



Health
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Santé
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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

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Dear Ms. Sharratt,

Thank you for your correspondence of November 14, 2013, addressed to the Honourable Rona Ambrose, Minister of Health, regarding genetically engineered (GE) salmon, the potential review of a novel foods submission by Canadian regulators, and transparency in the Canadian regulatory system. A copy of your correspondence was forwarded to Health Canada's Food Directorate for direct reply.

Health Canada's mandate is to ensure that all novel foods, including GE salmon, are safe and nutritious prior to entering the Canadian food supply. To accomplish this mandate, a pre-market notification requirement is in place for all novel foods intended for sale in Canada. This pre-market notification is mandatory as per Part B, Division 28 of the Canadian *Food and Drug Regulations* and ensures that the safety of each novel food is assessed and verified before it enters the Canadian marketplace.

Health Canada takes this responsibility seriously by hiring professional staff to conduct thorough, impartial, science-based reviews that adhere to the laws and regulations that govern these products. The GE food safety assessment conducted by Health Canada is a rigorous process that involves a scientific review of how the food was developed, comparison of its compositional and nutritional profile with non-modified counterparts, and the potential for the food to be toxic or to contain a toxin or allergen. Only when all the scientists evaluating a GE food product agree that there are no health or safety concerns is the food permitted in the Canadian marketplace.

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Health Canada continues to strive for openness and transparency as part of its overall decision making process, including in the safety assessment of substances it regulates. The Department must balance this objective with adhering to the regulations that govern the assessment of novel products and respecting confidential business information submitted by developers. As you may know, the Department is not legally permitted to release information that companies submit and consider confidential, as per 20 (1) of the *Access to Information Act*. This includes even the mere fact that a submission to the Department has been made. This is not unique to GE foods and is broadly applied to all products regulated by the Department.

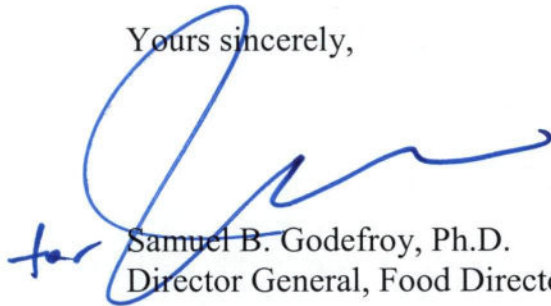
As you point out in your letter, if an authorisation for the GE salmon was granted, it would be the first GE animal permitted for sale in Canada. This has raised a significant amount of media and public interest in Canada and globally. Numerous news articles have been published and broadcast on this product in Canada. Furthermore, Aquabounty has been open about the status of this product in Canada and the United States, as well as about their plans for producing the fish. The amount of media coverage suggests that Canadians should be well aware of the existence of this product and its potential for introduction to the Canadian market at the conclusion of a safety assessment by Health Canada.

The level of media interest in this GE salmon is, however, an exception. Most GE products do not receive this level of interest and your larger point that Canadians should be made aware of the GE products being submitted for authorization is well understood by the Department. In the interest of transparency, Health Canada encourages companies to notify the public when GE products are submitted for assessment. To facilitate this for GE crops, a voluntary notification, known as a "Notice of Submission," is posted on the CFIA's website. This mechanism is useful in permitting the Department to notify the public of products submitted for authorisation, while remaining compliant with the laws respecting the release of information. At this time this mechanism exists only for GE crops. It is fortunate that the proponent for the GE fish has been so forthcoming regarding its submission.

The Department is continually looking at ways to improve the system for regulating novel foods in Canada and your comments regarding the transparency of the system will be considered in any future work in this area.

Thank you for writing.

Yours sincerely,



for Samuel B. Godefroy, Ph.D.
Director General, Food Directorate