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Natural Health Product Raw Material Policy

Natural Health Products Directorate
Health Products and Food Branch

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Canada 

“Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances.”

Health Canada

“Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity.”

Natural Health Products Directorate

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Contact the Natural Health Products Directorate

Natural Health Products Directorate
Health Canada
2936 Baseline Road, Tower A
Ottawa, Ontario
K1A 0K9

www.healthcanada.gc.ca/nhp

Telephone: 1-888-774-5555
Fax: (613) 948-6810
Email: NHPD_DPSN@hc-sc.gc.ca

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1.0 Issue

The *Natural Health Products Regulations* (NHP Regulations) do not specify whether raw materials *are* or *are not* included in the definition of a natural health product (NHP). The NHP definition¹ mentions neither raw material (e.g., ginger root that has just been harvested) nor finished product (e.g., encapsulated ginger that is packaged and labelled for the consumer). The *Natural Health Product Raw Material Policy* clarifies at which point a material becomes an NHP, and therefore when product and site licensing requirements are triggered².

¹ Natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is 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.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the Food and Drug Regulations, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations.

² Under the *Natural Health Products Regulations*, product and site licensing requirements are as follows:

- As per Section 27, a site licence is required to manufacture, package, label or import an NHP for sale (health care practitioners who compound products for a patient are excluded from the manufacturer definition); and
- As per section 4, a product licence is required to sell an NHP. Retailers do not need a product licence.

2.0 Rationale for Policy

- The safety and quality of NHPs must be assured through product and site licensing requirements.
- The safety and quality of those materials that truly are ingredients in the manufacture of NHPs is ensured through the manufacturing process, since a site licence (and therefore adherence to good manufacturing practices (GMPs)) is a requirement for manufacturing NHPs, and a product licence will be obtained for the final product.
- Health care practitioners must ensure the safety and quality of the materials used to compound products for their patients.

3.0 Policy Statement

The *Natural Health Product Raw Material Policy* outlines Health Canada's current approach with respect to raw materials.

A substance becomes an NHP, and therefore product and site licensing requirements are triggered when the material meets the substance component of the NHP Regulations³, and it is manufactured, sold, or represented for use as an NHP (i.e., it meets the function component of the NHP definition⁴).

General notes about raw materials:

- Raw materials are not NHPs.
- It was not the intent of the *Natural Health Products Regulations* to regulate raw materials.

Note: While the NHP Regulations do not apply to raw materials⁵, other Acts and regulatory frameworks may (for examples, the *Controlled Drugs and Substances Act*, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), etc.).

- Raw materials can be used for many purposes, for example in compounding by a health care practitioner, or in the manufacturing of an NHP, a food, a cosmetic, a fertilizer, etc.
- Raw materials become NHPs when they are manufactured, sold or represented for NHP use. For example, bulk powdered melatonin that is being shipped to a manufacturer for encapsulation and packaging would be considered an NHP, as it is manufactured for NHP use.

³ The substance component refers to the medicinal ingredient in an NHP, which can include substances on Schedule 1 of the NHP definition (Schedule 1 outlines the medicinal ingredients that NHPs may contain) or a homeopathic or traditional medicine. Schedule 2 of the NHP definition specifies those substances that are not permitted in an NHP (note the exceptions).

⁴ The function component refers to the NHP definition capturing those substances that are 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.

⁵ See the *Evidence for Quality of Finished Natural Health Products* guidance document, which outlines requirements for specifications and manufacturing information for raw materials: www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html. This document is intended to provide information to help product licence applicants determine the evidence required to support the quality of finished natural health products

There are a number of circumstances or features about a material that may lead Health Canada to conclude that a material is manufactured, sold or represented for use as an NHP, including the following:

- Nature of the substance and whether it is inherently therapeutic
- Packaging
- Labelling (including claims)
- Accompanying information/advertising
- Form (e.g., in dosage form)
- Sender
- Recipient (e.g., retail outlet)
- Manner in which it is being sold (i.e., to consumers versus as part of the chain of manufacturing)

Importation or sale of material not manufactured, sold or represented for use as an NHP for further processing by manufacturers (“further processing” is distinct from “directions for use”) does not trigger product licensing (PL) and site licensing (SL) requirements. Rather, these materials are treated as raw materials.

