Cellular Agriculture Canada

First Steps Towards a Regulatory Framework for Cultured Food Products in Canada

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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.

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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 needs to be paved. Therefore, based on a preliminary meeting with government officers, this white paper intends to outline the initial steps to achieve regulatory approval of cell cultured food products and serve as a guide for cell ag companies that will be required to undertake the approval process.

How will cell cultured food products be approved in Canada, and what type of oversight will be applied?

Food products manufactured using cell ag technologies will likely be regulated as novel foods by Health Canada's (HC) Food Directorate. As such, they will need to be pre-approved by HC before they can be commercialized. Regulations regarding novel foods are outlined in Division 28 of the *Food and Drug Regulations* (FDR). The current HC *Guidelines for the Safety Assessment of Novel Foods* were published in June 2006. Food derived from cell cultures is not mentioned in the guidelines nor are novel foods derived from animals, however, the requirements are broad enough and could be adapted to cell ag. Depending on the particular cell cultured food product, it could fit into one or more of the following definitions of novel foods found at s. B.28.001 FDR[1]:

1. *a substance, including a microorganism, that does not have a history of safe use as food;*
2. *a food that has been manufactured, prepared, preserved or packaged by a process that*
    i. *has not been previously applied to that food, and*
    ii. *causes the food to undergo a major change; and*
3. *a food that is derived from a plant, animal or microorganism that has been genetically modified such that*
    i. *the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,*

ii. *the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or*

i. *one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.*

The guidelines lay out the health and safety requirements for novel foods to be approved and commercialized, i.e., microbial safety, molecular characterization, dietary exposure, toxicology and nutrition.[2]

Since each cell cultured food product may require its own unique manufacturing process, the most plausible pathway could be a product-based approach, i.e., on a case-by-case assessment. Therefore, it is crucial that each company starts a dialogue with HC as soon as possible in the development process. As part of this dialogue, HC, through the Food Directorate, would provide specific instructions about the requirements for submission for premarket review. In the future, as the new technology applies general principles and becomes more standardized, it could be possible to determine a streamlined and more general regulatory pathway.

Based on the type of cell cultured food product, we expect that manufacturers will need to prepare a regulatory package for either novel foods or novel feeds or both, and an environmental assessment. This means that companies will need to work together not only with HC but also with the Canadian Food Inspection Agency (CFIA) and Environment and Climate Change Canada (ECCC). **Figure 1** summarizes the steps needed to start the approval process of a cell cultured food product, including a nutritional assessment that could require a nutritional profile of the product as well as studies on its nutritional equivalency to the traditional product. It is important to mention that cell ag manufacturers may request a pre-submission consultation to help them prepare their regulatory package.

The Animal Feed Division of the CFIA evaluates and regulates all feed ingredients, including novel feeds, in the same manner. Any feed ingredient that is new (i.e., is not already listed in Schedules IV or V of the Feeds Regulations), or has been modified such that it differs significantly from a conventional ingredient, is required to undergo a pre-market assessment and approval. The purpose of all feed assessments is the same: to ensure that the feed ingredient is safe (in terms of animal health, human health via residues in food and worker/by-stander exposure, and the environment) and effective for its intended purpose prior to marketing (*RG-1 Regulatory Guidance: Feed Registration Procedures and Labelling Standards*, c 2, s. 1(3) [3].

