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

## Expert Group

# Report on the Eighth Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety

**Purpose**

This paper reports on the major decisions made at the Eighth Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP8) and relevant decisions of the Thirteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP13).

**Introduction**

2. The meeting of the Parties to the Cartagena Protocol on Biosafety (the Protocol) currently meets every two years in conjunction with the meeting of the Conference of the Parties to the Convention on Biological Diversity (the Convention). The meeting aims to keep the implementation of the Protocol under regular review and to make decisions necessary to promote the effective implementation of the Protocol by its Parties. COP-MOP8 was held in Cancun of Mexico from 4 to 17 December 2016, concurrently with COP13. Representatives from the Agriculture, Fisheries and Conservation Department (AFCD) attended the meetings as members of the delegation of the People's Republic of China.

3. COP-MOP8 covered a wide range of issues concerning the implementation of the Protocol. Moreover, COP13 also discussed several issues of synthetic biology (SB) which has important implications to the implementation of the Protocol and the Convention. The final reports of COP13 and COP-MOP8 with the full list of the

decisions adopted can be downloaded from the Convention website[1]. Items of COP13 and COP-MOP8 which are relevant to the implementation of the Protocol and the enforcement of the Genetically Modified Organisms (Control of Release) Ordinance, Cap. 607, (the Ordinance) and the Genetically Modified Organisms (Documentation for Import and Export) Regulation, Cap. 607A, (the Regulation) in Hong Kong are highlighted below.

**Decision XIII/17. Synthetic biology**

4. SB shares features with modern biotechnology and builds on classical molecular biology techniques to attempt to design life according to humanity's needs, through controlling the design, characterisation and construction of biological parts, devices and systems[2]. Although the term SB has been used since 1970s, there is currently no universally accepted definition.

5. While SB builds on the classical genetic engineering techniques, many elements of SB are entirely novel. Hence, the component and modified organisms resulted from SB encompass a much wider range of natures and characteristics than classical living modified organisms[3] (LMOs). For instance, modified organisms may be "gene-edited" by mutation at multiple selected location(s) in the genome without any transgene insertion, and thus the organisms may not be distinguishable from those resulted from traditional breeding and selection techniques. In other instances, such as organisms engineered with "gene drive" transgene insertion, once the organisms are released, the transgene insert would spread through the wild population at a rate much faster than classical LMOs, thus allow manipulation at the population or community level. As such, the organisms resulted from SB may require evaluation and assessment different from that of classical LMOs. Given the potential implication of SB to the implementation of the Convention and its two protocols[4], its relevant issues were

[1] Websites of the Convention (https://www.cbd.int/decisions/cop/?m=cop-13 ) and the Protocol (http://bch.cbd.int/protocol/decisions/ )

[2] Science for Environment Policy (2016) *Synthetic biology and biodiversity.* Future Brief 15. Available at: http://ec.europa.eu/environment/integration/research/newsalert/pdf/synthetic_biology_biodiversity_FB15_en.pdf

[3] "Living modified organisms" as defined in the Protocol has the same meaning as genetically modified organisms (GMOs) in the Ordinance.

[4] Secretariat of the Convention on Biological Diversity (2015). Synthetic biology: Part I – Potential Impacts of Synthetic Biology on Biological Diversity, and Part II – Gaps and Overlaps with the Provisions of the Convention and Other Agreements, Montreal, Technical Series No. 82, 118 pages. Available at: https://www.cbd.int/doc/publications/cbd-ts-82-en.pdf

intensively discussed in COP13 and COP-MOP8.

6. COP13 acknowledged the operational definition of SB recommended by the Ad Hoc Technical and Expert Group on Synthetic Biology (AHTEG on SB) as "a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems". This definition was considered to be useful as a starting point for further deliberation under the Convention and its two protocols.

7. COP13 has also taken note of the conclusion of the AHTEG on SB that living organisms developed through current applications of SB, or living organisms currently in the early stages of research and development of SB, are similar to LMOs as defined in the Protocol, but it was not clear whether some organisms of SB would fall under the definition of LMOs under the Protocol. It was also noted that the general principles and methodologies for risk assessment under the Protocol and existing biosafety frameworks provide a good basis for risk assessment for organisms resulted from SB, but they may need to be updated and adapted for current and future applications of SB.

8. Discussions on SB will continue through the future meetings of ATHEG on SB which will make recommendations for consideration by COP14 in 2018. AFCD will keep in view the deliberations regarding SB and their likely implications to the implementation of the Protocol in Hong Kong. AFCD will also keep abreast of the latest development in the field of SB, including the components and organisms resulted from or related to SB, especially those which are near approval for commercialisation and environmental release in other countries, and assess their likely implications to the enforcement of the Ordinance and the Regulation in Hong Kong.

**BS-VIII/11. Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress**

9. The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress[5] (the Supplementary Protocol), which provides for international rules and procedure on liability and redress for damage resulting from LMOs to the conservation and sustainable use of biodiversity, was adopted by the Fifth Meeting of the Parties to the Protocol in 2010. Currently 36 countries (not including EU) have ratified the Supplementary Protocol. The Supplementary Protocol shall enter into force 90 days

[5] Text of the Supplementary Protocol: https://bch.cbd.int/protocol/NKL_text.shtml

after the date of deposit of the fortieth instrument of ratification by Parties to the Protocol.

