

on Adulteration of *Actaea racemosa*

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Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of black cohosh (*Actaea racemosa*, Ranunculaceae) to the international herbal industry and extended natural products community in general. It is intended to complement the previously published works with information on black cohosh adulteration, e.g., the American Herbal Pharmacopoeia monograph published by Upton et al.,¹ and the review paper by Foster,² by presenting new data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: black cohosh³

1.2 Other common names:

English: Black bugbane, snakeroot, rheumatism weed, fairy candle, tall bugbane, black bugbane, macrotyls, macrotrys, battleweed, columbine-leaved leontice, cordate rattle top, rattleweed, false cohosh, papoose root.⁴

Chinese: Zong zhuang sheng ma (总状升麻)

French: Actée à grappes noires, cimicaire à grappes, chasse-punaises, cimifuge, herbe à punaise, serpenteiraire noire

German: Traubensilberkerze, Wanzenkraut, Frauenwurz, langtraubiges Christophskraut, Nordamerikanische Schlangenzwurz, schwarze Schlangenzwurz

Italian: Cimicifuga, serpentaria nera, actea nera

Spanish: Cohosh negro, raíz de culebra negra

1.3 Accepted Latin binomial: *Actaea racemosa*^{5,6}

1.4 Synonym: *Cimicifuga racemosa*

1.5 Botanical family: Ranunculaceae



Black Cohosh *Actaea racemosa*
Photo ©2016 Steven Foster

1.6 Distribution range: Black cohosh is native to North America, where it occurs in Eastern Canada (Ontario, Quebec), and in the Eastern United States from Massachusetts to Georgia, and west to Illinois and Arkansas.⁷

1.7 Plant part, form and production method: Whole, chopped, and powdered dry rhizome and root, and aqueous ethanol or aqueous isopropanol extracts. Extracts are offered as fluidextracts (plant-solvent ratio 1:1), liquid extracts (hydroalcoholic extracts, dry extracts dissolved or suspended in glycerin-water mixtures), or dry extracts in tablet or capsule form. The dry extracts are often standardized to contain 2.5% triterpene glycosides.¹

1.8 General use(s): Currently, black cohosh is used to alleviate premenstrual discomfort, dysmenorrhea and symptoms of menopause (hot flashes, excessive sweating, sleep disorders, irritability).^{8,9} Traditionally, black cohosh is used for colds, dyspepsia, rheumatoid arthritis, sciatica, snake bites, tinnitus, and whooping cough, but such use is not supported by experimental or clinical data.⁸

2 Market

2.1 Importance in the trade: From 2012-2014, black cohosh has consistently been one of the 10 top-selling herbs in the mainstream market and has ranked within the 30 top-selling herbs in the natural foods sector in the United States (Table 1).

2.2 Supply sources: The majority of the black cohosh on the market comes from material that is harvested in the wild. Kentucky and Tennessee are the major areas of collection. Additional supplies are collected in other states along the Appalachian Mountains and in the Northeastern United States.¹ An evaluation of the trade in 2010 suggests that habitat loss and over-collection are threats to the black cohosh supply.¹⁰ There is some cultivated material available. For example, Schaper & Brümmer, the manufacturer of a leading black cohosh product, Remifemin®, grows a horticultural variety of black cohosh in Lower Saxonia and Thuringia, Germany that is registered by the company and protected by the Community Plant Variety Office (CPVO) of the European Union.

2.3 Raw material forms:

Bulk black cohosh crude raw material is sold as whole rhizome and roots, in form of a teabag, cut, or as powdered rhizome and roots.

2.4 Market dynamics: The annual harvest of black cohosh has seen some dramatic fluctuations (Table 2).¹¹

The reasons behind the changes in harvest volume are not clear, but excess inventory built up in the previous

years could have led to the sharp drop in harvest in 2005, and again in 2009.^{4,12} The large harvest amounts in 2003 and 2004 were possibly a reaction to increased sales of black cohosh dietary supplements after a large study suggested that hormone treatments of menopausal women increased their risk of cardiac problems.¹³ Additionally, *Actaea* species indigenous to Asia and represented as black cohosh may also have impacted demand for and, therefore, harvests of authentic *A. racemosa*. No harvest report data on black cohosh have been published since 2010.

Sales of branded black cohosh dietary supplement products have declined over the past several years, which is in line with the general trend in the market segment for menopause products. This decline may be due to the lower number of women entering menopause based on the lower birth rates in the 1960s compared to the 1950s.

