GOOD PRACTICES FOR PLANT IDENTIFICATION FOR THE HERBAL INDUSTRY

For the Saskatchewan Herb and Spice Association/
National Herb and Spice Coalition

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Agriculture and Agri-Food Canada (AAFC) is pleased to participate in the production of this publication. AAFC is committed to working with our industry partners to enhance food safety in Canada. Opinions expressed in this document are those of the Saskatchewan Herb and Spice Association and not necessarily the Department.

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This document developed by the below working group. A special thanks to each member for their insight and time donated to this collaborative project.

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LIST OF ABBREVIATIONS

C of A	Certificate of Authenticity
COFFS	Canadian on Farm Food Safety
EMEA	European Agency for the Evaluation of Medicinal Products
EUROPAM	European Herb Growers Association
GAP	Good Agricultural Practises
GMP	Good Manufacturing Practises
HACCP	Hazard Analysis Critical Control Point
WHO	World Health Organisation
GWP	Good Wild-crafting Practices

Good Practices for Plant Identification for the Herbal Industry

1. INTRODUCTION

The project to develop Good Practices for Plant Identification for the Herbal Industry had its origins in consultations with industry and government representatives aimed at laying the groundwork for the safe use of natural health products. With the support of the Canadian On Farm Food Safety (COFFS) program, the National Herb and Spice Coalition set out to build a HACCP (Hazard Analysis Critical Control Points) model for the herb and spice industry. During the development of the HACCP model, the technical working group identified plant identification as one of the two most critical components of the Good Agricultural Practices (GAPs) that needed to be developed for the industry. Proper plant identification is one of the keys to the development of an industry based on the safe use of high quality natural health products.

Building a practice for plant identification that would be embraced by producers and collectors means creating a practice that is both effective and workable for the production end of the value chain. To this end, a plant identification working group was created with representatives from industry, government, and educational institutions to provide advice on developing the practice. Parallel to this process, the consultants to the project began a search for published and unpublished literature as well as existing protocols related to plant identification. Little material was located that addressed in any detail the *process* for plant identification, especially a practice focused on the production end of the value chain where it is believed that the least costly and most effective intervention can occur.

The practice contained in this document is largely the result of the efforts of the working group to answer two key questions: “how can we create a high degree of certainty that plant materials will be properly identified at the production end of the value chain?” and “what practices can we recommend that will be workable for producers and collectors?”. In the end, the task of the working group has been to create a *framework* for plant identification that can be built on and adapted as needed. As such, this practice should be viewed as a ‘living’ practice that will continue to evolve as circumstances warrant.

It must be stressed that the practice described in this document is strictly a recommendation. [1]Participation in, and use of, the practice is voluntary. However, with new Natural Health Product regulations (*http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/index_e.html*) having gone into effect on January 1, 2004 in Canada, participants along the value chain for these products will have more at stake in ensuring their products are safe and of high quality. Accurate and traceable plant identification verification through-out the value chain will play a key role in ensuring the safety and legitimacy of the natural health products industry within Canada and around the world.

1 *This practice should only be used by acknowledging its creation by Saskatchewan Herb and Spice Association/National Herb and Spice Coalition.*

2. BACKGROUND

Examples of misidentification, adulteration, and contamination of natural health products have been widely recorded both within Canada and around the world (see Appendix viii. for case studies and discussion of this issue). Although the health impacts of these failures in due diligence or deliberate misrepresentation are sometimes benign, these failures have also had tragic consequences. Beyond the serious health risks to consumers, the impact on industry credibility of cases of misrepresentation that reach the press has been negative as well. Consumers are obviously concerned when information appears in the media suggesting that natural health products are ineffective, or worse, that they may present a risk to human health.

As the industry has developed and demand has grown in the industrialised countries, consumer awareness of these products and the issues associated with them has also grown. Concerns over safety, efficacy, purity, and product origins (i.e., country, cultivated or wild harvested) have become front and centre in the public consciousness surrounding these products. Within these various issues, questions of botanical identity are a key feature. Accurate plant identification is the foundation of the safe use of plant-based natural health products. Without proper identification as a starting point, the safe use of quality products cannot be guaranteed.

There is a recognition within industry and government that there is a need to protect access and choice by consumers when it comes to natural health products. At the same time, consumers have a right to expect that these products can be used with confidence regarding their safety and quality. Workable plant identification practices that will be widely adopted by producers and collectors will make a contribution towards the safe use of these products and ultimately, to public confidence in the industry.

2.1 Objectives

The objectives of the project “Good Practices for Plant Identification for the Herbal Industry” is to develop effective, practical tools for industry members to accurately identify medicinal herbs. The practice will also establish the groundwork for effective traceability of raw materials starting at the production level.

The target audience for this methodology is first and foremost the producers and wild harvesters of medicinal herbs. Numerous commentators on the industry stress that the production end of the value chain for medicinal herbs provides the best potential for addressing the challenge of accurate plant identification. Tadmor *et al.*(2002) stress that “… authentication of the plant identity at the grower/supplier end is unquestionably the most effective means of promoting quality, accuracy, and consistency of the botanical

products". However, this recognition must be contrasted with the lack of progress in the area. As McCutcheon (2002) points out,

> Since 1974, the WHO has asserted that the single greatest improvement in botanical quality would be the implementation of a program for the certification of botanical identity…. The fact that after more than 25 years, such a system has not yet been developed even though the technical requirements are minimal is indicative of the challenges involved.

At the same time, McCutcheon notes that the trend towards the establishment of organic certification procedures and guidelines, and Good Agricultural Practices (GAP) for medicinal plants (World Health organization, 2003) suggests that the time may be right for the development of a certification model(s) for plant identification.

The Natural Health Products regulations that went into effect on January 1, 2004, will create additional pressure on the production end of the value chain (growers and collectors of wild product) to meet the demands of the processors/manufacturers for safe and traceable products. If followed, a practical plant identification practice for growers and collectors will play an important role in ensuring producers have on-going – and hopefully improved – access to the markets for their products.

The secondary audience for the plant identification practice are manufacturers of herbal medicine products. Manufacturers will obviously benefit greatly from access to a supply of reliably identified raw material for use in production. Manufacturers also have an important role in both rewarding and demanding accurate plant identification from their suppliers. This 'push-pull' effect has the potential to create more widespread use of proper identification practice for herbs. The stakes are obviously high for manufacturers. Not only are the potential benefits of proper identification significant, but manufacturers may also stand to lose the most (in terms of liability and loss of potential future sales) from misidentification leading to product contamination.

Development of the plant identification practice is a part of a larger initiative to build a HACCP (Hazard Analysis Critical Control Point) based Good Agriculture Practice model for the herb and spice industry in Canada. The HACCP model identifies issues that must be addressed to ensure product safety, but stops short of developing the actual practices used to address these issues. The plant identification practice developed in this project will be incorporated into and form a key part of the HACCP Production Manual for on farm food safety being produced for the Herb and Spice industry.

2.2 The Process

Consultants from the Centre for Non-Timber Resources at Royal Roads University were contracted to facilitate the development of the plant identification practice. Development of the practice was largely based on two main activities:

- a review of the literature, both published and unpublished, related to the topic of plant identification for the medicinal herbs industry. This review included examining any existing protocols for plant identification; and

- expert consultations with representatives of the industry, government, associations, and educational institutions, drawn from both Canada and the United States. The Plant Identification Working Group convened two workshops and a number of conference calls where the plant identification practice described in this document (and the references and other supporting materials discussed) was developed and edited.

Literature Review

A number of documents were reviewed to survey existing approaches to plant identification relevant to the herbal industry. The key documents identified are summarized in a comparison table following this section. In summary, limited materials were located with information specific to plant identification. Overwhelmingly, the material located that was not included in this table stressed the importance of plant identification in the production of safe and effective herbal medicines, but provided no indication of how this proper identification might occur. A detailed discussion of the literature review is provided below.

Expert consultations

Two face-to-face expert consultations were held with national and international (United States) representatives from the industry, interested associations, the research and educational sector, and government (see Appendix vi. for a listing of participants) including the WHO from Geneva. The first meeting was held in Vancouver on January 31 – February 1, and due to the tight deadlines for the project, the second meeting was held two weeks later in Guelph (February 16). The time between the meetings was used to revise the draft identification process created during the Vancouver meeting. A number of teleconferences were also held to seek input into drafts of the plant identification verification process. In both meetings the draft identification practice was ‘workshopped’ to ensure clarity and accuracy of the results. The results of these efforts will be described below and are contained in the Recommended Practices for Plant Identification which appear later in the document.

