AHPA develops guidance policies to advance our Mission to promote responsible commerce in herbal supplements. These policies address a variety of labeling and manufacturing issues and reflect the consensus of AHPA's members and its Board of Trustees. Unlike AHPA's trade recommendations, compliance with AHPA's guidance policies is not a condition of membership. Nevertheless, AHPA encourages its members and non-member companies to adopt each of these policies in the interest of establishing consistent and informed trade practices.

AHPA Guidance Policies

Guidance on Heavy Metals (adopted October 2008; revised July 2012)

Dietary supplement manufacturers determine what, if any, tests or examinations are appropriate for their products, whether to meet specifications established for these products or for other purposes.

With respect to herbal supplements, there are a variety of heavy metals for which companies may consider implementing tests or examinations, if appropriate. This guidance discusses some of the more commonly used ones. Not all of these, however, are applicable to every herbal supplement, and others not included here may be relevant for some such products.

Where manufacturers choose to establish one or heavy metal specifications for herbal supplements, AHPA provides the following as guidance on maximum quantitative limits:

- for inorganic arsenic; 10 mcg/day;
- for cadmium; 4.1 mcg/day;
- for lead: 6 mcg/day;
- for methyl mercury: 2.0 mcg/day.

For purposes of this guidance the following definition applies:

- "Herbal supplement" means a dietary supplement, as described in 21 U.S.C. 321 (ff), that contains one or more herbal ingredients (i.e., an herb or other botanical, or a concentrate, extract, or combination of an herb or other botanical). An herbal supplement may or may not contain additional non-herbal dietary ingredients (e.g., vitamins, minerals, amino acids, etc.) or excipients.

In addition, for purposes of this guidance the following limitations and conditions apply:

- This guidance is not intended to suggest that manufacturers should establish specifications for any or all of the identified heavy metals in any specific herbal supplement, but is rather intended to provide guidance for limits in the event any such specifications are set. This guidance is not, in fact, applicable for some herbal supplements. In addition, it may not be relevant to test any specific herbal supplement to determine the level of any or all of the heavy metals identified in this guidance.
- The above quantitative limits are determined at the highest labeled dose of a supplement, and are applicable only to herbal supplements that are consumed in a total daily amount of 5 grams or less.
- A product in compliance with this guidance may require a warning in order to comply with California Proposition 65's listing of these chemicals. http://www.ahpa.org/Default.aspx?tabid=214 Click this link for information on Proposition 65.

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Guidance on Microbiology & Mycotoxins (adopted June 2003; last revised July 2012)

Food ingredient suppliers, dietary ingredient suppliers, and dietary supplement manufactures determine what, if any, tests or examinations are appropriate for their ingredients and products, whether to meet specifications established for these ingredients and products or for other purposes.

With respect to herbal ingredients and supplements, there are a variety of microbiological characteristics and mycotoxins for which companies may consider implementing tests or examinations, if appropriate. This guidance discusses some of the more commonly used ones. Not all of these, however, are applicable to every herbal ingredient and supplement, and others not included here may be relevant for some herbal ingredients or supplements.

Where manufacturers choose to establish one or more microbiological and/or mycotoxin specifications for herbal ingredients or dietary supplements identified in this guidance, AHPA provides the following as guidance on maximum quantitative limits:

(a) (i) for dried, unprocessed herbs for use as ingredients in dietary supplements, and (ii) for herbal supplements in solid form consisting of dried, unprocessed herbs:

- Total aerobic plate count: 10^7 colony forming units/gram
- Total yeasts and molds: 10^5 colony forming units/gram
- Total coliforms: 10^4 colony forming units/gram
- *Salmonella* spp.: not detected in 25 grams
- *Escherichia coli*: not detected in 10 grams
- Total aflatoxins ($B_1 + B_2 + G_1 + G_2$): 20 µg/kg (ppb)
- Aflatoxin B_1: 5 µg/kg (ppb)

and (b) (i) for powdered extracts and for soft extracts, and (ii) for herbal supplements in solid form consisting of powdered extracts or soft extracts:

- Total aerobic plate count: 10^4 colony forming units/gram
- Total yeasts and molds: 10^3 colony forming units/gram
- Total coliforms: 10^2 colony forming units/gram
- *Salmonella* spp.: not detected in 25 grams
- *Escherichia coli*: not detected in 10 grams
- Total aflatoxins ($B_1 + B_2 + G_1 + G_2$): 20 µg/kg (ppb)
- Aflatoxin B_1: 5 µg/kg (ppb)

For purposes of this guidance the following definitions apply:

- "Dried unprocessed herb" *means* an herb or other botanical that is dehydrated from its fresh state and that has not been subjected to any further processing other than cleaning, grading, or size reduction (e.g., cutting or powdering).

- "Dietary supplement" *has the same meaning as* described in 21 U.S.C. 321 (ff). For purposes of this guidance a dietary supplement is a product in finished form ready for consumer use.
- "Herbal supplement" *means* a dietary supplement, as described in 21 U.S.C. 321 (ff), that contains one or more herbal ingredients (i.e., an herb or other botanical, or a concentrate, extract, or combination of an herb or other botanical). An herbal supplement may or may not contain additional non-herbal dietary ingredients (e.g., vitamins, minerals, amino acids, etc.) or excipients.
- "Botanical extract" *means* the complex, multi-component mixture obtained after using a solvent to dissolve components of an herbal or other botanical biomass. Botanical extracts may be in dry, liquid or semi-solid form. Excipients may be added to botanical extracts for various technical purposes (e.g., to adjust concentration; enhance stability; limit microbial growth; or improve drying, flow or other manufacturing characteristics). Botanical extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents (though it should be noted that some chemical modifications might occur as the natural consequence of the extraction process).
- "Powdered extract" means a botanical extract that has been dried into a powder.
- "Soft (a.k.a. pilular, semi-solid, or solid) extract" means a botanical extract having a consistency of a thick liquid or paste.

In addition, for purposes of this guidance the following limitations and conditions apply:

- This guidance is not intended to suggest that manufacturers should establish specifications for any or all of the identified microbiological characteristics or mycotoxins in any specific herbal ingredient or supplement, but is rather intended to provide guidance for limits in the event any such specifications are set. This guidance is not, in fact, applicable for some herbal ingredients and supplements. In addition, it may not be relevant to test any specific herbal ingredient or supplement to determine the level of any or all of the microbiological characteristics or mycotoxins identified in this guidance.
- In determining whether *Salmonella* spp. and *E. coli* are not detected, the sample size may vary depending on the method used.
- Depending on the analytical methods used to detect *Salmonella* spp. or *E. coli*, failure to detect a microorganism may be reported as "absent," "not detected," "negative," or "less than" the detection limit.
- For dried, unprocessed herbs for use as ingredients in dietary supplements, the above quantitative limits may be exceeded in either of the following circumstances:
  - When, due to naturally occurring conditions, an individual herb requires higher limits on total aerobic plate count, total yeasts and molds, and/or total coliforms.
  - When acceptable techniques, such as steam sterilization, will be employed in subsequent processing to eliminate pathogens. However, such treatment is not acceptable if the untreated materials are spoiled prior to such treatment.
- For herbal products in solid form, the above quantitative limits do not apply to products where boiling water is added before use, and may not apply to products containing other dietary ingredients (such as vitamins and minerals) and excipients.

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Standardized Information on Dietary Ingredients (SIDI) (adopted July 2007)

AHPA recommends that its members who buy and sell dietary ingredients use the Standardized Information on Dietary Ingredients (SIDI) protocol as a standard reporting form for providing information about these ingredients. http://www.sidiworkgroup.com/ Follow this link for more information on SIDI and to be taken to the SIDI website.

