



### OVERVIEW

The Natural Health Product Directorate (NHPD) Mission is:

- To ensure that all 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.

The Natural Health Product (NHP) regulations:

- Outline requirements for manufacturing, packaging, labelling, importing, distributing and storing NHPs.
- Provide a framework for site and product licensing, good manufacturing practices (GMPs), clinical trials and labelling requirements.
- Provide a system for site licensing for all Canadian manufacturers, packagers, labellers and importers of NHPs conducting activities in Canada.

NHPs are defined by function and substance:

- **FUNCTION:** Those substances that are manufactured, sold or represented for use in: Diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.
- **SUBSTANCE:** Refer to Health Canada's *Overview of the Natural Health Products Regulations* for specific medicinal ingredients that natural health products may contain (Schedule 1) and those substances that are not permitted in a natural health product (Schedule 2).
- Health Canada's intent is to cover products that consumers select and use themselves without consulting a health care provider or obtaining a prescription. Accordingly, with the exception of homeopathic medicines, products with prescription ingredients are not NHPs.

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For current NHPs, the Food and Drug Regulations apply until a NHP site licence and/or product licence is obtained. New products must comply with the NHP regulations immediately and are subject to the full licence application process prior to sale in Canada. All NHPs must comply with the NHP Regulations by January 1, 2010.

See the overview of the *Natural Health Products Regulations Guidance Document* at:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/regula-regle\\_apercu\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/regula-regle_apercu_e.html)

## WHO DOES THIS APPLY TO

- Importers, packagers, labellers, manufacturers and distributors
- Warehouse/storage facilities

## WHAT'S NEW

- The transition period for all categories of NHP already on the market in January 1, 2004 and that were prioritized for submission has elapsed. All product licences must be submitted by January 1, 2010.
- A new Canadian Guidance Document, *Classification of Products at the Food-Natural Health Product Interface: Products in Food Format*, has been issued to facilitate decision-making for the classification of products by basing decisions on the following four criteria:
  - Product composition
  - Product representations
  - Product format
  - Public perception and history of use

Refer to *Classification of Products at the Food-Natural Health Product Interface: Products in Food Format*:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/food\\_nhp\\_aliments\\_psn-2009-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/food_nhp_aliments_psn-2009-eng.php)

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- The Food Directorate in collaboration with the NHPD will review Product Licence Applications for natural health products in food formats (e.g., juices, yogurts and butters). Both the Natural Health Product Regulations and the interim *Guidance Document for Preparing Submission for Foods with Health Claims* will be used for the assessment.

Refer to the *Interim Guidance Document - Preparing a Submission for Foods with Health Claims: Incorporating Standards of Evidence for Evaluating Foods with Health Claims*:  
[http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/abstract\\_guidance-orientation\\_resume-eng.php](http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/abstract_guidance-orientation_resume-eng.php)

- Bill C51 has been introduced that will create a unique category for natural health products, separate from drugs. The Natural Health Product Regulations effective from Jan 1, 2004, will remain in effect.
- Although Health Canada states that Bill C-51 will not result in more compliance and enforcement action taken for regulated products, maximum penalties for offenders have been increased substantially.
- The NHPD has developed a series of monographs intended as a tool for the timely and efficient review of the safety and efficacy of many commonly used NHPs. Each monograph contains information on the active ingredient, source material, route of administration; dosage form; use or purpose; dose; duration of use; risk information; specifications and non-medicinal Ingredients. The NHPD frequently adds new and revised product and single medicinal ingredient monographs to its *Compendium of Monographs*.

Refer to the *Compendium of Monographs*:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/compendium-eng.php#1\\_2](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/compendium-eng.php#1_2)

- The information provided in the Product Licence Application (PLA) and proposed label text must correspond in full to that which is outlined in the monograph or the PLA will be refused. Applications corresponding in full to the monograph will proceed directly to licensing.

