**Submitted by the Canadian Biotechnology Action Network (CBAN)**
**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)**

Submitted to Environment and Climate Change Canada back 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), proposed for production is expected to quickly increase in volume and diversity. Many precedents will be set through these ECCC assessments, including the current assessment of the safety of producing the first GM insect ("EntoEngine" GM fruit fly, NSN 21233[1]). Many new applications of genetic engineering are expected to raise profound environmental, social, and economic questions. Few of these questions are considered in government risk assessment processes.

Genetic engineering allows us to assert unprecedented direct power over organisms and natural systems. Applications of the technologies are moving from food and fuel production to proposals to release GE insects and trees into the wild to alter ecosystems.

The category of biotechnology includes genetic engineering but the description of biotechnology in the Discussion Paper situates genetic engineering in a historical continuity where "humans have used biotechnology for thousands of years." However, there is little continuity between "the production of cheese and bread" and, for example, the request before ECCC to approve the production of the "EntoEngine" genetically engineered fruit fly for use as a protein "bioreactor" in the production of cellular meat. Such contrived

associations are disconnected from the reality of how new genetic engineering techniques have allowed us to overcome the boundaries of reproduction, to move genes between species that would never mate in nature, and the new techniques that now promise tools to overcome the rules of inheritance. Even while, as mentioned in the Discussion Paper, ECCC insists on "technology-neutral" approach in terms of risk assessment, the risks inherent in processes of genetic engineering are highly relevant to risk questions.[2] For sound risk and technology assessment, the power of genetic engineering from both a scientific and societal viewpoint needs to be recognized and confronted.

As mentioned in the Discussion Paper, future requests to ECCC could include those to allow the use of gene drive organisms to modify, suppress, or eliminate wild species (a new survey finds 32 insect targets from six different orders are under development or have been proposed for development in the scientific literature or from another academic source[3]). The release of gene drives would be irreversible and cross national and territorial boundaries. Once released, gene drive organisms cannot be recalled nor controlled and release would therefore pre-empt and override the ability of governments, Indigenous Peoples, local communities, and future generations to take their own decisions. Their release will result in unpredictable effects on ecosystems. In the worst-case scenario, they could lead to further species extinction and the collapse of entire ecosystems, as well as endangering human health and food security. The risks and implications of gene drive release demand a response that applies the Precautionary Principle.

**We therefore ask the federal government to establish a ban on the release of gene drive organisms.**

The federal government has not yet taken the opportunity to evaluate the experience in Canada with genetically engineered crops and foods (genetically modified organisms or GMOs). There are observable economic, environmental and social impacts from over two decades of using GM crops that could provide important lessons to be applied in the question of NSNR (Organisms) review and to the assessment of the environmental risks of producing living organisms produced through biotechnology. Such an examination could also assist in identifying issues relevant to ECCC efforts to "modernize" the regulation of GMOs, such as highlight the current limitations in GMO tracking and tracing/data gathering.

For example:

- **Herbicide-tolerant crops:** The Canadian Food Inspection Agency (CFIA) approved the release of genetically engineered herbicide-tolerant (HT) crops (corn, canola, soy, sugar beet, and alfalfa) without a full assessment of the possible systematic and long-term impacts of their use on agricultural practice and the environment. The CFIA continues to approve new HT crops and allow the stacking of multiple GM herbicide-tolerant traits without evaluating, holistically, the impacts of herbicide-tolerant cropping systems and their expansion, which is now further facilitated by each new approval. The COSEWIC recommendation (2016) that the Monarch butterfly be classified as an endangered species in Canada named the role of herbicide-tolerant crops in critical habitat destruction, for example.[4] The CFIA has seemingly not assessed the connection between HT crop use and the increase in herbicide sales in Canada - 234% since GM crops have been introduced (1994 and

2020) – and related environmental and health impacts of any increased herbicide use.[5] **We ask that ECCC undertake holistic environmental assessment.**

- **GM Atlantic salmon:** CBAN and other environmental groups have raised concerns about the long-term and wider impacts of permitting GM salmon production beyond site-specific impacts that have been assessed.[6] Groups have raised the concern that the approval of one or more locations for GM salmon production could facilitate the gradual expansion of production to many more and diverse locations that could increase the risk of escape. To illustrate: the company AquaBounty first sought approval to produce up to 100,000 GM Atlantic salmon eggs at Bay Fortune PEI, to be shipped to Panama for grow-out and processing, but this changed to a proposal (now approved) produce the GM salmon in PEI (and increase egg production). The company has since built a production site in the US and is constructing another in the US, and says it plans to build a new site every two years (naming various countries around the world as possible sites).[7] Large-scale commercial production could involve the raising of GM salmon in the millions at numerous facilities, in diverse locations and ecosystems across the world. As the scale of an operation increases, the chances of escape increase, as does the probability that some escapees will be fertile and capable of breeding with wild Atlantic salmon and/or other species. Similarly, while there may be no risk to the environment in Canada, Canada's approval of the ornamental aquarium "Glofish" is, arguably, connected and complicit in the production of these GM fish in other countries - where researchers have found escaped GM "Glofish" (zebrafish) multiplying in streams in Brazil.[8] **We ask that ECCC undertake scoping in risk assessment that considers how single product/production site approvals may have wider and future implications for environmental safety.**

