Health Canada Santé Canada

NATURAL HEALTH PRODUCTS COMPLIANCE GUIDE

NATURAL HEALTH PRODUCTS DIRECTORATE

January 2007
Version 2.1

Canada

“Our mission is to help the people of Canada 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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1.0 INTRODUCTION

Purpose

The purpose of the *Natural Health Products Compliance Guide* (the Guide) is to provide clear guidance to the staff of the Health Products and Food Branch (HPFB), other regulatory bodies, industry and other stakeholders when dealing with natural health products (NHPs) that are on the market when the *Natural Health Product Regulations* (the Regulations) came into force January 1, 2004.

This document replaces former Natural Health Products Directorate (NHPD) compliance guides and supersedes both the Interim DIN Enforcement Directive (1998) and its associated Therapeutic Products Compliance Guide, which ceased to be in effect as of January 1, 2004. The *Natural Health Products Compliance Guide* is to be used alongside its attachments (**Appendix A**) and the *Compliance Policy for Natural Health Products* (the Compliance Policy).

The goal of the Guide is to assist all parties to operate in a fair and consistent manner, and to conduct a uniform application of the *Food and Drugs Act*, the *Food and Drug Regulations* and the *Natural Health Products Regulations*. The Guide provides the user with criteria to determine if a product meets the definition of a NHP under the provisions of the Regulations. This Guide also provides detailed criteria and steps for the approach to risk determination, as well as the product category priority approach as detailed in the Compliance Policy.

While developing and implementing the compliance approach, the Natural Health Products Directorate (NHPD) was aware of the consumers' desire to have access to NHPs, and the need to ensure they are safe and effective. The following approach continues to consider consumers' needs.

Scope

The Guide applies to all NHPs destined for human use. The Guide does not distinguish between a product that has previous market experience in Canada and one that is new to the Canadian market. In both cases, the compliance approach is identical. This guide does not apply to foods, drugs, or cosmetics as regulated under the *Food and Drug Regulations*, or NHPs that are veterinary drugs.

2.0 COMPLIANCE APPROACH

As of January 1, 2004, all NHPs must comply with the Regulations. The *Compliance Policy for Natural Health Products* and the *Natural Health Products Compliance Guide* outline Health Canada's approach with respect to non-compliant NHPs on the Canadian market.

Health Canada's compliance approach for NHPs focuses primarily on products that pose unacceptable risks to the health of Canadians. Accordingly, a risk-based approach followed by a category priority approach set out the criteria for the assessment of NHPs that do not have valid authorization to be sold on the Canadian market.

All non-compliant NHPs will be subject to appropriate compliance and enforcement actions, as determined by the NHPD and the Health Products and Food Branch Inspectorate (HPFBI). All NHPs identified as posing an unacceptable risk to the health of Canadians will be removed from sale. Any required compliance and enforcement actions will be carried out by HPFBI. The nature of the compliance action will be in accordance with the HPFBI's Compliance and Enforcement Policy (POL-0001).

A non-compliant NHP:

- does not have a valid market authorization (i.e. Drug Identification Number (DIN), Natural Product Number (NPN) or Homeopathic Medicines Number (DIN-HM)); or
- has a valid NPN or DIN-HM but is otherwise non-compliant with the Regulations.

In the case of NHPs that do not have a valid market authorization, the Compliance Policy for Natural Health Products and the HPFBI's Compliance and Enforcement Policy (POL-0001) will be applied. The steps to be taken in the assessment of these NHPs are summarized below.

Any holders of NPNs and DIN-HMs that do not comply with the Regulations will be addressed according to the provisions in the Regulations and the HPFBI's Compliance and Enforcement Policy (POL-0001).

Between January 1, 2004 and December 31, 2009, the *Food and Drug Regulations* continue to apply for products with a valid DIN that fit the definition of a NHP under the Regulations, until the product obtains a valid NPN or DIN-HM.

3.0 PRODUCT CLASSIFICATION

The criteria and steps for product classification are presented in Table 1. If the product is not an NHP, refer to the appropriate regulatory body for guidance. If, however, the product is determined to be an NHP, the HPFBI will apply the Regulations or the Compliance Policy alongside its Compliance and Enforcement Policy (POL-0001).

