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From Lab to Farm to Table: Regulation of Genetically Modified Food in Canada

On May 19, 2016, Health Canada published a decision approving the first genetically engineered animal for human consumption in Canada, the "AquAdvantage Salmon", once again bringing the issue of genetically-modified organism ("**GMO**") regulation to the forefront of consumers' minds. The AquAdvantage Salmon has DNA from two different fish, Pacific Chinook salmon and eelpout, allowing it to grow year-round and much faster than a normal salmon, reaching market size in about half the time. While it is too soon to determine the effect that this decision will have on the food industry, it provides an opportunity to review the approval process for genetically modified foods intended for human consumption and the labelling standards currently in place.

Approval Process

Notification

Genetically modified foods are classified as "novel foods" under Canada's *Food and Drug Regulations*, meaning they must undergo special "pre-market notification" procedures prior to being approved for human consumption. The definition of "novel foods" in the *Regulations* specifically includes foods derived from plants, animals, or microorganisms that have been genetically modified such that there are new characteristics exhibited or previously observed characteristics are no longer exhibited.

Health Canada is responsible for the regulations and guidelines governing novel foods, with the safety assessments for such foods

being conducted by the Food Directorate of its Health Products and Food Branch (the "**Directorate**"). As such, the first step in the approval process is for manufacturers and/or importers to notify the Directorate of their intention to sell or advertise a novel food (the "**Notification**"). The Notification must include basic product information, as well as disclosure respecting the food's development, the food's intended use, and the data relied upon to establish that the food is safe for consumption.

Safety Assessment Process

After a Notification is received, the Directorate has 45 days to respond with the results of the review. If the Directorate determines during the initial 45 days that further information is needed to conduct the safety assessment, an additional 90 days may be added to the assessment period from the date of receipt of the additional disclosure. The Novel Foods Section of the Directorate coordinates the review process by distributing submission material to the relevant specialized Directorate bureaux, including those that evaluate chemical, nutritional, and molecular biological elements. During the evaluation, there is rigorous analysis of the data provided in the Notification and the methods that were used to obtain such data to ensure both safety for consumption and research validity.

Although the Directorate notes that the assessment criteria are flexible and should reflect the novel characteristics of the particular product in question, the general framework utilized for novel foods derived from plant or microbial sources is Health Canada's *Guidelines for the Safety Assessment of Novel Foods* (the "***Guidelines***"). Since the most recent version of the *Guidelines* lists "Novel Foods Derived from Animals" as "Under Development", Health Canada's approval decision for the AquAdvantage Salmon employed a set of safety criteria specifically endorsed by the *Guidelines*, namely, the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals*.

Approval

Upon the completion of a successful safety assessment, a proposal is drafted submitting that the novel food be approved for sale. This proposal is presented to the Food Rulings Committee, which is chaired by the Director General of the Directorate and includes senior Directorate management, as well as representatives from the Canadian Food Inspection Agency ("**CFIA**"). If the Food Rulings Committee finds the proposal to be acceptable, the manufacturer or importer will be notified that Health Canada has no objection to the sale of the novel food product as human food in Canada as specified in the notification, thereby completing the approval process.

Labelling Requirements for Genetically Engineered Food in Canada

Health Canada and the CFIA share joint responsibility for federal food labelling policies under the *Food and Drugs Act*. While there is not currently a requirement to label genetically engineered foods, to recognize the interest in identifying them, a voluntary labelling standard, the National Standard of Canada *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering*, has been adopted for those producers, manufacturers and distributors wishing to have designations on their products. Although labelling is always mandatory where there are health or safety concerns that could be mitigated by labelling, i.e. the presence of allergens or a significant nutritional or compositional change, such a label would nevertheless not have to indicate that the food is genetically engineered.

As previously mentioned, it is too early to assess how the apparent trend towards approving genetically engineered animals for human consumption will affect the market and consumer behaviour, if at all. However, we do know that there is heightened attention being paid to labelling requirements for GMO-derived foods in North America, a perfect example being Vermont passing the USA's first law requiring mandatory GMO labelling (effective

July 2016). Given the relatively uneasy consumer response to the approval of the AquAdvantage Salmon, the question of whether Canada will adjust its labelling requirements remains live.

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a cautionary note