- **Glyphosate-tolerant alfalfa:** CBAN has documented market losses and other economic costs of GM commercialization.[9] The long-term environmental and economic impacts of GM alfalfa were not considered by the Canadian Food Inspection Agency,[10] and the CFIA approved the sale of glyphosate-tolerant alfalfa despite the objections of a wide range of farmers across Canada.

    - In 2017, 15 farm groups called for the government to cancel variety registration for all GM alfalfa until a full economic impact assessment is conducted.[11]
    - On April 9, 2013, protests were held in 38 communities as part of the "Day of Action to Stop GM Alfalfa," called for by the National Farmers Union of Ontario.[12]
    - In 2013, 140 groups from across Canada, including farmer associations and farm businesses, signed a statement opposing the sale, trade and production of GM alfalfa, saying "We want the public to understand the hazards, costs and market losses that would result if GMO Alfalfa were released into our environment."[13]

  **We ask that ECCC solicit and consider the concerns of affected communities, who may identify economic, social and ethical concerns.**

The challenge of assessing the risks of new GE products such as gene drives whose impacts will not be fully observed or understood for many generations comes into sharp focus with

the current proposal to release the genetically engineered American chestnut into the forests of the US (a proposal that may also be before the CFIA) (please see our comments to the US Department of Agriculture, December 22, 2022[14]).

In this context, we take this opportunity to also raise our concern that Canada has not yet ratified the Cartagena Biosafety Protocol whose objective is to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, specifically focusing on transboundary movements. **We ask that the federal government ratify the Cartagena Biosafety Protocol.**

In 2016, the Canadian Biotechnology Action Network made the following recommendations to the House of Commons Standing Committee on Agriculture and Agri-Food in their hearings on "Genetically Modified Animals for Human Consumption":

- There needs to be an assessment of economic impact before any GM product is approved for release;
- There is a need to strengthen environmental risk assessment including a need to assess the long-term, system-wide risks of each GM product and the use of this technology as a whole;
- Canada need systems for tracking and tracing all GM organisms;
- Canadians need transparency in regulation;
- Canadian consumers need mandatory labelling of all GM foods in the grocery store.

CBAN argued for a moratorium on the introduction of GM animals until Canadians have a chance to be heard, and until changes are made to increase the government's ability to regulate GM organisms (GMOs) and foods, including tracking and traceability, and transparency including mandatory GM food labelling. **The development and commercialization of GM animals in Canada should be subject to wide, national public debate.**

We note that this NSRR (Organisms) "pre-consultation" is ill-timed because it is happening while the Canadian Environmental Protection Act (CEPA), the statute governing these regulations, is being debated in the House of Commons Standing Committee on Environment and Sustainable Development. We recall a recent, similarly backwards process where Health Canada made important changes to regulatory guidance on GM foods while simultaneously announcing it will make proposals to change the regulations to "reflect" the guidance.[15] **We urge all federal departments to carefully coordinate the timing and content of processes between reviews, and public consultations, of regulatory guidance, regulations, and laws.**

## 4.1 Improving openness and transparency

The Discussion Paper notes that the first key driver for modernization is improving openness and transparency. It states,

- "The benefits to expanding transparency are clear: it builds public trust and improves the credibility of the regulatory process; provides Canadians with an opportunity to

make their voices heard and contribute to the regulatory process and improves the overall openness and accessibility of the regulations to the public."

- "Openness and transparency in the regulation of new organisms is important to Canadians' ability to make informed choices about the products they use and substances in the environment, and bolsters confidence in the regulatory process and regulatory decisions. As such, we are committed to improving openness and transparency in those areas of the regulatory process that are of the greatest concern for Canadians."

Despite these statements, the question is raised of "balancing enhanced transparency with potentially prolonging the time it takes to come to regulatory decisions." However, transparency is a priority that cannot be compromised.

### 4.1.1 Openness in risk assessments and decision-making

#### 4.1.1.1 Voluntary Public Engagement Initiative

**1. What would you consider to be effective forms of engagement and meaningful public participation other than Public Engagement Initiative, VPEI? What improvements to VPEI could be made?**

**The use of voluntary processes by federal departments for providing information to the public and inviting public "engagement" needs to be replaced with mandatory reporting/processes.**

The New Substances program of "Voluntary Public Engagement Initiative" runs counter to (obstructs) both the goals of transparency and public engagement. The VPEI is not a legitimate form of public engagement for two core reasons:

Firstly, this is a voluntary mechanism where the public is only invited to comment on the risk assessment of those products that product developers voluntarily choose to make public. As it is voluntary, this system relies on the cooperation of product developers. This arrangement therefore permits companies to withhold notice of requests for approval from the Canadian public.