Table 1 Product Classification

Step	Assessment Criteria	References	Y /N	Next Steps
PRODUCT CLASSIFICATION:				
1	Does the product meet the definition of a Homeopathic Medicine (HM)?[1]	*Glossary*	Yes	Proceed to Step 3.
			No	Proceed to Step 2.
2	Are the ingredients listed in Schedule 1 of the Regulations?	*Schedule 1 of the Regulations* (PART A, Section 1)	Yes	Proceed to Step 3.
			No	STOP. This is NOT an NHP.
3	Is any ingredient listed in Schedule 2 of the Regulations?	*Schedule 2 of the Regulations* (PART A , Section 2)[2] *Schedule C* (PART A, Section 3) *Schedule D* (PART A, Section 4)[3] *Controlled Drugs and Substances Act* (PART A, Section 5)	Yes	STOP. This is not an NHP.
			No	This is an NHP. Proceed to Step 4.

[1,2,3] Schedule D and Schedule F substances are acceptable in homeopathic medicines when prepared in accordance with the practices of homeopathic pharmacy.

4.0 RISK-BASED APPROACH

The Risk-based Approach, as detailed in the Compliance Policy, is applied when a NHP on the Canadian market does not have or has not applied for a valid market authorization or has previously been refused the issuance of a NPN or DIN-HM.

The criteria and steps for risk determination are set out in Table 2, which contains a series of guiding questions to be answered in combination with references in **Appendix A**, and the criteria for risk, as described in the Compliance Policy and subsequent actions to be carried out.

In assessing whether an NHP poses an unacceptable risk requiring immediate compliance action, consideration will be given to:

- earlier information provided to and decisions made by the Special Access Program; and
- whether the risk will be mitigated by the intervention of a practitioner who recommends the NHP to the patient and oversees its use.

In the case that the risk of the non-compliant NHP cannot be determined using available tools such as Table 2, NHPD will perform a Health Hazard Evaluation and identify the product risk classification.

Table 2 Risk-based Approach

Step	Assessment Criteria	References	Y /N	Next Steps
RISK DETERMINATION:				
4	Does the product have a valid market authorization number (e.g DIN)?	Drug Product Database (DPD)	Yes	STOP. Compliance Promotion: This is an NHP and will require an NPN by Jan 1, 2010.
			No	Proceed to Step 5.
5	Has earlier information been provided to and decisions made by the Special Access Program?	Available information	Yes	STOP. Consult with the HPFB Compliance and Enforcement Coordination Division and NHPD.
			No	Proceed to Step 6.
6	Will the risk be mitigated by the intervention of a practitioner who recommends the NHP to the patient and oversees its use?	Available information	Yes	STOP. Consult with the HPFBI Ottawa and NHPD.
			No	Proceed to Step 7.

Step	Assessment Criteria	References	Y /N	Next Steps
7	Does the product have an ingredient that is in Schedule F of the *Food and Drug Regulations*?	*Schedule F* (PART A, Section 6)	Yes	STOP. This is not an NHP (with the exception of homeopathic medicines (HMs)). Follow protocol of the HPFBI Compliance and Enforcement Policy (POL-0001).
			No	Proceed to Step 8.
8	Does the product make a claim as referred to in Schedule A of the *Food and Drugs Act*?	*Schedule A* (PART A , Section 7)	Yes	STOP. Follow protocol as stated in the HPFBICompliance and Enforcement Policy (POL-0001) and Compliance Promotion.
			No	Proceed to Step 9.
9	Is the intent of the product for use by pregnant and breast feeding women, or children aged 12 and under? (Refer to exclusions in Appendix B and C of the Compliance Policy.)		Yes	STOP. Follow protocol as stated in the HPFBI Compliance and Enforcement Policy (POL-0001) and Compliance Promotion.
			No	Proceed to Step 10.
10	Is the product a sterile dosage? (e.g. ophthalmic preparation)		Yes	STOP. Follow protocol as stated in the HPFBI Compliance and Enforcement Policy (POL-0001) and Compliance Promotion.
			No	Proceed to Step 11.
11	Does the product have an ingredient that is prohibited or restricted?	*Food and Drugs Regulations (FDR) List* (PART A, Section 8) *non-FDR List* (PART A, Section 9) *Restricted Substances for Homeopathic Medicines* (PART A, Section 10)	Yes	STOP. Follow protocol as stated in the HPFBI Compliance and Enforcement Policy (POL-0001) and Compliance Promotion
			No	If Step 12 does not apply, refer to Product Category Priority (Table 3).
HEALTH HAZARD EVALUATION (RISK CLASSIFICATION):				
12	The above list of questions is not exhaustive; rather, it is representative of the types of questions that indicate there may be safety issues with respect to a non-compliant NHP. If the risk of the NHP cannot be comprehensively determined by following the above assessment, NHPD will perform a health hazard evaluation/risk classification as requested by the HPFB Inspectorate.			

