the Secretary. The Director may refer any question in connection with "the administration of" the Bill to the expert group, or individual members of the group, for advice.

6. The Bill seeks to implement a regulatory scheme with respect to the control of release of GMO into the environment and the import and export of GMO. Certain legal and policy aspects of the Bill may warrant a detailed examination, for example -

- (a) Applicability of the Bill to the Government and the question of criminal liability of the Government and public officers;
- (b) The level of criminal sanctions for non-compliance with the various provisions of the Bill;
- (c) Various enforcement powers such as the powers to stop, board, enter, search, remove, detain and take samples;
- (d) Powers of disposal and forfeiture of things seized by the Director; and
- (e) Referral of questions in connection with the administration of the Bill to the expert group appointed by the Secretary.

Public Consultation

7. According to the Administration, relevant stakeholders, overseas authorities, the Advisory Council on Food and Environmental Hygiene, the Advisory Council on the Environment and its Nature Conservation Subcommittee and the Advisory Committee on Agriculture and Fisheries were consulted. 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. For details of the consultation exercise, members may refer to paragraphs 13 to 15 of the LegCo Brief.

Consultation with LegCo Panel

8. The proposed extension of the Protocol to Hong Kong was discussed by the Panel on Environmental Affairs at its meeting on 30 March 2009. The Administration informed the Panel that accidental release would not be an offence under the proposed legislation. Members of Panel were also advised by the Administration that 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, had been consulted. Members did not raise any objection to the legislative proposal for extending the Convention and Protocol to Hong Kong.

Conclusion

9. The Bill seeks to impose a regulatory scheme over genetically modified organisms. Members may wish to examine the policy perspective and operational aspects of the new regulatory scheme.

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