Response to Review of the *New Substances Notification Regulation (Organisms)* : Proposed Approach to Modernize NSNR (Organisms)
As per Stakeholder Engagement Document (Pre-*Canada Gazette*, Part I Consultation)

Submitted by the Canadian Biotechnology Action Network (CBAN)
To Environment and Climate Change Canada Substances@ec.gc.ca
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CBAN brings together 15 groups to research, monitor and raise awareness about issues relating to genetic engineering in food and farming in Canada. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups. CBAN has over a decade of experience in researching and monitoring the impacts of genetically modified organism (GMOs), including examining the issues raised by the possible release of genetically engineered trees. CBAN is a project of MakeWay's shared platform. www.cban.ca

Overview

The range of living modified organisms produced through biotechnology, and specifically through genetic engineering (here also referred to as genetic modification or GM, and including gene editing), proposed for research, contained production, and environmental release is expected to increase in volume and diversity, including higher life forms and microorganisms. Many future applications of genetic engineering will raise new and serious environmental risk questions, as well as profound social, economic and ethical questions.

The precautionary principle is one of the guiding principles of CEPA and it is clear that, in order to enhance protection of human health, the environment, and biodiversity in Canada, the NSNR need to carefully incorporate the application of the precautionary principle. This is particularly the case because many future proposed uses of genetically modified organisms (GMOs), such as GM microorganisms and GM insects, will pose serious threats and risk irreversible damage. Many applications will require extreme caution and the regulations need to be adequate to protect against rare but potentially disastrous risks. To be future-proof, the regulations need to be able to adequately regulate as-yet-unimagined applications of genetic engineering and to also accommodate full consideration of the complexity of the technology and of the receiving environment. One certainty is that both the GM techniques and our knowledge of the receiving environment with change and advance over time. The limitations of our tools and knowledge for assessing the

environmental risks must be recognized.

One major concern to be addressed is the contamination threat which, as our experience with genetically modified animals in Canada already shows, is not limited to small organisms.[1] For example, large GM organisms (pigs) in contained production have been inadvertently placed in the food system on at least two occasions. The record of escape and contamination incidents with GMOs in Canada demonstrates that the level of intended release of an organism can be different from the ultimate reality. This record shows the predictable role of human error and demands regulatory attention to seemingly improbable risk scenarios.

We note that the stated objective in developing a modernized regulatory framework is to enhance protection of human health, the environment, and biodiversity in Canada; strengthen transparency of the regulatory oversight for living organisms; increase regulatory efficiency, and; support innovation within a scientific risk-based regulatory regime, and that, "This phase of the NSNR (Organisms) modernization is focussed on three key themes, namely: (1) Improving openness and transparency; (2) Responding to advances in science and technology; and (3) Reducing regulatory inefficiencies."

We note the use of both policy and regulatory tools to meet these goals but caution that some proposals are reliant on policy tools where action should, or could additionally be, formalized in regulation. At the same time, it is clear that policy is needed to address the challenges ahead. For example, we recommend legislation to prohibit gene drives.

In the context of recent decisions by Health Canada and Canadian Food Inspection to exempt many gene edited organisms from pre-market regulation, we stress the need for government oversight over all products of genetic engineering including new techniques of gene editing.[2] Federal governmental authority over the use and release of living modified organisms is necessary to future-proof regulation in the context of rapidly changing technology as well as changing environmental conditions due to climate change.

The priority of the NSNR (Organisms) to ensure safety cannot be compromised to the "reduce the regulatory burden." Product developers will refer to risk assessment and management measures as a "regulatory burden" regardless of the need for such measures in order to protect human health, the environment, and biodiversity. In relation to government regulation of GMOs, redundancies should be understood as safeguards.

All higher organisms need to be subject to the same information requirements regardless of proposed/anticipated exposure, and plans for containment should be understood as intentions/systems that can fail.

Public Engagement

Despite the fact that the stakeholder engagement document states that the department, "has clearly heard from stakeholders that they are looking for enhanced opportunities for engagement and meaningful participation in the regulatory decision making process for new living organisms," non-vertebrates and "prescribed living organisms" remain subject only to "voluntary engagement." This remains a key concern for our organization, as detailed in our submission of January 30, 2023.[3]

Risk Assessment Timelines

In regards to mandatory consultations, we welcome the proposal (4.1.1) to lengthen the risk assessment timelines to accommodate public comment periods and a meaningful regulatory consideration of/response to those comments. However, we further **recommend a removal of defined timelines** so that timelines do not function as a constraint on fulsome risk assessment.

