

**Bills Committee on
Genetically Modified Organisms (Control of Release) Bill**

**List of follow-up actions arising from the discussion
at the meeting on 14 January 2010**

This paper seeks to respond to the issues raised at the meeting of the Bills Committee on Genetically Modified Organisms (Control of Release) Bill (the Bill) held on 14 January 2010, which are listed at Appendix I of the letter dated 15 January 2010 from the Bills Committee Secretariat –

- (1) To set out the general factors which the Secretary for the Environment (SEN) will take into account in granting exemptions under clause 42.
- (2) To advise the ordinances with express provisions on claims for compensation in the event of unsuccessful prosecution. To also consider grouping proposed sub-clauses 37(4) to 37(6) to form a new clause to provide for claims for compensation under specified circumstances.
- (3) To consider whether there is a need to empower the Director to attach conditions on how a released GMO should be maintained during the transitional period under proposed clause 50(3).
- (4) To review the Chinese rendition of the phrase “任何一名” under clause 51(c) if it is the policy intent to specify the rank of official who has made the decision.
- (5) To illustrate how the required information under Schedules 1 to 6 should be filled out in the specified form (using papaya as an example).
- (6) To include in the speech to be delivered by SEN at the Resumption of Second Reading debate on the Bill that the research done so far by the Administration has identified papaya as the only genetically modified organism (GMO) grown in Hong Kong. To also include in the speech the types of GMOs, including papaya, being considered for exemption.
- (7) To provide a full set of draft Committee Stage amendments (marked-up version).

Marked-up version of the Draft Committee Stage amendments

2. The full set of the Marked-up version of the English version of the Draft Committee Stage amendments is at **Annex A**.

Clause 42

3. Having considered Members' views, we will revise clauses 42 as shown in **Annex A**.

To review clause 37 to include a provision for compensation

4. Having considered Members' views, we will revise clause 37 and insert a new clause 38A as shown in **Annex A**. The revision has the effect of allowing, under prescribed circumstances, the owner of a thing seized in the course of enforcing the powers in the Ordinance, to claim for compensation from the Government in respect of the thing, irrespective of whether prosecution has been brought or not.

Clause 50 (3) - Empowering the Director to attach conditions on how a released GMO should be maintained during the transitional period.

5. Having considered Members' advice, we maintain the view that a general permission should be given to maintain a released GMO during the transitional period, and hence would not impose conditions for such maintenance until after the transitional period.

Chinese rendition of clause 51

6. Having considered Members' views, we will revise the Chinese renditions of clause 51 as shown in **Annex B**.

Sample of specified form

7. A sample of a completed specified form, using GM papaya as an example, is at **Annex C**.

The research done by the Agriculture, Fisheries and Conservation Department on the prevalence of GMO in Hong Kong

8. We confirm that in the speech to be delivered by SEN, we will set out the research done so far by the Administration, and the types of GMOs being considered by exemption.

**Environmental Protection Department
Agriculture, Fisheries and Conservation Department
January 2010**

6. Notification to Director of certain releases of GMOs

- (1) This section applies where a person who has control of a GMO knows that –
- (a) if the GMO is an approved GMO –
 - (i) the GMO has been released into the environment; and
 - (ii) any condition for the approval of the GMO, as set out in the register, has not been complied with;
 - (b) if the GMO is not an approved GMO but is exempted under section 42 from the application of section 5 –
 - (i) the GMO has been released into the environment; and
 - (ii) any condition for the exemption of the GMO, as set out in the register, has not been complied with; or
 - (c) if the GMO is not an approved GMO and is not exempted under section 42 from the application of section 5 –
 - (i) the GMO has been released into the environment; and
 - (ii) the GMO is not a pharmaceutical product for use by human beings.

(2) As soon as practicable after the person knows of the release, the person must, by written notice, inform the Director of the release.

- (2A) Subsection (2) does not require a person to inform the Director of the release if –
- (a) another person also has control of the GMO; and
 - (b) that other person has informed the Director of the release in compliance with that subsection.–

(3) A person who contravenes subsection (2) commits an offence and is liable to a fine at level 5 and to imprisonment for 6 months.

(4) A notice under subsection (2) must contain the information set out in Parts 1 and 2 of Schedule 1.

- (5) On receiving a notice under subsection (2), the Director may –
- (a) direct an authorized officer to enter, during reasonable hours, the place or premises in or on which the GMO was released to dispose of the GMO; or
 - (b) direct the person to dispose of the GMO.

15. Director's decisions on non-disclosure requests

(1) Within 30 days after receiving a non-disclosure request on a GMO approval application or variation request, the Director must –

(a) decide –

- (i) that none of the proposed confidential information is to be entered in the register;
- (ii) that only some of the proposed confidential information is to be entered in the register; or
- (iii) that all of the proposed confidential information is to be entered in the register; and

(b) give the applicant a written notice of the decision and the reason for it.

(2) The Director may decide not to enter certain proposed confidential information in the register if the Director is satisfied that –

(a) entering the information would adversely affect the applicant's interest; and

(b) not entering ~~non-disclosure of~~ the information would not be contrary to the public interest.

20. Withdrawal of GMO approval applications or variation requests

(1) An applicant under a GMO approval application or variation request may, in writing, withdraw the application or request at any time before the Director makes a decision on the application or request.

(2) If a GMO approval application or variation request is withdrawn under subsection (1), the Director must –

~~(a) — cease to process the application or request; and~~

~~(b) — return to the applicant any record or document, or part of the record or document, containing any confidential information in relation to the application or request.~~

21. Withdrawal of information or document provided

(1) An applicant under a GMO approval application or variation request may, in writing, withdraw any information or document provided for the purposes of the application or request at any time before the Director makes a decision on the application or request.

(2) Where any information or document provided for the purposes of a GMO approval application or variation request is withdrawn under subsection (1), the Director must –

~~(a) — continue to process the application or request as if the information or document had not been provided; and~~

~~(b) — if the information withdrawn is confidential information, return to the applicant any record or document, or part of the record or document, containing the information~~

PART 3A

DOCUMENTATION REQUIREMENTS FOR IMPORT AND EXPORT OF GMOs

24A. Application of this Part

This Part does not apply to or in relation to a GMO that is a pharmaceutical product for use by human beings.

24B. Documentation requirements for import and export of GMOs

(1) When being imported or exported GMOs –

(a) GMOs that are intended for direct consumption as food or feed, or for processing;

(b) GMOs that are intended for contained use; and

(c) GMOs that are intended for release into the environment,

must be accompanied by the prescribed documents when being imported or exported

(2) Subsection (1) does not apply to require GMOs falling within paragraph (a) or (b) of that subsection to be accompanied by the prescribed documents if –

(a) the GMOs are imported or exported in a lot together with other living organisms;

(b) the GMOs are unintentionally mixed with those other living organisms; and

(c) the percentage of the amount of the GMOs to the total amount of living organisms in the lot does not exceed the prescribed percentage.

(3) If subsection (1) is contravened, the person who imports or exports the GMOs commits an offence and is liable to a fine at level 3.

(4) In any proceedings for an offence under subsection (1), it is a defence for the person charged to establish that the person did not know and could not with reasonable diligence have known that GMOs falling within subsection (1)(a), (b) or (c) were being imported or exported.

(5) For the purposes of In subsection (2)(c) –

“prescribed percentage” () in relation to GMOs falling within subsection (1)(a) or (b), means -

(a) the percentage prescribed by the Secretary for the purposes of that subsection in relation to GMOs falling within subsection (1)(a), (b) or (c) by regulation made under section 46 for the GMOs; or

(b) if no percentage is prescribed, zero-percent.

25. Director must establish and maintain register

(1) The Director must establish and maintain a register for the purposes of this Ordinance.

(2) The Director may keep the register in such form as the Director considers appropriate;
~~including in a form other than a documentary form.~~

(3) The register must be available for inspection by members of the public, free of charge –

(a) through the Internet; and

(b) at the office of the Agriculture, Fisheries and Conservation Department during
normal business hours, ~~free of charge.~~

26. Contents of register

- (1) The register must contain –
- (a) subject to subsection (3) –
 - (i) every GMO approval application, and any information received by the Director for the purposes of the application; and
 - (ii) every variation request, and any information received by the Director for the purposes of the request;
 - (b) every decision of the Director made under section 10(1)(a), 11(5)(a) or 12(1);
 - (c) every decision of the Administrative Appeals Board on any appeal lodged against a decision of the Director made under section 10(1)(a), 11(5)(a) or 12(1); and
 - (d) every exemption granted by the Secretary under section 42.
- (2) The register may also contain any other information relating to the administration of this Ordinance or implementation of the Protocol that the Director considers appropriate.

- (3) The register must not contain –
- (a) any confidential information in relation to a GMO approval application or variation request; or
 - (b) any GMO approval application or variation request, or any information submitted for the purposes of the application or request, that has been withdrawn before it is to be entered in the register in accordance with section 13.

27. Appointment of authorized officers

The Director may, in writing, appoint any public officer not below the rank of Field Officer II~~er~~
class of public officer to be an authorized officer for the purposes of this Ordinance.

28. Powers to search vessels, detain persons, etc.

(1) An authorized officer may stop, board and search any vessel, vehicle, train or aircraft (other than a ship of war, military vehicle or military aircraft) if the officer ~~has~~ reasonably ~~to~~ suspects that an offence under section 5, 7 or 23 has been, is being or is about to be committed in or on the vessel, vehicle, train or aircraft.

(2) If an authorized officer ~~has~~ reasonably ~~to~~ suspects that a person has committed, is committing or is about to commit an offence under section 5, 7 or 23, the officer may without warrant –

- (a) stop and search the person, and search the property of the person, for anything that is likely to be relevant (whether by itself or together with anything else) to the investigation of the offence; and
- (b) detain the person for a reasonable period while the officer inquires about the suspected commission of the offence.

**29. Powers to inspect place or premises, take copies of documents, etc.
for verifying compliance with this Ordinance**

(1) If an authorized officer ~~has~~ reasonably ~~to~~ suspects that a GMO is being kept in any place or premises, the officer may, for the purpose of verifying compliance with this Ordinance, without notice –

- (a) enter and inspect the place or premises during reasonable hours;
- (b) require the production of, inspect and examine any thing that the officer ~~has~~ reasonably suspects ~~to believe~~ to be, or to contain, a GMO; and
- (c) require the production of, inspect, examine and take copies of any document that is related to compliance with this Ordinance, or any document that relates to the nature or origin of the GMO.

(2) Subsection (1) does not empower an authorized officer to enter –

- (a) any premises that are used ~~exclusively wholly or principally for a~~ dwelling ~~purposes~~ house; or
- (b) any part of any premises that is used ~~exclusively wholly or principally for a~~ dwelling ~~purposes~~ house.

30. Powers to enter and search place or premises on issue of warrant

(1) A magistrate may issue a warrant authorizing an authorized officer to enter and search any place or premises if satisfied by information on oath that there are reasonable grounds to suspect that –

- (a) an offence under this Ordinance has been, is being or is to be committed in or on the place or premises; or
- (b) there is in or on the place or premises any thing that is or contains evidence of the commission of an offence under this Ordinance.

(2) ~~Unless otherwise specified in it, a~~ warrant continues in force, ~~unless otherwise specified in the warrant,~~ until the purposes for which the entry is necessary have been satisfied.

(3) An authorized officer authorized by such a warrant to enter and search any place or premises –

- (a) may at the time specified in the warrant or, if no time is specified, at any time enter and search the place or premises, using necessary force; and
- (b) may remove any thing that obstructs the entry and search.

(4) An authorized officer may also detain any person found in or on the place or premises, for such period as is reasonably required to permit the search to be carried out, where the person might prejudice the purpose of the search if not so detained.

(5) An authorized officer entering any place or premises under a warrant may take with the officer such persons as may be necessary.

(6) This section does not prejudice any powers of entry and search conferred on police officers under any other law.

31. Powers to seize, remove and detain things

(1) An authorized officer may seize, remove and detain any thing ~~that appears to~~that the officer reasonably suspects to be or to contain evidence of the commission of an offence under this Ordinance.

