

Voluntary Report – Voluntary - Public Distribution

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Report Name: Health Canada Consulting on Policy Revision for Foods Derived from Somatic Cell Nuclear Transfer

Country: Canada

Post: Ottawa

Report Category: Biotechnology - Plants and Animals, Cloning

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Report Highlights:

Health Canada is proposing a policy revision for foods derived from somatic cell nuclear transfer (SCNT), cattle and swine and their progeny. Currently, Health Canada considers foods derived from SCNT cattle, swine, and their progeny as novel foods and subject to the regulations concerning novel foods including a pre-market notification and assessment prior to approval for sale in Canada. The policy revision would mean that these foods are no longer considered novel by Health Canada and would no longer require pre-market notification. The consultation will run from March 26, 2024 until May 25, 2024.

On March 26, 2024, Health Canada opened a [consultation](#) on a policy revision for the regulation of foods derived from somatic cell nuclear transfer (SCNT), concerning cattle and swine and their progeny. Health Canada is proposing that foods from SCNT cattle, swine, and their progeny no longer be:

- Considered as novel foods
- Subject to pre-market notification under Division 28, Part B of the *Food and Drug Regulations* (Source: Health Canada)

Health Canada defines SCNT animals as the reproductive animal cloning technique of creating an animal that is a twin of the original animal, by removing the nucleus from an unfertilized egg (egg donor) and replacing it with the nucleus of a somatic cell (genetic donor) to form an embryo which is then implanted into a surrogate.

Health Canada has had an interim policy in place on SCNT since 2003, which required all foods derived from products of SCNT and their progeny to be defined as novel food under the *Food and Drug Regulations*. As a result, these foods were subject to Division 28, Part B and required a pre-market assessment prior to being sold in Canada. In November 2023, Health Canada, the Canadian Food Inspection Agency, Agriculture and Agri-Food Canada, and Environment and Climate Change Canada (ECCC) released a [scientific opinion](#) on SCNT cattle and swine. This scientific opinion agreed with those already established in the United States, European Union, Japan, and New Zealand, and paved the way for a policy revision.

Health Canada notes that SCNT clones and their progeny are still considered as “new” living organisms under the *Canadian Environmental Protection Act* (CEPA) and require a pre-manufacture and/or import assessment under the *New Substances Notification Regulations (Organisms)* [NSNR(O)]. However, ECCC and Health Canada are jointly reviewing the NSNR(O) to propose amendments which may exempt SCNT cattle and swine clones from the NSNR(O). This process is ongoing.

Health Canada is aiming for a fall 2024 implementation for the new SCNT policy on cattle and swine, assuming that no new scientific data warranting a review of this policy position is submitted during consultation. To participate in the consultation, upon review of the [proposed policy revision](#), comments can be submitted through May 25, 2024 to bmh-bdm@hc-sc.gc.ca.

The Health Canada Food Directorate will consider all science-based comments on food safety.

Attachments:

No Attachments.