

A top-down photograph of a wooden cutting board. On the board, there are several slices of salmon, some of which are being cut with a knife. Next to the salmon are several pieces of steak, some of which are seared. In the bottom right corner of the board, there is a small bowl containing a brown sauce. The background is a dark, textured surface.

Cellular Agriculture Canada 🍁

CELLULAR AGRICULTURE & THE CANADIAN REGULATORY FRAMEWORK

Panel Event Report

DECEMBER 2021



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About Cellular Agriculture Canada

Cellular Agriculture Canada (CAC) is a not-for-profit organization supporting and promoting the emerging field of cellular agriculture. Our main goals include increasing public awareness and advocating for fair policies for the field.

Acknowledgements

This event report paper was written by Ahmed Khan, Avery Parkinson, and Vinay Mayya from CAC. CAC also acknowledges the support and valuable feedback provided by Lejly Gafour during the review process of this paper.

Notice: The information in this report is current at the time of publication.



Introduction

Cellular agriculture (also known as “cell ag”) is the field pertaining to the science and manufacturing of agricultural products from cells, rather than from entire animals or plants. It uses living cells grown in culture to create products that mimic traditional agricultural products, such as meat, dairy, or leather. It combines multiple fields such as biotechnology, genetics, tissue engineering, bioengineering, medicine, and food science.

Due to its novelty, the regulatory pathway that will allow these products to be commercialized in Canada is unknown to product developers. Based on a preliminary meeting with government officials, CAC published the white paper, “First Steps Towards a Regulatory Framework for Cultured Foods Products in Canada” in September 2020. The white paper aims to serve as a guide for cell ag companies that will be required to undertake the approval process.

To further explore what a regulatory framework could look like for cultured meat in Canada, CAC organized the “Cellular Agriculture and the Canadian Regulatory Framework” on March 4, 2021, with regulators and technical experts from the Canadian government. The event featured individual presentations by the Canadian Food Inspection Agency (CFIA), Health Canada, and Environmental and Climate Change Canada (ECCC). The event concluded with a panel discussion addressing questions set forth in the CAC white paper.

This report serves as a guide summarizing the key points from each of the individual presentations during the “Cellular Agriculture and the Canadian Regulatory Framework” event.



Presentation 1: The Regulation of Novel Foods and Novel Feeds in Canada

The first presentation was given by the Health Canada Food Directorate and the Animal Health Directorate of the Canadian Food Inspection Agency concerning regulatory pathways for novel foods and novel feeds in Canada.

The Regulation of Novel Foods

In Canada, there are many different biotech-related regulatory pathways. Health Canada oversees regulation of novel foods, drugs, medical devices, and biologics through the *Food and Drugs Act*. In addition, along with Health Canada oversight, Environment and Climate Change Canada and Fisheries and Oceans Canada also have responsibilities for ensuring novel products meet all environmental responsibilities. There are also non-regulatory considerations for biotech products, such as market access and socio-economic impacts, which are handled by Agriculture and Agri-Food Canada, Global Affairs Canada, and Innovation, Science and Economic Development Canada.

Since 1999, novel foods have been regulated in a product-based approach, where regulators look at the novelty of the final product as they assess its safety profile. Health Canada and the Canadian Food Inspection Agency require a mandatory pre-market safety assessment for novel foods and novel feeds that meet the definition of novel as found in Division 28 of the *Food and Drug Regulations* for foods and the *Feeds Act* for animal feeds. The regulators take a non-prescriptive scientific evidence based case-by-case approach, where the final products need to meet safety standards and requirements to obtain approval for sale in Canada.

The authorization and approval process for novel foods and novel feeds is a multifaceted approach which all takes place concurrently, or as close as possible:

1. Under the *Food & Drugs Act*, Health Canada carries out a Novel Food Assessment. The outcome of the assessment is a letter of no objection for sale in Canada for human food use.
2. At the same time, the Canadian Food Inspection Agency's livestock feed assessment is conducted according to the *Feeds Act*. If authorized, the assessment will lead to an authorization for livestock feed use.
3. Concurrently, under the *Canadian Environmental Protection Act (CEPA)*, an environmental assessment is conducted by Environment and Climate Change Canada and Health Canada.

In Canada, there is a no-split approval policy to prevent risk of bringing a novel biotechnology product to market when not in compliance with all applicable regulations. For example, there are timelines mandated under the New *Substances Notification Regulations (NSNR)* under CEPA,



to conduct the environmental assessment within 120 days (assessment periods range from 5-120 days depending on the substance types such as chemical, polymer, or living organism and other factors). Therefore, even if a novel food product receives its environmental authorization, the no-split policy means a novel product can only proceed if it receives all three approvals for sale in Canada. Beyond the three approval pathways, there are other regulatory requirements from the Canadian Food Inspection Agency, such as labelling requirements, before proceeding to commercialization.