(2) An authorized 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 power under this section.

32. Powers to take samples and carry out tests

(1) An authorized officer may, for the purpose of verifying compliance with this Ordinance or obtaining evidence of the commission of an offence under this Ordinance –

- (a) take a sample of any thing that the officer ~~has reason to believe~~reasonably suspects to be, or to contain, a GMO;
- (b) require any person in control of such thing to provide a sample of it; and
- (c) take any photographs of the thing.

(2) An authorized officer who takes a sample under subsection (1) must issue a receipt for the sample, but is not required –

- (a) to pay for it; or
- (b) to return it to the person from whom it was taken.

(3) An authorized officer may arrange to carry out any necessary test in respect of a sample taken under subsection (1) to ascertain –

- (a) whether the sample is or contains a GMO;
- (b) if the sample is or contains a GMO –
 - (i) the identity of the GMO; and
 - (ii) the quantity and percentage of the GMO in the sample.

(4) A certificate of analysis issued by an accredited laboratory on a sample taken under subsection (1) may be tendered in evidence in any proceedings under this Ordinance and is evidence of the facts stated in it unless the contrary is proved.

(5) In this section, “accredited laboratory” (獲認可實驗室) means a laboratory accredited under the Hong Kong Laboratory Accreditation Scheme managed by the Commissioner for Innovation and Technology on behalf of the Government.

33. Power to require identification

(1) If an authorized officer ~~has~~reasonably~~to~~ suspects that a person has committed, is committing or is about to commit an offence under section 5, 7, 23, 24B or 40~~this Ordinance~~, the officer may without warrant stop the person or, where the person is in or on a vessel, vehicle, train or aircraft (other than a ship of war, military vehicle or military aircraft), stop and board the vessel, vehicle, train or aircraft for the purposes of requiring that person –

- (a) to state the person's name and address; and
- (b) to produce the person's proof of identity for inspection.

(2) In this section, “proof of identity” (身分證明文件) means proof of identity within the meaning of section 17B of the Immigration Ordinance (Cap. 115).

33A. Power to require production of documents during import and export

If an authorized officer reasonably suspects that a GMO is being imported or exported, the officer may, for the purpose of verifying compliance with section 24B, require a person who has control of the thing suspected to be the GMO to produce any document that is related to the import or export of that thing for inspection.

34. Director's power to ~~sell or~~ dispose of certain things immediately after seizure

(1) If any of the things specified in subsection (2) has been seized under section 31, the Director may, ~~immediately~~ after the seizure, ~~sell the thing or~~ disposed of ~~it~~the thing in any ~~other~~-way (except by way of sale).

(2) The things are –

(a) any live animal –

(i) that, for any reason, it is not practicable for the Director to keep in captivity; or

(ii) that is likely to die or to be subject to unnecessary suffering if it is kept in captivity;

(b) any live plant that, for any reason, it is not practicable for the Director to keep; and

(c) any thing –

(i) that, for any reason, it is not practicable for the Director to keep; or

(ii) that is perishable.

~~(3) — Subject to sections 35, 36 and 37, the proceeds of sale of any thing sold under subsection (1) must be paid into the general revenue.~~

35. Return and forfeiture of things seized in respect of offences under section 5, 7 or 23

(1) If a person is convicted of an offence under section 5, 7 or 23, any thing seized under section 31 in connection with the offence that is a GMO or contains a GMO is, ~~or any proceeds of sale of that thing are,~~ to be forfeited to the Government.

(2) If a person is convicted of an offence under section 5, 7 or 23, the court or magistrate may order any thing seized under section 31 in connection with the offence that is not a GMO or does not contain a GMO, ~~or any proceeds of sale of that thing –~~

(a) to be returned to the person from whom it was seized or to its owner; or

(b) to be forfeited to the Government.

(3) If an offence is prosecuted under section 5, 7 or 23 and no defendant in the proceedings is convicted of the offence, the court or magistrate may order any thing seized under section 31 in respect of which the prosecution is brought, ~~or any proceeds of sale of that thing –~~

(a) to be returned to the person from whom it was seized or to its owner; or

(b) to be forfeited to the Government.

(4) This section does not apply to a thing seized under section 31 if it has been disposed of under section 34.

36. Return and forfeiture of things seized in respect of offences under other sections

(1) If an offence is prosecuted under a provision of this Ordinance other than section 5, 7 or 23, the court or magistrate may, whether or not any defendant in the proceedings is convicted of the offence, order any thing seized under section 31 in respect of which the prosecution is brought, ~~or any proceeds of sale of that thing~~ –

- (a) to be returned to the person from whom it was seized or to its owner; or
- (b) to be forfeited to the Government.

(2) ~~This section does not apply to a thing seized under section 31 if it has been disposed of under section 34.~~

37. Return and forfeiture of things seized if no prosecution for offences

(1) If a thing has been seized under section 31 but no prosecution has been brought in respect of that thing under this Ordinance, an authorized officer may apply to the court or magistrate for an order in respect of that thing ~~or any proceeds of sale of that thing~~.

(2) On an application under subsection (1), the court or magistrate may, subject to subsection (3), order the thing concerned ~~or any proceeds of sale of that thing~~—

- (a) to be returned to the person from whom it was seized or to its owner; or
- (b) to be forfeited to the Government.

(3) The court or magistrate must, if satisfied that the owner of the thing concerned is unknown or cannot be found, order the thing ~~concerned or any proceeds of sale of that thing~~ to be forfeited to the Government.

~~(4) This section does not apply to a thing seized under section 31 if it has been disposed of under section 34.~~

~~(4) If a thing forfeited to the Government pursuant to an order under subsection (3) is sold or disposed of under section 38(1), a person who considers that he, she or it is aggrieved by the sale or disposal may complain to the court or magistrate within 6 months after the sale or disposal.~~

~~(5) On a complaint under subsection (4), the court or magistrate may, if satisfied as to the complainant's title to the thing concerned, order such amount of compensation to be paid to the complainant as the court or magistrate considers just.~~

38. Director's powers to ~~sell or~~ dispose of and to give directions on disposal of forfeited things

(1) The Director may ~~sell, or~~ dispose of in any ~~other~~ way (except by way of sale), any thing that is forfeited to the Government under this Part in such manner as the Director thinks fit.

(2) ~~The proceeds of sale of any thing sold under subsection (1) must be paid into the general revenue.~~

~~(3)~~ — If —

- (a) a person has been convicted of an offence under section 5, 7 or 23; and
- (b) a thing in connection with the offence has been forfeited to the Government under section 35(1) or (2),

the Director may, by written notice, direct the person to dispose of the thing through repatriation or destruction.

(34) A person given a direction under subsection (23) must, subject to section 39(4), carry out the direction at the person's cost within the period specified in the notice.

(45) A person who contravenes subsection (34) commits an offence and is liable to a fine at level 6.

38A. Compensation for seizure, etc.

(1) Subject to subsection (2), if a thing has been seized under section 31, the Government is liable to compensate the owner of the thing for any loss suffered by the owner –

- (a) by reason of the seizure; or
- (b) by reason that the thing dies, perishes, deteriorates, or is lost or damaged, during the time when the thing is seized or detained.

(2) The owner is not entitled to compensation for the loss if –

- (a) the owner has been convicted of an offence under this Ordinance in relation to the thing; or
- (b) the thing is forfeited to the Government by an order of the court or magistrate under section 35, 36 or 37 (except where the thing is forfeited pursuant to section 37(3)).

(3) In any proceedings against the Government in respect of a claim for compensation on any of the grounds referred to in subsection (1), the amount of the compensation recoverable is an amount that is just and equitable in all the circumstances of the case, including the conduct and comparative blameworthiness of –

- (a) the owner of the thing seized;
- (b) the person in charge of the thing at the time it was seized;
- (c) the agents of the person specified in paragraphs (a) and (b); and
- (d) authorized officers, public officers and other persons concerned.

(4) No proceedings are maintainable in respect of any claim for compensation on any of the grounds referred to in subsection (1) unless the proceedings are commenced –

- (a) in the case of a claim for compensation in respect of any thing that was seized but subsequently delivered to its owner by order of a court or magistrate or by

any person having authority to deliver the thing to the owner, not later than 6 months after the delivery;

(b) in the case of a claim for compensation on the ground that the thing died, perished or deteriorated, or was lost or damaged, during the time when the thing was seized or detained, not later than 6 months from whichever of the following is the earlier—

(i) the discovery by the owner of the existence of the ground;

(ii) the date on which the owner could, by the existence of reasonable diligence, have discovered the existence of the ground.

(5) A claim for compensation under this section may be made —

(a) in the Small Claims Tribunal, if the claim is within the jurisdiction of the Tribunal; or

(b) in the District Court, irrespective of the amount claimed.

39. Appeals

(1) If an ~~person~~applicant under a GMO approval application or variation request is aggrieved by a decision under section 10(1)(a), 11(5)(a), 12(1) or 16(3)(a), or a direction under section 12(7)~~or 38(3)~~, the ~~person~~applicant may, within 28 days after receiving notice of the decision or direction, appeal to the Administrative Appeals Board against that decision or direction.

(1A) If a person who is directed under section 38(3) to dispose of a thing is aggrieved by the direction, the person may, within 28 days after receiving notice of the direction, appeal to the Administrative Appeals Board against that direction.

(2) After lodging an appeal under subsection (1), the ~~person~~applicant must, pending the Administrative Appeals Board's decision on the appeal, cause the GMO ~~that is the subject of~~to which the appeal relates to be kept in a manner that effectively limits its contact with, and its impact on, the environment.

(3) Subsection (2) does not apply if the GMO has already been released into the environment.

(4) If an appeal is lodged against a direction referred to in subsection (1) or (1A), the applicant or person is not required to carry out the direction pending the Administrative Appeals Board's decision on the appeal.

42. Secretary's power to grant exemptions

(1) The Secretary may, by notice published in the Gazette, exempt any person, any group or description of persons, or any GMO from the application of section 5, 7 or 23.

(2) An exemption may take effect generally or for any purposes or by reference to any circumstances, and either conditionally or unconditionally.

(3) The Secretary must not grant an exemption under subsection (1) unless the Secretary is satisfied that the possible adverse biosafety effect that may result from the exemption is acceptable or manageable.

43. Expert group

(1) The Secretary ~~must~~may establish an expert group consisting ~~of members appointed by the Secretary.~~—

(a) members who are public officers; and

(b) members who are not public officers and who are appointed from different sectors including the farming, biotechnology, environmental protection, academic and trading sectors.

(1A) ~~A member must be~~Members are appointed by the Secretary.

(2) 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, and the granting of exemptions, to the expert group, or individual members of the group, for advice.

46. Secretary's power to make regulations

- (1) The Secretary may make regulations for all or any of the following purposes –
- (a) to provide for ~~the requirements relating to~~ the documents ~~to be furnished for the import and export of~~ required to accompany –
 - ~~(i) a GMO intended for direct consumption as food or feed, or for processing;~~
 - ~~(ii) a GMO intended for contained use; or~~
 - ~~(iii) a GMO intended for release into the environment,~~GMOs falling within section 24B(1)(a), (b) or (c) when those GMOs are being imported or exported;
 - (b) to provide for the percentage referred to in section 24B(5)(a) in relation to –
 - ~~(i) GMOs that are intended for direct consumption as food or feed, or for processing; or~~
 - ~~(ii) GMOs that are intended for contained use;~~
 - (c) to enable any part of a Protocol instrument to have the force of law in Hong Kong with or without modification;
 - (ed) to provide generally for the better carrying out of the purposes of this Ordinance.
- (2) A regulation under subsection (1) 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 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.
- (3) A regulation under subsection (1) may provide –

- (a) that it is an offence for a person to contravene a provision of the regulation; and
- (b) that such an offence is punishable by a fine not exceeding level 6 and imprisonment for a term not exceeding 6 months.

