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

要求更改基因改造生物核准申請決定申請表格 Request Form for Variation of Decision on GMO Approval Application

要求更改基因改造生物核准申請決定的注意事項

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》(下稱《條例》)第 11 條第 (4) 款的規定,要求更改對基因改造生物核准申請的決定的申請須採用指明表格。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。
- (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格一同遞交。
- (d) 除特別指明外,必須填寫本表格所有部分。
- (e) 在遞交申請表格時,必須附上申請人**身份證/護照副本**或申請機構註冊文件副本及支持該項要求的有關資料。
- (f) 在遞交申請表格時,必須附同提出要求須付的訂明費用港幣 1,890 元。費用可以支票、銀行本票或網上方式支付。
- (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《條例》,繳付的費用不得退回。
- (i) 遞交表格前,申請人可使用內附的「遞交申請的覆核清單」以查對所需文件或費用是否準備妥當。
- (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。如以電郵遞交申請,請將申請表格及文件電郵至 biosafety@afcd.gov.hk,並在收到付款通知後才進行網上付款。

2. 遞交申請後的運作程序

- (a) 於接獲更改要求並收妥訂明費用後 90 天內,漁農自然護理署署長(下稱署長)將會決定確認或更改對有關基因改造生物 核准申請的決定。
- (b) 署長會以書面通知申請人該項決定。
- (c) 你可於接獲署長關於該項決定的通知後 28 天內,向行政上訴委員會提出反對該項決定的上訴。

3. 撤回更改要求申請或已提供的資料或文件

- (a) 你可於署長對要求作出決定前,隨時以書面要求撤回該項要求。署長會停止處理該項要求。
- (b) 你可於署長對該項要求作出決定前隨時以書面撤回就該項要求而提供的任何資料或文件。署長會繼續處理該項要求,猶 如該等資料或文件不曾被提供一樣。

4. 提出不披露要求

- (a) 署長須於接獲更改要求申請表格的資料後 14 天內,將資料記入基因改造生物紀錄冊。就該項要求而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 不披露要求或覆核不披露要求決定申請表格(GMO607-3)。
- (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。

5. 個人資料收集聲明

- (a) 你所提供的資料將用作處理與該更改要求有關的事宜。
- (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提出。同時請註明該更改要求在本署的檔案號碼。

6. 查詢

漁農自然護理署

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

電郵: <u>biosafety@afcd.gov.hk</u>

基因改造生物網頁: https://www.afcd.gov.hk/gmo

警告

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更改要求獲核准,則可隨時將該核准撤銷。

Notes to variation request on GMO approval decision

1. Notes to submitting the request

- (a) Subsection (4) of section 11 of the Genetically Modified Organisms (Control of Release) Ordinance (the Ordinance) requires that a request for variation of decisions on a GMO approval application must be in the specified form. This application form is prepared for the purpose of compliance with the above-mentioned requirement.
- (b) The form should be filled in block letters
- (c) If additional space is needed, please continue on a separate sheet, which must be clearly labelled and included as appendix to the variation request form.
- (d) Unless otherwise indicated, all sections of this form must be completed.
- (e) An application should be submitted with a **copy of identity card/passport of the applicant** or **organisation registration**, and **relevant information** in support of the request.
- (f) This variation request should be accompanied by the prescribed fee payable of **HK\$1,890** in cheque, cashier order or via online payment.
- (g) Cheque should be made payable to "The Government of the Hong Kong Special Administrative Region".
- (h) Any prescribed fee paid under the Ordinance is not refundable.
- (i) Before submission, the applicant can use the attached "Checklist for submission" to check if the required document or fee has been prepared.
- (j) This variation request should be submitted together with supporting documents and the prescribed fee payable by post or in person to Agriculture, Fisheries and Conservation Department, 6/F, Cheung Sha Wan Government Offices, 303 Cheung Sha Wan Road, Kowloon, Hong Kong, or email to biosafety@afcd.gov.hk, and proceed to online payment upon receiving the payment request.

2. Process after the submission of the request

- (a) Within 90 days after receiving this variation request and payment of the prescribed fee, the Director of Agriculture, Fisheries and Conservation (the Director) will decide whether to confirm or vary the decision on the genetically modified organism (GMO) approval application.
- (b) The Director will inform you the result of the variation request by written notice.
- (c) You may appeal to the Administrative Appeals Board against the Director's decisions on the variation request, within 28 days after receiving the notice of the decision.

3. Withdraw of application or information/document provided

- (a) You may, in writing, withdraw the request at any time before the Director makes a decision. In such case, the process of the variation request will cease.
- (b) You may, in writing, withdraw any information or document provided for the purposes of the variation request at any time before the Director makes a decision. In such case, the process of the variation request will continue as if the information or document had not been provided.

