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14 August 2009

Miss Kitty Cheng  
Assistant Legal Adviser  
Legislative Council Secretariat  
Legal Service Division  
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8 Jackson Road  
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Dear Miss Cheng

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

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Thank you for your letter of 31 July 2009. Our reply to the questions you raised is at Annex please. Thank you.

Yours sincerely,

(Miss Vivien LI)  
for Director of Environmental Protection

**Genetically Modified Organisms (Control of Release) Bill**  
**Reply to Legislative Council Secretariat**  
**Assistant Legal Advisor's letter of 31 July 2009**

**Clause 2(1)**

1. *Please explain why the term “genetically modified organism” is used in the Bill whilst “living modified organism” is used in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (“the Protocol”), though both terms bear the same meaning in the respective instruments.*

The literal meaning of the term “living modified organisms” (LMOs) covers all organisms resulting from biotechnology that are alive, and includes those modified using traditional techniques as well as those modified genetically through modern biotechnology. The Protocol, however, only covers LMOs with a novel combination of genetic material produced by using modern biotechnology (i.e. genetically modified). The term “genetically modified organisms” (GMOs) states the nature of these new organisms more explicitly and is widely used in domestic legislations around the world, including Austria, Brazil, China, Ireland, Italy, South Africa, Sweden, Switzerland and Vietnam etc., to describe LMOs covered by the Protocol. It is therefore considered more appropriate to adopt the term GMOs in the Bill.

2. *The interpretation of “living organism” as provided in Article 3(h) of the Protocol means “any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids”. The meaning of “living organism” in the Bill is same as the above except that it further provides that “but does not include a human being”. Please explain the reason for making such provision.*

GMOs are living organisms that possess a novel combination of genetic material obtained through the use of modern biotechnology. In the Protocol, living organisms cover any biological entity capable of transferring or replicating genetic material and include human beings. There is, however, no genetically modified human being for the time being. There are also a lot of concerns and issues in imposing the requirements under the Bill on human

beings, including human rights issues. It is therefore considered appropriate that the Bill should expressly provide that “living organism” does not cover human beings so that the Bill does not apply to human beings.

3. *“Modern biotechnology” in Article 3(i) of the Protocol means “the application of (a) in vitro nucleic acid techniques ..., or (b) fusion of cells beyond the taxonomic family...”. In the Bill, “modern biotechnology” means “the application of in vitro nucleic acid techniques..., or techniques involving the fusion of cells beyond the taxonomic family...”. Please clarify whether there is any difference, in law and in scientific application, between “the application of fusion of cells” and “techniques involving the fusion of cells”.*

The words “techniques involving” are added before “the fusion of cells” in the definition of “modern biotechnology” in the Bill because it is considered that “the application of techniques involving the fusion of cells” reads better than “the application of the fusion of cells” and there is no difference in law and in scientific application between the two phrases. It is clear from the definition of “modern biotechnology” in Article 3(i) (“Fusion of cells ..... and that are not techniques .....”) that “fusion of cells” means the techniques of cell fusion. It is also clear from the words “下列技術的應用” in the definition of “modern biotechnology” in the Chinese text of the Protocol that “超出生物分類學科的細胞融合” is a technique.

### **Clause 3(2)**

4. *What is the difference between an operation “that is undertaken within ... other physical barrier” in clause 3(2)(a) of the Bill and an operation “that is undertaken within ... other physical structure” in Article 3(b) of the Protocol?*

There is no significant difference between the two. The term “physical barrier” is used as it is more readily understood as any physical means that could effectively limit the contact of GMOs with, and the impact of the GMOs on, the external environment. For example, GM seeds enclosed in a sealed plastic bag that serve as an effective physical means to limit the contact of the seeds with the external environment would suit the meaning of contained use. In fact, the term “physical barrier” is also used to replace “physical structure” in legislation of other jurisdictions, such as Norway and Switzerland.

#### **Clause 4**

5. *The Bill applies to the Government but neither the Government nor any public officer is liable to be prosecuted for an offence against the Bill. What will be the consequences or sanctions imposed on the Government or its public officers in the event of a breach of the individual provisions of the Bill?*

According to clause 4(2) of the GMO Bill, neither the Government, nor any public officer in the officer's capacity as such, is liable to be prosecuted for an offence under the Ordinance, which is in line with the policy of the Government. However, if the public officer is not acting in his or her official capacity when he or she commits an offence under the Ordinance, the officer would be prosecuted for the offence.