In 2011, the price of *A. racemosa* to manufacturers reportedly ranged from US \$10-17/kg, with the usual cost being US \$14.5-16.5/kg. Material sourced from Asia and sold as “black cohosh” (e.g., *Actaea cimicifuga*), on the other hand, was reported to be available at US \$6-8/kg, providing an incentive for economically motivated adulteration (EMA).² Since 2014, prices of authentic black cohosh have been steadily increasing.

3 Adulteration

3.1 Known adulterants: Reports of adulteration of black cohosh have often involved species in the genus *Actaea* imported from Asia, e.g., the following taxa:

- *Actaea cimicifuga* (syn: *Cimicifuga foetida*)
- *A. dahurica* (syn: *C. dahurica*)
- *A. heracleifolia* (syn: *C. heracleifolia*)
- *A. simplex* (syn: *C. simplex*)
- *A. brachycarpa* (syn: *C. brachycarpa*).^{14,15}

A paper on frequently misidentified species on the Hong Kong market lists *Serratula chinensis* (Asteraceae) as an adulterant of Chinese cimicifuga,¹⁶ which may result in uninformed purchasing agents procuring an adulterant of the adulterant, further confusing the black cohosh market. Adulterants of *A. racemosa* may also include North American species of *Actaea* growing in the same area as black cohosh, e.g., *A. pachypoda*, *A. rubra*, and *A. podocarpa*. The native range of

Table 1: Sales data for black cohosh dietary supplements from 2012-2014.

Channel	2012		2013		2014	
	Rank	Sales [US\$]	Rank	Sales [US\$]	Rank	Sales [US\$]
Natural ^a	21	3,793,709	23	3,504,145	26	3,359,658
Mainstream Multi-Outlet ^b	4	44,646,587	4	46,007,332	5	42,463,816

^aAccording to SPINS (SPINS does not track Whole Foods Market sales, which is a major natural products retailer in the US)

^bAccording to SPINS/IRI (the Mainstream Multi-Outlet channel was formerly known as food, drug and mass market channel [FDM], possible sales at Walmart and club stores are excluded in 2013 and 2014)
n/a: not available

Source: T. Smith (American Botanical Council) e-mails, September 2, 2015 and September 3, 2015

black cohosh overlaps most with *A. pachypoda*, followed by *A. rubra* and then *A. podocarpa*. But overall the largest plant is *A. racemosa*, so most wildcrafters will dig black cohosh since it gets them more money for their effort.⁴ [E. Fletcher, e-mail communication, April 6, 2015]

3.2 Sources of information confirming adulteration:

The most extensive review on adulteration of black cohosh has been published by Foster.² Since its publication in 2012, there have been three new studies that used combinations of genetic and chemical methods to authenticate commercial black cohosh products. These studies provided additional evidence of continuing adulteration of purported *A. racemosa* products with *Actaea* species indigenous to Asia.^{15,17,18} Two of the studies used genetic authentication techniques (restriction fragment length polymorphism [RFLP] and amplification refractory mutation system [ARMS]¹⁷ or direct sequencing of the ITS1-ITS2, ITS1, and *trnL-F* regions¹⁸) combined with high-performance liquid chromatography (HPLC-ELSD¹⁷ or HPLC-MS¹⁸) to establish botanical identity. In the first study, 16 commercial black cohosh dietary supplements were analyzed that were purchased through the Internet, originating from the United States (n = 14), Australia (n = 1) and Canada (n = 1). Of these 16 samples, four were considered to be adulterated.¹⁷ Twenty-five samples from the United States (n = 19) or Europe (n=6) were evaluated in the second study, where seven out of the 25 samples were found to be adulterated.¹⁸ *Actaea dahurica* was identified as the primary botanical adulterant in both studies. DNA was obtained from eight out of 16, and 10 out of 19 dietary supplements products, respectively. The authors did not attempt to extract DNA from the six herbal medicinal products from Europe.^{17,18} Harnly et al. used a combination of DNA barcoding and two metabolic fingerprinting methods, flow injection mass spectrometry (FIMS) and proton nuclear magnetic resonance spectrometry (¹H-NMR), to establish the identity of the ingredients in one commercial black cohosh raw material and 14 finished products.¹⁵ The commercial raw material sample was purchased in China and was identified as *A. dahurica*.

