

## A NOVEL APPROACH FOR NOVEL FOODS

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As Canada's food supply continues to diversify, foods that have not been traditionally consumed in western cultures are becoming part of the Canadian diet. In mainstream stores it's now commonplace to find foods from different cultures, like aloe-beverages, or traditional foods with exotic additions, like maca ice cream. Globalization, lower transportation costs, and changing consumer preferences towards functional foods are driving the increased introduction of foods and ingredients that could be considered "novel" into the Canadian marketplace. The consumer-driven demand for these products poses a dilemma for industry and regulators alike - can the novel food regulatory framework provide the necessary flexibility to adapt to these trends while maintaining the safety standards Canadians expect? With the regulatory tools at our disposal, and a fresh perspective, the potential exists for both needs to be met.

The legal requirement to notify Health Canada prior to sale of a novel food, places the burden of determining if a food or ingredient is novel on manufacturers/importers. This determination can be complex as the legal definition for "novel food" is broad and includes foods or ingredients that do not have a history of safe use as food. Novelty status can be especially difficult to assess where an ingredient is an extract of a herb or food that does have a history of safe use, or where the food is consumed in other parts of the world but information is difficult to access or apply to use in Canada. So how do you know definitively if a food is novel? Well, foods are assessed on a case-by-case basis and when in doubt, manufacturers/importers are encouraged to consult with the [Novel Foods Section](#). In my experience, depending on the nature of the ingredient, the information provided, the volume of requests and whether a previous determination has been made, a response can be received within a short timeframe, or several months.

Given the rapidly changing marketplace, can this process be improved? Part of the answer might be in the new template for novelty determination developed by Food Directorate, which may provide structure to the process. As well, looking to the approach Food Directorate is considering to address novel ingredients in products that transitioned from the NHP to the food regulatory framework and are currently being sold under Temporary Marketing Authorizations (TMAs) as supplemented foods.

When these products originally gained market access as NHPs, they were subject to a safety assessment based on consumption of a limited dose – a different criteria than novel foods which are expected to be consumed freely (at one's pleasure). Now that these products are regulated as foods, to address this issue without immediate disruption to the marketplace, Food Directorate is considering using the TMA tool to exempt supplemented foods containing certain novel food ingredients from the novel food notification process. Under this approach, a list of ingredients eligible for exemption would be published and if a supplemented food contains those ingredients, a safety assessment would be undertaken during the TMA period.

The list of ingredients eligible for exemption is not an indication that these ingredients are safe for use in foods - rather these ingredients are being assessed for use only in supplemented foods considering that the sale of these products could be subject to certain conditions (e.g. labelling statements, directions of use, max. levels of use). What remains to be determined, is what will occur with respect to the novel status of these ingredients upon the expiry of the TMAs.

In exploring new approaches, it may be possible to continue to improve the novel foods framework – for example, expanding the TMA approach to a wider variety of potentially novel ingredients with a history of use in other cultures, or developing a searchable database identifying those ingredients that have been assessed for use in all foods and found either not to be novel or safe within certain usage levels. Improved transparency and efficiency would help Canada keep pace with the evolving global marketplace.

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