## INPUT INTO DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY (COP-12)

XII/24 - New and emerging issues: synthetic biology

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| **(i)How to address the relationship between synthetic biology and biological diversity.** |
| Canadian Food Inspection Agency  The relationship between synthetic biology and biological diversity depends on the scope and scale of the definition of synthetic biology. However, based on our knowledge in this capacity, we propose that the relationship between synthetic biology and biological diversity has the potential to be addressed in the same manner as with risk assessments for living modified organisms (LMOs): Case-by-case. The proposed mechanism to address this relationship will likely depend on the organism, trait(s) expressed, scope and scale of release and risk management measures in place.  Agriculture and Agri-Food Canada  Difficult to address without a firm definition. However, “synthetic biology” is a discipline, and care should be taken not to establish parameters on the relationship between biological diversity and an individual tool/technique/procedure whose use is value-neutral (need to focus on the “end product”, rather than the “process” of synbio).  With respect to “products” of synthetic biology:  •Relationship should depend on properties/characteristics/qualities/functions of the organism in question and its interaction with the local ecosystem (place-based approach).   * Environmental release of products of synthetic biology should conserve biological diversity as per the mandate of the CBD and either   a) Have a negligible impact on biological diversity, or  b) Be employed for the purposes of restricting damage to, maintaining, or improving biological diversity |
| **(ii) The similarities and differences between living modified organisms[[1]](#footnote-1) (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques.** |
| Canadian Food Inspection Agency  Once again this would depend on the definition of synthetic biology. In many cases, products of synthetic biology techniques will fall within the definition for LMOs. However, synthetic biology has the potential to create living organisms that could be significantly different from existing organisms and make use of techniques that fall outside the definition for LMOs. |
| **(iii) Adequacy of existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques.** |
| Canadian Food Inspection Agency  Based on current applications of synthetic biology, existing regulations and regulatory instruments are anticipated to be adequate for most products derived from synthetic biology techniques, from a Canadian Food Inspection Agency (CFIA) regulatory perspective. For example, in Canada it is the novelty of a plant product that triggers regulation and not the process through which it is developed. Thus, a plant product derived from synthetic biology techniques will likely trigger novelty regulation and require a pre-market safety assessment before it is authorized for food/feed use and environmental release in Canada.  Annex 3 of the Cartagena Protocol describes a comparative risk assessment approach for LMOs. In certain circumstances, existing comparative approaches are likely suitable for current applications of synthetic biology and it is anticipated that the comparative pre-market safety assessment model could be adaptable even in cases where a novel product differs vastly from existing comparators. However, for some products of synthetic biology, the choice of a comparator could be complicated and alternative approaches may be required.  Agriculture and Agri-Food Canada  •National regulatory systems for the approval/environmental release of products derived from synthetic biology techniques should be sufficient, provided they are science-based and use proper risk assessment/risk management standards   * Keep in mind, there are no direct international regulatory systems for the approval/environmental release of LMOs   •Additional purpose-based regional/international instruments such as the Biological and Toxin Weapons Convention (and Australia Group), the CBD, the OECD Harmonization of Regulatory Oversight in Biotechnology, and the International Plant Protection Convention have proven effective for supplementing national regulatory systems.   * Opportunities for other existing international fora to pursue initiatives regarding synthetic biology may be beneficial   •As synbio is relatively new, advocacy will likely be required to ensure trade-facilitative international standards (WTO-SPS) are respected and followed.  Health Canada  Health Canada regulates, evaluates and monitors the safety, efficacy, and quality of all drug products, including drug products derived from synthetic biology techniques. These activities are supported under the authority of the *Food and Drugs Act* and corresponding *Food and Drug Regulations*.  Public Health Agency of Canada  The Agency is responsible for the administration of the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR). The purpose of the HPTA and HPTR is to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins. As of December 1, 2015, anyone conducting specified activities with Risk Group 2 (RG2), RG3, and RG4 human pathogens and toxins must register under the HPTA and may require a licence. All licence applicants, who intend to carry out scientific research, must develop a Plan for Administrative Oversight of Pathogens and Toxins that sets out how they will administratively manage and control biosafety and biosecurity risks during the term of the licence.  Current biotechnology regulatory instruments may be deemed appropriate to capture organisms, products or substances derived from synthetic biology, but risk/safety assessment methodologies may not be comprehensive enough or sufficiently evolved to address new challenges. These challenges include, but are not limited to the following:   * + need for identification of appropriate comparator/surrogate organisms   + paucity of tools for predicting emergent properties of complex genetic systems   + unintended and unexpected properties from higher-order of combination of parts   + interaction between all the modular components/circuits and unexpected properties   + difficulty in predicting behaviour in natural environment (evolutionary fitness, ecological competitiveness, survival, multiplication and dispersal)   + implications with the use of non-standard biochemical systems in living cells |
| **(iv) An operational definition of synthetic biology, comprising inclusion and exclusion criteria.** |
| No comment as Canadian authorities have yet to agree on a definition. |
| **(v) Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols.** |
