



Government of Canada
Mission of Canada to
the European Union

Gouvernement du Canada
Mission du Canada auprès
de l'Union européenne

Avenue de Tervuren, 2
1040 Brussels, Belgium

April 30, 2012

Mr. Ladislav Miko
Deputy Director General
Health and Consumers / DG SANCO
Rue Breydel 4
B-1049, Brussels

Subject: Impact assessment on the animal cloning for food production in the EU

Dear Mr. Miko,

Thank you for your letter dated 14 March 2012 on the impact assessment on the animal cloning for food production in the EU.

As requested we are pleased to provide you with an update of the information on animal cloning for food production in Canada in the attached questionnaire.

I would like to emphasize that we are expecting that the regulatory approaches and any measures to be taken related to animal cloning for food production in the EU should be science-based and no more trade-restrictive than necessary to fulfill legitimate objectives, and should be consistent with international obligations.

Please do not hesitate to contact me should you have further questions.

Yours faithfully,



Encl: Questionnaire for animal cloning for food production

Canada

Questionnaire for animal cloning for food production

1. Country:	Canada
2. Competent Authority/ies:	<p>Health Canada, Food Directorate (food policy, novel food assessment).</p> <p>Canadian Food Inspection Agency, Animal Feed Division (registration of animal feed, including approval of animal feed ingredients of animal origin).</p> <p>Canadian Food Inspection Agency, Terrestrial Animal Health Division (import/export of live animals, semen, and embryos).</p> <p>Environment Canada / Health Canada (environmental/human health risks from environmental releases of new substances).</p> <p>Agriculture and Agri-Food Canada (animal registration).</p>
3. Please identify a contact person (name, institution, telephone and e-mail address)	<div style="background-color: #cccccc; width: 150px; height: 1.2em; margin-bottom: 5px;"></div> <p>Section Head Novel Foods Section Evaluation Division Bureau of Microbial Hazards Food Directorate Health Products and Food Branch Health Canada</p> <p>Jeanne Mance Building - Floor: 11 200 Eglantine Driveway, Tunney's Pasture Mail Stop: 1911C Ottawa, Ontario, Canada K1A 0K9 Telephone: Fascimile: email: @hc-sc.gc.ca</p>
4. Do you have national legislation regarding the use of animal cloning technique on your territory? If not, do you intend to draft a national legislation in the near future?	
YES	

NO	X
<p>If yes, please specify on which basis:</p> <p>Canada does not have specific legislation governing the use of animal clones; our existing regulations however, do provide this coverage where needed. Canada's regulations are not based on the method of production but rather on ensuring environmental, food, feed and human safety. If new methods of production give rise to products which would be considered new to the environment, a novel food or novel feed, the product must be notified to the federal government and assessed before being permitted in Canada. No other national legislation is intended. Canada's existing regulations are considered sufficient to address all aspects of the health and safety of new animals and their products regardless of how they are generated.</p> <p>In Canada, animal clones, their progeny and derived products are subject to the same rigorous health and safety regulations that apply to conventional animals and their derived products under the <i>Health of Animals Act and Regulations</i>, the <i>Food and Drugs Act and Regulations</i>, the <i>Meat Inspection Act and Regulations</i>, and the <i>Feeds Act and Regulations</i>, administered by the CFIA and Health Canada.</p> <p>In addition, animal clones are currently considered as "novel" or "new", triggering additional regulations administered by a number of organizations: Health Canada for food safety and indirect human health effects; CFIA for feed safety, animal health, certain aspects of animal welfare (animal welfare regulations are in place related to the humane slaughter within federally inspected facilities and humane transport of animals), and enforcement of food standards and regulations; and, Environment Canada for environmental release.</p> <p>Therefore, animal clones and their products are not presently permitted for sale in Canada without assessment and approval. Importers must notify Health Canada, the Canadian Food Inspection Agency (CFIA) and/or Environment Canada before importing such products into Canada and the appropriate assessments and approvals would need to be undertaken.</p> <p>However, Canada has not yet completed a final determination based on the latest science, of if or how animals, progeny and any products derived therefrom would fall under the regulations.</p> <p>In July 2003, as an interim policy, Health Canada stated that foods produced from livestock developed using somatic cell nuclear transfer (SCNT) cloning and from the progeny of such livestock will be considered to fall under the definition of "novel food." Novel foods are subject to the regulations in Division 28, Part B, of the <i>Food and Drug Regulations</i>. Developers producing animal clones through SCNT must, therefore, not introduce the products or by-products of any animal clones or their progeny to the human food supply in Canada, unless they have been subject to the pre-market safety assessment required for novel foods. This interim policy is posted on the Health Canada's website: http://www.hc-sc.gc.ca/fn-an/legislation/pol/pol-cloned_animal-clones_animaux_e.html</p> <p>The CFIA also considers products and by-products derived from SCNT animal clones and their progeny to be "novel feeds"; therefore, notification and assessment is required before any derived products from these animals are released in the feed chain. This</p>	