#### **Clause 6**

6. *In what circumstances is a person considered having "control" of a genetically modified organisms ("GMO") under section 6(1)? Does the concept of "control" apply to, for example, actual possession (with or without ownership), ownership or right to possession/ownership?*

"Control" is not defined in clause 6 and should be given its dictionary meaning of "exercising power or influence over". Depending on the circumstances of each case, if a person, by actual possession, ownership or right to possession/ownership of a GMO exercises power or influence over the GMO, the person would be considered as having control of a GMO.

#### **Clause 7**

7. *Clause 7(1) provides that the provision does not apply to, inter alia, (a) a GMO that is intended for direct consumption as food or feed, or (b) for processing. What is the meaning of "processing" in this clause? Please explain and give examples.*

The term "processing" means the use of GMOs as raw materials to produce products that are edible or non-edible. For example, GM maize may be imported for processing to produce edible maize oil for human consumption or ethanol as biofuel.

8. *Please also identify the particular provisions in the Protocol which exempt those GMO intended for the above uses from import restriction.*

Paragraph 2 of Article 7 of the Protocol provides that “intentional introduction into the environment” does not refer to “living modified organisms intended for direct use as food or feed, or for processing”. The effect of the paragraph is that living modified organisms intended for direct use as food or feed, or for processing are exempted from the Advance Informed Agreement procedure for the first intentional transboundary movement of living modified organisms to the Party of import.

### **Clause 10**

9. *The Director must not approve a GMO for release into the environment unless he is satisfied that the possible adverse biosafety effect of the GMO is “acceptable or manageable” (clause 10(2)). Please explain the meaning of the text “acceptable or manageable” and, if possible, provide examples.*

An approval application of GMO for release into the environment must be accompanied by a risk assessment report. The risk assessment will identify any potential adverse effects on biological diversity of the GMO and evaluate the likelihood and consequences of these adverse effects being realized. The acceptability of the adverse effects depends on the likelihood of and consequences of the effects being realized. On the other hand, the manageability of the adverse effects depends on whether it is easy to restrain the release of the GMO, to recover the GMO or to restore the adverse effects on the biological diversity posed by the GMO. For example, if a GM crop is introduced into an environment in which some native species are highly susceptible to cross-pollination by the GMO leading to contamination of the gene pools of these native species, the possible adverse biosafety effects of the GMO would not be considered acceptable. On the other hand, if the crop is to be planted in an isolated field equipped with effective measures to prevent cross-contamination, the possible adverse biosafety effects of the GM crop might be considered manageable.

10. *Under clause 10(3), on approving a GMO for release into the environment, the Director may attach any condition that he thinks fit to the approval. Under*

*clause 19(1), the Director may, for the purpose of determining a GMO approval application or variation request, require the applicant to provide additional information and to appear before the Director. Does procedure in clause 19 apply if the Director, whilst having no other queries, intends to impose a condition on the approval? In other words, will the applicant have an opportunity to address the Director on the condition to be imposed on him?*

Under clause 19, the Director may require the applicant to provide additional information or to appear before the Director to answer any questions raised for the purpose of determining a GMO approval application or variation request, including whether the GMO is to be approved and, if so, whether any condition is to be attached or varied. The main purpose of the clause is to enable the Director to obtain sufficient information to make a decision on the application or request, and not to consult the applicant on the Director's decision. If the Director considers that the applicant has provided all necessary information in the application or request submitted, it would not be necessary for the Director to require the applicant to provide additional information or answer questions under clause 19.

### **Clause 11**

*11. Is there a time limit for an applicant to request the Director to vary his decision under clause 11(1)? Similarly, is there a time limit for an applicant to request the Director to vary or cancel conditions attached to the approval under clause 11(2)?*

There is no time limit for an applicant to file a request for variation of decision under clauses 11(1) and 11(2) after receiving the written notice from the Director about the decision on the approval application. The grounds for filing such requests under clauses 11(1) and 11(2) include, among others, "additional scientific or technical information that may influence the Director's assessment". We appreciate setting a time limit for filing the request on such grounds may not be practicable.

