

## 《基因改造生物(管制釋出)條例草案》委員會

### 因應 2010 年 1 月 14 日會議席上所作討論 而須採取的跟進行動一覽表

文件旨在回應《基因改造生物(管制釋出)條例草案》委員會於2010年1月14日會議席上所討論的議題。有關議題刊列於條例草案委員會秘書處於2010年1月15日來信的附錄I內，並轉載如下：

- (1) 列出環境局局長在根據第42條批予豁免時一般會考慮的因素。
- (2) 說明哪些條例明文規定若檢控失敗可申索補償，並考慮把擬議第37(4)條至第37(6)條合併為新條文，以訂明在指明的情況下可申索補償。
- (3) 考慮是否需要賦權署長就根據擬議第50(3)條在過渡期內應如何育養已釋出的基因改造生物附加條件。
- (4) 若當局的政策意向是指明作出決定的官員的職級，檢討第51(c)條中"an"("任何一名")這個用語的中文譯法。
- (5) 舉例說明應如何在指定表格上填寫附表1至附表6所指的各項所需資料(以木瓜為例)。
- (6) 在局長於條例草案恢復二讀辯論時發表的演辭中，述明政府當局至今進行的研究已確定木瓜是唯一在香港種植的基因改造生物，並在演辭中述明當局現正考慮豁免的基因改造生物(包括木瓜)的種類。
- (7) 提供整套委員會審議階段修正案擬稿(標明修訂事項文本)。

#### 有標識的委員會審議階段修訂

2. 整份有標識的委員會審議階段修訂條文的中文版已經在附件A列出。

## **條例草案第 42 條**

3. 我們已經考慮了委員們的建議，並已經在**附件A**列出擬議的經過修訂的第42條。

## **修訂條例草案第37條以包括補償條文**

4. 我們已經考慮了委員們的建議，並已經在**附件A**列出擬議的經過修訂的第37條及新加的條文第38A條。該修訂將容許在主管當局執行法例權力時被沒收東西的物主，在訂明的情況下，不論有否受到檢控都可就該東西向政府申請賠償。

## **條例草案第50(3)條 Clause 50 (3) - 賦權署長對在過渡期間釋出的基因改造生物附加如何育養的條件**

5. 我們已經考慮了委員們的建議，我們認為在過渡期間，應一般性地容許育養已釋出的基因改造生物。因此只會在過渡期間屆滿後才就育養這些基因改造生物附加條件。

## **條例草案第51條的中文演繹**

6. 我們已經考慮了委員們的建議，並已經在**附件B**列出擬議的經過修訂的第51條。

## **指明表格的樣本**

7. 以基因改造木瓜為例子、完成了的指明表格樣本刊於**附件C**內。

## **漁農自然護理署已完成的關於基因改造生物在香港的普遍程度的研究**

8. 我們確定環境局局長在條例草案恢復二讀辯論時發表的演辭中，會列出政府直到目前為止所完成的研究及考慮豁免哪一類的基因改造生物。

環境保護署

漁農自然護理署

2010 年1月

## 2. 釋義

...

“署長”(Director)指 —

- (a) 漁農自然護理署署長；
- (b) 漁農自然護理署副署長；或
- (c) 任何一名漁農自然護理署任何一名助理署長；

...

### 3. “向環境釋出”及“圍封使用”的涵義

- (1) 就本條例而言，如符合下列所有說明，即屬向環境釋出基因改造生物 —
  - (a) 該生物並非在圍封使用中；及
  - (b) 該生物暴露於可讓它生長或繁殖的狀況。
- (2) 就本條例而言，如符合下列所有說明，基因改造生物即屬在圍封使用中 —
  - (a) 該生物屬在某一設施、裝置或其他實體屏障內進行的作業所涉及該生物者；及
  - (b) 該生物受特定措施控制，而該等措施有效地限制該生物與環境的接觸，以及該生物對環境的影響。

