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5 August 2010

By Email & Fax : 2877 5029

Mr Bonny LOO
Asst Legal Adviser
Legislative Council Building
8 Jackson Road
Central
Hong Kong

Dear Mr Loo,

Generically Modified Organisms
(Documentation for Import and Export) Regulation (L.N. 96)

Thank you for your letter of 27 July 2010 on the captioned matter. Our reply is as follows:

- (a) According to "An Explanatory Guide to the Cartagena Protocol on Biosafety", "relevant international rules and standards" (or "applicable existing international instrument" as used in the Regulation) could be the relevant international rules and standards covering handling, packaging and transport of GMOs and might extend to general international rules and standards governing health, safety and the environment of international trade. At present, specific GMOs may be covered by relevant international rules and standards on the basis of their characteristics rather than because they are GMOs as such. The International Plant Protection Convention by the World Health Organization, and the UN Recommendations on the Transport of Dangerous Goods are just two examples among the many relevant international instruments. Relevant rules and standards may also be developed in the future by the Conference of the Parties in accordance with Article 18(3). Given the wide range of applicable international instruments and that the application of individual instruments may change over time, it is considered appropriate to make a general reference to "any

applicable existing international instrument” in the Regulation, and not to make reference to any specific international instrument. Administrative guidelines will be prepared for the documentation requirements and examples of international instruments will be given for the applicant’s reference. The guidelines will be uploaded to the online GMO Register for public viewing.

- (b) Paragraph 3 of MOP BS-III/10 sets out that the documentation for GMOs intended for direct consumption as food or feed or for processing should contain the details of a contact point for further information: the exporter, the importer, and/or any appropriate authority, when designated by a Government as the contact point. As the Protocol allows Parties to take stricter measures of implementation, section 3 of the Regulation requires that the name, address and contact details of the importer and exporter of the GMO *as well as* the designated authority (if any) be provided in the documentation for GMOs intended for direct consumption as food or feed or for processing. On the other hand, MOP BS-1/6 sets out the documentation requirements for GMOs intended for contained use and for release into the environment. It does not require the provision of contact details of the designated authority in the documentation for these two groups of GMOs. The requirements regarding contact details as laid down in the Regulation reflect the detailed requirements as set out in MOP’s decisions.
- (c) The requirement to provide the Internet address of the Biosafety Clearing-House in the documentation for GMOs intended for direct consumption as food or feed or for processing is specified in paragraph 4(f) of MOP BS-III/10. No such requirement is specified for documentation for GMOs intended for contained use or for release into the environment. We understand that the provision of the Internet address is for the sake of the Parties which are developing countries, such that their enforcement authority would be prompted to look for relevant information about the GMOs from the Biosafety Clearing-House.
- (d) The formulation under section 4(2)(b) and (c) is to reflect paragraph 3(a)(ii) of Part B of MOP BS-1/6, that the name and address of the consignee, and exporter or importer, as appropriate should be provided in the documentation for GMOs intended for contained use. In case the GMO is to be imported into or exported from Hong Kong, the contact details of the respective local importer or the exporter (as the case may be) of the GMO must be provided. The contact details of the respective overseas exporter or overseas importer (as the case may be), however, is to be provided only if the details are available. As regards section 3(3)(b)(i) and 5(2)(a), the formulation is to reflect the documentation requirement to provide

the contact details of both the importer and exporter as required under paragraph 3 of Part A and paragraph 3(b)(iii) of Part B of MOP BS-1/6 respectively.

- (e) The requirement to provide the name, address and contact details of the consignee for GMOs intended for contained use is set out in paragraph 3(a)(ii) of Part B of MOP BS-1/6. No such requirement is specified for GMOs intended for direct consumption as food or feed or for processing, or GMOs intended for release into the environment.
- (f) According to the "An Explanatory Guide to the Cartagena Protocol on Biosafety", some States define a system of "biosafety levels" (i.e. risk class) according to which some GMOs may be classified according to various factors. Each biosafety level prescribes general levels of risk, and may also prescribe general requirements for handling. In view that various risk class systems have been or would be developed for different GMOs, and different systems could be adopted in different Parties, it is not possible to specify which particular risk classification system or classifying authority is acceptable. Further, as the meaning of "risk class" is well understood within the trade, it is considered not necessary to provide a definition for the term in the Regulation.

2. Thank you and please let me know if I could be of further assistance.



(Miss Vivien LI)
for Director of Environmental Protection

cc Agriculture, Fisheries and Conservation Department (Attn : Mr Simon Chan – 2314 2802)
Department of Justice (Attn : Ms Mabel Cheung – 2845 2215)