BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HOMELAND SECURITY

CUSTOMS AND BORDER PROTECTION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

PROPOSED REVOCATION OF THREE RULING LETTERS, MODIFICATION OF TWO RULING LETTERS AND REVOCATION OF TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF BILBERRY AND BLUEBERRY EXTRACT POWDERS

January 22, 2016

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Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On December 23, 2015, the U.S. Customs and Border Protection, Department of Homeland security issued notice of proposed revocation of three ruling letters, modification of two ruling letters and the revocation of treatment relating to the tariff classification of Bilberry and Blueberry Extract Powders ("the December 23rd Notice").

Numerous AHPA members would be affected by the proposed change in HTUS classification for bilberry and blueberry. AHPA therefore hereby submits these comments regarding the proposed change. After review of existing definitions of the word "extract" and review and discussion of relevant CBP Ruling precedents, AHPA has analyzed the reasoning behind the proposals in CBP's December 23rd Notice. On the basis of that analysis, AHPA opposes CBP's proposals in the December 23rd Notice.

1. Established meanings of the word "Extract"

In 1993, Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act[1] ("Title VI") of 1993 introduced two new concepts to Customs law, "informed compliance" and "shared responsibility." CBP says, "These concepts are premised on the idea that in order to maximize voluntary compliance with customs laws and regulations, the trade community needs to be clearly and completely informed of its legal obligations. Accordingly, the law imposes a greater obligation on CBP to provide the public with improved information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other information necessary to enable CBP to properly

[1] Pub. L. 103–182, 107 Stat. 2057.

assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met."[2]

Clear communication is essential to properly inform the regulated industry and for CBP and industry to properly share responsibilities, the two parties must communicate clearly. And in order to communicate clearly, CBP and industry must use a common language. In particular, it is essential that basic terminology be used in the same manner on both sides.

Specifically, the word "Extract" is understood by industry to mean a multicomponent mixture derived from treating botanical biomass with solvent. Various procedures may be used either to prepare the biomass for extraction or to concentrate, adjust, or otherwise modify the material after initial extraction without removing the product from the category of what is generally known as an "extract."

For example, Chapter <565> "Botanical Extracts" in the United States Pharmacopeia-National Formulary (USP-NF) describes extracts as follows: [3]

> "In the extraction practice for articles of botanical origin, the constituents of interest are completely or partially separated from other components with the aid of water, alcohol, alcohol-water mixtures, or other suitable solvents. This extraction process involves the removal of the desired constituents from the plant matter with suitable menstrua, the evaporation of all or nearly all of the solvent, and the adjustment of the residual fluids, masses, or powders to the prescribed standards. Suitable inert substances may be added as carriers or diluents to improve physical characteristics. Suitable antimicrobials and other preservatives may be added to preserve the integrity. *Extracts may be subjected to processes that increase the content of characterized constituents, decrease the content of unwanted constituents, or both.* [Emphasis added.] Extracts with no added inert substances and no processing beyond the extraction are called native extracts. In some preparations, the plant matter may be pretreated by inactivation of enzymes and microbial contaminants, grinding, defatting, or a similar procedure."

AHPA notes that CBP often cites the USP-NF along with Remington's Pharmaceutical Sciences (Remington's) in its Rulings (see for example HQ H121546 (2015), HQ H061203 (2010), HQ 966566 (2003)). These Rulings state that according to these references, extracts are made by "percolation, maceration, digestion, or infusion," and then treat these processes as the only manufacturing steps that

[2] Customs Bulletin and Decisions, Vol. 49, No. 51, December 23, 2015, p. 61.

[3] USP 38-NF33 S2, accessed 01/17/2016.

may legitimately be included in the production of an "extract." This is factually incorrect. As noted above, USP-NF Chapter <565> explicitly provides that extracts may be further processed after initial extraction. Remington's likewise provides that extracts "are obtained by removal of the active constituents…with suitable menstrua, evaporation of all or nearly all of the solvent, and *adjustment of the residual masses or powders to the prescribed standards.*" [Emphasis added.]

This point is reinforced by consideration of the USP-NF monographs themselves, which use the word "extract" to describe a wide variety of botanical preparations that consist of, or are enriched in, particular constituents. These include, for example:[4]

- Saw Palmetto Extract is obtained from comminuted Saw Palmetto by extraction with hydroalcoholic mixtures or solvent hexane, or by supercritical extraction with carbon dioxide. The ratio of starting crude plant material to Extract is from 8.0: 1 to 14.3: 1. The Extract contains NLT 80.0% of fatty acids, NLT 0.2% of sterols, and NLT 0.1% of β-sitosterol, all on the anhydrous basis….
- Powdered Bilberry Extract is prepared from the ripe fruits of Vaccinium myrtillus L. (Fam. Ericaceae) using suitable solvents such as alcohol, methanol, or water or mixtures of these solvents. The ratio of the starting plant material to Powdered Extract is between 153:1 and 76:1. It contains NLT 36.0% of anthocyanosides, calculated as cyanidin-3-O-glucoside chloride, and NMT 1.0% of anthocyanidins, calculated as cyanidin chloride; both are calculated on the anhydrous basis.
- Powdered Decaffeinated Green Tea Extract is prepared from the young, unfermented leaf and leaf buds of Camellia sinensis (L.) Kuntze (Fam. Theaceae), also known as Thea sinensis L., using suitable solvents such as alcohol, methanol, acetone, or water or mixtures of these solvents; the caffeine has been removed. The ratio of the starting crude plant material to Powdered Extract is 6:1–10:1. It contains NLT 60.0% of polyphenols, calculated as (–)-epigallocatechin-3-O-gallate, NLT 40.0% of (–)-epigallocatechin-3-O-gallate, and NMT 0.1% of caffeine, calculated on the anhydrous basis.
- Maritime Pine Extract is prepared from the pulverized Maritime Pine using suitable solvents. It contains NLT 65% and NMT 75% of procyanidins, calculated on the dried basis.

[4] AHPA cites these examples from USP-NF only to demonstrate that the word "extract" applies to various commodities that consist of, or are highly enriched in, particular targeted constituents. To AHPA's knowledge, such extracts are commonly made through use of sophisticated manufacturing processes, such as column chromatography, whether or not such processes are specified in the monograph description. AHPA is aware of many other versions of extracts which are made from these botanicals but which do not meet the USP-NF monograph; AHPA does not mean to imply that such non-USP/NF-grade extracts would not similarly qualify to be categorized as "extracts." It is AHPA's experience that all such materials are in fact "extracts" according to common usage of the word.

- Aztec Marigold Zeaxanthin Extract is a purified extract, derived from the flowers of Tagetes erecta L., grown from seeds of varieties of the Scarletade cultivar rich in zeaxanthin. The extract contains NLT 36.0% of total carotenoids calculated as zeaxanthin (C40H56O2), NLT 30.0% of all-trans-zeaxanthin, and NMT 8.0% of lutein, calculated on the dried basis.