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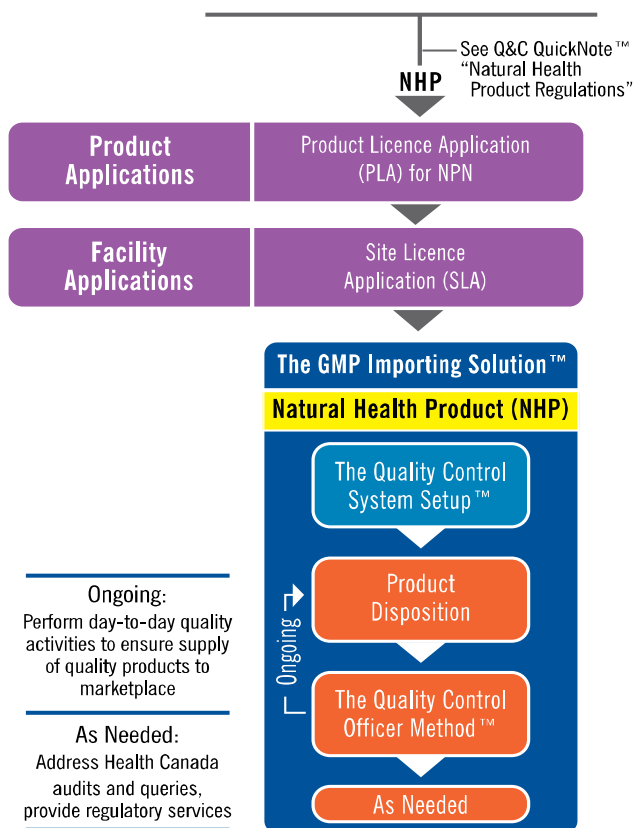
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- Health Canada has introduced the *Natural Health Products Online Solution*, an electronic and secure online system for processing licence applications for product, site, and clinical trial authorizations for natural health products in Canada. It simplifies the submission process for applicants by providing higher-quality applications that require fewer clarifications, and effectively contributes to faster decision-making.

Refer to the *NHP Online Solution*:  
<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/online-enligne/index-eng.php>

## KEY POINTS



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## Product Licence Application (PLA)

- All NHPs require a product licence prior to sale in Canada.
- The application lists medicinal and non-medicinal ingredients and provides recommended conditions of use and evidence of Safety and Efficacy (depending on the application type). It proposes label text and includes the finished product specifications and a proposed test schedule.
- Once the product has been assessed and granted market authorization, an eight-digit product licence number is issued preceded by the letters 'NPN' or in the case of homeopathic medicine by the letters 'DIN-HM'.
- Products licence applications have been characterised into various review streams. Compendial and DIN transitional products default to a 60-day approval cycle. Review of homeopathic medicines has been expedited but a performance standard has not been given. Remaining products are approved in two to three years.

See an overview of the *Product Licensing Requirements and Process* at:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence\\_guide\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm_e.html)

## Site Licence Application (SLA)

- Site licences are required for all sites in Canada where products are manufactured, packaged, labelled and/or imported.
- Foreign sites are not required to be licensed but a Quality Assurance Report (QAR) for each site is required to be submitted with the importers SLA.
- Site licences are not required for domestic distributors and storage facilities, although these activities are required to meet the requirements of the *Canadian Good Manufacturing Practices* and they are included in the relevant site licence of the manufacturer or importer.
- The application contains requirements for procedures and records that demonstrate that all activities are conducted according to the Canadian GMPs for NHPs.
- The current approximate timeline for approval is one to three months.

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## Good Manufacturing Practices

In order to ensure natural health products are safe and effective when they reach the consumer, the Natural Health Product Regulations include requirements for how manufacturers, importers and distributors should operate. These good manufacturing practices (GMPs) are interpreted in the *Good Manufacturing Practices Guidance Document*.

The GMPs cover the following areas:

- Places – Premises & Equipment
- People – Personnel & Quality Assurance
- Processes – Sanitation Program & Operations
- Products – Specifications, Stability, Samples, Records, Recall Reporting, Sterile Products
- Homeopathic medicines (in a supplement)

Refer to the following documents:  
*Site Licence Guidance Document:*

[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgd-drle\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/slgd-drle_e.html)

*Good Manufacturing Practices:*

[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf_e.html)

*Good Manufacturing Practices Guidance Document:*

<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf-eng.php>

## Adverse Events Reporting

- Product licence holders are required to monitor all adverse reactions associated with their products.
- Serious adverse events must be reported to Health Canada.

