

LEGISLATIVE COUNCIL BRIEF

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

Genetically Modified Organisms (Control of Release) (Exemption) Notice

INTRODUCTION

Pursuant to section 46 of the Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607 (the Ordinance), the Secretary for the Environment (the Secretary) has made the Genetically Modified Organisms (Control of Release) (Exemption) Notice (the Exemption Notice) as at **Annex A**, in order to provide for certain exemption of genetically modified papaya and genetically modified organism (GMO) contained in a veterinary vaccine from the application of sections 5 and 7 of the Ordinance.

JUSTIFICATIONS

The Ordinance

2. The objectives of the Ordinance are to give effect to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, and to control the release into the environment, and the import and export, of GMOs. It aims to protect the local biological diversity from possible adverse impacts arising from the transboundary movement of GMOs intended for release into the environment, for example, commercial planting of crops or trial planting in the fields for scientific researches. The Ordinance commenced on 1 March 2011. Under the Ordinance, release of a GMO or import of a GMO that is intended for release into the environment requires prior approval from the Director of Agriculture, Fisheries and Conservation (the Director).

3. Section 46 of the Ordinance empowers the Secretary to exempt any GMO from the application of sections 5, 7 or 23 of the Ordinance, if the Secretary is satisfied that the possible adverse biosafety effect that may result from the exemption is acceptable or manageable. Section 5 provides that a person must not knowingly cause a GMO to be released into the environment or maintain the life of a GMO that is in a state of being released into the environment (subject to conditions specified in section 5(4)). Section 7 of the Ordinance provides that a person must not knowingly import a GMO that is intended for release into the environment (subject to conditions specified in section 7(2)(a) to (c)). If a person fails to comply with the control under sections 5 and 7, the person will be liable to a fine at level 6 and to imprisonment for one year.

4. An expert group was established under section 47 of the Ordinance (the Expert Group) to advise the Director on the administration of the Ordinance including exemption arrangements. The Expert Group comprises members from the academic, environmental protection, farming, biotechnology, and trading sectors.

Exemption of Genetically Modified Papaya

5. To keep track of the prevalence of GMOs in the territory, the Agriculture, Fisheries and Conservation Department (AFCD) has been conducting surveys on the presence of GMOs in various imported and locally grown crop produce since 2008. The survey results revealed that most of the crop produce examined were non-transgenic. On the other hand, it was found that papaya growing is very popular in the local environment, especially in the backyards of village houses, farmlands and orchards. The total number of papaya trees in the territory is estimated to be around 350,000, of which some 60-70% might be genetically modified¹. However, under the Ordinance, growing or maintenance of GM papaya in the field is considered as release of

¹ Papaya is vulnerable to infection by a plant pathogenic virus named the papaya ringspot virus (PRSV) which is one of the major limiting factors for commercial production of papaya in many parts of the world. As there is no known natural resistance of papaya to PRSV, unprotected plants would have about 95% chance to be infected. Therefore, efforts have been made by scientists to develop GM papaya with PRSV resistance through the use of modern biotechnology. In Hong Kong, papaya is also widely cultivated for its fruits. While a few organic farmers grow small quantities of organic papaya for the local market, many villagers and subsistence farmers also grow papaya trees in their backyards or in small plantings on farmlands for their own consumption and sell modest surpluses in local markets. Most of them grow papaya from seeds collected from fruits after consumption. The fruits may be bought from markets or collected from papaya trees they are growing. They are of unknown identity but might mostly be genetically modified.

GMO into the environment and requires prior approval from the Director. If anyone would like to grow a GM papaya, he is required under the Ordinance to submit an application for approval to the AFCD together with a risk assessment report and an application fee (\$14,250 at present). As mentioned in paragraph 3 above, if a person knowingly grows or maintains an unapproved or unexempted GMO, the person will be liable to a fine at level 6 and to imprisonment for one year.

6. Due to the prevalence of GM papaya growing in the local environment, AFCD conducted a risk assessment to assess the possible adverse effect of GM papaya on the conservation and sustainable use of biological diversity in the local environment. Based on the risk assessment, AFCD concluded that GM papaya is unlikely to pose any adverse biosafety effect on the biological diversity of the local environment, mainly because papaya is an exotic species, and that it does not have any close relatives in Hong Kong, making it unlikely for the release of GM papaya to the environment to affect the local biodiversity². In other words, the possible adverse biosafety effect that may result from granting exemption to GM papaya under the Ordinance is acceptable.