*12. Will the applicant be given an opportunity to make representations to the Director before the Director exercises the powers to vary his previous refusal or cancel conditions under clause 11?*

The Director will consider a variation request based on the information submitted by the applicant. There is no provision in the Bill under which the applicant will be given an opportunity to make representations to the Director before the Director makes a decision on the request. However, if the applicant is aggrieved by a decision under clause 11(5)(a), he or she may, within 28 days after receiving notice of the decision, appeal to the Administrative Appeals Board against that decision according to clause 39.

### **Clause 19**

13. *Clause 19(1) provides that the Director may require the applicant to provide additional information or appear before the Director to answer any question raised by the Director. Does the applicant have a right to make representations to the Director before the Director exercises his powers to refuse an approval application (under clause 10) or to vary his previous decisions on approval applications or variation request on his own initiative (under clause 12)?*

There is no provision in the Bill under which the applicant has a right to make representations to the Director before the Director refuses an approval application (under clause 10) or varies his previous decisions on approval applications or variation request on his own initiative (under clause 12). However, if the applicant is aggrieved by a decision under clause 10 or 12, he or she may, within 28 days after receiving notice of the decision, appeal to the Administrative Appeals Board against that decision according to clause 39.

### **Clause 22**

14. *Similar to clause 7, clause 22(a) provides that the provision does not apply to, inter alia, (a) a GMO that is intended for direct consumption as food or feed, or (b) for processing. Again, please explain (with examples, if possible) the meaning of “processing” in this clause.*

Same as answer set out in para. 7.

15. *Please also identify the particular provisions in the Protocol which exempt from export restriction those GMO intended for the above uses as provided in clause 22(a).*

Same as answer set out in para. 8.

### **Clause 27**

16. *What would be the rank(s) of the public officers who will be appointed under this clause for the purposes of the Bill? What will be the criteria for determining the eligibility of such appointment?*

Forestry Officers and Field Officers of AFCD who have the background of ecology/applied biology and professional knowledge in local biodiversity will be appointed as the public officers for the purpose of the Bill.

### **Clause 28**

17. *Is a warrant required for a public officer to exercise his powers to stop, board and search vessels, vehicles, trains or aircrafts under clause 28(1)? If not, please explain the reason for the absence of this requirement.*

Under clause 28(1), a warrant is not required for an authorized officer to stop, board and search vessels, vehicles, trains or aircrafts if the officer has reason to suspect that an offence under clause 5, 7 or 23 has been, is being or is to be committed in or on the vessels, vehicles, trains or aircrafts. This provision is essential as it is necessary to allow stopping and searching without any delay, otherwise the vessels, vehicles, trains or aircrafts may have already crossed the border or the GMO may have already been released prior to the issue of a warrant. It would then be difficult to recover the GMO or restore any damage to the environment resulting from the release. This provision is also in line with that of similar ordinances, e.g. section 32 of the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586).

18. *What is the difference between this provision and clause 30 (powers to enter and search place or premises on issue of warrant)?*

Under clause 30, an authorized officer may enter and search any place or premises, including dwelling house, upon the issuance of a warrant by the magistrate. An authorized officer authorized by such a warrant to enter and search any place or premises may use necessary force to enter and search the



place or premise, and may remove any thing that obstructs the entry and search. As this clause gives comparatively intrusive power to the authorized officer, we consider it appropriate for a warrant to be applied before the authorized officer may exercise such power. This provision is also in line with that of similar ordinances, e.g. section 33 of the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586). Separately, in contrast to vessels, vehicles, trains or aircrafts, any evidence relevant to the offence would likely remain in the place or premises after the warrant is issued.

### **Clause 30**

19. *Clause 30(3) provides that an authorized officer who is authorized by a warrant to enter and search any place or premises may at any time enter and search the place or premises and may remove any thing that obstructs the entry and search. By reason of this provision, does the magistrate have power to specify the time and/or date for the execution of a search warrant when he issues the search warrant?*

The magistrate may not exercise his power under clause 30 in a manner that is inconsistent with the section. The warrant must not limit the power of an authorized officer to enter and search the relevant place or premises at any time under clause 30(3).