## 6. 將若干基因改造生物的釋出通知署長

(1) 如控制基因改造生物的人知道有下列情況，本條即適用 —

(a) 如該生物是核准基因改造生物 —

(i) 該生物已向環境釋出；及

(ii) 有不符合紀錄冊列明核准該生物的任何條件的情況；

(b) 如該生物並非核准基因改造生物，但根據第 42 條獲豁免而不受第 5 條的規限 —

(i) 該生物已向環境釋出；及

(ii) 有不符合紀錄冊列明豁免該生物的任何條件的情況；或

(b) 如該生物並非核准基因改造生物，並且沒有根據第 42 條獲豁免而不受第 5 條的規限 —

(i) 該生物已向環境釋出；及

(ii) 該生物並非供人類使用的藥劑製品。

(2) 上述人士須在知道有關釋出後，在切實可行範圍內，盡快以書面通知將該項釋出告知署長。

(2A) 如有下列情況，第(2)款並不規定任何人將有關釋出告知署長 —

(a) 另一人亦控制該基因改造生物；及

(b) 該另一人已遵守該款，將該項釋出告知署長。

(3) 任何人違反第(2)款，即屬犯罪，可處第 5 級罰款及監禁 6 個月。

(4) 第(2)款所指的通知須載有附表 1 第 1 及 2 部列明的資料。

(5) 署長接獲第(2)款所指的通知後，可 —

(a) 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

(b) 指示上述人士處置該生物。

## 15. 署長對不披露要求的決定

(1) 署長須於接獲就基因改造生物核准申請或更改要求提出的不披露要求後 30 天內 —

(a) 決定 —

- (i) 全部建議機密資料均不予記入紀錄冊；
- (ii) 僅將部分建議機密資料記入紀錄冊；或
- (iii) 將全部建議機密資料記入紀錄冊；及

(b) 給予申請人關於該項決定及其原因的書面通知。

(2) 署長如信納有以下情況不披露若干建議機密資料，不會違反公眾利益，可決定不將若干建議機密該等資料記入紀錄冊 —

(a) 記入該等資料，會對申請人的利益有不利影響；及

(b) 不記入該等資料，不會違反公眾利益。

## 20. 撤回基因改造生物核准申請或更改要求

(1) 提出基因改造生物核准申請或更改要求的申請人，可於署長對申請或要求作出決定前，隨時以書面要求撤回該項申請或要求。

(2) 如基因改造生物核准申請或更改要求根據第(1)款被撤回，署長須——

~~(a) 停止處理該項申請或要求；及~~

~~(b) 將載有關於該項申請或要求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。~~

## 21. 撤回已提供的資料或文件

(1) 提出基因改造生物核准申請或更改要求的申請人，可於署長對申請或要求作出決定前，隨時以書面撤回就該項申請或要求而提供的任何資料或文件。

(2) 如就基因改造生物核准申請或更改要求而提供的任何資料或文件，根據第(1)款被撤回，署長須——

~~(a) 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~~

~~(b) (如被撤回的資料屬機密資料)將載有該等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。~~

## 第 3A 部

### 輸入及輸出基因改造生物的文件規定

#### 24A.本部的適用範圍

本部不適用於屬供人類使用的藥劑製品的基因改造生物，亦不就該類基因改造生物而適用。

#### 24B.輸入及輸出基因改造生物所須的文件

(1) 符合以下說明的基因改造生物在被輸入或輸出時，須附同訂明文件 —

- (a) 擬作為食物或飼料而直接食用，或作加工；
- (b) 擬作圍封使用；或
- (c) 擬向環境釋出。

(2) 如有下列情況，第(1)款不規定不適用於屬該款(a)或(b)段所指的基因改造生物須附同訂明文件 —

- (a) 該等基因改造生物連同其他活生物體作為同一批次物品而輸入或輸出；
- (b) 該等基因改造生物混入該等其他活生物體中，並非出於故意；及
- (c) 該等基因改造生物的數量在該批次的活生物體的總量中所佔的百分比，不超逾訂明百分比。

(3) 如第(1)款遭違反，輸入或輸出有關基因改造生物的人即屬犯罪，一經定罪，可處第 3 級罰款。

(4) 在任何就第(1)款所訂罪行而進行的法律程序中，被檢控的人如確立他並不知道(而即使作出合理努力亦不會能夠知道)屬第(1)(a)、(b)或(c)款所指的基因改造生物被輸入或輸出，即可以此作為免責辯護。

(5) 在第(2)(c)款中就第(2)(c)款而言 —

“訂明百分比”(prescribed percentage)就屬第(1)(a)或(b)款所指的基因改造生物而言，指 —

- (a) 由局長為施行該款而就屬第(1)(a)、(b)或(c)款所指的以根據第 46 條訂立的規例就該等基因改造生物訂明的百分比；或
- (b) (如局長無訂明百分比)百分之零。



## 25. 署長須設立和備存紀錄冊

- (1) 署長須為施行本條例而設立和備存紀錄冊。
- (2) 署長可採用他認為適當的形式保存紀錄冊，~~包括非文件的形式。~~
- (3) 紀錄冊須 ~~於正常辦公時間內，於漁農自然護理署的辦事處供公眾免費查閱。~~
  - (a) 透過互聯網免費查閱；或
  - (b) 於正常辦公時間內，於漁農自然護理署的辦事處免費查閱。

## 26. 紀錄冊的內容

- (1) 紀錄冊須載有 —
- (a) (除第(3)款另有規定外)下列各項 —
    - (i) 每項基因改造生物核准申請，及署長就該項申請接獲的任何資料；  
及
    - (ii) 每項更改要求，及署長就該項要求接獲的任何資料；
  - (b) 署長根據第 10(1)(a)、11(5)(a)或 12(1)條作出的每項決定；
  - (c) 行政上訴委員會就針對署長根據第 10(1)(a)、11(5)(a)或 12(1)條作出的決定的上訴而作出的每項決定；及
  - (d) 局長根據第 42 條批予的每項豁免。
- (2) 紀錄冊亦可載有署長認為適當的、關於施行本條例或實施《議定書》的任何其他資料。
- (3) 紀錄冊不得載有 —
- (a) 關於基因改造生物核准申請或更改要求的任何機密資料；或
  - (b) 在按照第 13 條記入紀錄冊前被撤回的基因改造生物核准申請或更改要求，或就該等申請或要求而提交的任何資料。

## 27. 委任獲授權人員

署長可為施行本條例，以書面委任任何職級不低於二級農林督察的公職人員~~或任何類別的公職人員~~擔任獲授權人員。

## 28. 搜查船隻、將人扣留等的權力

(1) 如獲授權人員有理由合理地懷疑已有、正有或即將有第 5、7 或 23 條所訂的罪行在任何船隻、車輛、鐵路列車或飛機(軍用船艦、軍用車輛及軍用飛機除外)之上發生，他可截停、登上和搜查該船隻、車輛、鐵路列車或飛機。

