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

List of follow-up actions arising from the discussion at the meeting on 30 November 2009

This paper seeks to respond to the issues raised at the meeting of the Bills Committee on Genetically Modified Organisms (Control of Release) Bill (the Bill) held on 30 November 2009, which are listed at Appendix I of the letter dated 1 December 2009 from the Bills Committee Secretariat –

(1) To advise whether there is a need to report to the Director in the event that a genetically modified organism (GMO) is lost in transit or transshipment under clause 7.

(2) To consider specifying in clause 7 the need for approval if a GMO is intended for release into the environment.

(3) To include in the speech to be delivered by the Secretary for the Environment at the resumption of the Second Reading debate on the Bill that a written acknowledgement of receipt of GMO approval application will be issued to the applicant in an expeditiously manner and in any case less than 90 days even though a 90-day period is provided in clause 9 of the Bill, and that such performance pledge will be spelt out in the practice guidelines of the Agriculture, Fisheries and Conservation Department (AFCD).

(4) To provide a flow chart on the applications of different clauses, such as time frames (including extensions) as required under the Cartagena Protocol on Biosafety and performance pledges made by the Administration taking into account local circumstances, exemptions, appeal mechanisms etc.

(5) To consider including in the practice guidelines the requirement for approval of the container for GMO to prevent inadvertent release into the environment.

(6) To consider specifying in clause 25 that the register will be made available for public inspection on the website of AFCD.

(7) To advise the criteria which the Director will adopt in assessing non-disclosure requests, and whether the criteria will be set out in the Bill. To also review the drafting of clauses 14 and 15 to ensure consistency in the reference of "confidential information".

Report to the Director in the event that a genetically modified organism (GMO) is lost in transit or transshipment

2. Clause 7 does not require a person who imports a GMO intended for release into the environment to report to the Director in the event that the GMO is lost in transit or transshipment. The main concern of GMO that is lost in transit or transshipment is the unintentional release of the GMO into the environment. While the restrictions on import of GMOs intended for release into environment do not apply to a GMO that is in transit or transshipment in accordance with the provisions in the Cartagena Protocol on Biosafety (Protocol), there are provisions under clause 6 for notification to the Director of certain release of GMOs. Under clause 6, if a person who has control of a GMO knows that a GMO is released into the environment, and the GMO is not an approved GMO or the GMO's approval conditions have not been complied with, the person must, by written notice, inform the Director of the release. In case the lost GMO is found to be released into the environment under the above circumstances, the person has to report to the Director of the release so that the Director can either direct an authorized officer or the person to properly dispose of the GMO. We consider that the above measures should already be sufficient to deal with situations where GMOs are lost in transit or transhipment.

Specifying in clause 7 the need for approval if a GMO is intended for release into the environment

3. Clause 7(2)(a) specifically provides that a person must not knowingly import a GMO that is intended for release into the environment unless the GMO is an approved GMO. "Approved GMO" is defined in clause 2 as "a GMO that is approved for release into the environment by ... a decision of the Director … a decision of the Administrative Appeals Board". Clause 8, which immediately follows clause 7, sets out in detail the requirements on an application for approval. It is clear from the above-mentioned clauses that a GMO that is intended for release into the environment must have been approved, whether by a decision of the Director or the Administrative Appeals Board. Last but not the least, in the guidelines that we

will prepare for the stakeholders (in particular traders) on the legislative requirements of the Bill (Guidelines), we will set out in clear and layman terms the application requirements, so that traders would be well briefed of these requirements.

Performance pledge in relation to issuing written acknowledgement of receipt of GMO approval application

4. We confirm that the points raised by the Bills Committee will be included in the speech to be delivered by the Secretary for the Environment at the Resumption of Second Reading debate on the Bill.

Flow Chart

5. Please see the flow chart at **Annex A**.

Provide in the Guidelines the requirement for storing the GMOs well to prevent inadvertent release into the environment

6. We will provide in the Guidelines recommended requirements for storing GMOs (in particular for GMOs that are for food, feed or for processing (FFP)), so as to reduce their risk of being inadvertently released into the environment.

7. We wish to add that, when applying for approval of a GMO for release into the environment, the applicant needs to submit, inter alia, suggested methods for storage of the GMO (see item 10 in Part 1 of Schedule 2 of the Bill). Further, depending on the need of each case, the Director, when approving a GMO for release into the environment, may also attach specific conditions on how the GMO should be stored or contained.

Clause 25

8. We have considered Members' advice, and we have set out the proposed

revised clause 25 at **Annex B**.

Non-disclosure request

9. When submitting an approval application under clause 8, an applicant is required to provide to the Director all the information set out in Part 1 of Schedule 2 of the Bill. Under clause 13, all information submitted by an applicant on a GMO approval application or variation request will be entered in the Register (established under clause 25) which is available for inspection by the public. If the applicant does not want any of the submitted information to be entered in the Register, the applicant may submit a written request to the Director (non-disclosure request) and provide justifications for the request. Clauses 14 and 15 set out the detailed requirements relating to non-disclosure requests and the Director's decisions on the requests.

