Adulteration of Saw Palmetto
(Serenoa repens)

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Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of saw palmetto (Serenoa repens) to the international herbal industry and the extended natural products and natural health communities in general.

1 General Information

1.1 Common name: Saw palmetto\textsuperscript{1}

1.2 Other common names:

- English: Scrub-palmetto, sabal palm, saw palmetto berry
- Chinese: Ju zonglu (锯棕榈)
- French: Sabal, palmier nain, palmier scie
- German: Sabal, Sägepalme, Zwergpalme
- Italian: Palma nana, cavolo di palma
- Spanish: Sabal, palma enana americana\textsuperscript{1,2}

1.3 Accepted Latin binomial: Serenoa repens (W. Bartram) Small

1.4 Synonyms: Chamaerops serrulata Michx., Corypha repens W. Bartram, Sabal serrulata (Michx.) Nutt. Ex Schult. & Schult. f., Serenoa serrulata (Michx.) G. Nicholson\textsuperscript{3}
1.5 Botanical family: Arecaceae

1.6 Plant part, form, and production method: Dried powdered berries; lipophilic extracts made from the comminuted berries (fruits) of saw palmetto; extracts are primarily made using water-ethanol mixtures (not less than 90% ethanol according to the European Pharmacopoeia [Ph. Eur.]), hexanes (a mixture of n-hexane and methylpentane isomers), or a supercritical CO₂ extraction technique.4,5

1.7 General use(s): Saw palmetto extracts (SPE) are indicated for urinary problems associated with benign prostatic hyperplasia (BPH).2,6-9 According to a survey in the United States, 0.7% and 0.4% of adults in 2007 and 2012, respectively, reported use of a saw palmetto in the 30 days prior to the survey.10 BPH is associated with elevated concentrations of dihydrotestosterone in men.8 Specifically, extracts of S. repens fruit inhibit the conversion of testosterone to dihydrotestosterone by 5α-reductases.11-13

2 Market

2.1 Importance in the trade: According to a press release in 2010, worldwide sales of saw palmetto supplements were approximately US $700 million, with the United States accounting for US $200 million alone.14 Data by the market research firm SPINS ranked saw palmetto in the top 16 of botanicals sold in the United States from 2010-2017.15-21 Sales in the mainstream multi-outlet channel (excluding sales at Walmart and club stores) declined from $21.6 million in 2013 to $16.8 million in 2015, but climbed back to $19.3 million in 2017. Saw palmetto sales in the natural channel (excluding sales at Whole Foods Market) remained fairly constant over the past 5 years, fluctuating between $6.4 and $7.9 million between 2013 and 2017.

2.2 Supply sources: Saw palmetto fruits/berries are harvested from mid-August to mid-November across its natural growing range. Saw palmetto grows across Florida and as far north as South Carolina. It is important to note that saw palmetto is primarily a wild-harvested (wild-crafted) botanical (E. Fletcher [Herbal Ingenuity], oral communication, June 25, 2015). According to the American Herbal Products Association’s (AHPA’s) 2005-2010 tonnage survey,22 which is the most recent data collected by AHPA, there were 680.4 metric tons (1.5 million pounds) of saw palmetto fruits harvested in 2009 and 635 metric tons (1.4 million pounds) harvested in 2010. A small amount of saw palmetto fruits were harvested from cultivated sources (998 kg in 2009, and 1,227 kg in 2010). Other estimates set the harvest volume between 4,500 and 8,000 metric tons/year, depending on the weather conditions. (G. Woodman [Euromed] email to S. Gafner, June 25, 2018). The total extract volume in 2016 was approximately 520 metric tons, valued at US $105 million prior to encapsulation.23