Health Hazard Evaluation (Risk Classification[4])

The risk classification scheme is an evidence-based approach that classifies a product into a level of risk based on relevant information from published and unpublished sources such as, but not limited to, journals, textbooks, reports from regulatory bodies, etc. The evidence will primarily be from experience of the product or ingredient in humans, but may also include relevant information, when necessary, from animal studies.

The intent is for the HPFB to couple the level of risk of non-compliant NHPs with the appropriate measures to ensure these products comply with the NHP regulatory requirements.

[4] To be finalized pending revisions from the HPFB (Risk Classification) Working Group.

5.0 PRODUCT CATEGORY PRIORITY

This strategy complements, but is superseded by, the Risk-based Approach.

A product category strategy, as detailed in the Compliance Policy for NHPs, addresses non-compliant NHPs not captured by the risk-based questions of Table 2. Health Canada will focus on compliance-promoting efforts following the six NHP categories outlined in Table 3.

Critical dates mapped in Compliance Policy for NHPs serve to guide the priority-driven process. These should not be interpreted as deadlines to submit the Product Licence Application. In other words, any NHP posing a health risk will be subject to appropriate measures according to the Risk-based Approach, regardless of its position on Table 3.

The following are the NHP categories and the rationale for their prioritization:

1. **NHPs on the Therapeutic Product Directorate's (TPD's) Listing of Drugs Currently Regulated as New Drugs, Revised April 1999:**
   Health Canada considers these top priority NHPs, as they are substances and formulations for which the lack of, or inadequate information on, their safe use indicates that their safety and efficacy for medicinal purposes have not been established.
2. **Isolates, amino acids, fatty acids, concentrated volatile (essential) oils indicated for internal use, and extracts other than those prepared by traditional methods:**
   These are Priority 2 NHPs as they may increase the concentration of select constituents and thus might be consumed in a higher dose than would normally occur with the whole organism (e.g. a plant); moreover, adequate pharmacological and safety information may not be present.
3. **Algal, bacterial, probiotic, fungal and non-human animal materials:**
   These substances are considered Priority 3 NHPs because, while they generally present less risk than selective concentrates, problems may arise from the application of these products as a result of improper concentration, inadequate ingredient identification, or lack of adherence to Good Manufacturing Practices. Safety issues surrounding non-human animal materials relate to risk mitigation for products potentially contaminated with the causative agents of transmissible bovine spongiform encephalopathy.
4. **Plants, plant materials, extracts prepared by traditional methods, and volatile (essential) oils other than those that are concentrated and indicated for internal use:**
   Plants and plant materials are considered Priority 4 because plant materials present less risk than extracts or isolates. Still, the safety information for many species may be limited.
5. **Vitamins and minerals:**
   Vitamins and minerals are considered Priority 5 NHPs because most are well-known with regard to safe conditions of use as dietary supplements. However, there may be associated potential risk concerns such as: a) dosing of certain fat-soluble vitamins and micronutrient minerals as dietary supplements; and b) recommendations for use without adequate supporting evidence in the treatment of serious diseases.
6. **Homeopathic medicines:**
   Homeopathic medicines are considered to present low risk because most do not contain a material dose of a medicinal ingredient, and standards for product quality are well-established in pharmacopoeias. However, concerns may arise over low dilution products or nosodes where cross-contamination may present a health risk.

Table 3 Product Category Priority Approach

NHPs posing a health risk according to the Risk-based Approach (Table 2) are subject to appropriate compliance action, regardless of their position in the following table.

