



Supplementary News

Volume 1, Fall 2009

2010: The NHP Compliance Odyssey

January 1, 2010 is a big day for the natural products industry in Canada – the day that the six-year transition period for all natural health products (NHPs; a.k.a. dietary supplements) to comply with the *Natural Health Products Regulations* (the Regulations) comes to an end. As of this date, every NHP for sale in Canada must have a Natural Product Number to be permitted for sale within the Canadian market. But will this be the case?

The Regulations took effect in 2004 and require the premarket approval of NHPs through a product licence application (PLA) process. A six-year transition period was established, during which time the Natural Health Products Directorate (NHPD) undertook a risk-based approach for compliance to ensure consumer safety. A product could continue to be sold in Canada provided that a PLA was submitted to the NHPD by a compliance deadline. Those products deemed by the NHPD to have the highest amount of risk (e.g., products containing isolates, concentrated extracts, amino acids) had the earliest compliance deadlines, while products with the least amount of risk (e.g., vitamins and minerals) were evaluated later in the transition period. Although several compliance deadlines have come and gone, many NHPs have not received a product licence from the NHPD, raising several questions and concerns within the natural products industry in regards to potential compliance and enforcement actions come January 1, 2010.

Since promulgation of the Regulations, approximately 40,000 PLAs have been submitted to the NHPD and as of June 2009, approximately 34% of all applications have been granted a product licence. Thus, a large number of the applications submitted have been refused or are still awaiting evaluation by the NHPD. Of the PLAs that are awaiting the NHPD's review,

approximately 13,000 were submitted between January 1, 2004 and April 1, 2008 and are defined as the NHPD's backlog. The NHPD has committed itself to addressing the entire backlog by March 31, 2010; however, as of June 30, 2009, less than 50% have been addressed.

Canadian natural product industry representatives, like the Canadian Health Food Association (CHFA), are working to raise awareness regarding the potential effect that the end of the transition period will have on the industry. With the help of the website www.SaveOurNaturalHealthProducts.ca, the CHFA is calling for changes to the compliance and enforcement policy to ensure that unlicensed NHPs are not subject to compliance and enforcement in 2010.

Recently, the NHPD released an information sheet to stakeholders regarding the significance of the 2010 date and what it means in terms of the NHPD's intended compliance and enforcement actions. In this update, the NHPD stated that they are working towards developing a revised risk-based compliance and enforcement approach in light of their backlog and are likely to implement the approach sometime in the fall of 2010; however, the NHPD will provide additional information to stakeholders this November during cross-Canada workshop sessions.

Until the NHPD can give final guidance regarding how and when the compliance and enforcement policy will be implemented, the true impact of the Regulations will not be felt within the industry or the Canadian marketplace. With so much depending on how quickly NHPD can eliminate the backlog of PLAs and implement the compliance and enforcement policy, it is evident that 2010 will be a monumental year for the Canadian natural products industry.

Did You Know?

The Canadian *Natural Health Products Regulations* outline the requirements for the licencing of finished products as sold to consumers. With the exception of ingredients that are the subject of a NHPD monograph, or abbreviated labelling standard, there are no provisions for the approval of medicinal ingredients. However, data pertaining to the manufacture of individual medicinal ingredients included in a finished product that is the subject of a product licence application (PLA) must be disclosed. How can you keep your proprietary data confidential while assisting your customers with the requirements they must meet for their PLAs? Cantox can help!

Upcoming Events

5th Nutraceutical Summit

October 28-30, 2009
Mumbai, India

4th International Functional Food Symposium

October 29-30, 2009
Kowloon, Hong Kong

ISNFF 2009 Annual Conference

October 31 - November 4, 2009
San Francisco, CA
Don't miss Lina Paulionis' presentations on 'How to Obtain Health Claim Approval for Omega-3 Oils in Your Products' and 'Health Claim Substantiation for Nutraceuticals, Functional Foods and Dietary Supplements: A Global Approach'.

Supplieside West

November 11-13, 2009
Las Vegas, NV, USA
Visit Cantox at booth #14086

Food Ingredients Europe

November 17-19, 2009
Frankfurt, Germany
Visit Cantox at booth #8H75

HFMA Autumn 2009 Workshop

November 24, 2009
London, England

2nd Nutrients & Food Supplements in Europe Regulatory Issues

December 3, 2009
Brussels, Belgium
Don't miss Nigel Baldwin's presentation on 'Health Claims Harmonisation in the Food Supplements Market'.