How to Start the Regulatory Approval Process for Cell Cultured Food Products

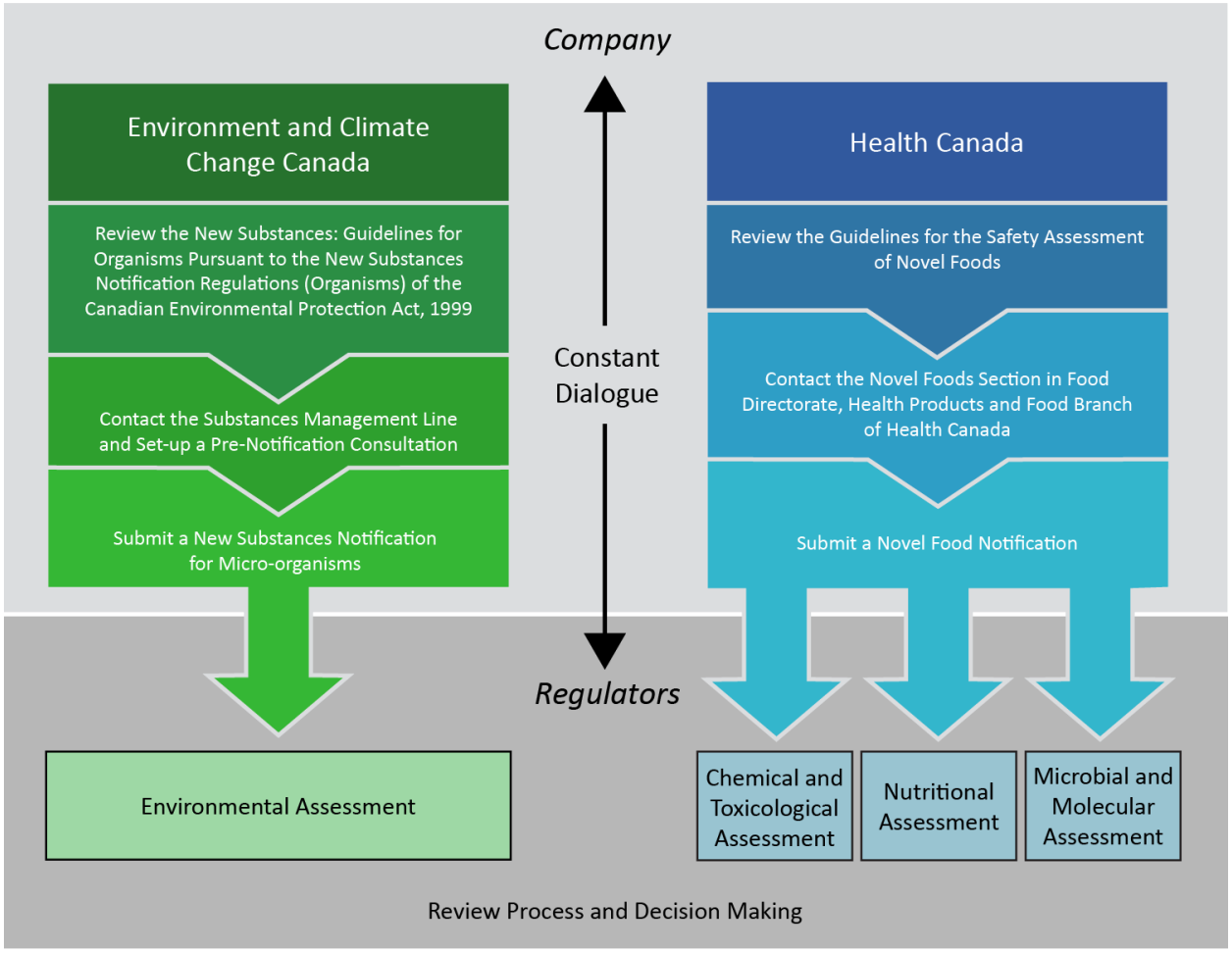

Figure 1. Starting the Regulatory Approval Process for Cell Cultured Food Products. For companies developing Novel Feeds, the approval process will require safety and environmental assessments conducted by the CFIA.

