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By Fax (2136 3304)

31 July 2009

Miss Vivien Li
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Dear Miss Li,

Genetically Modified Organisms (Control of Release) Bill

I am looking at the legal and drafting aspects of the abovementioned Bill and would be pleased if you could provide advice on the enclosed list of questions.

Your reply in bilingual form before 14 August 2009 will be most appreciated.

Yours sincerely,

Kitty Cheng
Assistant Legal Adviser

Encl

cc. Legal Adviser
CCS(1)1

Genetically Modified Organisms (Control of Release) Bill

Clause 2(1) - Interpretation

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.

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.

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 fusions of cells".

Clause 3(2) - Meaning of "contained use"

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?

Clause 4 - Application to Government

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?

Clause 6 - Notification to Director of certain releases of GMO

6. In what circumstances is a person considered having "control" of a genetically modified organism ("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?

Clause 7 - Restrictions on import of GMO intended for release into environment

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.

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

Clause 10 - Approval of GMO

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 test "acceptable or manageable" and, if possible, provide examples.

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?

Clause 11 - Request for variation of decisions on GMO approval applications

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)?

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?

Clause 19 - Provision of additional information on GMO approval applications and variation requests

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 requests on his own initiative (under clause 12)?

Clause 22 - Application of export restriction

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.

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).

Section 27 - Appointment of authorized officers

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 for such appointment?

Section 28 - Powers to search vessels, detain persons, etc

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.

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

Clause 30 - Search warrants

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?

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?

Clauses 31 and 34 - Powers to seize and detain things and the Director's power to sell or dispose of certain thing immediately after seizure

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 clauses 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 return 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 36 - Return and forfeiture of things seized whether or not there is criminal conviction

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?

Clause 43 - Expert group

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 44 - Director's power to specify forms

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?

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?

Clause 46 - Secretary's power to make regulations

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?