

**BEFORE THE
CANADIAN FOOD INSPECTION AGENCY**

**REPRESENTATION OF THE
AMERICAN HERBAL PRODUCTS ASSOCIATION**

ON CFIA's PROPOSED REGULATORY TEXT:

Organic Products Regulations
Canada Gazette Part I. 14 February 2009;143(7):343-372

April 29, 2009



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Michel Saumur
Canada Organic Office
Canadian Food Inspection Agency
1400 Merivale Road, T1-4-142
Ottawa, Ontario K1A 0Y9, Canada
via email: OPR.RPB@inspection.gc.ca

RE: Canadian Food Inspection Agency. Proposed Regulation: Organic Products Regulations, 2009. *Canada Gazette Part I*. February 14, 2009;143(7):343-372.

Dear Mr. Saumur,

Canada promulgated Organic Products Regulations (OPR) on December 14, 2006 to provide a framework for a federally regulated organic regime in Canada. The original OPR has subsequently been reviewed by the Canadian Food Inspection Agency (CFIA), and certain clarifications and elaborations were included in a proposed OPR issued in the *Canada Gazette Part I* on February 14, 2009.

Interested persons have been invited to make representations concerning the proposed OPR. The American Herbal Products Association (AHPA) is the United States trade association and voice of the herbal products industry, and is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA's members include companies that market in Canada products wholly or partly derived from organically cultivated plants, including conventional foods as well as natural health products and cosmetics. AHPA therefore has an interest in the cited proposed regulation.

This representation is addressed to just one aspect of the February 14 proposed OPR, which is the proposal's limitation on the scope of application of the OPR to only food and drink for human consumption, food intended to feed livestock, agricultural crops used for the above purposes, and cultivation of plants. Of specific interest to AHPA at this time is the fact that this proposed limitation would exclude natural health products (NHPs) from the scope of the OPR, including NHPs that are agricultural products as that term is defined in the Canada Agricultural Products Act (CAPA).

Trade will be disrupted for many currently marketed products and crops

One of the objectives stated in the February 14 Gazette notice is "avoiding a potential disruption in the trade of organic products both domestically and internationally." But exclusion of NHPs from the OPR would have the opposite effect. By limiting the OPR to the proposed narrow scope, a wide range of certified organic herbal NHPs would be excluded, such as

certified organic medicinal herbal teas, tinctures, fluidextracts, syrups, lozenges, ointments, glycerites, and organic herbal powders in capsules or tablets. Many such products are already licensed by or in queue for licensing by Canada's Natural Health Products Directorate (NHPD). **Annex 1** to this representation provides a listing of NHPs that are presently labeled as organic in the Canadian market. This table is not exhaustive and does not include all organic NHPs, for example those that are in queue awaiting final marketing authorization from NHPD, with the exception of products listed from AHPA member Traditional Medicinals. The number of certified organic NHPs is highly likely to increase significantly once NHPD works through its backlog of thousands of applications.

It should thus be obvious that the stated objective of avoiding disruption in trade in organic products cannot be realized if the OPR maintains its currently proposed narrow scope, and can only be realized by expanding that scope to include NHPs.

Plant-based NHPs are agricultural products and should be within the scope of the OPR

In the February 14 Gazette it is acknowledged that NHPs¹ are included in the Canadian General Standards Board's (CGSB) 310 Standard, that is, Canada's standards for organic production systems. The Gazette also states that NHPs "do not fall within the mandate" of CFIA.

AHPA recognizes that it is NHPD that has sole authority to ensure that NHPs comply with all of the aspects of NHPD's regulations for this class of goods. Nevertheless, NHPD's clear authorities in areas covered by its own regulations does not prevent or obstruct CFIA from having clear authority for compliance of NHPs with the proposed OPR. AHPA therefore believes that CAPA can and should be read to mean that NHPs do, in fact, fall within the mandate of CFIA insofar as the proposed OPR is concerned. AHPA's rationale to support such a reading is as follows:

1. CAPA defines "agricultural product" to mean:
 - “(a) an animal, a plant or an animal or plant product,
 - “(b) a product, including any food or drink, wholly or partly derived from an animal or a plant, or
 - “(c) a product prescribed for the purposes of this Act” (CAPA, section 2)
2. The use of the words "including any food or drink" in paragraph (b) of CAPA's definition of "agricultural product" does not limit the definition to only foods or drinks (if such

¹ The Gazette's discussion on this matter groups NHPs with cosmetics and pet food, as is logical from the point of view of understanding existing Canadian regulation of agricultural products. Many of the points expressed in this representation may therefore also be applicable to agricultural products that are cosmetics or pet food.

limitation were intended the paragraph would state, for example, “a food or drink product wholly or partly derived from an animal or a plant”).