50. Notification of or application for approval of released GMOs during transitional period

~~(1) This section applies if a person knows that—~~

- ~~(a) the person caused a released GMO to be so released;~~
- ~~(b) the person, before the commencement date, maintained the life of a released GMO that was in a state of being released into the environment; or~~
- ~~(c) the person, during the transitional period, maintains the life of a released GMO that is in a state of being released into the environment.~~

(12) If a person, during the transitional period, knowingly maintains the life of a released GMO that is in a state of being released into the environment, the person must, during the transitional before that period expires –

- (a) inform the Director of the ~~release or~~ maintenance by written notice; or
- (b) submit a GMO approval application in accordance with section 8 in respect of the released GMO.

(2) A person who contravenes subsection (1) commits an offence and is liable to a fine at level 1.

(3) On receiving a notice under subsection (12)(a), the Director may –

- (a) direct an authorized officer to enter the place or premises in or on which the released GMO was released or maintained during reasonable hours to dispose of the GMO; or
- (b) direct the person to dispose of the released GMO.

(4) Section 5 does not prohibit a person who has informed the Director of the ~~release or~~ maintenance of a released GMO under subsection (12)(a) from knowingly maintaining the life of the GMO that is in a state of being released into the environment, during the period from the date of the notice to the date when the GMO is disposed of.

(5) Section 5 does not prohibit a person who has submitted a GMO approval application under subsection (12)(b) from knowingly maintaining the life of the released GMO that is in a state of being released into the environment, during the period from the date of the application to the date when the decision on the application is entered in the register under section 18.

(6) A notice under subsection (12)(a) must contain the information set out in Schedule 6.

51. 修訂附表

《行政上訴委員會條例》(第 442 章)的附表現予修訂，加入 —

67. 《基因改造生物(管制釋出)條例》(2009 年第 號)
- (a) 漁農自然護理署署長、漁農自然護理署副署長或任何一名漁農自然護理署任何一名助理署長作出的以下決定 —
- (i) 根據第 10(1)(a) 條對基因改造生物核准申請的決定；
 - (ii) 根據第 11(5)(a) 條就要求更改一項對基因改造生物核准申請的先前決定而作出的決定；
 - (iii) 根據第 12(1)條就更改一項先前決定而作出的決定，而該項先前決定是關於一項基因改造生物核准申請的，或是

關於要求更改該
項前述的先前決
定的。

(b) 漁農自然護理署署長、
漁農自然護理署副署長
或任何一名漁農自然護
理署任何一名助理署長
作出的以下指示 —

(i) 根據第 12(7)條
就妥善看管或處
置基因改造生物
或載有該生物的
容器而給予的指
示；

(ii) 根據第 38(3)條
就透過送返或銷
毀而處置被沒收
的東西而給予的
指示。

(c) 漁農自然護理署署長、
漁農自然護理署副署長
或任何一名漁農自然護
理署任何一名助理署長
根據第 16(3)(a)條將若
干就核准基因改造生物

而提交的資料記入紀錄冊的決定。”。

In accordance with Schedule 1 of the Bill

已釋出基因改造生物的書面通知

基因改造生物(管制釋出)條例

Written Notice on Released GMO

Genetically Modified Organisms (Control of Release) Ordinance

SAMPLE

填寫此申請表前請先詳閱附加的注意事項內容

Please read the attached notes before filling in this application form

1. 通報人資料 Information of the Person Making the Notification		
(a) 通報人姓名 Name of the Person Making the Notification	(c) 身分證/護照號碼 Identity Card/Passport Number	
CHAN Tai-man	A123456(7)	
(b) 通訊地址 Mailing Address	(d) 電話 Telephone	(e) 傳真 Fax
123, ABC Building, ABC Street, Hong Kong	1234 5678	2345 6789
	(f) 電郵	
	Email Address	chantaiman@xxx.com
2. 該書面通知的性質 (請選擇其中一項) Nature of this Notification (Please choose either one)		
<input checked="" type="checkbox"/> (a) 該被釋出的基因改造生物並非核准基因改造生物 The released GMO is not an approved GMO		
<input type="checkbox"/> (b) 該基因改造生物於不符合紀錄冊列明核准該生物的任何條件的情況下被釋出 The release did not comply with any conditions for the approval of the GMO, as set out in the register		
3. 該釋出所不符合的條件 Condition(s) which was not Complied by the GMO's Release		
N/A		
4. 已釋出的基因改造生物的資料 Information of the Released GMO		

<p>(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name</p> <p>Sunset / Hawaii papaya</p>	<p>(g) 基因改造生物的用途 Use of GMO</p> <p>The papaya fruit was bought as food for consumption.</p>
<p>(b) 基因改造生物的標識 GMO's Identity</p> <p>transformation event code: 55-1</p>	<p>(h) 釋出的基因改造生物的數量或體積</p> <p>Quantity or Volume of the GMO Released 5 seeds</p>
<p>(c) 基因改造生物的受體生物體的學名 Scientific Name of the GMO's Parental Organism</p> <p><i>Carica papaya</i></p>	<p>(i) 有關該基因改造生物的釋出的任何其他資料 Any Other Information Relating to the Release of the GMO</p>
<p>(d) 釋出的日期 Date of Release</p> <p>15 October 2008</p>	<p>The plants from the released seeds are still very young and have not had flowers.</p>
<p>(e) 釋出的時間 Time of Release</p> <p>19:00</p>	
<p>(f) 基因改造生物在何種情況下釋出 Circumstances under which the GMO was Released</p> <p>The seeds were released after the fruit was consumed. The seeds were then germinated and the plants were found later.</p>	
<p>5. 已釋出的基因改造生物的生物安全資料 Biosafety Information of the Released GMO</p>	
<p>(a) 可能帶來的生物安全不利影響的任何可得的資料 Any Available Information on the Possible Adverse Biosafety Effect of the GMO</p> <p><i>Carica papaya</i> is an exotic species and it is the sole member in the family Caricaceae in Hong Kong.</p>	<p>(b) 針對向環境釋出該生物而可能採取的任何風險管理措施 Any Possible Risk Management Measures on the Release of the GMO into the Environment</p> <p>The plants can be eradicated easily by uprooting and incinerating.</p>
<p>6. 聲明 Declaration</p>	

本人已閱畢附加的應注意事項及警告，並聲明上面各項填報詳情均為正確無訛。

I have read the attached notes and warning and I declare that all the particulars given above are true and correct.

申請人簽署 Signature of Applicant : CHAN Tai-man

公司印鑑 Company chop

日期 Date : 18.01.2010

此欄由辦理機關填寫 For Official Use only

Date Received	Remarks/Additional Information
Officer	Follow Up Action

已釋出基因改造生物的書面通知的注意事項

1. 遞交書面通知的注意事項

- 所有資料必須以英文正楷填寫或以打字機打印。
- 一份書面通知只供一種基因改造生物之用，如有多於一種基因改造生物，就必須使用額外的書面通知表格。
- 如空位不夠，請另附紙張填寫，並具清晰標記，以附頁形式與申請表一同遞交。
- 除非特別指明，否則必須填寫本表格所有部分。

- (e) 以親身或郵寄方式遞交至香港九龍長沙灣道 303 號長沙灣政府合署六樓漁農自然護理署生物多樣性護理科。

2. 遞交書面通知後的運作程序

漁農自然護理署署長(下稱署長) 接獲通知後，可指示獲授權人員，於合理時間進入釋出上述基因改造生物所在的地方或處所，以處置該生物；或指示你處置該生物。

3. 個人資料收集聲明

- (a) 你所提供的資料只會用作處理該基因改造生物的有關事宜。
- (b) 個人資料的提供純屬自願性質。若你未能提供足夠的資料，本署可能無法辦理你的書面通知。
- (c) 本署可能會將你的資料的任何部分提供給予其他政府部門作為調查或統計之用途。
- (d) 你所提供的資料可能會被提供給專家小組以汲取其對處理該基因改造生物的意見。
- (e) 你所提供的資料或會被記入紀錄冊及上傳至生物安全資料交換所以供公眾查閱。
- (f) 除個人資料(私隱)條例所訂明的豁免外，你有權查閱和改正你的個人資料。
- (g) 查閱和改正個人資料的要求應以書面形式向漁農自然護理署生物多樣性護理科提出。同時請註明有關申請／要求在本署的檔案號碼。

4. 查詢

生物多樣性及自然護理系

地址： 九龍長沙灣道二零三號

長沙灣政府合署六樓

電話： 2150 6918

傳真： 2314 2802

網址： <http://www.afcd.gov.hk/GMO>

電郵： biosafety@afcd.gov.hk

熱線電話： 1823

警告

- 如控制基因改造生物的人知道有下列情況，
 - 該核准基因改造生物在不符合紀錄冊列明核准該生物的任何條件的情況下向環境釋出；或
 - 該生物向環境釋出時，既非核准基因改造生物，也非供人類使用的藥劑製品。而不向本署作書面通知，可處罰款港幣 50,000 及監禁半年。
- 任何提供的資料須為事實。

Notes to Written Notice on Released GMO

1. Notes to Submitting the Written Notice

- (a) Information should be written or typed in BLOCK LETTERS in English.
- (b) A notice should be made for only one GMO. If there is more than one GMO, you should use additional notice forms.
- (c) If additional space is needed, please continue on a separate sheet, which must be clearly labelled and included as appendices to the application form.
- (d) Unless otherwise indicated, all sections of this form must be completed.
- (e) A notice should be submitted by mailing or in person to Biodiversity and Conservation Division, Agriculture, Fisheries and Conservation Department, 6/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon, Hong Kong .

2. Subsequent Procedures for the Notification

On receiving a notice, the Director of Agriculture, Fisheries and Conservation may direct an authorized officer to enter, during reasonable hours, the place or premises in or on which the GMO was released to dispose of the GMO; or direct you to dispose of the GMO.

3. Personal Information Collection Statement

- (a) The Information provided by you will be used for the processing of the released GMO.
- (b) The provision of personal data is voluntary. If you do not provide sufficient information, this department may not be able to process your notification.
- (c) The said information of any part thereof may be supplied by this department to other government departments for investigation or statistics purposes.
- (d) The Information provided may be supplied to the Expert groups to seek advice on the processing of the released GMO
- (e) The information provided may be entered in the Register and uploaded to the Biosafety Clearing House for inspection by members of the public.
- (f) Subject to exemptions under the Personal Data (Privacy) Ordinance, you have a right of access and correction with respect to personal data.
- (g) Request for personal data access and correction should be addressed to Conservation Biodiversity Division of Agriculture, Fisheries and Conservation Department. Please also quote the reference number of the application/request in this department.

4. Enquiries

Biodiversity Conservation Division

Address: 6/F, Cheung Sha Wan Government Offices,
303 Cheung Sha Wan Road, Kowloon

Tel: 2150 6918

Fax: 2314 2802

Website: <http://www.afcd.gov.hk/GMO>

E-mail: biosafety@afcd.gov.hk

Hotline: 1823

WARNING

1. If a person who has control of a GMO knows that:
 - (a) an approved GMO has been released without complying with any condition for the approval of the GMO, as set out in the register; or
 - (b) a GMO, which is not approved or is not a pharmaceutical product for use by human beings, has been released into the environmentbut does not inform the Director of the release by written notice, will be subjected to a maximum penalty of a fine of HK\$50,000 and imprisonment for 6 months.
2. Any information provided for the notification should be true and correct.