## Government Enforcement

- Health Canada is applying a risk-based approach to enforcement of the NHP Regulations.
- NHPs identified as posing an unacceptable risk will be removed from the shelves.

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- Products with no submission number may be stopped at the border.
- Site licences are only granted when adequate evidence of adherence to GMPs is demonstrated.
- Site licence holders will be audited by Health Canada for adherence to GMPs. Inspections may commence in 2009 or 2010.

## FAQ

### 1. What are Natural Health Products?

Natural health products (NHPs) are defined as:

- Vitamins and minerals
- Herbal remedies
- Homeopathic medicines
- Traditional medicines such as traditional Chinese medicines
- Probiotics
- Other products like amino acids and essential fatty acids

NHPs must be safe for consideration as over-the-counter products, be available for self-care and self-selection and not require a prescription to be sold.

### 2. Do I need to comply with the Natural Health Product Regulations?

Yes. The Natural Health Product Regulations came into effect on January 1, 2004 and apply to all natural health products and activities as of this date.

### 3. Does a Product Licence Application submission number constitute an authorization for sale?

No. A submission number is proof of the receipt of a complete PLA and is not an authorization for sale. However, compliance efforts will be focussed on products that do not have a submission number or that pose an unacceptable risk to Canadians.

### 4. Do I need to release each lot of an imported product?

Yes. A Quality Assurance Person is required to review the test results of each lot and release each lot of product received in/destined for Canada.

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## 5. What sites are required to be listed on the Site Licence?

Canadian importers must ensure that the foreign sites where imported products are manufactured and the Canadian importation sites to which they are being shipped are listed on their site licences.

## 6. How are NHP regulations different from drug regulations?

NHPs have a specific and separate set of regulations that apply to them. The guidelines interpreting the requirements are less specific and stringent than those for drugs with respect to raw material testing, sampling, on-going stability and validation. The NHP GMP regulations are written in very similar terms to the drug GMPs.

## 7. How are NHP Regulations different from foods?

Food regulations are focused on safety. There are limited testing requirements on raw materials and finished products, limited requirements for maintaining standard operating procedures, and there is no requirement for a separate QA function.

## 8. If there are updates to the product monographs included in a submitted Product Licence Application, do the changes have to be made?

Yes. Applicants should note that any submission in queue is assessed against the new and updated monograph.

## 9. What is Bill C-51 and how will it affect my business?

Under Bill C-51, natural health products would be defined within the Act as a unique category apart from food and drugs. The proposed amendments would support the existing Natural Health Products Regulations, which are separate from the framework for the regulation of drugs. There should be no effect on businesses that currently meet the requirements. However, fines for those who do not meet the regulations have been substantially increased.

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## ABBREVIATIONS

BPRA	Bureau of Product Review and Assessment
cGMP	Current Good Manufacturing Practices
CofA	Certificate of Analysis
CofC	Certificate of Compliance
CofM	Certificate of Manufacture
DIN-HM	Drug Identification Number -Homeopathic Medicines
EL	Establishment Licence (Drugs)
EP	European Pharmacopeia
FCC	Food Chemical Codex
FDA	Food and Drugs Administration (U.S.A.)
GMP	Good Manufacturing Practices
HPFBI	Health Products and Food Branch Inspectorate
IRN	Information Request Notice
MRA	Mutual Recognition Agreement
NHP	Natural Health Product
NHPD	Natural Health Product Directorate
NHPR	Natural Health Product Regulations
NPN	Natural Health Number
NMI	Non-Medicinal Ingredients
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
QAP	Quality Assurance Person
QAR	Quality Assurance Report
PLA	Product Licence Application

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SLA	Site Licence Application
SLR	Site licence renewal
SOP	Standard Operating Procedure
TPD	Therapeutics Products Directorate
UPC	Universal Products Code
USP	United States Pharmacopeia

**Contact NHP Compliance**  
with your questions about Natural Health Products.  
Phone Graham Mills toll-free at 1-877-877-5152,  
extension 210, or email him at [g mills@qualityandcompliance.com](mailto:g mills@qualityandcompliance.com).

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