BC Centre for Disease Control
An agency of the Provincial Health Services Authority

Environmental Health Services

Food Issue

Notes from the Field

Risk assessment of chaga mushroom tea

Request received from:	Interior Health Authority
Date of request:	April 2016
Issue *(brief description)*:	What is chaga tea and are there any safety concerns with this product being sold at farmers' markets?

Disclaimer: The information provided in this document is based on the judgement of BCCDC's Environmental Health Services Food Safety Specialists and represents our knowledge at the time of the request. It has not been peer-reviewed and is not comprehensive.

Summary of search information:

1. Internet sources: google scholar
2. Contacted BC Drug Poison Information Centre and Health Canada

Background information:

Chaga is the common name for a fungus, *Inonotus obliquus*, used to brew chaga tea. It is also commonly known as cinder conk, and to some mycologists as 'clinker polypore'. Although it is classified as a mushroom, its appearance is as a hard, sharp edged black coloured growth on host trees. It grows on birch trees (*Betula papyrifera*) nearly exclusively, and only rarely has been found attacking other tree spp. The fungus is a cancerous growth on the tree, and will often kill the tree once it invades the cambrium (interior) of the tree. Chaga tea has been used in Russia since the 16th century, and was popularized in a 1968 novel, called 'The cancer ward' where the tea was purported to cure cancer.[1] Health claim benefits for chaga tea is that it is a strong antioxidant, and can slow tumor growth. It is also reported to be effective for gastrointestinal cancer, cardiovascular disease, diabetes, and arthritis.[2,3]

Photo of black chaga conk growing on birch tree, from Fungi volume 5:3 (2012)[4]

The fungus appears to contain compounds that would treat diabetes via antihyperglycemic effects. It is of interest to medical pharmacological researchers, with most studies based on in vitro (cell line based) experiments, however, few human clinical trials have been conducted to validate claims [2,5]

There is ethnobotanical historical use in Pacific Northwest First Nations as well. Gitksan First Nations would use this for arthritis, by treating skin irritation with cinder burned directly on the swollen joint (termed moxibustion treatment).[6] While drinking chaga as a tea by soaking in hot water is mentioned, the principal use of this substance was for fire embers. Once ignited, the embers can be preserved for later use for making or transporting fire.[6]

What are the risks associated with chaga tea and chaga powder consumption?

Five cases of illness potentially associated with the consumption of commercially sourced chaga tea have been reported to the BC Drug and Poison Information Centre since 2014. A review of the symptoms associated with each of the illnesses follow:

1. Hepatitis and renal failure following ingestion of chaga and alder bark. Dialysis was still required on last follow-up 2 months later.
2. Hepatitis following ingestion of chaga and other plant products (Maca powder, ginseng).
3. Bradycardic episode including vomiting and hypotension following consumption of 3 cups of chaga for treatment of arthritis.
4. Preiodic lightheadedness and bradycardia with syncope following several days' of chaga tea consumption.
5. Lightehdeadedness 1 hour after consuming chaga tea

Patients 1 and 2 denied taking acetaminophen but were both treated with N-acetylcysteine, and both recovered. No chaga tea or powder has recovered for any of these cases, so evidence for toxicity is circumstantial.

A literature search by DPIC found one report of renal failure associated with chaga mushroom use due to high oxalate content in the products [7] and brief mention of hepatitis related to chaga mushroom associated with two cases of drug induced liver injury.[8] These reports, together with the DPIC cases, suggest consumption may occasionally be linked to liver and kidney issues, either in combination with other pre-disposing factors, or in vulnerable groups.

One concern is if the fungus is misidentified, when an incorrect canker is harvested from a tree. The metabolic effects of unknown wild mushroom harvest cannot be assessed once the false chaga has been ground up and made into an edible substance. Chaga has been misidentified as *Phellinus robineae, Phellinus tremulae,* and *Daldinia grandis,* or more commonly corky bark disease, black knot or other tree galls.[9]

Previous guidance on chaga use and consumption from British Columbia

None specifically for chaga, however, previous guidance has been given by BCCDC and other health authorities on how to manage wild mushroom harvesting and sales in the province. A previous food issue note provided a summary for approval of wild mushroom (see this link): essentially, the province has no authority to legislate standards for wild mushroom harvesting food sources (this is Health Canada's domain) or to approve the food source.

