Health Canada's proposed new regulatory guidance on genetically engineered foods

Update and Summary

» **CBAN submitted comments to Health Canada on May 11, 2021:**
www.cban.ca/NoExemptions/CommentsHC

» **CBAN's Guide to the consultations:**
www.cban.ca/NoExemptions/Guide

» **Send your comments to Health Canada**
hc.bmh-bdm.sc@canada.ca

DEADLINE: MAY 24

Genome editing (also called gene editing) techniques are a type of genetic engineering that results in the creation of genetically modified organisms (GMOs).

—cban.ca/GenomeEditingReport

Health Canada's core proposal is to remove its regulatory authority from some genetically engineered foods, particularly those produced through genome editing. Health Canada proposes to allow companies to determine the safety of some of their own products, without any government oversight. This would amount to an abdication of Health Canada's responsibility to regulate for the safety of Canada's food supply.

The proposals define foreign DNA as a trigger for regulation (a "novel trait"). This means that some genome edited products without foreign DNA would be allowed to be assessed for safety by product developers themselves, rather than by Health Canada. This focus on foreign DNA is simplistic and overlooks a range of potential unintended effects that could have an impact on food safety.

This would be a shift from government regulation to corporate self-regulation. It would jeopardize food safety, result in less transparency for the public and the agri-food industry, further erode public trust in our food system, and put the possibility of improved democratic governance of the use of genetic engineering in food and farming further out of reach.

The proposals would mean some unregulated, possibly some unreported, genome-edited foods onto the market.

The Canadian Biotechnology Action Network (CBAN) objects to this proposed devolution of responsibility for food safety assessment from Health Canada to product developers.

- Health Canada is proposing to surrender its regulatory authority over some genetically engineered foods.
- Canada proposes to hand some safety assessments over to product developers.
- Health Canada would have no ability to require information from product developers about these unregulated foods, and they may go entirely unreported.
- There is an inherent conflict of interest in product developers determining if regulations apply to their own products, and in determining their safety.
- The new genetic engineering techniques of genome editing require mandatory, independent, rigorous safety assessment.
- Health Canada's proposals do not reflect the scientific findings which clearly show that genome editing can result in a range of possible unintended effects that need to be detected and evaluated for their potential impacts on food safety.
- Narrowly focussing on the presence of foreign DNA as a trigger for government safety assessment is simplistic and overlooks many possible safety issues that could result from genome editing.
- Health Canada would be asking Canadians to accept corporate safety assurances: to accept unseen corporate safety assessments and corporate science, without any government checks.
- Health Canada's job is to be an independent regulator on behalf of the Canadian public.
- Implementing this guidance could initiate a crisis of legitimacy for Health Canada.
- All products of genetic engineering, including those produced with the newer techniques of genome editing, should be regulated in the public interest.

Demand mandatory, independent safety assessments

For information and more action **www.cban.ca/NoExemptions**

MORE DETAIL

CBAN's analysis of Health Canada's proposals

Canada does not regulate genetic engineering, it regulates "novel foods" and "plants with novel traits". The regulations define novel foods as including, for example, those where a food has undergone a major change or exhibits characteristics that were not previously observed in that plant. The new proposals for regulatory guidance put forward by Health Canada would further narrow the definition of novelty. The changes would mean that many products of the new genetic engineering techniques of genome editing (also called gene editing) may not fit the definition of a novel food and could therefore come to market without a Health Canada safety assessment or any government oversight.

So far, all of the genetically engineered foods eaten in Canada have been regulated as novel, with the exception of one genome-edited corn that Health Canada determined to be non-novel.[1] All of these genetically modified organisms (GMOs) have been subject to government oversight. However, while some genome-edited products could still fit the definition of "novel" and therefore be subject to a government safety assessment, under the new proposals many may circumvent the product approval system entirely.

This is because Health Canada is proposing that if foreign DNA (used to "edit" the organism) has been removed from the genome-edited GMO, and if there is no other obvious "novel" characteristic, then safety assessments can be left solely to product developers. This is how, in the proposals, Health Canada would surrender its regulatory authority over some genome-edited organisms entering the food system.

The proposed focus on the presence or absence of foreign DNA in a genetically engineered organism is simplistic and overlooks a range of possible unintended effects that can result from genome editing, that may have food safety impacts. (See our report at www.cban.ca/GenomeEditingReport)

If Health Canada excludes these products from regulation, it will have no access to the science used to determine their safety. The department would have no ability to require information from product developers, not even a notice that a new genome-edited food is coming to market. To compensate for this gap, Health Canada also proposes a "Voluntary Transparency Initiative," to "encourage" companies to voluntarily send the government a notice of any unregulated (determined by developers to be non-novel) genome-edited product being commercialized. This is a clear pathway for some unknown, unregulated genome-edited products to get to market.

Critically, the Voluntary Transparency Initiative would also encourage product developers to submit several, limited areas of information about their non-novel product for "further

1 https://cban.ca/wp-content/uploads/GM-Waxy-Corn-Corteva-product-profile-CBAN.pdf

review." Health Canada specifies that this review will not be a safety assessment but will verify corporate self-determinations of non-novelty. This means that the initiative would also serve as a system of voluntary, ad hoc government checks. Only those products submitted voluntarily by developers would be subject to this minimal government oversight.

The proposals from Health Canada also include further "updates" to regulatory guidance which would spell out differing information requirements and "tiers" of regulation for GMOs that are said to be "identical" to previously assessed GMOs. Health Canada calls these "retransformants" and proposes a form of fast-track review. CBAN contests Health Canada's characterisation of such plants as "identical" and argues that each genetic engineering event, even using the same methods to create the same characteristics, can result in new unintended effects. Initially, these proposals would particularly apply to fast-tracking approvals for more herbicide tolerant crops, because these are the majority of GMOs approved thus far.

CBAN argues that all genetically engineered products, including those produced with the newer techniques of genome editing, should be subject to mandatory, independent, rigorous safety assessments.

MORE INFORMATION

CBAN's May 11 submitted comments to Health Canada are posted at www.cban.ca/NoExemptions/CommentsHC

Health Canada has released two consultation documents that propose new guidance for the interpretation of regulations governing foods derived from plants with novel traits. The documents are available upon request from Health Canada but are also posted at www.cban.ca/NoExemptions/Consultationdocs

Health Canada's consultation site is https://www.canada.ca/en/health-canada/programs/consultation-guidance-novel-foods-regulation-plant-breeding.html

For more information about genome editing see www.cban.ca/gene-editing

For more discussion of the consultation see www.cban.ca/NoExemptions

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Canadian Biotechnology Action Network

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The Canadian Biotechnology Action Network (CBAN) brings together 16 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.

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