on Saw Palmetto
(Serenoa repens)
Adulteration

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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 (\textit{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:

\begin{itemize}
  \item \textit{English}: Scrub-palmetto, sabal palm, saw palmetto berry
  \item \textit{French}: Sabal, palmier nain, palmier scie
  \item \textit{German}: Sabal, Sägepalme, Zwergpalme
  \item \textit{Italian}: Palma nana, cavolo di palma
  \item \textit{Spanish}: Sabal, palma enana americana\textsuperscript{1,2}
\end{itemize}

1.3 Accepted Latin binomial: \textit{Serenoa repens} (W. Bartram)
Small

1.4 Synonyms: \textit{Chamaerops serrulata} Michx., \textit{Corypha repens} W. Bartram, \textit{Sabal serrulata} (Michx.) Nutt. Ex Schult. & Schult. f., \textit{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), hexanes (a mixture of n-hexane and methylpentane isomers), or a supercritical CO₂ extraction technique.⁴

1.7 General use(s): Saw palmetto extracts (SPE) are indicated for urinary problems associated with benign prostatic hyperplasia (BPH).⁵ ⁶ 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.⁷ BPH is associated with elevated concentrations of dihydrotestosterone in men.⁸ Specifically, extracts of Serenoa repens fruit inhibit the conversion of testosterone to dihydrotestosterone by 5α-reductases.⁸

2 Market

2.1 Importance in the trade: According to a press release in 2010, worldwide sales of saw palmetto supplements were approximately $700 million, with the United States accounting for $200 million alone.⁹ Data by the market research firm SPINS ranked saw palmetto in the top 15 of botanicals sold in the United States from 2010-2015.¹⁰-¹⁴ 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. Saw palmetto sales in the natural channel (excluding sales at Whole Foods Market) varied between $6.1 and $7.6 million from 2012 to 2015. According to the American Herbal Products Association’s 2005-2010 tonnage survey,¹⁵ there were 680.4 metric tons (1.5 million pounds) of saw palmetto fruits harvested in 2009 and 635.0 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 1227 kg in 2010).

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 (wildcrafted) botanical (E. Fletcher [Herbal Ingenuity], oral communication, June 25, 2015).

2.3 Market dynamics: Authentic 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 gloeosporioides, causing lesions in flowers and fruit and leading to the dropping of premature fruit.¹⁶ 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). 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%).¹⁷ A number of monographs/extract definitions have been published.⁴,¹⁷,¹⁸ SPE can be distinguished from other plant oils based on the relative amounts of the individual free fatty acids,¹⁹ and the higher concentration of total free fatty acids in SPE. The United States Pharmacopeia (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

Table 1: Sales data for saw palmetto dietary supplements from 2012-2015.

<table>
<thead>
<tr>
<th>Channel</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural¹</td>
<td>8</td>
<td>6,115,161</td>
<td>10</td>
<td>6,424,306</td>
</tr>
<tr>
<td>Mainstream Multi-Outlet⁵</td>
<td>6</td>
<td>35,139,536</td>
<td>11</td>
<td>21,560,716</td>
</tr>
</tbody>
</table>

¹According to SPINS (SPINS does not track Whole Foods Market sales, which is a major natural products retailer in the US)
⁵According 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 and September 3, 2015; K. Kawa (SPINS) e-mail to S. Gafner, July 11, 2016.
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SPE have been published: thin-layer chromatography (TLC),4,17 gas chromatography (GC),20-22 and nuclear magnetic resonance (NMR) profiling.22,23

