Guideline on Health Canada Regulations on Making Products

Information gathered by Lee Anne Downey January 2021

Good Manufacturing Practices GMP

If you are making products, you need to review and follow the GMP standards to ensure clean surfaces and handling, quality control, pest management, air filters, record keeping etc.

https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/good-manufacturing-practices.html#a2

Food production

Comes under both Health Canada – Canadian Food Inspection Agency CFIA for federal ***and***

OMAFRA/Public Health for Ontario

Federal - CFIA

If you are selling food outside of Ontario or importing or exporting any food or ingredients, you need a CFIA license. Take this online questionnaire to confirm if you need a license.

https://ca1se.voxco.com/SE/default.aspx

Provincial – Ministry of Health

Contact your local Public Health Department *before* you start making food.

A Guide to Starting a Home-based Food (no license but subject to inspection)

https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/selling_low_risk_food.pdf

New Regulations as of Jan 1 2021 have reduced some of the rules around preparation of **low risk, home prepared foods.** Example of low-risk foods are:

Most breads and buns (without meat, cream filling, etc.);
- Most baked goods (with no custard);
- Chocolate, hard candies and brittles;
- Fudge and toffees;
- Pickles, jams and preserves;
- Granola, trail mix, nuts and seeds;
- Cakes (icing that doesn't require refrigeration), brownies, muffins and cookies.
- Coffee beans and tea leaves

The new regulations for low-risk foods means you:
- Don't need a separate hand washing station
- Do not need an industrial dishwasher
- Do not need to have Food Handling training for employees

1) You must still follow the Health Protection and Promotion Act (HPPA) for a food premise

Section 16 of **https://www.ontario.ca/laws/statute/90h07**
Follow Regulations of:

- Notice of intention to commence operation
- Employee Compliance
- Information
- Records

You will still be required to have your kitchen inspected by your local Public Health Dept even for farm gate. Each local Public Health Unit will advise you on the requirement for a separate kitchen. This means no pets, it much be sterilized and inspected. Inspections are done based on priority so meat, dairy, etc will be priority over you. OMAFRA will do the inspection instead of Public Health if you are a large operation. ***You can rent a licensed kitchen therefore eliminating having a second separate kitchen.***

2) You must still follow the Food Premises Regulations

O. Reg. 493/17: FOOD PREMISES (ontario.ca)

Examples:

Lavender Jams Keep in mind that jams are high risk because of botulism risk. PH level must below 4.9. Very dangerous. Heat process the jar, measure the ph of the food, heat product, ensure proper seal, acid level. **Or you can rent a licensed kitchen or hire someone to make it for you**. If you are making something that requires refrigeration, you need a site license.

Lavender Cookies -the use of eggs and butter means you need a separate inspected kitchen.

Labelling
If you are selling only on your farm or local farm market, you don't need to have as rigorous labelling requirements but still there are rules that apply. Volume in mg, ingredients, address, etc

- ingredient lists must accurately reflect the contents and their relative proportions in a food
- Nutrition Facts tables must accurately reflect the amount of a nutrient present in a food
- net quantity declarations must accurately reflect the amount of food in the package

Language
If you are selling on your farm or just in your electoral region or immediate electoral region, you can use just local language. As soon as you sell products outside of your electoral or adjacent electoral region, then you must have bilingual labels.

Harvesting and Drying

- Very few insects nest in lavender so that is an advantage. Book lice and tobacco moth/Indian meal moth are possible. No chemicals are used on lavender.
- Yeast and mold is a risk however. Dehumidifiers, proper drying with small diameter bundles is required.
- Make sure drying facility is clean, protected from parasites, insects and rodents
- When it is stored, container has to be clean.

Traceability

If you sell outside of the province or sell to the US, you need a license. If you sell to another province you need to keep a record of who you bought your ingredients from, lot number and where it was sold to. **We recommend traceability on all products.**

Cosmetics

Comes under Health Canada - Consumer Product Safety

If you are making products that go on the body, you are required to register with Cosmetic Notification within 10 days of final product being ready to market. "Any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.

