ANIMAL JUSTICE
CANADA

December 5, 2022

MP Greg McLean
Ottawa, Ontario,
Canada
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House of Commons Standing Committee on Environment and Sustainable Development
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6

***Via email***

Dear MP McLean, Chair Scarpaleggia, and Standing Committee Members,

**Re: Bill S-5 and Amendments to Part 6 of the *Canadian Environmental Protection Act, 1999***

Thank you once again for the opportunity to appear before the Standing Committee on behalf of Animal Justice Canada (hereinafter "**Animal Justice**") and for the invitation to provide further, more detailed, written submissions regarding amendments to Part 6 of the *Canadian Environmental Protection Act, 1999* ("**CEPA**").

There appears to be widespread agreement that Part 6 of the Act is in need of a significant overhaul. Although there have been relatively few genetically modified ("**GM**") animals developed or manufactured in Canada to-date, an increasing number of GM animals will likely be developed for varying uses in the coming years. Examples include hens genetically engineered so that their eggs containing male embryos will not develop;[1] GM pigs whose bodies can be used both for human medical products and for human consumption;[2] and cows whose genomes are altered to prevent the growth of horns.[3]

Because few amendments to Part 6 were contained in Bill S-5 when it was introduced, and the government indicated at the time that reforms to that Part would be made at a later date, Animal Justice did not propose amendments to Part 6 when Bill S-5 was before the Senate. With respect to more comprehensive future amendments to this Part, in general Animal Justice supports the recommended reforms to Part 6 set out in the

[1] See: https://www.wattagnet.com/articles/43518-can-gene-editing-solve-the-male-layer-chick-dilemma
[2] See: https://www.cnn.com/2020/12/14/health/gm-pig-fda-approved
[3] See: https://www.technologyreview.com/2019/08/29/65364/recombinetics-gene-edited-hornless-cattle-major-dna-screwup/; https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0216542.

November 15, 2016 brief to this Standing Committee by Ecojustice, Environmental Defence, and Équiterre (the "**2016 brief**").[4]

Given that the Senate amended Bill S-5 in order to amend portions of Part 6 of CEPA, including s 114 in particular, Animal Justice has requested that this Standing Committee make one amendment to s 114 (see below). To be clear, we believe the entire Part 6 is in need of a comprehensive review and this amendment is intended more or less as a stop gap to enable the protection of GM animals until such time as Part 6 is reviewed and amended.

As an organization focused on improving legal protections for animals, Animal Justice's main concern with regard to Part 6 is that it treats GM animals the same way as it treats chemicals, focusing only on whether they pose a risk to human health or the environment and ignoring entirely the very real animal health and welfare risks associated with deliberate attempts to influence the genetic makeup of animals, including through the direct manipulation of genetic information in an organism using gene editing technology such as CRISPR. Even with more refined gene editing techniques like CRISPR, poor efficiency and specificity are acknowledged to be a serious welfare issue, with every stage. The increased ease of manipulating animal genomes makes it all the more important that CEPA include strong statutory and/or regulatory mechanisms to ensure that in any instance where such options are being considered, thorough ecological, welfare, and other ethical considerations are given due regard.

Specific animal welfare risks include: a) unanticipated "off-target" effects that cause significant welfare concerns (such as developmental abnormalities, skeletal abnormalities, enhanced growth of tumours, ulcerative colitis, and increased incidence of infectious disease), b) harmful procedures specific to GM technologies (e.g. induced superovulation of females, harvesting of fertilized eggs, vasectomy of males, painful tail or ear biopsies for genotyping, etc.), and c) large numbers of "surplus" animals who go through harmful procedures but do not end up expressing the genetic modification of interest.[5]

### A. Proposed amendment to section 114

As noted in our November 10, 2022 brief to the Standing Committee, Animal Justice urges this Standing Committee to amend s 114 to provide the Governor in Council with the authority to make regulations to protect the welfare of GM animals. This a relatively

[4] Available through the Standing Committee's website: https://www.ourcommons.ca/Content/Committee/421/ENVI/Brief/BR8693959/br-external/Ecojustice-e.pdf.