10. COP-MOP8 welcomed Parties to the Protocol that have deposited their instrument of ratification, acceptance, approval or accession to the Supplementary Protocol[6]. COP-MOP8 also called upon other Parties to the Protocol to expedite their internal processes for the ratification of the Supplementary Protocol as soon as possible with a view to ensuring the expeditious entry into force of the Supplementary Protocol.

11. China has not yet signed the Supplementary Protocol but has initiated steps towards its ratification[7]. The Ministry of Environmental Protection is taking the lead in coordinating and communicating with various departments with regard to the ratification of the Supplementary Protocol and will undertake initial studies in this regard. AFCD will keep in view the development and assess the likely implications of the Supplementary Protocol to Hong Kong.

**BS-VIII/12. Risk assessment and risk management**

12. COP-MOP8 has taken note of the revised version of the voluntary *Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment*[8] (the Guidance), and invited interested Parties, Governments and relevant organisations to take it as one of the voluntary tools, including other guidance documents and national approaches for similar purpose, for conducting risk assessment. It should be noted that the Guidance had been aimed to provide a voluntary reference that may assist the risk assessment and its evaluation. As such, it is not prescriptive and does not impose any obligations upon the Parties in accordance with the Protocol[9].

13. It is worth noting that the requirements on the biosafety risk assessment under the Ordinance follow those set out in the Protocol[10]. The Ordinance outlines the key

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[6] Text of the Supplementary Protocol: http://bch.cbd.int/protocol/NKL_text.shtml

[7] Third National Report to the Protocol, China.
https://bch.cbd.int/database/record.shtml?documentid=109097

[8] COP-MOP Document: UNEP/CBD/BS/COP-MOP8/8/Add.1
https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf
Also available as technical publication of the CBD Secretariat
http://bch.cbd.int/protocol/cpb_technicalseries/cpb-ts-04-en.pdf

[9] Decision BS-V/12 https://bch.cbd.int/protocol/decisions/?decisionID=12325

[10] Article 15 and Annex III of the Protocol.

steps of the risk assessment process and the key points to consider in the process for risk assessment depending on the particular case of the GMOs concerned[11]. On the other hand, the Guidance provides a detailed roadmap for the design of the risk assessment, and elaborates on the steps and points to consider in identifying and evaluating the potential adverse effects. With regard to the implementation of the Ordinance in Hong Kong, the Guidance may be used as a voluntary reference by any stakeholder involved in the risk assessment process, including risk assessors representing the applicant of the GMO, as well as AFCD.

**BS-VIII/16. Unintentional transboundary movements and emergency measures**

14. COP-MOP8 adopted the operational definitions of "illegal transboundary movements" and "unintentional transboundary movements", and deemed it appropriate to use them for implementation of the Protocol. COP-MOP8 has also taken note of a draft training manual on the detection and identification of LMOs[12].

15. "Illegal transboundary movement" is a transboundary movement of LMOs carried out in contravention of the domestic measures to implement the Protocol that have been adopted by the Party concerned. "Unintentional transboundary movement" is a transboundary movement of a LMO that has inadvertently crossed the national borders of a Party where the LMO was released. The requirements of Article 17 of the Protocol apply to unintentional transboundary movement only if the LMO involved is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, in the affected or potentially affected States.

16. As far as the illegal transboundary movements of GMO in Hong Kong is concerned, the Ordinance prohibits the import of unapproved or un-exempted GMOs intended for environmental release[13]. The export of GMO intended for environmental release is also restricted if the GMO has not been approved in the country to which it is exported[14]. Moreover, all shipments of GMOs, except for those intended for human pharmaceutical uses, have to be accompanied by prescribed documents, when they are

[11] Schedule 3 of the Ordinance, 3 (a) to (e).

[12] COP-MOP Information Document: UNEP/CBD/BS/COP-MOP8/INF/6
https://www.cbd.int/doc/meetings/bs/mop-08/information/bs-mop-08-inf-06-en.pdf

[13] Section 7 of the Ordinance.

[14] Section 23 of the Ordinance.

being imported or exported[15].

17. In relation to the provisions in the Protocol regarding unintentional transboundary movement[16], the Ordinance requires person who are in control of GMOs to notify the AFCD in cases of release of the unapproved or un-exempted GMOs[17]. On receiving such notice, the Director may direct the proper disposal of the GMO.

18. With a view to supporting the enforcement of the Ordinance, we have made reference to the list of released GMOs of our neighbouring regions in the formulation of the sampling plan for our regular GMO survey. In the future, we will make reference to the draft training manual on the detection of LMOs and its future versions for the selection of testing markers for our GMO survey.

**Advice Sought**

19. Members are invited to note the relevant decisions made in COP13 and COP-MOP8, and provide views and comments in relation to the implementation of the Protocol.

**Agriculture, Fisheries and Conservation Department**
**February 2017**

[15] Section 26 of the Ordinance and Section 3, 4 and 5 of the Regulation.

[16] Article 16(2) and 17 of the Protocol.

[17] Section 6 of the Ordinance.