3. An NHP that is wholly or partly derived from a plant is an agricultural product under CAPA.
4. CAPA defines “agricultural product legend” to mean “a legend prescribed for an agricultural product” (CAPA, section 2)
5. CAPA authorizes the making of certain regulations, including “prescribing agricultural product legends and grade names and generally respecting agricultural product legends, grade names and other labels” (CAPA, section 32^a).
6. The February 14 Gazette identifies CAPA, section 32^a as the authority for the proposed OPR (at page 363).
7. The proposed OPR includes as a fundamental feature an organic logo, defined in the proposal as “an agricultural product legend” (OPR, section 23).

The points delineated above provide a clear argument and rationale to conclude that CAPA can be read to mean that NHPs fall within the mandate of CFIA insofar as the proposed OPR is concerned. AHPA requests and encourages CFIA to accept this rationale. AHPA also suggests that more efficient enforcement of the proposed OPR for NHPs may be able to be achieved by entering into one or more inter-agency memoranda of understanding (MOUs), for example with NHPD, and that prompt consideration of such MOUs can have the effect of creating a Canadian marketplace for organic NHPs that is consistent with that for organic foods and that will avoid consumer and trade confusion that would likely be caused by the proposed OPR if NHPs are excluded from its scope.

Consumer confusion may increase rather than decrease

AHPA notes that the February 14 Gazette notice states that the proposal addresses a number of issues identified in the OPR, including “consumer confusion through the introduction of a single organic agricultural product legend” (February 14 Gazette, p. 345). It is AHPA’s view, however, that the proposed OPR’s exclusion of NHPs from its scope, and thus restriction of this class of agricultural products from using the “Canada Organic Regime” logo, would create more rather than less confusion, both for consumers and at all levels of commerce (e.g., manufacturer, distributor, and retailer).

As an example, appended here as **Annex 2** are images of two very similar certified organic agricultural products marketed in Canada by an AHPA member company that has marketed its organic herbal products in Canada for nearly 30 years. Some of their organic herbal tea products

are food products (e.g., Organic Spearmint) but most of their organic herbal tea products are NHPD-licensed NHPs (e.g., Organic Peppermint; Natural Product Number: NPN 80001178). These two CCOF-certified organic herbal tea products sit on the Canadian retail shelf side-by-side. Under the proposed regulation, one would be eligible for certification and use of the new Canadian logo (Organic Spearmint because it is a food product) but the other would not be eligible for certification and use of the Canadian logo (Organic Peppermint because it is an herbal medicinal NHP). Nonetheless, both products are composed of 100% cultivated plants and are agricultural products.

This example presents an unexpected negative outcome of the proposed regulation that will cause significant consumer and trade confusion.

Regulatory guidance exists for organic labeling of NHPs

Certain NHPD guidelines already in existence for NHPs specify the conditions under which organic labeling and advertising may be used on such products. For example, NHPD has published a guidance for industry document titled “*Evidence for Quality of Natural Health Products*,² which include requirements for certified organic NHP applications. This NHPD guidance document on page 26 states the following:

Organic products: An application for finished products containing organic ingredients must be accompanied by a proof of certification. Organic ingredients should comply with the *Organic Products Regulations of Canada*, December 2006. Certification of the plant/plant material or fungi (e.g., organic mushrooms) by accredited agencies is considered to be acceptable. Note: Organic products must not contain the same ingredients in both organic and non-organic forms. Ingredients that do not meet the organic requirement may be used only when they make up less than 5% of the total ingredients and when the following information is supplied: a description of efforts made in good faith to locate or develop a source of the certified organic form of the ingredient, and progress made over the years to eliminate non-organic material.

And on pages 40-41 of the aforementioned NHPD guidance document it states further:

Organic. A labelling and advertising term denoting a plant or plant material, alga, fungus or non-human animal material certified to have been produced in accordance with the production, processing, packaging, storage and distribution provisions of the National Standard of Canada for Organic Agriculture. Certification according to other organic standards is also acceptable. Products not within the scope of agricultural standards (e.g., aquatic non-human animal material, alga, cyanobacteria (“blue algae”)) must be certified to have been produced in accordance with an aquacultural or other applicable organic standard.