10. In particular, clause 14 provides that a non-disclosure request must specify the information that the Director is requested not to enter in the Register, and the justifications for not entering those information. However, key information such as a general description of the GMO, and the summary of the risk assessment on the possible adverse biosafety effect of the GMO, cannot be withheld. Clause 15 provides that the Director may, on receiving a non-disclosure request, decide that none, only some, or all of the information that is specified in the non-disclosure request under clause 14(2)(b) is to be entered in the Register. The Director, however, may decide not to enter any of such specified information in the Register only if the Director is satisfied that not disclosing the information to the public would not be contrary to the public interest. As explained at the Bills Committee meeting, we expect that information that is not to be entered in the Register would include trade secret, or sensitive commercial information, and keeping them undisclosed is essential to respecting the intellectual property rights of the producer or designer of the GMO.

11. We consider that the scheme set out in para 9 and 10 above is sufficient to reflect the considerations that the Director will take into account when processing

non-disclosure request, and which also aligns with that provided in the Protocol.

12. As to the consistency in the reference of “confidential information” in clauses 14 and 15, Members may wish to note that in clause 15, "proposed confidential information" is a defined term and is used as a convenient label to refer to "any information specified under section 14(2)(b) in a non-disclosure request", so that it is not necessary to repeat the words "any information specified under section 14(2)(b) in a non-disclosure request" in clauses 15(1)(a)(i), (ii) and (iii) and 15(2)."