2.3 Scope of the plant identification practise

The recommended practice for plant identification is focused strictly on the establishment of a practical, effective model for proper plant identification. It does not cover sustainable or ethical harvesting practices (except as ethics relate to providing the proper plant material to buyers), nor does it address toxicity issues or Good Manufacturing Practices as they relate to activities further up the value chain. If properly followed, these practices should, however, preclude misidentification of materials at the producer level. If misidentification is suspected higher up the chain, the use of unique lot or shipment numbers prescribed in this practice will allow for the traceability of the questionable material back to the supplier.

Given that no independent certification body for the identification of herbal plant material currently exists, the practice as it stands now is strictly voluntary and to a large degree based on the honour system. The practice also may not prevent deliberate adulteration of products further up the value chain. What the practice will do when properly followed is provide a higher degree of confidence to raw material buyers that the plant material they are purchasing has been accurately identified. The requirement to sign off on the certificate of authenticity should preclude deliberate attempts at deception to a large degree, though, as always, much depends on the buyer's knowledge of the supplier. Putting a signature on the paper may also encourage a higher degree of diligence on the part of suppliers of material, knowing that an incorrect identification could be tied to them in the future. Taking the time to properly identify and sign off the certificate should also provide some additional piece of mind to suppliers. A supplier who felt wrongly accused of providing the wrong material, will under this practice have the ability to return to a sample of the shipment for confirmation of identity.

3. TOWARDS THE PRACTICE OF PLANT IDENTIFICATION

The task of the working group on plant identification practice was to create a practical, accurate, and effective tool for the identification of herbal materials. To the knowledge of the working group assembled to draft the practice, and based on the information that could be located on this topic in the time available, no similar practice is known to exist for the herbal industry.

3.1 Plant Identification in the Literature

As suggested, although the literature is replete with references to the *need* for plant identification for the industry, little was found that addressed this process in any detail. Among the literature located that did address the question of identification (and is summarized in the comparison table in this section), considerable overlap was found, likely because of the extensive cross-referencing on the topic. In these materials, a variety of common themes emerged that are used in the organization of the comparison tables. Among the key recurring themes are:

- **Personnel and education**
  The documents stress the need for growers and collectors to have the education, training and/or experience necessary to properly identify the plant materials they are producing; there is also recognition that there is a shortage of personnel trained in the more technical procedures used for plant identification (i.e., organoleptic techniques) once these products have undergone some initial processing and have moved higher up the value chain.

- **Propagation material**
  The sources that discuss propagation material in relation to plant identification state that botanical identity must be verified; the WHO document also calls for the name of the supplier of the material to be recorded.

- **Harvest/collection/acquisition of material from third party**
  Material should be verified at harvest/collection/acquisition, being careful to watch for contamination with non-target species. If more than one identification method is used, the results should be consistent before assuming accurate identification has taken place.

- **Primary processing**
  The WHO document recommends re-confirmation of identity prior to any processing, given the additional challenges involved in identifying material post-

processing. The Europam GAP and GWP documents also stresses that one person should take responsibility for verification as the product moves through the primary processing step. The Health Canada GMP document states that identification numbers must be in place at this stage, and that labels should be carefully stored to avoid any potential for misidentification of material.

- **Packaging**
  Controls must be in place to avoid contamination with foreign material; labelling must be clear and contain the scientific name of the plant.

- **Storage and transport**
  Care must be taken in storage to prevent the mix-up of material; the lot/batch/shipment should be identified with a unique number.

- **Documentation**
  All batches/lots/shipments should have a number assigned to them early in the process that remains with them as they move through the value chain; a sample should be kept of each lot of a finished product, and a voucher specimen created; the name of the person identifying the material should be recorded; photographic images should be taken of the material; good records should be maintained for a sufficient period (up to 5 years).

3.2 Building the Practice: The Plant Identification Working Group

The results of the literature review were provided to the plant identification working group and the development of the practice proceeded from there. Not all of the themes identified in the literature were necessarily strictly within the confines of our activities (which were determined to be restricted to the raw material harvesting/collecting stage). However, to meet the recommendations contained in the various documents required establishing proper practices at the production stage of the chain. For example, a common theme running through many of the recommendations is to assign a number to each lot to ensure traceability of the material through the chain. In our practice, an identification number is assigned to each lot at the retention sample and certificate of authenticity stage. In general, the practice developed in this project meets or exceeds any of the recommendations found in the existing protocols for plant identification located to date.

Another key area of concern for the working group was that the process should enable widespread participation by those involved in the industry now, as well as those who may enter the industry in the future. Because of this, the group recognized that many producers without a formal education still have extensive knowledge of the plant materials they work with (in some cases, beyond the capabilities of more formally trained experts). Therefore, the group recognized that the identification process can be pursued by anyone with the experience, education, or training to reliably identify plant materials.

3.3 The Need for Industry Education

One of the key lessons originating from the process of developing the practice is the need for effective education on plant identification at all levels of the value chain. Many of the growers and collectors of medicinal herbs have extensive knowledge of the plants they are harvesting and need no assistance with accurate plant identification. Others would benefit from short workshops in basic methods for plant identification using reference guides containing binomial keys. Experiences from the wild crafting industry demonstrate that although a person lives surrounded by forest, it does not mean they can identify (or even recognize) many of the plants found there. Education in plant identification techniques, as well as in learning to recognize when they CANNOT accurately identify a plant, would provide significant benefits, especially for new collectors.

To assist with the widespread application of the identification practice described in this document, workshops on plant identification could be combined with the ‘how to’ of using the practice. Participants could be walked through the process, with examples of completing forms, examples of specific species and what to look for, creating voucher specimens and retention samples, etc. Local resources to assist with plant identification (both books and experts) would also be discussed. Workshops for manufacturers, processors, brokers, etc. could also be provided to encourage broader adoption of the program on behalf of raw material suppliers. As a voluntary program, it will be its acceptance and use within the industry that leads to wider acceptability and effectiveness.

3.4 COMPARISON TABLE OF LITERATURE RELATED TO PLANT IDENTIFICATION

These systems are only compared to each other with the focus on plant identification issues. Naturally there are more criteria that are similar or differ, but no attention has been paid to them in this table.

Organisation / Criteria	Europam		EMEA	Health Canada
	GAP	GWP		
The environment	> enhance biodiversity on farms (1.2)	> avoid damage of plants > apply "collection rotation" > consider CITES		
Personnel and education	> adequate education (2.1)	> appropriate education (2.2)	> adequate botanical training (4.6) > collectors must have sufficient knowledge on plant id (4.7) > local supervisor to guarantee education, supervision, documentation (4.8) > all collectors should be instructed on all environmental issues (4.9)	> adequate education and/ or experience (Sec. 47/1) > personnel have the knowledge, and proof of that knowledge, in the form of a diploma, certificate or degree from a recognized Canadian or international institution (3.1.1) > Provide training in good manufacturing practices (3.1.2)
Seeds and propagation material	> all material must be botanically identified (3.1) > all impurities must be eliminated immediately along the whole production process (3.3)		>all material must be botanically identified (8.1) > all impurities must be eliminated immediately along the whole production process (8.2)	

Harvest/ Collection/ receive material from third party	> when plant delivers best quality (5.1) > best conditions (5.2) > watch out for toxic weeds (5.5) > eliminate damaged plants (5.6) > clean containers (5.7) > one person in charge to verify all steps (5.12)	> right time (3.1) > best conditions (3.2) > watch out for toxic weeds (3.4) > clean containers, tools (3.5) > one person in charge to verify all steps (3.10)	> identify supervisor who verifies material (10.1) > no collection of endangered species (10.3) > harvest at best quality (11.1) > exclude damaged plants/ or part of plants from crop (11.2) > watch out for toxic weed (11.6) > clean containers (11.7)	> verify all incoming/ received material/ assess compliances (Sec.44/2) > Periodically evaluate complete confirmatory testing of at least one lot per material type per supplier per year (Sec.44/3) > Confirm that all test methods (e.g. chemical, microscopic, organoleptic) provide accurate and consistent results (Sec.44/4)
Primary processing	> eliminate foreign matters (6.9) > one person in charge to verify all steps (6.12)	> inspect all material (4.9) > one person in charge to verify all steps (4.12)		> control numbers for batches (Sec.49,50/12,13) > effective measures to prevent and identify foreign matters (Sec.49,50/17,18) > securely store labels to prevent mix- ups (Sec.49,50/20,22)
Packaging	> repeated control for foreign matters (7.1) > follow European and national labelling regulations (7.3)	> repeated control for foreign matters (5.1) > follow European and national labelling regulations (5.3)		
Storage and transport				> ensure effective control to prevent mix- up of material (Sec. 45) > set up written procedure of transportation (Sec. 49, 50) > identify lots with numbers (Sec. 49,50)