2.3 Market dynamics: Saw palmetto grows in a small geographical range in the Southeast United States. In most years, there is ample supply of berries to meet market demand to produce SPE. Main supply disruptions are due to environmental factors, i.e., hurricanes and heavy rains. For example, when Florida was hit by five hurricanes in 2004-2005, fresh berries were not available and the prices increased. Another potential supply problem is heavy rains during the flowering season. Heavy rains will knock flowers from the palm and can prevent fruit from setting. Heavy rains also provide the perfect conditions for a disease caused by the fungus Colletotrichium gloesporioides, causing lesions in flowers and fruit and leading to the dropping of premature fruit.24 While less common, heavy rains (preventing fruit set) have happened in the past. Keeping track of weather disruptions in the saw palmetto growing range is important to predict the likelihood of adulteration (E. Fletcher oral communication, June 25, 2015). In particular, in 2016 and 2017 when below-average harvest volumes for saw palmetto were obtained, there were low-cost materials, falsely labeled as saw palmetto, which appeared on the market. The situation has been exacerbated by extensive rain in 2018, which interrupted the flowering period and resulted in widespread berry drop (see above) across the state. According to the saw palmetto mid-season harvest

Table 1: Sales data for saw palmetto dietary supplements from 2012-2017.

<table>
<thead>
<tr>
<th>Channel</th>
<th>2013</th>
<th>2014</th>
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<th>2016</th>
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<tr>
<td>Naturala</td>
<td>10 6,424,306</td>
<td>11 6,363,119</td>
<td>8 7,555,435</td>
<td>10 7,555,383</td>
<td>11 7,875,432</td>
</tr>
<tr>
<td>Mainstream Multi-Outletb</td>
<td>11 21,560,716</td>
<td>10 17,990,612</td>
<td>14 16,849,069</td>
<td>16 17,403,324</td>
<td>14 19,294,711</td>
</tr>
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*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, 2014 and 2015)

Source: T. Smith (American Botanical Council) e-mail to S. Gafner, September 2, 2015, September 3, 2015, and June 19, 2018; K. Kawa (SPINS) e-mail to S. Gafner, July 11, 2016.
report by the American Herbal Products Association, the price has increased rapidly based on the short supply and a need for pickers to move into more remote areas in order to harvest the berries. In the first week of September 2018, costs for the berries were reportedly about three times higher than the average price in 2017.25

It remains to be seen how the requirement to obtain landowner permission and a permit for saw palmetto harvesters and sellers issued by the Florida Department of Agriculture and Consumer Services in July 2018 will impact the supply chain. Estimated price ranges for SPE varied from US$ 150-235/kg in 2016, and rose to US$ 190-275/kg in 2017. The market is significantly impacted by adulterated materials from China and India, which are priced between US$ 50-135/kg (G. Woodman [Euromed] email to S. Gafner, June 25, 2018). The substantial increase (2-3-fold) in raw material costs since 2009 has been attributed to more competition and higher costs for the labor force (Umasudhan C.P. [Valensa] oral communication, October 31, 2016).

3 Adulteration

3.1 Background about extract/product: The main components of SPE are fatty acids (70-95%), phytosterols (0.2-0.5%), and long-chain alcohols (0.15-0.35%).5 A number of monographs/extract definitions have been published4,5,27 SPE can be distinguished from other plant oils based on the relative amounts of the individual free fatty acids,28 and the higher concentration of total free fatty acids in SPE. The United States Pharmacopoeia (USP) monograph specifies a ratio of naturally occurring caproic, caprylic, capric, myristic, palmitic, stearic, oleic, linoleic and linolenic acids to lauric acid for authentication of SPE. A number of analytical methods for the authentication of SPE have been published: thin-layer chromatography (TLC),4,5 gas chromatography (GC),29-31 and nuclear magnetic resonance (NMR) profiling.29,32-34