Cells cultured for novel food products may also meet the definition of a micro-organism under the *New Substances Notification Regulations (Organisms) [NSNR(O)] of the Canadian Environmental Protection Act, 1999 (CEPA)*. Individuals wishing to import or manufacture "new" cultured cells for introduction anywhere in Canada are required to submit a notification to Environment and Climate Canada a minimum of 120 days prior to import or manufacture. The Domestic Substances List (DSL) is the sole basis for determining if a substance is considered to be "new" according to CEPA. For further information, consult the New Substances: Guidelines

for Organisms pursuant to the *New Substances Notification Regulations (Organisms) of the Canadian Environmental Protection Act, 1999.*[4]

Developers of cell cultured food products can seek advice and submit technical inquiries using a Pre-Notification Consultation through the Substances Management Information Line.[5] This is a mechanism for companies to discuss with regulators how they can comply with the *New Substances Notification Regulations (Organisms)* and the *Canadian Environmental Protection Act, 1999.*

It is important to note that any cell cultured product to be imported into Canada, in addition to the above, will be subject to all applicable import requirements. Companies interested in importing should follow the *Importing Food to Canada: A Step-by-Step Guide* found on CFIA's website.[6]

Ingredients included in the manufacturing of a cell cultured food product that meet the definition of "food additive" according to s. B.01.001 (1) FDR, and are not yet approved for use in food will need to be reviewed by HC pursuant to s. B.16.002 FDR.

There are substances that do not meet the definition of "food ingredients" nor "food additives," which are known as "processing aids." Although there is no regulatory definition for the latter, they are considered by Canadian regulators as *"substances used as adjuncts in food processing and manufacture."* New processing aids do not require preclearance by the Minister of Health. However, like all substances used with food, the use of a processing aid would be controlled by section 4(1) of the FDR. To determine if any substance used during the manufacturing of cultured food products is considered a food additive or a processing aid, cell ag manufacturers can follow the decision tree in the *Policy for Differentiating Food Additives and Processing Aids* from HC.[7]

Products that have previously been approved and used as medicines or natural health products would be considered novel foods and subject to pre-market review based on their lack of history of safe use as food. Although products may have been introduced into the body parenterally, the concern is that they may lead to allergic or other reactions as they enter the digestive system.

What about labelling?

HC is responsible for the labelling of products regarding health and safety. The CFIA Consumer Protection and Market Fairness Division is responsible for the labelling of products and certain compositional standards.

The issue of labelling and compositional standards needs to be addressed as soon as possible in order to determine and define cell cultured food products in Canada. For example, the current definition of "meat" refers to the edible part of the skeletal muscle of an animal that was healthy at the time of slaughter (s. B.14.0002 FDR). Amendments to the FDR will likely be required to accommodate the labelling of cell cultured food products that do not involve animal slaughter. Any changes to regulations involve broad stakeholder engagement such as with consumers, industry, associations, government, and other jurisdictions.

The role of genetic modification is still a topic for research in the field. Focusing on cultured meat, products may consist solely of the same unmodified cells as conventional meat (e.g. muscle, fat, and connective tissue). However, if a company decides to use genetically modified cells, they will need to take into consideration that several categories of food labelling may apply including those of genetically engineered food products. The Canadian General Standards Board has developed the *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering* standard. The latter defines terms, sets out criteria for claims for products sold in Canada, and overall ensures that any such claims are consistent with an appropriate set of parameters to help consumers make informed decisions.[8]

It is important to mention that HC's novel food and CFIA's animal feed regulatory oversight does not include pet food.

What is next?

Regulators worldwide are working together in order to harmonize and streamline the requirements for drugs and medical devices submissions. However, the efforts to align food regulations between Canada and other jurisdictions are still a work in progress.

In March 2019, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) entered into a formal agreement to address the regulatory oversight of cell cultured food products from cell lines of livestock and poultry.[9] The FDA will oversee cell collection, cell banks, and cell growth and differentiation. Then, during the cell harvest stage, when cells are ready to become meat, oversight will be transitioned to the USDA, which will supervise the production and labelling of cell cultured food products. The FDA will continue to regulate seafood-based cell aquaculture products as it regulates seafood in general.

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 industry. Therefore, we believe it is crucial to start a dialogue with regulators and establish thorough documenting procedures to ensure transparency and evidence-based practices that will help to establish 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.

References

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