(2) 如獲授權人員有理由合理地懷疑某人已犯、正犯或即將犯第 5、7 或 23 條所訂的罪行，該人員可在無手令的情況下 —

- (a) 截停和搜查該人，以及搜查該人的財產，以搜尋相當可能攸關(不論其本身屬攸關或連同任何其他東西而屬攸關)該罪行的調查的任何東西；及
- (b) 在該人員對有關的懷疑犯罪行為進行查訊期間，將該人扣留一段合理時期。

## 29. 視察地方或處所、複製文件等的權力以核實遵守本條例

(1) 如獲授權人員有理由合理地懷疑基因改造生物被置於任何地方或處所，該人員可為核實本條例是否獲遵守，而在無須給予通知的情況下 —

- (a) 在合理時段內，進入和視察該地方或處所；
- (b) 要求交出該人員有理由合理地懷疑相信是或載有基因改造生物的東西，並查看和檢驗該東西；及
- (c) 要求交出任何關乎遵守本條例的文件，或任何關乎該生物的性質或來源的文件，並查閱、審查和複製該等文件。

(2) 第(1)款並不賦權獲授權人員進入 —

- (a) 任何純粹用作或主要用作住宅用途的處所；或
- (b) 任何處所中純粹用作或主要用作住宅用途的部分。

### 30. 發出手令後進入和搜查地方或處所的權力

(1) 如裁判官因經宣誓作出的告發，而信納有合理理由懷疑在任何地方或處所有下列情況，他可發出手令授權獲授權人員進入和搜查該地方或處所 —

(a) 有人已在、正在或將在該地方或處所犯本條例所訂罪行；或

(b) 在該地方或處所內，有任何東西是或包含犯本條例所訂罪行的證據。

(2) 除非手令另有指明，否則手令一直有效，直至需要進入上述地方或處所要達到的目的經已達到為止。

(3) 獲手令授權進入和搜查任何地方或處所的獲授權人員 —

(a) 可使用所需武力，於手令指明的時間或(如手令沒有指明時間)隨時進入和搜查該地方或處所；及

(b) 可移走任何妨礙進入和搜查該地方或處所的東西。

(4) 獲授權人員如在上述地方或處所發現任何人，亦可在為使搜查得以進行而合理地需要扣留該人的期間內將該人扣留，但該扣留權力，只可在以下情況下行使：若不如此扣留該人，該人便可能會妨害搜查的目的。

(5) 根據手令而進入任何地方或處所的獲授權人員，可帶同所需的人進入。

(6) 本條不損害根據任何其他法律賦予警務人員的進入和搜查權力。

### 31. 檢取、移走和扣留東西的權力

(1) 獲授權人員可檢取、移走和扣留他 合理地懷疑覺得 是或包含犯本條例所訂罪行的證據的任何東西。

(2) 獲授權人員無須就他根據(或本意是根據)本條行使任何權力時真誠地作出或不作出的任何事情，而承擔民事法律責任。

## 32. 抽取樣本及進行測試的權力

- (1) 獲授權人員可為核實本條例是否獲遵守，或為取得犯本條例所訂罪行的證據，而 —
- (a) 取走任何他 合理地懷疑有理由相信 是或包含基因改造生物的東西的樣本；
  - (b) 要求任何控制該東西的人，提供該東西的樣本；及
  - (c) 拍攝該東西的任何照片。
- (2) 獲授權人員如根據第(1)款從某人處取走樣本，須就該樣本發出收據，但無須 —
- (a) 為該樣本付款；或
  - (b) 將該樣本交還該人。
- (3) 獲授權人員可安排就根據第(1)款抽取的樣本進行任何所需測試，以確定 —
- (a) 該樣本是否基因改造生物，或是否包含該生物；
  - (b) 如該樣本是或包含基因改造生物 —
    - (i) 該生物的識辨屬性；及
    - (ii) 該生物在該樣本內所佔的數量及所佔百分率。
- (4) 獲認可實驗所就根據第(1)款取走的樣本發出的驗析證明書，可在根據本條例進行的任何法律程序中提出作為證據，而除非相反證明成立，否則該證明書是它所述事實的證據。
- (5) 在本條中，“獲認可實驗所”(accredited laboratory)指根據由創新科技署署長代表特區政府管理的“香港實驗所認可計劃”認可的實驗所。



### 33. 要求證明身分的權力

(1) 如獲授權人員 合理地有理由 懷疑某人已犯、正犯或 即將犯 本條例第 5、7、23、24B 或 40 條 所訂罪行，該人員可在無手令的情況下截停該人，或如該人身處某船隻、車輛、鐵路列車或飛機(軍用船艦、軍用車輛及軍用飛機除外)，該人員可截停和登上該船隻、車輛、鐵路列車或飛機，以要求該人 —

(a) 述明其姓名及地址；及

(b) 出示其身分證明文件，以供查驗。

(2) 在本條中，“身分證明文件”(proof of identity)指《入境條例》(第 115 章)第 17B 條所指的身分證明文件。

### 33A. 要求交出關乎輸入及輸出的文件的權力

如獲授權人員合理地懷疑基因改造生物正被輸入或輸出，該人員可為核實第 24B 條是否獲遵守，而要求控制懷疑屬該基因改造生物的東西的人交出任何關乎該東西的輸入或輸出的文件，以供查閱。

