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à améliorer
leur état de santé

Helping the people
of Canada maintain and
improve their health

The NHP On-line Solution NHPD

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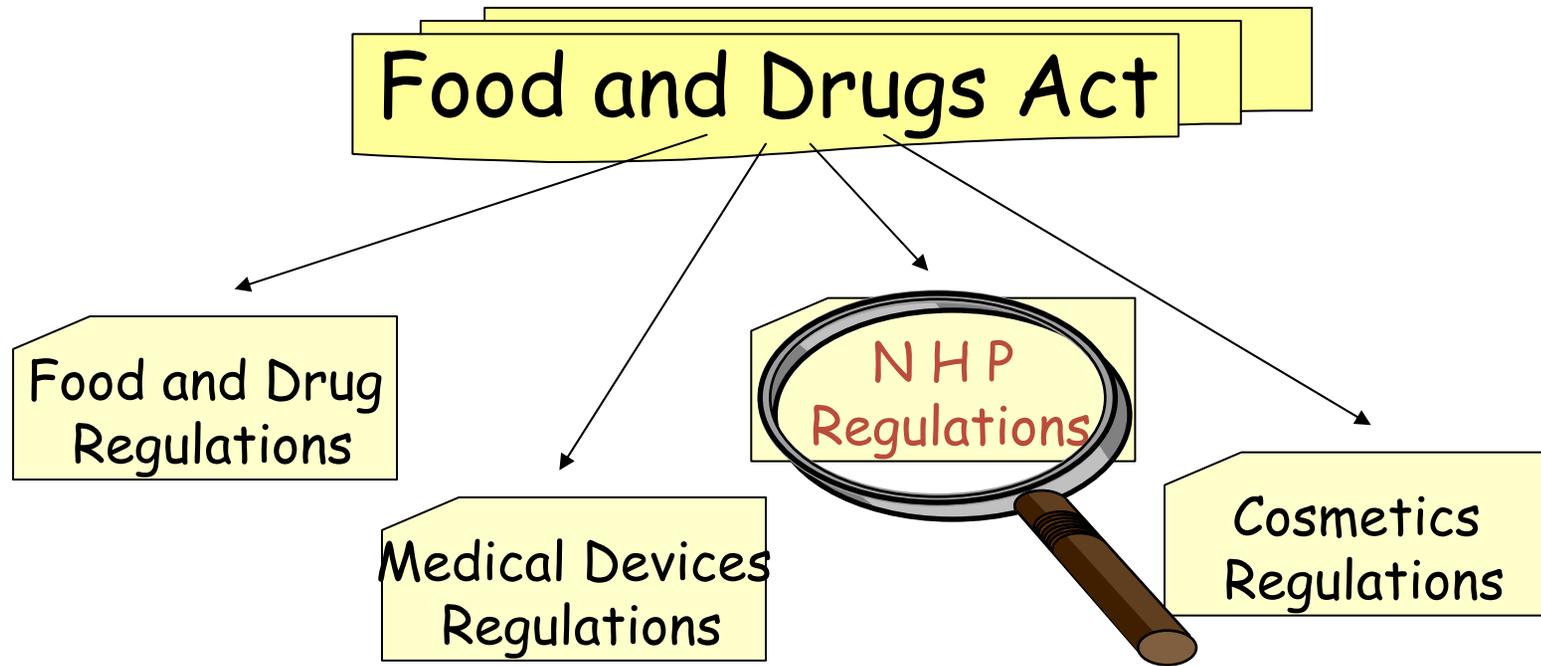
32nd National Nutrient Databank Conference

May 13, 2008



Canada

Regulations for NHPs under the Food and Drug Act



The *Natural Health Products Regulations* came into force
January 1, 2004



Natural Health Product Directorate (NHPD)

- The *Natural Health Products Regulations* are intended to ensure 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 Products Regulations* are administered by the Natural Health Products Directorate (NHPD), Health Products and Food Branch, Health Canada.
- Natural Health Products (NHPs) are assessed for their safety & efficacy and their quality by NHPD.



NHP Definition: What they are what they aren't

NHPs are:

- Traditional medicines, e.g. TCM, Ayurvedic, western herbals
- Homeopathic medicines
- Plant, algal, fungal, bacterial, non-human animal materials, their extracts and purified isolates
- **Vitamins and minerals**
- **Amino acid and fatty acid supplements**
- **Synthetic duplicates of the substances above**
- Probiotics



They are not:

- Radiopharmaceuticals, biologics (e.g. vaccines), antibiotics, prescription medications, conventional OTC drugs of synthetic origin, drugs to be injected, tobacco, controlled substances, medical devices, cosmetics, foods (These products are regulated under separate regulations.)



NHP On-line Solution

- 2006, NHPD launched the NHP On-line Solution Project to:
 - Address backlog; and
 - Provide more consistent and timely assessment of licence applications;
- NHP On-line Solution Project consists of two (2) key initiatives:
 - NHP Ingredients Database System;
 - NHP On-line System;



NHP Ingredients Database

- Leverages recognized ingredient terminology for naming ingredients Australian Therapeutics Goods Administration (TGA) system and internationally recognized standards such as ICH-M5; Allows for consistent storing of approved ingredient information
- Public consultation is on-going.
- Used to dynamically validate the contents of product licence applications prepared electronically;
- Ongoing enhancements include 1) representation of NHPD monographs, 2) and the ability to capture and retrieve approved safety and efficacy ingredient information improving on knowledge management to facilitate the assessment process;
- Consistent structuring of monograph information is utilized to expedite additional validation, assessment and acceptance of incoming product licence applications.