Information

https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/notification-cosmetics.html

Application Form

https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/notification-cosmetics/guidance-document-complete-cosmetic-notification-form.html

Modifications

Any changes to the Cosmetic Notification Form CNF can be amended and resubmitted for things such as:

- modification of the cosmetic formulation
- change of product name
- discontinuation of sale
- new company name, address or contact information

Labelling for Cosmetics

Labelling is regulated by the Food and Drugs Act, the Cosmetic Regulations and the Consumer Packaging and Labelling Act and Regulations. To meet these requirements, cosmetic labels must show:

- the ingredient list
- the common name of the product (for example hairspray)
- the amount of product in metric units or count (for example, 2 bars or 55 mL)
- the name and address of the manufacturer or distributor
- warnings or cautions
- directions for safe use of the product

All the information listed above must be in English and French, except for the ingredient list which needs to be indicated using the INCI nomenclature.

https://www.canada.ca/en/health-canada/services/cosmetics/cosmetic-advertising-labelling-ingredients.html

Making a Health Claim

Comes under Health Canada - Natural Product Number NPN
If you are making a health claim, you need to have an NPN number.
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html

Making Insect Repellent

Falls under Health Canada – Pest Management Division

Insect repellent –Anything that is used on the body or in the air for the purpose of deterring or killing insects must be approved by Pest Management. This is an arduous process requiring human trials.

Scientific research can be submitted for each ingredient that proves that humans are not adversely affected by:

-topical skin application
-accidental consumption
-in the eyes
-inhalation
-hormonal impact
-effect on unborn children

You need to do a study on how effective it is and for how long. When do you need to reapply?
This is an expensive process requiring animal studies and eventually human bite trials.

Several years ago, there was a special review to consider essential oils for a less rigorous approval process, however it is still quite rigorous and costly. You need a chemical profile of your oil. **There is no scientific evidence that lavender oil deters mosquitos or other insects. There is no exception for essential oils or home-based formulations. The same rules apply to you that apply to big corporations.**

If you make and market a bug repellant, you can expect a warning from PCRM and then a fine. If someone makes a claim that they were adversely affected by your product then you are at risk of a big fine and lawsuit.

https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/electronic-pesticide-regulatory-system.html#doc

Application site

https://pesticide-registry.canada.ca/en/index.html

Pre-submission consultation

https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/submission-consultations.html

Pre-consultation request form

https://sec2.hc-sc.gc.ca/pmra6117-eng.php

Product Search

https://pesticide-registry.canada.ca/en/product-search.html

Hand Sanitizer

Comes under Health Canada – Drug and Health Products

Are regulated under the Natural Health Products Regulations (NHPR)

A site licence (SL) is required to manufacture, package, label or import an NHP hand sanitizer in Canada. An SL is required to produce finished NHPs, but not to produce raw materials.

A product licence (PL) is represented by a Natural Product Number (NPN). This number is required to legally distribute (for instance, donate or sell) the product.

You would require a site licence and a product license to produce hand sanitizer. There was an expedited process to process applications but that has ended. Now you must go through the more complex route including a GMP from your quality control person.

https://www.canada.ca/en/health-canada/services/cosmetics/cosmetic-advertising-labelling-ingredients.html

Product Liability Insurance

If you are producing products that go on the skin or are consumed you need liability insurance in case someone has an adverse reaction.

Please note:

This information may not be complete. You are required to do your own research to ensure you are compliant. The Ontario Lavender Association takes no responsibility for any errors or omissions.

Information was gathered from Health Canada website as well as conversations with:

- Carrie Mountford – Canadian Food Inspection Agency
- Robert Martin – PMRC, Regulatory Information Officer
- Carol McLellan – OMAFRA, Information Resource Agent
- Wellington Dufferin Guelph Public Health Unit