AHPA itself has published documents relevant to this point. Toward the end of the last century, AHPA convened a Botanical Extracts Committee to create guidance documents and white papers for use by U.S. industry, discussing various aspects of commercial practice related to botanical extracts. The participants were experts with knowledge of the botanical products industries in the U.S., European Union, China, India, and elsewhere. The Committee eventually produced a number of documents, including "Guidance for the Manufacture and Sale of Botanical Extracts" (2001) and "Standardization of Botanical Products: White Paper" (2003).[5]

The first of these documents defines "extract" as follows:[6]

> "Extract: The complex, multicomponent mixture obtained after using a solvent to dissolve components of the biomass. Extracts may be in dry, liquid, or semisolid form. Excipients may be added to extracts in order to adjust the concentration; enhance stability; limit microbial growth; and to improve drying, flow, or other manufacturing characteristics. Extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents."

While this definition, unlike the USP-NF chapter, does not explicitly state that extracts may be further processed to concentrate or remove certain constituents and yet still remain "extracts," this idea is made explicit elsewhere in the committee's work. For example, "Guidance for the Manufacture and Sale of Botanical Extracts" describes a number of purification steps that may be used during manufacture of a botanical extract, including various types of chromatography. Furthermore, the white paper "Standardization of Botanical Products" includes the following definition:[7]

[5] Available at ahpa.org.

[6] "Guidance for the Manufacture and Sale of Botanical Extracts," The American Herbal Products Association, 2001, p. 4.

[7] "Standardization of Botanical Products: White Paper," The American Herbal Products Association, 2003, p. 30.

> "Semi-Purified Extract: An extract containing only a narrow range of the native constituents from the plant, which is made by partially purifying the desired components from an initially broader spectrum extract."

Thus, to AHPA's knowledge, the word "extract" is used the world over to refer to chemical mixtures derived from a botanical using solvent, including mixtures that have been purified or enriched – even highly enriched - in particular constituents.

AHPA believes that CBP's use of the word "extract" in a manner largely inconsistent with common usage of the word undermines CBP's legal mandate under Title IV to ensure the trade community is properly "informed" and able to properly "share responsibility" with CBP. CBP's non-standard word usage inevitably causes confusion and increased errors by industry, because most members of the regulated industry naturally assume that English words are used according to their plain, common sense meanings. Only in edge cases (e.g., a botanical constituent purified to nearly 100% purity) is an importer likely to wonder whether CBP will consider the imported goods to be an "extract."

Furthermore, as CBP acknowledges in HQ H237599 (2015), where a term is not defined in the Nomeclature, section notes, or chapter notes, it must be construed in accordance with its common meaning. *Mita Copystar Am. v. United States*, 21 F.3d 1079, 1082 (Fed. Cir. 1994). The word "extract" is not defined in the Nomenclature, section notes, or chapter notes, and therefore CBP is legally bound to use the common meaning of the word. As described above, the word "extract" is commonly understood to include extracts that have been subject to various purification processes, including a high degree of enrichment.

AHPA therefore urges CBP to ensure its use of the word "extract" mirrors established usage as closely as possible, and to include in the category "extracts"those materials that have been further processed after the initial solvent-based extraction step, including when such processing results in purification or enrichment of certain categories of constituents.

2. Review of CBP Ruling precedents

CBP is required to classify imported merchandise according to the General Rules of Interpretation (GRIs) and the Additional U.S. Rules of Interpretation, both of which are considered for all purposes as statutory provisions of law. Botanical extracts have long been classified under heading 1302 of the Harmonized Tariff Schedule of the United States (HTSUS), provided they are not specified or included in more specific headings of the Nomenclature (e.g., coffee, extracts constituting alcoholic beverages, extracts used for tanning or dyeing, etc.). A list of such exclusions occurs in the prefatory Note to

Chapter 13 of the HTSUS. Notably, none of the listed exclusions provides circumstances under which a botanical extract is to be classified under heading 3824.

Most commonly, botanical extracts have been classified under subheading 1302.19.91, HTSUS, which provides for "Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products: Vegetable saps and extracts: Other: Other." In a few cases, botanical extracts have been classified under subheading 1302.19.40, HTSUS, which provides for "Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products: Other: Ginseng; substances having anesthetic, prophylactic or therapeutic properties: Other." There are also a few heading 1302 subheadings that apply to specific individual extracts (ginseng, opium, licorice, etc.).

Such classifications in heading 1302 are supported by a long line of CBP Rulings dating back at least to the 1990's.[8]

In the 2000's, however, CBP began to classify certain botanical preparations into Chapter 38, especially heading 3824, "Prepared binders for foundry molds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included."[9]

CBP's practice has not been entirely consistent in this area, but as a general rule there have been two criteria needed to move a botanical preparation out of heading 1302 and into heading 3824: (1) the manufacturing process included various steps other than "percolation, maceration, digestion, or infusion," *and* (2) the final product consisted of one constituent or group of chemically similar constituents concentrated to a very high degree. Examples include:

- HQ 966566 (2003): classifying in heading 3824 pine bark extract and grape seed extract containing 90 and 95% oligomeric proanthocyanidins (OPCs) and made using a complex, sophisticated manufacturing process.

[8] Based on searches of the Customs Rulings Online Search System, accessed most recently on 01/22/2016.

[9] A few extracts were classified in Chapter 38 prior to the year 2000, but to AHPA's knowledge this occurred only in cases where the extract was mixed with other ingredients such as potassium sorbate or soy phospholipids.

- NY N036655 (2004): classifying in heading 3824 a pine bark extract containing more than 96% polyphenols. The Ruling does not discuss the nature of the manufacturing process in any detail but appears to assume that extensive processing has occurred.

- HQ W967214 (2006, reaffirming NY K84522, 2004), classifying in heading 3824 purified lo han guo fruit juice containing 80% mogroside and made using a complex, sophisticated manufacturing process that includes use of ion exchange resin.

- HQ W968424 (2006): classifying in heading 3824 pine bark extract containing 76-87% procyanidins plus 10-15% other flavonoids and made using a complex, sophisticated manufacturing process that includes use of ultra-filtration and/or reverse osmosis to fractionate the dissolved components by molecular size and shape.

- NY N046672 (2009): classifying in heading 3824 a lo han fruit extract containing 80% mogroside. The Ruling does not discuss the nature of the manufacturing process in any detail but appears to assume that extensive processing has occurred.

- HQ H056377 (2010): classifying in heading 3824 a grape pomace extract containing up to 90% polyphenols (depending on the analytical method used) and made with a manufacturing process that "is more complex than those discussed in the ENs, and appears designed to specifically target the polyphenol compounds in the grape pomace source material."

In contrast, goods produced using manufacturing processes CBP deems to be less sophisticated, and/or which contain lower levels of constituents, have generally remained classified in heading 1302. Examples include:

- HQ 964139 (2002): classifying in heading 1302 a bilberry extract made with a sophisticated manufacturing process, including the use of column separation, and containing 25% anthocyanides.

- HQ 963848 (2002): classifying in heading 1302 a pyrethrum extract containing 50% pyrethrin and made using solvent partitioning.

- HQ W967653 (2008): classifying in heading 1302 a pine bark extract containing 41% to 60-75% procyanidins (depending on the lab performing the test) and made using an extraction process that the Ruling describes only as "solvent based."

- HQ W968370 (2008): classifying in heading 1302 a pine bark extract containing 40% OPCs and 60-75% procyanidins, and made using an extraction process that the Ruling describes as "water extraction" and "solvent based," such that the process "leaves intact a variety of naturally occurring phenolic and polyphenolic compounds and their derivatives as well as non-flavonol components."