The MS and NMR fingerprints of the 14 dietary supple-

ments were different from any of the authentic black cohosh raw material samples (extracted using 70% aqueous methanol for the ¹H-NMR and FIMS analysis), indicating that variations in the manufacturing process lead to significantly different phytochemical profiles. Therefore, in the absence of a sufficiently large number of finished product samples with well-established provenance, the chemometric methods were considered unsuitable for adequate authentication of the ingredients in the dietary supplements. However, the techniques are promising, and could potentially be proven reliable with a properly designed series of experiments. DNA barcoding was successful for identifying four of the seven capsule supplements tested as *A. racemosa*. One supplement contained *A. brachycarpa*, while the two remaining supplements contained either no DNA, or DNA from an excipient. The remaining seven liquid supplements were not subjected to DNA barcode analysis since it was expected that DNA would not be present.¹⁵

3.3 Accidental or intentional adulteration: The reasons for adulteration of black cohosh are manifold. Domestic wild harvesting of root and rhizome biomass growing in the proximity of similar co-habiting species, especially when the berries are absent, has resulted in unintentional collection of the wrong species by inexperienced, or irresponsible wildcrafters. The more common adulteration is substitution of Asian species of *Actaea* for *A. racemosa* by suppliers who either knowingly or unknowingly apply the common name “black cohosh” inappropriately to the Asian species of herbal material from the genus *Actaea*. According to the *American Herbal Products Association’s Herbs of Commerce*, 2d edition,³ the standard common name “black cohosh” should be exclusively applied to *A. racemosa*, while the standard common name “Chinese cimicifuga” refers to *A. cimicifuga* (syn. *A. foetida*) and *A. heracleifolia*. Intentional adulteration of black cohosh with Asian species is mainly due to economic reasons,¹⁹ since the price for Asian *Actaea* materials is significantly lower (see section 2.4).

3.4 Frequency of occurrence: There are no large studies

on the frequency of black cohosh adulteration. However, there are five published papers that investigated black cohosh adulteration in commercial finished products, mainly products sold in North America and Europe.^{17,18,20-22} In these studies, the adulteration rate overall (excluding subsets of the sample pool) was between 25% and 36%. Compiling the data from all five studies, a total of 92 commercial products were analyzed, of which 65 were determined to contain authentic black cohosh, while 25 samples (27%) were found to be adulterated. Since the brand names of the analyzed samples were not iden-

Table 2. Estimated Cultivated and Wild Harvest Tonnage for Black Cohosh¹¹

Year	Estimated harvest (metric tons) from cultivation	Estimated material (metric tons) collected in the wild
1997	0	102.97
1998	16.07	329.30
1999	1.18	65.94
2000	0.07	53.45
2001	2.96	80.97
2002	0.13	76.86
2003	0.17	144.31
2004	1.50	144.58
2005	3.14	61.86
2006	0.93	139.48
2007	1.01	155.93
2008	0.72	129.81
2009	0.63	76.51
2010	4.47	142.74

tified, it is possible that the same commercial product was analyzed in more than one study, which might skew the percentage number. It is also unclear if the products analyzed represent a large part of the sales volume of black cohosh or if those were samples with a small market share. Interestingly, the study by Masada-Atsumi et al. found that all six herbal medicinal products purchased from pharmacies in Europe contained authentic black cohosh, while seven out of 19 products (36.8%) purchased through the Internet from US sellers were adulterated.¹⁸

3.5 Possible safety/therapeutic issues: As noted previously, the consumption of supplements labeled as black cohosh has been associated with hepatotoxicity. There is speculation that some of these cases may be due to the presence of an adulterant, specifically a species of *Actaea* other than *A. racemosa*. A report in Health Canada's Adverse Event Newsletter in 2010 concluded that four of six products associated "black cohosh" liver toxicity were adulterated, while the other two cases included products of unknown composition that were not authorized for sale in Canada.²³ The phytochemical profiles of several of the products were consistent with those of Asian *Actaea* species. There is no evidence in the English language medical literature suggesting that *A. dahurica*, *A. heracleifolia*, or *A. cimicifuga* are harmful to the liver. In fact, one study found that methanolic extracts of *A. dahurica* have liver-protective effects in mice.²⁴ High doses of both black cohosh and Chinese cimicifuga have been reported to cause headaches, tremors, limb contractions, apathy, vertigo, and abnormal erections. Overdoses may result in nausea, vomiting, and gastroenteritis.²⁵⁻²⁷