In accordance with Schedule 2 of the Bill

基因改造生物作環境釋出核准申請表

基因改造生物(管制釋出)條例

SAMPLE

Application for Approval of GMO for Environmental Release

Genetically Modified Organisms (Control of Release) Ordinance

填寫此申請表前請先詳閱附加的注意事項內容

Please read the attached notes before filling in this application form

1. 申請人/機構資料 Information of Applicant/Organisation		
(a) 申請人姓名/機構名稱 Name of Applicant/ Organisation CHAN Tai-man	(d) 聯絡人姓名 Contact Person's name CHAN Siu-man	
(b) 申請人/機構通訊地址 Mailing Address of Applicant/ Organisation 123, ABC Building, ABC Street, Hong Kong	(e) 電話 Telephone . 1234 5678	(f) 傳真 Fax 2345 6789
(c) 申請人身分證/護照號碼或機構的香港登記證號碼 Identity Card/Passport Number of Applicant or H.K. Registration No. of Organisation A123456(7)	(f) 電郵 Email Address chantaiman@xxx.com	(g) 聯絡人通訊地址 Contact Person's Mailing Address 123, ABC Building, ABC Street, Hong Kong
2. 基因改造生物的資料 Information of the GMO		
(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name Sunset / Hawaii papaya	(e) 該生物或其產品的預定用途 Intended Use of the GMO or Products from the GMO The seeds will be germinated in a papaya farm and the plants will be grown for commercial fruit production.	
(b) 基因改造生物的標識 GMO's Identity transformation event code: 55-1		
(c) 擬釋出的日期 Intended Date of Release 15 October 2010		

(d) 擬釋出和輸入(如適用)的數量或體積 the Quantity or Volume of the GMO to be (i) Imported (if Applicable) And (ii) Released 50 seeds to be imported and released	
3. 受體生物體或親本生物體 (如適用) 的資料 Information of the Recipient Organism and/or Parental Organisms (if Applicable)	
(a) 學名 Scientific Name(s) <i>Carica papaya</i>	(e) 起源中心和遺傳多樣性中心 (如已知的話) Centre of Origin and Centre of Biodiversity (if Known)
(b) 通用名稱 Common Name(s) Papaya	The centre of origin might be southern Mexico and neighbouring Central America. The centre of biodiversity is not known.
(c) 收集點或獲取點 Point(s) of Collection or Acquisition Hawaii, USA	(f) 有關受體生物體及親本生物體可在其中存活或繁衍的各種生存環境的說明
(d) 可能帶來生物安全不利影響的特徵 Characteristics Related to Possible Adverse Biosafety Effect <i>Carica papaya</i> is an exotic species and it is the sole member in the family Caricaceae in Hong Kong. A risk assessment report is attached.	Description of Habitats Where that Recipient Organism and Parental Organism may Persist or Proliferate Papaya cultivation is practiced in all tropical countries and many sub-tropical regions of the world. Fruit production is optimal in areas with a minimum monthly rainfall of about 100 mm, minimum relative humidity of 66% and where temperatures range between 21 and 33° C.
4. 供體生物體的資料 Information of the Donor Organism	

(a) 學名 Scientific Name(s)	(d) 可能帶來生物安全不利影響的特徵
Papaya Ringspot Virus (PRSV)	Characteristics Related to Possible Adverse Biosafety Effect
(b) 通用名稱 Common Name(s)	Papaya ringspot virus is an aphid-transmissible RNA virus that commonly infects papaya, causing serious disease and economic loss.
Papaya Ringspot Virus (PRSV)	
(c) 收集點或獲取點 Point(s) of Collection or Acquisition	
Hawaii, USA	

5. 基因改造的資料 Information of the Genetic Modification

(a) 引入該生物的核酸或改變的說明 Description of the Nucleic Acid or the Modification Introduced

The gene *prsv-cp* is derived from PRSV HA 5-1, which is a mild mutant strain developed from the severe strain PRSV HA from Hawaii. The gene was fused with the sequence encoding the first 16 amino acid of the coat protein of cauliflower mosaic virus before its introduction into the gene cassette.

(b) 所使用的基因改造技術的說明 Description of the Technique(s) Used for the Genetic Modification

The *prsv-cp* gene was introduced into the papaya as part of a genetic construct. The construct was introduced into Sunset' papaya via a particle bombardment technique.

(c) 由此而產生的該生物的特徵的說明 Description of the Resulting Characteristics of the GMO

The inserted *prsv-cp* gene enables the papaya to resist PRSV disease by an uncertain mechanism. One suggestion is that the expression of the sequence interferes with one of the first steps in viral replication. The inserted construct also included two plant-expressible, genetic marker genes, *nptII* and *uidA* (*gus*), which enabled researchers to easily select those plant tissues that have been successfully transformed with the genetic construct.

6. 建議用於安全處理、儲存、運輸及使用該基因改造生物的方法，包括包裝、標籤、文件紀錄、處置及應變程序

Suggested Methods for the Safe Handling, Storage, Transport and Use of the GMO, Including Packaging, Labelling, Documentation, Disposal and Contingency Procedures, Where Appropriate

The seeds should be enclosed in sealed containers that serve as an effective physical means to limit the contact of the seeds with the external environment. The words “This product contains genetically

modified organisms” or “This product contains genetically modified papaya 55-1’ shall appear either on a label or in a document accompanying the product.

For accidental release, the plants can be eradicated easily by uprooting and incinerating.

第 7 及第 8 項適用於輸入擬向環境釋出的基因改造生物 Section 7 and 8 are applicable for import of GMOs intended for release into environment

7. 有關該基因改造生物的輸入的資料 Information of the GMO's Importation

(a) 輸出地 the Exporting Place

Hawaii, USA

(d) 聯絡人姓名 Contact Person's Name

John Lee

(b) 輸出的日期 (如已知的話) Intended Date of Export (if known)

After the receipt of the approval for release into environment from the Director of Agriculture, Fisheries and Conservation

(e) 電話 Telephone

(01) 123-4567

(f) 傳真 Fax

(01) 123-4567

(g) 電郵 Email Address

johnlee@xxx.com

(c) 輸出者/公司名稱及地址 Name of Exporter/Company & Address

Cornell University, USA

8. 基因改造生物於輸出地的生物安全資料 Biosafety Status of the GMO at the Exporting Place

(a) 基因改造生物於當地的生物安全水平分類 (如有的話)

the Domestic Classification of the GMO's Biosafety Level (if Any)

Not regulated

(c) 向其它地方的主管當局作出的輸出通知的結果及目的

the Result and Purpose of Any Notification Made to Competent Authorities of Other places Regarding the Export of the GMO to that Place

(b) 基因改造生物於當地的規管狀況及被禁制的原因(如適用)

the Regulatory Status of the GMO at the Exporting Place and the Reason for the Refusal (if Applicable)

Not regulated

This genetically modified papaya was not exported to other places for environmental release before.

9. 付款資料 Remittance Details

(a) 請在支票背面寫上你的姓名及日間聯絡電話號碼。 Please write down your name and daytime contact telephone No. on the back of the cheque.

(b) 請填上你的付款資料。 Please fill in your remittance details.

銀行名稱 Name of Bank	支票/銀行本票號碼 Cheque/Cashier Order No.
.....	

10. 聲明 Declaration

本人已閱畢附加的應注意事項及警告，並聲明上面各項填報詳情均為正確無訛。

I have read the attached notes and warning and I declare that all the particulars given above are true and correct.

申請人簽署 Signature of Applicant : **CHAN Tai-man**

公司印鑑 Company chop

日期 Date : **18.01.2010**

此欄由辦理機關填寫 For Official Use only

Date Received	Remarks/Additional Information
Officer	Follow Up Action

基因改造生物作環境釋出核准申請的注意事項

1. 遞交申請表的注意事項

- (a) 所有資料必須以英文正楷填寫或以打字機打印。
- (b) 一份申請表只供申請一種基因改造生物之用，如有多於一種基因改造生物，就必須使用額外的申請表。

- (c) 如空位不夠，請另附紙張填寫，並具清晰標記，以附頁形式與申請表一同遞交。
- (d) 除非特別指明，否則必須填寫本表格所有部分。
- (e) 在遞交申請表時，必須附上對該基因改造生物的風險評估報告。
- (f) 在遞交申請表時，必須附上提出申請須付的費用**港幣 14,250**。費用以支票或銀行本票支付。
- (g) 如用支票付款，收款人須寫明「香港特別行政區政府」。
- (h) 根據本條例繳付的訂明費用不得退回。
- (i) 以親身或郵寄方式遞交申請表及所需文件和費用至香港九龍長沙灣道 303 號長沙灣政府合署六樓漁農自然護理署生物多樣性護理科。

2. 遞交申請表後的運作程序

- (a) 於接獲基因改造生物核准申請後 90 天內，你將會收到由本署發出的書面認收書，以確認接獲該項申請。
- (b) 於接獲基因改造生物核准申請後 270 天內本署將會決定是否核准有關生物以向環境釋出並以書面通知申請人該項決定。
- (c) 在 270 天的限期屆滿前，本署可藉給予申請人書面通知以延長該限期及列明延長的原因。
- (d) 本署可藉書面通知，要求申請人就該項申請或要求，提供額外資料或支持文件以及與漁農自然護理署署長(下稱署長)會面，回答署長提出的任何問題或提供署長要求的任何澄清。
- (e) 從上述書面通知發出日期起計至本署接獲所需的額外資料或支持文件的日期止所涵蓋的日子的數目不得計算在 270 天的限期之內
- (f) 申請一旦被核准及記入紀錄冊，該基因改造生物隨後的環境釋出不需再作申請。
- (g) 含有作環境釋出用途的基因改造生物的入口貨物必須附有適當的文件紀錄。詳細的文件紀錄要求可從漁農自然護理署或以下網址取得：
www.afcd.gov.hk/GMO。

3. 要求更改對基因改造生物核准申請的決定

- (a) 如署長拒絕核准基因改造生物以作環境釋出或核准時附加條件，提出有關核准申請的申請人可要求署長更改拒絕核准的決定或取消、更改核准該生物時所附加的條件，其前提為：
 - (i) 情況有所改變，而該改變可能影響署長對有關基因改造生物可能帶來的生物安全不利影響的評估；
 - (ii) 已有額外科學或技術資料，而該資料可能影響署長對該生物可能帶來的生物安全不利影響的評估。
- (b) 更改要求須採用指定表格 (要求更改基因改造生物核准決定申請表 AF992)。
- (c) 你也可以於接獲本署關於該核准申請的決定的通知後 28 天內，向行政上訴委員會提出反對該項決定的上訴。

4. 撤回基因改造生物核准申請或已提供的資料或文件

- (a) 你可於署長對申請作出決定前，隨時以書面要求撤回該項申請。本署會停止處理該項申請及將載有關於該項申請的任何機密資料的任何紀錄或文件，或該類紀錄或文件中載有該等資料的部分，交還有關申請人。
- (b) 你可於署長對申請作出決定前隨時以書面撤回就該項申請而提供的任何資料或文件。本署會繼續處理該項申請或要求，猶如該等資料或文件不曾被提供一樣及將載有機密資料的任何紀錄或文件或載有該等資料的部分，交還有關申請人。
- (c) 撤回通知可以使用指定表格 AFXXX

5. 提出不披露要求

- (a) 署長須於接獲基因改造生物核准申請的資料後 14 天內，將資料記入紀錄冊。就該核准申請向署長提供任何資料時，你可要求署長不將該等資料記入紀錄冊。
- (b) 不披露要求必須採用指定表格 (不披露要求申請表 AF99x)。
- (c) 該不披露要求不適用於下列資料：
 - (i) 申請人的姓名或名稱及地址；
 - (ii) 有關基因改造生物的一般描述；
 - (iii) 該生物可能帶來的生物安全不利影響的風險評估摘要；及
 - (iv) 於緊急情況處理該生物可能帶來的生物安全不利影響的任何建議方法及計劃。

6. 個人資料收集聲明

- (a) 你所提供的資料將用作申請基因改造生物作環境釋出的有關事宜。
- (b) 個人資料的提供純屬自願性質。若你未能提供足夠的資料，本署可能無法辦理你的申請。
- (c) 本署可能會將你的資料的任何部分提供給予其他政府部門作為調查或統計之用途。
- (d) 你所提供的資料可能會被提供給專家小組以汲取其對該項申請的意見。
- (e) 所有非機密資料會被記入紀錄冊及上傳至生物安全資料交換所以供公眾查閱。
- (f) 除個人資料(私隱)條例所訂明的豁免外，你有權查閱和改正你的個人資料。
- (g) 查閱和改正個人資料的要求應以書面形式向漁農自然護理署生物多樣性護理科提出。同時請註明有關申請／要求在本署的檔案號碼。

7. 查詢

生物多樣性及自然護理系

地址： 九龍長沙灣道三零三號

長沙灣政府合署六樓

電話： 2150 6918

傳真： 2314 2802

網址： <http://www.afcd.gov.hk/GMO>

電郵： biosafety@afcd.gov.hk

熱線電話： 1823

警告

- 1. 任何人如果明知而：
 - (c) 向環境釋出未被核准的基因改造生物；
 - (d) 進口作環境釋出用途的未被核准的基因改造生物；

- (e) 育養處於向環境釋出的狀態的未被核准基因改造生物；
 - (f) 導致未被核准基因改造生物在不符紀錄冊列明核准該生物的任何條件的情況下向環境釋出
- 可處罰款港幣 100,000 及監禁一年。

2. 倘若漁農自然護理署署長認為申請人由於虛報任何事實或作出不法行為而導致該基因改造生物之申請獲核准，則可隨時將該核准取銷。

Notes to Approval Application of GMO for Environmental Release

1. Notes to Submitting the Application Form

- (a) Information should be written or typed in BLOCK LETTERS in English.
- (b) An application should be made for only one GMO. If there is more than one GMO, you should use additional application forms.
- (c) If additional space is needed, please continue on a separate sheet, which must be clearly labelled and included as appendices to the application form.
- (d) Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
- (e) A risk assessment report for the GMO should be submitted together with the application form
- (f) An application should be accompanied by the prescribed fee payable of **14,250 HK Dollars** in cheque or cashier order.
- (g) Cheque should be made payable to “The Government of the Hong Kong Special Administrative Region”.
- (h) Any prescribed fee paid under this Ordinance is not refundable.
- (i) An application should be submitted together with supporting documents and the prescribed fee payable by mailing or in person to Biodiversity and Conservation Division, Agriculture, Fisheries and Conservation Department, 6/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon, Hong Kong .