A removal of risk assessment timelines is especially needed because of the possible diversity of hitherto unimagined proposals for the use of GMOs that regulators may be confronted with, along with the sheer volume at any given time. The priority of enhancing the protection of human health, the environment, and biodiversity in Canada could be compromised by artificially constructed timelines that do not accommodate the time needed to grapple with complexity and uncertainty.

Constraining assessments to specific timelines may also create unnecessary pressure on regulators. Regulators need to be empowered with the flexibility to fully address the risk questions posed, in service of the primary goal to enhance protection of human health, the environment and biodiversity.

While moving timelines to guidelines may increase the time taken to reach some decisions, this increased time would be necessary and any resulting increase in the "regulatory burden" for regulated parties would be due to the required rigour of the risk assessment itself.

Set timelines could prove to be a dangerous contrivance. The removal of specified, arbitrary timelines would accord with the application of the precautionary principle.

Monitoring and Post-Assessment Review

We welcome the articulation that, "CEPA is designed to remain adaptive and agile (i.e., responsive) to new information that becomes available following the risk assessment in order to provide regulatory oversight of animate products of biotechnology throughout their lifecycle" along with the acknowledgement that there are many new living organisms that could be proposed where there is no history of safe globally.

We agree that regulatory oversight should be established to allow for ongoing and/or long-term monitoring and reporting requirements under CEPA for new living organisms based on the level of risk they pose.

We welcome the proposal to proactively and predictably exercise the existing authorities under CEPA to help to ensure that new and relevant scientific information is incorporated in the regulation of living organisms in Canada on an ongoing basis, thus accounting for any information that would not have been available at the time of the initial assessment. **However, we pose the question: What further authorities could be employed and/or established in regulation for this purpose?**

We welcome the proposal to develop a policy to prioritize organisms for post-assessment review, to identify if new and relevant scientific information that has become available would impact the conclusion of the original risk assessment. However, for those GMOs identified as priorities for this purpose, there should be a formal process to signal regulator

attention. This is required to ensure that new information does in fact come to the attention of regulators, without precluding the review of new information at any other time. We therefore **propose that, in addition, the regulations incorporate a specific obligation for review of listed organisms at specific intervals**. These reviews would survey the scientific literature but would also need to cast a wider net in order to examine emerging developments that may not yet be discussed in the peer reviewed literature such as escape incidents or other issues observed in the field.

We also raise the issue that successful monitoring in the environment is not possible for some living organisms, such as microorganisms or insects, and their impacts cannot therefore be reliably tracked and studied. Risk assessments should also therefore consider the question of the ability to monitor because **some organisms released into the wild will be unmonitorable**. Where there are limits to monitoring, there are limits to post-release assessment. While monitoring can be viewed as one tool to mitigate potential risks, this is less the case where release of GMOs is irreversible. In this case, monitoring may be less relevant to risk management because few remedies will be possible.

Regulations for Higher Organisms Commensurate to the Level of Intended Release

We caution that the intended level of release is the not the same as the actual level of release. We argue that all organisms should be assessed to determine if they are CEPA toxic, regardless of the containment plans.

As documented by the Canadian Biotechnology Action Network in our 2019 report, twenty-five years of experience with GMO escape warns that it will be challenging to develop regulatory requirements that reflect, as proposed, "the nature and degree of possible environmental exposure by considering some of the different circumstances under which an organism may be imported or manufactured in Canada, such as in contained facilities, as part of experimental field studies, or in accordance with confinement procedures."[4] Proposals for containment should not be used to limit risk assessment.

We therefore do not support a new shorter Schedule for the import or manufacture of higher organisms into a contained facility, and for the import or manufacture as part of an experimental field study.

We are additionally concerned that a new definition for "contained facility" (that "would require notifiers to have physical and operational requirements in place such that they can demonstrate the prevention of release of the organism or its biological materials") **not assume that the articulation of a plan for containment is the same as 'demonstrating' containment**. A plan for containment is an articulation of the intention and attempt to contain organisms. Such plans can fail.

We stress that the definition of "containment" or "contained facility" should not include attempts at biological containment such as sterility (e.g. via triploidy or genetic use restriction technology), or "methods used to inactivate organisms" or otherwise render them irrelevant (e.g. the curly wing of the *EntoEngine*). Such proposals to genetically engineer sterility or implement other means of biological containment are unreliable and particularly vulnerable to failure, e.g. due to changes in genetic expression triggered by exposure to environmental stresses.

