RE: Comments on Health Canada's proposed revised policy regarding the regulation of foods derived from somatic cell nuclear transfer (SCNT) cloned cattle and swine, and their offspring as novel foods in Canada.

May 24, 2024 - Submitted to bmh-bdm@hc-sc.gc.ca

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Overview

The Canadian Biotechnology Action Network, Vigilance OGM and The Non-GMO Project are writing to object to the proposal to no longer consider products from non-genetically engineered somatic cell nuclear transfer (SCNT) cloned cattle and swine and their offspring as novel foods and to therefore exclude them from pre-market safety assessments/notifications under Division 28, Part B of the *Food and Drug Regulations.*

Health Canada's 2003 interim policy to regulate foods derived from SCNT clones and their offspring as novel was implemented to allow for further study. We argue that this study is not complete and needs to continue, especially as the technology continues to develop. The policy proposal is premature and unnecessary. Instead, we urge departments to create a timeframe for continued regulation as a means to gather more evidence and experience, and to ensure government safety oversight and transparency for Canadians.

The timing of this proposal on SCNT cloned animals comes amidst other, controversial regulatory guidance changes that exempt foods from many gene edited plants from the novel food regulations. This systematic deregulation of genetically engineered foods raises serious safety and transparency concerns.[1]

Recommendations:

- We urge all departments to maintain pre-market regulation over products of SCNT clones and their offspring, and of all genetically engineered organisms including all products of gene editing.
- Recent decisions to exempt many gene edited products from pre-market regulation should be reversed, to reinstate government oversight and mandatory transparency.
- We urge the federal government to reorient policy to prioritize safety and transparency by implementing the precautionary principle in relation to the use of new technologies in the food system.

- **Higher incidence of animal health problems**

As acknowledged in the Scientific Opinion,[2] there is a higher incidence of health problems associated with SCNT cloning technologies than with natural breeding and other assisted reproductive technologies, though less so with progeny than with clones.

We remain concerned that, as acknowledged in the Scientific Opinion, the origins and mechanisms of animal health problems associated with SCNT cloning, such as lower rates of reproductive success, altered birth weights and higher organ failure rates, "are not completely understood". Uncertainty remains and, at a minimum, needs to be addressed through continued government oversight and monitoring. For example, "abnormalities can arise due to any of these manipulations, and may not be exclusive to SCNT animal cloning" and silent mutations can be passed to future generations. We argue that such uncertainty demands the use of the precautionary principle.

Continued pre-market government regulation of SCNT clones as novel could increase knowledge about these health problems and provide important public sector expertise on safety questions.

- **Dietary exposure assumptions**

While, as stated in the Scientific Opinion, there is a low proportion of SCNT clones that develop into healthy adult animals at the present time, we are concerned that the current limitations and uses of the technology not be the basis for an assumption of food system uses into the future.

The Scientific Opinion states an "expected low likelihood of human exposure to SCNT clones in Canada." However, while most animal clones are anticipated to be used primarily as breeding stock, we are concerned that dietary exposure could change over time. Such changes and increases need to be anticipated as the technology develops. Health Canada's earlier assumptions of dietary exposure to genetically engineered Bt corn, for example, were proven incorrect due to multiple factors.[3] In particular, the use of cloning could become commonplace in the production of genetically engineered animals.

We are similarly concerned about the assumption that, "the most common sources of human exposure to cloned animals are anticipated to be from agronomical applications mainly involving cattle, pigs and sheep."

Such assumptions do not appropriately accommodate potential development of the techniques and increased commercial interest. We urge the departments to consider more future-proof policy and regulatory proposals that would maintain a novelty trigger in order to observe the use of the technology through regulatory assessment.

- **Containment and escape assumptions**

Based on the escape and contamination incidents with genetically engineered animals in Canada and globally,[4] we contest the assumptions made regarding pets and prize winning animals (2.4.2.1). The assumption made is that, "the impact of cloned pets and prize winning animals into the Canadian environment is expected to be low given that they are expected to mainly be kept in private care, thus greatly reducing the likelihood of release into the environment." However, private care does not reduce the likelihood of release. On the contrary, some of Canada's most harmful invasive species came about from the improper disposal of plants and animals,[5] and we already observe that the world's only genetically engineered pet animal (GloFish) has already become an environmental contaminant (in Brazil).[6] The assumption that, "cloned pets would likely originate from species that have well-established populations in Canada and thus no new species would be introduced into the environment" is not also not appropriate.

