AC APP NONPR Botanical Adulterants Prevention Program BOTANICAL ADULTERANTS PREVENTION BOTANICAL ADULTERANTS PREVENTION CONTRACT ADULTERANTS PREVENTION Adulteration of Maca (Lepidium meyenii)

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Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of maca (*Lepidium meyenii*, Brassicaceae) to the international herbal industry and extended natural products and natural health communities in general.

1. General Information

1.1 Common name: Maca^{1,2}

1.2 Other common names:

- Chinese: Ma ka (玛卡); hei ka (黑卡), or hei ma ka (黑玛 卡) for black maca; huang ka (黄卡), or huang ma ka (黄玛卡) for yellow maca
- French: Maca
- German: Maca
- Italian: Maca
- *Quechua*: Ayakwillku. Other names used in Peru: Maka, maca-maca, maino, ayak, chichira, ayak willku, huto-huto^{3,4}
- Spanish: Maca¹ Swedish: Maca¹

1.3 Accepted Latin binomial: Lepidium meyenii Walp.

1.4 Synonyms: Lepidium peruvianum G.Chacón,¹ Lepidium affine Wedd., Lepidium gelidum Wedd., Lepidium weddellii O.E.Schulz⁴



1.5 Botanical family: Brassicaceae

1.6 Plant part, form and production method:

The Government of Peru has published national technical standards that define the raw material, the processed forms and processing methods:⁵⁻⁷

- NTP 011.180:2011 Dried maca, requirements
- NTP 011.181:2014 Toasted flour of maca requirements
- NTP 011.182:2014 Gelatanized flour of maca requirements

Drafts of Peruvian national standards for three additional processed forms (crude flour, liquor, and nectar) are expected to be published.⁸

Whole hypocotyls and roots are field dried and separated according to size and color. The material is ground and left as is, "raw" or can be "gelatinized" using water, temperature, and pressure, and then further processed into powder. According to one supplier, maca is also offered cut into large pieces for further processing (R. Das [BI Nutraceuticals] email communication, October 17, 2017). Extracts are offered as liquid extracts (hydroethanolic extracts, dry extracts dissolved or suspended in glycerinwater mixtures) or dry extracts plated onto a suitable starch base, such as maltodextrin or acacia gum (*Acacia* *senegal*, Fabaceae). Extracts can be standardized to contain macamides, macaenes, and glucosinolates, although the use of glucosinolates as biomarkers has decreased due to inherent instability and metabolism to isothiocyanates.⁹

1.7 General use(s): As dietary supplement products in the United States, maca products are used to support energy levels, reproductive function, and/or as a nutrient-dense food.^{10,11} As a medicinal ingredient of licensed Natural Health Products (NHPs) in Canada, Health Canada authorizes the following indications for use: (1) Provides antioxidants; (2) Helps to support healthy mood balance during menopause; and (3) Helps to support emotional aspects of sexual health.¹²

2. Market

2.1 Importance in the trade: According to data from the market research company SPINS, maca was the fourth bestselling herbal supplement in the United States natural market channel and was 36th in the mass market in 2016 (Tables 1 and 2).¹³ Maca experienced substantial growth in 2014, 2015, and 2016 in the United States in the natural channel (Table 1). The current decline in retail maca sales in Peru has a direct correlation to escalating raw material prices caused by an infiltration of foreign influ-

ence on the legal trade routes involving illegal export and artificial inflation of a raw material. According to data supplied by Sunat, the Peruvian tax agency, in the first nine months of 2015, Peru exported 752,351 kg of dried maca root powder. The total 2014 export volume was 1,831,984 kg. Main export destinations for Peruvian maca (during a nine-month period of Jan-Sept 2015), in terms of FOB (free on board) value, include the United States (38%), Canada (7%), People's Republic of China (7%), Hong Kong Special Administrative Region (SAR) (3%), and Japan (7%), leaving 38% unaccounted for, possibly due to illegal exportation.