Secondly, the VPEI provides no real information on the GMO in question beyond a few lines describing the GMO and its purpose, all of which is provided by the product developer itself and is not, seemingly, verified by ECCC. For example, in the current case of the "EntoEngine" GM fruit fly, two short paragraphs were provided for public comment.[16]

- In 2018, in relation to GM salmon, CBAN stated that, "The public engagement initiative lacks transparency and, because it provides no information of substance, it is too vague to allow for relevant scientific comment and meaningful public participation."[17]

- In 2018, 28 groups requested "transparency and precaution" from the Minister of Environment and Climate Change Canada in relation to the assessment of the GM Atlantic salmon: "We see notice that Environment and Climate Change Canada is currently assessing the risks and toxicity, as per the Canadian Environmental Protection Act, 1999, of releases to the environment due to rearing GM

"AquAdvantage" salmon for commercial sale. This notice was lacking any specifics and we have requested basic information regarding the facilities and locations under consideration. We continue to request transparency in this process."[18]

- In 2010, public interest groups in PEI asked the Premier to insist Environment Canada notify the Government of Prince Edward Island when it begins an environmental assessment for GE salmon egg production in the province, that the province be consulted on environmental risk questions and be notified immediately if approval is granted.[19]

The Discussion Paper notes that, "Participation in public comment periods tends to be highly variable, with some reports receiving many comments and some receiving very few." We suggest that participation in the VPEI is variable due to factors including uneven access or minimal awareness of notifications as well as the lack of information provided in the VPEI. Engagement cannot be expected where information is lacking.

The paper reports that, "While most of the comments received have not been the scientific information, test data, and traditional knowledge originally sought by the VPEI…" It is hard to see how the VPEI can expect scientific information in response to a total absence of data or detail of any relevance provided.

(We note that the Discussion Paper says, "Through the VPEI, risk assessment reports for higher organisms are published for a public comment period." However, we understand that the VPEI does not provide risks assessment reports for comment but that ECCC provides a summary of risk assessments after approval decisions have been made. Please provide precision on this point.)

We also note with concern that the VPEI uses what we presume is the company's own description of its GMO and utility of the GMO. For example, in the 2018 VPEI on the GM Atlantic salmon, the summary repeats AquaBounty's claim that they are constructing new production facilities "to meet the growing global demand for AquAdvantage salmon." However, ECCC did not evaluate the accuracy of this statement, and there is no data to support it. This company assertion was one line out of five that was provided to describe the technology and the production intent of the company.

In noting that most comments submitted to the VPEI have not been the scientific information sought, the Discussion Paper continues that, "…the initiative has nonetheless given stakeholders a chance to participate in risk assessments and have their concerns heard, helping to promote confidence in the regulatory process." This statement adds to our concern that the VPEI is not designed as a genuine tool for public comment and involvement, but is a superficial public engagement exercise to serve public relations purposes. The Discussion Paper states, "The aim of the VPEI is to provide for public participation and allow stakeholders to share scientific information, test data, and traditional knowledge related to potential risks to the environment or human health from the new living organisms, so that this information can be incorporated early on in the risk assessment process. While the aim of the VPEI is to collect information that can be incorporated into the risk assessment process, it also gives an opportunity for Canadians to provide input into the process." However, it is not clear that the VPEI provides an opportunity for the public to provide input into the process if these concerns cannot be addressed. If there are no mechanisms to respond to public concerns and incorporate them into risk assessments, these concerns may not be described as "heard."

We also note our concern that the risk assessment timeframe is limited to 120 days (unless extensions are added) and public comment is invited during this timeframe, offering little time for the public to consider the request and little time for ECCC to consider public comment. A longer timeframe for public comment is needed, happening before risk assessment begins (and the timeline for this risk assessment should not be constrained).

**Meaningful public engagement would necessarily require providing more information than the few lines currently provided to the public through the VPEI, and it would require mandatory notification to the public of requests for GMO approvals.**

CBAN has long critiqued such limited, voluntary federal government "engagement" that invites public comment without providing meaningful information and without real mechanisms to respond to public comments (see, for example, CBAN's 2012 concerns about the Canadian Food Inspection Agency's Biotechnology Notices of Submission Project[20]). The need for true transparency via mandatory mechanisms is of the upmost urgency because Health Canada has also recently implemented of a "Voluntary Transparency Initiative" in relation to some GM foods and the CFIA is proposing a similar reliance on voluntary corporate reporting in relation to some GM gene-edited seeds (see our analysis of the implications for transparency in our 2022 report "New Proposals Would Eliminate Transparency on GMOs in Canada"[21]). In 2021, 105 groups in Canada together called for transparency and government oversight of all genetically engineered foods and seeds (see the November 17 joint letter[22]). The Canadian public has consistently demanded increased transparency on all GMOs and their regulation, across government departments.