4. Making non-disclosure requests

- (a) The Director will enter all information submitted for the purposes of a variation request in the GMOs Register within 14 days after receipt of it. When providing the information, you could request the Director not to enter the specified information in the register.
- (b) A **non-disclosure** request should be made in the specified form Non-disclosure or Review of Decision on Non-disclosure (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.

5. Personal information collection statement

- (a) The information provided by you will be used for the purposes relating to the processing of the variation request.
- (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 request.
- (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

Please also quote the file reference number of the variation request.

6. Enquiries

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

E-mail: biosafety@afcd.gov.hk

GMO website: https://www.afcd.gov.hk/gmo

WARNING

The Director may at any time revoke the approval on the variation request if the request was approved as a result of false representation of any fact made by the applicant or an unlawful act of the applicant.

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

要求更改基因改造生物核准申請決定申請表格

[基因改造生物(管制釋出)條例第11條第(4)款]

Request Form for Variation of Decision on GMO Approval Application

[Subsection (4) of Section 11 of the Generically 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 for	m

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					
	(如曾提供聯絡方法並沒有資料需要更新,則不需要填寫 Please leave contact details blank if they have been provided and no changes are made) (c) 電話號碼 Telephone number 傳真號碼 Fax number 電郵 Email					
	(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) 向環境釋出基因改造生物核准申請的檔案編號					
	File reference number of the application for approval of GMO for release into the environment					
	The revenue number of the approximent of approximent for the section and the section of the sect					
3.	要求更改的内容 (請選擇其中一項)Variation to be requested (Please choose either one)					
	□ 更改核准所附加的條件(請完成第 4 及第 5 部分) Vary the decision on the approval conditions (Please complete Part 4 and 5)					
	□ 更改對基因改造生物核准申請的決定(請完成第 5 部分) Vary the decision on GMO approval application (Please complete Part 5)					
4.	要求更改核准基因改造生物附加的條件 Request for variation on the conditions for the approval of the GMO					
	請列明(i)欲更改的條件及(ii)如何更改 Please specify (i) the condition(s) to be varied and (ii) how it should be varied					

	GMO607		
5.	作出要求的理據 Reasons for the request		
L	□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 There is a change in circumstances that may influence the Director's assessment on the possible adverse biosafety effect of the GMC		
	has occurred		
] 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		
	There is additional scientific or technical information that may influence the Director's assessment on the possible adverse biosafety		
	effect of the GMO has become available		
	請指明作出要求的理由並附同支持該項要求的有關資料		
	Please specify the grounds for the request accompanied by relevant information in support of the request		
6.	付款方法及資料 Payment method and details		
	□ 支票 Cheque		
	□ 銀行本票 Cashier Order		
	■ 網上付款 Online payment(遞交申請後會收到付款通知 Payment request will be sent to applicant after submission of application)		
	銀行名稱 Name of bank 支票/銀行本票號碼 Cheque/cashier order number		
1			

7. 聲明 Declaration							
		頁及警告,並聲明上面各項填報詳情均為正確無訛。					
I have read the attached notes and warnings and I declare that all the particulars given above are true and correct.							
That's read the attached hotes and warnings and r declare that an the particulars given above are true and correct.							
	申請人簽署/	機構印鑑 Signature of applicant/organisation chop	日期 Date				
	1 8/1/ 3/20 11/	此欄由辦理機關填寫 For official use only	794				
Date	received	Remarks/additional information					
O CC		P. II.					
Officer		Follow up action					
源交	申請的覆核清單 Checkli	st for submission					
	,中明时便仅有平 Circum	St 101 Submission					
	我已提供身份證/護照副》	本或機構註冊文件副本。					
	I have provided a copy of identity card/passport or organisation registration.						
	□ 我已隨表格附上該項要求的相關資料。						
	Relevant information in support of the request has been attached for submission.						
	□ 我已隨表格附上支付的訂明費用港幣 1,890 元的支票或銀行本票。如用支票付款,收款人已寫明「香港特別行政區政府」 若使用網上付款方式支付訂明費用,則不需理會此項。						
	The cheque or cashier order for the prescribed fee of HK\$1,890 has been attached for submission. If cheque is used, it has made payable to "The Government of the Hong Kong Special Administrative Region". Please ignore this item if the prescribed fee wil be paid via online payment approach.						
□ 我已填簽署或蓋章,以表示閱畢附加的應注意事項及警告及聲明申請的資料正確無訛。							
I have signed or chopped, to indicate that I have read the attached notes and warnings and to declare that all the particulars given							
	in the application are true and correct.						