2.2 Supply sources: Maca is indigenous to an area of the high Andean mountains of South America. While its original growing range is not known, it is believed that it spanned a much larger geographical area than the locations where it is currently cultivated.¹⁴ Maca is now grown in three primary Provinces in central Peru, adjacent to Lima in the Andes mountains: Junin, Pasco, and Huancayo at altitudes between approximately 3500 and 4500 meters (11,483 – 14,764 ft.).^{8,14,15} In addition, smaller amounts of maca are grown in the adjacent Provinces. Junin is the best-known cultivation area and has the most farmers. Maca that is cultivated in specified areas within the Junin and Pasco provinces has been protected by the World Intel-

| Natural Channel Maca | 2013ª | 2014ª | 2015 ^b | 2016 ^b | 2017 ^c | |
|-------------------------|-----------|-----------|-------------------|-------------------|-------------------|--|
| Sales | 6,066,809 | 7,077,409 | 8,224,352 | 8,824,679 | 8,741,619 | |
| Year over year growth % | | 17% | 16% | 7% | -1% | |
| Delivery Format | 2013ª | 2014ª | 2015 ^b | 2016 ^b | 2017¢ | |
| Powder | 3,034,249 | 3,871,898 | 4,185,608 | 4,595,139 | 4,332,762 | |
| Capsule/Tablet | 2,822,604 | 2,961,626 | 3,407,055 | 3,504,330 | 3,610,393 | |
| Liquid | 199,117 | 216,895 | 211,686 | 201,704 | 215,127 | |
| Unspecified | 10,840 | 26,990 | 420,002 | 523,404 | 583,336 | |

Table 1. Maca dietary supplement sales in the United States (natural channel; sales in US\$)

^aSPINS scan data Natural channel- herbal formulas and singles 52 weeks ending December 2014 and 2015, respectively ^bSPINS scan data Natural channel herbal formulas and singles 52 weeks ending January 2016 and 2017, respectively ^cSPINS scan data Natural channel herbal formulas and singles 52 weeks ending February 25, 2018

Table 2. Maca dietary supplement sales in the United States (mass market; sales in US\$)

| | 2013 | 2014 | | 2015 | | 2016 | | 2017 | |
|------|-----------|------|-----------|------|-----------|------|-----------|------|-----------|
| Rank | Sales |
| 35 | 4,844,103 | 30 | 6,650,181 | 30 | 7,194,683 | 36 | 6,251,160 | 36 | 6,250,846 |

Sales data according to SPINS/IRI, exclusive of possible sales at big-box stores, e.g., Walmart and Costco, and outlets with no scanning capabilities (small retailers, health professionals). Also not included are direct sales through the internet, and sales from multilevel marketing. Sources: Smith et al. 2017.¹³ T. Smith (American Botanical Council) email to S. Gafner, September 2, 2015, September 3, 2015, and June 19, 2018. K. Kawa (SPINS) email to S. Gafner, July 11, 2016.

lectual Property Organization (WIPO) as an "Appellation of Origin", recognizing the unique characteristics of maca grown in these regions. The production around the city of Huancayo and Huancavelica Province have less maca and suppliers indicated it was of lesser quality, even though the two regions have adequate elevation, soil, and climate for growing maca. Suppliers estimated that over 70% of the maca in Peru is grown in Junin Province. While most sources of maca raw materials are in Peru, there are some other countries of origin that export small amounts of maca material, e.g., Ecuador and Bolivia. China had a substantial impact on the supply and demand logistics of this botanical in the summer of 2014 when Chinese merchants invested large amounts of human resources and capital in buying maca at unprecedentedly high levels from Peru.¹⁶ Maca's importance to Peruvian culture and economy cannot be overstated. In October of 2010 Peru joined in the ratification of the Nagoya Protocol. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. The United States and China did not enter into this agreement.

2.3 Raw material forms: The export of maca is regulated by the Peruvian Government through an Executive Order (Decreto Supremo N. 039-2003-AG), which regulates and oversees the prohibition of commercializing and exporting of seeds, botanicals, and vegetables in their natural "fresh-raw" state. This decree was created to protect products like maca and help prevent illegal exports, since the objective for the State of Peru is to keep its "Product from Peru" origin meaningful and intact. The only way maca can be exported from Peru is as dried maca, toasted flour of maca, or gelatinized flour of maca.5-7 The Ministry of Agriculture presented the decree and enforcement is handled by the National Superintendency of Tax Administration (SUNAT) within Peru. The decree ensures that tax dollars are collected, export statistics can be calculated, and that the raw material is being exported legally, in addition to protecting the seed as a resource unique to the Peruvian Andes.

2.4 Market dynamics: The following excerpt is from a report to Gaia Herbs executive team in August of 2014 regarding a "market takeover" by Chinese buyers that caused prices to elevate beyond normal ranges starting in the early summer of 2014 (Table 3).