Under the *Foods & Drugs Act*, there are three regulatory definitions of a novel food that would trigger a premarket notification to be made. All three definitions may be applicable to cell-cultured food products derived from cellular agriculture:

1. A substance that does not yet have a history of safe use as a food in Canada.
2. Food has been manufactured, prepared, preserved, or packaged by a process that has not been previously used for that food and causes the food to undergo a major change.
3. Food that is derived from a plant, animal, or microorganism that has been genetically modified such that it exhibits new or the food has characteristics removed or characteristics that fall outside the normal anticipated range.

All food products derived from cellular agriculture are currently considered novel foods. Food products from cellular agriculture will be required to undergo a mandatory pre-market safety assessment before being made available for sale. The specific regulatory definition that would be triggered depends on the cellular agriculture product itself.

A pre-market safety assessment is required for novel foods. A premarket novel food notification involves addressing several main safety endpoints to be evaluated:

1. Molecular characterization: describing what the product is; how the product is made; and what the final product looks like in terms of characteristics.
2. Nutritional composition: evaluation of how the novel food would compare to its non-modified counterpart in terms of nutrition and composition.
3. Toxicology and allergenicity: evaluation of the novel food to assess if the product would introduce new toxicological risks or cause foods to be allergenic that once were not foods with allergenic concerns; or cause a food to be more allergenic.
4. Chemical contaminants: evaluation of ensuring the novel product does not introduce any new chemical contaminant risks into the Canadian food supply.

The Regulation of Novel Feeds

Novel feed regulation is linked to novel food regulation because of the possibility that cellular agriculture-derived food products may end up being rendered into the animal feed chain.

In Canada, a novel feed is any feed ingredient that is new or has been modified in such a way that differs the product from the conventional parameters that exist for feed. Currently, only



feed ingredients which have been approved and evaluated by the CFIA may be used in livestock feeds. All approved feed ingredients are listed in Schedules IX and X of the *Feeds Regulation*.

Feeds with novel traits can be developed using a wide range of methods such as traditional breeding, mutagenesis, cell fusion, recombinant DNA techniques, etc. Products derived from biotechnology are treated the same as non-biotech feeds in terms of the safety endpoints that the products need to meet.

Similar to the premarket novel food notification, the novel feed premarket notification requires data describing the methods and results of the same safety endpoints:

1. Molecular characterization;
2. Nutritional composition; and
3. Toxicological data.

The key difference between novel food and novel feed premarket notification is the route of exposure that is calculated differently for animal feed compared to novel foods. Animal feed is consumed in different and larger amounts compared to human food, and the premarket novel feed notification evaluates the differences.

Stakeholders engagement is important in product development, especially when it comes to the regulation of novel foods and novel feeds in Canada. The regulators consistently engage with stakeholders through biotechnology working groups, technical meetings with industry, academia, and others. Broad and through consultations are also required prior to making regulatory changes. Government regulators encourage the cellular agriculture industry to participate in stakeholder consultations, as they occur.

Cellular agriculture companies and players are encouraged to contact regulatory authorities early on in the product development process to discuss potential regulatory requirements, such as novelty requirements, through a pre-submission consultation. By contacting the Health Canada Submission Management Information Unit (SMIU), by email at smiu-ugdi@hc-sc.gc.ca, a pre-submission consultation with regulatory experts from Health Canada, the CFIA and ECCC as needed, can be coordinated. **All pre-submission consultations and communications are treated as confidential.** A public facing announcement will be made if and when, a letter of no objection is issued upon the completion of a pre-market safety assessment. It will be published on a list of completed novel food safety assessments.

Canadian regulators are aware of cellular agriculture regulatory developments in other nations. The Canadian system is well designed to assess innovative products and functions independently of approvals elsewhere. However, the approval of cultured meat products elsewhere, could be used as a weight of evidence as part of a product's overall rationale, as to why the product is safe in a submission seeking regulatory approval in Canada.



Presentation 2: Overview Of The New Substances Notification Regulations Of CEPA

The second presentation was given by the Regulatory Affairs Unit within the New Substances program at Health Canada, concerning the *New Substances Notification Regulations (NSNR)* of CEPA.

New Substances Program

The Canadian Environmental Protection Act, 1999 (CEPA) is a part of Canada's federal environmental legislation that aims at protecting the environment and the health of Canadians from risks associated with pollution. CEPA sets the criteria for toxicity and ensures that no new substances are introduced into Canadian commerce before their potential risk to human health and the environment has been assessed.