| Canadian Food Inspection Agency  The potential benefits and risks are anticipated to be similar to those observed with LMOs although some novel phenotypes arising from synthetic biology may provide benefits or risks that cannot be easily anticipated.  Agriculture and Agri-Food Canada  Synthetic biology techniques, as value-neutral tools, do not present a benefit or risk in and of themselves. Based on (i) the relationship between synthetic biology and biological diversity:  •Benefits and risks will be determined by the effects of the products’ interaction with other organisms naturally present in the local ecosystem, and the subsequent impacts on the conservation and sustainable use of biological diversity.   * The effects/impacts of an organism, component or product of synthetic biology on the organisms and species native to a particular region or ecosystem should be assessed using science-based criteria according to a precautionary approach, including an evaluation of any health, safety, and, where necessary, socioeconomic considerations, as per the mandate of CBD and its Protocols.   As per the mandate of the Convention and its Protocols,  •Potential benefits of synbio organisms, components and products:   * Disaster response to prevent damage to biodiversity (ex: cleaning up oil, chemical spills) * Intercepting and/or responding to emerging threats to biodiversity (ex: invasive species) * Restoring damaged ecosystems back to their original state (ex: floods, wildfire, major environmental events)   •Potential risks of synbio organisms, components and products:   * Unintended release outside of a target area/ecosystem * This may be caused by failure of biological containment mechanisms or unanticipated genetic drift * Unforeseen second- and third-order impacts on biodiversity and local flora/fauna   It should be noted that both of these risks are not unique to synbio and can also occur with naturally occurring organisms (invasive/alien species)  Public Health Agency of Canada  The synthetic biology has transformative potential to improving human health (i.e., diagnostics, disease surveillance, and therapeutic treatments), agriculture, and the environment. |
| **(vi) Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes.** |
| Canadian Food Inspection Agency  Further to our comments above, we feel that a comparative approach to pre-market safety assessment, such as is currently used for LMOs, is adaptable for use in this domain; however, some advanced products of synthetic biology techniques that differ greatly from existing living organisms may require more than one comparator or some novel approaches. Standard problem formulation approaches to pre-market safety assessments should still apply.  Agriculture and Agri-Food Canada  From an AAFC perspective, benefits of Canada’s system:  • Science-based, focused on protecting human and animal health and environmental safety   * Main role of Government is to uphold health and safety * Non-science/socioeconomic factors, such as market impacts and consumer opposition, not considered in regulatory approvals (however significant socioeconomic impacts caused by environmental damage that come to light during environmental assessments may be considered)   • Triggered by novelty (product, rather than process)   * This flexibility allows the system to keep pace with advances in biotechnology, plant breeding, etc.   In terms of monitoring, regulators also consult peer-reviewed publications and can reassess an approved product if new information concerning its safety comes to light. |
| **(vii) The degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity.** |
| Canadian Food Inspection Agency  Same comments as above, from a CFIA plant business line perspective, existing arrangements should be sufficient to address impacts and threats. It could reasonably be expected that this question will be best addressed by real experience with the products of synthetic biology but that the existing systems are sufficiently robust to evolve with the sophistication and complexity of the products.  Agriculture and Agri-Food Canada  Based on response to (iii) and (vi), existing arrangements constitute a fairly comprehensive framework to address synbio.  Some benefit may be derived from additional international instruments including synbio in their mandate/area of consideration.  However it is not necessary, and would likely prove counterproductive, for the CBD to establish any new Protocols or broaden any of its existing provisions to specifically focus on synthetic biology. As mentioned in (ii), the majority of synbio applications are covered under the Cartagena Protocol as LMOs. For those not meeting this criterion, such as “the redesign of existing natural biological systems”, the lack of novelty poses no greater risk than the original, naturally-occurring organism. Regulating based on process alone, rather than the final product, runs counter to science-based risk assessment standards and does nothing to address threats of significant reduction or loss of biological diversity. This reinforces the notion that a value-neutral technique/tool/process such as synbio should not be regulated in and of itself. |
| **(b) Information on measures undertaken in accordance with paragraph 3 of the decision, including the identification of needs for guidance.** |
| Canadian Food Inspection Agency  No comment.  Agriculture and Agri-Food Canada  **3. Urges Parties and invites other Governments to take a precautionary approach, in accordance with paragraph 4 of decision XI/11, and:**  **(a) To establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques, consistent with Article 3 of the Convention;**  Effective risk assessment and management procedures in place; Interdepartmental Working Group on Oversight of Emerging Life Science Technologies conducting review of legislation, policies and regulations.  **(c) To approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out in accordance with national, regional and/or international frameworks, as appropriate;**  Acknowledged.  **(d) To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health and addressing, as appropriate, and according to national and/or regional legislation, other issues such as food security and socioeconomic considerations with, where appropriate, the full participation of indigenous and local communities;**  Acknowledged. Scientific assessments will address food security and socioeconomic considerations only as they related to human, animal, and environmental health and safety impacts, as per previous comments in (vi).  **(e) To encourage the provision of funding for research into synthetic biology risk assessment methodologies and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socioeconomic considerations;**  Acknowledged. Funding for positive and negative impacts on conservation and sustainable use of biodiversity (as per benefits and risks listed in (v)) may be encouraged by Interdepartmental Working Group on Oversight of Emerging Life Sciences. Interdisciplinary research by regulatory Departments/Agencies remains focused primarily on scientific health, safety, and environmental outcomes, not socioeconomic impacts, as per previous comments in (vi).  **(f) To cooperate in the development and/or strengthening of human resources and institutional capacities, including on methodologies for risk assessments in synthetic biology and its potential impacts on biodiversity, in developing countries, in particular the least developed countries and small island developing States, and countries with economies in transition, including through existing global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement. The needs of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, for financial resources; access to and transfer of technology consistent with Article 16 of the Convention; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, should be taken fully into account in this regard;**  Acknowledged. Canada will continue to actively participate in international fora with mandates to assist developing countries and small island developing States develop methodologies for risk assessments and establish and strengthen regulatory frameworks for synbio. |
| **(c)Further information on the components, organisms and products resulting from synthetic biology techniques that may have impacts on the conservation and sustainable use of biological diversity and associated social, economic and cultural considerations.** |
| Canadian Food Inspection Agency  No comment.  Agriculture and Agri-Food Canada  AAFC may conduct a literature review of existing studies on the impacts of synthetic biology on the conservation and sustainable use of biological diversity. |