**All Canadian regulatory agencies should ensure mandatory notification to the public of all GMO submissions for approval.**

Effective forms of engagement and meaningful participation could include national or regional public workshops to discuss specific GMOs. For example, in 2017, public interest groups in Prince Edward Island asked the provincial government for "an Island-wide public consultation process to find out if Islanders think this development would be good for PEI."[23]

**ECCC should engage directly with civil society organizations and Indigenous peoples, governments and organizations to design "effective forms of engagement and meaningful public participation other than Public Engagement Initiative."**

**2. During the CEPA risk assessment, what aspects of public engagement should be kept voluntary (through the VPEI) and/or made mandatory?**

All aspects of public engagement should be mandatory, such as:

- All living organisms produced through genetic engineering (GMOs) should be submitted for approval by ECCC should be made public.
- What information is provided to the public for engagement should not be determined by product developers.
- The full data package submitted by product developers should be available to the public.
- The full government risk assessment should be available to the public, for comment before final decision-making.

**3. What aspects of the CEPA risk assessment process and decision-making require greater openness and transparency than is currently available?**

**In order to solicit an answer to this question, ECCC needs to provide detailed information to the public on all the steps and aspects of decision-making.**

(We note that the Discussion Paper's description of "openness in risk assessment and decision-making" includes mention that the requirement that any waiver of information be published in the Canada Gazette. However, in the case of the GM Atlantic salmon, ECCC failed to meet the requirement to publish such waivers in a timely fashion.)

**4. Should first-in-class organisms require higher levels of openness and transparency/engagement?**

It is important that the Discussion Paper recognizes that some products may be of more interest to the public than others: "These novel products may be of greater interest to the public, and may receive additional information and perspectives, which could be beneficial in informing the risk assessment processes and risk management outcomes." We are pleased to see recognition of the importance of precedent-setting organisms, uses, and risk assessments because many precedents have been set by federal regulators without, for example, particular attention to increased openness and transparency nor inclusion of non-scientific considerations. The importance of these precedents should not only require higher levels of openness, transparency and public engagement, but also require strengthened regulation including attention to non-scientific criteria.

However, we are concerned that a focus on increasing openness and transparency in relation to "first class" products could marginalize other products where the government will not provide the same transparency for other classes of products. **We urge ECCC to increase openness and transparency for all GMOs and to recognize the importance of decision-making relating to "first class" GMOs while not compromising openness and transparency for other products.**

Furthermore, ECCC appears to propose defining which organisms are "first-class" without public consultation on that question. Where ECCC defines "first-class" animate products of biotechnology as "those products with no existing comparators on the market. First in class could be determined by application of new technological platforms, or by the development of innovative animate products within the confines of an existing technology platform," this question of classification could also benefit from public input.

Similarly, the Discussion Paper mentions, for example, that more transparency could be possible for products where "market access is not critically time-sensitive." But who will make the assessment of which requests are "critical and time-sensitive," and based on what criteria?

### 4.1.2 Labelling of Animate Products of Biotechnology

**1. What safety concerns or risks to the environment and/or human health would be addressed by the labelling of products which contain living organisms, including GMOs, under CEPA?**

Labelling is necessary to enable tracking and traceability, with implications for safety. Labelling is a basic tool to enable long-term safety monitoring and, for those GMOs that be can be recalled, to enable product recalls if safety issues arise. Post-market monitoring programs, for example, would require labelling or other identification of products. As flagged in the Discussion Paper, post-assessment environmental monitoring may be particularly relevant as environmental conditions and risk factors change due to climate change. Without mechanisms such as labelling for monitoring and tracking, the ability of to identify safety issues and respond to new scientific research will be hampered. Labelling will allow for risk monitoring and management of those products released as non-toxic. **Labelling is therefore a necessary tool to secure environmental safety and human health.**

As well as supporting long-term environmental safety and human health monitoring, labelling for monitoring purposes can also support non-scientific assessment, for example to assess the environmental benefits of use of a GMO or the economic costs. Without data, claims of benefits are difficult for the federal government to verify. **Such information about genetic engineering would be an important policy-making tool.**

Labelling is also necessary to secure transparency. The history of the consistent public demand for mandatory labelling of GM foods in Canada – demonstrated through polling[24] and protest[25] - shows the high value that Canadians place on this mechanism for transparency.