CEPA defines 'substance' as any distinguishable kind of organic or inorganic matter, whether animate or inanimate. Substances include chemicals, biochemicals, polymers, biopolymers, and living organisms. Accordingly, the NSNR is divided into two separate sets of new substances provisions. New living organisms (e.g., bacteria, viruses, cells) are subject to the NSNR (Organisms), while new chemicals and polymers are subject to the NSNR (Chemicals and Polymers). Substances that are not listed on the Domestic Substances List (DSL) are considered new substances and may require notification under the NSNR prior to import into or manufacture in Canada.

Relevant to the cultured meat industry, cultured cells, if not already on the DSL, would most likely be subject to the NSNR (Organisms). Tissues that are generated through cell culture, as well as substances used in the cellular agriculture process, would likely be subject to NSNR (Chemicals and Polymers).

NSNR for Chemicals and Polymers, and NSNR for Organisms

The NSNR for chemicals and polymers, and the NSNR for organisms differ in aspects related to types of substances, trigger quantities (the amount that can be imported or manufactured before notification), length of the assessment period (the amount of time the New Substances program has to conduct a risk assessment), and the information that has to be submitted to the New Substances program (described in schedules).

Information requirements are listed in schedules in the NSNR and depend on several factors. For instance, for chemicals and polymers, required information is determined by the type of the substance, its intended use, NDSL status, and import/manufacture quantity.

A detailed overview of the NSNR for chemicals and polymers, and organisms is shown below.



| | NSNR Chemicals and Polymers | NSNR Organisms |
|-----------------------------|---|--|
| Types of Substances | Chemicals Biochemicals Polymers Biopolymers | Microorganisms Organisms other than microorganisms |
| Trigger Quantities | 100 kg/yr 1,000 kg/yr 10,000 kg/yr 50,000 kg/yr | 0 kg/yr |
| Length of assessment period | 5 days 30 days 60 days 75 days | 30 days 90 days 120 days |
| Schedules | Tiered Schedules based on: Type of substance Quantities imported/manufactured NSDL Status | Based on where the organisms are introduced into Canada: Anywhere in Canada In contained facility or export only Experimental Field Study At same site where isolated & manufactured |
| Information Requirements | Administrative Information Substance Identity Physical-chemical test data Toxicity test data Exposure information | Administrative Information Organism identity Health effects information Ecological effects information Environmental fate and Exposure information |

Chart adapted from presentation

New Substances Notification

Before importing or manufacturing a new substance in Canada, a submission of prescribed information may be required. A New Substances Notification (NSN) should include a cover letter, NSN reporting form, and attachments (information required by the schedule), and fees (if applicable). For instance, for chemicals and polymers, attachments must consist of all required physical-chemical, toxicity, and exposure data. The government then assesses the information provided in the NSN package within the prescribed time frame. The flowchart below provides an overview of the New Substances program's notification process and assessment outcomes.

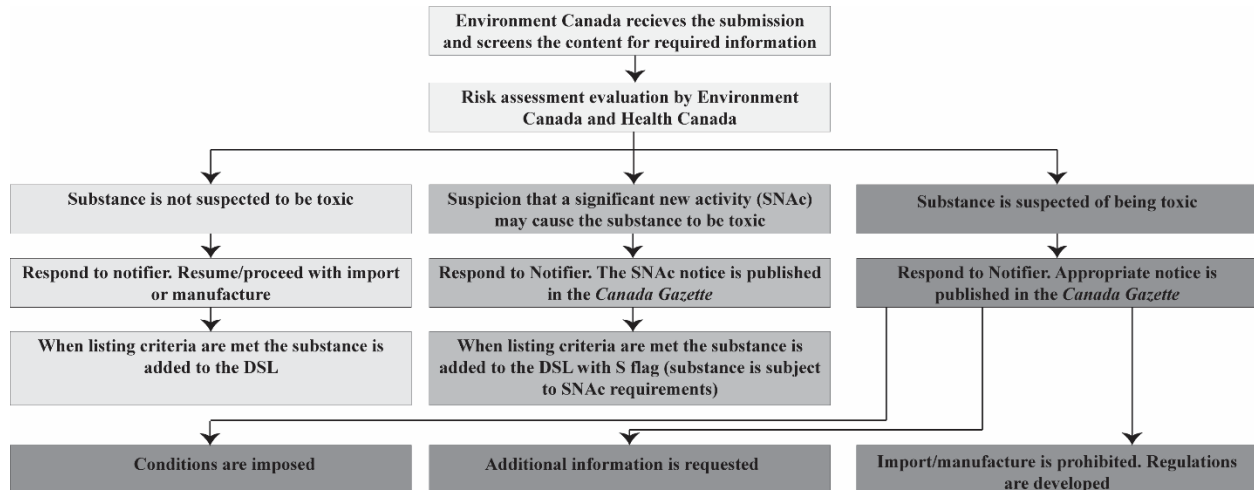


Chart adopted from presentation

Substances such as chemicals, polymers, and organisms that are not listed on the DSL may require notification under the NSNR before manufacture in or import into Canada. It is the responsibility of the importers/manufacturers to provide a complete NSN package to the New Substances program, prior to exceeding trigger quantities. The New Substances program then assesses this information and takes any necessary actions.