**APPENDIX 1**

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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

Twelfth meeting

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Agenda item 24

## DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

XII/24. New and emerging issues: synthetic biology

*The Conference of the Parties,*

*Reaffirming* paragraph 4 of decision XI/11, in which it recognized the development of technologies associated with synthetic life, cells or genomes, and the scientific uncertainties of their potential impact on the conservation and sustainable use of biological diversity, urged Parties and invited other Governments to take a precautionary approach, in accordance with the preamble of the Convention and with Article 14, when addressing threats of significant reduction or loss of biological diversity posed by organisms, components and products resulting from synthetic biology, in accordance with domestic legislation and other relevant international obligations,

*Noting* decision BS-VII/12 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, recommending a coordinated approach on the issue of synthetic biology taking into account that the provisions of the Cartagena Protocol may also apply to living organisms resulting from synthetic biology,

1. *Takes note* of the conclusions of the Subsidiary Body on Scientific, Technical and Technological Advice at its eighteenth meeting, as contained in paragraph 1 of recommendation XVIII/7*, recognizes* that this issue is of relevance to the Conventionand *concludes* that there is currently insufficient information available to finalize an analysis, using the criteria set out in paragraph 12 of decision IX/29, to decide whether or not this is a new and emerging issue related to conservation and sustainable use of biodiversity;

2. *Awaits* the completion of a robust analysis using the criteria set out in paragraph 12 of decision IX/29;

3*. Urges* Parties and *invites* other Governments to take a precautionary approach, in accordance with paragraph 4 of decision XI/11, and:

(a) To establish, or have in place, effective risk assessment and management procedures and/or regulatory systems to regulate environmental release of any organisms, components or products resulting from synthetic biology techniques, consistent with Article 3 of the Convention;

(c) To approve organisms resulting from synthetic biology techniques for field trials only after appropriate risk assessments have been carried out in accordance with national, regional and/or international frameworks, as appropriate;

(d) To carry out scientific assessments concerning organisms, components and products resulting from synthetic biology techniques with regard to potential effects on the conservation and sustainable use of biodiversity, taking into account risks to human health and addressing, as appropriate, and according to national and/or regional legislation, other issues such as food security and socioeconomic considerations with, where appropriate, the full participation of indigenous and local communities;