**2. Are there alternative means of arriving at the same outcome as requiring labelling of GMOs? If so, what are they?**

**No, there are no alternatives to clear, mandatory labelling.** Canada's experience with GM food clearly shows that regimes for voluntary labelling will be ineffective. In 1999, the Canadian General Standards Board formed a *Committee on Voluntary Labelling of Foods Obtained Through Biotechnology* (which promptly changed its name to the Committee on Voluntary Labelling for Foods Obtained or Not Obtained through Genetic Engineering and then to switched terminology again to Genetic Modification). To our knowledge, no companies have used this standard to label their products. Clearly, if labelling is needed to ensure traceability and enhance safety, then a voluntary request will not provide the required tools.

**3. What advantages would such labelling bring? If not, what disadvantages would it bring?**

As discussed above, labelling would provide transparency and support a range of important regulatory and policy tools for ensuring safety. We also refer you to CBAN's 2022 report "New Proposals Would Eliminate Transparency on GMOs in Canada" which discusses some of the various roles of transparency.[26]

The Discussion Paper stresses the need for public trust in regulation. We bring your attention to an Ipsos Reid poll conducted for CBAN in 2015 that found that six in ten (57%) of Canadians are not confident in the government's safety and regulatory systems for genetically modified foods.[27] Of the 88% of Canadians who said they wanted labelling, they identified a range of concerns which suggest many possible advantages of labelling:

- 87% just want to know what is in the food they are eating,
- 55% are concerned about safety,
- 47% are concerned about government transparency in regulation,
- 46% are concerned about corporate control,
- 46% think GM is not natural,
- 45% have environmental concerns,
- 30% have ethical concerns,
- 58% are concerned that not enough research has been done on the long-term health and environmental impacts.

Labelling would increase the ability of Canadians to find out information about how genetic engineering is a part of daily life and increase public access to other information about genetic engineering.

**4.2 Responding to advances in science and technology**

**4.2.1 Innovative medicines**

**4.2.2 Facilitating access to products of biotechnology, including biologic drugs subject to the F&DA**

**1. In which areas of environmental risk assessment of F&DA biologics should greater alignment be achieved with other international jurisdictions?**

**2. Should Canada continue to conduct risk assessments of unmodified living organisms?**

**4.2.3 Ease of accessibility and affordability of living organisms resulting from advanced tools**

**1. How aware and/or familiar are you with the NS Program? Do you think the NS Program needs to conduct more activities to promote awareness of the NSNR (Organisms)?**

**2. Is the NSNR (Organisms) adequately addressing animate products of biotechnology created by amateur/DIY scientists or biohackers?**

### 4.2.4 Strengthening post-assessment monitoring information requirements for achieving sustainability goals

1. **Should additional regulatory oversight 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?**

    a. **Should there be additional long-term monitoring for organisms that are not determined to meet the section 64 definition of "toxic" under CEPA?**

    b. **What types of monitoring would be most useful in mitigating potential risks to health or the environment?**

The Discussion Paper raises the question of unpredictability where changing environmental conditions could alter risk factors. For those GMOs that will be released into the wild or threaten to escape into the wild, the question of unpredictable circumstances in the future is key to assessing environmental risk. As mentioned, these may not be accounted for during the risk assessment. The answer cannot solely lie in enhanced monitoring. In many cases, such monitoring will not be possible or will not be possible stretching into the unforeseeable future. The Precautionary Principle is a tool to assist decision-making when faced with such uncertainty and unpredictability**. ECCC should consider how the Precautionary Principle can be applied such that certain GMOs are not allowed to be produced/released, and the development and use of certain classes of GMOs such as gene drives can be banned.**

The proposal to release a genetically engineered American chestnut tree (current requested in the US, and possibly also in Canada) illustrates the challenge of risk assessment for the release of GMOs into the wild, and the question of monitoring. In CBAN's December 2022 comments to the US Department of Agriculture on their proposed release, we raised concern over the timescale relevant for risk assessment, stating that, "The question of this release is complex and profound because the impacts are far-reaching in time and space. The timescale involved reaches beyond our sight to impact many future generations, and the release has the potential to impact ecosystems at the far-reaches of where the American chestnut can grow in North America."[28]

We commented that, if released, the future of this GM tree "would be entangled with the future of many ecosystems and landscapes, and many generations of species, including humans. The long timeframe and wide scale of this release should trigger use of the Precautionary Principle." We also stated that, "A comprehensive assessment of the environmental impacts of planting genetically engineered trees in the wild is not possible given the complexity of trees and their long life, and the complexity of forest ecosystems and size of the habitats involved." The limitations of our tools and knowledge for assessing the environmental risks must be recognized. **ECCC should consider how its decision-making can address irreversibility, a high degree of uncertainty, and impacts that will extend into the unforeseeable future of many generations hence.**

In the case of the GE American chestnut, the release would be irreversible and the impacts are unknown. The nature of this release is one that cannot be monitored or controlled, and

may be difficult or impossible to recall. **Where release of GMOs is irreversible, monitoring will be largely irrelevant.**

**2. What changes, if any, to Part 6 or CEPA or NSNR (Organisms) would enable the federal government to better address considerations for environmental sustainability and climate change?**

This question would have been better asked a number of years ago, before the current review of CEPA.