Ingredients that are or are produced from genetically modified organisms (GMOs) (adopted June 2003; revised July 2007)

WHEREAS, the use of genetically modified organisms (GMO)[1] as a tool in agriculture is viewed by its proponents as providing the potential to meet basic global food needs and deliver a wide range of health, environmental and economic benefits;
WHEREAS, concerns have been expressed about the potential impact of agricultural use of GMO on the environment and health, such that the European Union requires labeling of novel foods or foods containing ingredients as "no longer equivalent to an existing food or food ingredient" and has proposed additional laws regarding labeling of foods that are derived from GMO crops;
WHEREAS, AHPA supports positions that are based on scientific reasoning and also supports positions that favor a sustainable approach to environmental issues and a responsible approach to health issues related to commerce in herbs and herbal products;
WHEREAS, AHPA supports consumers' right to be informed on issues that affect their purchasing decisions;
THEREFORE, BE IT RESOLVED THAT AHPA encourages companies that grow, process, manufacture, market or sell herbal products to refrain from using herbal raw agricultural products that are cultivated with GMO technologies, or extracts and natural flavors thereof,[2] at least until such time as the above identified concerns have been suitably addressed;
BE IT FURTHER RESOLVED THAT AHPA supports labeling of consumer goods to identify any ingredients that are herbal raw agricultural products knowingly and intentionally cultivated with GMO technologies, or extracts and natural flavors thereof, in a manner that assures that consumers are informed that the ingredient was cultivated with GMO technology;
EXCEPT THAT nothing in this policy is meant to comment on research regarding GMO technology; and that nothing in this policy is meant to comment on minimal and/or unintentional mixing of GMO and non-GMO crops; and that this resolution does not create an obligation for any AHPA member.

1) GMO is used here as it is a commonly recognized term that refers to genetically modified materials (also known as genetically engineered). Genetically modified is defined as: Made with techniques that alter the molecular or cell biology of an organism by means that are not possible under natural conditions or processes. Genetic modification includes but is not limited to recombinant DNA, cell fusion, micro-and macro-encapsulation, gene deletion and doubling, introducing a foreign gene and changing the position of genes. The term as used here does not include breeding, conjugation, fermentation, hybridization, in-vitro fertilization and tissue culture. Definition adapted from the International Federation of Organic Agriculture Movements (IFOAM) http://www.ifoam.org/press/positions/geposition.html, accessed March 15, 2007. FDA has developed a Draft Industry Guidance that includes comments for use of the term GMO (Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, http://www.cfsan.fda.gov/~dms/biolabgu.html, accessed on March 19, 2007).
2) This is inclusive of extracts made from GMO herbal raw materials and excipients, fillers, carriers, etc. used to make, or that are present in, extracts. "Natural flavor" ingredients are those composed of the essential oils, oleoresins or natural extractives of herbs and spices, and various undisclosed excipients, which could include corn or soy-based carriers (e.g. maltodextrin or lecithin).

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Known Adulterants (adopted July 1997; revised July 2012)

AHPA recommends that appropriate steps be taken to assure that the raw materials in the following table are free of the noted adulterant. This list identifies herbs and potential adulterants that are known at this time to have been encountered in trade. Additional information may be added if further such instances are observed. Marketers of products that contain herbal ingredients are responsible for assuring accurate identification of all ingredients. Contact AHPA for additional information regarding relevant analytical methods or follow this link (http://www.ahpa.org/Default.aspx?tabid=242) for more information from the AHPA website – also found under the Technical Guidance/Scientific Affairs/Adulteration Information menu.