- NY N219927 (2012): classifying in heading 1302 a bilberry fruit extract containing 70% phenols and 38% flavanoids [sic] and which is made using "absorption by resin."

- HQ H121546 (2015): classifying in heading 1302 a grape seed extract containing 60% OPCs and 20% other polyphenols, for which the extraction process "involves four main steps: extraction with water (separation of the substance/compound from the seed), solid/liquid separation by filtration, purification by (dissolution in) ethyl acetate, and evaporation of the ethyl acetate by vacuum and spray-drying" and is thus what CBP deems to be a "solvent extraction method…[that is] less complex than extraction techniques such as reverse osmosis or column chromatography."

AHPA is aware of only two pre-2015 Rulings inconsistent with the examples above. In these Rulings, imported materials were classified in heading 3824 on the basis of being made using a complex, sophisticated manufacturing process – in particular, via use of column chromatography – despite the fact that the resulting material does not consist primarily of a single pure or nearly pure constituent or group of chemically similar constituents. These Rulings are:

- NY L86773 (2005): classifying in heading 3824 a bitter melon extract containing 15% charantin and made using a complex, sophisticated manufacturing process that includes "chromatographic processing (i.e., adsorption of the filtrate by an adsorption resin, elution by grain alcohol, and collection of the 'useful part')."

- HQ H061203 (2010): classifying in heading 3824 a rosemary extract containing 4-4.5% rosemarinic acid and made using a complex, sophisticated manufacturing process that includes use of an adsorption column.

In 2015, CBP began to issue Rulings similar to the two described above in that imported goods are classified in heading 3824, rather than 1302, despite the fact they do not consist primarily of a single pure or nearly pure constituent or group of chemically similar constituents. These Rulings held in essence that use of column chromatography in the manufacturing process and/or the purported fact of a high degree of enrichment compared to other extracts of the same botanical were sufficient to

preclude classification in heading 1302. There have been two such Rulings to date of which AHPA is aware:

- HQ H237599 (2015): classifying in heading 3824 a bergamot extract powder. This material was variously characterized in the Ruling as having "an active ingredient strength of 39.50% derived in part from 9.4% total neoeriocitrin content, 8.4% total naringin content, 10.7% total neohesperidin content, 1.5% total melitidine content, and 3.0% total bruteridine content"; containing "25% total bioflavonoids, of which 23% is neoeriocetrin (i.e., 5.75% of product), 25% is naringin (i.e., 6.25% of product), and 29% is neohesperidin (7.25% of product), and equating this 25% bioflavonoid content to 25% active strength"; and comprised "16.22% of polyphenols (although the actual polyphenol content may be as high as 40% due to overlap with other compounds), 33.90% of bioflavonoids (including 9.32% neoeriocitrin, 12.42% naringin, and 12.16% neohesperidin), and of a number of other compounds, including flavor and fragrance compounds, essential oils, fatty acids, and sugars." The manufacturing process for the material includes a number of steps, among them "selective chromatographic absorption by membrane separation." The Ruling states that "an orange extract referenced by the lab contains 0.025% hesperidin, while a grapefruit extract contains 0.042% naringin."

- HQ H238484 (2015): classifying in heading 3824 four types of citrus extracts. These extracts were described as: (a) containing "48.91 percent hesperidin, 13.93 percent polyphenols, 6.74 percent protein, 1.17 percent citric acid, and 4.62 percent ash…[along with] numerous natural compounds…including fatty acids, quinic acid, oleamide, beta sitosterol, and naringenin, all of which collectively comprise 25% of the product"; (b) containing "12.83 percent hesperidin, 10.83 percent crude fiber, 6.29 percent polyphenols, 2.61 percent citric acid, 0.31 percent extractable fat, 10.79 percent total sugars, of which 4.03 percent is fructose, 2.50 percent is glucose, 3.33 percent is sucrose, and 0.93 percent is maltose, and 5.14 percent ash…[along with] 41 percent of various naturally-occurring compounds, which include ten different flavor and fragrance compounds and the essential oil limonene, as well as fatty acids, organic acids, and beta sitosterol…"; (c) containing "56.95 percent eriocitrin, 33.33 percent protein, 22.68 percent polyphenols, 10.91 percent citric acid, and 8.37 percent ash…[along with]…various natural compounds…including twelve different flavor and fragrance compounds and the essential oils limonene, terpinene, terpineol, and terpin hydrate, as well as levoglucosenone, sugar-related compounds, naringenin, hesperidin, eriodictyol, and claposporide A"; and (d) containing "61 percent total flavonoids, 14.55 percent total polyphenols, 0.77 percent protein, 0.16 percent citric acid, 0.38 percent ash, and less than 1 percent starch or dextrin….[with the]PMF [polymethoxylated flavone] content [consisting] of naringin, hesperidin, tangeretin, and nobiletin." The extracts are made using a variety of sophisticated manufacturing processes,

including in at least one case the use of a resin-filled column (the Ruling cites some discrepancies between various versions of the manufacturing processes submitted by the Protestant so it is unclear whether columns are used in the other cases). The Ruling states that "a simple orange extract typically contains 0.025 percent hesperidin."

3. Discussion of the CBP Ruling precedents

AHPA agrees with many of the CBP Ruling precedents, especially the earlier ones, and disagrees with some of the Rulings, especially the later ones.

As an initial matter, AHPA notes that heading 3824, which provides for "other" chemical products and preparations, can only be used to classify a mixture of natural products as such if the product is not provided for in another heading of the HTSUS, because heading 3824 is a residual heading. *See Cargill, Inc. v. United States*, 318 F. Supp. 2d 1279, 1278-88 (Ct. Int'l. Trade 2004) (characterizing heading 3824 as a basket provision). Therefore, if it is determined that the merchandise is described by the terms of heading 1302 then heading 3824 cannot be considered for classification of the merchandise.

CBP has used a variety of rationales by which to disqualify imported goods from heading 1302 and/or place them instead in heading 3824.

3.1 Post-extraction purification does not disqualify a material from heading 1302.

CBP has occasionally disqualified a material from heading 1302 on the basis that it is purified or refined subsequent to initial extraction. For example, HQ 966448 (2004) states in classifying bitter orange extracts, "We find that the treatment used to remove some of the components found in the crude extract constitutes further processing (manipulation) of the basic extract. In this regard, we find that [the extract] is excluded from classification as a vegetable extract in heading 1302, HTSUS."

The above rationale is inconsistent with long-established, worldwide industry understanding of extract manufacture and with common usage of the term "extract," as discussed in Comment #1 above.

The rationale is also inconsistent with CBP's own Rulings in other cases. For example, HQ H121546 (2015) classifies in heading 1302 a grape seed extract in which the initial water extraction is further processed "by filtration, purification by (dissolution in) ethyl acetate, and evaporation of the ethyl acetate by vacuum and spray-drying." In this Ruling, the merchandise was subjected to a number of post-extraction purification steps, yet remained classified in heading 1302. Similarly, HQ 963848

(2002) classifies a pyrethrum extract in heading 1302 "even though the original extracted oleoresin had been further purified removing much of the variety of material in the pyrethrum plant and thereby concentrating the pyrethrum content." In the latter case, CBP states that the Chapter 13 Explanatory Notes (ENs) do not contain any "explicit exclusion for a product which undergoes additional extractions, effectively concentrating the pyrethrin content, before standardization occurs."