3.2 Known adulterants: A number of ways to adulterate saw palmetto extracts and dietary supplements have been described: substitution of the saw palmetto fruit with fruit from closely-related palm species, dilution of products with exhaustively extracted berry powder, the use of unripe berries to produce an extract, the addition of vegetable oils to extracts, full substitution of SPE with other vegetable oils based on the relative amounts of the individual free fatty acids,28 and the higher concentration of total free fatty acids in SPE. The United States Pharmacopoeia (USP) monograph specifies a ratio of naturally occurring caproic, caprylic, capric, myristic, palmitic, stearic, oleic, linoleic and linolenic acids to lauric acid for authentication of SPE. A number of analytical methods for the authentication of SPE have been published: thin-layer chromatography (TLC),4,5 gas chromatography (GC),29-31 and nuclear magnetic resonance (NMR) profiling.29,32-34

3.3 Sources of information confirming adulteration: Several papers on the quality of commercial SPE were obtained that also provided analytical data on the samples.29,30,32,40,41 The investigation into the authenticity of commercial saw palmetto samples from the North American market by Mikaelian et al. and Perini et al.
confirm product adulteration. In the study by Mikaelian et al., nine of the 10 samples were correctly labeled, and one was found to be adulterated with an unidentified vegetable oil based on a different pattern of free fatty acids, and an unusually low content of free fatty acids. The 2018 investigation by Perini et al. into the composition of SPEs obtained from suppliers in Asia found all of the nine ingredients to be adulterated. Three samples were adulterated with vegetable oil (two samples being coconut or babacu (Attalea speciosa, Arecaceae) oil, and one case of an unidentified mixture), the other six samples were designer blends composed of fatty acids of animal origin. In another study from 2018, a vegetable oil, possibly coconut oil, was determined as the adulterant based on the results of a 1H NMR investigation of a commercial sample labeled to contain saw palmetto. Cases of SPE adulteration with vegetable oils (olive oil, palm oil, peanut oil, and sunflower oil), or with animal fat-derived blends have also been reported from quality control departments at leading suppliers of saw palmetto extract: Euromed (Mollet del Vallès, Spain), Indena (Milan, Italy), and Valensa (Eustis, FL, USA). Two other publications suggest the dilution of SPE with various vegetable oils is commonly occurring, but the documents do not provide data to support the statements.

3.4 Accidental or intentional adulteration: A distinction between raw saw palmetto fruit material and fruit extract adulteration is warranted. Adulteration of saw palmetto berries with berries from A. wrightii may be due to harvests from the Caribbean entering the saw palmetto trade. Acoelorrhaphe wrightii grows in a different habitat than saw palmetto, and has considerably larger fruit; therefore, the two species are not likely to be confused by saw palmetto harvesters, making such an adulteration intentional (S. Foster, e-mail to S. Gafner, December 20, 2016). The addition of lower-cost vegetable oils or fatty acids from animal sources to SPEs is for economic gain, either by willfully increasing profitability through the use of less expensive adulterating materials or to supplement market demands in times of shortage. As stated above, costs for authentic SPEs ranged from US $190-275/kg in 2017. Materials that are offered at considerably lower prices are likely adulterated. Such adulteration by unscrupulous suppliers is intentional and purposefully deceives the finished herbal product manufacturer and consumer.

3.5 Frequency of occurrence: There are no statistical data available on the frequency of the overall occurrence of saw palmetto fruit and extract adulteration. As noted above, an evaluation of 10 commercial samples, purchased in local stores in the United States and from the Internet, found that one product was adulterated. The nine commercial ‘saw palmetto’ extracts of Asian origin analyzed by Perini et al. were all adulterated. As saw palmetto is native to the United States, SPE shipments labeled to contain saw palmetto originating in Asia are generally viewed with suspicion. There have been three known broad attempts to buy and analyze commercial saw palmetto products. Two were studies carried out by universities and one was conducted by a commercial consumer products testing program, ConsumerLab.com in 2003. Similar to the findings of Mikaelian et al. reported above, tests on 22 commercial saw palmetto products by ConsumerLab.com in 2003 revealed possible addition of an undeclared vegetable oil in one product. The rather comprehensive overview on the quality of saw palmetto supplements in the marketplace by Booker et al. also indicated a low occurrence of adulteration, since all 57 commercial products actually contained saw palmetto and the presence of additional vegetable oils was declared on the labels (most likely as appropriate excipients in soft-gel capsules). Highly variable contents in free fatty acids (40.7%-80.7%) and triglycerides (6.8%-52.2%) were also found during an investigation into the quality of 14 European saw palmetto products. The authors, however, did not hypothesize about the reason behind the differences with the exception of one product known to contain 50% olive oil (which is declared on the label).