2. Subsequent Procedures for the Approval Application

- (a) Within 90 days after receiving the GMO Approval Application, you will be issued a written Acknowledgement from the Director of Agriculture, Fisheries and Conservation (the Director) confirming the receipt.
- (b) The Director will inform you the result of the application within 270 days by written notice.
- (c) Before the expiry of the 270-day period, the Director may extended that period with a written notice stating the duration of the extended period and the reason for the extension.
- (d) The Director may, by written notice, require the applicant to provide additional information or supporting documents or to appear before the Director to provide any clarification or answer any question raised.
- (e) The period from the date on the written notice to the date on which the additional information or supporting documents required is received by the Director, will be disregarded from the 270-day period.
- (f) The approval to the GMO applies to all subsequent releases after it is entered in the GMO Register as an approved GMO.
- (g) The importing shipment containing GMOs for release into environment must be accompanied by proper documentation. Details of the

documentation requirements are available from AFCD upon request or from the website www.afcd.gov.hk/GMO.

3. Request for Variation of Decisions

- (a) If the Director refuses to approve a GMO for release into the environment or approve the release with conditions, you can apply for variation of decision on the disapproval or to cancel or vary the conditions attached to the release, if there is:
 - (i) a change in circumstances that may influence the Director's assessment on the possible adverse biosafety effect of the GMO;
 - (ii) additional scientific or technical information that may influence the Director's assessment on the possible adverse biosafety effect of the GMO.
- (b) The application for variation of decision must be made in the specific form (Application for Variation Request on GMO Approval Decision, AF992).
- (c) You can also appeal to the Administrative Appeals Board against the Director's decisions on GMO approval applications, within 28 days after receiving notice of the decision.

4. Withdraw of Application or Information/Document Provided

- (a) You may, in writing, withdraw the application at any time before the Director makes a decision. In such case, the process of the application will be ceased. The records and documents containing the confidential information will be returned to you.
- (b) You may, in writing, withdraw any information or document provided for the purposes of the application at any time before the Director makes a decision. In such case, the process of the application or request will continue as if the information or document had not been provided. The records and documents containing the confidential information will be returned to you.
- (c) The withdrawal notice could be in the specific form (AFXXX)

5. Making of non-disclosure requests

- (a) The Director will enter all information submitted for the purposes of a GMO approval application or variation request, in the register within 14 days after receipt of it. When providing the information, you could request the Director not to enter the submitted information in the register.
- (b) A confidential request should be made in the specific form (Application for Non-disclosure Request, AF991).
- (c) The request must not be related to the following information:
 - (i) the name and address of the applicant;
 - (ii) a general description of the GMO;
 - (iii) a summary of the risk assessment on the possible adverse biosafety effect of the GMO; and
 - (iv) any proposed methods and plans for dealing with the possible adverse biosafety effect of the GMO in emergency circumstances.

6. Personal Information Collection Statement

- (a) The Information provided by you will be used for the processing of GMO approval application in this department.
- (b) The provision of personal data is voluntary. If you do not provide sufficient information, this department may not be able to process your application.
- (c) The said information of any part thereof may be supplied by this department to other government departments for investigation or statistics purposes.

- (d) The Information provided may be supplied to the Expert groups to seek advice on the approval application.
- (e) All non-confidential information will be entered in the Register and uploaded to the Biosafety Clearing House for inspection by members of the public.
- (f) Subject to exemptions under the Personal Data (Privacy) Ordinance, you have a right of access and correction with respect to personal data.
- (g) Request for personal data access and correction should be addressed to Conservation Biodiversity Division of Agriculture, Fisheries and Conservation Department. Please also quote the reference number of the application/request in this department.

7. Enquiries

Biodiversity Conservation Division

Address: 6/F, Cheung Sha Wan Government Offices,
303 Cheung Sha Wan Road, Kowloon

Tel: 2150 6918

Fax: 2314 2802

Website: <http://www.afcd.gov.hk/GMO>

E-mail: biosafety@afcd.gov.hk

Hotline: 1823

WARNING

1. A person who knowingly:
 - (g) releases an unapproved GMO to be released into the environment;
 - (h) imports an unapproved GMO for release into the environment;
 - (i) maintains the life of an unapproved GMO that is in a state of being released into the environment;
 - (j) causes an approved GMO to be released into the environment that not every condition for the approval of the GMO has been complied withwill be subjected to a maximum penalty of a fine of HK\$100,000 and imprisonment for one year.
2. The Director of Agriculture, Fisheries and Conservation Department may at any time revoke the approval on the GMO if the GMO was approved as a result of false representation of any fact made by the applicant or an unlawful act of the applicant.

In accordance with Schedule 4 of the Bill

輸出基因改造生物作環境釋出用途通知書
基因改造生物(管制釋出)條例

SAMPLE

Export Notice on GMO Intended for Release Genetically Modified Organisms (Control of Release) Ordinance

填寫此申請表前請先詳閱附加的注意事項內容

Please read the attached notes before filling in this application form

1. 輸出者/機構資料 Information of Exporter /Organisation	
(a) 輸出者姓名/機構名稱 Name of Exporter / Organisation CHAN Tai-man	(d) 聯絡人姓名 Contact Person's name CHAN Siu-an
(b) 輸出者/機構通訊地址 Mailing Address of Exporter / Organisation 123, ABC Building, ABC Street, Hong Kong	(e) 電話 Telephone 1234 5678 (f) 傳真 Fax 2345 6789
(c) 輸出者身分證/護照號碼或機構的香港登記證號碼 Identity Card/Passport Number of Exporter or H.K. Registration No. of Organisation A123456(7)	(f) 電郵 Email Address chantaiman@xxx.com (g) 聯絡人通訊地址 Contact Person's Mailing Address 123, ABC Building, ABC Street, Hong Kong
2. 輸入者/機構資料 Information of importer /Organisation	
(a) 輸入者姓名/機構名稱 Name of Importer / Organisation Dr. ZHANG San	(e) 輸入者/機構通訊地址 Mailing Address of Importer / Organisation 123 Beijing Road, Beijing 1000, China
(b) 電話 Telephone +86-10-98765432. (c) 傳真 Fax +86-10-98765432	Department of ABC, University of ABC, PRC
(d) 電郵 Email Address zhang.wenguo@xxx.gov.cn	
2. 基因改造生物的資料 Information of the GMO	
(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name Sunset / Hawaii papaya	(e) 擬輸出和釋出的數量或體積 the Quantity or Volume of the GMO to be Exported And Released 50 seeds

(b) 基因改造生物的標識 GMO's Identity	(f) 該生物或其產品的預定用途
transformation event code: 55-1	Intended use of the GMO or products from the GMO
(c) 擬輸出的地方 Intended Place of Export	The seeds will be germinated in a papaya farm and the plants will be grown for commercial fruit production.
Guangdong, China	
3. 受體生物體或親本生物體 (如適用) 的資料 Information of the Recipient Organism and/or Parental Organisms (if Applicable)	
(a) 學名 Scientific Name(s)	(e) 起源中心和遺傳多樣性中心 (如已知)
<i>Carica papaya</i>	Centre of Origin and Centre of Biodiversity (if Known)
(b) 通用名稱 Common Name(s)	The centre of origin might be southern Mexico and neighbouring Central America. The centre of biodiversity is not known.
Papaya	
(c) 收集點或獲取點 Point(s) of Collection or Acquisition	
Hawaii, USA	
(d) 可能帶來生物安全不利影響的特徵	(f) 可在其中存活或繁衍的各種生存環境的說明
Characteristics Related to Possible Adverse Biosafety Effect	Description of Habitats Where the Organisms may Persist or Proliferate
<i>Carica papaya</i> is an exotic species and it is the sole member in the family Caricaceae in Hong Kong.	Papaya cultivation is practiced in all tropical countries and many sub-tropical regions of the world. Fruit production is optimal in areas with a minimum monthly rainfall of about 100 mm, minimum relative humidity of 66% and where temperatures range between 21 and 33° C.
4. 供體生物體的資料 Information of the Donor Organism	
(a) 學名 Scientific Name(s)	(d) 可能帶來生物安全不利影響的特徵
Papaya Ringspot Virus (PRSV)	Characteristics Related to Possible Adverse Biosafety Effect
(b) 通用名稱 Common Name(s)	Papaya ringspot virus is an aphid-transmissible RNA virus that commonly infects papaya, causing serious disease and economic loss.
Papaya Ringspot Virus (PRSV)	

(c) 收集點或獲取點 Point(s) of Collection or Acquisition

Hawaii, USA

5. 基因改造的資料 Information of the Genetic Modification

(a) 有關引入或被改變的核酸的說明 Description of the Nucleic Acid or the Modification Introduced

The gene *prsv-cp* is derived from PRSV HA 5-1, which is a mild mutant strain developed from the severe strain PRSV HA from Hawaii. The gene was fused with the sequence encoding the first 16 amino acid of the coat protein of cauliflower mosaic virus before its introduction into the gene cassette.

(b) 有關所使用的技術的說明 Description of the Technique(s) Used

The *prsv-cp* gene was introduced into the papaya as part of a genetic construct. The construct was introduced into Sunset' papaya via a particle bombardment technique.

(c) 由此而產生的該生物的特徵的說明 Description of the Resulting Characteristics of the GMO

The inserted *prsv-cp* gene enables the papaya to resist PRSV disease by an uncertain mechanism. One suggestion is that the expression of the sequence interferes with one of the first steps in viral replication. The inserted construct also included two plant-expressible, genetic marker genes, *nptII* and *uidA* (*gus*), enable researchers to easily select those plant tissues that have been successfully transformed with the genetic construct.

6. 建議用於安全處理、儲存、運輸及使用該基因改造生物的方法，包括包裝、標籤、文件紀錄、處置及應變程序

Suggested Methods for the Safe Handling, Storage, Transport and Use of the GMO, Including Packaging, Labelling, Documentation, Disposal and Contingency Procedures, Where Appropriate

The seeds should be enclosed in sealed containers that serve as an effective physical means to limit the contact of the seeds with the external environment. The words “This product contains genetically

modified organisms” or ‘This product contains genetically modified papaya 55-1’ shall appear either on a label or in a document accompanying the product.

For accidental release, the plants can be eradicated easily by uprooting and incinerating.

8. 基因改造生物於出口地的生物安全資料 Biosafety Status of the GMO at the Exporting Place

(a) 基因改造生物於香港的規管狀況及被禁制的原因(如適用) the Regulatory Status of the GMO in Hong Kong and the Reason for the Refusal (if Applicable)

The genetically modified papaya (55-1) was approved for release into environment by the Director of Agriculture, Fisheries and Conservation on 15 October 2009 on that condition that the GMO cannot be planted within 5km of the nearest organic farm.

