

香港法例第 607 章基因改造生物（管制釋出）條例
Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607

向環境釋出基因改造生物核准申請表格
Application Form for Approval of GMO for Release into Environment

向環境釋出基因改造生物核准申請的注意事項

1. 遞交申請的注意事項

- (a) 根據《基因改造生物（管制釋出）條例》第 8 條的規定，基因改造生物核准申請須採用指明表格及載有附表 2 列明的資料。此申請表格是為符合有關規定而制定。
- (b) 所有資料必須以正楷填寫或以打字機打印。
- (c) 一份申請表格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，請使用額外的申請表格。
- (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格一同遞交。
- (e) 除特別指明外，必須填寫本表格所有部分。
- (f) 在遞交申請表格時，必須附上該基因改造生物的風險評估報告。
- (g) 在遞交申請表格時，必須附上提出申請須付的訂明費用**港幣 14,250 元**。費用須以支票或銀行本票支付。
- (h) 如用支票付款，收款人須寫明「香港特別行政區政府」。
- (i) 根據本條例繳付的費用不得退回。
- (j) 以親身或郵寄方式遞交申請表格、所需文件及須付的訂明費用至香港九龍長沙灣道 303 號長沙灣政府合署 6 樓漁農自然護理署生物多樣性護理科。

2. 遞交申請後的運作程序

- (a) 於接獲基因改造生物核准申請後 90 天內，你將會收到由漁農自然護理署署長（下稱署長）發出的書面認收書，以確認接獲該項申請。
- (b) 於接獲申請後 270 天內署長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，及與署長會面，回答署長就有關申請所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) 申請一旦獲核准及記入基因改造生物紀錄冊（www.afcd.gov.hk/gmo），有關核准將適用於該基因改造生物隨後的所有環境釋出及擬向環境釋出的輸入。
- (g) 包含擬向環境釋出的基因改造生物的貨物批次，在輸入時必須附同訂明文件。詳細的文件要求可從本署或基因改造生物紀錄冊取得。

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向環境釋出或對有關核准附加條件，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，或取消或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；或
 - (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申請決定申請表格 GMO607-2）。
- (c) 你也可以於接獲署長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。
- (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。
- (c) 撤回通知可以使用撤回通知表格（GMO607-10）。

5. 提出不披露要求

- (a) 署長須將所接獲的關於基因改造生物核准申請及更改要求的資料記入基因改造生物紀錄冊。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基因改造生物紀錄冊。

- (b) 你必須指明要求署長不要將哪些資料記入紀錄冊，及列明該項要求的理據。不披露要求必須採用指定表格（不披露要求申請表格 GMO607-3）。
- (c) 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處理與該基因改造生物核准申請有關的事宜。
- (b) 個人資料的提供純屬自願性質。若你未能提供足夠的資料，本署可能無法辦理你的申請。
- (c) 本署可能會將你的資料的任何部分提供給予其他政府部門作為調查或統計之用途。
- (d) 被記入基因改造生物紀錄冊的資料亦可能會被上傳至生物安全資料交換所（<http://bch.cbd.int>）以供公眾查閱。
- (e) 除個人資料（私隱）條例所訂明的豁免外，你有權查閱和更正你的個人資料。
- (f) 查閱和更正個人資料的要求應以書面形式向本署生物多樣性護理科提出。同時請註明有關申請在本署的檔案號碼。

7. 查詢

漁農自然護理署	生物多樣性護理科
地址：	九龍長沙灣道 303 號 長沙灣政府合署 6 樓
電話：	2150 6918
傳真：	2314 2802
基因改造生物紀錄冊：	http://www.afcd.gov.hk/gmo
電郵：	biosafety@afcd.gov.hk