Article of Trade	Adulterant
Eleuthero root (*Eleutherococcus senticosus*)	*Periploca sepium* root
Plantain leaf (*Plantago lanceolata*	*Digitalis lanata* leaf
Skullcap herb (*Scutellaria lateriflora*)	Germander herb (*Teucrium chamaedrys*)
Stephania root (*Stephania tetrandra*)[a]	*Aristolochia fangchi* root (*guang fang ji*)
Asian species of *Cocculus*, *Diploclisia*, *Menispermum* and *Sinomenium* root	*Aristolochia fangchi* root (*guang fang ji*)
Asian species of *Akebia* and *Clematis* stem	*Aristolochia manshuriensis* stem (*guan mu tong*)
Costus root (*Saussurea costus*[b])	*Aristolochia debilis* root (*qing mu xiang*)
Vladimiria souliei root	*Aristolochia debilis* root (*qing mu xiang*)
Black cohosh root/rhizome(*Actaea racemosa*[c])	Chinese cimicifuga root/rhizome[d] (*Actaea* spp.)
Ginkgo (*Ginkgo biloba*) leaf extract standardized to flavonol glycosides and terpenes	Ginkgo (*Ginkgo biloba*) leaf extract with added flavonol glycosides or aglycones (e.g., rutin, quercetin, etc.)
Bilberry fruit extract	Red dye #2 (amaranth dye)
Hoodia gordonii aerial parts powder	Various powders, possibly including *Opuntia* spp. and other Hoodia species
(Chinese) star anise (*Illicium verum*) fruit	Japanese star anise (*Illicium anisatum*) fruit
Grapefruit Seed extract	Benzalkonium chloride, benzethonium chloride, triclosan, methyl paraben, or any other synthetic antimicrobial agent

a. For a complete list of species that FDA has identified as potentially adulterated with *Aristolochia* spp. see http://www.cfsan.fda.gov/~dms/ds-bot2.html.
b. Synonym = *Saussurea lappa*
c. Synonym = *Cimicifuga racemosa*
d. Also known as *sheng ma* or Rhizoma Cimicifugae; consists of *Actaea cimicifuga*, syn. *Cimicifuga foetida*; *Actaea dahurica*, syn. *C. dahurica*; *A. heracleifolia*, syn. *C. heracleifolia*; and possibly other Asian species of *Actaea*.

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Disclosure of herb use to healthcare providers (adopted October 2001)

AHPA recommends that consumers of herbal supplements inform their healthcare provider(s) of such use. In the interest of seeing this recommendation broadly accepted by consumers, AHPA encourages healthcare providers to receive such communication with respect for the consumers' healthcare choices. In addition, AHPA encourages healthcare providers to seek out accurate and truthful information about herbs.

Product Labeling for St. John's Wort (*Hypericum perforatum*) (adopted July 2000)

AHPA recommends the following or similar language appear on the label of products containing St. John's wort:

> *Notice: Do not use this product while taking any prescription drug(s) without the advice of your prescribing physician. Avoid excessive exposure to UV irradiation (e.g., sunlight; tanning) when using this product.*

Retail Labeling of Dietary Supplements Containing Soft or Powdered Botanical Extracts (adopted July 2000)

AHPA recommends the following labeling standards:

- **Standardized statement of quantity.** For soft or powdered botanical extracts listed in the Supplement Facts box (as defined by 21 CFR §101.36) the quantity stated shall correspond to the total amount of that extract included in the product (i.e., the quantity shall include carriers and other excipients.[1]) If they so choose, AHPA members may also disclose the percent of native extract for each extract listed in the Supplement Facts Box.[2]
- **Extract ratios.** Listing of the extract ratio of a soft or powdered botanical extract is not a mandatory labeling requirement for retail products. There are differing opinions concerning the value of listing extract ratios on the retail label. However, where such ratios are stated, they shall conform to the following convention[2]: The first number shall represent the amount of dried botanical starting material, the second number shall represent the amount of finished total extract. For example, a 4:1 extract is one in which each kilogram (or other unit) of finished total extract represents the extractives from four kilograms (or other unit) of dried botanical starting material.[3] Where fresh rather than dried starting material is used in determining the ratio, this fact must be disclosed.
- **Statement of manufacturing ranges.** For soft or powdered extracts where the percent native extract or the concentration ratio varies from lot to lot of extract, this variation may be expressed on the label in either of the following forms:
- **The range.** The range of percent of native extract or of concentration ratios described in the extract manufacturer's product specification may be stated on the retail label. Any range specified by the extract manufacturer must correspond to the actual variability that occurs from batch to batch of extract. Where the percent native extract range or ratio is listed on the label, it shall be stated in the form "x–y% native" (e.g., "40–50% native") or "x–y:1" (e.g., "4–5:1)
- **The average.** The average of the range described in the extract manufacturer's product specification may be stated on the retail label, so long as (a) The range does not vary by more than ± 20% from the stated average; and (b) The fact that the labeled value represents the average of a range is disclosed on the label. If the range varies by more than 20% from the average, the average may not be stated on the label; rather, the entire range must be disclosed.

Where an average value is listed on the label, it shall be in the form "average % native" or "average x:1." Where desired, the word "average" may be abbreviated to "av." or "avg."

1) Carriers and other excipients are required to be listed in the ingredients statement in accordance with §101.4(g).
2) It is not meant to imply that the items discussed (i.e., listing of percent native extract and the extract ratio) are the optimal or proper way to describe the extract on the retail label.
3) Any appropriate unit may be used, so long as the amounts of starting plant material and finished extract are expressed in the same unit of measure.

"Guidance for the Retail Labeling of Dietary Supplements Containing Soft or Powdered Botanical Extracts" is also available from the AHPA Bookstore, as part of AHPA's *Guidance Documents for the Manufacture and Sale of Botanical Extracts.*

Guidance on Extract Labeling[1] (adopted March 2010)

Any non-liquid herbal extract that discloses a quantitative extraction ratio stated as a ratio of two numbers represents the first number as the weight of starting plant material and the second number as the weight of the finished extract produced from the starting plant material, and that information on the condition of the starting material should be indicated when it is fresh and may be indicated when it is dried*.

*Herbal extracts in liquid form are required by federal regulation, whether or not a concentration ratio is declared, to disclose the condition of the starting material when it is in a fresh state (21 CFR 101.36 (b)(3)(ii)(B)

[1]See additional information on AHPA's Trade Requirement for extract labeling in AHPA's Code Of Ethics

Guidance on Residual Solvents in Extracts (adopted October 2010, revised July 2011)

AHPA recommends that herbal extracts marketed in the U.S. limit any contained residual solvents to the levels established by the current International Conference on Harmonization's (ICH's) document, Impurities: Guideline for Residual Solvents, except that this guidance does not apply to the ICH limit of 50 mg per day for the class 3 solvent ethanol when it is present in liquid extracts formulated to contain ethanol, or for the class 3 solvent acetic acid when it is present in liquid extracts formulated to contain acetic acid or vinegar.

With regard to this guidance, solvents identified in the cited ICH document as class 1 solvents (benzene;* carbon tetrachloride;* 1,2-dichloroethane;* 1,1-dichloroethene; and 1,1,1-trichloroethane), which are considered by ICH as unacceptably toxic or an environmental hazard, are not appropriate for use, and should not be used, in the manufacture of herbal extracts.

With regard to this guidance, solvents identified in the cited ICH document as class 2 solvents, which are considered by ICH to be inherently toxic, are listed in the table below with the ICH recommended upper limits for Permissible Daily Exposures (PDE) and concentration limits given in ppm assuming a 10 gram daily dose.