Similar results were observed in the study by Wang et al. where eight commercial samples (seven capsules and one softgel product) purchased on the Internet were analyzed by GC with mass spectrometric (MS) detection. The fatty acid composition of the capsule products was consistent with authentic saw palmetto berry. The softgel product had a different fatty acid composition, with a larger amount of oleic acid due to the presence of olive oil, which was declared on the label. The use of added vegetable oils is consistent with preparation of soft gelatin capsule technology. However, since the adulteration rate seems to be to some extent dependent on the weather and harvest conditions in current or immediately prior seasons (see Section 2.4), a yearly fluctuation in the number of adulterated products on the market may be expected. While there is little evidence of adulteration of saw palmetto finished supplements in the current market based on published reports thus far, as shown above (see Section 3.3) unpublished analyses by suppliers of authentic SPE suggest there is some adulterated SPE present in the botanical ingredient supply chain.

3.6 Possible safety/therapeutic issues: None of the vegetable oils linked to saw palmetto adulteration is considered to be a health hazard. Similarly, the sale of designer blends made from animal-derived fatty acids does not represent a health hazard, although many countries demand specific documents for the customs inspection process, in particular ingredients derived from bovine origin to reduce the risk of bovine spongiform encephalopathy (BSE). In addition, the presence of animal-derived fatty acids may represent a moral issue for vegetarians, vegans, and/or persons of certain religious traditions, in which the undeclared presence of fats of possible porcine or bovine origin would be considered anathema. Concerning adulteration with berries from closely related species,
the fruits of *A. wrightii* are edible according to Austin, and some parts of the plants are used as medicine in Belize. However, to our knowledge, no extensive review on the safety of *A. wrightii* has been performed.

### 3.7 Analytical methods to detect adulteration

There are four monographs on saw palmetto materials in the USP: Saw Palmetto, Powdered Saw Palmetto, Saw Palmetto Extract, and Saw Palmetto Capsules. Two of the monographs (Saw Palmetto and Powdered Saw Palmetto) include a TLC assay for authentication, and all four of them describe a method for quantification of the fatty acids by GC using a flame ionization detector (FID). For extracts, the organoleptic assessment may give a hint on the presence of an adulterant: SPE has a characteristic odor; the color depends on the type of extract: ethanol extracts are of a dark greenish-brown color, the supercritical carbon dioxide extract has a yellowish-brown or orange-brown color, and the hexane extract is yellowish-green to orange-yellow. In addition, the SPE and saw palmetto capsule monographs contain a GC-FID method to determine the contents in long-chain alcohols and phytosterols (campesterol, stigmasterol, β-sitosterol, and stigmasterol), which provides another parameter with regards to the authenticity of the material. The Ph. Eur. has a monograph for saw palmetto berries, which again uses TLC for authentication and GC-FID to determine the concentrations of individual fatty acids relative to lauric acid. In addition to TLC and GC methods, 1H NMR with subsequent statistical analysis has been used to characterize saw palmetto dietary supplements. De Combarieu et al. have used principal component analysis (PCA) of proton nuclear magnetic resonance (1H NMR) data to evaluate the phytoequivalence of extracts obtained with different solvents. In 2018, Perini et al. published a comprehensive analytical approach to authenticate saw palmetto, which included GC-FID, high-performance liquid chromatography (HPLC), 1H NMR and isotopic fingerprinting analysis with a subsequent statistical assessment by principal component analysis (PCA). Isotopic fingerprinting is an analytical approach in which the ratios of stable isotopes, e.g., hydrogen (H), carbon (C), oxygen (O), strontium (Sr), and/or other chemical elements are measured. The determination of the $^{18}$O/$^{16}$O, and $^{2}$H/$^{1}$H ratios proved to be particularly useful, since these ratios differed substantially from those of the authentic SPEs and allowed to determine that six out of the nine commercial samples were derived from animal fats.