### 34. 署長檢取後隨即出售或處置若干東西的權力

(1) 如第(2)款指明的任何東西根據第 31 條被檢取，署長可在檢取後，~~隨即出售該東西，或~~以任何~~其他~~方式將之~~(出售除外)~~處置該東西處置。

(2) 上述東西指 —

(a) 符合下列說明的任何活體動物 —

(i) 基於任何原因，由署長關禁該動物並非切實可行；或

(ii) 該動物如遭關禁，便相當可能會死亡或蒙受不必要的痛苦；

(b) 由署長將之保存並非切實可行(不論基於任何原因)的任何活體植物；及

(c) 符合以下說明的任何東西 —

(i) 基於任何原因，由署長將之保存並非切實可行；或

(ii) 屬易毀消的。

~~(3) 除第 35、36 及 37 條另有規定外，根據第(1)款出售任何東西的售賣得益，須撥入政府一般收入。~~

### 35. 發還和沒收就第 5、7 或 23 條所訂罪行而檢取的東西

(1) 如某人被裁定犯第 5、7 或 23 條所訂罪行，而任何在與該罪行有關連的情況下根據第 31 條檢取的東西，是或包含基因改造生物，則該東西~~或出售該東西的售賣得益~~，~~一~~須沒收歸政府所有。

(2) 如某人被裁定犯第 5、7 或 23 條所訂罪行，而任何在與該罪行有關連的情況下根據第 31 條檢取的東西，不是或不包含基因改造生物，則法庭或裁判官可命令將該東西~~或任何其售賣得益~~ —

(a) (如該東西從某人處檢取)發還該人，或發還該東西的擁有人；或

(b) 沒收歸政府所有。

(3) 如有人就任何根據第 31 條檢取的東西被控犯第 5、7 或 23 條所訂罪行，而在有關法律程序中，沒有被告人被裁定犯該罪行，則法庭或裁判官可命令將該東西~~或出售該東西的售賣得益~~ —

(a) (如該東西從某人處檢取)發還該人，或發還該東西的擁有人；或

(b) 沒收歸政府所有。

(4) 本條不適用於任何根據第 31 條檢取並已根據第 34 條處置的東西。

### 36. 發還和沒收就其他條文所訂罪行而檢取的東西

(1) 如有人就任何根據第 31 條檢取的東西被控犯本條例第 5、7 或 23 條以外的條文所訂罪行，則不論有否被告人在有關的法律程序中被裁定犯該罪行，法庭或裁判官可命令將該東西，~~或出售該東西的售賣得益~~ —

- (a) (如該東西從某人處檢取)發還該人，或發還該東西的擁有人；或
- (b) 沒收歸政府所有。

(2) 本條不適用於任何根據第 31 條檢取並已根據第 34 條處置的東西。

### 37. 沒有檢控罪行時發還和沒收被檢取的東西

(1) 如有東西根據第 31 條被檢取，但沒有就該東西根據本條例提出檢控，則獲授權人員可向法庭或裁判官提出申請，要求就該東西或出售該東西的售賣得益作出命令。

(2) 除第(3)款另有規定外，法庭或裁判官可應根據第(1)款提出的申請，命令將有關東西或出售該東西的售賣得益 —

(a) (如該東西從某人處檢取)發還該人，或發還該東西的擁有人；或

(b) 沒收歸政府所有。

(3) 法庭或裁判官如信納有關東西的擁有人身分不詳或不能尋獲，則須命令將該有關東西或出售該東西的售賣得益沒收歸政府所有。

**(4) 本條不適用於任何根據第 31 條檢取並已根據第 34 條處置的東西。**

~~(4) 如依據第(3)款的命令被沒收歸政府所有的東西，根據第 38(1)條被出售或處置，任何人如對該項出售或處置感到受屈，可在該東西被出售或處置後的 6 個月內，向法庭或裁判官投訴。~~