² Health Canada Natural Health Products Directorate. *NHPD Evidence for Quality of Natural Health Products*, Version 2. Ottawa, Ontario: Natural Health Products Directorate. June 2007. Available at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq-eng.php>

Additionally, NHPD has published other guidance for industry titled “*NHPD Labelling Guidance Document*,”³ which under Chapter 5 Special Labelling Requirements includes the sub-chapter 5.5 Organic Products:

5.5 Organic Products

“Organic” is a labelling and advertising term that denotes a plant or a plant material, a fungus or a non-human animal material certified to have been produced in accordance with the production, processing, packaging, storage and distribution provisions of the National Standard of Canada for Organic Agriculture. Certification according to other organic standards is also acceptable. Products not within the scope of agricultural standards (e.g. aquatic non-human animal material, algae, cyanobacteria, (“blue-green algae”)) must be certified to have been produced in accordance with an aquacultural or other applicable organic standard.

Organic labeling is voluntary if a NHP is labelled as “organic” or contains organic ingredients. However, it is recommended that the following conditions be met. Products that are certified organic or contain certified organic ingredients may display the following terms and symbols on the label:

- organic;
- organically grown;
- organically raised;
- organically produced;
- biological or biodynamic; and
- symbols for, alternative spellings of, word sets of and phonetic renderings of these words.

Each of the above terms may be preceded by the term *certified*.

In addition to the above-cited NHPD organic guidance, Chapter 2.18 of Health Canada’s Health Products and Food Branch (HPFB) document, “*Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*,”⁴ provides the following guidelines and applications for certified organic nonprescription drugs:

Guideline

An advertisement must not mislead a consumer to believe a product is “organic” unless it is certified according to organic standards.

Application

- Advertisers must provide evidence of certification, i.e. copy of Organic Certificate. Certification according to any standard reference by a certification body is acceptable.
- Products that are certified organic or contain certified organic ingredients may display the following terms and symbols:
 - Organic
 - Organically grown
 - Organically raised
 - Organically produced
 - Trademark of the certification body

³ Health Canada Natural Health Products Directorate. Chapter 5.5 Organic Products. In: *NHPD Labelling Guidance Document*, Version 2. Ottawa, Ontario: Natural Health Products Directorate. October 2006. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/labelling-etiquetage-eng.pdf

⁴ Health Canada. Chapter 2.18 Organic. In: *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*. Ottawa, Ontario: Health Canada Health Products and Food Branch. 18 October 2006. Available at: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/advert-publicit/guide-ldir_consom_consum-eng.pdf

Thus, both NHPD and HPFB already have some familiarity with certification and labeling requirements for organic NHPs and other nonprescription drugs, and have existing frameworks for the licensing of these products when made with certified organic herbs. AHPA has suggested elsewhere in this representation that CFIA promptly consider entering into an inter-agency MOUs with other Canadian federal agencies to clarify how the OPR can be implemented for NHPs. It should be evident by the existence of the guidance cited here that CFIA would encounter knowledgeable and interested government partners in this matter. AHPA therefore repeats here its suggestion, and believes that CFIA must collaborate with NHPD, and possibly also with HPFB, in order to make certain that NHPs do not find themselves at a market disadvantage in the Canadian natural products market by exclusion from Canadian certification.

Summary

It is AHPA's view that the scope of the proposed OPR must be expanded to include agricultural products marketed as NHPs. Contrary to CFIA's stated objectives, excluding NHPs from the Canada Organic Regime will disrupt trade for many already-marketed organic NHPs and will lead to greater consumer confusion. NHPs that are derived from plants clearly fit within CAPA's definition of an agricultural product, and CFIA should determine that NHPs should therefore be included within the scope of the OPR. AHPA has suggested here that CFIA act promptly to establish MOUs as necessary with other Canadian agencies, and particularly with NHPD. It is obvious that NHPD, and also HPFB, has already acquired significant knowledge about the regulation and labeling of organic products.

AHPA therefore respectfully requests that CFIA reconsider its proposal to exclude NHPs from the scope of the proposed OPR. AHPA strongly believes that to do otherwise would place undue burdens on many marketers of organic herbal products in Canada and would reduce demand in Canada for organically cultivated herbal crops.

Respectfully submitted,



Michael McGuffin
President, American Herbal Products Association
8630 Fenton Street, Suite 918
Silver Spring, MD 20910
(301) 588-1171 x201
mmcguffin@ahpa.org

**Proposed Organic Products Regulations
AHPA Representation, ANNEX 1**

ANNEX 1: Organic NHPs with Natural Product Numbers (NPNs)