**Phytoequivalence** is a term used to describe the similarity of the plant metabolites in extracts made from the same part of a plant species in order to determine if the same physiological effects can be expected. Another way to check for adulteration is to determine the lauric acid content. SPE is unique due to its high content of lauric acid. The Ph. Eur. monograph requires a minimum content of 23% lauric acid in anhydrous SPE. In addition, SPE has a very high acid value which is different from other plant oils; therefore, the acid value range of SPE is specified in the Ph. Eur. However, when vegetable oils are added to the product, for example in softgel capsules, and the addition of such products is indicated on the label, it is very difficult to verify if the amount of SPE indicated on the label is accurate. For crude raw material, the DNA mini-barcode method described by Little et al. provides an additional tool to determine if species other than saw palmetto are present, though it will not satisfy GMP requirements for identification of the appropriate plant part. For extracts, a combination of analytical methods, including the organoleptic evaluation, the determination of the fatty acid profile, the acid value, and the content of fatty alcohols should allow authenticating SPE.

### 4 Conclusions

Saw palmetto is an important herbal supplement. SPE has been well characterized and phytochemical profiles for the supercritical and alcoholic extracts have been established, thus defining SPE. Multiple analytical methods (DNA barcoding, HPLC, GC, TLC, 1H NMR, and isotopic fingerprinting) to authenticate saw palmetto have been
published. In recent years, saw palmetto fruits have not been in abundant supply, since environmental conditions have adversely affected their availability. Preliminary feedback suggests that heavy rain, and the new state permitting requirement for picking saw palmetto berries suggest that the 2018 harvest will also be negatively impacted. Manufacturers need to be particularly vigilant in years when the harvested amount of saw palmetto berries is low, and in immediately subsequent years when possible adulterated materials may more likely be found in the marketplace. SPE ingredient specifications should be developed in a manner that will ensure the absence of adulterants. Quality control analysts should be informed of the appropriate tests that can be used to verify the authenticity of the material. Establishing the country of origin for a shipment of saw palmetto berries may reduce the likelihood of a substitute species being used, as authentic saw palmetto grows only in a small range in the southeast U.S. (e.g., material labeled to originate from China is unlikely authentic saw palmetto since to these authors’ knowledge, there are no commercial saw palmetto cultivations in that country).

5 References


REVISION SUMMARY

<table>
<thead>
<tr>
<th>Version # , Author,</th>
<th>Date Revised</th>
<th>Section Revised</th>
<th>List of Changes</th>
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<tr>
<td>Version 1, S. Gafner, S. Baggett</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Version 2, S. Gafner, S. Baggett</td>
<td>03/14/2017</td>
<td>3.7</td>
<td>All these monographs describe a TLC method for authentication and quantification of the fatty acids by GC using a flame ionization detector (FID), replaced with Two of them (Saw Palmetto and Powdered Saw Palmetto) include a TLC method for authentication, and all four monographs describe quantification of the fatty acids by GC using a flame ionization detector (FID)</td>
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<td>Version 3, S. Gafner</td>
<td>10/23/2018</td>
<td>All</td>
<td>Addition of common name in Chinese Update of sales and market data Addition of new regulations to harvest saw palmetto berries issued by the Florida Department of Agriculture and Consumer Services in sections 2.3 and 4 Inclusion of additional evidence for adulteration (i.e., references 28, 29, and 33) Inclusion of documentation requirements related to the presence of animal products in section 3.6 Addition of color characteristics and stable isotope analysis to section 3.7</td>
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