警告

1. 如果基因改造生物不是：
 - (a) 已獲核准及紀錄冊列明核准該生物的每項條件(如有的話)，均已符合；或
 - (b) 已獲豁免及紀錄冊列明豁免該生物的每項條件(如有的話)，均已符合，
 任何人明知而：
 - (a) 向環境釋出該生物；
 - (b) 輸入該生物擬向環境釋出；或
 - (c) 育養處於向環境釋出的狀態的該生物。
 即屬犯罪，可被處罰款港幣 100,000 元及監禁一年。
2. 倘若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的申請獲核准，則可隨時將該核准取銷。

Notes to application for approval of GMO for release into the environment

1. Notes to submitting the application

- (a) Section 8 of the Genetically Modified Organisms (Control of Release) Ordinance requires that a GMO approval application must be in the specified form and contain the information set out in Schedule 2. This application form is prepared for the purpose of compliance with the above-mentioned requirements.
- (b) Information should be written in block letters or typed.
- (c) Each application form should be used for one type of genetically modified organism (GMO) only. If there is more than one type of GMO, please use additional application forms.
- (d) If additional space is needed, please continue on a separate sheet, which must be clearly labelled and included as appendix to the application form.
- (e) Unless otherwise indicated, all sections of this form must be completed.
- (f) A risk assessment report for the GMO should be submitted together with the application form
- (g) An application should be accompanied by the prescribed fee payable of **HK\$14,250** in cheque or cashier order.
- (h) Cheque should be made payable to “The Government of the Hong Kong Special Administrative Region”.
- (i) Any prescribed fee paid under this Ordinance is not refundable.
- (j) An application should be submitted together with supporting documents and the prescribed fee payable by post or in person to Biodiversity Conservation Division, Agriculture, Fisheries and Conservation Department, 6/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon, Hong Kong .

2. Process after the submission of the application

- (a) Within 90 days after receiving the GMO approval application, a written acknowledgement from the Director of Agriculture, Fisheries and Conservation (the Director) confirming the receipt will be issued to you.
- (b) Within 270 days after receiving the application, the Director will decide whether the GMO should be approved for release into the environment and inform you the result of the application 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 and 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 and imports intended for release into the environment, after it is entered in the GMOs Register (www.afcd.gov.hk/gmo) as an approved GMO.
- (g) Shipments containing GMOs intended for release into the environment, when being imported, must be accompanied by the prescribed documents. Details of the documentation requirements are available from this department upon request or from the GMOs Register.

3. Request for variation of decisions on GMO approval application

- (a) If the Director refuses to approve a GMO for release into the environment or approve the release with conditions, you may 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; or
 - (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 specified form (*Request Form for Variation of Decision on GMO Approval Application*, GMO607-2).
- (c) You may also appeal to the Administrative Appeals Board against the Director’s decisions on the GMO approval application, within 28 days after receiving the 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 cease.
- (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.
- (c) You may use the *Withdrawal Notice Form* (GMO607-10) to submit the withdrawal request.

5. Making non-disclosure request

- (a) The Director will enter all information submitted for the purposes of a GMO approval application and variation request, in the GMOs Register. When providing the information, you may request the Director not to enter specified information in the GMOs Register.
- (b) You must specify the information that the Director is requested not to enter in the GMOs Register and set out the justifications for the request. A **non-disclosure** request should be made in the specified form (*Non-disclosure Request Form*, GMO607-3).
- (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 purposes relating to the processing of the GMO approval application.
- (b) The provision of personal data is voluntary. However, if you do not provide sufficient information, this department may not be able to process your application.
- (c) The information provided of any part thereof may be supplied by this department to other government departments for investigation or statistics purposes.
- (d) Information entered in the GMOs Register may also be uploaded to the Biosafety Clearing-House (<http://bch.cbd.int>) for inspection by members of the public.
- (e) Subject to exemptions under the Personal Data (Privacy) Ordinance, you have a right of access and correction with respect to personal data.
- (f) Request for personal data access and correction should be addressed to Biodiversity Conservation Division of this department. Please also quote the file reference number of the application.