AHPA therefore disagrees with CBP's characterization that processing, purification, or refinement subsequent to initial extraction disqualifies a material from heading 1302.

3.2 Standardization does not disqualify a material from heading 1302.

CBP has occasionally disqualified a material from heading 1302 on the basis that it is manufactured to "target" a certain substance or that it is "standardized" to that substance. For example, HQ H061203 (2010) states in classifying a rosemary extract containing 4-4.5% rosemarinic acid, "It is thus the opinion of this office that phenolic compunds [sic] are targeted and further concentrated in the extraction and purification process, resulting in a relatively pure chemical product that can no longer be considered a simple extract of heading 1302, HTSUS. The description of the product on the importer's website supports this conclusion. [Protestant] notes in its product brochure that the extracted material is standardized to rosmarinic acid, 'the most potent water soluble antioxidant compound from rosemary.' [Protestant] also markets its…products for their antioxidant properties, noting that [one of its products] 'contains the most polar part of rosemary leaves in which many different phenolic compounds are found.'"

AHPA disagrees that "targeting" a certain constituent or groups of constituents, or "standardization" of an extract to a defined content of constituent(s), is an adequate basis for removing a botanical substance from heading 1302. It is common for extract manufacturers to select their extraction conditions and process steps in order to control or enhance the content of target constituents. This is discussed in great detail in AHPA's white paper, "Standardization of Botanical Extracts," which was written with contributors knowledgeable in the industrial practice of botanical extract manufacture worldwide.[10] Furthermore, the chapter 13 ENs explicitly state that extracts may be "standardized" to a target substance (e.g., "pyrethrum extract may be standardized…[to] a standard pyrethrins content of, e.g., 2%, 20% or 25%").

[10] The American Herbal Products Association, 2003.

In some cases the content of targeted substances will be highly enriched compared to other extracts of the same botanical; in other cases it will not. In some cases the control or enrichment occurs as a result of the initial solvent extraction, and in other cases it results from subsequent processing steps. Nevertheless, the resulting material is still an "extract" according to common usage of the term; see Comment #1 above.

Furthermore, AHPA notes that a wide variety of CBP Rulings have classified extracts in heading 1302 despite having been "standardized" to, or enriched in, one or more constituents. For example, HQ W967653 (2008) classifies in heading 1302 a pine bark extract "standardized to contain 60-75% procyanidins"; HQ H121546 (2015) classifies in heading 1302 a grape seed extract enriched and standardized to contain 60% OPCs and 20% other seed polyphenols; NY N060119 (2009) classifies in heading 1302 a lotus leaf extract "standardized to a polyphenol (flavonoids) content of 50 percent"; and HQ 963848 (2002) classifies in heading 1302 a pyrethrum extract standardized to 50% pyrethrin.

Thus, CBP's stated position in HQ H061203 (2010) is inconsistent with worldwide industrial practice and understanding, with the ENs provided for Chapter 13, and with CBP's own precedents.

With respect to CBP's reliance in HQ H061203 (2010) on Protestant's marketing materials that identified rosemarinic acid as a potent antioxidant or the most polar part of the rosemary leaf, AHPA does not believe such statements form any basis to disqualify the merchandise as an "extract." AHPA is not aware of any provision of the Nomenclature, Legal Notes, or Explanatory Notes that would support moving a product out of heading 1302 on the basis of such statements.

3.3 Enrichment does not disqualify a material from heading 1302.

In two recent Rulings, CBP relies in part on a quantitative evaluation of "enrichment" to remove the subject merchandise from heading 1302.

In HQ H237599 (2015), CBP uses a quantitative comparison of naringin and hesperidin contents to assert that the subject merchandise is too highly enriched to be classified in heading 1302. CBP asserts, "While 25-33.90% bioflavonoid content is lower than that of the mogroside and OPCs in the aforementioned rulings, it is nevertheless exceptionally high compared to the levels of bioflavonoids in normal citric extracts. For example, assuming *arguendo* that the product contains only 6.25% naringin, this represents a near 150-fold increase over the trace amounts of the compound present in the CBP's laboratory representative grapefruit extract. Similarly, the 7.35% neohesperidin

content reported by Protestant in its certification is nearly 300 times higher than the content of hesperidin in the CBP laboratory's orange extract sample.[11]"

Similarly, in HQ H238484 (2015) CBP uses a quantitative comparison of hesperidin contents to assert that the subject merchandise is too highly enriched to be classified in heading 1302. For example, with respect to one of the four citrus extracts CBP asserts, "The citrus eriocitrin powder is made up 56.95 percent of the bioflavonoid eriocitrin and 22.68 percent of total polyphenols, and while it is also high in protein content, contains no starch. Similarly, the citrus PMF powder contains 61 percent total flavonoids and 14.55 percent total polyphenols, but contains only 1 percent starch and less than 1 percent protein. The laboratory reports that these compositions are far purer than those that would normally be achieved through simple extraction of citrus fruits or peels…[T]he chemical composition of the hesperidin powder is, like those of the citrus eriocitrin and citrus PMF powders, so unnaturally homogenous as to leave no other conclusion than that its production involved extensive concentration, purification, or similar refinement. The 48.91 percent hesperidin content in the powder represents a near 2,000-fold increase over the trace amounts of the compound present in the laboratory's representative orange extract and, according to the laboratory's analysis, imparts the powder with the principal character of an extract enriched in bioflavonoids. While not quite as pure as the hesperidin powder, the citrus bioflavonoid powder boasts a hesperidin content 500 times greater than that of the representative orange extract."

AHPA disagrees both that the level of enrichment is a valid basis on which to disqualify a botanical substance from classification in heading 1302, and also that comparison with another, arbitrarily-chosen extract of the same botanical is a valid basis on which to evaluate the degree of enrichment.

As discussed above in Comment # 1 as well as # 3.1 and # 3.2, enrichment - including to a high degree – is a normal and common element of botanical extract manufacture, and cannot logically be used to disqualify merchandise from the "extract" category. CBP appears to be conflating "enrichment" with "purity." As mentioned in Comment # 3.4 below, AHPA is proceeding in these comments, *assuming only for the sake of argument*, on the basis that materials which have been processed after initial extraction to a very high degree of purity might be removed from heading 1302, but this does not mean that materials that have been enriched to a lesser degree of purity should also be removed.

[11] Although differing slightly in stereochemistry, hesperidin and neohesperidin are highly similar in molecular composition and are identical in molecular weight, and are thus comparable for our purposes.

Furthermore, AHPA disputes the validity for classification purposes of comparing imported goods to a hypothetical, arbitrarily-chosen "representative" or "normal" extract. For any given botanical, there is no "representative" or "normal" extract. The same botanical starting material can be processed into a myriad of different extracts with very different chemical compositions, even simply through choice of solvent: extraction with water, ethanol, vinegar, or oil will each yield completely different end products.

As a result, AHPA rejects the strategy of examining extract "enrichment" as a criterion for HTSUS classification purposes.

3.4 Refinement to an extremely high degree of purity may in some cases disqualify a material from heading 1302.

In HQ 966566 (2003), CBP found that "substances obtained from a plant are not considered 'vegetable extracts' if they only contain one ingredient divorced from the composition of the vegetable source."