Licence Number	Product Name	Licence Holder
02242689	Treemenda Organic Tea Tree Oil	SunOpta Inc.
80000042	Organic Flaxseed Oil Softgels	GFR Pharma Ltd.
80000166	Certified Organic Flax Seed Oil 1000 Mg	Swiss Herbal Remedies Ltd /TheraPro
80000346	Genestra Brands™ Organic Flax Oil Capsules	Seroyal International Inc.
80000385	Herbal Select- Organic Flaxseed Oil 1000 Mg	Puresource Inc.
80000928	Spectrum Organic Flax Oil	Spectrum Organic Products Inc.
80000969	Viva Organic Flaxseed Oil 1000 Mg Softgels	Viva Pharmaceutical Inc.
80000975	Viva Organic Flaxseed Oil 500 Mg Softgels	Viva Pharmaceutical Inc.
80001327	Solaray® Organically Grown Excipient-Free Ginger Root	Au Naturel Inc.
80001436	Solaray® Organically Grown Excipient-Free Dandelion	Au Naturel Inc.
80001855	Sangster'S Organic Flax Seed Oil	Darwen Holdings Ltd.
80001859	Solaray Organically Grown Excipient-Free Nettle Leaves	Au Naturel Inc.
80001946	Herbal Select- Organic Flax Oil, Omega Oil	Puresource Inc.
80001984	Now Certified Organic Flax Seed Oil 355ml	Now Foods
80002088	Solaray® Organically Grown Excipient-Free Saw Palmetto	Au Naturel Inc.
80002313	Now Organic Flaxseed Oil 1000 Mg	Now Foods
80002862	Solaray® Organically Grown, Excipient -Free Valerian	Au Naturel Inc.
80002947	Soloray® Organically Grown, Excipient-Free St. John's Wort	Au Naturel Inc.
80002949	Solaray® Organically Grown, Excipient-Free Garlic	Au Naturel Inc.
80002966	Now Organic Golden Flax Seed Meal	Now Foods
80003139	Solaray® Organically Grown, Excipient-Free Licorice	Au Naturel Inc.
80003279	Soloray® Organically Grown Excipient-Free Eleuthero	Au Naturel Inc.
80003788	West Coast Naturals Certified Organic Flaxseed Oil 1000 Mg Softgel Capsules	W.C. Bio-Pharm Inc.
80004000	Protocol For Life Balance Organic Flaxseed Oil 1000 Mg	NHG
80004424	New Organic Certified Omega 3-6-9	Now Foods
80004977	Nature's Gate® Organics Advanced Care™ Natural Results™ Body Wash	Levlad, LLC
80005203	Nature's Gate® Organics Baby Soothing Diaper Rash Cream	Levlad, LLC
80005655	Solaray® Organically Grown Excipient-Free Fenugreek	Au Naturel Inc.
80005678	Certified Organic Premium Flax Seeds Whole	Source of Life Products
80005892	Organic Garlic - 500 Mg	SunOpta Inc.
80005925	Vitality Organic Cranberry 330 Mg.	Vitality Products Inc.

**Proposed Organic Products Regulations
AHPA Representation, ANNEX 1**

80005999	Vitality Organic St. John's Wort 500 Mg.	Vitality Products Inc.
80006022	Vitality Organic Saw Palmetto 460 Mg.	Vitality Products Inc.
80006035	Vitality Organic Echinacea 500 Mg.	Vitality Products Inc.
80006064	Nature's Gate® Organics Advanced Care™ Natural Results™ Acne Treatment System Controlling Lotion With Salicylic Acid	Levlad, LLC
80006066	Nature's Gate® Organics Advanced Care™ Natural Results™ Acne Treatment System Corrective Cleanser With Salicylic Acid	Levlad, LLC
80006201	Pure-Le Natural Oregaplus Organicaps	Health4all Products Limited
80006364	Aim Aimega Organic Seed Oil	NAIM Canada Inc. o/a AIM Canada
80006415	Now Organic Flax Oil 1000mg	Now Foods
80006439	Organic Peppermint	Vitaminol Inc.
80006511	Pc Organics Heartburn Relief	Naturally Nova Scotia Health Products Ltd.
80006540	Nature's Gate® Organics Natural Results® Extra Strength Spot Corrector Salicylic Acid Acne Treatment	Levlad, LLC
80007083	Vitality Organic Milk Thistle 5,250 Mg.	Vitality Products Inc.
80007572	Thompson's Organic Flaxseed Oil 1000	Thompson Group Limited
80008360	Pc Organics Saw Palmetto	Naturally Nova Scotia Health Products Ltd.
80008367	Pc Organics Milk Thistle	Naturally Nova Scotia Health Products Ltd.
80008395	Pc Organics St. John's Wort	Naturally Nova Scotia Health Products Ltd.
80009046	Alfalfa luzerne-Certified Organic	Vitazan Herbs and Vitamins Inc.
80009098	Certified Organic Evening Primrose Oil	Vitazan Herbs and Vitamins Inc.
80009149	Evening Primrose Oil-Certified Organic	New Roots Herbal Inc.
80009642	North Coast Naturals - Organic Calcium (Powder)	Fit Foods Manufacturing Ltd.
80009739	Soleo Organics Natural Sunscreen	Skin Elements USA LLC
Pending	Breathe Easy® (with Organic Licorice Root); Submission No 112494	Traditional Medicinals, Inc.
00659819	Cold Formula (made with Organic Elder)	Traditional Medicinals, Inc.
00708038	Eater's Digest® (made with Organic Peppermint)	Traditional Medicinals, Inc.
Pending	Organic Chamomile with Lavender; Submission No 121103	Traditional Medicinals, Inc.
Pending	Organic Classic Chamomile; Submission No 121099	Traditional Medicinals, Inc.
Pending	Organic Cran-Aid®; Submission No 120457	Traditional Medicinals, Inc.