However, health authorities can provide oversight under the *Food Premises Regulation* of the premises where food products are made. Operators must not offer contaminated foods (sec. 13), and are required to follow food safety management procedures (division 6). Vendors and market manager are reminded they are liable to ensure wild mushrooms are not poisonous, per Health Canada's *Food and Drugs Act* (section 4).

*Guidance on chaga use (*Inonotus obliquus*) from Health Canada*

Health Canada defines chaga (*Inonotus obliquus)* as a mushroom product. The monograph for *Mushrooms* can be found at the following link: http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=mushrooms.champignons&lang=eng . One caution and warning ascribed to this product is to consult a health care practitioner prior to use if you are pregnant or breastfeeding. The product may be prepared as a powder, tincture, or fluid extract, and dosage is limited to up to 3.6 grams of dried mushroom per day.

Natural Health Product. If the vendor chooses to advertise and promote health benefits on the label or during sale this product may be considered a Natural Health Product (NHP). For this mushroom, a use or purpose statement on the immunomodulating properties of the fungal polysaccharides may be made**, as long as all the regulatory requirements for NHP are met.** To be legally sold in Canada, NHPs must have been issued a product licence; a product licence demonstrates that a product has been reviewed by Health Canada for its safety, efficacy and quality. The NHPR (http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/) came into force on January 1, 2004 and establishes the requirements for site licence for activities such as manufacturing, packaging, labelling and importation of NHPs. A site licence demonstrates that theses activities are being conducted in accordance with Good Manufacturing Practices. Presently there are no fees associated with the review and issuance of either a Product or Site licence. A description of NHP from the website is shown in Appendix A.

Novel Food. If the vendor chooses to sell without health claims, then a food product may also be classified as a novel food. **We have confirmed with the Food Directorate that chaga is considered a novel food,** as defined in Division 28 of Part B of the Food and Drug Regulations (pers. comm., A. Saleh, SMIU office, Health Canada, Apr 17, 2018). Products made with chaga powder, such as chaga teas or chaga kombucha may not be sold until an application is made to Health Canada. The product would require a pre-market safety assessment by the Food Directorate. Vendors should consult directly with

the Food Directorate's Submission Management Information Unit at smiu-ugdi@hc-sc.gc.ca. Further information about novel foods is shown in Appendix B.

Recommendations from BCCDC:

The initial harvesting of chaga is considered as a wild mushroom harvest. Wild mushroom harvesting is an unregulated activity in Canada. The province has no authority to grant approval to a harvester to harvest wild mushrooms, or any method to approve the food source. Vendors and market managers are reminded they have a responsibility and liability for products sold at farmers' markets. These include wild mushrooms and products made with wild mushrooms.

A. Vendors of wild mushrooms oversight:

Wild mushrooms: information to request from harvesters (pickers), mushroom identifiers and/or vendors to demonstrate the wild mushrooms offered are legitimate.

1. Harvesters (pickers), mushroom identifiers and/or vendors should identify the mushroom by scientific name and by at least one common name. For example, Pine mushroom , *Tricholoma magnivelare*. Also known as Matsutake
2. Harvesters, mushroom identifiers and/or vendors should identify the mushroom while the mushroom is in the fresh state. This is crucial if the mushroom is to be sold dehydrated, frozen or in some other processed state.
3. The name and contact information of the person who identified the mushroom should be retained by the vendor. This may or may not be the same person as the harvester. In some cases, mushroom harvesters have their picks checked by a more knowledgeable mushroom identifier.
4. Documentation or assurance from the person from whom you've purchased the mushrooms that the mushrooms have been properly identified. The mushroom identifier (whether or not they are the harvester/picker or vendor) must demonstrate that they are very knowledgeable and able to verify mushroom species. Information to support claims of mushroom identification should include the following:
    - The mushroom identifier should have a certificate or documentation that they have successfully taken a recognized course in the identification of local, wild mushrooms from a recognized institution or from an experienced mushroom harvester, AND,
    - The mushroom identifier should be able to demonstrate that they are well experienced in local , wild mushroom identification. This can include things like:
        - having a history of local, wild mushroom harvesting;
        - having taught others how to identify local, wild mushrooms;
        - being a long standing member of a local mushroom club;
        - maintaining their own wild mushroom website;

- having written books or guides on wild mushroom identification;
- others.