Documentation	> keep field records (10.1) > early assignment of batch number (10.4) > keep batch processing records (10.5 and 10.6) > mix of material only when perfectly similar (10.8) > material on the way with a way bill (10.11)	> collect general data (8.1) > early assignment of batch number (8.2) > keep batch processing records (8.4) > mix of material only under perfect similar conditions (8.6) > material on the way with a way bill (8.9)	> all processes must be documented (7.1) > document location of cultivation (7.3) > early assignment of batch number (7.7) > only mix homogenous material, and document that (7.8)	> Retain a sample of each lot of a finished product (Sec.61/1) > Ensure that samples are of sufficient size to permit complete testing according to specifications (Sec 61/4) > maintain records of any testing conducted (Sec.53/c,d) >
Education	> organisation should educate their personnel (11.1)	> organisation should educate their personnel (9.1)		
Quality Assurance				> Manufacturers, packagers, labellers, importers and distributors must have quality assurance person (Sec. 51/1) > to establish written proof on testing, inspections > to approve test methods and results (3) > to approve all (incoming) plant identifications along the production (4) > to ensure complete batch records (5) > specifications for raw and/or packaging materials must include plant id (Sec.44/1) > Set up and follow written procedures that describe tests to be conducted to ensure the identity (Sec.44/10)
Self inspection				> Establish written procedures that define controls to ensure the effective recall of a product (Sec.49,50/27)

Organisation / Criteria	Quality Control and Product Standards, Draft	WHO	GMPs for traditional Chinese medicinal materials	Good Agricultural and Collection practices for medicinal plants, Japan
Personnel and education	> lack of training for personnel to be qualified for microscopic and organoleptic identification of plants	> growers and producers should have adequate training and knowledge of the medicinal plant > training should be conducted regularly	> Persons in charge of quality contol should have at least two years of higher education training and experience in quality control	> training for all personnel handling or managing crops by experts from local agricultural institute or buyers is highly recommended
Seeds and propagation material		> identity verified and recorded (incl. common, English and botanical names) > provide the name of cultivar and supplier > organic material needs to be certified > avoid adulterations	> species, subspecies and variety or type should be accurately identified	
Harvest/ Collection/ receive material from third party		> harvest at the right time > avoid adulterations with foreign matters > if harvested from the wild, set up a collection management plan which includes species id etc. > use photographs or other illustrated material to harvest from the field > use botanical keys and other taxonomic information to identify species that are similar to the target plant and grow close to it > newly introduced species should be identified and documented as the source material used an described in traditional medicine	> efforts should be made to remove and avoid foreign matters during harvest and primary processing	> all containers used for harvesting must be kept clean from previous plant material

Primary processing		> prior to primary processing, a visual and organoleptic inspection for cross contamination and right identification should be conducted		
Packaging	> adulteration with inexpensive material may happen to increase weight or the sale of exhausted botanicals	> continues quality control prior to packaging to avoid foreign material > clear label incl. scientific name	> Inspection is necessary before packaging to avoid substandard products and foreign objects	> all foreign material must be removed
Storage and transport		> keep containers clean of foreign material		
General quality insurance	> there are numerous bioassays in routine use in academic and pharmaceutical labs that could be adapted to botanicals to identify species and/ or ingredients of finished products > apply organoleptic practises for identification			
Documentation		> collectors should prepare a botanical specimen for submission to herbaria for authenticication > keep voucher specimen for sufficient period of time > record the name of person who identified the specimen > if the plant is not well known to the community, the botanical identification should be recorded and maintained > keep record of batch packaging > keep and produce as many photographic images as possible	> Keep record of batch packaging, including product name, specifications, etc > before packaging a quality identification should be made and approved by the authorities > inspection records should be kept on file > all documents should be kept on file for at least 5 years	> keeping records of each batch of harvested material is highly desirable

Referred documents:

Europam Good Agricultural practices, 24 November 2003, http://www.europam.net/Working%20documents.htm

Europam Good Wild crafting Practices, 24 November 2003, http://www.europam.net/Working%20documents.htm

EMEA "Points to consider on good agricultural and collection practices for starting materials of herbal origin", 2 May 2002, http://www.emea.eu.int/pdfs/human/hmpwp/003199en.pdf

Health Canada Natural Health Products Regulations, Part 3 – Good manufacturing Practices, valid from 1 January 2004, http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/gmp_e.html

McCutcheon, A., 2002. Quality Control and Product Standards: an exploration of current issues in botanical quality, draft

WHO, 2004, WHO Guidelines for Good Manufacturing and Collection Practises (GACP) for medicinal plants, http://www.who.int/medicines/library/trm/medicinalplants/agricultural.pdf

Good manufacturing Practises for Traditional Chinese Medicine Materials, Peoples Republic of China

Good Agricultural and Collection Practises for Medicinal Plants, Japan

4. RECOMMENDED PRACTICES FOR PLANT IDENTIFICATION

Establishment, growth and harvest stages

For plants under cultivation[1]:

1. IF the producer has utilised authenticated or certified seeds, transplants, seedlings, cuttings, etc.

- retain documentation of authenticity
- once crop is grown, conduct visual inspection pre-, during, and post-harvest to re-confirm correct identity
- if produced from seed, retain seed sample for each authenticated seed source and crop (see Appendix i. for seed storage methods).
- retain representative voucher sample of plant at harvest and reproductive stage for each authenticated seed, transplant, seedling, etc. source and crop (see Appendix ii. for voucher sample collection methods and storage).

Go to (4).

2. IF NOT utilising authenticated or certified seed, transplants, seedlings, etc. vouch for identity and uniformity of crop

2.1 IF grower qualified by experience, education, and/or training, conduct a visual inspection looking for plants outside the acceptable range of variation for the crop

[1] 'Under cultivation' refers to plants being cultivated in a field or forest setting.

2.1.1 IF the crop conforms to the acceptable range of variation:

2.1.1.1 IF familiar crop for grower, or if grower holds knowledge of plant/species

Go to (4).

2.1.1.2 IF NOT familiar, or if new crop, confirm identity by comparison with an identification guide (see Appendix iii.) through visual inspection pre-, during, and post-harvest, and/or confirm sample with individual with experience, education, and/or training (e.g. other grower, buyer, educator, etc.).

Go to (4).

2.2 IF NOT qualified through experience, education, and/or training to conduct a visual inspection on site:

2.2.1 IF possible have an individual with experience, education, and/or training perform an on-site inspection to confirm the uniformity and identity of the crop

Go to (4).

2.2.2 IF NOT possible to access resource person with experience, education and/or training, collect representative sample (see Appendix i. for methods/ requirements) and send to a qualified person

Go to (4).

For wild harvested plants:

1. IF the harvester is qualified through experience, education, and/or training to reliably identity the plant/species, confirm species against a reference (see Appendix v.).

Go to (4).

2. IF NOT competent through experience, education, and/or training to identify species, confirm identity of sample with individual with experience, education, and/or training (e.g. other harvester, buyer, educator, etc.).

Go to (4).

For BOTH plants under cultivation and wild harvested:

3. IF crop does **NOT** conform, take appropriate remedial action to salvage or discard.

3.1. If salvaged, create and retain a salvage plan consisting of the practices that will be followed to remove unwanted material from a crop and render it homogeneous within acceptable limits.

4. Collect voucher sample(s)[2] of each crop/species harvested, retain for minimum of 3 years (see Appendix ii. for voucher sample collection methods and storage).

[2] To assist with identification, recommended practice is to collect a voucher specimen at the reproductive stage of the plant. Creating a photographic record of the cultivation or collection site and of the plant material is also recommended.

Raw Material stage

For BOTH plants under cultivation and wild harvested:

5. IF steps have been followed for identification at establishment, growth, and harvest stages, no further verification required.

Go to (8).

6. IF reliable identification has **NOT** been achieved at establishment, growth, and harvest stages, utilise appropriate analytical methods (i.e., organoleptic, micromorphology, or chemical tests as applicable) to confirm identity of the raw material.

Go to (8).

7. IF raw material **cannot** be reliably identified, take appropriate remedial action to salvage or discard.

7.1. If salvaged, create and retain a salvage plan consisting of the practices that will be followed to remove unwanted material from the raw material and render it homogeneous within acceptable limits.