We refer you to the recommendations regarding Part 6 made by Nature Canada,[29] some of which are currently under discussion in the House of Commons Standing Committee on Environment and Sustainable Development.

**4.2.5 Demonstration of need for new living organisms, including GMOs, and its impacts on biodiversity and ecosystem sustainability**

As mentioned in the Discussion Paper, neither CEPA nor the NSNR (Organisms) currently require a demonstration of need of the living organism. However, such provision is currently being debated in the House of Commons committee review of CEPA.

Since the introduction of genetic engineering into the Canadian food system and environment, Canadians have variously asked for assessments of non-scientific questions such as economic and social considerations.

- In 2010, public interest groups in PEI asked the Premier to hold public consultations on whether or not AquaBounty should be permitted to produce GE salmon eggs on PEI.[30] These groups also called on the Canadian government to ban the sale of any GE animal, and to introduce legislation declaring PEI a GMO-free province.

- Globally, in relation to gene drives, over 140 groups have called for "Inclusive and participatory processes of technology assessment that include multi-disciplinary expertise and respect for diverse knowledge systems are needed to address and to avert the range of potential risks, including adverse environmental, socio-economic, cultural and ethical impacts."[31]

- Groups have also taken a wide view to the question of sustainability. In 2014, 74 groups from across Canada stated their objection to GM fish ("No GE Fish Research, Production, Consumption in, and Export from, Canada"), **"**to protect the health and future of our food system and our aquatic ecosystems."[32]

Incorporating the question of need into risk assessment (technology assessment) is in concert with the Precautionary Principle which includes a reflection on need and alternatives.

The public is already playing an important role in assessing the question "Are these products necessary and what is their social worth?" but this analysis currently has no place in GMO regulation in Canada:

- This question of need was asked by much of civil society and many Canadians in relation to the GM "Enviropig," approved by ECCC in 2009. In this case, communities and public interest groups assessed the Enviropig and provided analysis that no government department was undertaking. The need to genetically engineer pigs, and the claim that this was an environmental solution, was examined in relation to the alternatives (production practices and other technologies already accessible) and the economic risks to hog producers.[33]

- This question of need is also relevant to the financial and human resources spent by ECCC to assess and approve 15 different species of the ornamental aquarium "Glofish" which have no purpose beyond recreation/decoration.[34] The Discussion Paper mentions public comments received on these applications: "While most of the comments received have not been the scientific information, test data, and traditional knowledge originally sought by the VPEI, the initiative has nonetheless given stakeholders a chance to participate in risk assessments and have their concerns heard, helping to promote confidence in the regulatory process." We wonder how many of these comments questioned the need for these GM fish.

ECCC has assessed 15 ornamental recreational fish – these fish do not need to exist. ECCC approved the production of the "Enviropig" which was subsequently shelved by the product developers due to consumer protest in Canada. The GM Atlantic salmon, the only other GM animal assessed by ECCC, is, arguably, unwanted and unnecessary: it is subject to huge public controversy with an absence of mandatory labelling that precludes consumers demonstrating their rejection in the market, and the GM fish growth rates claimed by the company are disputed. **Arguably, all the GM animals thus far assessed and approved by ECCC are unnecessary and unwanted.**

The Discussion Paper states that, "Long regulatory processes can act as a barrier to innovation and prolong market access to products of biotechnology." However, market access to unwanted or unnecessary products is meaningless. We also raise our concern that, in this context, the Discussion Paper mentions how longer processes may be problematic in "gaining rapid access to novel ecological technologies environment which could benefit the environment (i.e. reduce greenhouses gases)." Yet, without a needs assessment, ECCC will not be evaluating these claims to benefit.

The Discussion Paper mentions that "an increase in meaningful public participation can result in longer assessment periods and increase in resources and time to reach a regulatory decision. There is cost and time associated with administering public comment periods, processing comments and feedback, and incorporating changes into regulatory decision-making." However, a process to assess need could assist in creating a more efficient and responsive (and responsible) regulatory system.

CBAN has previously argued that the development and commercial introduction of genetically engineered animals should be subject to broad societal debate whereby the questions of need, social worth and ethics are addressed.

**1. What types of information would be necessary to establish a demonstrable need for an animate product of biotechnology?**

Currently, ECCC provides extremely limited information to the public about any request to approve a GMO. This information seemingly comes direct from the product developer with no independent verification on claims made or implied in the description, and the information/notification itself is only provided if the product developer allows for its release. Clearly, the voluntary nature of the notifications needs to be moved to mandatory. ECCC needs to assert sufficient regulatory authority to access all information from product developers and provide this information the public.