AHPA agrees that "substances consisting of one ingredient," if interpreted to mean a single, chemically defined, pure or nearly pure botanical constituent, are properly excluded from heading 1302. Such a position is fully consistent with the industry-developed definition of an extract which explicitly provides, "Extracts are not the same as…pure chemicals isolated from an herb…." Thus, AHPA has no objection to CBP Rulings that exclude botanically-derived substances from heading 1302 based on the merchandise consisting of a single, chemically defined, pure or nearly pure constituent.

However, when "one ingredient" is interpreted to mean a single, highly purified *group* of chemically similar constituents derived from the source botanical through extensive refinement of the initial extract, it is not clear that the material should be removed from heading 1302. By the industry-developed definition, such a material would remain within the category of "extract."

For the purposes of providing comments to CBP's December 23rd Notice, AHPA concedes *only for the sake of argument* that CBP may be able to construct an argument to exclude such materials (i.e., those in which the target constituents have been isolated from the initial extract using unusually sophisticated processing techniques such that the final product is pure or nearly pure) from heading 1302 and place them instead in heading 3824 (unless a more-specific heading applies). However, this should not be interpreted to mean that AHPA agrees with such an argument. Nevertheless, AHPA is proceeding with its comments *assuming arguendo* the correctness of CBP Rulings that

remove from heading 1302 various botanical substances which consist of a single, highly purified group of chemically similar constituents *and* are created through extensive refinement of the initial extract using sophisticated manufacturing processes.

AHPA notes, however, that the mere fact of a botanical extract consisting entirely or nearly entirely of one group of chemically similar constituents is not, by itself, sufficient to exclude it from heading 1302. For example, USP-NF includes a monograph for "Saw Palmetto Berry Extract" containing NLT 80% fatty acids; to AHPA's knowledge, such a high concentration of fatty acids can be obtained directly using solvent extraction. The Explanatory Notes (ENs) to Chapter 13 clearly indicate that heading 1302 is intended to encompass botanical substances made through solvent extraction. The ENs, although not dispositive or legally binding, provide a commentary on the scope of each heading, and are generally indicative of the proper interpretation of the HTSUS. See T.D. 89-80, 54 Fed. Reg. 35127 (August 23, 1989). AHPA notes that CBP has generally been careful not to exclude materials from heading 1302 when they are made using solvent extraction, even if the resulting material contains a high content of one or more groups of chemically similar constituents. AHPA agrees with this practice.

3.5 Column chromatography does not disqualify a material from heading 1302.

HQ H238484 (2015) states, "We have long held that when chromatography achieves chemical homogeneity, the resulting chemical substance is not classified in heading 1302. See, e.g., HQ H061203, dated August 12, 2010 (excluding merchandise from heading 1302 due to use of chromatography and other purification methods during its manufacture); and HQ 966448 ('The use of this chromatographic procedure in the preparation of these products exclude them from classification as vegetable extracts in heading 1302, HTSUS.')"

AHPA strongly disagrees that any and all uses of chromatography automatically disqualify a material from classification in heading 1302. In HQ H061203 (2010) CBP asserts as part of its basis for excluding the subject merchandise from heading 1302, "The use of column chromatography is particularly indicative of a highly processed substance." AHPA disagrees with this statement. To AHPA's knowledge, the use of column chromatography does not, in and of itself, indicate that an extract has been processed to an unusually high degree.

Furthermore, in HQ H237599 (2015), CBP states that chromatography is "a method used solely for purification whose application to a product supports exclusion of the product from heading 1302." AHPA strongly disagrees with this assertion. While in some cases chromatography is used to purify one or a group of chemically similar constituents to a pure or nearly pure state, in other cases

chromatography results in material that, although enriched in the target constituents, is nevertheless far from pure; rather, the material remains a "complex substance…containing a large portion of the plant profile," which is one criterion used in HQ 966566 (2003) and elsewhere to distinguish extracts of heading 1302 from chemical mixtures of heading 3824. In yet other cases, chromatography is used to remove toxins (e.g., safrole), contaminants (e.g., pesticides), or other undesirable components (e.g., caffeine). Such processing techniques do not render the material as something other than an "extract."

Thus, the mere fact of chromatography use during manufacture of a botanical substance is not an adequate basis on which to disqualify the substance from classification in heading 1302.

3.6 A few existing CBP Rulings are poorly reasoned.

A few CBP Rulings misrepresent the precedents on which they rely as well as the merchandise that is the subject of the Ruling. HQ H238484 (2015) cites HQ H061203 (2010) and HQ 966448 (2004) as examples in which chromatography has been used to achieve "chemical homogeneity," but this is not in fact the case. HQ H061203 (2010) classifies in heading 3824 a rosemary extract containing 4-4.5% rosemarinic acid among 60-75% native rosemary extractives and an inert ingredient (ethanol). HQ 966448 (2004) classifies in heading 2106 two bitter orange extracts containing 6% or 30% alkaloids along with an inert ingredient (maltodextrin) and "a great deal of other plant constituents."

The rosemary extract appears unambiguously to use column chromatography in its manufacturing process, insofar as it appears from the text of the Ruling that such a step is identified in materials submitted by the Protestant. It is unclear to AHPA whether the bitter orange extracts are in fact made using column chromatography, insofar as the Protestant does not appear to describe such a process step; rather, the Ruling states that the use of column chromatography is imputed by the CBP laboratory. As a factual matter, AHPA does not believe that laboratory analysis of a finished botanical material can reliably be used to determine whether column chromatography was used in its manufacture.[12] Moreover, as indicated in Comment # 3.5, the use of column chromatography in the manufacture of an extract does not change the nature of the material as an "extract."

[12] For example, CBP appears to believe that the absence of sugars, starch, and protein and/or the relative abundance of less hydrophilic/more hydrophobic compounds may be reliable indicators that column chromatography was used. The laboratory is quoted in HQ H238484 (2015) as follows: "It has been our observation that the selective chromatographic absorption processes using either resins or membranes may tend to produce a product that is enriched in natural compounds that are either or both less hydrophilic and contain a more hydrophobic character in their structure, such as the flavonoids. These extracts are usually very low in the highly water soluble sugars, starches, and water soluble protein content." Even if this is true, it does not follow that this chemical profile is a good indicator of the use of resins or membranes. To the contrary, a similar chemical

In any case, these materials are far from "chemically homogeneous"; rather, they appear to comprise a wide variety of different botanical constituents. The same is true of the bergamot extract that is the subject of HQ H237599 (2015) and the citrus extracts that are the subject of HQ H238484 (2015).

In the latter two Rulings, several of CBP's assertions in making the classification determination are flatly contradicted by the data presented. For example, in HQ H238484 (2015) CBP describes as "unnaturally homogenous" an extract enriched in hesperidin, despite the fact that CBP's own laboratory report reveals the product to contain 48.91% hesperidin, 13.93% polyphenols, 6.74% protein, 1.17% citric acid, and 4.62% ash as well as numerous natural compounds, including fatty acids, quinic acid, oleamide, beta sitosterol, and naringenin, all of which collectively comprise 25% of the product.