7. Enquiries

Biodiversity Conservation Division,
Agriculture, Fisheries and Conservation Department

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

Tel: 2150 6918

Fax: 2314 2802

GMOs Register: <http://www.afcd.gov.hk/gmo>

E-mail: biosafety@afcd.gov.hk

WARNINGS

1. If the GMO is not:
 - (a) an approved GMO and any condition (if any) for the approval of the GMO, as set out in the GMOs Register, has been complied with; or
 - (b) an exempted GMO and any condition (if any) for the exemption of the GMO, as set out in the GMOs Register, has been complied with,
 a person who knowingly:
 - (a) releases the GMO to the environment;
 - (b) imports the GMO which is intended to be released into the environment; or
 - (c) maintains the life of the GMO that is in a state of being released into the environment,
 commits an offence and is liable to a fine of HK\$100,000 and to imprisonment for one year.
2. The Director may at any time revoke the approval of 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.

香港法例第 607 章基因改造生物（管制釋出）條例
Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607

向環境釋出基因改造生物核准申請表格

〔基因改造生物（管制釋出）條例第 8 條〕

Application Form for Approval of GMO for Release into Environment

[Section 8 of the Genetically Modified Organisms (Control of Release) Ordinance]

填寫此申請表格前請先詳閱附加的注意事項內容

Please read the attached notes before filling in this application form

1. 申請人／機構資料 Information of applicant/organisation

(a) 申請人姓名／機構名稱 Name of applicant/organisation

(b) 申請人身分證／護照號碼或機構的註冊號碼

Identity card/passport number of applicant or registration number of organisation

(c) 電話號碼 Telephone number

傳真號碼 Fax number

(d) 申請人／機構地址 Address of applicant/organisation

2. 基因改造生物的資料 Information of the GMO

(a) 該生物的名稱 Name of the GMO

(b) 該生物的識辨屬性 Identity of the GMO

(c) 擬向環境釋出該生物的日期 Intended date of release into the environment

(d) 擬釋出和輸入（如適用的話）該生物的數量或體積 Quantity or volume of the GMO to be released and, if applicable, imported

(e) 該生物或其產品（即源於基因改造生物並經過加工的材料，其中含有透過使用現代生物技術獲得的、可檢測到的新異組合的可複製性遺傳材料）的預定用途

Intended use of the GMO or products from the GMO, namely, processed materials that are of genetically modified organism origin and that contain detectable novel combinations of replicable genetic materials obtained through the use of modern biotechnology

3. 受體生物體或親本生物體的資料 Information of the recipient organism or parental organism

- (a) 生物分類狀況及通用名稱 Taxonomic status and common name
- (b) 收集點或獲取點 Point of collection or acquisition
- (c) 受體生物體或親本生物體的關乎該基因改造生物可能帶來的生物安全不利影響的特徵
Characteristics of that recipient organism or parental organism related to possible adverse biosafety effect
- (d) 受體生物體及親本生物體（如適用的話）的起源中心和遺傳多樣性中心（如已知的話）
Centre of origin and centre of genetic diversity, if known, of the recipient organism and, if applicable, the parental organism
- (e) 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
Description of the habitats where that recipient organism and parental organism may persist or proliferate

4. 供體生物體的資料 Information of the donor organism

- (a) 生物分類狀況及通用名稱 Taxonomic status and common name
- (b) 收集點或獲取點 Point of collection or acquisition
- (c) 供體生物體的關乎該基因改造生物可能帶來的生物安全不利影響的特徵
Characteristics of that donor organism related to possible adverse biosafety effect

5. 基因改造的資料 Information of the genetic modification

(a) 引入該生物的核酸或改變的說明 Description of the nucleic acid or the modification introduced

(b) 所使用的基因改造技術的說明 Description of the technique used for the genetic modification

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

**6. 建議用於安全處理、儲存、運輸及使用該生物的方法，包括包裝、標籤、文件紀錄、處置及應變程序（如屬適當的話）
Suggested methods for the safe handling, storage, transport and use of the GMO, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate**

此欄由辦理機關填寫 For official use only

Date received	Remarks/additional information
Officer	Follow up action