Class 2 Solvent	***PDE (mg/day)***	***limit (ppm)***
Acetonitrile	4.1	410
Chlorobenzene	3.6	360
Chloroform*	0.6	60
Cyclohexane	38.8	3880

1,2-Dichloroethene	18.7	1870
Dichloromethane*	6.0	600
1,2-Dimethoxyethane	1.0	100
N,N-Dimethylacetamide*	10.9	1090
N,N-Dimethylformamide	8.8	880
1,4-Dioxane*	3.8	380
2-Ethoxyethanol	1.6	160
Ethyleneglycol	6.2	620
Formamide	2.2	220
Hexane	2.9	290
Methanol	30.0	3000
2-Methoxyethanol	0.5	50
Methylbutyl ketone*	0.5	50
Methylcyclohexane	11.8	1180
N-Methylpyrrolidone*	5.3	530
Nitromethane*	0.5	50
Pyridine*	2.0	200
Sulfolane	1.6	160
Tetrahydrofuran	7.2	720
Tetralin	1.0	100
Toluene*	8.9	890
1,1,2-Trichloroethene	0.8	80
Xylene	21.7	2170

With regard to this guidance, solvents identified in the cited ICH document as class 3 solvents, which are considered by ICH as having low toxic potential, should be limited to 50 mg/day,† which equates to 5000 ppm or 0.5% in 10 grams. Their use should be limited by good manufacturing practice (GMP) or other quality based requirements. They are identified as the following:

Class 3 Solvents		
Acetic acid	Ethanol*	3-Methyl-1-butanol
Acetone	Ethyl acetate	Methylethyl ketone
Anisole	Ethyl ether	Methylisobutyl ketone
1-Butanol	Ethyl formate	2-Methyl-1-propanol
2-Butanol	Formic acid	Pentane
Butyl acetate	Heptane	1-Pentanol
tert-Butylmethyl ether	Isobutyl acetate	1-Propanol
Cumene*	Isopropyl acetate	2-Propanol
Dimethyl sulfoxide	Methyl acetate	Propyl acetate

†This limit does not apply for ethanol when it is present in liquid extracts formulated to contain ethanol or for acetic acid when it is present in liquid extracts formulated to contain acetic acid or vinegar.

Adherence to this AHPA guidance does not infer compliance with California Proposition 65. Several of these solvents are listed by the State of California as chemicals known to the State to cause cancer or reproductive toxicity, including, as of the date of the last revision of this guidance, at least those solvents marked with an asterisk (*). The listing of ethanol with regard to California Proposition 65 refers only to its presence in alcoholic beverages.

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Trade Requirement and Guidance Policy for Labeling of Undiluted Essential Oils Used Topically and Offered for Retail Sale (Trade Requirement adopted July 2009, revised July 2011; Guidance Policy adopted July 2012)

Undiluted plant essential oils offered for retail sale and intended for topical use:

1. Do include all of the information and statements, or significantly similar statements, identified in the table below as a "trade requirement," directly on package labels;
2. May include any of the information identified in the table below under "Guidance Policy," either directly on package labels or on labeling. *

SUBJECT	TRADE REQUIREMENT	GUIDANCE POLICY
Identity of the source plant:	▪ Latin name ▪ Plant part	▪ Common or usual name
Product identity:		▪ An expiration date or date of manufacture. ▪ A lot number or other batch identifier. ▪ The extraction process, (i.e., distilled; expressed; solvent extraction; etc.), with any additional specific accurate information. *For more information on specific types of extraction, click here.*
Storage cautions:	▪ "Keep out of reach of children."	▪ "Keep away from flame."
Usage instructions:		▪ Instructions for use with, at minimum, the recommended amount for each application method described.
Usage cautions:	▪ "External Use Only" **or** "Not for Internal Use" **or** "Not for Ingestion" ▪ "Keep away from eyes and mucous membranes." ▪ "Do not apply undiluted directly on skin," except that information may be included on direct application in an undiluted state if the marketer has expert support that such use is appropriate and safe for the intended use.	▪ "If swallowed, seek medical attention or contact a Poison Control Center." ▪ "If skin irritation or sensitivity develops or increases, stop use and, if condition persists, seek medical attention." ▪ Risk and safety information regarding photosensitizing effects, if applicable to the specific essential oil. ▪ Risk and safety phrases for specific oils as identified by the Research Institute for Fragrance Materials (RIFM) and the International Fragrance Association (IFRA), if applicable to the specific essential oil.