Market managers and vendors are reminded that while there is no formal approval process for the sale of wild mushrooms at retail, through wholesalers, or to restaurants, it is the vendor's responsibility to ensure that the following conditions under the Food and Drug Act (Canada) are met:

4. No person shall sell an article of food that

(a) has in or on it any poisonous or harmful substance;

(b) is unfit for human consumption;

(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

(d) is adulterated; or

(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

B. Health Authorities oversight of wild mushroom products

Health Authorities may choose to review the premises where wild mushrooms are sold, offered for sale, supplied, handled, prepared, packaged, displayed, served, processed, stored, transported or dispensed. At this current point in time, there is no procedure in place to provide "approvals" of the "source" of wild mushrooms that the harvesters/pickers sell to wholesalers, food retailers or restaurants. Health Authorities should remind premises that purchase wild mushrooms, including restaurants, food retailers and farmers' market managers and vendors of their liability, and provide the information above as guidance for how they might ascertain the veracity of the identification regarding the wild mushrooms they have purchased.

C. Provincial oversight of wild mushroom products

1. BCCDC and other provincial agencies should seek ways to inform consumers that wild mushroom products are not inspected or approved by any regulatory health authority, so they may make an informed decision when purchasing these products.
2. DPIC and public health should monitor for future adverse reactions linked to consumption of Chaga products.
3. BCCDC should advise food safety managers and Health Authorities on how to best determine if a food application may be subject to natural health food and novel food requirements under Health Canada.

Appendix A: What is a Natural Health Product (NHP)?

Information in this appendix was taken from this site. Consult with Health Canada for more information about NHPs.

https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html

An NHP is defined as:

- vitamin and mineral supplements;
- herbal and other plant-based remedies;
- homeopathic medicines;
- traditional medicines, like Traditional Chinese Medicines or Ayurvedic (Indian) Medicines;
- probiotic;
- amino and essential fatty acids

The fact that a product contains natural substances does not necessarily translate into it being classified as a NHP. Before filing an application you must ensure that the product meets both the function and substance components of the NHP definition, as per the NHPR. In short, a health claim must appear on the label of an NHP and the product must contain acceptable substances as set out in Schedule 1 of the NHPR.

HEALTH CLAIMS

The function component refers to the intended use of the product. For a product to be considered a NHP, it must be manufactured, sold or represented for use in:

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
b. restoring or correcting organic functions in humans; or
c. modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Appendix B. 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 shc.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.

References

1. Spinosa R. The chaga story. Fungi. 2012:22-6. Available from: http://www.fungimag.com/fall-2012-articles/V5I3NotChagaLR.pdf.

2. Patel S. Chaga (Inonotus Obliquus) Mushroom: Nutraceutical Assesement Based on Latest Findings. Emerging Bioresources with Nutraceutical and Pharmaceutical Prospects. Cham: Springer International Publishing; 2015. p. 115-26. Available from: https://doi.org/10.1007/978-3-319-12847-4_11.

3. Naveen J, Baskaran V. Antidiabetic plant-derived nutraceuticals: a critical review. European Journal of Nutrition. 2017 October 11.

4. McFarland J. Is there a responsible way to harvest chaga? Fungi. 2012:8-9. Available from: http://www.fungimag.com/fall-2012-articles/V5I3NotChagaLR.pdf.

5. Lau BF, Abdullah N. Chapter 7 - Sclerotium-Forming Mushrooms as an Emerging Source of Medicinals: Current Perspectives A2 - Petre, Marian. Mushroom Biotechnology. San Diego: Academic Press; 2016. p. 111-36. Available from: https://www.sciencedirect.com/science/article/pii/B9780128027943000072.

6. Gottesfeld JM. Use of cinder conk (*Inonotus obliquus)* by the Gitksan of northwestern British Columbia, Canada. Journal of Ethnobiology. 1992;12(1):153-6.

7. Kikuchi Y, Seta K, Ogawa Y, et al. Chaga mushroom-induced oxalate nephropathy. Clin Nephrol. 2014 Jun;81(6):440-4.

8. Takikawa H. Drug-induced liver injury by dietary supplements in Japan. Japan Medical Association Journal 2006;49(9-10):327-9.

9. Spinosa R, Bunyard B. No, that's not chaga! Fungi. 2012:45-7. Available from: http://www.fungimag.com/fall-2012-articles/V5I3NotChagaLR.pdf.