assessment considers the safety of the feed to livestock, to humans via worker/bystander exposure and consumption of animal products, and to the environment. More information regarding the use of products and by-products derived from SCNT animal clones into feeds can be found at the Canadian Food Inspection Agency's web site:
<http://www.inspection.gc.ca/english/animal/feebet/bio/bfeebetae.shtml>

SCNT animal clones, their progeny and their products and by-products are also considered "new substances" under the *Canadian Environmental Protection Act, 1999* and, therefore, require notification under the *New Substances Notification Regulations (Organisms)*. Prior to import or manufacture in Canada, importers and manufacturers of such substances are required to supply to the Minister of the Environment the information prescribed in these regulations that will allow this Minister and the Minister of Health to perform a risk assessment to determine if the new substance poses a risk to the environment and to the health of Canadians. More information regarding the requirements for notification of new substances is posted on Environment Canada's website: <http://www.ec.gc.ca/subsnouvelles-news/subs/default.asp?lang=En&n=E621534F-1>

5. Is the animal cloning technique used by private companies for breeding purposes in your territory?

YES	X
NO	

If yes, please specify the name of the companies and the estimated number of clones by species and the destination and quantities of the cloned animals and products thereof (reproductive materials):

To date, animal cloning has been done on a very limited scale in Canada, primarily in veterinary college research laboratories. Animal clones are not currently permitted on the market in Canada. There are no companies of which Canada is aware that are using cloning techniques for breeding purposes in Canada. All major livestock genetics distribution companies and breed associations in Canada are aware of Canada's current regulatory position.

In recent years, a few Canadian bovine artificial insemination centres have produced clones of their elite bulls to serve as potential replacements for elite sires. However, all of these cloned animals have since been euthanized and disposed by burial or incineration, without entry into the food chain nor animal feed system.

6. Do cloned animals in your country have a special identification or register?

YES	X
NO	

If yes, please specify how it is done. Please specify the species covered by the identification procedure or register.

Under the current federal regulations, there are no compulsory identification or registration requirements for animal clones. However, some Canadian livestock breed registries have provisions to identify animal clones through a supplemental designation on the registration documents, to differentiate animal clones from the animals which were derived through conventional breeding. The animal registration process is voluntary.

Seedstock animals in Canada are registered by breed associations operating under the authority of the *Animal Pedigree Act* and in accordance with approved by-laws, which must include provision for unique identification of animals. Breed associations may register animals, semen and embryos, including those which derive from cloning technology. However, Agriculture & Agri-Food Canada has requested any breed associations wishing to register clones, to confirm that protocols are in place to ensure unique identification of the clones and their progeny. A list of recognized breed associations in Canada can be found at <http://www.agr.gc.ca/apa> Although registration is principally for breeding stock, animals not approved for commercial use, such as clones, may also be registered.

Holstein Canada established special protocols for recording clones to ensure they would be uniquely identified and distinguished on Certificates of Registration.