Priority	NHP Category	Reference	Product Licence Application (PLA)	Y/N	Next Steps
JUNE 1, 2004					
1	NHPs on TPD's Listing of Drugs Currently Regulated as New Drugs, Revised April 1999	NHP-SAS New Drugs List	PLA submitted?	Yes	Pending NPN ruling, compliance action based on risk (Table 2)
				No	As of JUNE 1, 2004, compliance action as stated by the HPFBI Compliance and Enforcement Policy (POL-0001)
JANUARY 1, 2005					
2	Isolates, amino acids, fatty acids, concentrated volatile (essential) oils indicated for internal use, and extracts other than those prepared by traditional methods	NHP-SAS	PLA submitted?	Yes	Pending NPN ruling, compliance action based on risk (Table 2)
				No	As of JANUARY 1, 2005, Compliance action as stated in the HPFBI Compliance and Enforcement Policy (POL-0001)
JUNE 1, 2005					
3	Algal, bacterial, fungal, probiotic, and non-human animal materials	NHP-SAS	PLA submitted?	Yes	Pending NPN ruling, compliance action based on risk (Table 2)
				No	As of JUNE 1, 2005, Compliance action as stated in the HPFBI Compliance and Enforcement Policy (POL-0001)
JUNE 1, 2007					
4	Plants, plant materials, extracts prepared by traditional methods, and volatile (essential) oils other than those that are concentrated and indicated for internal use	NHP-SAS	PLA submitted?	Yes	Pending NPN ruling, compliance action based on risk (Table 2)
				No	As of JUNE 1, 2007, Compliance action as stated in the HPFBI Compliance and Enforcement Policy (POL-0001)
JANUARY 1, 2008					
5	Vitamins and minerals	NHP-SAS	PLA submitted?	Yes	Pending NPN ruling, compliance action based on risk (Table 2)
				No	As of JANUARY 1, 2008, Compliance action as stated in the HPFBI Compliance and Enforcement Policy (POL-0001)
JUNE 1, 2008					
6	Homeopathic Medicines	NHP-SAS	PLA submitted?	Yes	Pending DIN-HM ruling, compliance action based on risk (Table 2)
				No	As of JUNE 1, 2008, Compliance action as stated in the HPFBI Compliance and Enforcement Policy (POL-0001)

6.0 GLOSSARY

b.w.: Body weight

Compliance: The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement or a recognized standard.

Cosmetic: Any substance or mixture of substances manufactured, sold or represented for use in cleaning, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.

Drug: Any substance or mixture of substances manufactured, sold or represented for use in:

- diagnosing, treating, mitigating or preventing a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
- restoring, correcting or modifying organic functions in human beings or animals;
- disinfection in premises in which food is manufactured, prepared or kept.

Enforcement Activities: Refers to the the range of actions that may be taken to induce, encourage or observance of the requirements of the *Food and Drugs Act* and the NHP Regulations and the associated regulations to safeguard the health and safety of Canadians.

FDA: *Food and Drugs Act*

FDR: *Food and Drug Regulations*

Homeopathic Medicines: *This definition is currently under review.*

HPFB: The Health Products and Food Branch, Health Canada.

HPFBI/HPFB Inspectorate: The HPFBI delivers a national compliance and enforcement program for all products under the mandate of the HPFB, with the exception of products regulated as foods.

NHP: Natural health product (see **chapter 8, Appendix A**)

NHPD: The Natural Health Products Directorate regulates NHPs. It promotes and oversees the administration of the NHP framework. Its activities include product and site licensing, product and site assessment, and risk classification.

NHP-SAS: Natural Health Product - Submission Approval System Database.

Nosodes: Attenuations of pathological organs or tissues; causative agents such as bacteria, fungi, ova, parasites, virus particles, and yeast; disease products; excretions or secretions.

PLA: NHP Product Licence Application

Practitioner: A person authorized by the law of a Province of Canada to treat patients with any drug listed or described in Schedule F of the Regulations; (pratician)

Traditional medicine: The sum total of the knowledge, skills, and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. Traditional medicine has a long history (50 consecutive years) of use.

Traditional methods of preparation include:

- the use of a whole plant or specific parts of the plant (leaf, root, seeds, etc.), whether fresh, dried or freeze-dried, or preserved with alcohol, honey or sugar;
- aqueous extracts such as infusions, decoctions and syrups;
- ethanol-based extracts such as tinctures, fluid extracts and succi;
- glycerine-based extracts;
- vinegar-based extracts;
- oil, grease or fat-based infusions; or
- beeswax salves and ointments

TPD: The Therapeutic Products Directorate regulates pharmaceuticals and medical devices.