7. During the discussion of the Bills Committee on Genetically Modified Organisms (Control of Release) Bill (the Bills Committee), Members noted the Administration's intention to exempt GM papaya from the application of the Ordinance, having regard to the reasons set out above. Furthermore, during the resumption of the second reading debate of the Bill, the Secretary, in response to the Bills Committee's request, also reiterated the Government's intention to exempt GM papaya from the control of the Ordinance, particularly in the light of the prevalence of GM papaya in Hong Kong. During the debate, a Member recommended that GM papaya shall be exempted as soon as possible so as to avoid affecting members of the public who are growing papaya as a hobby and could not possibly distinguish whether it is a GM papaya.

² Due to species barrier, the inserted genes of GM papaya cannot pass on to local wild plants, making it impossible for the release of GM papaya to the environment to affect the local biological diversity. Besides, the risk of GM papaya establishing as weed is very low and not likely to be greater than that of conventional papaya. Papaya is not a problematic weed of natural ecosystems and the genetic modifications are unlikely to alter those aspects of the biology of papaya that may potentially affect its tweediness. In other words, the possible adverse biosafety effect that may result from the exemption is deemed acceptable.

8. The AFCD's risk assessment was endorsed by the Expert Group³. Taking into account the very low potential biosafety risk of GM papaya to the local biological diversity, the Secretary is satisfied that the possible adverse biosafety effect that may result from the exemption of GM papaya is acceptable. In this connection, the Secretary has decided to exempt all varieties of GM papaya from the application of section 5 of the Ordinance and to exempt two commercialized varieties of GM papaya (GM papaya with the unique identifier code of CUH-CP551-8 and GM papaya with the transformation event code of Huanong 1) from the application of section 7 of the Ordinance.

Exemption of GMO Contained in Live Recombinant Veterinary Vaccine

9. Veterinary vaccines containing one or more GMOs (i.e. live recombinant veterinary vaccines) are commonly used for veterinary purposes. A variety of such vaccines has been developed and is commercially available in the international market. Live recombinant veterinary vaccines could be imported into Hong Kong for vaccination of pet animals against diseases such as rabies. They could also be used on farm animals, such as poultry or horse, to prevent outbreak of diseases, like avian flu and equine influenza.

10. As vaccination with live micro-organisms may lead to the shedding of the administered micro-organisms into the environment, the administration of live recombinant veterinary vaccine may be considered as release of GMO into the environment. Administration or import with the purpose of administration of such veterinary vaccines thus requires prior approval from the Director under all circumstances, including in emergency situations such as

³ The Expert Group has critically examined the risk assessment report with respect to the potential biosafety effects of GM papaya to the local environment, including the gene flow to wild relatives of papaya, horizontal gene transfer, impact on soil microbial diversity, weed potential and production of harmful substances. The Expert Group endorsed the findings of the risk assessment in that GM papaya is very unlikely to pose any adverse biosafety effect to the local environment, in particular members agreed that the potential of gene flow from GM papaya to its wild relatives, which is the major concern of the objectors to the proposed exemption, did not exist given no native species of the papaya family was known to occur in Hong Kong. Besides, having regarded to the concern that GM papaya to be developed in future may have adverse biosafety effects on the local environment, it was pointed out in the meeting that there were established mechanisms to produce GM papayas, hence the biosafety of existing and new varieties of GM papayas would be similar.

In view of the above, the Expert Group concluded that the proposed exemption of GM papaya from sections 5 and 7 of the Ordinance was supported. It was also recommended that AFCD should continue to monitor the latest progress and development of GM papayas and carry out a review of the exemption of GM papaya in a three years' time for reporting to the Expert Group. AFCD would also step up publicity on GM crops and organic farming to both the general public and the stakeholders.

an outbreak of a pandemic disease where there would be a genuine need of urgent application of live recombinant veterinary vaccines.

11. In view of the recent development in the production of live recombinant veterinary vaccines and the potential application of such vaccines in Hong Kong, AFCD conducted a risk assessment to assess the possible adverse biosafety effect of live recombinant veterinary vaccines on the local natural environment. Based on the risk assessment, AFCD concluded that the possible adverse effect to the biological diversity of the natural environment posed by live recombinant veterinary vaccines is acceptable, mainly because either the recombinant micro-organisms of such vaccines are non-pathogenic in nature or the possibility for the recombinant micro-organisms to spread to the environment is very low. In other words, the possible adverse biosafety effect that may result from granting exemption to the live recombinant veterinary vaccines under the Ordinance is acceptable. The above conclusion was endorsed by the Expert Group.

12. Furthermore, it is considered necessary to cater for the need of application of live recombinant veterinary vaccines in emergency situations such as an outbreak of a pandemic disease. The application of such vaccines in case of emergency could be hindered by the lengthy approval process as stipulated in the Ordinance. Hence, the Secretary has also decided to grant exemption to live recombinant veterinary vaccines from the application of sections 5 and 7 of the Ordinance.