8. Collect a retention sample of positively identified material for each shipment, batch, or lot and label appropriately; samples should be retained for a minimum of three years (see Appendix i. for retention sample collection methods and storage, and an example of a retention label).

9. IF verification steps complete to step (8), complete and sign certificate of authenticity (see Appendix iv. for certificate of authenticity example). Certificate of authenticity can **ONLY** be completed if identity is reliably established.

APPENDICES

i. Retention sample form and seed storage methods
   a. Example of label for retention sample
ii. How to collect plants for a voucher specimen
iii. Testing techniques
iv. Certificate of authenticity
v. Glossary
vi. Working group members
vii. References
viii. Cases of herbal product contamination
   a. By Rob McCaleb
   b. By Allison McCutcheon

APPENDIX I. RETENTION SAMPLE FORM AND SEED STORAGE METHODS

Collecting a Retention Sample

A retention sample is a representative sample of a lot, batch, or shipment of a herb that is retained by the supplier when the lot, batch, or shipment is sold up the supply chain. Should questions arise at a future date regarding the identity or quality of the material shipped, the seller and buyer can use the retention sample to resolve questions about the material. Maintaining a retention sample for properly identified material provides an important back-up resource for suppliers when dealing with questions from buyers. Suppliers with properly catalogued retention samples (with the same identification number as the lot/batch/ shipment from which it has been retained) will be able to quickly address any suggestions that the 'wrong' material was supplied.

A retention sample must be representative of the material shipped if it is to provide an accurate snapshot of the shipment. Samples must be taken only after the lot or batch has been made up or mixed together. If it is removed prior to mixing, there is the risk that only a portion of the shipment will be sampled – for example, the material provided by an individual wildcrafter – which may not provide a good representation of the larger shipment. Once the material is combined and ready to be shipped, a small portion (at least a handful) should be removed from the shipment. If multiple bags are being shipped, it is recommended that a small portion is extracted from each bag and then mixed together as the sample.

Retention samples should be stored away from heat and direct sunlight and protected from insects. Samples should be retained for a period of at least three years.

Storing Seed Samples

As with the retention sample and the voucher specimen, keeping a representative sample of the seed you use for sowing your crop will assist in answering any questions about crop identity that may arise pre- or post-harvest. Provided the sample is stored properly, seed will remain viable for a number of years and can therefore be grown out to confirm the identity of the plant should some discrepancies between the identity of the seed and the resulting crop occur.

Storage temperature, relative humidity, and seed moisture are all important factors in determining how long seed can be stored without a significant decline in viability. The storage life of seed also varies greatly between species.

In general, longer seed life in storage is obtained when seeds are kept dry and at low temperatures. Dry seed should be placed in packages and stored in moisture-proof containers. Containers such as sealed cans or jars with air-tight caps work satisfactorily. Storage temperatures between 1°C and 10°C are satisfactory when the moisture content of the seed is low, especially if seeds only need to be maintained in a viable condition for 3-5 years. If space is available in your freezer, the seeds of many species can be stored for extremely long periods at freezing temperatures.

How much seed should you save? The simple answer is ‘enough to ensure a sample of viable seed can be maintained for that specific seed source and crop’. Seed size varies tremendously between species. More than the bulk of the seed, it may be more appropriate to consider how much seed (under proper storage after three years) would be required to successfully grow a small plot of the species in question.

APPENDIX IA. EXAMPLE OF LABEL FOR RETENTION SAMPLE

Scientific name[3]: _____

Common name(s): _____

Seed source (if applicable): _____

Harvest location: _____

Harvest date: _____

Batch/lot/shipment #:_____

Grower/Harvester (Name & company/organisation if applicable):_____

Grower/Harvester I/D #:_____

Date of sampling: _____

[3] Recommended Reference "Herbs of Commerce 2nd edition", American Herbal Products Association, ISBN 0967871905

APPENDIX II. HOW TO COLLECT PLANTS FOR A VOUCHER SPECIMEN

1. Equipment List

Not all of this equipment will be needed at any one time.

1.1 The bare minimum:

- **a field press (as described below)**
- **knife**
- **permanent marker**
- **pencils**
- **field notebook (as described below)**
- **a plastic bag to keep things dry if it rains (garbage size and smaller)**.

1.2 Other equipment that may prove useful:

- A global positioning system (GPS) instrument if mapping of the resources is intended
- pruning shears
- trowel
- hand lens
- camera
- map and/or aerial photographs to locate the sampling area
- whistle (to call for help or signal a partner)
- flagging tape for marking routes or collection sites
- tape measure
- high-visibility clothing (especially during hunting season!)
- tape recorder to make verbal notes (especially useful in bad weather when it is hard to write)
- folding shovel if deep roots must be collected
- pole pruner for collecting tree branch samples
- portable drier
- string tags (to quickly label specimens by number so they do not get mixed up in the collection bag).

2. Plant Press Materials

Field press: a corrugated cardboard box (bottom approximately 45 cm x 30 cm is best), cut so sides fold nicely over bottom, newspaper sheets cut to size, rope to close it.

Drying press: 2 plywood or lattice boards (45 cm x 30 cm), 2 webbing belts or ropes with slip-knots, corrugated cardboard sheets, sponge (carpet underfelt), blotter sheets, newspaper; plants will be sandwiched between newspaper, blotters, and then cardboard sheets.

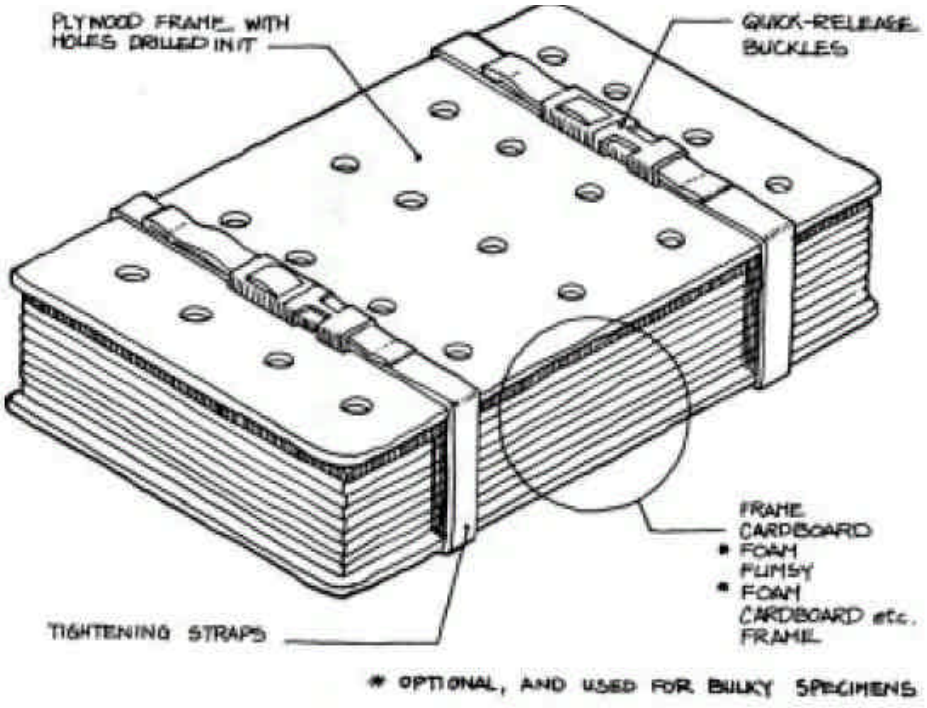

Figure 1: A plant press showing arrangement of parts

3. The Plants

3.1 When to Collect

Dry, sunny weather is best in terms of getting plants dried easily, but if that is not possible, a drier of some sort is recommended. The faster the plants are dried, the better they will look, especially in terms of colour and lack of mould, although care must be taken not to overheat the press. Press plants as soon as possible after collection; using a field press will provide better specimens than if they are collected in plastic bags and pressed later.

3.2 What to Collect

For herbaceous plants always collect at least part of the root system, stems, leaves, and, if possible, the flowers and/or fruit, and seeds. For woody plants collect a small stem and/or a piece of the bark (in addition to leaves, flowering and/or fruiting structures). Large fruit or succulent stems may be split or cut into pieces for drying or placed in separate folded paper (e.g. cones) if too large and juicy to be pressed. Note that some plants, e.g. willows, have separate sexes, both of which must be collected with flowers to identify them with certainty.