3.2 Known adulterants: A number of ways to adulterate saw palmetto 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, and the addition of vegetable oils to extracts, and/or full substitution of SPE with other vegetable oils.20,24-26 The closest relative of saw palmetto is Acoelorrhaphe wrightii (common names include everglades palm and silver saw palm). Little and Jeanson (2013) reported that out of 29 commercial dietary supplements (purchased at retail stores in the United States or from the Internet) labeled to contain dry, cut-and-sifted saw palmetto, one contained A. wrightii instead, and another product contained an unidentified adulterant.24 Acoelorrhaphe wrightii grows in the United States, the Bahamas, Cuba, southeastern Mexico, Belize, Guatemala, Honduras, Nicaragua, Colombia, and Costa Rica. Saw palmetto extract adulterated with other plant oils, such as canola (Brassica napus ssp. napus, Brassicaceae) oil, coconut (Cocos nucifera, Arecales) oil, olive (Olea europaea, Oleaceae) oil, palm (Elaeis guineensis, Arecales) oil, peanut (Arachis hypogaea, Fabaceae) oil, and sunflower (Helianthus annuus, Asteraceae) oil has been reported on a number of occasions.25-27 Mikaelian and Sojka20 describe possible methods of such SPE adulteration: Unscrupulous suppliers can dilute the initial SPE with less expensive plant oils; the price of SPE is much higher (US$ 170-200/kg in March 2016; G. Mikaelian [Valensa] e-mail to S. Gafner, March 28, 2016) than that of any commercially-available food-based plant oils. These suppliers use this approach to take advantage of manufacturers that evaluate only the amount of total fatty acids rather than the individual fatty acid composition. Another type of adulteration occurs when the SPE is diluted with a specially formulated blend of lower-cost oils in an attempt to emulate the fatty acid profile found in SPE.

3.3 Sources of information confirming adulteration: Only one paper on adulteration of commercial SPE was located that also provided analytical data on the samples – i.e., the investigation into the authenticity of ten commercial saw palmetto samples from the North American market by by Mikaelian et al.21 Nine of the ten samples in this study were correctly labeled, but one was found to be adulterated with an unidentified vegetable oil based on a different pattern of free fatty acids, and the unusually low content of free fatty acids. Cases of saw palmetto extract adulteration, mainly with olive oil, palm oil, peanut oil, and sunflower oil, have also been reported from quality control departments at reputable suppliers of saw palmetto extract: Euromed (Mollet del Vallès, Spain), Indena (Milan, Italy), and Valensa (Eustis, FL, USA)27,28 (P. Pais [Euromed] e-mail to S. Gafner, April 11, 2016; R. Pace [Indena] e-mail to S. Gafner, April 18,2016; Umasudhan C.P. oral communication, October 31, 2016). Two other publications suggest the dilution of saw palmetto extracts with various vegetable oils is commonly occurring, but the papers do not provide data to support the statements.25,26

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. wrightii24 maybe 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 [S. Foster, e-mail to S. Gafner, December 20, 2016]. The addition of lower-cost vegetable oils to SPEs is for economic gain. For extract manufacturers, the average price for saw palmetto berries in 2015 was $15 per
kilogram for dried material. Considering an extract yield of 10-12% from dried berries, the expected manufacturing costs for a kilogram of saw palmetto extract are between $195-200. 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: No data on the frequency of the occurrence of saw palmetto fruit and extract adulteration are available. 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. 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. 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. seems to indicate 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). 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 conditions in current or immediately prior seasons (see 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 on the market, there is little evidence of adulteration of saw palmetto finished supplements on the market. While there is little evidence of adulteration of saw palmetto finished supplements based on published reports thus far, as shown above (see 3.3) unpublished analyses by reputable suppliers of authentic saw palmetto extract suggests that there is adulterated saw palmetto extract 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. 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. All these monographs describe a TLC method for authentication and quantification of the fatty acids by GC using a flame ionization detector (FID). 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). The EP 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. Phytoequivalence is a term 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 EP monograph requires a minimum content of 23% lauric acid in anhydrous SPE. In addition, saw palmetto extract has a very high acid value which is different from other plant oils; therefore, the acid value range of SPE is specified in the EP. 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 authenticate saw palmetto.

4 Conclusions

Saw palmetto is an important herbal supplement. Saw palmetto extract 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, and NMR) to authenticate saw palmetto have been published. Saw palmetto fruits are generally in abundant supply, although environmental conditions can adversely affect their availability. Therefore, 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 be found in the marketplace. 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 saw palmetto since the plant does not grow there naturally).
5 References
19. Suter A. New perspectives on saw palmetto (Serenoa repens):