~~(5) 如有人根據第(4)款作出投訴，法庭或裁判官在信納投訴人具有有關東西的所有權的情況下，可命令向投訴人支付補償，補償款額為法庭或裁判官認為公平者。~~

### 38. 署長出售或處置以及作出指示處置被沒收東西的權力

(1) 署長可按他認為合適的方式，出售或以其他任何方式(出售除外)處置任何根據本部沒收歸政府所有的東西。

(2) ~~根據第(1)款出售任何東西的售賣得益，須撥入政府一般收入。~~

~~(3) 如 —~~

(a) 某人被裁定犯第 5、7 或 23 條所訂罪行；而

(b) 與該罪行有關連的東西，根據第 35(1)或(2)條被沒收歸政府所有，

署長可藉書面通知，指示該人以送返或銷毀方式，處置該東西。

(43) 除第 39(4)條另有規定外，根據第(32)款接獲指示的人，須於有關通知指明的限期內，自費遵行該項指示。

(54) 任何人違反第(43)款，即屬犯罪，可處第 6 級罰款。

### 38A. 為檢取作出補償等

- (1) 除第(2)款另有規定外，如有東西根據第 31 條被檢取，政府有法律責任補償該東西的擁有人，以彌補該人基於下列理由而蒙受的任何損失 —
- (a) 該東西被檢取；或
  - (b) 該東西在被檢取或扣留期間死亡、毀消、變壞、遭遺失或遭損壞。
- (2) 在下列情況下，有關擁有人無權就有關損失獲補償 —
- (a) 該擁有人已被裁定就有關東西犯本條例所訂的罪行；或
  - (b) 該東西按法庭或裁判官根據第 35、36 或 37 條作出的命令，被沒收歸政府所有(依據第 37(3)條而被沒收則除外)。
- (3) 在基於第(1)款所提述的理由而針對政府進行的索償法律程序中，可追討的補償的款額，是考慮個案中整體情況(包括下列人士的行為及相對過失程度)後屬公平及公正的款額 —
- (a) 被檢取的東西的擁有人；
  - (b) 在有關東西被檢取時掌管該東西的人；
  - (c) (a)及(b)段所指明的人士的代理人；及
  - (d) 獲授權人員、公職人員及其他相關的人。
- (4) 基於第(3)款所提述的理由的索償法律程序，須符合以下規定，否則不得進行 —
- (a) 如索償所關乎的東西，已在被檢取之後，按法院或裁判官命令交付其擁有人，或已由任何有權將之交付其擁有人的人交付該擁有人，該法律程序須在交付後的 6 個月內展開；
  - (b) 如有關東西在被檢取或扣留期間死亡、毀消、變壞、遭遺失或遭損壞，基於這項理由的索償法律程序須在以下限期內展開，兩個限期中以較早者為準 —
    - (i) 有關擁有人發現該項理由後的 6 個月；
    - (ii) 有關擁有人假使已盡合理努力則本可發現該項理由的日期後的 6 個月。
- (5) 本條所指的索償 —
- (a) 可在小額錢債審裁處提出，但申索數額以該審裁處的最高司法管轄權為限；或
  - (b) 可在區域法院提出，不論申索數額為何。



### 39. 上訴

(1) 任何基因改造生物核准申請或更改要求的申請人如因根據第 10(1)(a)、11(5)(a)、12(1)或 16(3)(a)條作出的決定，或因根據第 12(7)或38(3)條作出的指示，而感到受屈，可於接獲該項決定或指示的通知後 28 天內，向行政上訴委員會提出反對該項決定或指示的上訴。

(1A) 任何人如因根據第 38(3) 條作出的指示，而感到受屈，可於接獲該項指示的通知後 28 天內，向行政上訴委員會提出反對該項指示的上訴。

(2) 任何申請人根據第(1)款提出上訴後，須在行政上訴委員會對上訴作出決定之前，安排屬關乎該上訴標的之的基因改造生物，以有效地限制它與環境的接觸及對環境的影響的方式保存。

(3) 如上述基因改造生物已向環境釋出，則第(2)款不適用。

(4) 如第(1)或(1A)款所述提出上訴反對某項指示的申請人或人，不須在行政上訴委員會對上訴作出決定之前遵行該指示。

## 42. 局長批予豁免的權力

(1) 局長可藉在憲報刊登的公告，豁免任何人士、任何組別或類別的人，或任何基因改造生物，使該等人士或生物不受第 5、7 或 23 條的規限。

(2) 豁免可對一般情況，或為任何目的，或藉提述任何情況而具有效力，並可在附帶或不附帶條件下具有效力。

(3) 除非局長信納根據第(1)款批予豁免可能引致的生物安全不利影響，屬可以接受或可加以管理，否則局長不得批予該項豁免。

### 43. 專家小組

(1) 局長可須成立專家小組，小組由局長委任的下列成員組成。

(a) 屬公職人員的成員；及

(b) 不屬公職人員的來自不同界別(包括農業界、生物科技界、環境保護界、學術界及貿易界)的成員。

(1A) 專家小組成員由局長委任。

(2) 署長可將與施行本條例有關連的任何問題，包括處理個別基因改造生物核准申請、更改要求及不披露要求，以及批予豁免，轉介予專家小組或其個別組員，以汲取其意見。

## 46. 局長訂立規例的權力

(1) 局長可就下列所有或任何事宜訂立規例 —

(a) 就~~關乎輸入和輸出下列生物而屬第 24B(1)(a)、(b)或(c)條所指的下列基因改造生物在輸入及輸出時須提交附同~~的文件~~的規定，訂定條文~~ —