In relation to animate products of biotechnology, containment plans and intentions should not be used to differentiate regulatory requirements. **Regulations should not be "streamlined" for higher organisms commensurate with the level of intended release** because containment plans have repeatedly failed. Standards, guidelines, or regulations can be overlooked, underused, or neglected by self-interested product developers and users who are seeking efficiencies for profit-making.[5] It is the role and responsibility of the federal government to ensure environmental protection and safety in the public interest. All efforts should be made to strengthen government regulation, including of reporting containment failures, and ensure government oversight rather than allow for corporate self-regulation.[6] ECCC needs to assess the potential ecological and health impacts of escape in all scenarios.

The only way to prevent contamination from certain GMOs is to stop their release. Some GMOs are too prone to escape and others have impacts that are too serious if escape occurs. This needs to be recognized and understood in policy and regulation. Commensurate with the consequences of escape, in some cases, minimizing the risks associated with accidental release will require preventing this risk by not allowing research and development and/or production. This approach is consistent with the Precautionary Principle.

Other

Templates: We agree that the inclusion of formal information requirements for regulated parties will assist consistent government oversight.

Control Organisms: While we welcome the inclusion of control organisms in the definition of R&D Organism we remain concerned that all R&D Organisms should be subject to risk assessment.

Vulnerable Environments: We welcome the concern about vulnerable environments while stating our concern that other environments not be marginalized by this consideration.

Policy recommendations

As the proposals also outline the use of policy options, we add the following policy recommendations:

The federal government should establish long-awaited mandatory labelling of all GMOs and ratify the Cartagena Protocol on Biosafety.

Environment and Climate Change Canada should develop policy and regulatory instruments to **prevent the production and release of certain categories of GMOs such as gene drives and the release of genetically engineered insects and microorganisms**, that are accompanied by huge uncertainty, cannot be monitored or recalled and could therefore result in impacts that are irreversible. The federal government should prohibit the use of gene drive technology and support a prohibition at the international level. These actions are consistent with the application of the precautionary principle, as required. In addition to presenting unnecessarily risks, these GMOs would be costly to regulate and such prohibitions would establish clear regulatory efficiencies.

[1] Canadian Biotechnology Action Network (CBAN). 2019. GM Contamination in Canada: The failure to contain living modified organisms – Incidents and impacts. https://cban.ca/contaminationReport2019 ; Canadian Biotechnology Action Network (CBAN). 2022. GM Contamination Update: Animals. February 22. https://cban.ca/wp-content/uploads/GM-Contamination-Animals-Feb-2022-Update.pdf

[2] Canadian Biotechnology Action Network (CBAN). 2023. New Proposals Would Eliminate Transparency on GMOs in Canada, April 13. https://cban.ca/wp-content/uploads/New-proposals-would-eliminate-transparency-on-GMOs-in-Canada-3.pdf

[3] Canadian Biotechnology Action Network (CBAN) 2023. Response to the Discussion Paper for Consultation Review of Part 6 of the Canadian Environmental Protection Act, 1999 (CEPA) and the New Substances Notification Regulation (Organisms) January 30. https://cban.ca/wp-content/uploads/CBAN-response-re-CEPA-Part-6-and-NSNR-Jan-2023.pdf

[4] Canadian Biotechnology Action Network (CBAN). 2019. GM Contamination in Canada: The failure to contain living modified organisms – Incidents and impacts. https://cban.ca/contaminationReport2019

[5] For example, see allegations of practices in AquaBounty's production of GM salmon: Block Corporate Salmon Campaign (2022) AquaBounty Exposed, October 25. https://cban.ca/wp-content/uploads/AquaBounty-Exposed-REPORT-public.pdf and Canadian Biotechnology Action Network (2022) GM Contamination Update: Animals. February 22. https://cban.ca/wp-content/uploads/GM-Contamination-Animals-Feb-2022-Update.pdf

[6] 2021. Joint letter from 105 groups to the Minister of Health and the Minister of Agriculture and Agri-Food. Call for Transparency and Government Oversight of All Genetically Engineered Foods and Seeds: No Regulatory Exemptions. November 17. https://cban.ca/wp-content/uploads/105-Groups-Call-for-Transparency-GMOs-Nov-2021.pdf