**Proposed Organic Products Regulations
AHPA Representation, ANNEX 1**

Pending	Organic Easy Now®; Submission No 121098	Traditional Medicinals, Inc.
Pending	Organic Echinacea Elder; Submission No 121250	Traditional Medicinals, Inc.
80005962	Organic Echinacea Plus®	Traditional Medicinals, Inc.
Pending	Organic Everyday Detox®; Submission No. 122468	Traditional Medicinals, Inc.
80001164	Organic Ginger	Traditional Medicinals, Inc.
Pending	Organic Ginger Aid®; Submission No121244	Traditional Medicinals, Inc.
Pending	Organic Golden Ginger®; Submission No 121102	Traditional Medicinals, Inc.
02243711	Organic Herbal Laxative / Smooth Move® Senna	Traditional Medicinals, Inc.
Pending	Organic Lemon Echinacea Throat Coat®; Submission No 122467	Traditional Medicinals, Inc.
80003649	Organic Licorice Root	Traditional Medicinals, Inc.
80003176	Organic Nettle Leaf	Traditional Medicinals, Inc.
00708011	Organic Nighty Night®	Traditional Medicinals, Inc.
Pending	Organic Nursing Tea; Submission No 123558	Traditional Medicinals, Inc.
80001178	Organic Peppermint	Traditional Medicinals, Inc.
Pending	Organic Pregnancy Tea; Submission No 122939	Traditional Medicinals, Inc.
Pending	Organic Raspberry Leaf; Submission No 121156	Traditional Medicinals, Inc.
80001158	Organic Roasted Dandelion Root	Traditional Medicinals, Inc.
00659797	Organic Throat Coat® / Formerly Throat Formula	Traditional Medicinals, Inc.
00708046	PMS Tea® (made with Organic Roasted Dandelion Root)	Traditional Medicinals, Inc.
00726591	Weightless® / formerly Herbal Diuretic (made with Organic Fennel)	Traditional Medicinals, Inc.

ANNEX 2: Comparison of Eligible and Ineligible Herbal Tea Products for Canadian Organic Labeling

CCOF-CERTIFIED ORGANIC NATURAL HEALTH PRODUCT HERBAL TEA DOSAGE FORM	CCOF-CERTIFIED ORGANIC FOOD PRODUCT HERBAL TEA DOSAGE FORM																
<p>This herbal tea label would not be eligible to carry the new Canadian logo because it is a licensed Natural Health Product</p> 	<p>This herbal tea label would be eligible for us of the new logo because it is a food / beverage product</p>  <table border="1" data-bbox="1528 602 1816 820"> <thead> <tr> <th colspan="2">Nutrition Facts Valeur nutritive</th> </tr> <tr> <th colspan="2">Per 1 cup (240 mL) / pour 1 tasse (240 mL)</th> </tr> <tr> <th>Amount</th> <th>% Daily Value</th> </tr> <tr> <th>Teneur</th> <th>% valeur quotidienne</th> </tr> </thead> <tbody> <tr> <td>Calories / Calories 0</td> <td></td> </tr> <tr> <td>Fat / Lipides 0 g</td> <td>0 %</td> </tr> <tr> <td>Carbohydrate / Glucides 0 g</td> <td>0 %</td> </tr> <tr> <td>Protein / Protéines 0 g</td> <td></td> </tr> </tbody> </table>	Nutrition Facts Valeur nutritive		Per 1 cup (240 mL) / pour 1 tasse (240 mL)		Amount	% Daily Value	Teneur	% valeur quotidienne	Calories / Calories 0		Fat / Lipides 0 g	0 %	Carbohydrate / Glucides 0 g	0 %	Protein / Protéines 0 g	
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