THE EXEMPTION NOTICE

13. To give effect to the proposed exemptions, the Secretary has made the Exemption Notice –

- (a) to exempt GM papaya and any GMO that is contained in a veterinary vaccine from the application of section 5 of the Ordinance; and
- (b) to exempt two varieties of GM papaya (as more particularly described in paragraph 8 above) and any GMO that is contained in a veterinary vaccine from the application of section 7 of the Ordinance.

LEGISLATIVE TIMETABLE

14. The legislative timetable is as follows –

Publication in the Gazette	27 April 2012
Tabling at the Legislative Council	2 May 2012
Commencement	23 June 2012

IMPLICATIONS OF THE EXEMPTION

15. The Exemption Notice is in conformity with the Basic Law, including the provisions concerning human rights. It will not affect the current binding effect of the Ordinance. As indicated by the results of the risk assessments on the possible adverse biosafety effects, which are highlighted in paragraphs 6 and 11 of this brief, the exemption will not have environmental implications. As far as sustainability implications are concerned, the assessment conducted by AFCD affirmed that possible adverse effects to the biodiversity of the environment are acceptable. Regarding the economic implications, the compliance cost of the relevant trades and those domestic growers of GM papaya would be alleviated, although this is not expected to be onerous as commercial farming is limited in Hong Kong. On the other hand, the exemption of live recombinant veterinary vaccine should provide veterinary treatment with more choices and may help prevent outbreaks of pandemic diseases, which should be considered beneficial as for economic implication. There is no productivity, financial and civil service implication.

CONSULTATION

16. The Expert Group, which has been set up under the Ordinance to advise the Director on the administration of the Ordinance (including the granting of exemptions), was consulted on the legislative proposal in July 2011 and supported the exemption on GM papaya and live recombinant veterinary vaccines.

17. Furthermore, having regard to the Expert Group's advice, AFCD would continue to monitor the latest progress and development of GM papaya

and live recombinant veterinary vaccines, and carry out a review of the exemption of GM papaya and live recombinant veterinary vaccines in three years' time. AFCD would also step up publicity on GM crops and organic farming to both the general public and the stakeholders.

18. We consulted the Panel on Environmental Affairs (the Panel) on 28 November 2011 on the original exemption proposal. Taking account of the comments received, we have revised the exemption proposal and further consulted the Panel on 26 March 2012. Whilst there were written submissions urging exemption of GM papaya as soon as possible, submissions have also been received from an environmental group and some organic farmers commenting on the proposed exemption of GM papaya. The issues raised include the possible biosafety effect of new varieties of GM papayas on the local environment, the planting of GM papaya in overseas countries and the labelling requirement for GM papayas. The Administration's responses to these issues are given at **Annex B**. At its March meeting, the Panel raised no objection for the Administration to table the Exemption Notice at the Legislative Council for negative vetting.

PUBLICITY

19. A press release will be issued on the commencement date of the exemption so that members of the public, including those who grow papaya in their backyards, will be aware of the exemption. Stakeholders will also be informed of the above exemption and its commencement date.

ENQUIRY

20. Any enquiry on this brief should be directed to Mr Elvis Au, the Assistant Director (Nature Conservation and Infrastructure Planning Division) of the Environmental Protection Department at 3509 8617 or Mr Simon Chan, Senior Conservation Officer (Biodiversity) of the Agriculture, Fisheries and Conservation Department at 2150 6910.

Environmental Protection Department
Agriculture, Fisheries and Conservation Department
25 April 2012

Genetically Modified Organisms (Control of Release) (Exemption) Notice

(Made by the Secretary for the Environment under section 46 of the
Genetically Modified Organisms (Control of Release) Ordinance
(Cap. 607))

1. Commencement

This Notice comes into operation on 23 June 2012.

2. Interpretation

In this Notice—

genetically modified papaya (基因改造木瓜) means a living organism of the species *Carica papaya* that possesses a novel combination of genetic materials obtained through the use of modern biotechnology;

transformation event code (轉基因事件編碼), in relation to a GMO, means the code given to the GMO by the person who develops the GMO on the integration of a transgene into the cell of the GMO;

unique identifier code (獨特標識編碼), in relation to a GMO, means the unique code that is—

- (a) assigned to the GMO in accordance with the Organisation for Economic Co-operation and Development Guidance for the Designation of a Unique Identifier for Transgenic Plants; and
- (b) entered into the Biosafety Clearing-House or other unique identification systems adopted by the Conference of the Parties.

3. GMOs exempt from section 5 of Ordinance

The GMOs specified in Schedule 1 are exempt from the application of section 5 of the Ordinance.