20. *Should the time and manner for the execution of a search warrant be matters for the magistrate's consideration when he grants the application for such search warrant?*

The key consideration by the magistrate when deciding whether to issue a warrant for entering and searching a place or premises is set out in clause 30(1)(a) and (b). The magistrate may not exercise his power under clause 30 in a manner that is inconsistent with the section.

### **Clause 31 and 34**

21. *Clause 31 provides that 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 the Bill and he 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 these powers.*

22. *Under Clause 34, if any of the things specified in clause 34(2) has been seized under clause 31, the Director may, “immediately after the seizure, sell the thing or dispose[d] of it any other way”. Clause 34(3) provides that, subject to clause 35, 36 and 37, the sale proceeds of any thing sold must be paid into the general revenue.*
23. *Clauses 35 and 36 deal with the return and forfeiture of things seized at the conclusion of criminal prosecution. Clause 37 deals with the returns and forfeiture of things seized if there is no prosecution for offences at all. Please explain how clauses 35, 36 and 37 become relevant to clause 34 where the Director has already sold or disposed of the thing immediately after seizure and the sale proceeds have already been paid into the general revenue before the relevant criminal proceedings conclude.*

Clause 34 empowers the Director to sell or dispose of any thing that is perishable or not practicable for the Director to keep immediately after its seizure. The handling of the proceeds of sale is subject to clause 35, 36 and 37. If any of those sections is applicable, the proceeds should be handled in accordance with the relevant sections. If not, the proceeds should be paid into the general revenue. This provision is also in line with that of similar ordinances, e.g. section 40 of the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586).

### **Clause 36**

24. *Clause 36 provides that if an offence is prosecuted under a provision of the Bill other than clauses 5, 7 or 23, the court may, whether or not any defendant in the proceedings is convicted of the offence, order any thing seized in respect of which the prosecution is brought, or any proceeds of sale of that thing to be returned to the person from whom it was seized or to its owner, or to be forfeited to the Government. Please advise the factors which will be taken into consideration by the court when it makes such an order. Should those factors be expressly provided in the Bill?*

The court may take into account all the relevant facts of a case (for example, the nature of the thing seized, the culpability of the defendant, whether the owner can be found, etc) before making an order under clause 36. It is considered not appropriate to expressly provide for specific factors in the Bill

as this would limit the discretion of the court or magistrate. It should also be noted that section 41 of the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586), on which clause 36 is modeled, does not specify the factors to be considered by the court.

### **Clause 43**

25. *The Secretary may establish an expert group and the Director may refer “any question in connection with the administration of this Ordinance” to the expert group, or individual members of the group, for advice. Please give an account of the matters intended to be covered by “the administration of this Ordinance”. Will questions such as the enforcement policy of the legislation, exercise of the Director’s discretion (e.g. imposition of conditions to an approval for GMO release under clause 10(3)), etc. be considered questions “in connection with the administration of this Ordinance”?*

Clause 43(2) specifies that 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. It is our intention that the expert group would mainly be consulted on technical matters relating to the GMO approval application such as the validity of the result of the risk assessment carried out for the GMO in question and the imposition of conditions to an approval for the release of a GMO. We shall explain the composition of the Expert Group to the Bills Committee as requested by the Clerk to Bills Committee in her letter dated 14 July 2009.

### **Clause 44**

26. *Are the forms to be specified by the Director to be used for the purposes of any matter provided for in this Bill subsidiary legislation?*

A number of forms will be specified by the Director to facilitate applications under various provisions of the Bill such as GMO approval application. No form will be specified for the purpose of any matter to be provided for in any subsidiary legislation under the Bill.

27. *Has the Administration prepared the draft of the forms to be specified by the*

*Director? If so, will the Administration provide such draft for the information of the Bills Committee?*

We are drafting the specified forms to the Bill. The draft forms would be presented for the information of the Bills Committee when available.

**Clause 46**

28. *Clause 46(2) provides that a regulation made by the Secretary 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 to 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.*
29. *Please explain, from a law drafting point of view, whether the above provision is necessary. What will be the consequence if no such provision is made in a law with enabling powers to make subsidiary legislation?*

Clause 46(2) makes it clear that the Secretary has the flexibility to make different provisions (including incidental, supplementary, consequential, transitional and saving provisions) to provide for different and particular circumstances and cases. Similar provisions are also included in many other Ordinances.