"The three main issues driving this situation as related by corroborating details from all suppliers we met with are as follows:

- 1. Chinese traders are paying the farmers cash, approximately \$20/Kg for whole sundried mixed maca, and up to \$30/Kg for whole sundried black maca. In a cash sale the farmers avoid taxation. Any sale of goods over \$1,000 in Peru requires a bank transaction, invoice and documentation.
- 2. Chinese traders are smuggling whole sundried root out of Peru into Bolivia and Ecuador for export to China.
- 3. Chinese traders are exporting Maca Seed for cultivation in the Yunnan Province.

It is estimated that Chinese traders had already exported or smuggled 25% of the 2014 maca crop in the first available months of July/August. All suppliers indicated that the 2014 crop would be gone by the end of the year. Suppliers have also indicated that decreasing supply will continue to drive the price of material up from this point forward. Suppliers have changed their sales terms to "cash in advance", in order to be able to afford to buy from their farmers and to secure their customers' material at these higher prices. All Peruvian suppliers have indicated that there are no guarantees that the farmers will sell to them, as opposed to the Chinese traders, as long as supplies last, and that many of their farmers have already cancelled preexisting contracts."

One strategy attempted by US buyers was to educate the farmers on the lure of "quick cash" in trade for a longstanding sustainable price that all parties could continue supporting, right through to the consumer. These efforts did not fully materialize as the high price paid to these farmers was promised in future years by the Chinese, which did not happen. The result was that three to four times as much maca was planted in anticipation of high cash, but in 2015 the influence had waned, and the Chinese traders, for

| | 2013 | | | 2014 | | | 2015 | | |
|-----------|---------------------------|---------|----------------------------|---------------------------|---------|----------------------------|------------------------|---------|----------------------------|
| Month | FOB Value ^b | Kilos | Avg. Price ^c | FOB Value ^b | Kilos | Avg. Price ^c | FOB Value ^b | Kilos | Avg. Price ^c |
| September | 871,199 | 115,510 | 7.54 | 2,756,656 | 200,577 | 13.74 | 2,169,287 | 110,945 | 19.55 |

Table 3. Fluctuation in price of legally exported maca from Peru^a

^aOne factor making analysis difficult is the unknown amounts of illegally exported material during the years 2014-2016. ^bFOB value in USD

^cAvg. Price: average price in USD/kg

Data taken from: Koo W. Maca Harina Perú Exportación Septiembre 2015. AgroDataPeru.¹⁷

whatever reason, did not return to fulfill their promises. It was only after the sharp decline in price caused by an excess supply created by the artificial demand by the Chinese traders that the farmers began to agree to a standard pricing structure that all parties agreed was sustainable. The decline in maca raw material costs after 2015 may have lowered the incentive for economically motivated adulteration of maca.

3. Adulteration

3.1 Background about extract/product: Maca is a food source for native Peruvians living in the central Andes. The dried, stone-hard hypocotyl is typically boiled to obtain a soft product consumed as juice and/or eaten.^{10,11} The hypocotyl is a rich nutrient source of protein (~10%), carbohydrates (~59%), fats (~2%), fiber (~9%), as well as minerals (calcium, iron, copper, zinc, and potassium). Several interesting secondary metabolites have been isolated from maca hypocotyls, such as macamides, macaenes, and glucosinolates.¹⁰ As a dietary supplement, maca is consumed as powder (raw or gelatinized), an ethanol-based extract, or a powdered extract. A number of analytical methods for the authentication of maca can be found in the literature, such as genetic methods, near infrared spectroscopy (NIR), Fourier transform infrared spectroscopy (FTIR), thin-layer chromatography (TLC), gas chromatography with mass spectrometry (GC/MS), liquid chromatography coupled with UV detection and/or mass spectrometry (HPLC/UV, UHPLC/ESI/Orbitrap-MS, UHPLC/ESI/QqQ-MS and HPLC/UV/MSⁿ), as well as flow injection mass spectrometry (FIMS).18-32

3.2 Known adulterants: Reports of maca adulteration have involved substitution of maca powder with wheat (*Triticum* spp., Poaceae) flour or yam (*Dioscorea* spp., Dioscoreaceae), spiking supplements with synthetic phosphodiesterase type 5 (PDE5) inhibitors (active pharmaceutical ingredients to treat erectile dysfunction, in which case the resultant product is an illegal pharmaceutical drug masquerading as maca, whether it actually contrains any maca material or not), or maca extracts being represented as maca root powder (see section below).^{8,18-20,33} Other articles found in the literature make cases for potential adulteration, such as substitution with other root crops (see below) and the ability to easily synthesize bioactive marker compounds used in the quality control of maca ingredients and formulations.²¹⁻²³