USA/Ireland Functional Foods

March 9-11, 2010
Cork City, Ireland

SupplyExpo/Nutracon

March 10-11, 2010
Anaheim, CA, USA

Headlines from Around the World

The [U.S. Food and Drug Administration \(FDA\)](#) recently issued a consumer update outlining the benefits of vitamin supplements. *Fortify Your Knowledge About Vitamins*, available both as a video and in text format, provides information on when vitamin supplements can be useful and recommends that Americans develop a vitamin strategy to ensure they achieve adequate vitamin intakes.

The [Canadian Organic Products Regulations](#) took effect June 30, 2009. The Regulations outline the provisions for mandatory certification and labelling of products represented as organic and apply only to foods, animal feed, and products used for the cultivation of plants.

On September 30, 2009, the [Canadian Natural Health Products Directorate \(NHPD\)](#) issued a communiqué to clarify requirements for product licence applications for natural health products (NHPs) that contain probiotics. The document outlines the definition of a probiotic, permitted formats for probiotic NHPs, and clarification on evidence requirements for safety and efficacy.

At a meeting held June 29 to July 4, 2009, the [Codex Alimentarius Commission](#) adopted several key provisions for food supplements, including Recommendations for the Scientific Substantiation of Health Claims, Nutritional Risk Analysis Principles, Provisions on Gum Arabic, definition and conditions for dietary fibre, and the use of 8 food colours in food supplements. The recommendations were supported by the International Alliance of Dietary/Food Supplement Associations and will become official Codex Standards and Guidelines.

The [European Food Safety Authority \(EFSA\)](#) has published guidance on the safety assessment of herbal preparations for use in food supplements, which incorporates a two-tiered approach for safety evaluation, depending on the amount and type of data available. The document outlines a set of criteria to be used to prioritize the assessment of botanicals currently in use. In addition, EFSA has developed a compendium of botanicals that have been reported to contain substances of concern. The purpose of the compendium is to flag plants that may be of concern to human health; however, the inclusion or exclusion of plants in this compendium is not intended to be used as evidence for whether a particular botanical is suitable for use in supplement products.

The [UK Medicines and Healthcare Products Regulatory Agency](#) has issued a warning about the dangers of aconite, also known as monkshood, based on two reports of suspected adverse reactions. The herb, referred to as "herbal valium", is suspected to have caused kidney problems in one person, and dizziness and paresthesia in another. Aconite is known to be extremely toxic to the heart. It is permitted for use in registered homeopathic medicines, where it is sufficiently diluted, but has been identified in some unregistered herbal medicines at higher levels.

On October 13, 2009, the [European Commission](#) released their updated list of substances that can be added to foods for particular nutritional uses under Commission Regulation (EC) No. 953/2009. The list has been expanded to include amino acids, carnitine and taurine, nucleotides, and choline and inositol.

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We're Here to Help!

Cantox has been successfully delivering regulatory and scientific consulting services for more than 23 years. Cantox's dedicated team of scientists have a thorough knowledge of the scientific and regulatory requirements for supplement and natural products in several jurisdictions, including Australia/New Zealand, Canada, European Union, and United States. In the area of supplement and natural products, Cantox:

- Conducts feasibility assessments to determine whether sufficient data exist to pursue successful applications in different jurisdictions;
- Provides recommendations for the collection of appropriate data should the current scientific evidence be inadequate to support safety, efficacy, and quality requirements;
- Provides product development support;
- Assists in the design, placement, monitoring, and management of clinical trial protocols for claim substantiation;
- Compiles and oversees product licence applications, new dietary ingredient notifications, and other types of applications submitted to regulatory authorities;
- Prepares expert opinion letters; and
- Administers programs to meet post-market requirements, including adverse event reporting, regulatory monitoring, and surveillance programs.

Cantox is dedicated to your marketing pursuits! By strengthening your product's image, you will have a competitive advantage as you enter marketplaces around the world. To find out how Cantox can help you navigate through the complex regulatory environments for supplements and natural products contact us at food@cantox.com.

Supplementary News is a periodic newsletter published by Cantox Health Sciences International (Cantox) for the purpose of keeping our clients and other interested parties informed of new research results, brief reviews of current research, and exciting events of interest to the global market for Natural Health Products/Supplements.

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