**2. What criteria would be required to perform an analysis of a demonstrable need?**

Nature Canada has articulated this issue in the following way: "As stewards of the Earth's natural heritage, Canadians, particularly Indigenous Peoples, need the opportunity to consider the safety, efficacy, and public acceptability of GE organisms before irreversible decisions are made."[35]

The Canadian Biotechnology Action Network has long argued for an assessment of the potential economic impact of new GMOs before they are commercially introduced. Many farm organizations in Canada have, in particular, argued for an assessment of export market harm before a new GMO is introduced.[36]

An Ipsos Reid poll conducted for CBAN in August 2015 shows that 59% of Canadians oppose genetically modifying crops and animals to produce food, and 34% say they support it.[37] 48% support a ban on all genetically modified food. On the GM fish, 45% of Canadians said they would definitely not eat the GM salmon - 11% said they would; 32% say maybe; and 12% say they don't know or did not have an opinion.

The diversity of issues that of concern to the public was made clear in the 2015 poll that found, of the 88% of Canadians who said they want GM foods labeled:

- 87% just want to know what is in the food they are eating,
- 55% are concerned about safety,
- 47% are concerned about government transparency in regulation,
- 46% are concerned about corporate control,
- 46% think GM is not natural,
- 45% have environmental concerns,
- 30% have ethical concerns,
- 58% are concerned that not enough research has been done on the long-term health and environmental impacts.

Many of the above concerns are highly relevant to deciding which criteria ware important to discussing the environmental and health impacts as well as economic, ethical and social impacts.

To more fully address this important question, CBAN and other civil society organizations would need further time to discuss.

**ECCC should engage directly with civil society organizations and Indigenous peoples, governments and organization to address this question.**

**3. Who would be best placed to make a determination of demonstrable need?**

Product developers should be excluded from determining need. Product developers will have a perspective on how their product could be beneficial but any pronouncements on benefit would need to be independently assessed and other claims from developers would need to be independently verified.

Any determination of need would need broad public participation and explicitly seek out the input of communities who would be affected.

**To more fully address this important question, CBAN and other civil society organizations would need further time to discuss.**

**ECCC should engage directly with civil society organizations and Indigenous peoples, governments and organization to address this question.**

**4. At what stage(s) in a product development life cycle would a decision be made?**

A decision would be need to be made at the earliest possible step in the research and development of a product.

A great deal of study is currently underway to examine how to design public participation in decision making over gene drives. However, civil society groups across the world are calling for a ban on the use of the technology. **A ban would be an efficient and effective way to protect the environment from these profound risks**:

- In December 2022, over 140 groups called for "No environmental release of gene drive organisms": We urge governments to prevent the environmental release of gene drive organisms and to establish a global moratorium on the release of gene drive organisms at the UN Convention on Biological Diversity (CBD).[38]

- In, 2016: 163 groups including CBAN called upon governments at the 13th Conference of the Parties to the Convention on Biological Diversity, in accordance with the precautionary principle, to put in place a moratorium on 1) any further technical development and experimental application of gene drives, and 2) environmental release of genetically-engineered gene drives.[39]

**The federal government should ban the use of gene drive technology and support a ban at the international level.**

**5. At what stage would this new concept involve regulators?**

To more fully address this important question, CBAN and other civil society organizations would need further time to discuss.

**ECCC should engage directly with civil society organizations and Indigenous peoples, governments and organization to address this question.**

**6. How would this concept influence a risk-based decision making process?**

To more fully address this important question, CBAN and other civil society organizations would need further time to discuss.

**ECCC should engage directly with civil society organizations and Indigenous peoples, governments and organization to address this question.**

## 4.3. Reducing Identified Inefficiencies

### 4.3.1 Streamlining the regulatory scope for unmodified organisms

*1. Does the regulation of unmodified and naturally occurring organisms impact your sector? If so, how?*

*2. How would your sector be impacted if unmodified and naturally occurring organisms were not regulated under the NSNR (Organisms)?*

1. *Do you foresee any risk? Any opportunities?*
2. *Should unmodified and modified organisms be regulated in the same way, or differently? Why?*

### 4.3.2 Refining the NSNR (Organisms) definitions for micro-organism and research and development organisms

1. *Should the definition for micro-organisms be refined to remove cultured cells from higher organisms (i.e. human, animal, and plant cell cultures), and VLPs, and SVPs lacking genetic material, that cannot replicate autonomously in the environment?*
2. *Should the quantity thresholds for research and development micro-organisms remain as they are? If so, should more consideration be given to quantities as they are near the prescribed thresholds? (For example, should research and development micro-organisms being manufactured in a 1L volume be treated the same way as ones being manufactured in 1000L volumes?)*
3. *If the thresholds were modified to the concentration of the organism, how would this impact your activities and obligations under the NSNR (Organisms)?*
4. *Should the definition of "Research and Development Organism" be expanded to include QA/QC organisms, organisms used as models for studying human diseases, and organisms used as experimental controls?*

### 4.3.3 Streamlining the regulations for higher organisms commensurate to level of intended release

**1. Would different assessment timelines for different context of higher organism use (e.g. contained use, experimental field studies, release with confinement procedures and full environmental release) help to reduce the regulatory burden to industry?**

The priority of the NSNR (Organisms) to ensure safety cannot be compromised to "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 relation to government oversight, redundancies can also be understood as safeguards.