7.0 REFERENCES

- A Fresh Start - Final Report of the ONHP Transition Team, March 31, 2000
- Compliance and Enforcement Policy (POL-0001), November 22, 2001
- Compliance Policy for Natural Health Products, March 2006
- *Evidence for Homeopathic Medicines*, October 2006
- *Evidence for Safety and Efficacy of Finished Natural Health Products*, October 2006
- Interim DIN Enforcement Directive (POL-0003), January 1, 1998.
- *Natural Health Products Regulations* (Canada Gazette II), June 18, 2003.
- Therapeutic Products Compliance Guide, November 30, 1999

APPENDIX A - DEFINITIONS AND LISTINGS OF INCLUDED, EXCLUDED OR RESTRICTED SUBSTANCES

Definition of a Natural Health Product

A substance set out in Schedule 1 of the *Natural Health Products Regulations* 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.

(Taken from the *Natural Health Products Regulations*)

A NHP does not include a substance set out in Schedule 2 of the *Natural Health Products Regulations* or any combination of substances that includes a substance set out in Schedule 2. See **Schedules 1 and 2 of the Regulations** below.

Definition of a Homeopathic Medicine

Medicines that are manufactured from or contain as medicinal ingredients only those substances or sources referenced in the *Homeopathic Pharmacopeia of the United States* (HPUS), the *Homöopathische Arzneibuch* (HAB), the *Pharmacopée française* (PhF), the *European Pharmacopoeia* (Ph.Eur.), or the *Encyclopedia of Homeopathic Pharmacopeia* (EHP) as amended from time to time, and that are prepared in accordance with these pharmacopoeias.

Schedule 1 of the *Natural Health Products Regulations*

Item	Substances
1	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3	Any of the following vitamins: • biotin; • folate; • niacin; • pantothenic acid; • riboflavin; • thiamine; • vitamin A; • vitamin B_6; • vitamin B_{12}; • vitamin C; • vitamin D; or • vitamin E.
4	An amino acid
5	An essential fatty acid
6	A synthetic duplicate of a substance described in any of items 2 to 5
7	A mineral
8	A probiotic

Schedule 2 of the *Natural Health Products Regulations*

Item	Substances	References
1	A substance set out in Schedule C of the *Food and Drugs Act*	Appendix 3
2	A substance set out in Schedule D of the Act, except for the following: (a) drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out in Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy	Appendix 4
3	A substance regulated under the *Tobacco Act*	
4	A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*	Appendix 5
5	A substance that is administered by puncturing the dermis	
6	An antibiotic prepared from an alga, bacterium or fungus or a synthetic duplicate of that antibiotic	

Scheduled Substances

Schedule C (Radiopharmaceuticals) of the Food and Drugs Act

http://lois.justice.gc.ca/en/F-27/240957.html#rid-240959

Schedule D of the Food and Drugs Act

http://lois.justice.gc.ca/en/F-27/240957.html#rid-240960

Schedule I of the Controlled Drugs and Substances Act (CDSA)

http://laws.justice.gc.ca/en/C-38.8/229687.html

Schedule II of the CDSA

http://laws.justice.gc.ca/en/C-38.8/229687.html#rid-229688

Schedule III of the CDSA

http://laws.justice.gc.ca/en/C-38.8/229687.html#rid-229689

Schedule IV of the CDSA

http://laws.justice.gc.ca/en/C-38.8/229687.html#rid-229690

Schedule F of the Food and Drug Regulations (Part I)

http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/234354.html

Schedule F of the Food and Drug Regulations (Part II)