Of grave concern is the potential to apply this technology (and genetic engineering) to wild species (2.4.2.2). The Scientific Opinion states that, "It is still difficult to adapt the technology to wildlife species; rapid gain in the understanding of the molecular clues underlying nuclear reprogramming using gene editing at the gene and whole genome levels, will help accelerate successful cloning for wildlife conservation. There is currently no available information on the impact of SCNT restored wildlife species on the environment." We urge departments to take the possibility of genetic engineering in wild species seriously as a grave environmental threat, requiring the application of the precautionary principle. We also strenuously object to the implication that cloning or gene editing could be used for wildlife conservation and we request that departments be careful not to integrate statements that offer judgements on this use in documents such as the Scientific Opinion.

Conclusion

Genetically engineering animals

We are concerned that these proposals will facilitate increased research and development, and faster market entry, of genetically engineered animals, and that departments are unprepared to regulate these animals for safety and transparency. We are further concerned that the federal government is preparing to remove pre-market regulation from genetically engineered animals, further subordinating the public interest to the commercial pursuit of the technology.

Prioritize safety and transparency

We are particularly alarmed by regulatory guidance that removes pre-market government safety assessments and mandatory transparency from many products of gene editing (seeds, foods from plants, and livestock feed). Lack of independent government oversight raises safety concerns. These changes have also removed transparency that is critical to tracing for businesses in the food system, and information for Canadians.

In this context, we urge departments to reconsider the proposed deregulation of SCNT clones and their products, in order to prioritize safety and transparency in the Canadian food system.

The Canadian Biotechnology Action Network (CBAN) brings together 15 groups to research, monitor and raise awareness about issues relating to genetic engineering in food and farming. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups. CBAN is a project of MakeWay's shared platform. *www.cban.ca*

Vigilance OGM is a Quebec non-profit organization made up of groups and individuals from diverse backgrounds – farmers, environmentalists, consumers, citizens – all concerned about what we put on our plates every day and by the impact of modes agricultural production on the environment and human health. *www.vigilanceogm.org*

The Non-GMO Project is a non-profit organization dedicated to building and protecting a non-GMO food supply in North America. The Non-GMO Project provides third-party verification for GMO avoidance, backed by a rigorous Standard. Today, Non-GMO Project verification is one of the fastest-growing labels in the retail sector in Canada and the United States. *www.nongmoproject.org*

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[1] See CBAN (2022) 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; CBAN (2023) Briefing to Members of Parliament, Reverse New GMO Regulatory Guidance, to Ensure Safety and Transparency, May. https://cban.ca/wp-content/uploads/CBAN-GMO-regulation-briefing-May-2023.pdf; CBAN (2022) RE: Primary Roles of CFIA Regulation – The Need to Regulate Gene Edited Seeds, Submitted to the Canadian Food Inspection Agency, July 25. https://cban.ca/wp-content/uploads/Part-V-Guidance-CBAN-brief-to-CFIA-mtg-follow-up-July-25-2022.pdf

[2] Scientific opinion on the impact of somatic cell nuclear transfer (SCNT) cloning of cattle and swine on food and feed safety, animal health and the environment https://www.canada.ca/en/health-canada/programs/consulation-food-derived-somatic-cell-nuclear-transfer-clones-offspring-policy-update/scientific-opinion.html

[3] Canadian Biotechnology Action Network (2024) Genetically engineered Bt insect-resistant corn poses human health risks, May. https://cban.ca/wp-content/uploads/BT-factsheet-web.pdf

[4] Canadian Biotechnology Action Network and the Organic Agriculture Protection Fund (OAPF) of SaskOrganics (2019) GM Contamination in Canada: The failure to contain living modified organisms – Incidents and impacts https://cban.ca/wp-content/uploads/GM-contamination-in-canada-2019.pdf

[5] Canadian Council on Invasive Species, Don't Let it Loose. https://canadainvasives.ca/programs/dont-let-it-loose/

[6] See Canadian Biotechnology Action Network (2022) GM Contamination Update: Animals, February 22. https://cban.ca/wp-content/uploads/GM-Contamination-Animals-Feb-2022-Update.pdf