**In relation to animate products of biotechnology, containment plans and intentions should not be used to differentiate regulatory requirements.** CBAN has documented all the known cases of escape and contamination with living modified organisms in Canada (see our 2019 report "GM Contamination in Canada: The failure to contain living modified organisms – incidents and impacts"[40] and our 2022 supplemental "GM Contamination Update: Animals"[41]). Over the almost two and half decades of GM commercialization in Canada, we have observed the escape of a number of GMOs from a diversity of circumstances that warn against ECCC differentiating risk assessment and regulation based on the planned level of intended release.

For example, in Canada:

- Some escape events occurred with GMOs that were approved by regulators for cultivation (canola and flax), and others were unapproved experimental GE plants and animals (wheat and pigs),
- Escapes were observed from laboratory experiments, field tests, and commercial cultivation.
- Escape incidents occurred with large and small organisms,
- Escapes were due to diverse causes, some of which remain undetermined.

In particular, we bring your attention to two contamination incidents, at two different institutes, with experimental GM pigs:

- In 2002, eleven GM piglets from experiments at the University of Guelph in Ontario were accidentally sent to a meat rendering plant and turned into animal feed instead of being destroyed as biological waste.
- In 2004, three experimental GM pigs from the now-defunct Quebec company TGN Biotech were accidentally turned into chicken feed instead of being incinerated.

These incidents illustrate the relevant role of human error in containment failure, which is relevant to considering the risks associated with GMOs regardless of the level of intended release. The two containment failures with GM pigs, along with others like it, illustrate the basic truth that **the containment of GMOs may fail even when containment seems feasible**. In response to the incident at the University of Guelph, the Vice President of Research provided the insight that, **"Things you don't expect to happen can happen."**[42]

The key lesson that needs to be heeded is our inability to contain living modified organisms. This lesson has been learned over and over, by companies, universities, farmers, and governments. Our 2019 report concluded that the diverse incidents of GM escape and contamination in Canada show that the risks cannot be managed by current government regulation nor through industry-developed best practices. **Subjecting new higher organisms to Schedule 5 is not an "unnecessary regulatory burden on notifiers intending to use higher organisms in contained scenarios."**

**Regulations should not be "streamlined" for higher organisms commensurate with the level of intended release because containment plans have repeatedly failed.**

**ECCC needs to assess the potential ecological and health impacts of escape in all scenarios.**

### 4.3.4 Accidental release of living organisms

**1. What do you think would be the best way (through e.g. regulations, policies, standards, guidance) to minimize the risks associated with accidental or unauthorized releases that occur after a product is manufactured, after or during import, and/or during the research and development phase of living organisms?**

**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. Our experience with GM escape incidents and contamination in Canada – as documented in our 2019 report[43] - supports our conclusion that the only way to prevent contamination from certain GMOs is to stop their release.

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.

Regulations and policy are the necessary instruments rather than standards and guidelines, which can be overlooked, underused, or neglected by self-interested product developers and users who are seeking efficiencies for profit-making. 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.[44]

### 4.3.5 Consideration of vulnerable populations

**1. Are current requirements for risk assessments sufficient to protect vulnerable populations? If not, what additional requirements do you think are needed?**

To more fully address this important question, CBAN and other civil society organizations would need further time to discuss.

**ECCC should engage directly with civil society organizations and Indigenous peoples, governments and organization to address this question.**

### 4.3.6 Overlap and Gaps with *Human Pathogens and Toxins Act* and *Regulations*

With the above context on the overlap between CEPA/NSNR (Organisms) and the HPTA/HPTR, we are seeking to gather responses to the following question:

1. *As a manufacturer or importer of living organisms, have your operations been impacted by duplication between CEPA/NSNR (Organisms) and the HPTA/HPTR in the regulation of substances manufactured or imported under containment? If so, how and what would you recommend to reduce this impact?*

### 4.3.7 Inefficiencies in regulatory requirements for contained use (Schedule 2)

*1. Should additional requirements be included in the regulations to gather information on the effectiveness of inactivation procedures?*

*2. What would be the impact to the biotechnology sector if the incorporated US National Institutes of Health (NIH) guidelines Appendix K were removed from the NSNR (Organisms)?*

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