http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/234355.html

Schedule A Claims

Schedule A of the Food and Drugs Act

http://lois.justice.gc.ca/en/F-27/240957.html

Prohibited or Restricted Substances

Prohibited Substances in the Food and Drug Regulations

Prohibited Substances in the *Food and Drug Regulations*			
Item	**Substances**	**Synonyms**	**Tolerance Limits**
1	Arsenic and its salts and derivatives	Arsenic acid, *Arsenicum album*, arsine gas, arsenic trioxide, arsenic disulfide	<0.14 µg/kg b.w./day
2	Cadmium		<0.09 µg/kg b.w./day
3	Chloroform	*Chloroformum Anesthesicum, Chloroformum, Chloroformum pro Narcosi*, trichloromethane, formyl trichloride	
4	Lead		<0.29 µg/kg b.w./day
5	Echimidine and its salts; and any of the following plant species or extracts or tinctures thereof: (i) *Symphytum asperum*, (ii) *Symphytum x uplandicum*, or (iii) any other plant species containing echimidine	Prickly comfrey (*S.asperum*), russian comfrey (*S.uplandicum*, a non officially recognized name) (*Symphytum x uplandicum*)	
6	Mercury and its salts and derivatives	Hydrargyrum, liquid silver, quick silver	<0.29 µg/kg b.w./day
7	Methapyrilene and its salts	Methapyrilene fumarate, methapyrilene hydrochloride, thenylpyrilene fumarate, thenylpyrilene hydrochloride	
8	Methyl salicylate (for internal use in humans)	Methyl 2–hydroxybenzoate, wintergreen oil, betula oil, sweet birch oil, teaberry oil, checkerberry oil, gaultheria oil	
9	Nitrous oxide	Dinitrogen monoxide, Dinitrogen oxide, Nitrogen monoxide, Laughing gas, Hyponitrous acid anhydre, Facticious air	
10	Oxyphenisatin	Dihydroxyphenylisatin, oxyphenisatine	
11	Oxyphenisatin acetate	Oxyphenisatin diacetate, acetphenolisatin, diacetoxydiphenylisatin, oxyphenisatine acetate	
12	Phenacetin in combination with any salt or derivative of salicylic acid	Aceto–p–phenetidide, acetophenetidin, acetylphenetidin, paracetophenetidin; phenacetinum, p–Acetophenetidide, p–acetophenetide, 4'ethoxyacetanilide	
13	Phenisatin	Triacetyldiphenolisatin, 1–acetyl–3,3–bis (p–hydroxyphenyl) oxindole diacetate	

Prohibited Substances in the *Food and Drug Regulations*			
Item	**Substances**	**Synonyms**	**Tolerance Limits**
14	Strychnine and its salts, extracts or tinctures of (i) *Strychnos nux vomica* (ii) *Strychnos Ignatii*, or (iii) a Strychnos species containing strychnine, other than those species mentioned in (i) and (ii)	*Strychnos nux vomica, Nux Vomica, Strychnos ignatii, Ignatia*, Ignatius bean	

Restricted Substances not in the Food and Drug Regulations

The following list may not be complete and will be revised annually. Where the product does not have a valid market authorization in Canada, the compliance approach to the substances listed here should be taken in conjunction with the Risk-Based Approach.

Restricted Substances not in the *Food and Drug Regulations*				
Item	**Substances**	**Synonym(s) and constituents**	**Considerations**	**Notes**
1	*Aristolochia* and all other herbs containing aristolochic acid	*Akebia, Asarum, Bragantia spp., MuTong*	Known to have been interchanged with: *Clematis, Stephania, Diploclisia, Menispermum, Sinomenium, Vladimiria souliei* and *Soussurea lappa*	**Potential health risk:** Carcinogenic, mutagenic and nephrotoxic effects
2	Calamus	*Acorus calamus, Calamus aromaticus*, sweet flag root, sweet sedge, sweet root, sweet myrtle, rat root, shuichangpu, kalmus		**Potential health risk:** Risk of severe liver toxicity
3	*Cantharis vesicatoria*	Cantharides (pl.), spanish fly, blistering beetle, cantharidin (constituent)	*Cantharis* is acceptable in homeopathic medicines at potencies of 3X or higher[2], and *Cantharidinum* or cantharidin is acceptable in homeopathic medicines at potencies of 8X or higher[3]	
4	Cedar oil	*Juniperus virginiana*		
5	Chaparral *	*Larrea tridentata, Larrea divaricata*, creosote bush, greasewood, hediondilla	*Larrea divaricata* is acceptable in homeopathic medicines at potencies of 1X or higher[1]	**Potential health risk:** Risk of severe liver toxicity in humans; nephrotoxicity was observed in animals as well