3.6 Analytical methods to detect adulteration: The roots of black cohosh are readily distinguished macroscopically from *A. dahurica*, *A. foetida*, and *A. heracleifolia*. Chinese cimicifuga is almost always sliced, displaying a sinusoid pattern that is not generally observed in authentic black cohosh. The Chinese cimicifuga adulterant *Serratula chinensis* can be similarly distinguished since it has no morphological resemblance to either species. (R. Upton e-mail, May 6, 2016) The phytochemical profiles of authentic black cohosh and the various adulterating species are similar and therefore identification by these profiles alone is difficult.¹⁴ The *European Pharmacopoeia* (EP) Monograph *Cimicifugae rhizoma* includes a high-performance thin layer chromatography (HPTLC) test to detect possible substitution with *A. cimicifuga*, *A. dahurica*, *A. heracleifolia*, and *A. podocarpa*.²⁸ The high-performance liquid chromatography-evaporative light scattering detector (HPLC-ELSD) methods in the EP and *United States Pharmacopoeia* (USP) reportedly also provide a suitable way to distinguish black cohosh from adulterating species.^{28,29} Genetic methods can be used to differentiate the species in materials where intact DNA is present, however, it may not be appropriate for extracts or processed material that contain highly fragmented DNA, or where DNA is absent altogether. The most robust approach for discerning the identity of black cohosh and for ruling out substitution with non-target *Actaea* species is to use multiple methods of identification, preferably a combination of a genetic approach (if applicable) and

a chemical fingerprinting method that provides data on peak identity (e.g., HPLC-MS). The Black Cohosh Adulteration Laboratory Guidance Document, a comprehensive evaluation of published analytical methods with regard to their ability to authenticate black cohosh and to detect adulteration, was published by the ABC-AHP-NCNPR Botanical Adulterants Program in November 2015.¹⁴

3.7 Perspectives: Of the *Actaea* species sharing the same habitat, *A. podocarpa* is morphologically the most similar to black cohosh with regard to both the aerial parts and the root. However, with some training, the underground parts can be visually distinguished from those of *A. racemosa* just as readily as can the aboveground parts (E. Fletcher, e-mail communication, April 6, 2015). While misidentification at collection sites is always possible, adulteration of black cohosh is mainly associated with products imported from Asia (K. Morel [Naturix], e-mail communication, February 9, 2015; Michael McGuffin [American Herbal Products Association], oral communication, March 8, 2015).^{15,17,18}

4 Conclusions

Black cohosh has been one of the best-selling botanical supplements for many years and is used primarily for the relief of menopausal symptoms. While black cohosh has been a staple in North American herbal medicine for hundreds of years,³⁰ the popularity of black cohosh to alleviate symptoms of menopause is largely due to the introduction of a proprietary product, Remifemin by the German company Schaper & Brümmer in the 1950s. Habitat destruction and overharvesting in some areas of the United States have decreased the availability of wild populations of this important medicinal plant.^{4,10} In addition, the higher price of authentic black cohosh compared to Chinese cimicifuga has created an incentive for economically-motivated adulteration. While accidental adulteration of domestically wild-crafted black cohosh with North American species of *Actaea* may occur, it is rarely reported. Most often black cohosh is adulterated with or substituted by Chinese species of *Actaea*.

Authentic black cohosh is not native to Asia, and currently there is no large-scale cultivation of authentic black cohosh root in Asia. Therefore, any offering of black cohosh from sources outside of North America, especially if occurring at unexpectedly low prices relative to market value, should be viewed with suspicion and appropriate measures should be taken to analytically confirm the identity of such botanical material. Most of the reports of hepatotoxicity associated with black cohosh products provide no information about the composition of the product, and causality has been difficult or impossible to determine. There has been a single report of a series of cases of hepatotoxicity associated with adulterated black cohosh products,²³ making it imperative to positively identify black cohosh raw materials and extracts and to assure the absence of non-target botanical and other adulterants.

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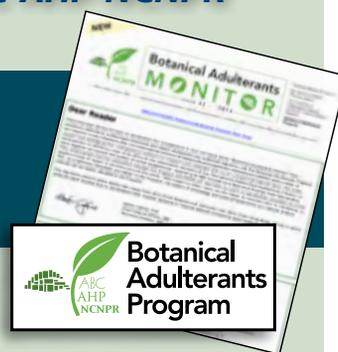
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Version 1, S. Gafner new	n/a	n/a	none