(b) 向其它地方的主管當局作出的輸出通知的結果及目的

the Result and Purpose of Any Notification Made to Competent Authorities of Other places Regarding the Export of the GMO to that Place

The GM papaya was exported to Hong Kong for release into environment and nowhere else.

9. 聲明 Declaration

本人已閱畢附加的應注意事項及警告，並聲明上面各項填報詳情均為正確無訛。

I have read the attached notes and warning and I declare that all the particulars given above are true and correct.

申請人簽署 Signature of Applicant : CHAN Tai-man

公司印鑑 Company chop

日期 Date : 18.01.2010

此欄由辦理機關填寫 For Official Use only

Date Received	Remarks/Additional Information

Officer	Follow Up Action

輸出基因改造生物作環境釋出用途通知書的注意事項

1. 遞交通知書的注意事項

- (a) 所有資料必須以英文正楷填寫或以打字機打印。
- (b) 一份通知書只供一種基因改造生物之用，如有多於一種基因改造生物，就必須使用額外的通知書。
- (c) 如空位不夠，請另附紙張填寫，並具清晰標記，以附頁形式與申請表一同遞交。
- (d) 除非特別指明，否則必須填寫本表格所有部分。
- (e) 以親身或郵寄方式遞交所有文件至香港九龍長沙灣道 303 號長沙灣政府合署六樓漁農自然護理署生物多樣性護理科。

2. 出口通知的程序

- (a) 該輸出通知書應送交該生物的輸出目的地的主管當局。
- (b) 任何人必須在送交輸出通知書後 14 天內，向漁農自然護理署署長（下稱署長）送交 (i) 該通知書的副本一份及 (ii) 述明該副本為該通知書的真實副本及盡該人所知及所信，該通知書所載的資料屬真實無誤的聲明一份。聲明必須採用指定表格（輸出基因改造生物作環境釋出通知書的聲明 AFXXX）。
- (c) 如任何人從該生物的輸出目的地的主管當局獲得對該項輸出的核准（不論是否有附加條件），向下稱署長 送交 (i) 該核准通知書的副本一份及 (ii) 述明該副本為該核准通知書的真實副本的聲明一份。聲明必須採用指定表格（輸出基因改造生物作環境釋出核准通知書的聲明 AFXXX）。
- (d) 如根據上述基因改造生物的輸出目的地的法律或規管性規定，無須就輸出該生物往當地而向上述主管當局送交事先通知書，則第 2 (a) 和 (b) 款不適用。
- (e) 如根據上述基因改造生物的輸出目的地的法律或規管性規定，無須就輸出該生物往當地而從上述主管當局獲得事先核准，則第 2 (c) 款不適用。
- (f) 含有作環境釋出用途的基因改造生物的出口貨物必須附有適當的文件紀錄。詳細的文件紀錄要求可從漁農自然護理署或以下網址取得：
www.afcd.gov.hk/GMO。

3. 個人資料收集聲明

- (a) 你所提供的資料將用作申請基因改造生物作環境釋出的有關事宜。
- (b) 個人資料的提供純屬自願性質。若你未能提供足夠的資料，本署可能無法辦理你的申請。
- (c) 本署可能會將你的資料的任何部分提供給予其他政府部門作為調查或統計之用途。
- (d) 你所提供的資料可能會被提供給專家小組以汲取其對該項申請的意見。
- (e) 所有非機密資料會被記入紀錄冊及上傳至生物安全資料交換所以供公眾查閱。
- (f) 除個人資料(私隱)條例所訂明的豁免外，你有權查閱和改正你的個人資料。
- (g) 查閱和改正個人資料的要求應以書面形式向漁農自然護理署生物多樣性護理科提出。同時請註明有關申請／要求在本署的檔案號碼。

4. 查詢

生物多樣性及自然護理系

地址： 九龍長沙灣道三零三號

長沙灣政府合署六樓

電話： 2150 6918

傳真： 2314 2802

網址： <http://www.afcd.gov.hk/GMO>

電郵： biosafety@afcd.gov.hk

熱線電話： 1823

警告

1. 任何人明知而輸出擬向環境釋出的基因改造生物，卻沒有事先向該生物的輸出目的地的主管當局送交關於該項輸出的通知書及獲得主管當局對該項輸出的核准(不論是否有附加條件)，可處罰款港幣 100,000 及監禁一年。
2. 任何人明知而輸出擬向環境釋出的基因改造生物，卻沒有在規定時間內送交漁農自然護理署署長該項輸出的通知書的副本及其聲明和核准通知書的副本及其聲明，可處罰款港幣 50,000 及監禁半年。

Notes to Export Notice on GMO Intended for Release

1. Notes to Submitting the Export Notice

- (a) Information should be written or typed in BLOCK LETTERS in English.
- (b) An Export Notice should be made for only one GMO. If there is more than one GMO, you should use additional Export Notice forms.
- (c) If additional space is needed, please continue on a separate sheet, which must be clearly labelled and included as appendices to the application form.

- (d) Unless otherwise indicated, all sections of this form must be completed for the application to be progressed.
- (e) All documents related to the Export Notice should be submitted by mailing or in person to Biodiversity and Conservation Division, Agriculture, Fisheries and Conservation Department, 6/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon, Hong Kong .

2. Procedures for the Export Notification

- (a) The Export Notice should be sent to the competent authority of the place to which the GMO is to be exported.
- (b) Within 14 days after sending the export notification, a person must send to the Director of Agriculture, Fisheries and Conservation (the Director) (i) a copy of the notification and (ii) a declaration by the person that the copy is a true copy of the notification and the information contained in the notification is true and correct to the best of the person's knowledge and belief. The declaration must be in the specific form (Declaration for Export Notice on GMO Intended for Release, AFxxx).
- (c) Within 14 days after receiving an approval (whether or not with conditions attached) from the competent authority of the place to which the GMO is to be exported for that export, a person must send to the Director (i) a copy of the notification and (ii) a declaration by the person that the copy is a true copy of the approval. The declaration must be in the specific form (Declaration for Approval Notice on GMO Intended for Export and Release, AFxxx).
- (d) Section 2(a) and (b) do not apply if prior notification to the competent authority for exporting the GMO to the place is not required under the legal or regulatory requirements of that place.
- (e) Section 2(c) does not apply if prior approval from the competent authority for exporting the GMO to the place is not required under the legal or regulatory requirements of that place.
- (f) The exporting shipment containing GMOs for release into environment must be accompanied by proper documentation. Details of the documentation requirements are available from AFCD upon request or from the website www.afcd.gov.hk/GMO.

3. Personal Information Collection Statement

- (a) The Information provided by you will be used for the processing of GMO approval application in this department.
- (b) The provision of personal data is voluntary. If you do not provide sufficient information, this department may not be able to process your application.
- (c) The said information of any part thereof may be supplied by this department to other government departments for investigation or statistics purposes.
- (d) The Information provided may be supplied to the Expert groups to seek advice on the approval application.
- (e) All non-confidential information will be entered in the Register and uploaded to the Biosafety Clearing House for inspection by members of the public.
- (f) Subject to exemptions under the Personal Data (Privacy) Ordinance, you have a right of access and correction with respect to personal data.
- (g) Request for personal data access and correction should be addressed to Conservation Biodiversity Division of Agriculture, Fisheries and Conservation Department. Please also quote the reference number of the application/request in this department.

4. Enquiries

Biodiversity Conservation Division

Address: 6/F, Cheung Sha Wan Government Offices,

303 Cheung Sha Wan Road, Kowloon

Tel: 2150 6918

Fax: 2314 2802

Website: <http://www.afcd.gov.hk/GMO>

E-mail: biosafety@afcd.gov.hk

Hotline: 1823

WARNING

1. A person knowingly export a GMO that is intended for release into the environment before (i) an export notification has been sent to the competent authority of the place and (ii) the approval (whether or not with conditions attached) for that export has been received from the authority, will be subjected to a maximum penalty of a fine of HK\$100,000 and imprisonment for one year.
2. A person knowingly export a GMO that is intended for release into the environment without sending copies of export notifications, copies of approval notifications and their declarations to the Director of Agriculture, Fisheries and Conservation within the required time limits, will be subjected to a maximum penalty of a fine of HK\$50,000 and imprisonment for half year.

In accordance with Schedule 6 of the Bill

釋出或育養已釋出的基因改造生物的書面通知

基因改造生物(管制釋出)條例

Written Notice on Release or Maintenance of Released GMO

Genetically Modified Organisms (Control of Release) Ordinance

SAMPLE

填寫此申請表前請先詳閱附加的注意事項內容

Please read the attached notes before filling in this application form

1. 通報人資料 Information of the Person Making the Notification		
(a) 通報人姓名 Name of the Person Making the Notification CHAN Tai-man	(c) 身分證/護照號碼 Identity Card/Passport Number A123456(7)	
(b) 通訊地址 Mailing Address 123, ABC Building, ABC Street, Hong Kong	(d) 電話 Telephone 1234 5678	(e) 傳真 Fax 2345 6789
	(f) 電郵 Email Address chantaiman@xxx.com	
2. 該書面通知的性質 (可選擇多於一項) Nature of this Notification (More than one options can be chosen)		
<input type="checkbox"/> (a) 我曾釋出一基因改造生物 I released a GMO		
<input checked="" type="checkbox"/> (b) 在生效日期之前，曾育養處於向環境釋出的狀態的已釋出的基因改造生物 Before the commencement date, I maintained the life of a released GMO that was in a state of being released into the environment		
<input type="checkbox"/> (c) 在過渡期內育養處於向環境釋出的狀態的已釋出的基因改造生物 During the transitional period, I maintain the life of a released GMO that is in a state of being released into the environment.		
3. 已釋出的基因改造生物的資料 Information of the Released GMO		

<p>(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name Hawaii papaya</p> <p>(b) 基因改造生物的標識 GMO's Identity Unknown</p> <p>(c) 釋出及/或育養的地點 Location of Release and/or Maintenance Lot 123, XYZ Village, New Territories</p> <p>(d) 釋出及/或育養的日期 Date of Release and/or Maintenance Released in October 2009</p> <p>(e) 釋出及/或育養的時間 Time of Release and/or Maintenance Unknown</p>	<p>(f) 基因改造生物在何種情況下釋出 Circumstances under which the GMO was Released The seeds were released after the fruit flesh was consumed. The seeds then germinated and the plants were maintained since then.</p> <p>(g) 基因改造生物的用途 Use of GMO The papaya fruit was bought as food for consumption.</p> <p>(h) 釋出的基因改造生物的數量或體積 Quantity or Volume of the GMO Released A few seeds</p> <p>(i) 有關該基因改造生物的釋出的任何其他資料 Any Other Information Relating to the Release of the GMO Nil.</p>
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4. 聲明 Declaration

本人已閱畢附加的應注意事項及警告，並聲明上面各項填報詳情均為正確無訛。

I have read the attached notes and warning and I declare that all the particulars given above are true and correct.