3.3 Pressing Plants

Clean all soil from roots (rinse off mud, then brush when dry). Arrange your plant specimen on the newspaper carefully, so that it looks as natural as possible, without too many parts overlapping each other (this will slow the drying process and look ugly). Prune if necessary. Arrange tall plants by folding the stem like an upside-down V, N or M. Turn at least one leaf upside down so the undersurface can be seen when pressed. Leave room for a 7 cm x 18 cm label at the lower right hand corner. Sandwich herbs between two blotters and then two cardboard sheets. For thicker specimens use a sponge sheet in place of one of the blotters to press around the thick stem or root and still flatten the leaves. When the “sandwiches” of collected herbs are ready to press, stack them and place the stack between the two plywood or lattice boards. Tighten the belts around the press by standing on the press as you pull on the ends of the belts. Further tightening will be necessary later as the specimens dry and shrink. Drying can be done at room temperature or over a couple of heat lamps, but take care not to overheat the press which would discolour the plants.

4. The herbarium

4.1 Sheets

Arrange the plants carefully with a minimum of overlap on the herbarium page (acid-free mounting paper). Attach the specimen to the mounting paper with thin ribbons of glue running from the paper across the plant part to the paper. The glue should not cover any parts necessary for identification, for example, the nodes and ligules of grass.

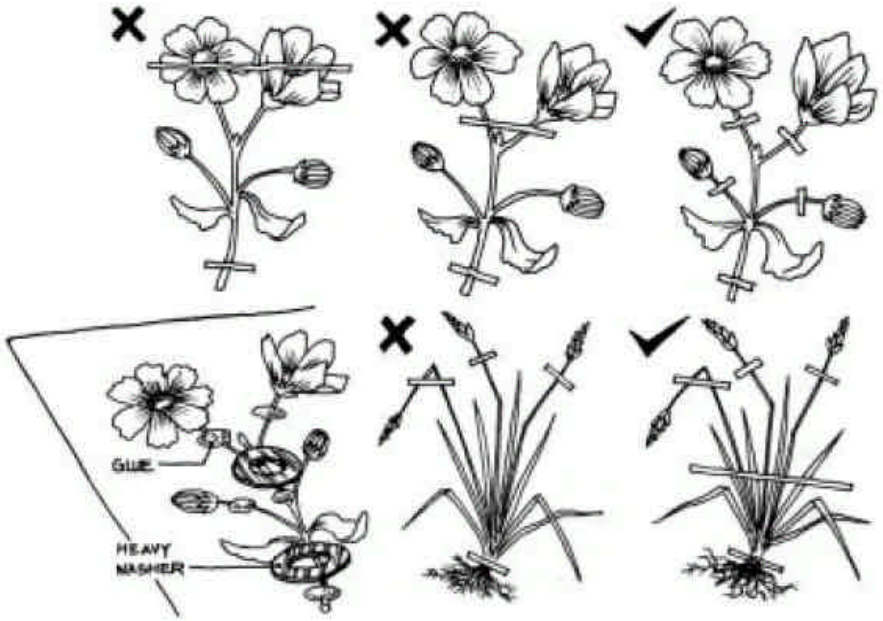

Figure 2: Placement of glue or linen straps across mounted specimens

Glue the label to the bottom right corner of the herbarium sheet.

4.2 Voucher specimen label

Labels for the dry specimens can be prepared before the plants are identified, recording information known at that time. The genus/species and identifier can be added in later. Using a standardized label ensures that all necessary data are transcribed from the field book to the label accurately and efficiently.

Example for a label

Scientific Name: _____

Common Name: _____

Location/ Habitat: _____

_____

Collector: _____

Collection Date: _____ **and No:** _____

Identified by: _____

A picture is worth a thousand words either as a photo or a sketch, although not a replacement for good field notes. If a picture is taken it is a good idea to note the roll number and exposure number.

Always number your specimens consecutively! It doesn't matter if you collect the same species a hundred times on different occasions, each collection should have a separate number. Only multiple specimens of the same plant collected at the same time and place can share a single collection number.

Last but not least
Store the herbarium pages in a dry and dark place (it may be a good idea to store them together with the retention samples of the product being shipped). To avoid insect damage, the herbarium pages may be frozen at -20°C for 48 hours and checked on regularly. For every plant you are collecting, prepare a new voucher specimen every 5 years.

Adopted from Marles, R. 2003 *How to collect plants*, draft
and
BC Ministry of Forestry, 1996, *Techniques and Procedures for Collecting, Preserving, Processing and Storing Botanical Specimens*, Forestry Division Service Branch

APPENDIX III. TESTING TECHNIQUES

A sufficient number of tests should be performed on representative samples as necessary to establish ingredient identity. Although the focus here is on tests that establish identity, the unique properties of the material are also considered in selecting tests.

Testing techniques include:

1. **Macroscopic/Organoleptic:** The unaided senses of sight, smell or taste. Included here, however, would be use of a hand lens with 4-20x magnification for visual identification. These methods are typically used for an herb or botanical ingredient in whole or uncut form.

    a. Analysis is based on attributes such as:

    (1) Defined morphological and/or anatomical characteristics of the whole plant or individual plant parts (e.g., leaf, flower, fruit, seed, root and rhizome, bark) and
    (2) Characteristic color, fracture, smell, or taste.

    b. Identification is achieved by positive comparison of morphological characteristics with authenticated or in-house plant reference material or an authoritative technical reference description or test that can assure the identity of the botanical ingredient.

    c. Herbs and plant parts that have been cut or ground to the point where morphological characteristics are no longer observable to the unaided eye are best analyzed by microscopic and/or chemical means.

    d. Observations:

    (1) It is possible that processing variables may promote some difference in taste or colors of herbal raw materials, thus confounding proper and positive identification by macroscopic or organoleptic techniques.
    (2) It is possible that reliance on taxonomic or botanical characters including macroscopic, anatomical, and organoleptic characteristics alone may not confirm identity and may not detect adulterants unless the tests are sufficiently precise to distinguish the species from those that it can be confused with in the area that the botanical was collected.
    (3) The harvest of plants for use as dietary ingredients often does not coincide with the plant's flowering season. All of the distinguishing morphological characteristics of the plant are not present at such times. While this is not always a significant obstacle to identification, a manufacturer should use good judgment in determining whether this technique can effectively identify plant material at such times without an

identity test that has been proven to distinguish the desired species from know and potential adulterants where the botanical is collected.
(4) In the case of plants harvested from wild populations, it is possible that material from different locations and different collectors may be mixed prior to identification by the representative specimen. The integrity of such methodology is suspect in such situations unless the training of collectors and shipping of the material is sufficient to assure the proper identity of all the material and that sampling protocols are designed to detect the adulteration of heterogeneous lots of material.

2. **Microscopic analysis:** Use of higher magnification (than provided by a hand lens) and special light or staining techniques to examine powdered or chopped representative sample material. Analysis is based on observation of specific microscopic characteristics that have been established for the specific dietary supplement ingredient. This analysis also is used to identify some adulterants.

   a. Identification is based on microscopic observation of cell and tissue structures of plants and animals such as:

   (1) Defined histological characteristics of plant parts (e.g. stems, roots and rhizomes, bark, leaves, flowers, seeds, wood);
   (2) Defined histological characteristics of animal tissues and cells; and
   (3) Defined staining or microscopic chemical reactions.

   b. Identification is achieved by use of a validated method, comparison of a representative sample from the commercial batch with authenticated or in-house working plant reference material, or authoritative technical descriptions of established microscopic characteristic(s).

   c. Observation:

   (1) While microscopy can be used in the identification of ingredients, additional quality or purity data (e.g., contamination by mould, insect, rodent hair, microbe, heavy metal, and economic substitution) can also be obtained from microscopy and
   (2) It is possible that finely powdered material may obliterate microscopic characteristics. In this case, other tests such as chemical assays should be employed.

3. **Chemical analysis:** chromatography: Techniques that are based on the differential affinities of substances for a gas or liquid mobile medium and a stationary adsorbing medium. Analysis is based on observational comparison of a test pattern and a reference chromatogram for the dietary supplement ingredient of interest.