~~(i) 擬作為食物或飼料而直接食用的基因改造生物，或作加工的基因改造生物；~~

~~(ii) 擬作圍封使用的基因改造生物；或~~

~~(iii) 擬向環境釋出的基因改造生物；~~

(b) ~~就下列基因改造生物訂定第 24B(5)(a)條所提述的百分比~~ —

~~(i) 擬作為食物或飼料而直接食用的基因改造生物，或作加工的基因改造生物；或~~

~~(ii) 擬作圍封使用的基因改造生物；~~

~~(c)~~ 使《議定書》文書的任何部分能夠在經修改或不經修改的情況下，在香港具有法律效力；

~~(d)~~ 一般性地為更妥善施行本條例的目的，訂定條文。

(2) 根據第(1)款訂立的規例可 —

(a) 為不同情況作出不同規定，並可為某特定個案或某特定類別個案作出規定；

(b) 經訂明為只適用於指明的情況；及

(c) 包含因該規例的訂立而需要有或適宜有的附帶、補充、相應、過渡性或保留條文。

(3) 根據第(1)款訂立的規例可規定 —

(a) 任何人違反規例的條文，即屬犯罪；及

(b) 犯該罪行可處不超逾第 6 級的罰款及不超逾 6 個月的監禁。

50. 在過渡期內申請核准已釋出的基因改造生物或就該等生物作通報

~~(1) 如任何人知悉下列情況，本條即適用——~~

~~(a) 該人曾致使已釋出的基因改造生物如此釋出；~~

~~(b) 該人在生效日期之前，曾育養處於向環境釋出的狀態的已釋出的基因改造生物；或~~

~~(c) 該人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。~~

(21) 如任何人上述人士須於過渡期內明知而育養處於向環境釋出的狀態的已釋出的基因改造生物，該人須於過渡期屆滿前——

(a) 以書面通知，告知署長上述釋出或該人育養該生物；或

(b) 按照第 8 條，就已釋出的基因改造生物提交基因改造生物核准申請。

(2) 任何人違反第(1)款，即屬犯罪，可處第 1 級罰款。

(3) 署長在接獲第(21)(a)款所指的通知後，可——

(a) 指示獲授權人員在合理時段內，進入已釋出的基因改造生物被釋出或育養所在的地方或處所，以處置該生物；或

(b) 指示上述人士處置該已釋出的生物。

(4) 任何人如已根據第(21)(a)款告知署長已釋出的基因改造生物被釋出或育養一事，第 5 條並不禁止該人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。

(5) 任何人如已根據第(21)(b)款提交基因改造生物核准申請，第 5 條並不禁止該人在提交申請當日至對申請的決定根據第 18 條被記入紀錄冊當日的期間，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。

(6) 第(21)(a)款所指的通知須載有附表 6 列明的資料。

## 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。”。

## 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。”。

## 根據條例草案附表1

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

樣本

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

<b>1. 通報人資料 Information of the Person Making the Notification</b>		
(a) 通報人姓名 Name of the Person Making the Notification 陳大文	(c) 身分證/護照號碼 Identity Card/Passport Number A123456(7)	
(b) 通訊地址 Mailing Address 香港甲乙丙街甲乙丙大廈 123 室	(d) 電話 Telephone 1234 5678	(e) 傳真 Fax 2345 6789
	(f) 電郵 Email Address	chantaiman@xxx.com
<b>2. 該書面通知的性質 (請選擇其中一項) Nature of this Notification (Please choose either one)</b>		
<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 / exempted 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		
<b>3. 該釋出所不符合的條件 Condition(s) which was not Complied by the GMO's Release</b>		
不適用		
<b>4. 已釋出的基因改造生物的資料 Information of the Released GMO</b>		
(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name Sunset /夏威夷木瓜	(f) 基因改造生物在何種情況下釋出 Circumstances under which the GMO was Released 進食果實後釋出種子。之後種子發芽，長成的植物隨後被發現。	
(b) 基因改造生物的標識 GMO's Identity 轉型事項碼：55-1	(g) 基因改造生物的用途 Use of GMO 木瓜果實是買來作食用的	

(c) 基因改造生物的受體生物體的學名

Scientific Name of the GMO's Parental Organism

*Carica papaya*

(d) 釋出的日期 Date of Release

15.10.2008

(e) 釋出的時間 Time of Release

19:00

(h) 釋出的基因改造生物的數量或體積

Quantity or Volume of the GMO Released 5 顆種子

(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

從被釋出的種子而來的植物仍很年幼，未曾開花。

**5. 已釋出的基因改造生物的生物安全資料 Biosafety Information of the Released GMO**

(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

木瓜是外來品種，而且它是香港唯一的番木瓜科植物。

(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 Environment

利用連根拔起及焚燒可以容易地清除這些植物。

**6. 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: 陳大文

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

- (a) 所有資料必須以英文正楷填寫或以打字機打印。
- (b) 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。
- (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. 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 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](mailto: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 environment but 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.

## 根據條例草案附表2

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

樣本

### 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

<b>1. 申請人/機構資料 Information of Applicant/Organisation</b>	
(a) 申請人姓名/機構名稱 Name of Applicant/ Organisation 陳大文	(d) 聯絡人姓名 Contact Person's name 陳小文
(b) 申請人/機構通訊地址 Mailing Address of Applicant/ Organisation 香港甲乙丙街甲乙丙大廈 123 室	(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 香港甲乙丙街甲乙丙大廈 123 室
<b>2. 基因改造生物的資料 Information of the GMO</b>	
(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name Sunset /夏威夷木瓜	(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 將輸入及釋出 50 顆種子
(b) 基因改造生物的標識 GMO's Identity 轉型事項碼：55-1	(e) 該生物或其產品的預定用途 Intended Use of the GMO or Products from the GMO 種子將會在木瓜農場種植，其長成的植物會用作木瓜的商業生產。
(c) 擬釋出的日期 Intended Date of Release 15.01.2010	
<b>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)</b>	

<p>(a) 學名 Scientific Name(s)</p> <p><i>Carica papaya</i></p> <p>(b) 通用名稱 Common Name(s)</p> <p>木瓜</p> <p>(c) 收集點或獲取點 Point(s) of Collection or Acquisition</p> <p>美國夏威夷</p> <p>(d) 可能帶來生物安全不利影響的特徵</p> <p>Characteristics Related to Possible Adverse Biosafety Effect</p> <p>木瓜是外來品種，而且它是香港唯一的番木瓜科植物。</p>	<p>(e) 起源中心和遺傳多樣性中心 (如已知的話)</p> <p>Centre of Origin and Centre of Biodiversity (if Known)</p> <p>起源中心可能是在墨西哥中部及其周邊中美洲地區。未知遺傳多樣性中心。</p> <p>(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</p> <p>Description of Habitats Where that Recipient Organism and Parental Organism may Persist or Proliferate</p> <p>木瓜在所有熱帶及亞熱帶國家都有種植。木瓜生產最理想的環境是月降雨量最少 100 毫米，最低濕度 66%及溫度攝氏 21 至 33 度。</p>
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#### 4. 供體生物體的資料 Information of the Donor Organism

