

INFORMATION TO HEALTH AUTHORITIES ABOUT NOVEL FOODS

When evaluating new food applications, if the product is

1. Being sold at retail or a farmers' market (not in a restaurant), &
2. Is a new or unfamiliar food (for example, Chaga tea, Chaga kombucha), &/OR
3. Is a food without a history of safe use as a food, &/OR
4. Is being made with a process that hasn't been evaluated before, &/OR
5. Is being made with a supplement to the ingredients beyond what is already in the regulation or is a genetically modified (GM) food , THEN

The operator is required to comply with Health Canada's Novel Food Regulations (see Division 28 of Part B of the Food and Drug Regulations). As a first step, a novelty determination will be made for the food product, ingredient or process. If the food or process is found to be novel, then a full novel food assessment would be required before the food is allowed to be sold in Canada. An assessment can take up to 14 months.

What is a novel food? See this [Guidance document](#), and particularly the list of information that the operator would be expected to provide on the form. Novel foods include novel processes as well as GMO and non-GMO foods that do not have a history of safe use as a food (see section 4.1.1.1 for history of use). For example non-GMO foods with novel processes include [in shell pasteurization of eggs](#) or [high pressure processing of raw fruit juices](#). A full list of novel foods that have been approved by HC can be found [here](#).

Guidance for operators:

Step 1. The SMIU office may be contacted to inquire about the novelty status of a food, ingredient or process. Ask the office if any novelty determination, decision or opinion has been made that is not posted yet on the web-site. If there is no opinion or internal decision, or if more information is required, then the SMIU office will require that the operator fill out a Novelty Determination Information Form (NDIF). At this time this document is not on the HC website. It can be requested by sending an e-mail to the SMIU office, at smiu-ugdi.sc@canada.ca, and is attached [here](#).

Step 2: Contact the [SMIU office](#) with the NDIF. Health Canada recommends the NDIF form is filled out prior to contacting the [SMIU office](#).

Operators should be reminded that it is their responsibility to ensure their products are in compliance with all applicable statutory and regulatory requirements. The sale of a food or a food ingredient that poses a risk to the health of consumers would contravene the provisions of the Food and Drugs Act. If the operator chooses not to seek an assessment of whether foods are considered novel, products found not in compliance by CFIA can result in enforcement actions (for e.g., fines and penalties to the operator).

If you have any questions about novel foods, there is more information on the [Health Canada website](#).

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