Adapted from:
U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition, 1999 *Ingredient Identity Testing Records and Retention*, Draft
http://vm.cfsan.fda.gov/~dms/facgmp.html, 29.02.04

APPENDIX IV. CERTIFICATE OF AUTHENTICITY

Certificate of Authenticity

SCIENTIFIC NAME: (GENUS) _____

(SPECIES) _____

Common name: _____

Cultivated (including woods grown) **Wildcrafted**

SEED SOURCE (IF APPLICABLE): _____

PLANT PART:

Fruit/Seed: •
Inflorescence: •
Whole Plant: •
Aerial: **Leaves** • **Stems** • **Both** •
Bark: **Aerial bark** • **Root bark** •
Root: •

Country & Province/State of Origin: _____

Date of Harvest: _____

Stage of plant development at time of Harvest:

Pre-bloom • **In bloom** • **Post bloom** • **Dormant** •

Batch/Lot/Shipment ID #: _____

Grower/Harvester ID #: _____

Certification: I certify that this plant material is correctly identified as described, following the Recommended Practices for Verification of Plant Identification.

Name (Please print) _____ **Date (M/D/Y)** _____

Signature _____

APPENDIX V. GLOSSARY

Assess. Steps taken by the site licence holder to ensure that the requirements in the Food and Drugs Act, the Natural Health Products Regulations and in-house standards are met. The steps could include, among others, monitoring and testing of raw and/or packaging materials, tracking of production, maintenance of records and testing of finished products.

Batch. (or lot) Material that is intended to have uniform composition, character, and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

Batch number. A distinctive combination of numbers and/or letters that specifically identifies a batch, and appears on documents such as the batch record and certificate of analysis.

Batch record. Production document that captures the quantity and lot number of all Materials used, as well as production steps in the manufacturing of a single batch of a natural health product in dosage form.

Biomarker. A distinctive biological or biologically derived indicator (as a biochemical metabolite in the body) of a process, event or condition (as aging or exposure to a toxic substance).

Bulk natural health product. Unpackaged dosage form, usually in quantities larger than the largest commercially available package size.

Bulk preparation. Unpackaged homeopathic preparation, usually in quantities larger than the largest commercially available package size.

Certificate. A legally authenticated written declaration issued by a recognized institution to a person completing a course of study.

Certificate of Analysis. A document signed by a qualified person with information including, but not restricted to, the product name, ingredient listing, lot number of the product, test or identification conducted, test method and results, conclusion of the test (satisfactory or unsatisfactory), name and position of the person performing the assessment, and date of issuance.

Certificate of Manufacture. A document issued by a vendor to a distributor or importer that attests that a specific lot of product has been produced according to its master production document. Such certificates include a summary of the current batch documentation, with reference to respective dates of revision, manufacture and packaging, and are signed and dated by the vendor's authorized quality assurance person**.**

Certified. A formal statement declaring something to be true; holding appropriate documentation and officially on record as qualified to perform a specified function or practice a specified skill

Comminution. The act of reducing to a fine powder or to small particles.

Common Name. For any medicinal or non-medicinal ingredient contained in a natural health product, the name by which it is commonly known and is designated in a scientific or technical reference.

Constituent. A component part i.e. a single chemical isolated from a whole herb.

Container. The blister pack, bottle, cover, sachet, strip pack, tube, vessel, vial, wrapper or other similar article that covers the natural health product.

Critical process. A process that may cause significant variation in the quality of the Finished product.

Cultivated. Botanical plants that are produced (grown or tended) as a crop.

DIN (drug identification number). A numerical code assigned to each drug product marketed under or in accordance with the Food and Drugs Act and Food and Drug Regulations.

Diploma. A document issued by an educational institution, such as a university, college, or technical institute, vouching that the recipient has earned a degree or successfully completed a particular course of study.

Distributor. A person who sells a natural health product to another person for the purpose of further sale by that other person.

Dosage form. The final physical form of the natural health product which may be used by the consumer without requiring any further manufacturing.

Education. The act or process of imparting or acquiring knowledge or skills; the learning of information by instruction, training, or study can be testified to by a degree, certificate or diploma.

Experience: Active participation in events or activities leading to the acquirement of knowledge or skills; the knowledge or skills retained from personally observing, encountering, or undergoing something.

Extract. A substance prepared by treating a plant or a plant material, an alga, a bacterium, a fungus, or non-human animal material with solvents to remove any constituents.

Family. In biology a group of related genera.

Filling. Transferring and enclosing a bulk product into its final container.

Finished product. A product that has undergone all stages of production, including packaging in its final container and labelling.

Formulating. Preparing components and combining raw materials into a bulk natural health product.

Fungus. A member of the biological kingdom Fungi, consisting mostly of complex multicellular eukaryotes with a cell wall, usually composed primarily of chitin. Fungi are heterotrophs that absorb nutrients from their surroundings after decomposing organic material. They reproduce by unicellular spores produced sexually and/or asexually.

Genus. (Genera, pl.) A group of closely related species.

Good manufacturing practices. Measures to ensure an overall effective approach to product quality control and risk management. They apply to places, people, processes and products with respect to which activities are being conducted.

Hazard Analysis and Critical Control Points (HACCP). An internationally recognized system of food safety methods. It is a systematic approach to the identification, evaluation, and control of food safety hazards that can be applied to other production systems.

Health Canada inspection report. A written inspection report prepared by an inspector from Health Canada, using either the drug or natural health product good manufacturing practices as the basis for the site assessment.

Health claim. This is a synonym of a “Recommended Use or Purpose” found within the definition for “Recommended conditions of use”.

Herbarium. A reference collection of pressed, dried (preserved) botanical specimens.

Immediate Container. Means the container that is in direct contact with a natural health product.

Import. To bring a product into a country for the purpose of sale.

Importer. A person who imports a product for the purpose of sale.

Ingredient. A single substance that is a component part of any combination or mixture. for example, vitamin C is a common ingredient in a multi-vitamin product. (see also 'product')

In-process control. Checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the finished product conforms to its specifications. The control of the production environment or equipment may also be regarded as a part of in-process control.

In-process product. Any materials or mixture of materials that must, to become a product in dosage form, undergo further processing.

In-process testing. The examination or testing of any materials or mixture of materials during the manufacturing process.

ISO (International Organization for Standardization). A world wide organization of national standards bodies; ISO is a non-governmental organization that maintains a group of global standards.

Isolate. A purified constituent of a defined molecular structure obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material.

Key. In botany, a plant identification tool; a series of steps where the presence or absence of characteristics eliminates possible choices.

Label (noun). Includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. Natural health products are included.

Label (verb). To affix the inner or outer label of the natural health product.

Licensee. A person who is issued a licence.

Lichen. A plant formed by the permanent symbiotic relationship of a fungus with photosynthetic algae or cynobacteria cells; these cells are interwoven with filaments of the fungus to form a plant body.

Lot. A quantity of any natural health product in dosage form, a raw material or a packaging material, homogeneous within specified limits, constituting all or part of a single batch and identified by a distinctive lot number which appears on the label of the finished product.

Lot number. Any combination of letters, figures or both, by which any natural health product can be traced in manufacture and identified in distribution.

Maceration. Processing method using unheated solvent (cold or room temperature water, alcohol, or other organic solvent) to extract medicinal properties from a raw material.

Manufacturer. A person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of the patient, compounds a natural health product for the purpose of sale to that patient.

Manufacture. To fabricate or process a product for the purpose of sale.

Manufacturing order. Instructions that outline in detail the materials and procedures required to manufacture, prepare and preserve a single batch of a natural health product in dosage form.

Margin of Safety. The difference between the minimal therapeutic dose and the minimal toxic dose of a therapeutic substance.

Marker compound: a constituent that occurs naturally in the material and that is selected for special attention (e.g. for identification or standardization purposes) by a researcher or manufacturer. Marker compounds are not necessarily pharmacologically active.

Master formula. A document or set of documents specifying the raw materials with their quantities and the packaging materials, together with a detailed description of the procedures and precautions required to produce a specified quantity of a finished product.

Master production document. A document that includes specifications (raw material, packaging material, packaged dosage form), master formula, sampling procedures and critical processing related standard operating procedures, whether or not these procedures are specifically referenced in the master formula. It also includes a complete list of raw materials used in the manufacture of the product, designated by names or codes; the amount of each raw material required for the theoretical product formulation; manufacturing and process control instructions and in-process testing requirements (e.g. checks on materials, pre-treatments, sequence of adding materials, mixing time and temperatures); a statement of the principal equipment to be used; a statement of the theoretical weight or measure of the manufactured product and the acceptable limits beyond which an investigation is required; a description of the finished product containers, closures and packaging labels; any special precautions to be observed; and dates and times (if applicable) of commencement and completion of significant intermediate stages, such as blending or heating, and of completion of production.

Medicinal Ingredient. Any substance set out in Schedule 1 of the Natural Health Products Regulations that is intended to furnish pharmacological activity or other direct effect in: (a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; or
(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.

