## CBD NOTIFICATION 2017-025:

**Submission of information on synthetic biology**

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| 1. **Research, cooperation and activities on the benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity**
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| The term synthetic biology is generally not used to classify research and other activities in Canada. No specific research, cooperation or activities have been identified by Federal Government Departments on the benefits and potential adverse effects of organisms, components or products of synthetic biology on biodiversity.  |
| 1. **Evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention (**namely the conservation of biological diversity (or biodiversity); the sustainable use of its components; and the fair and equitable sharing of benefits arising from genetic resources.)
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| Environment and Climate Change Canada: There is no evidence to date that a so-called product of synthetic biology has had an adverse effect. ECCC does not possess information on evidence of benefits. Canadian Food Inspection AgencyThe 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 CanadaSynthetic 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 synthetic biology 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 synthetic biology 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 synthetic biology and can also occur with naturally occurring organisms (invasive/alien species)Public Health Agency of CanadaSynthetic biology has transformative potential to improving human health through disease surveillance, diagnostics, preventative and therapeutic treatments, and response to public health emergencies.  |
| 1. **Experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks**
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| Canadian Food Inspection AgencyA 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 CanadaFrom 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.Environment and Climate Change CanadaProducts of biotechnology are regulated in Canada according to the principle that it is the ‘new’ or ‘novel’ product, that is regulated and not the particular process that was used to modify it; this principle is not triggered by whether or not that process was termed ‘synthetic biology’ although technologies we might associate with synthetic biology might have been used. In one example in which one could apply the term ‘synthetic biology’, a microorganism had had dozens of genetic modifications to modify a specific biochemical pathway. The lesson learned in this specific case was that more time to conduct the risk assessment would be needed in order to consider the sum total of the number of modifications. The risk assessment framework itself, however, was still relevant.  |
| 1. **Examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology**
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| CFIAEnvironment and Climate Change CanadaThere are no examples of risk management that ECCC is aware of regarding the organisms that are the products of synthetic biology. Agriculture and Agri-Food CanadaEffective risk assessment and management procedures in place. .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 synthetic biology products. |
| 1. **Regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology**
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| Environment and Climate Change CanadaThe *Canadian Environmental Protection Act* and its *New Substances Notification Regulations (Organisms)* are the relevant legislation for certain micro-organisms and animals that are the products of synthetic biology in terms of biodiversity protection. Canadian Food Inspection AgencyBased on current applications of synthetic biology, existing Canadian Food Inspection Agency (CFIA) regulations are anticipated to be adequate. 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 may or may not trigger a pre-market safety assessment before it is authorized for use in livestock feed 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 may be 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.The Canadian Food Inspection Agency’s Plant Biosafety Office regularly requires product stewardship plans for Plants with Novel Traits that have herbicide tolerance and/or insect resistance traits. These stewardship plans are intended to manage risks to the environment posed by these traits and to encourage grower practices that will protect the longevity of the novel traits. 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• 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 synthetic biology is relatively new, advocacy will likely be required to ensure trade-facilitative international standards (WTO-SPS) are respected and followed.* Existing arrangements constitute a fairly comprehensive framework to address synthetic biology.
* Some benefit may be derived from additional international instruments including synthetic biology 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 previously, the majority of synthetic biology 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 synthetic biology should not be regulated in and of itself.

Health CanadaHealth 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*.Health Canada also regulates, evaluates and monitors the quality, health and environmental risks, and value of all pest control products, including products derived from synthetic biology techniques. These activities are supported under the authority of the *Pest Control Products Act* and corresponding Pest Control Products Regulations.Public Health Agency of CanadaThe 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 that are naturally occurring, genetically modified or synthetically produced.. 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
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| 1. **Knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology.**
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| Assembly of First Nations statement on Honouring Earth: <http://www.afn.ca/en/honoring-earth> |