Note: Processing by manufacturers requires a site licence for the activity of manufacturing. An activity is not considered to be “processing of an NHP” until it is determined that a substance is in fact an NHP. For example, infusing licorice root with honey would not be considered processing of an NHP because licorice root could also be a food.

Importation or sale of material not manufactured, sold or represented for use as an NHP for compounding by health care practitioners does not trigger PL and SL requirements. Instead, these materials are treated as raw materials.

Under this policy, those products that are manufactured, sold or represented for use as NHPs are regulated as NHPs. Those products that are manufactured, sold or represented for use as foods are regulated as foods. Those products that are clearly neither foods nor finished NHPs are considered raw materials.

Note: the Natural Health Products Directorate (NHPD) will keep in mind cultural practices when determining whether or not a substance has a food use.

See Appendix I for information regarding raw materials and NHPs for export only.

Examples of the Regulation of Various Materials

Scenario #	Material	Regulated as NHP	Regulated as Food	Treated as Raw Materials
1	<p>Importation or sale⁶ of botanical manufactured, sold or represented as beverage or soup.</p> <p>Examples:</p> <ul style="list-style-type: none"> • Package of loose mint as beverage (no claims) • Chamomile tea bags (no claims) • Astragalus sliced root (no claims) 		X	
2	<p>Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract manufactured, sold or represented as an NHP.</p> <p>Examples:</p> <ul style="list-style-type: none"> • Encapsulated garlic. • Chamomile tea bags (with claim as treatment for upset stomach) • Bulk astragalus sliced root (with claim as an adaptogen and Qi Tonic) • Tincture (with claim) 	X		
3	<p>Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract (e.g., of chamomile) manufactured, sold or represented as an NHP for further processing by manufacturer.</p>	X		
4	<p>Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract (e.g., of chamomile) for further processing by manufacturer (i.e., not manufactured, sold or represented for NHP use).</p>			X
5	<p>Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract (e.g., of chamomile) manufactured, sold or represented as an NHP as <i>treatment</i></p>	X		

⁶ Reference to “sale” in these scenarios could include sale in a health food store or a grocery store, at the farm gate, to a manufacturer or a distributor, etc.

	<p><i>for a health condition for</i> compounding by health care practitioner.</p> <p>The sale of an NHP requires a product licence.</p> <p>The sale of a compounded NHP does not require a product licence, as per the <i>Natural Health Product Compounding Policy</i>.</p>			
6	<p>Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract (e.g., of chamomile) for compounding by health care practitioner (i.e., not manufactured, sold or represented for NHP use).</p>			X

Appendix I: Raw Materials and NHPs for Export Only

The *Natural Health Products Regulations* do not regulate raw materials.

Section 37 of the *Food and Drugs Act* provides an exemption for products being exported from Canada. If claiming this exemption, companies do not have to meet the requirements of the *Natural Health Products Regulations*. However, certain conditions must be met. Section 37 states:

37. (1) *This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word "Export" or "Exportation" and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.*

The Export Certificate under Section 37 of the *Food and Drugs Act* is a certificate signed by the manufacturer and a Commissioner for Taking Oaths to attest that the product for which the certificate is prepared is not manufactured or sold for Canadian consumption and its package and the contents do not contravene any known requirement of the law of the country for which it is or is about to be consigned. This export certificate will satisfy Health Canada that the specified product(s) does not fall under the purview of the *Natural Health Products Regulations*.

Companies not claiming an exemption under Section 37 may request an International Trade Certificate (ITC) from Health Canada's Natural Health Products Directorate (NHPD). International Trade Certificates speak to the regulatory and marketing status of the natural health products in Canada. They will be issued upon request to companies holding a valid site licence for natural health products that have received a product licence. The Natural Health Products Directorate provides this information to foreign regulatory authorities to facilitate the export of natural health products from Canada.