Environmental Protection Department
Agriculture, Fisheries and Conservation Department
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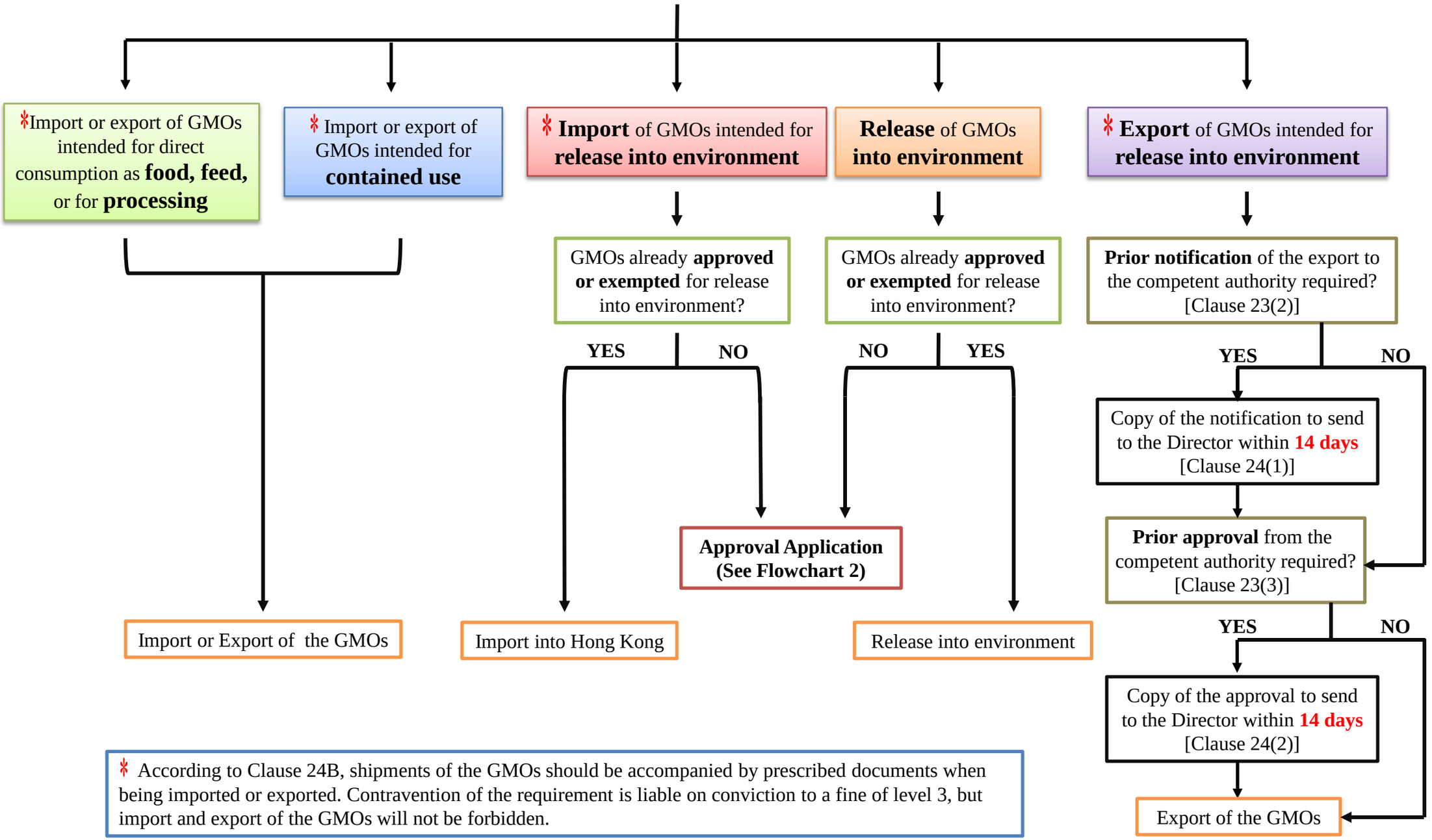
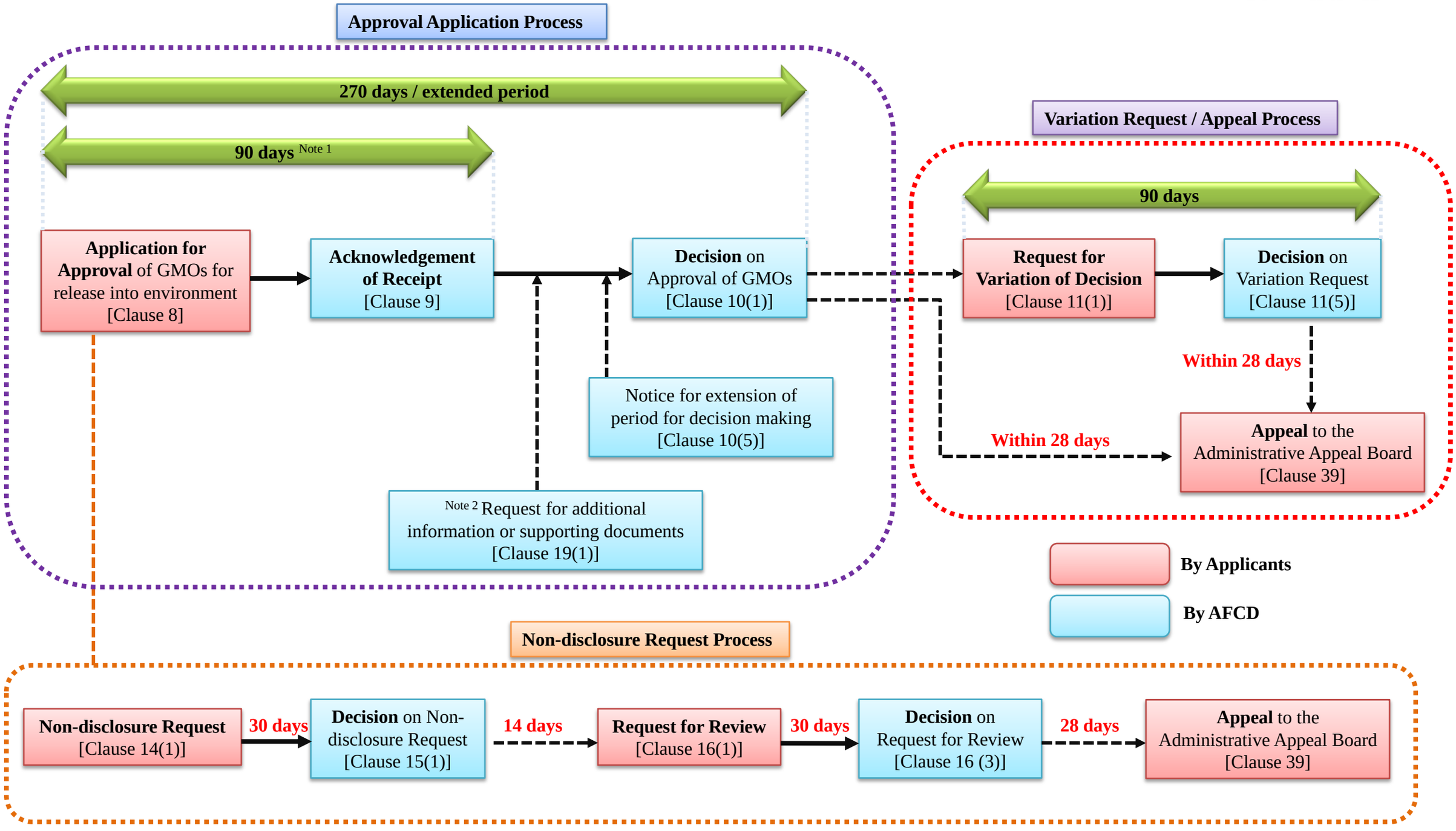
Flowchart I

Regulations on GMOs in Hong Kong



* According to Clause 24B, shipments of the GMOs should be accompanied by prescribed documents when being imported or exported. Contravention of the requirement is liable on conviction to a fine of level 3, but import and export of the GMOs will not be forbidden.

Flowchart II



Note 1 The 90-day period for acknowledgement of receipt of GMO approval application is a requirement of the Protocol. Nevertheless, the Administration pledges to issue the written acknowledgement to the applicant within a reasonable period and in any case less than 90 days.

Note 2 The number of days falling within the period between the date of written notice and the date on which the additional information or supporting documents required were received by the Director will be disregarded in calculating the 270-day or extended period.

25. Director must establish and maintain register

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

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

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

(a) through the Internet; and

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