7. Do reproductive materials (semen and embryo) from cloned animals produced in your country have a special identification or register?

YES	X
NO	

If yes, please specify how it is done. Please also specify the species covered by the identification procedure or register and if exported to which countries.

Semen and embryos may be registered by breed associations under the authority of the *Animal Pedigree Act* but are not generally, since breed associations rely on other measures for the tracking of semen and embryos.

Semen and embryos are collected, identified and transferred in accordance with protocols established by the Canadian Embryo Transfer Association which is a member of the International Embryo Transfer Society.

The documentation for semen and embryos must identify animal clones through a supplemental designation on the registration documents, so that the germplasm from

animal clones can be differentiated from that of conventionally derived animals. Canadian facilities employ identification procedures and export certification that conform with technical standards developed by the International Embryo Transfer Society and Office Internationale des Epizooties / World Organisation for Animal Health for trade in animal germplasm.

The identity of animal clones is noted on animal registration documents, and semen and embryo identification documents.

8. Do breeding centres or farmers on your territory import cloned animals or reproductive materials (semen and embryo) from cloned animals?

YES	
NO	
Unknown	X

If yes, please specify the species, the intended food production (milk or meat) and an estimated annual number of animals or amount of reproductive materials.

The importation and exportation of live animals and germplasm are regulated by the Canadian Food Inspection Agency (CFIA). The regulatory controls also apply to bovine artificial insemination centres and, for export purposes only to embryo transfer facilities. To date, there has been very limited domestic production or importation of cloned animals in Canada.

Breed associations in Canada have been informed of the regulatory status of clones in Canada, which does not currently permit commercial use of clones or their reproductive material. Canada's regulations have a pre-import notification requirement for any organism that may be "new" to Canada, which at this time includes clones and their reproductive material. At this time, there has been no pre-import notification submitted to government authorities.

9. Do imported clones or reproductive materials (semen and embryo) from cloned animals have a special identification or register?

YES	
NO	X
Unknown	

If yes, please specify how it is done. Please also specify the species covered by the identification or register.

10. Are you aware of any new information about possible improvements related to the health and welfare problems on the use of the animal cloning technique?

YES	
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NO	X	
Unknown		

If yes, please provide the documents.

Research on clones has been limited in Canada and no new information on the health and welfare of animals deriving from cloning technology has been generated in Canada that has been made available to the Government of Canada.

11. Do you have scientific risk assessments on the animal health and welfare and on the food safety of the products from clones and offspring of clones?

YES	X	
NO		

If yes, please provide the documents.

A draft scientific opinion on food animal cloning has been prepared, however it has not been approved for distribution outside the government of Canada. In the meantime, it is available for internal reference.

12. Do you have in place, or do you envisage to put in place, a traceability and labelling system for food derived from cloned animals?

YES		
NO	X	

If yes, please specify how it is done and for which type of products.

The development of policies relating to the acceptability of foods derived from cloned animal, including policies for traceability or labelling, is led by the Food Directorate, Health Canada, in conjunction with CFIA. Such policies would be put in place if a human health risk was identified which could be managed through such risk management tools.

13. Do you have in place, or do you envisage to put in place, a traceability and labelling system for food derived from offspring of cloned animals?

YES		
NO	X	

If yes, please specify how it is done and for which type of products.

The development of policies relating to the acceptability of foods derived from cloned animal, including policies for traceability or labelling, is led by the Food Directorate, Health Canada, in conjunction with CFIA. Such policies would be put in place if a human health risk was identified which could be managed through such risk management tools.

14. Is the animal cloning technique used for research purposes on your territory?

YES	X
NO	

If yes, please provide the names of the laboratories and indicate the field and scope of the research area, the number of cloned animals by species and the final destination of these animals and their products.

Animal cloning research is not regulated by the CFIA, however researchers are required to ensure that animal clones do not enter the food chain or animal feed system and are not released into the environment. The research would primarily be done within veterinary colleges or bovine artificial insemination facilities.