Dictionary.com defines "homogeneous" as "composed of parts or elements that are all of the same kind."[13] Indeed, a reference cited in CBP's Ruling itself, Hawley's Condensed Chemical Dictionary, defines "homogeneous" as follows: "Homogeneous. (Latin, 'the same kind'). This term, in its strict sense, describes the chemical constitution of a compound or element. A compound is homogeneous since it is composed of one and only one group of atoms represented by a formula. For example, pure water is homogeneous because it contains no other substance than is indicated by its formula, H_2O. Homogeneity is a characteristic property of compounds and elements (collectively called substances) as opposed to mixtures."[14]

AHPA does not believe that the hesperidin extract described in HQ H238484 (2015), which consists of polyphenols, protein, organic acids, fatty acids, phytosterols, etc., can accurately be described as "unnaturally homogeneous." Similarly, AHPA does not believe that the other extracts described in

profile can be achieved in a myriad of other ways, including simply through the use of appropriately selective extraction solvents. AHPA therefore believes CBP and/or the CBP laboratory are drawing erroneous conclusions from the data available to them.

[13] http://dictionary.reference.com/browse/homogeneous, accessed 01/20/2016.

[14] Hawley's Condensed Chemical Dictionary, 15th Edition, 2007, John Wiley and Sons, p. 655. The definition continues on to discuss "homogeneous" used loosely to mean "uniformly dispersed," but this is not the meaning used by CBP in its Ruling; and AHPA does not believe the uniformity of dispersal, or lack thereof, in a mixture of heterogeneous botanical constituents would have any bearing on the classification of the goods for HTSUS purposes.

HQ H238484 (2015), or the merchandise at issue in HQ H237599 (2015), HQ H061203 (2010), and HQ 966448 (2004), can accurately be described as "homogeneous."

In each of these instances, the materials at issue are "complex substances containing a large portion of the plant profile,"[15] rather than being "inordinately pure in chemical content."[16] For these and other reasons articulated elsewhere, AHPA does not agree with the factual basis on which these goods were excluded from heading 1302, and finds these CBP Rulings to be both illogical and inconsistent with worldwide industrial understanding of "botanical extract manufacture" as well as with the GRIs, the ENs to Chapter 13, and with CBP precedents.

3.7 Reclassifications to more-specific headings cannot be used to support reclassification to a less-specific heading.

In a number of Rulings, CBP has relied on certain exclusions in the ENs to disqualify botanical substances from heading 1302.

For example, HQ W968424 (2006, classifying in heading 3824 a highly processed pine bark containing at least 76% proanthocyanidins) states, "[T]here is a limit on the degree and extent of purification that can occur for the product to remain in heading 1302. *See* HQ 967972 (March 2, 2006). For instance, EN 13.02, explicitly excludes certain refined extracts of opium, quassia amare, papaw juice, and cashew nut shell liquid, once the refining process concentrates a certain group of chemical compounds to a particular point. Hence poppy straw concentrates containing more than 50% alkaloids are excluded from heading 1302. Likewise, quassin, a chemical compound extracted and refined from the quassia amara shrub is classified in Chapter 29. Papain enzyme, once purified from the extraction process of papaw juice, is classified as an enzyme of Chapter 37. And polymers extracted and refined from cashew nut shell liquid are classified in Chapter 39 as polymers." The Ruling then goes on to use the highly purified nature of the subject merchandise, along with its complex and sophisticated manufacturing process (including use of selective ultra-filtration and/or reverse osmosis), as reasons to remove the goods from heading 1302.

[15] This is one criterion used in HQ 966566 (2003) and elsewhere to distinguish extracts of heading 1302 from chemical mixtures of heading 3824.

[16] The criterion of being "inordinately pure" is cited in HQ H238484 (2015) and elsewhere to distinguish extracts of heading 1302 from chemical mixtures of heading 3824. As examples of products that are "inordinately pure," HQ H238484 (2015) cites a lo han guo product containing 80% mogrosides as well as grape seed extract and pine bark extract containing 90% or more of OPCs.

AHPA disagrees with Rulings that have relied on these provisions of the ENs to disqualify from heading 1302 certain extracts that are not processed to an extremely high degree of purity, such as HQ H061203 (2010) classifying in heading 3824 a rosemary extract containing 4-4.5% rosemarinic acid. AHPA believes these Rulings violate the rules by which goods are classified under HTSUS.

As explained by CBP in the December 23rd Notice, "Merchandise imported into the United States is classified under the HTSUS. Tariff classification is governed by the principles set forth in the General Rules of Interpretation (GRIs) and, in the absence of special language or context which requires otherwise, by the Additional U.S. Rules of Interpretation. The GRIs and the Additional U.S. Rules of Interpretation are part of the HTSUS and are to be considered statutory provisions of law for all purposes. GRI 1 requires that classification be determined first according to the terms of the headings of the tariff schedule and any relative section or chapter notes and, unless otherwise required, according to the remaining GRIs taken in their appropriate order."

The December 23rd Notice continues, "The Harmonized Commodity Description and Coding System Explanatory Notes (ENs), constitute the official interpretation of the Harmonized System at the international level. While neither legally binding nor dispositive, the ENs provide a commentary on the scope of each heading of the HTSUS and are generally indicative of the proper interpretation of the headings. It is CBP's practice to consult, whenever possible, the terms of the ENs when interpreting the HTSUS. *See* T.D. 89–80, 54 Fed. Reg. 35127, 35128 (August 23, 1989)."

GRI 3(a) provides, "The heading which provides the most specific description shall be preferred to headings providing a more general description." AHPA notes that the EN exceptions cited by CBP all serve to move the subject merchandise out of the general category of "extracts" (heading 1302) and into *more specific* classifications: (a) opium concentrate classified as a "vegetable alkaloid" in heading 2939; (b) purified quassin classified as a "heterocyclic compound with oxygen hetero-atom(s) only" in heading 2939; (c) purified papain classified as an "enzyme" in heading 3507; and (d) cashew nut polymers classified as an "petroleum resins, coumarone-indene resins, polyterpenes, polysulfides, polysulfones and other products specified in note 3 to this chapter" in heading 3911.

Thus, the ENs reinforce and exemplify the principle articulated in GRI 3(a), namely that where more than one option exists, goods should be classified under the heading that provides the most specific description.

In contrast, when CBP classifies goods under heading 3824 ("prepared binders for foundry molds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included") rather than 1302

("vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products"), it is using a heading that is less specific rather than more specific. As noted previously, heading 3824 is a residual or "basket" provision.

AHPA therefore believes CBP is required to present extremely strong and valid reasons to move merchandise out of the more-specific heading 1302 and into the less-specific heading 3824. In a number of cases, as described above, AHPA does not believe CBP has met this burden since the subject merchandise unquestionably meets the commonly-accepted definitions of the word "extract." In particular, AHPA disputes the validity of the following Rulings: HQ 966448 (2004), HQ H061203 (2010), H237599 (2015), and HQ H238484 (2015). These Rulings were based on erroneous assumptions and faulty logic, and should be revoked.

4. Additional comments regarding "traditional extraction methods"

In a number of Rulings, CBP has cited use of routine extract processing steps as reasons to exclude the subject merchandise from heading 1302, stating for example that these processes are "far removed from traditional extraction methods." [17] AHPA believes that CBP is fundamentally misinformed on this point, and therefore seeks to explain the use of certain processes during botanical extract manufacture.