3.3 Sources of information supporting confirmation of adulteration: Maca has grown in popularity as a dietary supplement, and together with its use as a sexual enhancement product, it has the potential for adulteration. Hajdu et al. reported that out of 14 maca products tested, six did not contain any detectable amount of the marker compound, *N*-benzyl-(9Z,12Z)-octadecadienamide, and one of the six outlying products tested positive for the presence of the synthetic PDE5 inhibitor thiosildenafil.¹⁸ In all six cases, the formulations were multicomponent preparations packaged in a capsule, ampule, or spray delivery system.¹⁸ A separate incident of maca adulteration with a PDE5 inhibitor occurred in a maca supplement. Huang et al. reported a new sildenafil analogue, desethylcarbode-nafil, in a multicomponent maca formula.¹⁹ An incident of powdered extract being sold as powdered root material was discovered in 2014. A large shipment of maca "root powder" from a Chinese commercial source was found to contain many of the naturally occurring secondary metabolites as compared to validated botanical reference material; however, no maca DNA was detected, and the only viable DNA present belonged to corn (*Zea mays*, Poaceae) and an unidentified plant material in the family Asteraceae. Direct contact with the supplier by the manufacturer led to the conclusion that the material was an extract of maca on corn starch.²⁰

Zhao et al. evaluated the authenticity of 31 commercial maca products (root powder only, no extracts) from the US market by proton nuclear magnetic resonance (¹H NMR) and subsequent multivariate statistical analysis. The authors stated that "for all the 31 investigated products, we could confirm one was adulterated. Many others (8-10) were suspected." One of the adulterated products did not provide any meaningful signals in the ¹H NMR spectrum, suggesting that this product may have contained predominantly inert materials.²⁴

Several papers describe the *potential* for maca to be adulterated with other root crops, such as turnip (*Brassica rapa*, Brassicaceae), radish (*Raphanus sativus*, Brassicaceae), potatoes (*Solanum tuberosum*, Solanaceae), corn (*Zea mays*, Poaceae), or yam. As of yet, the reports of maca adulteration by one of these crops is the alleged substitution with yam, and the incident described above regarding the powdered extract using corn starch.^{20-22,33} Adulteration with wheat flour has been described by Hermann and Bernett.⁸

Another issue is non-Peruvian-grown maca being masqueraded as Peruvian-grown maca.³⁴ A significant price difference between Chinese-grown and Peruvian-grown maca has been reported in China (E. Brand, email communication, February 18, 2016). Price discrepancies set the stage for mislabeling and/or economically motivated adulteration. ²⁵⁻²⁷

Another potential for adulteration is spiking maca extracts with synthetically produced macamides, which are alkylamides characteristic of maca. Maca extracts standardized to macamides are being sold commercially, and the synthesis of macamides has been reported.²³ In 2005, McCollom et al. described a one-step synthesis for producing several macamides, including the main macamide, N-benzyl-hexadecanamide, as well as N-benzyl-(9Z)-octadecenamide, N-benzyl-(9Z,12Z)-octadecadienamide, and N-benzyloctadeca-namide.²³ The reagents and reactants for the syntheses of these macamides are commercially-available, fairly inexpensive, and the reactions give yields >85%.23 The occurrence of spiking herbal extracts with synthetic or exogenously produced biomarkers, such as with ginkgo (Ginkgo biloba, Ginkgoaceae) leaf extract, saw palmetto (Serenoa repens, Arecaceae) berry extract, and turmeric (Curcuma longa, Zingiberaceae) rhizome extract, to name only a few,

has already been observed in the dietary supplement industry, and the situation with maca is very similar.³⁵⁻⁴⁰

3.4 Accidental or intentional adulteration: The maca market has created an incentive for economically motivated adulteration, and multiple possibilities for intentional adulteration have been described in previous sections. An article published by Meissner et al. provided phytochemical evidence supporting a claim made by Chacón in 2001 that two distinct species of *Lepidium* exist in Peru, *L. meyenii* and *L. peruvianum*.^{28,29} Chacón's report describes *L. meyenii* as wild-type maca and *L. peruvianum* as cultivated maca that has the long traditional use associated with Incan culture.²⁸ If such is the case, then accidental mixing between these two species would be likely.

