For Discussion on
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Genetically Modified Organisms (Control of Release) Ordinance Cap. 607

Expert Group

Vetting Criteria for Approval of Genetically Modified Organisms

Purpose

This paper seeks members' view on the proposed criteria for vetting an application for approval of a genetically modified organism (GMO) for release into the environment.

Background

2. The Genetically Modified Organisms (Control of Release) Ordinance Cap. 607 (the Ordinance) commenced on 1 March 2011. The objective of the Ordinance is to give effect to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and to regulate the release into the environment and the import and export of GMOs.

3. Under the Ordinance, release of a GMO or import of a GMO that is intended for release into the environment requires prior approval from the Director of Agriculture, Fisheries and Conservation (the Director).

4. The approval application should comprise a completed specified application form and a report on a risk assessment on the possible adverse biosafety effect of the GMO, and submit to the Agriculture, Fisheries and Conservation Department together with the prescribed fee payable on the application. Upon the receipt of a GMO approval application, the Director will seek members' advice on the approval application. The Director will not approve a GMO for release into the environment unless he is satisfied that the possible adverse effect of the GMO on the conservation and sustainable use of biological diversity (i.e. the biosafety effect) is acceptable or

manageable. On approving a GMO for release into the environment, the Director may attach any condition that he thinks fit to the approval.

Risk Assessment Report

5. The risk assessment must be carried out, or caused to be carried out, by the applicant in accordance with Schedule 3 of the Ordinance on the possible adverse biosafety effect of the GMO. It must be carried out in a scientifically sound and transparent manner, and may take into account expert advice of, and guidelines developed by, relevant international organizations. The report should contain a recommendation as to whether or not the risks are acceptable or manageable, including, if necessary, identification of strategies to manage those risks. The detailed requirements for the risk assessment as laid down in Schedule 3 are reproduced at Annex I.

Vetting Criteria

6. To facilitate members' discussion and evaluation of an application for approval of a GMO for release into the environment, a set of criteria for vetting the approval application is prepared. It would allow an objective and consistent evaluation of the risk assessment conducted and hence the GMO approval application in accordance with the requirements of the Ordinance. The set of proposed vetting criteria is attached at Annex II.

Advice Sought

7. Members are invited to comment on the proposed vetting criteria at Annex II for GMO approval application.

Agriculture, Fisheries and Conservation Department
June 2011

Annex I

Schedule 3 – Requirements on Risk Assessment on Possible Adverse Biosafety Effects on GMOs

1. Risk assessment must be carried out in a scientifically sound and transparent manner, and may take into account expert advice of, and guidelines developed by, relevant international organizations.

2. Risks associated with the GMO or products from the GMO, namely, processed materials that are of genetically modified organism origin and that contain detectable novel combinations of replicable genetic materials obtained through the use of modern biotechnology, must be considered in the context of the risks posed by the non-modified recipient or parental organism in the likely potential receiving environment.

3. Risk assessment must entail, as appropriate, the following steps—
   (a) an identification of any novel genotypic and phenotypic characteristics associated with the GMO that may have an adverse effect on biological diversity in the likely potential receiving environment;
   (b) an evaluation of the likelihood of the adverse effect being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO;
   (c) an evaluation of the consequences should the adverse effect be realized;
   (d) an estimation of the overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the adverse effect being realized;
   (e) a recommendation as to whether or not the risks are acceptable or manageable, including, if necessary, identification of strategies to manage those risks;
   (f) where there is uncertainty regarding the level of risk, obtaining further information on the specific issues of concern or implementing appropriate risk management strategies or monitoring the GMO in the likely potential receiving environment.

4. Risk assessment must take into account the relevant technical and scientific details regarding the characteristics of the following subjects—
   (a) recipient organism or parental organism: biological characteristics of the recipient organism or parental organism, including information on taxonomic status, common name, origin, centre of origin and centre of genetic diversity, if known, and a description of the habitat where that recipient organism or

parental organism may persist or proliferate;

(b) donor organism: the taxonomic status, common name, source, and other relevant biological characteristics of the donor organism;

(c) vector: characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) insert and modification—

(i) if modification was introduced through the application of in vitro nucleic acid techniques: genetic characteristics of the inserted nucleic acid and the function it specifies, and characteristics of the modification introduced;

(ii) if modification was introduced through the application of techniques involving the fusion of cells: characteristics of the modification introduced;

(e) GMO: identity of the GMO, and the differences between the biological characteristics of the GMO and those of the recipient organism or parental organism;

(f) detection and identification of the GMO: suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) information relating to the intended use of the GMO: information relating to the intended use of the GMO, including new or changed use compared to the recipient organism or parental organism;

(h) likely potential receiving environment: information on the location, and geographical, climatic and ecological characteristics, including relevant information on biological diversity and centre of origin of the likely potential receiving environment.

Annex II

Vetting Criteria for Approval of GMO

Under the Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607, a person may apply to the Director of Agriculture, Fisheries and Conservation for approval of a GMO for release into the environment. Section 10 of the Ordinance specifies that 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.

The following broad criteria would be used in assessing whether a GMO should be approved for release into the local environment:

(a) The presence of any identified novel genotypic and phenotypic characteristics associated with the GMO that may have an adverse effect on the biological diversity in the likely potential receiving environment;

(b) The likelihood of the adverse effect being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the GMO;

(c) The environmental/ecological consequences brought about by the GMO on the biological diversity of the local environment should the adverse effect be realized;

(d) The estimated overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the adverse effect being realized;

(e) The acceptability of the risk to the local environment;

(f) The manageability of the risk and availability of scientifically sound and practical strategies to manage the risk; and

(g) The availability of suggested plan to implement appropriate risk management strategies or monitor the GMO in the likely potential receiving environment if there is uncertainty regarding the level of risk.