申請人簽署 Signature of Applicant : CHAN Tai-man

公司印鑑 Company chop

日期 Date : 18.01.2010

此欄由辦理機關填寫 For Official Use only

Date Received	Remarks/Additional Information

Officer	Follow Up Action

釋出或育養已釋出的基因改造生物的書面通知的注意事項

1. 遞交書面通知的注意事項

- (a) 此書面通知表格僅限於過渡期內使用。“過渡期”指由本條例開始實施的日期起計的 6 個月期內。
- (b) 所有資料必須以英文正楷填寫或以打字機打印。
- (c) 一份書面通知只供一種基因改造生物之用，如有多於一種基因改造生物，就必須使用額外的書面通知。
- (d) 如空位不夠，請另附紙張填寫，並具清晰標記，以附頁形式與申請表一同遞交。
- (e) 除非特別指明，否則請盡量填寫本表格所有部分。
- (f) 以親身或郵寄方式遞交至香港九龍長沙灣道 303 號長沙灣政府合署六樓漁農自然護理署生物多樣性護理科。

2. 遞交書面通知後的運作程序

- (a) 漁農自然護理署署長(下稱署長) 接獲通知後，可指示獲授權人員，於合理時間進入釋出上述基因改造生物所在的地方或處所，以處置該生物；或指示你處置該生物。
- (b) 你如已告知署長已釋出的基因改造生物被釋出或育養一事，你可以在通知當日起至該生物被處置當日的期間，明知而育養該處於向環境釋出的狀態的已釋出的基因改造生物。
- (c) 除了遞交書面通知此一途徑，你也可以就已釋出的基因改造生物提交基因改造生物核准申請。在提交申請當日至將申請的決定被記入紀錄冊當日的期間，你可以明知而育養該處於向環境釋出的狀態的已釋出的基因改造生物。

3. 個人資料收集聲明

- (a) 你所提供的資料只會用作處理該基因改造生物的有關事宜。

- (b) 個人資料的提供純屬自願性質。若你未能提供足夠的資料，本署可能無法辦理你的書面通知。
- (c) 本署可能會將你的資料的任何部分提供給其他政府部門作為調查或統計之用途。
- (d) 你所提供的資料可能會被提供給專家小組以汲取其對處理該基因改造生物的意見。
- (e) 你所提供的資料或會被記入紀錄冊及上傳至生物安全資料交換以供公眾查閱。
- (f) 除個人資料(私隱)條例所訂明的豁免外，你有權查閱和改正你的個人資料。
- (g) 查閱和改正個人資料的要求應以書面形式向漁農自然護理署生物多樣性護理科提出。同時請註明有關申請／要求在本署的檔案號碼。

4. 查詢

生物多樣性及自然護理系

地址： 九龍長沙灣道二零三號

長沙灣政府合署六樓

電話： 2150 6918

傳真： 2314 2802

網址： <http://www.afcd.gov.hk/GMO>

電郵： biosafety@afcd.gov.hk

熱線電話： 1823

警告

1. 如控制基因改造生物的人知道有下列情況，
 - (a) 該核准基因改造生物在不符合紀錄冊列明核准該生物的任何條件的情況下向環境釋出；或
 - (b) 該生物向環境釋出時，既非核准基因改造生物，也非供人類使用的藥劑製品。而不向本署作書面通知，可處罰款港幣 50,000 及監禁半年。
2. 任何提供的資料須為事實。

Notes to Written Notice on Release or Maintenance of Released GMO

1. Notes to Submitting the Written Notice

- (a) The use of this Written Notice form is for the transitional period only. “transitional period” means the 6-month period beginning on the date on which this Ordinance comes into operation
- (b) Information should be written or typed in BLOCK LETTERS in English.
- (c) A notice should be made for only one GMO. If there is more than one GMO, you should use additional notice forms.

- (d) If additional space is needed, please continue on a separate sheet, which must be clearly labelled and included as appendices to the application form.
- (e) Unless otherwise indicated, please try to complete all sections of this form.
- (f) A notice should be submitted by mailing or in person to Biodiversity and Conservation Division, Agriculture, Fisheries and Conservation Department, 6/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon, Hong Kong .

2. Subsequent Procedures for the Notification

- (a) On receiving a notice, the Director of Agriculture, Fisheries and Conservation (the Director) may direct an authorized officer to enter, during reasonable hours, the place or premises in or on which the GMO was released to dispose of the GMO; or direct you to dispose of the GMO.
- (b) If you have informed the Director of the release or maintenance of a released GMO, you are not prohibited from knowingly maintaining the life of the GMO that is in a state of being released into the environment, during the period from the date of the notice to the date when the GMO is disposed of.
- (c) Besides informing the Director of the release or maintenance by written notice, you can also submit a GMO approval application in respect of the released GMO. You are not prohibited from knowingly maintaining the life of the GMO that is in a state of being released into the environment, during the period from the date of the application to the date when the decision on the application is entered in the register.

3. Personal Information Collection Statement

- (a) The Information provided by you will be used for the processing of the released GMO.
- (b) The provision of personal data is voluntary. If you do not provide sufficient information, this department may not be able to process your notification.
- (c) The said information of any part thereof may be supplied by this department to other government departments for investigation or statistics purposes.
- (d) The Information provided may be supplied to the Expert groups to seek advice on the processing of the released GMO
- (e) The information provided may be entered in the Register and uploaded to the Biosafety Clearing House for inspection by members of the public.
- (f) Subject to exemptions under the Personal Data (Privacy) Ordinance, you have a right of access and correction with respect to personal data.
- (g) Request for personal data access and correction should be addressed to Conservation Biodiversity Division of Agriculture, Fisheries and Conservation Department. Please also quote the reference number of the application/request in this department.

4. Enquiries

Biodiversity Conservation Division

Address: 6/F, Cheung Sha Wan Government Offices,
303 Cheung Sha Wan Road, Kowloon

Tel: 2150 6918

Fax: 2314 2802

Website: <http://www.afcd.gov.hk/GMO>

E-mail: biosafety@afcd.gov.hk

Hotline: 1823

WARNING

1. If a person who has control of a **GMO** knows that:
 - (a) an approved GMO has been released without complying with any condition for the approval of the GMO, as set out in the register; or
 - (b) a GMO, which is not approved or is not a pharmaceutical product for use by human beings, has been released into the environmentbut does not inform the Director of the release by written notice, will be subjected to a maximum penalty of a fine of HK\$50,000 and imprisonment for 6 months.
2. Any information provided for the notification should be true and correct.

In accordance with Schedule 3 of the Bill

USDA/APHIS Petition 96-051-01P for the Determination of Nonregulated Status for Transgenic Sunset' Papaya Lines 55-1 and 63-1

Environmental Assessment and Finding of No Significant Impact

September 1996

The Animal and Plant Health Inspection Service (APHIS) of the U. S. Department of Agriculture has prepared an environmental assessment before issuing a determination of nonregulated status for two genetically engineered (transgenic) papaya lines designated as Sunset' papaya lines 55-1 and 63-1. APHIS received a petition from Cornell University and the University of Hawaii regarding the status of these papaya lines as regulated articles under APHIS regulations at 7 CFR Part 340. APHIS has conducted an extensive review of the petition, supporting documentation, and other relevant scientific information. Based upon the analysis documented in this environmental assessment, APHIS has reached a finding of no significant impact on the environment from its determination that these lines of virus-resistant papaya shall no longer be regulated articles.

John H. Payne, Ph.D. Acting Director Biotechnology, Biologics, and Environmental Protection Animal and Plant Health Inspection Service U.S. Department of Agriculture Date:

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I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has prepared an Environmental Assessment (EA) prior to making a determination on the regulated status of two genetically engineered, virus-resistant lines of papaya (*Carica papaya*) designated as Sunset' papaya lines 55-1 and 63-1. The developers of these papaya lines, the University of Hawaii and Cornell University, believe that these papayas do not present a plant pest risk, and therefore petitioned APHIS to make a the determination that these

lines shall no longer be considered as regulated articles under APHIS regulations (7 CFR Part 340). Under these APHIS regulations, the importation, interstate movements and field tests of these papaya lines have required permits issued by APHIS.

The transgenic Sunset' papaya lines 55-1 and 63-1 were developed to resist infection by papaya ringspot virus (PRV), a major limiting factor in papaya production. Sunset' papaya lines 55-1 and 63-1 were developed by using genetic engineering (recombinant DNA) techniques to introduce the PRV coat protein (CP) gene into papaya plants of the cultivar Sunset.' Incorporation of the PRV CP gene into the papaya plant does not cause plant disease, but rather enables the papaya plants to resist infection by PRV. The PRV CP gene was introduced into the papaya as part of a genetic construct which also included two plant-expressible, genetic marker genes, nptII and uidA (gus) (Line 55-1 contains both nptII and gus, whereas line 63-1 contains nptII). These marker genes enable researchers to easily select those plant tissues that have been successfully transformed with the genetic construct. The construct was introduced into Sunset' papaya via a particle bombardment technique.

From 1991 through 1996, APHIS has authorized the University of Hawaii to conduct field tests with these lines of transgenic papaya. Prior to the authorizations for field testing, APHIS prepared an EA that addressed issues pertinent to any plant pest risks associated with a field test conducted under physical and reproductive confinement. The previous EA did not address several issues relevant to the unconfined growth of these transgenic papaya lines. In the course of considering the current petition, APHIS has considered potential impacts of the unconfined growth of the transgenic Sunset' papaya lines 55-1 and 63-1. APHIS has reached the following conclusions:

1. The transgenic Sunset' papaya lines 55-1 and 63-1 exhibit no plant pathogenic properties. Although plant pathogenic organisms were used in the development of these papaya lines, these papaya plants are not infected with PRV, nor can they incite disease in other plants.
2. Cultivation of the transgenic papaya lines 55-1 and 63-1 will not increase the likelihood of the emergence of new plant viruses. In assessing the potential for new plant viruses to appear, APHIS has carefully considered the biology and epidemiology of the plant viruses that infect papaya, and has determined that the unconfined cultivation of these transgenic papaya lines would be no different than nontransgenic, PRV-infected papayas.
3. The transgenic Sunset' papaya lines 55-1 and 63-1 are no more likely to become weeds than any other types of papaya. Papaya is not considered to be a weed pest, and there is no reason to believe that the ability of these papayas to resist infection by PRV will lead to them becoming weed pests.
4. The transgenic Sunset' papaya lines 55-1 and 63-1 will not increase the weediness potential of any other cultivated plant or native wild species with which they can interbreed. Transfer of the PRV-resistance trait from lines 55-1 or 63-1 to another Carica species, although unlikely, would not result in the resulting offspring which are weed pests.
5. The transgenic Sunset' papaya lines 55-1 and 63-1 will not harm threatened or endangered species or other organisms, such as bees, which are beneficial to agriculture.
6. The transgenic Sunset' papaya lines 55-1 and 63-1 will not cause damage to processed agricultural commodities.

APHIS has also concluded that any new papaya varieties bred from transgenic papaya lines 55-1 and 63-1 should not exhibit new plant pest properties, i.e., properties substantially different from any observed for the papaya lines already field tested, or those observed for papayas in traditional breeding programs.

Therefore, after review of the available evidence, APHIS concludes that the transgenic Sunset' papaya lines 55-1 and 63-1 will be just as safe to grow as papaya cultivars developed through traditional breeding practices. The cultivation of these transgenic papaya lines should present environmental impacts that are no different from those - associated with cultivating papaya varieties that are not subject to regulation under 7 CFR Part 340 before they enter agriculture. Based upon the analysis documented in this EA, APHIS has reached a finding of no significant impact on the environment from its determination that the transgenic Sunset' papaya lines 55-1 and 63-1 will no longer be considered regulated articles under the regulations in 7 CFR Part 340.

II. BACKGROUND

Development of Papaya Lines 55-1 and 63-1. The transgenic Sunset' papaya lines 55-1 and 63-1 have been developed to resist infection by papaya ringspot virus (PRV). The gene conferring viral resistance was introduced via recombinant DNA (genetic - engineering) techniques rather than conventional breeding techniques. The recombinant techniques enabled the developer to introduce a viral coat protein gene from a mild strain of PRV into the genome of Sunset' papaya. Incorporation of the PRV coat protein gene into papaya to yield the transgenic Sunset' papaya lines 55-1 and 63-1 does not cause plant disease, but rather enables the plants to resist infection by PRV. The PRV coat protein gene was introduced into the papaya as part of a genetic construct that also included the nptII and uidA (gus) genes which serve as genetic marker genes. These marker genes are widely used in the development of transgenic plants to enable researchers to easily select those plant tissues that have been successfully transformed with a genetic construct that includes the marker(s) and other genes of interest (A more detailed description of the genetic constructs and other technical aspects of APHIS' review can be found in the appended determination document that is hereby incorporated by reference). The genetic construct containing the PRV coat protein gene and the marker genes was introduced into Sunset' papaya tissue via a particle bombardment technique.