Restricted Substances not in the *Food and Drug Regulations*				
Item	**Substances**	**Synonym(s) and constituents**	**Considerations**	**Notes**
6	Croton oil	*Croton tiglium*		
7	Germander	*Teucrium spp.* including *Teucrium chamaedrys* (wall germander), *Teucrium scordium* (water germander), *Teucrium scorodonia* (sage-leaved germander, wood sage, garlic sage), *Teucrium marum*	*Teucrium scorodonia* and *Teucrium marum* are acceptable in homeopathic medicines at potencies of 1X or higher[1]	**Potential health risk:** Risk of severe liver toxicity
8	Ephedra	ma huang, Chinese Ephedra, *Ephedra sinica*, *Sida cordifolia* or epitonin	Dosage restriction of 400 mg/dose 1600 mg/day	
9	Ephedrine		Dosage restriction of 8 mg/dose, 32 mg/day	
10	*Piper methysticum*	kava, kava kava, kava root, kavain, kava pepper, kavapiper, kawa, kawa kawa, kawa pepper, kawapfeffer, maori root, rhizoma di kava-kava, ava, ava pepper, ava root, awa, gea, gi, intoxicating pepper, intoxicating long pepper, kao, malohu, maluk, meruk, milik, kew, rauschpfeffer, sakau, tonga, Wurzelstock, yagona, yangona, yaqona, yongona		
11	Sanguinarine		Sanguinarine is not permitted as an isolate. *Sanguinarinum nitricum* is acceptable in homeopathic medicines at potencies of 4X or higher.[4]	

[1] acceptable potencies: 1X, 2X, etc.
[2] acceptable potencies: 3X, 4X, etc.
[3] acceptable potencies: 8X, 9X, etc.
[4] acceptable potencies: 4X, 5X, etc.
* Please note: Topical chaparral is not intended to be on this restricted list.

Restricted Substances in Homeopathic Medicines

Restricted Substances in Homeopathic Medicines		
Item	**Substances**	**Synonyms**
1	Arsenic	*Antimonium arsenicicum, a. album, a. bromatum, a. iodatum, a. sulphuratum flavum, a. sulphuratum rubrum, calcarea arsenicica, chininum arsenicicum, chinimum arsenicosum, cuprum arsenicosum, ferrum arsenicicum, kali arsenicosum, natrum arsenicicum* 6X or higher (i.e. MT, 1X, 2X, 3X, 4X, 5X or its equivalent are unacceptable) **Exception:** *Arsenicum metallicum*: 8X or higher (i.e. MT, 1X, 2X, 3X, 4X, 5X, 6X, 7X or its equivalent are unacceptable) MT= mother tincture (starting solution)
2	Mercury	*Aethiops antimonialis, aethiops mercurialis-mineralis, m. aceticus, m. auratus, m. bromatus, m. corrosivius, m. dulcis, m. iodatus flavus, m. iodatus ruber, m. methyenus, m. nitricus, m. praecipitatus albus, m. praecipitatus ruber, m. solubilis, m. sulphocyanatus, m. sulphuratus ruber, m. sulphuricus, m. vivus* 6X or higher (i.e. MT, 1X, 2X, 3X, 4X, 5X or its equivalent are unacceptable) **Exception:** *Mercurius cyana*tus: 8X or higher (i.e. MT, 1X, 2X, 3X, 4X, 5X, 6X, 7X or its equivalent are unacceptable)
3	Strychnine	*Strychnimum, s. arsenicicum, s. nitricum, s. phosphoricum, s. sulphuricum* 6X or higher (i.e. MT, 1X, 2X, 3X, 4X, 5X or its equivalent are unacceptable) *Ignata amara, nux vomica* 3X or higher (i.e. MT, 1X, 2X or its equivalent are unacceptable)
4	Chloroform	*Chloformum* 3X or higher (i.e. MT, 1X, 2X or its equivalent are unacceptable)
5	Tansy	*Tanacetum vulgare* 3X or higher (i.e. MT, 1 X, 2 X are unacceptable) **Note:** Equivalent terms: X or DH; CH or C; CK or K **Equivalent Dilution Units:** 1X 2X 1C 1K 3X 4X 2C 2K 5X 6X 3C 3K 7X 8X 4C 4K **Example:** Arsenic 2CH is equivalent to Arsenic 4X. Therefore, the concentration of arsenic is non-compliant.