NHP On-line System

- Supports the electronic preparation and submission of licence applications and supporting documents throughout the product lifecycle;
- Enables the scanning and conversion to electronic format of paper submissions (including the backlog) for immediate availability and ease of shared access;
- Increases efficiencies for the adjudication process.



NHPD Monographs

- A monograph is a **written** description of particular elements on an identified topic. The compendium is a compilation of monographs based on Natural Health Product ingredients.
- Evidence information indicated on the monograph which meets NHPD standard of evidence supporting an aspect of safety and/or efficacy.
- Natural Health Products Directorate (NHPD) developed the Compendium of Monographs as a tool for the **timely and efficient** evaluation of the safety and efficacy of many commonly used medicinal ingredients that comprise natural health products.



NHPD Monographs

1. 101 single ingredient monograph
 - 9 new (published in the past 6 months: Oct 2007-March 2008)
 - 58 revised (revised in the past 6 months: Oct 2007-March 2008)
2. Of the 101 single ingredient monographs there are:
 - 8 mineral monographs
 - 12 vitamin monographs (including beta-carotene)
 - 3 amino acid monographs
 - 68 herbal/botanical
3. 14 product monographs



NHP Ingredients Database: NHPD Monographs

- The NHP Ingredients Database has been extended to capture monograph elements for single and product monographs.
- Capturing Monographs in the NHP Ingredients Database serves two major purposes:
 1. Dynamically generate monographs from the database through the Web Application;
 2. Interface with NHP On-line System tools such as the Compendial electronic product license application form to validate applications attesting to NHPD monographs.

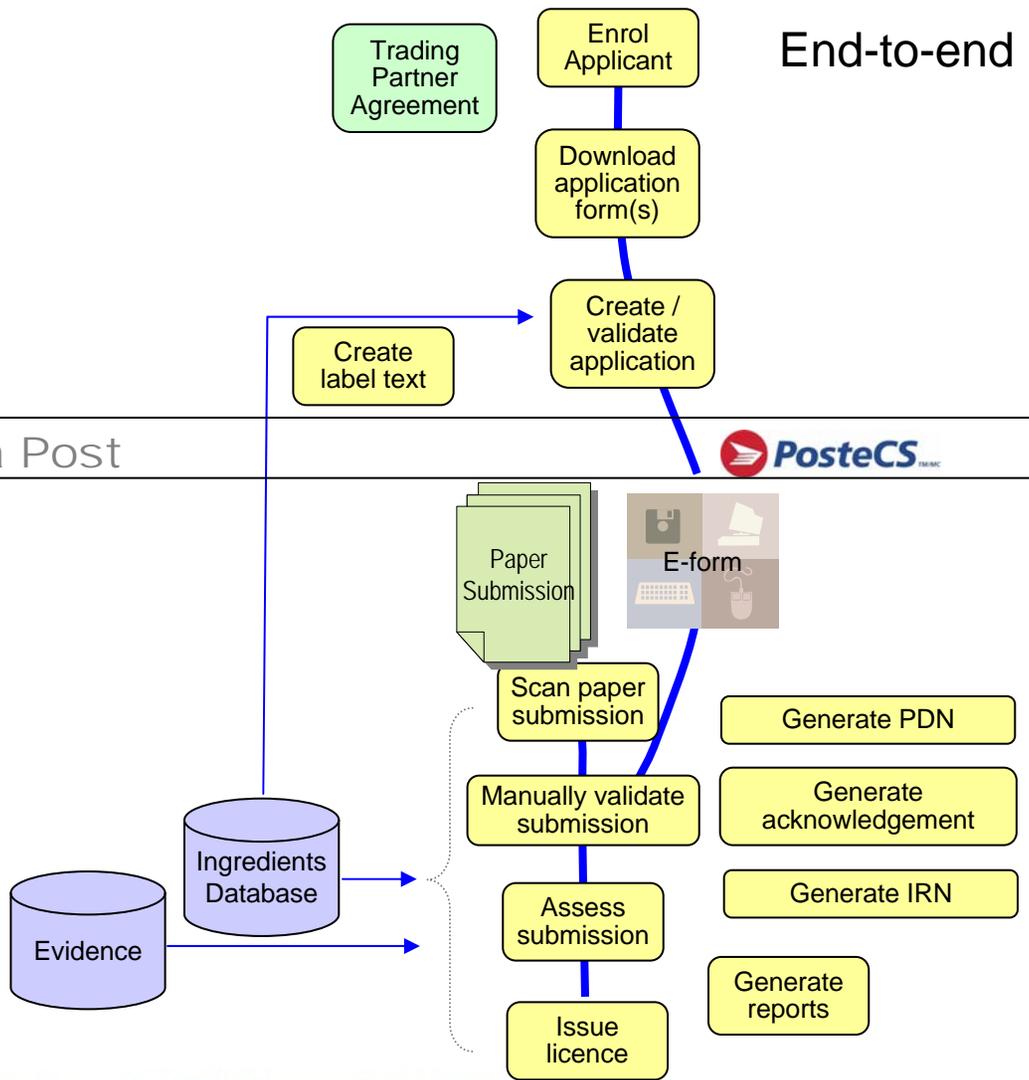


End-to-end Processing

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