3.5 Frequency of occurrence: There are few data on the extent of adulteration found in commercially available maca ingredients and supplements. As noted above, one study analyzed 31 maca root products purchased from a major US retailer and found one clear case of adulteration, with the sample being mostly inert ingredient(s).²⁴ Another study included results of 14 commercial maca products assayed for the quality indicating marker compound N-benzyl-(9Z,12Z)-octadecadienamide, as well as PDE5 inhibitors. The dosage formats included in the study represented maca powder (raw and gelatinized), tablets, capsules, and one spray; with nine of the 14 samples representing multicomponent formulas and five representing single maca. Eight of the multicomponent formulas were found to contain little or no detectable amount of N-benzyl-(9Z,12Z)-octadecadienamide, and one of the eight tested positive for thiosildenafil.¹⁸ A similar study found a sildenafil analogue, desethylcarbodenafil, in a multicomponent maca formula.¹⁵ A multitude of media reports and articles

from 2014-2015, when maca prices were skyrocketing, suggested a high potential for intentionally selling Chinese-grown maca as Peruvian-grown material. The lack of studies to date has less to do with interest and more to do with the dearth of methods capable of determining the geographical origin. The importance of the subject matter is evidenced by published methods starting to emerge in the literature.²⁵⁻²⁷

3.6 Possible therapeutic issues: In two reported cases, maca supplements were shown to be adulterated by PDE5 inhibitors, which are a specific class of conventional drugs for treating erectile dysfunction.^{18,19} The most common adverse side effects for PDE5 inhibitors include headaches and cutaneous flushing, both of which are related to vascular dilation, as well as visual disturbances, due to partial PDE6 activity.^{30,31} PDE5 drugs are contraindicated for individuals taking organic nitrates, such as nitroglycerin, and concomitant use can cause a significant decrease in blood pressure.³²

3.7 Analytical methods to detect adulteration: To date, there are no compendial methods for qualifying maca. However, a number of analytical methods have been published in the peer-reviewed literature. Ganzera et al. developed and validated a HPLC-UV method to quantify two macamides and three macaenes in maca raw materials.⁴¹ McCollom et al. described a method using HPLC-UV-MS/MS for characterizing and quantifying macamides in maca root material from different sources and provided a simple procedure for synthesizing the macamide, N-benzylhexadecanamide, for use as an external standard.²³ However, neither of these two methods were evaluated for their appropriateness to detect adulteration. The two reports of PDE5 inhibitor adulteration in maca supplements used a combination of either TLC and HPLC-DAD or TLC, GC-MS, and LC-MS/MS.18,19 The report of a maca powder extract's being represented as maca root powder was discovered using DNA, principal component analysis (PCA) UV-VIS, and HPLC-UV.20 A combination of FTIR, TLC, and GC-MS was able to distinguish maca, radish, Asian ginseng (Panax ginseng, Araliaceae) root, and American ginseng (P. quinquefolius) root, and a DNA barcoding approach using the ITS sequence could discriminate turnips, radishes, potatoes, corn, and 15 Lepidium species, including maca.21,22

Several recent papers provide methods for establishing the origin of maca. Zhou et al. were able to correlate higher concentrations of glucosinolates and β -carboline alkaloids in maca samples from Peru versus China utilizing UHPLC-



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ESI-Orbitrap-MS and UHPLC-ESI-QqQ-MS.²⁵ A chemometric technique using data from flow injection MS has been described by Harnly et al. that allows for the separation of Peruvian- and Chinese-grown maca, and Wang et al. employed chemometrics with NIR diffuse reflectance data to differentiate Peruvian-grown maca from Chinese-grown maca.^{26,27} Meissner et al. used HPLC-DAD and DNA to distinguish three phenotypes of maca; yellow, red, and black, and in a later report, used hypocotyl weight and the concentrations of glucosinolates, as determined by HPLC-UV, to discriminate four phenotypes, yellow, red, purple, and black, grown in two geographical regions in Peru.⁴²⁻⁴³

4. Conclusions

Maca is an important herbal supplement as evidenced by continued sales growth in the United States and China over several years (Tables 1 and 2). Multiple analytical methods have been described and allow for the quality control of maca, including adulteration detection. The common theme to successfully detecting adulteration in maca supplements appears to be a reliance on orthogonal techniques, including a screening for the potential presence of undisclosed conventional medications, specifically erectile dysfunction drugs such as PDE5 inhibitors, in extracts of unknown origin. At the time of publication of this document, maca is in relatively good supply and prices have stabilized; however, the recent history has demonstrated wide fluctuations in the pricing of this crop, which creates situations ripe for economically-motivated adulteration.

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REVISION SUMMARY

| Version # , Author, | Date Revised | Section Revised | List of Changes |
|-----------------------------------|--------------|-----------------|-----------------|
| Version 1, J. Stewart, B. Chioffi | n/a | n/a | none |
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