[5] See, e.g. Ormandy EH, Dale J, Griffin G. Genetic engineering of animals: ethical issues, including welfare concerns. Can Vet J. 2011 May;52(5):544-50. PMID: 22043080; PMCID: PMC3078015. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078015/; Bailey, J. (2019) Genetic modification of animals: Scientific and ethical concerns. Chapter in: Animal Experimentation: Working Towards a Paradigm Change. Eds K. Herrmann and K. Jayne. pp. 443-479. Available at: https://library.oapen.org/bitstream/handle/20.500.12657/38145/9789004391192_webready_content_text.pdf?sequence=1#page=482.

minor amendment that we believe is tremendously important, particularly in light of the recently initiated review of the New Substances Notification (Organisms) Regulation – a review which, as it stands, ignores animal welfare considerations.

We recommend that the Standing Committee amend s 114 of the Act by adding the following:

> (h.1) respecting requirements and prescribing information for the purpose of assessing risks to the welfare of animals resulting from:
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> (i) modifications to a living organism,
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> (ii) the manufacture of the living organism,
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> (iii) research and development to manufacture the living organism,
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> (iv) the release of the living organism into the environment; or
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> (v) activities in relation to the living organism.

If and when Part 6 is subject to a more comprehensive review, Animal Justice is of the view that animal health and welfare considerations should be incorporated directly into the Act (particularly at s 108(1)). In this respect, Canada can and should take an approach similar to the EU, whereby the risk assessment approach to new GM animals includes an evaluation not only of possible risks to human health and the environment, but also related animal health and welfare risks.[6]

### B. Demonstrable need

MP McLean's question to me at the Committee meeting on November 29, 2022 focused in large part on the question of incorporating a requirement for "demonstrable need" into the Act as some groups have proposed, and as incorporated by the Senate in s 108(1)(b). Animal Justice has not proposed that "demonstrable need" be incorporated into CEPA. As noted above, because few amendments to Part 6 were included in Bill S-5 as originally drafted, and because our understanding was that a comprehensive review of this Part was outside the scope of the Bill, we did not proposed amendments to Part 6 when the Bill was before the Senate.

Though we do not have a position regarding where or how the concept is incorporated in the Act, we generally agree that before a new living organism – including a new GM animal in particular – is introduced in Canada, consideration should be given not only to the risks associated with that organism, but also its corresponding environmental sustainability or other public benefits. For instance, Norway has incorporated

[6] See, e.g. https://www.efsa.europa.eu/en/topics/topic/genetically-modified-animals.

considerations related to sustainability and "benefit to society" in its legislation governing GM organisms.[7]

That said, the notion of "benefit" or "demonstrable need" would require clear definition to ensure that the analysis focuses not only on economic factors, but on whether there is a clear and demonstrated human health, environmental, or animal health or welfare benefit associated with the new animal such that its introduction in Canada truly is in the public interest. Bill S-5 currently refers to "demonstrable need" without a clear definition and we believe this is problematic.

If the requirement to demonstrate the need for a new animal is incorporated via legislation, regulation, or policy, Animal Justice is strongly of the view that it should not be restricted to animals with a "wild counterpart". We oppose any incorporation of a "demonstrable need" requirement that is restricted only to such animals, as has been proposed by some organizations. Because many GM animals in development around the world are farmed animals, an approach to "demonstrable need" restricted only to animals with a wild counterpart would exclude these animals.

By way of example, scientists are working to develop a hen whose eggs containing male embryos will not develop.[8] This would no doubt reduce costs in the egg industry, and could potentially save millions of male chicks each year from death given that it is standard practice in the egg industry to kill male chicks shortly after they hatch (generally by grinding them alive in a macerator) since they serve no economic purpose. Would the use and manufacture of these GM hens be in the public interest, in that there is a "demonstrable need" for them or a public interest benefit to their manufacture and use? Or would the welfare of the hens themselves be compromised, thus offsetting the potential welfare benefits to male chicks? Such questions are incredibly complicated, involving both scientific and ethical considerations, but should indeed be examined prior to such animals being approved for use and manufacture in Canada. Questions related to human health and environmental risk are important as well, but they are not the only questions to be asked, particularly when the GM organism at issue is a sentient animal.

### C. Public Participation

In its present form, and as exemplified by the AquAdvantage Salmon approval process in particular, Part 6 is opaque and anti-democratic, and effectively shuts the public out of all decision-making regarding new genetically modified organisms. Even when individuals or groups have proactively contacted the Ministers to ask if a risk assessment of a new organism is being conducted, they have been refused an answer. Finding out that a risk assessment has already been conducted and a decision already made by the Ministers does little to promote transparency, public participation, or perceptions of legitimacy amongst members of the public.

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[7] See, e.g. https://www.miljodirektoratet.no/globalassets/dokumenter/publikasjoner/faktaark/faktaark-gmo-sosiookonomi.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7550366/.