(e) To encourage the provision of funding for research into synthetic biology risk assessment methodologies and into the positive and negative impacts of synthetic biology on the conservation and sustainable use of biodiversity, and to promote interdisciplinary research that includes related socioeconomic considerations;

(f) To cooperate in the development and/or strengthening of human resources and institutional capacities, including on methodologies for risk assessments in synthetic biology and its potential impacts on biodiversity, in developing countries, in particular the least developed countries and small island developing States, and countries with economies in transition, including through existing global, regional and national institutions and organizations and, as appropriate, by facilitating civil society involvement. The needs of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, for financial resources; access to and transfer of technology consistent with Article 16 of the Convention; establishing or strengthening regulatory frameworks; and the management of risks related to the release of organisms, components and products resulting from synthetic biology techniques, should be taken fully into account in this regard;

4. *Decides*, subject to the availability of resources, to establish an Ad Hoc Technical Expert Group, with terms of reference contained in the annex to the present decision, to be convened after the Executive Secretary has completed the requests in paragraph 7 below;

5. *Invites* Parties, other Governments, relevant organizations and stakeholders to submit information to the Executive Secretary relevant to the work of the Ad Hoc Technical Expert Group established by the present decision, as well as on measures undertaken in accordance with paragraph 3 above, including the identification of needs for guidance;

6. *Invites* Parties, other Governments, relevant international organizations, indigenous and local communities and relevant stakeholders to continue to provide further information to the Executive Secretary in response to decision XI/11, paragraph 3 (a);

7. *Requests* the Executive Secretary, subject to the availability of financial resources:

(a) To make available the information reported in accordance with paragraphs 5 and 6 above, through the clearing-house mechanism of the Convention and other means;

(b) To convene a moderated open-endedonline forum[[2]](#footnote-2) to support the work of the Ad Hoc Technical Expert Group established in paragraph 4 above in meeting its terms of reference;

(c) To prepare an updated report on the work specified in paragraphs 3 (a), 3 (b) and 3 (c) of decision XI/11, taking into account information submitted in paragraphs 5 and 6 above and a synthesis of the outcomes of the process mentioned in paragraph 7 (b) and to submit these for consideration by the Ad Hoc Technical Expert Group;

(d) To submit for consideration by a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties, the peer‑reviewed reports of the outcomes of the process mentioned in paragraphs 7 (b) and 7 (c) above;

8. *Invites* relevant organizations, including relevant United Nations organizations and bodies, to consider the possible implications of synthetic biology as it relates to their mandates.

*Annex*

**TERMS OF REFERENCE FOR THE AD HOC TECHNICAL EXPERT GROUP  
ON SYNTHETIC BIOLOGY**

The Ad Hoc Technical Expert Group will include balanced representation of Parties from all regions and include representation of indigenous and local communities and all relevant stakeholders, including other Governments, with knowledge of the Convention and its Protocols,[[3]](#footnote-3) and will report on its work to a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties.

The Ad Hoc Technical Expert Group will:

(a) Take note of the exchange of views on how to address the relationship between synthetic biology and biological diversity;

(b) Identify the similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques to determine if living modified organisms derived from synthetic biology fall under the scope of the Cartagena Protocol;

(c) Identify if other national, regional and/or international instruments adequately regulate the organisms, components or products derived from synthetic biology techniques in so far as they impact on the objectives of the Convention and its Protocols;

(d) Work towards an operational definition of synthetic biology, comprising inclusion and exclusion criteria, using all relevant information, based on scientific and peer-reviewed studies;

(e) Identify the potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols;

(f) Building on the work on risk assessment and risk management undertaken by the Cartagena Protocol, compile information on best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes and to help those Parties and other Governments to regulate organisms, components and products from synthetic biology techniques appropriately;

(g) Identify if the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology relevant to the objectives of the Convention on Biological Diversity and its Protocols, in particular threats of significant reduction or loss of biological diversity.

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1. As defined in the Cartagena Protocol on Biosafety, a “living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. A “living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids. “Modern biotechnology” means the application of: a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid

   into cells or organelles, or b) Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. [↑](#footnote-ref-1)
2. The open-ended online forum will be open to all interested participants and continue for a finite period of time. [↑](#footnote-ref-2)
3. The Ad Hoc Technical Expert Group will be convened in accordance with the *modus operandi* of the Subsidiary Body on Scientific, Technical and Technological Advice, except that there will be 5 to 8 experts nominated by each of the five regions. [↑](#footnote-ref-3)