<p>(a) 學名 Scientific Name(s)</p> <p>木瓜輪點病毒 (PRSV)</p> <p>(b) 通用名稱 Common Name(s)</p> <p>木瓜輪點病毒 (PRSV)</p> <p>(c) 收集點或獲取點 Point(s) of Collection or Acquisition</p> <p>美國夏威夷</p>	<p>(d) 可能帶來生物安全不利影響的特徵</p> <p>Characteristics Related to Possible Adverse Biosafety Effect</p> <p>木瓜輪點病毒是依靠蚜蟲傳播的核糖核酸病毒。這種常見於木瓜的病毒能導致木瓜嚴重的病害及帶來嚴重的經濟損失。</p>
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#### 5. 基因改造的資料 Information of the Genetic Modification

<p>(a) 引入該生物的核酸或改變的說明 Description of the Nucleic Acid or the Modification Introduced</p> <p>引入的基因 <i>prsv-cp</i> 是從 PRSV HA 5-1 取得的。這是從夏威夷的一種嚴重型病毒 PRSV HA 發展出的溫和型病毒。這基因在和花椰菜花葉病毒外殼蛋白的頭 16 個胺基酸的基因序列聯接後才被引入基因載體。</p> <p>(b) 所使用的基因改造技術的說明 Description of the Technique(s) Used for the Genetic Modification</p> <p><i>prsv-cp</i> 基因是以基因載體的組成部分引入木瓜的，然後該基因載體以粒子轟擊法“打入”Sunset 木瓜。</p>
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(c) 由此而產生的該生物的特徵的說明 Description of the Resulting Characteristics of the GMO

引入的 *prsv-cp* 基因使該木瓜能夠抵抗木瓜輪點病毒。抵抗的機制並不清楚，有一個解釋是基因序列的表達干擾了病毒自我複製的第一步。引入的基因載體同時包含有兩個可在植物表達的標記基因 *nptII* and *uidA (gus)*。這兩個標記基因使研究人員能夠輕易地找出哪些植物組織已經成功地被上述基因載體轉型。

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**

該些種子應該存放於密封的塑料袋中作為有效的實體去限制種子與外界環境的接觸。產品的標籤或附帶文件應印有字句“該產品含有基因改造生物”或“該產品含有基因改造木瓜 55-1”。

如被意外釋出，利用連根拔起及焚燒可以容易地清除這些植物。

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	(d) 聯絡人姓名 Contact Person's Name	
美國夏威夷	John Lee	
(b) 輸出的日期 (如已知的話) Intended Date of Export (if known)	(e) 電話 Telephone	(f) 傳真 Fax
於收到漁農自然護理署署長的环境釋出核准通知後	(01) 123-4567	(01) 123-4567
(c) 輸出者/公司名稱及地址 Name of Exporter/Company & Address	(g) 電郵 Email Address	
美國康奈爾大學	johnlee@xxx.com	

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

<p>(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) 沒有規管</p>	<p>(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</p>
<p>(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) 沒有規管</p>	<p>該基因改造木瓜此前沒有被輸出往其它地方作環境釋出之用。</p>

**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 : 陳大文	公司印鑑 Company chop	日期 Date : 18.01.2010
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**此欄由辦理機關填寫 For Official Use only**

Date Received	Remarks/Additional Information
Officer	Follow Up Action

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## 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](http://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](mailto: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 extend 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](http://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](mailto: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.

## 根據條例草案附表4

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

樣本

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

<b>1. 輸出者/機構資料 Information of Exporter /Organisation</b>	
(a) 輸出者姓名/機構名稱 Name of Exporter / Organisation 陳大文	(d) 聯絡人姓名 Contact Person's name 陳小文
(b) 輸出者/機構通訊地址 Mailing Address of Exporter / Organisation 香港甲乙丙街甲乙丙大廈 123 室	(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 香港甲乙丙街甲乙丙大廈 123 室
<b>2. 輸入者/機構資料 Information of importer /Organisation</b>	
(a) 輸入者姓名/機構名稱 Name of Importer / Organisation 張叁博士	(e) 輸入者/機構通訊地址 Mailing Address of Importer / Organisation 中國北京北京道 123 號 中華人民共和國甲乙丙大學甲乙丙系
(b) 電話 Telephone +86-10-98765432. (c) 傳真 Fax +86-10-98765432	
(d) 電郵 Email Address zhang.wenguo@xxx.gov.cn	
<b>2. 基因改造生物的資料 Information of the GMO</b>	
(a) 基因改造生物的商業及通用名稱 GMO's Commercial and Common Name Sunset /夏威夷木瓜	(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 顆種子
(b) 基因改造生物的標識 GMO's Identity	