[8] See: https://www.wattagnet.com/articles/43518-can-gene-editing-solve-the-male-layer-chick-dilemma.

For these reasons, Animal Justice supports amendments to Part 6 (incl. s108 and 114) that would establish meaningful opportunities for public participation in the review of new GM organisms, including animals. At a minimum, the Act should set out requirements for public notice that an assessment is taking place and the opportunity to comment as part of the risk assessment process. Where the nature of the organism is such that Indigenous rights may also be impacted (e.g. Atlantic salmon) the Act should clearly mandate consultation with and the need for prior informed consent from, impacted First Nations.

Animal Justice is concerned that the current language in Bill S-5 that would incorporate a requirement that the Ministers ensure opportunities for the public to "meaningfully" participate in risk assessments under Part 6 is unduly vague, though we appreciate that regulations passed pursuant to s 114(1)(g.1) could provide the needed clarity. As an alternative to the current language of the Bill, s 108 could be amended to more closely mirror the public consultation language in s 105.2 (as amended by Bill S-5). That is, s 108 could clearly note that the Minister shall provide public notice that a risk assessment is taking place and that members of the public shall be given a 60 day window within which to provide comments, though sufficient information about the risk assessment would need to be made available to ensure public participation is informed and meaningful. Such proposed language can also be found in the above-noted 2016 brief to this Committee submitted by Ecojustice, Environmental Defence, and Équiterre (see Recommendation 20).

**D. Comprehensive amendments needed**

While we appreciate that a comprehensive review of Part 6 is not taking place at the present time, we wish to be clear that the above-noted amendments, while important, are not sufficient to fix the current problems with Part 6. In addition to being opaque, Part 6 in its current form is also excessively complex and difficult to comprehend, leaving numerous loopholes and areas of regulatory uncertainty.

As noted above, a modernized Part 6 should clearly mandate the assessment of considerations related to animal health and welfare prior to the approval a new GM animal in Canada. This includes all vertebrate animals and certain species of invertebrates (e.g. cephalopods such as octopuses) who are known to have the capacity to experience pain and suffering. Two other examples of areas of reform needed are set out below.

***"Use" vs. "Manufacture" of GM animals***

As set out in the 2016 brief, if and when a comprehensive review of Part 6 is conducted, amendments are required to address the fact that because GM animals are self-reproducing it can be difficult to distinguish between permitted activities in relation to such animals, in that "use" at times cannot be easily distinguished from "manufacture" despite the Act's treatment of use and manufacture as two generally distinct categories (e.g. use of adult animals to create eggs/offspring). As such, greater certainty is needed

in Part 6 of the Act with respect to "use" and "manufacture" (see, e.g. Recommendation 24 in 2016 brief).

***Waivers of information***

There is one existing mechanism in Parts 5 and 6 that can (potentially) result in public notification prior to the conclusion of a risk assessment. Subsections 106(9) (as with s 81(9)) states that where the Minister waives information requirements, notice must be posted in the *Canada Gazette*. But the Act is silent with respect to the timing of that notice. This has led to troubling results in the form of waivers being published years after the fact. For instance, until February 2014, after the practice was subject to a legal challenge (involving the assessment of AquAdvantage Salmon), no notices under these sections had been posted since March 2008. Significant delays such as this do little to promote transparency and result in notices that are of little to no utility at all.

Consistent with the 2016 brief, if and when Part 6 is subject to a more comprehensive review we recommend a requirement that notice of a waiver of information requirements be published in the Canada Gazette within a specified period of time to avoid such delays (see, e.g. Recommendation 21).

The content of notices of waivers of information requirements are also problematic. The present requirement in s 106(9) is only that the notice contain "the name of any person to whom a waiver is granted and the type of information to which it relates". Notices of waivers are thus vague and largely unintelligible – it is unclear what organism or substance a given notice relates to. Wording along the following lines would be an improvement (see Recommendation 21 in the 2016 brief):

> **106(9)** The Minister shall publish in the *Canada Gazette* a notice stating the name of any person to whom a waiver is granted, the type of information to which it relates, and the living organism to which it relates.

In the event that this Committee does amend Bill S-5 to establish public notice and/or comment opportunities related to waivers of information requirements at this time, Animal Justice is strongly of the view that, for the reasons noted above, such requirements should apply to all GM animals, regardless of whether they have a "wild counterpart".

Yours truly,

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