4. GMOs exempt from section 7 of Ordinance

The GMOs specified in Schedule 2 are exempt from the application of section 7 of the Ordinance.

Schedule 1

[s. 3]

GMOs Exempt from Section 5 of Ordinance

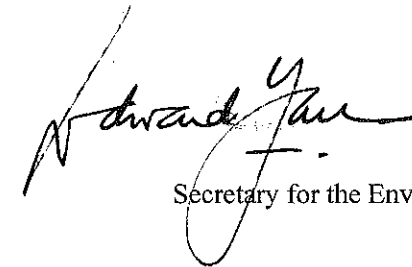
1. A genetically modified papaya.
 2. A GMO that is contained in a veterinary vaccine.
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Schedule 2

[s. 4]

GMOs Exempt from Section 7 of Ordinance

1. A genetically modified papaya the unique identifier code of which is CUH-CP551-8.
2. A genetically modified papaya the transformation event code of which is Huanong 1.
3. A GMO that is contained in a veterinary vaccine.



Secretary for the Environment

16 April 2012

Explanatory Note

Section 5 of the Genetically Modified Organisms (Control of Release) Ordinance (Cap. 607) provides that a person must not knowingly cause a GMO (GMO means a living organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology) to be released into the environment or maintain the life of a GMO that is in a state of being released into the environment. Section 7 of that Ordinance provides that a person must not knowingly import a GMO that is intended for release into the environment.

2. This Notice exempts all varieties of genetically modified papaya (defined in section 2) and any GMO that is contained in a veterinary vaccine from the application of section 5 of that Ordinance. It also exempts two particular varieties of genetically modified papaya and any GMO that is contained in a veterinary vaccine from the application of section 7 of that Ordinance.

**The Administration's Response to Major Issues Raised
at the Panel on Environmental Affairs**

Possible Biosafety Effect of New Varieties of GM Papayas

GM papaya is produced through genetic engineering using the same transformation system, all varieties of GM papaya that were developed or are developing would share the same basic genetic makeup. The only difference would be the target gene for the desirable traits for the particular variety of GM papaya. Since GM papaya has similar genetic construction by nature, new varieties of GM papaya would share similar biological and safety properties as existing varieties of GM papaya that are proven to be safe with respect to their possible effect on local biological diversity when planted.

Planting of GM papaya in Overseas Jurisdictions

2. As regards the planting of GM papaya in overseas jurisdictions, GM papaya is cultivated in many places, including Mainland China, Taiwan, US, Hawaii, Brazil, Jamaica, Indonesia, Mexico, Tanzania, Australia, Malaysia, Philippines and Vietnam. For example, the majority of papayas grown in Hawaii are GM papaya which covers more than 1,000 acres of the arable land. In Mainland China, GM papaya is mainly grown in Guangdong, Guangxi and Hainan.

3. At present, a number of varieties of GM papaya resistant to PRSV have been developed to confer papaya with specific resistance to different strains of PRSV. Among them, two varieties have been commercialized and a few others approved for field planting. It should be noted that various varieties of GM papaya are being grown in many subtropical and tropical countries. As papaya is one of the major crops in these countries and that branding of specific cultivar of GM papaya is important for its commercialization, approval of specific cultivars of GM papaya rather than exemption of broad varieties of GM papaya through administrative or statutory means were given to their commercial production or field planting in these countries. On the

other hand, it is worthwhile to point out that similar exemption as the current proposal of exemption of GM papaya in Hong Kong has been made in Canada. As set out in Canada's Seeds Regulations, GM plants are exempted from authorization requirements if the plants have been openly grown and formed a stable population in Canada. Similarly, GM papaya is very widespread and is known to have existed in the village environments of Hong Kong for many years.

Labeling Requirement for GM Papayas

4. The objectives of the Ordinance are to give effect to the Protocol, as well as to control the release into the environment and the import and export of GMOs. The food safety aspect of GM food has to be dealt with separately. According to the World Health Organisation, GM foods currently traded on the international market are not likely, nor have been shown, to present risks for human health. The Centre for Food Safety encourages the local food trade to label GM food in accordance with the "Guidelines on Voluntary Labelling of Genetically Modified Food" which were published in 2006 and provided reference for the trade to make truthful and informative labels in a consumer-friendly manner. In 2007, the Administration conducted an assessment of voluntary labelling of GM food by the trade, which findings illustrated that there was no pressing need for mandatory labelling, as measured by the level of use of GM material in the samples. The Administration will continue its efforts in promoting the voluntary labelling regime and also keep in view the international development in GM technology and GM food labelling standards, in deciding on the future course of action.