For assistance preparing a New Substances Notification, or for guidance about potential regulatory obligations, contact: Substances Management Information Line by email eccc.substances.eccc@canada.ca or by phone 1-800-567-1999; Environmental Assessment Unit by email HC.eau-uee.SC@canada.ca or by phone 1-866-996-9913.



Presentation 3: Canadian Food Labelling Framework

The third presentation was given by the Food Safety and Consumer Protection Directorate from the Canadian Food Inspection Agency (CFIA) concerning the Canadian Food Regulatory Framework.

Under the *Safe Food for Canadians Regulations (SFCR)*, food businesses that are involved in interprovincial trade, import and export, are required to meet certain requirements. These include:

1. A food license.
2. Preventive controls which address food safety hazards and reduce the likelihood of contaminated food entering the market [Part 4 SFCR].
3. A Preventive Control Plan (PCP) which demonstrates how risk to food are identified and controlled.
4. Traceability records which ensure the traceability of products through the supply chain [Section 92 SFCR].

Food must also comply with compositional and labelling requirements under the *Food and Drug Regulations (FDR)* and SFCR. Under the current regulatory framework (*FDR*), 'food' includes any 'article manufactured, sold or represented for use as food or drink for human beings'.

The regulations require that foods have a common name. The use of specific common names (such as those prescribed for standardized foods) may subject the food to certain composition, fortification, nutrition and labelling requirements that are prescribed in the regulations. For example, there are specific requirements for meat and poultry products, as well as simulated meat and poultry. The term 'meat' and 'meat product' is defined as the muscle or the carcass of a food animal that was slaughtered, whereas 'simulated meat' and 'simulated poultry' products are defined as any food that does not contain meat, poultry or fish product but has the appearance of a meat or poultry product.

The common name that defines the food has to be the name that is required in regulations or in a standard. If it is not defined in either of those, then it must be a name by which the food is commonly known or name that is not generic and describes the food. Additionally, the common name should clearly indicate the nature of the product without creating an erroneous impression.

Furthermore, claims and statements about a product are voluntary and must be truthful and not misleading. The CFIA has guidance to assist with labelling for method of production claims (e.g., environmental, genetically engineered) and compositional claims (e.g., vegetarian and vegan).



Producers of cultured meats should take these requirements into account as they develop new products. The CFIA encourages discussion of labelling at the earliest stages of product development and has made its labelling guidance publicly available in the CFIA's [Industry Labelling Tool](#).

Cellular agriculture companies are encouraged to contact regulatory authorities early on in the product development process to discuss potential regulatory requirements including labelling. The CFIA is available to participate in confidential pre-submission consultations and communications one-on-one with product developers or jointly with Health Canada and ECCC.

CFIA's online service [AskCFIA](#), provides regulated parties with one point of entry to ask questions that help them understand and comply with CFIA regulatory requirements. Additionally, the CFIA welcomes input from the cellular agriculture field on potential solutions to regulatory challenges. Interested parties can stay informed regarding future CFIA consultations by visiting the [CFIA's Consultations and Engagement](#) web page.

The CFIA and Health Canada are working to use incorporation by reference to allow food compositional standards to be maintained and updated in a transparent, timely and efficient manner. The work of moving standards into documents that are incorporated by reference will help address innovation and changing market practices. This work is described in further detail in the CFIA's [Forward Regulatory Plan](#).



Conclusion

The industry is in its early stages in Canada with only a few companies developing cell cultured products and paving the way for the rest of the industry. Therefore, we believe it is important for startups to commence a dialogue with regulators as early as possible, as well as to develop thorough documenting procedures to ensure transparency and evidence-based practices that will help to promote fair regulations for the industry. We also encourage dialogue among regulators in different countries where the industry is flourishing to promote an early regulatory alignment.

As a not-for-profit organization, Cellular Agriculture Canada (CAC) will continue its dialogue with regulators to serve as the liaison between them and the cell ag industry. We would also welcome updates from the companies on how their regulatory development is evolving, and to provide assistance with their challenges.