The transgenic Sunset' papaya lines 55-1 and 63-1 have been evaluated extensively in laboratory, greenhouse, and field experiments to confirm that they exhibit the desired agronomic characteristics and that they do not present a plant pest risk. Researchers have evaluated these lines in field tests conducted continuously from 1991 to the present 1996 field tests. These field tests have been conducted under APHIS permits which stipulate confinement of the transgenic plant material in controlled agricultural settings.

APHIS Regulatory Authority. APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Federal Plant Pest Act (7 U.S.C. 150aa-150jj), as amended, and the Plant Quarantine Act (7 U.S.C. 151-164a, 166-167), as amended, regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to - believe that it is a plant pest. The transgenic papaya plants described in this petition have been considered regulated articles because DNA sequences incorporated into these lines were derived from plant pests, specifically bacterial and viral plant pathogens (see appended determination document for additional details).

An organism is not subject to the regulatory requirements of 7 Part 340 when it is demonstrated not to present a plant pest risk. Section 340.6 of the regulations, entitled "Petition Process for Determination of Nonregulated Status," provides that a person may petition the agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If the agency determines that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism, APHIS can grant the petition in whole or in part. As a consequence of determining nonregulated status, APHIS permits are no longer required for field testing, importation, or interstate movement of that article or its progeny.

III. PURPOSE AND NEED

APHIS has prepared this EA prior to making a determination on the status of Sunset' papaya lines 55-1 and 63-1 as regulated articles under APHIS regulations. The developer of these papaya lines, the University of Hawaii and Cornell University, submitted a petition to USDA/APHIS requesting that APHIS make a determination that Sunset' papaya lines 55-1 and 63-1 shall no longer be considered regulated articles under CFR Part 340. This EA was prepared in compliance with: (1) the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.), (2) Regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372; 60 FR 6000-6005, February 1, 1995).

IV. ALTERNATIVES

No Action. Under the Federal "no action" alternative, APHIS would not come to a determination that papaya is no longer a regulated article under the regulations at 7 CFR Part 340. Permits from APHIS would still be required for introductions of the transgenic Sunset' papaya lines 55-1 and 63-1. APHIS might choose this alternative if there were insufficient evidence to predict the lack of plant pest risk from unconfined cultivation of papaya.

Determination That Papaya Lines 55-1 and 63-1 Are No Longer Regulated Articles. Under the Federal action to render a determination that Sunset' papaya lines 55-1 and 63-1 are no longer regulated articles under the regulations at 7 CFR Part 340, these papaya lines would be subject to the same regulatory oversight as papaya cultivars that result from traditional breeding practices. As such, permits from APHIS would no longer be required for introductions of Sunset' papaya lines 55-1 and 63-1 or their progeny.

V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS

This EA addresses potential environmental impacts from a determination that transgenic papaya lines 55-1 and 63-1 would no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. Previous EAs prepared by APHIS in conjunction with the issuance of permits for field tests of have addressed various attributes of these papaya lines. This EA discusses the genetic modification of these papaya lines, the resultant phenotype, and the potential environmental impacts that might be associated with the unconfined cultivation of Sunset' papaya lines 55-1 and 63-1.

Additional technical information is included in the determination document appended to this EA, and incorporated by reference. This includes detailed discussions of the biology of papayas, the genetic components used in the development of papaya lines 55-1 and 63-1, and the potential plant pest risks associated with a determination that these papaya lines will no longer be regulated articles under 7

CFR Part 340.

Potential for the Introduced DNA Sequences to Cause Disease in the Transgenic Lines 55-1 and 63-1. Although some DNA sequences used in the transformation process were derived from bacterial and viral plant pathogens, these genes do not cause disease in the papaya plant. Once inserted into the genome of the papaya plant, the introduced DNA sequences are maintained and transmitted in the same manner as any other DNA sequences within the plant. Papaya plants pass their genes to their progeny by sexual reproduction that involves self pollination, or pollination of other papaya plants or sexually compatible relatives.

The Sunset' papaya lines 55-1 and 63-1 were produced using a microprojectile bombardment protocol to transform papaya with genes designed to confer resistance to PRV. The PRV CP gene that confers this resistance was derived from a strain of the virus originally isolated from infected papayas growing in Hawaii. Expression of this PRV CP gene in the papaya does not cause plant disease, but rather confers resistance to infection by PRV.

The introduced DNA that encodes the CP gene also has accompanying DNA regulatory sequences that modulate the expression of the CP gene in the transgenic lines. The DNA regulatory sequences were derived from plant pathogenic organisms: the bacterium *A. tumefaciens*, cucumber mosaic virus (CMV), and cauliflower mosaic virus (CaMV). Although these regulatory sequences were derived from plant pathogens, the regulatory sequences cannot cause plant disease by themselves or with the genes that they regulate. During characterization of the performance of the transgenic Sunset' papaya lines 55-1 and 63-1 in laboratory, greenhouse, and field experiments, the plants exhibited the typical agronomic characteristics of the parent papaya cultivar, with the addition of resistance to PRV infection.

Potential for the Appearance of New Plant Viruses. As mentioned above, papaya was developed by engineering the viral coat protein gene of PRV into the Sunset' papaya cultivar, a plant which is frequently infected by PRV. As part of its analysis, APHIS evaluated whether the expression of this viral gene in these papayas might present some unusual circumstances that could lead to the appearance of new plant viruses.

In the course of the infection of a plant cell by more than a single type of virus, it is possible for some of the constituents of the viruses to become mismatched. Such occurrences can lead to recombination of the nucleic acid genome or a mixture of the protein subunits (called transcapsidation), which comprise the coat of the virus particle. It is theoretically possible for new plant viruses to arise in the papaya through the recombination or transencapsidation, and APHIS considered this issue carefully in making its determination. A technical discussion of this issue is found contained in the determination document appended to this EA. After careful consideration of the physical and biological properties of PRV, APHIS concludes that it is unlikely that new viruses will arise as a consequence of the widespread cultivation lines 55-1 and 63-1, because no other virus infects papayas in the United States.

Potential Increased Weediness of Papaya Lines 55-1 and 63-1 Relative to Traditionally Bred Papaya. APHIS evaluated whether the papaya itself is likely to present a plant pest risk as a weed pest. The parent plant in this petition, Sunset' papaya, is an agricultural crop plant that exhibits no appreciable weedy characteristics. None of the standard texts and lists of weeds indicate that papaya is regarded as a weed (Holm et al., 1979; Muenscher, 1980; Reed, 1970; Weed Science Society of America, 1992).

The relevant introduced trait, resistance to infection by PRV, is unlikely to make

the papaya into a weed. Before PRV infection became a commercial limitation for papaya production, nonengineered Sunset' papaya cultivars were not considered as weeds. Thus, there is no indication that resistance to PRV will result in papaya becoming a weed pest (see the appended determination document).

No other attributes of the transgenic papaya lines 55-1 and 63-1 suggest that they are any more "weedy" than papaya cultivars that are the result of traditional breeding. The transgenic Sunset' papaya lines 55-1 and 63-1 have retained the agronomic characteristics of the parental Sunset' papaya.

Potential Impacts on the Free-Living Relatives of Papaya Arising From Pollination by Sunset' Papaya Lines 55-1 and 63-1. APHIS evaluated the potential impacts that papaya lines 55-1 and 63-1 might have on the free-living, sexually compatible relatives of papaya. *C. papaya* is usually described as sexually incompatible with other member of the genus. Initial steps have been taken to develop methods for somatic hybridization of *C. papaya* with *C. stipulata* (Litz and Conover, 1979; Litz and Conover, 1980) and with *C. pubescens* (Jordan et al., 1986), but no hybrid plants have been regenerated to date. No *Carica* species is considered a weed, and there is no evidence in the scientific literature to suggest that susceptibility to PRV is the factor that prevents these plants from being weed pests. Therefore, it seems likely that even if the PRV-resistance trait could be transferred from line 55-1 or 63-1 to another *Carica* species, the resultant offspring would not be weed pests.

Potential Impacts on Nontarget Organisms, Including Beneficial Organisms Such as Bees and Earthworms. APHIS considered the potential impact that papaya lines 55-1 and 63-1 might exert either directly or indirectly on organisms that are recognized as beneficial to agriculture. APHIS concludes that there is no reason to believe that the unconfined growth of papaya will pose any deleterious effects or significant impacts on nontarget organisms, including beneficial organisms. The coat protein expressed in papaya is not known to have any toxic properties. In fact, this viral coat protein is routinely ingested by virtually all animals, including humans, when papaya is - consumed. Naturally occurring infections of susceptible papaya varieties result in concentrations of coat proteins far higher than those that occur in the tissues of the transgenic papaya lines 55-1 and 63-1 (see the determination document).

APHIS believes that the transgenic papaya lines will have no deleterious effects on - organisms recognized as beneficial to agriculture (e.g., earthworms, honeybees). In addition, there is no reason to believe that the presence of these transgenic papaya lines would have any adverse effect on other organisms, including any species recognized as threatened or endangered in the United States.

Potential Impact on Processed Agricultural Commodities. Consistent with its statutory authority which defines plant pests as those organisms which cause direct or indirect damage to plants and plant products, APHIS evaluated whether papaya lines 55-1 and 63-1 might indirectly harm plant products such as some agricultural commodities. Analysis of the components and processing characteristics of Sunset' papaya lines 55-1 and 63-1 lines reveal no differences in any component that could have an indirect plant pest effect on any processed plant commodity.

VI. CONCLUSIONS

APHIS has evaluated information from the scientific literature as well as data submitted by Cornell University and the University of Hawaii that characterize the papaya lines 55-1 and 63-1. After careful analysis, APHIS has identified no significant impact to the environment from issuance of a determination that papaya lines 55-1 and 63-1 would no longer be regulated articles under APHIS regulations

at 7 CFR Part 340.

APHIS has considered the foreseeable consequences of removing the transgenic Sunset' papaya lines 55-1 and 63-1 from its regulation and reached the following conclusions:

1. The transgenic Sunset' papaya lines 55-1 and 63-1 exhibit no plant pathogenic properties. Although plant pathogenic organisms were used in the development of these papaya lines, these papaya plants are not infected with PRV, nor can they incite disease in other plants.
2. Cultivation of the transgenic papaya lines 55-1 and 63-1 will not increase the likelihood of the emergence of new plant viruses. In assessing the potential for new plant viruses to appear, APHIS has carefully considered the biology and epidemiology of the plant viruses that infect papaya, and has determined that the unconfined cultivation of these transgenic papaya lines would be no different than nontransgenic, PRV-infected papayas.
3. The transgenic Sunset' papaya lines 55-1 and 63-1 are no more likely to become weeds than any other types of papaya. Papaya is not considered to be a weed pest, and there is no reason to believe that the ability of these papayas to resist infection by PRV will lead to them becoming weed pests.
4. The transgenic Sunset' papaya lines 55-1 and 63-1 will not increase the weediness potential of any other cultivated plant or native wild species with which they can interbreed. Because no *Carica* species is considered a weed, transfer of the PRV-resistance trait to any other *Carica* species, although unlikely, would not result in the resulting offspring becoming a weed.
5. The transgenic papaya lines 55-1 and 63-1 will not harm threatened or endangered species or other organisms, such as bees, which are beneficial to agriculture.
6. The transgenic Sunset' papaya lines 55-1 and 63-1 will not cause damage to processed agricultural commodities.

APHIS has also concluded that any new papaya varieties bred from transgenic papaya lines 55-1 and 63-1 should not exhibit new plant pest properties, i.e., properties substantially different from those observed for the papaya lines already field tested, or those observed for papayas in traditional breeding programs.

Therefore, after review of the available evidence, APHIS concludes that the transgenic Sunset' papaya lines 55-1 and 63-1 will be just as safe to grow as papaya cultivars developed through traditional breeding practices. The cultivation of these transgenic papaya lines should present environmental impacts that are no different from the impacts associated with other papaya varieties that are not subject to regulation under 7 CFR Part 340 before they enter agriculture. Based upon the analysis documented in this EA, APHIS has reached a finding of no significant impact on the environment from its determination that the transgenic Sunset' papaya lines 55-1 and 63-1 will no longer be considered regulated articles under the regulations in 7 CFR Part 340.

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