<p>轉型事項碼：55-1</p> <p>(c) 擬輸出的地方 Intended Place of Export</p> <p>中國廣東</p>	<p>(f) 該生物或其產品的預定用途</p> <p>Intended use of the GMO or products from the GMO</p> <p>種子將會在木瓜農場種植，其長成的植物會用作木瓜的商業生產。</p>
<p><b>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)</b></p>	
<p>(a) 學名 Scientific Name(s)</p> <p><i>Carica papaya</i></p> <p>(b) 通用名稱 Common Name(s)</p> <p>木瓜</p> <p>(c) 收集點或獲取點 Point(s) of Collection or Acquisition</p> <p>美國夏威夷</p> <p>(d) 可能帶來生物安全不利影響的特徵</p> <p>Characteristics Related to Possible Adverse Biosafety Effect</p> <p><i>Carica papaya</i> 是外來品種，而且它是香港唯一的番木瓜科植物。</p>	<p>(e) 起源中心和遺傳多樣性中心 (如已知)</p> <p>Centre of Origin and Centre of Biodiversity (if Known)</p> <p>起源中心可能是在墨西哥中部及其周邊中美洲地區。未知遺傳多樣性中心。</p> <p>(f) 可在其中存活或繁衍的各種生存環境的說明</p> <p>Description of Habitats Where the Organisms may Persist or Proliferate</p> <p>木瓜在所有熱帶及亞熱帶國家都有種植。木瓜生產最理想的環境是月降雨量最少 100 毫米，最低濕度 66%及溫度攝氏 21 至 33 度。</p>
<p><b>4. 供體生物體的資料 Information of the Donor Organism</b></p>	
<p>(a) 學名 Scientific Name(s)</p> <p>木瓜輪點病毒 (PRSV)</p> <p>(b) 通用名稱 Common Name(s)</p> <p>木瓜輪點病毒 (PRSV)</p> <p>(c) 收集點或獲取點 Point(s) of Collection or Acquisition</p> <p>美國夏威夷</p>	<p>(d) 可能帶來生物安全不利影響的特徵</p> <p>Characteristics Related to Possible Adverse Biosafety Effect</p> <p>木瓜輪點病毒是依靠蚜蟲傳播的核糖核酸病毒。這種常見於木瓜的病毒能導致木瓜嚴重的病害及帶來嚴重的經濟損失。</p>
<p><b>5. 基因改造的資料 Information of the Genetic Modification</b></p>	

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

引入的基因 prsv-cp 是從 PRSV HA 5-1 取得的。這是從夏威夷的一種嚴重型病毒 PRSV HA 發展出的溫和型病毒。這基因在和花椰菜花葉病毒外殼蛋白的頭 16 個胺基酸的基因序列聯接後才被引入基因載體。

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

prsv-cp 基因是以基因載體的組成部分引入木瓜的，然後該基因載體以粒子轟擊法“打入”Sunset 木瓜。

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

引入的 prsv-cp 基因使該木瓜能夠抵抗木瓜輪點病毒。抵抗的機制並不清楚，有一個解釋是基因序列的表達干擾了病毒自我複製的第一步。引入的基因載體同時包含有兩個可在植物表達的標記基因 nptII and uidA (gus)。這兩個標記基因使研究人員能夠輕易地找出哪些植物組織已經成功地被上述基因載體轉型。

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**

該些種子應該存放於密封的塑料袋中作為有效的實體去限制種子與外界環境的接觸。產品的標籤或附帶文件應印有字句“該產品含有基因改造生物”或“該產品含有基因改造木瓜 55-1”。

如被意外釋出，利用連根拔起及焚燒可以容易地清除這些植物。

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)

基因改造木瓜(55-1)已經在 2009 年 10 月 15 日獲漁農自然護理署署長核准向環境釋出，其附加條件是該基因改造生物不能在有機農場的 5 公里範圍內種植。

(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

該基因改造木瓜只會輸往香港作環境釋出之用。

#### 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

- 所有資料必須以英文正楷填寫或以打字機打印。
- 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。
- 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](http://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](mailto: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](http://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](mailto: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.

## 根據條例草案附表6

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

樣本

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

陳大文

(c) 身分證/護照號碼 Identity Card/Passport Number

A123456(7)

(b) 通訊地址 Mailing Address

香港甲乙丙街甲乙丙大廈 123 室

(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)

(a) 我曾釋出一基因改造生物 I released a GMO

(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

(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

(a) 基因改造生物的商業及通用名稱

GMO's Commercial and Common Name

夏威夷木瓜

(f) 基因改造生物在何種情況下釋出

Circumstances under which the GMO was Released

(b) 基因改造生物的標識 GMO's Identity

不知道

進食果實後釋出種子。之後種子發芽，長成的植物隨後被發現。

(c) 釋出及/或育養的地點 Location of Release and/or Maintenance

新界辛壬癸村第 123 號地段

(g) 基因改造生物的用途 Use of GMO

木瓜果實是買來作食用的

(d) 釋出及/或育養的日期 Date of Release and/or Maintenance

於 2009 年 10 月釋出

(h) 釋出的基因改造生物的數量或體積

Quantity or Volume of the GMO Released

幾顆種子

(e) 釋出及/或育養的時間 Time of Release and/or Maintenance

不知道

(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

沒有

**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



## 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](mailto: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](mailto: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.

## 根據條例草案附表3

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.

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

## TABLE OF CONTENTS

I. SUMMARY . . . . .	3
II. BACKGROUND. . . . .	5
III. PURPOSE AND NEED. . . . .	6
IV. ALTERNATIVES. . . . .	6
V. AFFECTED ENVIRONMENT AND POTENTIAL ENVIRONMENTAL IMPACTS. . . . .	7
VI. CONCLUSIONS . . . . .	10
VII. LITERATURE CITED. . . . .	11
VIII. PREPARERS AND REVIEWERS. . . . .	12
IX. AGENCY CONTACT. . . . .	12

## 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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