*For purposes of this guidance, the following definitions apply:

- "Label" has the meaning ascribed in 21 U.S.C. 321(k) and means a display of written, printed, or graphic matter upon the immediate container of any article.

- "Labeling" has the meaning ascribed in 21 U.S.C. 321(m) and means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

In addition, for purposes of these policies, the following notes apply:

- These policies do not address the safety of specific essential oils. Contraindications exist for the use of some essential oils in special populations, such as infants and children; pregnant and lactating women; and those with certain health conditions (e.g., hypertension). Such individuals should use essential oils under the supervision of a professional or qualified person.
- All of the required storage and usage cautions can be stated succinctly, for example, as: "Keep away from children. No use orally, in eyes or mucus membranes, or undiluted on skin."

Specific Types of Extraction

Types of Distillation

- **Steam distillation:** Natural raw material is placed in or above water in a retort and exposed to steam, which carries the volatile oils into a condenser where the mixture is cooled.[1] The oils separate from the water and can be collected.
- **Hydro distillation:** Steam distillation in which the natural raw material is exposed to steam from above, rather than from below, the raw material.
- **Water distillation:** Natural raw material is submerged in water. The water is then slowly heated and brought to a boil.
- **Dry distillation:** Used primarily to obtain essential oils from wood. Natural raw material is heated in a retort in the absence of liquid to release vapors or liquids. The heat applied to the retort is commonly direct flame. This process may or may not involve pyrolysis.

Types of Expression

- **Cold-pressing:** Used primarily to obtain citrus essential oils. Fruit is punctured and then mechanically pressed. No external heat is applied during the extraction process.
- **Sponge expression:** Pulp is removed from the fruit and the remaining rind and pith are soaked in water. The softened peel is pressed against a sponge, which absorbs the exuded oil.
- **Scarification (aka: Écuelle à piquer):** Outer peel of a fruit is scarified. The liquid exuding from the ruptured oil glands collects in stem.
- **Machine abrasion:** Outer peel of a fruit is scarified and then removed by machine and dropped into a flow of water, which carries the result to a large centrifugal separator machine.

Types of Solvent

- **Enfleurage:** Flower petals are placed on solid sheets of warm fat that absorbs the essential oil from the flowers. A solvent, usually alcohol, is then added to the saturated fat, which separates the essential oil from the fat.
- **Supercritical CO_2:** Carbon dioxide is liquefied and used as extraction solvent.
- **Solvent:** Use of a solvent other than those mentioned thus far, such as hexane. Solvent should be identified.
- **Extrait:** Extraction of flower oils (generally organic) without the use of harmful solvents, such as benzene and hexane, etc.

[1] When the natural raw material is placed in water during steam distillation it is sometimes called "water and steam distillation."

Guidance on Labeling of Protein in Food and Dietary Supplements (adopted March 2014)

Marketers of conventional foods and dietary supplements adhere to the following guidelines in labeling the protein in any such product:

- Notwithstanding the allowance in 21 CFR § 101.9(c)(7) to calculate the amount of protein to be declared in nutrition labeling of a food or dietary supplement on the basis of the factor of 6.25 times the nitrogen content of the food, the quantity of protein in a product is calculated to include only proteins that meet the following definition: "A chain of amino acids connected by peptide bonds."
- As further clarification, non-protein nitrogen-containing (NPN) substances are not counted toward total protein content on product labels. NPN substances are accounted for and subtracted from the total nitrogen content when protein is measured by nitrogen content.
- Nothing in this guidance is intended to replace or conflict with any regulatory requirement established under any other subpart or section of 21 CFR Part 101 for labeling of food and dietary supplement products.