- Filtration and centrifugation: All extracts, by their nature, are manufactured by treating botanical material with solvent such that soluble constituents ("extractives") are drawn into the solvent. Once the initial extraction is complete, it is necessary to separate the insoluble botanical material (the "marc") from the mixture of solvent and extractives (the "miscella"). This separation is commonly achieved by use either of filtration or centrifugation. Filtration is often used when the particle size of the marc is relatively large, and centrifugation is often used when the particle size is relatively small. In either case, such a step constitutes an inherent and necessary part of the extract manufacturing process. These procedures are extremely common and quite routine, and it is not tenable to cite them as a reason to disqualify a material from classification as an "extract" under heading 1302.

- Concentration: The extract manufacturing step known as "concentration" typically refers to a process whereby the extraction solvent is evaporated using elevated temperature and/or reduced pressure to yield a liquid containing only, or primarily, the moisture and other liquids

[17] HQ H237599 (2015).

native to the botanical itself. This step is used in the manufacture of the vast majority of extracts, other than those that are intended to be consumed or otherwise used in liquid form. This procedure is extremely common and quite routine, and it cannot logically be used as a reason to disqualify a material from classification as an "extract" under heading 1302.

AHPA notes that the process steps described above do not constitute a complete list of the manufacturing procedures used during "traditional extraction." AHPA has singled them out for discussion, along with column chromatography as discussed in comment 3.5 above, to correct the misapprehensions that are evident in some of CBP's Rulings.

5. Discussion of CBP's proposals in the December 23rd Notice

In its December 23rd Notice, CBP proposes to revoke or modify several previous CBP Rulings pertaining to what it represents to be merchandise derived from bilberry and blueberry. Specifically, CBP proposes to revoke HQ 964139 (2002), NY N219927 (2012), and NY N037866 (2008), and to modify HQ 967972 (2006) and NY 814027 (1996).

5.1 CBP states in its Notice that each of the above Rulings pertains to either bilberry or blueberry, two closely related botanicals in the genus *Vaccinium*. In particular, CBP states that HQ 967972 (2006) is one among several that "involve classification of bilberry extracts under heading 1302, HTSUS."

In reviewing HQ 967972 (2006) as downloaded from the Customs Rulings Online Search System,[18] AHPA notes that this Ruling does not in fact involve classification of a bilberry extract under heading 1302. Rather, it pertains to the classification of silymarin derived from milk thistle in subheading 2932.99.6100 and leucoanthocyanin derived from grape seeds in subheading 3824.90.2800.

Neither milk thistle (*Silybum marianum*) nor grapes (*Vitis vinifera*) is in the genus *Vaccinium*, and neither of the subject items are classified in heading 1302 by this Ruling. Indeed, the Ruling does not contain the words "bilberry" or "*Vaccinium*" at all. Therefore, AHPA does not believe this Ruling should be included in the decisions that might be modified under the December 23rd Notice. Accordingly, AHPA will omit discussion of this Ruling from the comments that follow.

5.2 In attempting to disqualify from heading 1302 the subject merchandise of HQ 964139 (2002), NY N219927 (2012), NY N037866 (2008), and NY 814027 (1996), the December 23rd Notice states, "It is our long-standing position that, consistent with EN 13.02, heading 1302 applies to products that

[18] http://rulings.cbp.gov/index.asp, accessed most recently on 01/22/2016.

have been created through standard extraction methods, but not to those that have subsequently been enriched, purified, or otherwise refined so as to increase the contents of certain desirable compounds.

AHPA finds that this sentence misrepresents the body of historical CBP Rulings and therefore does not accurately reflect CBP's "long-standing tradition" with respect to the classification of extracts. To the contrary, CBP has consistently classified in heading 1302 any botanical substance made using solvent extraction, including those which have been "enriched, purified, or otherwise refined so as to increase the contents of certain desirable compounds," except where the substance has been both (a) processed using various steps other than "percolation, maceration, digestion, or infusion," *and* (b) the final product consisted of one constituent or group of chemically similar constituents concentrated to a very high degree. See Comment #2 above.

AHPA acknowledges that there have been a handful of Rulings that deviate from this convention, but AHPA believes such Rulings to be based on erroneous assumptions and faulty logic. AHPA also believes such Rulings to be inconsistent with CBP precedents; with the rules by which merchandise is classified under HTSUS; with the ENs; with worldwide extract manufacturing practice; and with the common definition of "extract" as used both by industry internationally and by the very references that CBP has cited in an attempt to support its position. See Comment #3.6 above.

5.3 The December 23rd Notice cites HQ H106785 (2010) as establishing that "CBP has determined that extensive processing can exclude a product from 1302."

AHPA proceeds for the moment, *assuming arguendo* and purely for the sake of the current comments, on the basis that in some cases extensive post-extraction processing can exclude a product from 1302 when the resulting final product consists of a pure or nearly pure constituent or group of constituents. However, AHPA does not agree that the materials that are the subject of HQ 964139 (2002), NY N219927 (2012), and NY N037866 (2008), and NY 814027 (1996) have been so extensively processed. Based on the facts in the Rulings, each of these materials appears to be a fairly typical botanical extract, processed with techniques that are commonly used in botanical extract manufacture, and of no especially high degree of purity.

5.4 The December 23rd Notice quotes HQ 959099 (1998) to support its proposed reclassifications, stating, "As pointed out in the ENs to heading 1302, what is covered in the heading are vegetable products obtained by natural exudation or by incision or by solvent extraction."

AHPA believes that the above statement misrepresents the ENs and erroneously implies that *only* solvent extraction is permitted to be used in the manufacture of an extract of heading 1302. To begin with, the relevant phrasing in the ENs includes the word "usually" (as in, "usually obtained"), which is omitted in CBP's quote above. Furthermore, although treatment with solvent is a necessary step in the manufacture of an extract, it is improper to assume that no subsequent processing of the initial extract may occur. To the contrary, it is routine for botanical extracts to be manufactured using multi-step procedures. The very references that CBP frequently cites in its Rulings (USP-NF and Remington's), as well as industry-developed guidance on the subject, explicitly provide that subsequent processing of the initial extract may occur and the final product yet remain an "extract." See Comment #1 above.

5.5 The December 23rd Notice cites HQ H195716 (2015) to support its proposed reclassifications, quoting as follows: "CBP's position is supported by the text of EN 13.02. For example, opium is the dried sap of the unripe capsules of the poppy (*Papaver somniferum*), obtained by incision of or extraction from the stems or seed pods. Opium contains about 10% morphine. However, concentrate of poppy straw is a different product. A procedure for obtaining concentrate of poppy straw was first patented in 1935, and describes a process of drying the stems and pods of the poppy plant, treating them with sodium bisulphite, concentrating the aqueous solution into a paste by application of a vacuum, treating the paste with alcohol, and then precipitating the morphine base by treating the solution with ammonium sulphate and benzene, to yield a product with over 50% morphine. EN(1) to 13.02 (and Note 1(f) to Chapter 13, HTSUS) excludes concentrates of poppy straw containing not less than 50% by weight of alkaloids. In another example, quassia amara extract obtained from the bark of the *Quassia amara* shrub. The extract is used in herbal medicine, and contains numerous compounds including both beta-carbonile and cantin-6 alkaloids as well as, primarily, the bitter compounds known as quassinoids. Quassin (2,12-dimethoxypicrasa-2,12-diene-1,11,16-trione, CAS No. 76–78–8) however, is a specific chemical compound contained in the *Quassia amara* shrub. A patented procedure for obtaining quassin describes a process which percolates first the gum or residue of the wood chips of the *Quassia amara* shrub in ethanol and evaporates the solvent, then dissolves the residue in water and washes it with hexane. The hexane fraction is discarded, and sodium chloride is added to the aqueous fraction. A residue is extracted using ethyl acetate and the crystallized into quassin and neoquassin. This process yields a crystal composed of 39% quassin. This chemical is one of the most bitter substances found in nature, and is used mainly as a food additive. EN(11) to 13.02 excludes quassin from classification under the heading, and directs it to be classified under heading 29.32. In these examples, EN 13.02 excludes products extracted from plants which undergo extensive further processing. *See* EN(1), (11), (18), and (20) to 13.02."