Mother tincture. A relatively concentrated aqueous alcoholic extract from which subsequent attenuations are prepared. Synonyms: mother liquor, stock solution, starting solution.

Natural health product. A substance set out in Schedule 1 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.
However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. (*produit de sant* é *naturel*) (nhpd regs)

Nodes. The point of attachments of leaves to stem.

NPN/DIN-HM: Natural Product Number is an eight (8) digit numerical code assigned to each natural health product approved to be marketed under the Natural Health Products Regulations. DIN-HM is an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the Natural Health Products Regulations.

Observation. A deviation or deficiency of good manufacturing practice noted by an inspector or assessor.

Organic. 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.

Organoleptic. The effect or impression produced by any substance on the organs of touch, taste, or smell, and also on the organism as a whole; in testing the use of these senses to identify specific materials.

Outer Label. The label on or affixed to the outside of a package of a natural health product.

Package (noun). Includes anything in which any natural health product is wholly or partly contained, placed or packed.

Package (verb). To put a product in its immediate container.

Packaging material. Labels, printed packaging materials and those components in direct contact with the dosage form.

Packaging order. Instructions that outline in detail the materials and special procedures required to package and label a single lot of a product in dosage form.

Percolation. A method used for the extraction of dried substances that have been reduced to the proper degree of fineness.

Plant. In this document, 'plant' is considered to not only include flowering plants, but also algae, lichens, mosses, and fungi; a living organism lacking the power of locomotion

Principal Display Panel. The principal display panel is that part of the inner or outer label applied to all or part of the principal display surface of the container that is displayed or visible under normal or customary conditions of sale or use.

Processing deficiency notice. A notice issued by the processing unit to request missing information or clarification.

Product. A substance or combination of substances manufactured or refined for sale. (see also 'ingredient')

Production. All operations involved in the preparation of a finished product, from receipt of materials, through processing and packaging, to completion of the finished product, including storage.

Propagule. Any structure capable of giving rise to a new plant by asexual or sexual reproduction, including cuttings, seeds, leaf buds, etc.

Proper name. In respect of an ingredient of a natural health product, one of the following:

(a) if the ingredient is a vitamin, the name for that vitamin set out in item 3 of Schedule 1;

(b) if the ingredient is a plant or a plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet; and

(c) if the ingredient is other than one described in paragraphs (a) or (b), the chemical name of the ingredient.

Purity. The extent to which a raw material or a product in dosage form is free from undesirable or adulterating chemical, biological or physical entities as defined by specification.

Qualification. To make competent or eligible for an office, position, or task by having the proper or necessary skills, knowledge, credentials, accomplishments or qualities.

Quality assurance. All the planned and systematic activities applied within the quality system to provide adequate confidence that the predetermined standards for quality and safety will be met.

Quality assurance person. The person who is responsible for assuring the quality of the natural health product before it is made available for sale. This person should be qualified by education, training and/or experience relating to the specific activity (i.e manufacturing, packaging, labelling and importing).

Quality assurance report. A report prepared by either a quality assurance person or a third party auditor who meets the requirements with respect to education, training, and experience according to section 51(a) (ii) of the *Natural Health Products Regulations*. This report is based on the assessment against the good manufacturing practices regulations and requirements set out in the good manufacturing practices guidance document. It is considered a self-assessment document and evidence of good manufacturing practices compliance.

Quarantine. Effective restriction of the availability of material or product for use (physically or by system), until released by the quality assurance person.

Raw material. Any substance, other than in-process product or packaging material, intended to be used in the manufacture of products, including those that appear in the master formula but that do not appear in the product such as solvents and processing aids.

Recognized building. In respect of the fabrication, packaging/labelling or testing of a natural health product, a building that a regulatory authority that is designated under subsection(1) in respect of that activity for that natural health product has recognized as meeting its good manufacturing practices standards in respect of that activity for that natural health product.

Recognized institution. A Canadian or international educational facility (e.g. a university, college or professional or post-secondary institute) generally approved of or having a secure reputation; credible, reputable, and authoritative.

Recommended conditions of use. With regard to a natural health product:

- its recommended use or purpose;
- its dosage form;
- its recommended route of administration;
- its recommended dose;
- its recommended duration of use, if any; and
- its risk information, including any cautions, warnings, contra-indications or known adverse reactions associated with its use.

Reconciliation. A comparison, making due allowance for normal variation, between the amount of product or materials theoretically produced or used and the amount actually produced or used.

Reprocessing. Subjecting all or part of a batch or lot of an in-process product or finished product to a previous step or alternate manufacturing process due to failure to meet predetermined specifications.

Retention sample. A representative sample of each lot/batch/shipment that is held back by the supplier to allow for future confirmation of identity, quality, etc.; the retention sample will have the same identification number as the lot/batch/shipment from which it has been retained.

Returned product. Bulk or finished product sent back to the manufacturer, distributor or importer.

Salvage. To remove unwanted material (i.e., contaminants such as weeds, dirt, and other material other than the target crop or product) from a given batch or lot of product.; the act of saving goods or property that were in danger of damage or destruction

Sampling. Collection of a number of units that comprises a representative sample from a designated lot or batch of product.

Sell. Includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

Site. A place of or for a activity specified under the Regulations.

Site licence applicant. An individual with legal responsibility for the site of manufacturing, packaging, labelling or importation of a natural health product to be sold in Canada.

Site licence number. A number issued by Health Canada's Natural Health Products Directorate based on the requirements set out in the Natural Health Products Regulations as proof of authorization to conduct specified activities at the listed locations.

Species. The narrowest taxonomic grouping; a group of closely related animals or plants that are capable of interbreeding.

Spent herb. Means the botanical material remaining after the extraction process is complete.

Standardization: The application of product knowledge, good agricultural or wildcrafting practices, and good manufacturing practices to minimize inherent variations in the composition of natural substances in order to ensure consistent product quality from one batch to the next.

Standard operating procedures. An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g. equipment operation, maintenance and cleaning, cleaning of premises and environmental control, sampling and inspection). Certain standard operating procedures may be used to supplement product-specific master production documents.

Standards of Evidence. Clearly defined criteria used by regulators to evaluate the safety, quality and effectiveness of a claim regarding a health product or food. The criteria define the amount and type of data required to support the safety of a product and all health claims that are associated with it. Although Standards of Evidence may differ from one type of product to another, they are consistent within a similar category of products.

Sterile dosage form. A dosage form that is free from microbial contamination.

Sterile Product. It is a product that is free from viable microorganisms.

Third-party auditor. An auditor who is independent of the company he or she is auditing and who is qualified by education, training, and experience to conduct a natural health product good manufacturing practices site audit.

Traditional medicine. The sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, 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.

Training, Education. Training, education means attainment of knowledge, skills, and abilities pertinent to the position held. It is permissible to gain knowledge, skills, and abilities through relevant academic studies, trade association seminars and workshops, and on-the-job activities in addition to continuing education through relevant courses, seminars, or workshops.

Voucher Specimen. A representative specimen preserved to permit independent verification of identity and to allow further examination (e.g. pressed plants, non-human animal material in preserving fluids).

(Adapted from "*Good Manufacturing Practises Guidance Document*", 2003, Health Canada, and "*Techniques and Procedures for Collecting, Preserving, Processing, and Storing Botanical Specimens"*, 1996, BC Ministry of Forests)

APPENDIX VI. WORKING GROUP MEMBERS

Connie Kehler, Executive Director, Saskatchewan Herb and Spice Association/National Herb and Spice Coalition

Dave Buck, Manager, Non-Timber Forest Products, Northern Forest Diversification Centre (Manitoba)

Rob McCaleb, President, Herb Research Foundation (Colorado)

Wanda Wolf, Lonewolf Native Plant and Herb Farm (Saskatchewan)

Allison McCutcheon, President, Natural Health Product Research Society of Canada

Edward Fletcher, American Herbal Products Association (North Carolina)

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Robin Marles, Director of Research and Science, Natural Health Products Directorate, Health Products and Food Branch, Health Canada

Donna Fleury, Business Development Specialist, Business Development Branch, Alberta Agriculture Centre

Bev Gray, Herbalist, Aroma Borealis (Yukon)

Ross Wadell, Native Plant Society of British Columbia

Michelle Hull, Wildcrafter (Ontario)

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USDA Plants National Database:

http://plants.usda.gov/

Missouri Botanical Garden's w^{3}TROPICOS:

http://mobot.mobot.org/W3T/Search/vast.html

International Organization for Plant Information:

http://www.bgbm.fu-berlin.de/IOPI/GPC/query.asp

International Plant Name Index Query:

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Internet Directory for Botany:

http://www.botany.net/IDB/botany.html

Index Nominum Genericorum:

http://rathbun.si.edu/botany/ing/

Index to Organism Names:

http://www.biosis.org.uk/triton/indexfm.htm

International Code of Botanical Nomenclature

http://www.bgbm.fu-berlin.de/iapt/nomenclature/code/SaintLouis/0000St.Luistitle.htm

CABI – Index Fungorum:

http://www.indexfungorum.org/Names/Names.asp

Committee on the Status of Endangered Wildlife in Canada (COSEWIC):

http://www.cosewic.gc.ca/index.htm

Canadian Botanical Conservation Network

http://www.rbg.ca/cbcn/en/index.html

Native Plant Society of British Columbia

http://www.npsbc.org/

APPENDIX VII. CASES OF HERBAL PRODUCT CONTAMINATION

Case Study: *Scutellaria* and *Teucrium*

By Rob McCaleb, February 2004

In the late 1970s and 1980s, reports began appearing of liver damage from products containing North American skullcap, *Scutellaria lateriflora*. The first case involved a woman who had taken a combination product believed to contain mistletoe, motherwort, kelp, wild lettuce, and American skullcap. After taking the formula for several weeks, she developed a nausea, malaise, and a dull pain in the upper right abdomen, which was attributed to liver inflammation (hepatitis) with mistletoe as the suspected toxin. (Harvey and Colin-Jones, 1981). However, this view was challenged by others because European mistletoe is not hepatotoxic (Fletcher Hyde, 1981; Farnsworth and Loub, 1981). The mistletoe component was later reported to be absent from the herbal product in question (McIntyre, 1984).

Another report described four women with hepatitis or jaundice after the use of herbal tablets containing skullcap. Liver biopsies revealed acute hepatitis in two of the patients, and their liver function returned to normal 2 to 3 months after discontinuing the herbs. A liver biopsy was unsuccessful in the third patient, but liver function returned to normal in 19 months. The fourth patient showed jaundice after ingesting approximately 30 tablets over a 3-week period. A liver biopsy revealed chronic aggressive hepatitis with advanced fibrosis.. Investigators suggested that, of several ingredients common to the products taken, American skullcap (*S. lateriflora*) and valerian were the most likely offenders, even though there were no reports to show that these ingredients can actually produce liver damage (MacGregor *et al.,* 1989).

Weight loss, jaundice, and hepatomegaly with elevated liver function tests were seen in a 56-year-old Australian woman. Liver biopsy demonstrated a chronic active hepatitis of unclear origin. The patient had taken three different herbal remedies in addition to her conventional medicines. The first herbal preparation reportedly contained mistletoe, the second one celery fruit, guaiacum, burdock root and sarsaparilla, and the third one valerian, skullcap (*S. lateriflora*), and passionflower. After stopping all medications with the exception of thyroxine, the patient improved and was discharged after 2 weeks (Weeks, 1989).

Norwegian workers have reported additional case reports of liver damage, even with fatal consequences. Some patients had been taking several herbal remedies, including skullcap (*S. lateriflora*), whereas others had used an herbal remedy in which skullcap was the only ingredient (Leander and Skogstrom, 1991; Moum *et al.,* 1992).

Herbal experts have pointed out that *S. lateriflora* may have been mistakenly identified as being hepatotoxic. *S. lateriflora* is known to have been adulterated with various species of *Teucrium*, some of which may be hepatotoxic. Tyler notes that

germander (*Teucrium* spp.) was found in the skullcap products taken by people who experienced liver damage (Tyler and Foster, 1999). The adulteration of *S. lateriflora* is also documented by DeSmet.[4]

> DeSmet cites an "...increasing number of case reports to suggest that the ingestion of skullcap-containing preparations can induce hepatotoxic reactions." Yet in an appended clarification, he acknowledges the adulteration of skullcap with species of *Teucrium*. This adulteration, along with recent reports of hepatitis associated with *Teucrium* consumption, lead De Smet to conclude that it is "...unclear at the moment, whether the hepatotoxic effects that have been associated with preparations containing skullcap should be attributed to *Scutellaria*, *Teucrium*, or both."

Due to the prevalence of this adulteration with the North American specie, the Association of Official Analytical Chemists (AOAC) has published a method for detecting the presence of this compound (Gafner et al. 2003).[5]

No known hepatotoxicity has been confirmed for *S. lateriflora*, and the North American species of *Teucrium* (primarily *T.* canadensis) have also not been shown to be liver-toxic. It is speculated that European herbal product companies began substituting European *Teucrium* species for skullcap, including *T. chamaedrys* which contains hepatotoxic pyrrolizidine alkaloids and has been investigated for hepatoxicity including fatalities.[6]

The above information is included to clarify a potential point of confusion. Despite the existence of these few reports of “skullcap” hepatotoxicity, these episodes were probably caused by substitution with hepatotoxic *Teucrium* species.

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Botanical Identity

By Allison McCutcheon, 2002

When adverse event reports (AERs) from herbal products are rigorously investigated, it is invariably found that the AER was not due to the intended herb, but rather due to the presence of an unintended or undeclared substance – most commonly a toxic botanical.[7] The occurrence of toxic plants may be classified as substitutions, contamination or adulteration.

Contamination with other botanicals

The term contamination is generally used to describe the accidental inclusion of undeclared substances. There have been numerous cases of contamination with toxic botanicals of which the following are just a few examples:

- *Rauwolfia serpentina* and *Mandrogora officinarium* (toxic alkaloids) in Ginseng.[8]
- Seeds of Poison hemlock in anise seed
- Burdock root contaminated with *Atropa belladonna*.[9] [10]
- Two Canadians poisoned by Comfrey tea contaminated with *Atropa belladonna.*[11]
- Belladonna has also been reported as a contaminant of Mallow, Nettles and Mate.[12]
- Plantain contaminated with *Digitalis lanata* (Foxglove), disseminated to over 150 companies over two years before ADRs prompted a FDA investigation.[13]

Some toxic botanical contaminants that are reported to be commonly found[14]in industry include: *Atropa belladonna, Conium maculatum, Digitalis lanata, Illicium anisatum, Symphytum* x *uplandicum*.

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Herb research & scientific publications

Unfortunately, the scientific literature is also fraught with reports based upon misidentified or unidentified "herbal" products. The most common mistake made by health professionals and scientists new to the field of phytomedicine research is the failure to adequately identify and characterize the herbal material being used.

For example, much of the *Echinacea angustifolia* research published prior to 1989 must now be considered suspect for two reasons. Chemotaxonomic research provided irrefutable evidence that at least some of the "angustifolia" material under study must have been a common substitute for Echinacea, *Parthenium integrifolium*.[15] Secondly, taxonomic studies revealed that most of the genuine Echinacea material supplied was in fact *E. pallida* not *E. angustifolia*.[16] In North America, investigations have revealed there is wide-spread contamination of commercial *E. angustifolia* crops with non-medicinal species.

Undeserved reputations for toxicity have dogged a number of herbs because the correct identity and plant part were not indicated or properly established in the original report. Unfortunately, authors continue to cite these erroneous reports and so perpetuate the misinformation. Some of these cases are summarized below.[17]

Herbs Incorrectly Blamed for Toxic Effects

Burdock	(*Arctium lappa*)
Borage	(*Borago officinalis*)
Chamomile	(*Matricaria recutita*)
Eleuthero	(*Eleutherococcus senticosus*)
Ginseng	(*Panax ginseng*)
Magnolia	(*Magnolia officinalis*)
Mallow	(*Malva sylvestris*)
Mate	(*Ilex paraguariensis*)
Nettle	(*Urtica dioica*)
Stephania	(*Stephania tetrandra*)
Skullcap	(*Scutellaria lateriflora*)
Valerian	(*Valeriana officinalis*)

[15] Bauer R, Khan I, and Wagner H. Echinacea nachweis einer verfalschung von *Echinacea purpurea* (L.) Moench mit *Parthenium integrifolium*. Deutsche Apotheker Zeitung 1987; 127: 1325-1330.

[16] Bauer R. The Echinacea Story – The scientific development of an herbal immunostimulant. In Prendergst HDV, Etkin NL, Harris DR, Houghton PJ (Eds.) Plants for Food and Medicine. Proceedings of the Joint Conference of the Society of Economic Botany, July 1-6, 1996. Pp. 317-332. Kew: Royal Botanic Gardens; 1998.

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