The December 23rd Notice also cites HQ H061203 (2010), HQ H237599 (2015), and HQ W968424 (2006) to support its proposed reclassifications, quoting: "There appears to be a limit on the degree and extent of purification that can occur for the product to remain in heading 1302. For instance, EN 13.02, explicitly excludes certain refined extracts of opium, quassia amare, papaw juice, and cashew nut shell liquid, once the refining process concentrates a certain group of chemical compounds to a particular point. Hence, poppy straw concentrates containing more than 50% alkaloids are excluded from heading 1302. Likewise, quassin, a chemical compound extracted and refined from the quassia amara shrub is classified in Chapter 29. Papain enzyme, once purified from the extraction process of papaw juice, is classified as an enzyme of Chapter [35]. And polymers extracted and refined from cashew nut shell liquid are classified in Chapter 39 as polymers."

AHPA does not agree that these cited exclusions support CBP's proposed reclassifications. Consistent with the requirements of GRI 3(a), the exclusions cited above move the subject merchandise from a less-specific heading (1302) to a more-specific heading applicable to the merchandise. See Comment #3.7 above.

In contrast, CBP's proposed reclassifications from heading 1302 to heading 3824 would do the opposite, moving merchandise from a more-specific heading (extracts under heading 1302) to a less-specific heading (chemical preparations under heading 3824, which is a residual heading to be used only if a more-specific heading does not apply). This is inconsistent with the requirements of GRI 3(a).

The proposed reclassification is also inconsistent with GRI 1, which requires that classification be determined first according to the terms of the headings of the tariff schedule and any relative section or chapter notes and, unless otherwise required, according to the remaining GRIs taken in their appropriate order. Because the common definition of the word "extract" clearly applies to these materials (see Comment #1), by the terms of the headings of the tariff schedule (and without contradiction from the relevant section or chapter notes), these materials should rightly be classified in heading 1302.

5.6 In support of its proposed reclassifications, the December 23rd Notice goes on to say, "Accordingly, we have consistently ruled that products in which certain chemical compounds have deliberately been targeted and enriched cannot be classified in heading 1302."

AHPA does not find this to be an accurate representation of CBP's "consistent" practice, as discussed in Comment # 2 as well as # 5.2 above. Furthermore, AHPA strongly disagrees that

"targeting" or "enriching" certain "chemical compounds" can logically be used to disqualify a botanical substance from classification in heading 1302; see Comments # 3.1, 3.2, and 3.3 above.

5.7 In support of its proposed reclassifications, the December 23rd Notice quotes HQ H061203 (2010): "It is thus the opinion of this office that phenolic compounds are targeted and further concentrated in the extraction and purification process, resulting in a relatively pure chemical product that can no longer be considered a simple extract of heading 1302, HTSUS.")

As discussed in Comment # 3.6 above, AHPA believes this Ruling to rest on extremely shaky factual and logical foundations. AHPA therefore does not believe it provides support for the currently proposed reclassifications.

5.8 The December 23rd Notice cites HQ H195716 (2015; classifying in heading 3824 a grape seed extract containing 100% polyphenols); HQ W968424 (2006; classifying in heading 3824 a pine bark extract containing at least 76% proanthocyanidins); and HQ H056377 (2010; classifying in heading 3824 a grape pomace extract containing up to 90% polyphenols) as precedents that support its proposed reclassifications.

AHPA disagrees that these Rulings are relevant to the December 23rd proposal. In each of these Rulings, the subject merchandise has been processed after initial extraction to a nearly pure state, and the extremely high degree of purity was cited as a key reason in their classification.

Those materials are quite different from the merchandise at issue in HQ 964139 (2002; a bilberry extract containing 25% anthocyanides), NY 814027 (1996; a bilberry extract containing 25% anthocyanosides), NY N037866 (2008; a blueberry extract containing 20% anthocyanosides and 40% polyphenols), and NY N219927 (2012; a bilberry extract containing 70% phenols/38% flavanoids [sic]). None of these extracts has been processed into an exceptionally pure state.

5.9 The December 23rd Notice cites HQ H023701 (2009) as precedent that supports its proposed reclassifications.

AHPA disagrees that this Ruling is relevant to the December 23rd proposal. The merchandise at issue in this Ruling consisted of purified red cabbage anthocyanins labeled for use as a food color.

Due to the very high degree of purity of the material and its labeling for a specialized use, this material is not comparable to the merchandise at issue in the December 23rd proposal.

5.10 The December 23rd Notice claims that use of chromatography in the manufacturing processes of the subject merchandise in HQ 964139 (2002), NY N219927 (2012), NY N037866 (2008), and NY 814027 (1996) disqualifies the goods from classification in heading 1302.

AHPA does not agree that the mere fact of chromatography use during manufacture of a botanical extract is an adequate basis on which to preclude classification in heading 1302. See Comment # 3.5 above.

5.11 The December 23rd Notice states in conclusion, "In all cases, the application of these procedures enables the targeted engineering of products whose chemical compositions are standardized to contain 20 to 25 percent anthocyanosides. Having been purified following extraction, the instant powders are not described by the terms of heading 1302."

AHPA disagrees that "targeting" of specific constituents or "standardization" of an extract to a standard strength is grounds to disqualify the material from classification in heading 1302. See Comments # 1, # 3.2, and # 3.3 above.

AHPA similarly disagrees that purification following extraction is grounds to disqualify the material from classification in heading 1302. See Comment # 3.1 above.

AHPA takes issue with each of the rationales that CBP has advanced to justify removing from heading 1302 the merchandise at issue in HQ 964139 (2002), NY N219927 (2012), NY N037866 (2008), and NY 814027 (1996). AHPA finds that CBP's proposal is based on a fundamental misunderstanding of botanical extracts and their manufacture, along with various erroneous assumptions, unsupported leaps of logic, and mischaracterizations of the cited precedents.

Having found that CBP has advanced no legitimate reason to exclude the subject merchandise from heading 1302, AHPA opposes CBP's proposals to revoke HQ 964139 (2002), NY N219927 (2012), and NY N037866 (2008), and to modify NY 814027 (1996). As mentioned previously (Comment # 5.1), AHPA finds that HQ 967972 (2006) bears no relation to the merchandise or proposed reclassifications at issue in the other Rulings, and therefore believes that Ruling also should not be modified.

Conclusions

AHPA's analysis of the relevant facts concerning botanical extract manufacture as well as the GRIs, ENs and CBP Rulings precedents, does not support the proposed reclassifications in CBP's December 23rd Notice. AHPA therefore opposes the proposed reclassifications.

AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,

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