

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 18-07]

RIN 1515-AE38

IMPORT RESTRICTIONS IMPOSED ON ARCHAEOLOGICAL AND ETHNOLOGICAL MATERIAL FROM LIBYA

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the U.S. Customs and Border Protection (CBP) regulations to continue the import restrictions on archaeological and ethnological material from Libya previously imposed on an emergency basis in a final rule published on December 5, 2017. These restrictions are being imposed pursuant to an agreement between the United States and Libya that has been entered into under the authority of the Convention on Cultural Property Implementation Act. The document also contains the Designated List of Archaeological and Ethnological Material of Libya that describes the articles to which the restrictions apply. Accordingly, this document amends the CBP regulations by removing Libya from the listing of countries for which emergency actions imposed the import restrictions, and adding Libya to the list of countries for which an agreement has been entered into for imposing import restrictions.

EFFECTIVE DATE: July 9, 2018.

FOR FURTHER INFORMATION CONTACT: For regulatory aspects, Lisa L. Burley, Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325-0030, ot-otrrculturalproperty@cbp.dhs.gov. For operational aspects, William R. Scopa, Branch Chief, Partner Government Agency Branch, Trade Policy and Programs, Office of Trade, (202) 863-6554, William.R.Scopa@cbp.dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the Convention on Cultural Property Implementation Act, Pub. L. 97–446, 19 U.S.C. 2601 *et seq.* (hereinafter, “the Cultural Property Implementation Act” or “the Act”), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (hereinafter, “1970 UNESCO Convention” or “the Convention” (823 U.N.T.S. 231 (1972))), the United States may enter into international agreements with another State Party to the 1970 UNESCO Convention to impose import restrictions on eligible archaeological and ethnological material under procedures and requirements prescribed by the Act. In certain limited circumstances, the Cultural Property Implementation Act authorizes the imposition of restrictions on an emergency basis (19 U.S.C. 2603). The emergency restrictions are effective for no more than five years from the date of the State Party’s request and may be extended for three years where it is determined that the emergency condition continues to apply with respect to the covered material (19 U.S.C. 2603(c)(3)). These restrictions may also be continued pursuant to an agreement concluded within the meaning of the Act (19 U.S.C. 2603(c)(4)).

Libya has been one of the countries whose archaeological and ethnological material has been afforded emergency protection. On December 5, 2017, U.S. Customs and Border Protection (CBP) published a final rule, CBP Dec. 17–19, in the **Federal Register** (82 FR 57346) which amended CBP regulations in 19 CFR 12.104g(b) to reflect that archaeological material and ethnological material from Libya received import protection under the emergency protection provisions of the Act.

Import restrictions are now being imposed on the same categories of archaeological and ethnological material from Libya as a result of a bilateral agreement entered into between the United States and Libya. This agreement was entered into on February 23, 2018, pursuant to the provisions of 19 U.S.C. 2602. Protection of the archaeological and ethnological material from Libya previously reflected in § 12.104g(b) will be continued through the bilateral agreement without interruption. Accordingly, § 12.104g(a) of the CBP regulations is being amended to indicate that restrictions have been imposed pursuant to the agreement between the United States and Libya, and the emergency import restrictions on certain categories of archaeological and ethnological material from Libya are being removed from § 12.104g(b) as those restrictions are now encompassed in § 12.104g(a).

In reaching the decision to recommend that negotiations for an agreement with Libya should be undertaken to continue the imposition of import restrictions on certain archaeological and ethnological material of Libya, the Acting Under Secretary for Public Diplomacy and Public Affairs, State Department, after consultation with and recommendations by the Cultural Property Advisory Committee, determined that the cultural heritage of Libya is in jeopardy from pillage of certain categories of archaeological and ethnological material, and that import restrictions should be imposed for a five-year period until February 23, 2023. Importation of such material continues to be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

Designated List

The bilateral agreement between Libya and the United States covers the material set forth below in a Designated List of Archaeological and Ethnological Material of Libya. Importation of material on this list is restricted unless the material is accompanied by documentation certifying that the material left Libya legally and not in violation of the export laws of Libya.

The Designated List covers archaeological material of Libya and Ottoman ethnological material of Libya (as defined in section 302 of the Convention on Cultural Property Implementation Act (19 U.S.C. 2601)), including, but not limited to, the following types of material. The archaeological material represents the following periods and cultures: Paleolithic, Neolithic, Punic, Greek, Roman, Byzantine, Islamic and Ottoman dating approximately 12,000 B.C. to 1750 A.D. The ethnological material represents categories of Ottoman objects derived from sites of Islamic cultural importance, made by a nonindustrial society (Ottoman Libya), and important to the knowledge of the history of Islamic Ottoman society in Libya from 1551 A.D. through 1911 A.D.

The Designated List set forth below is representative only. Any dimensions are approximate.

I. Archaeological Material

A. Stone

1. Sculpture

a. *Architectural Elements*—In marble, limestone, sandstone, and gypsum, in addition to porphyry and granite. From temples, forts, palaces, mosques, synagogues, churches, shrines, tombs, monuments, public buildings, and domestic dwellings, including doors, door frames, window fittings, columns, capitals, bases, lintels, jambs,

friezes, pilasters, engaged columns, altars, mihrabs (prayer niches), screens, fountains, mosaics, inlays, and blocks from walls, floors, and ceilings. May be plain, molded, or carved. Often decorated with motifs and inscriptions. Approximate date: 1st millennium B.C. to 1750 A.D.

b. *Architectural and Non-architectural Relief Sculpture*—In marble, limestone, sandstone, and other stone. Types include carved slabs with figural, vegetative, floral, geometric, or other decorative motifs, carved relief vases, stelae, and plaques, sometimes inscribed in Greek, Punic, Latin, or Arabic. Used for architectural decoration, funerary, votive, or commemorative monuments. Approximate date: 1st millennium B.C. to 1750 A.D.

c. *Monuments*—In marble, limestone, and other kinds of stone. Types include votive statues, funerary and votive stelae, and bases and base revetments. These may be painted, carved with relief sculpture, decorated with moldings, and/or carry dedicatory or funerary inscriptions in Greek, Punic, Latin, or Arabic. Approximate date: 1st millennium B.C. to 1750 A.D.

d. *Statuary*—Primarily in marble, but also in limestone and sandstone. Large-and small-scale, including deities, human, animal, and hybrid figures, as well as groups of figures in the round. Common types are large-scale and free-standing statuary from approximately 3 to 8 ft. in height, life-sized portrait or funerary busts (head and shoulders of an individual), waist-length female busts that are either faceless (aniconic) and/or veiled (head or face), and statuettes typically 1 to 3 ft. in height. Includes fragments of statues. Approximate date: 1st millennium B.C. to 1750 A.D.

e. *Sepulchers*—In marble, limestone, and other kinds of stone. Types of burial containers include sarcophagi, caskets, and chest urns. May be plain or have figural, geometric, or floral motifs painted on them, be carved in relief, and/or have decorative moldings. Approximate date: 1st millennium B.C. to 1750 A.D.

2. *Vessels and Containers*—In marble and other stone. Vessels may belong to conventional shapes such as bowls, cups, jars, jugs, lamps, and flasks, and also include smaller funerary urns. Funerary urns can be egg-shaped vases with button-topped covers and may have sculpted portraits, painted geometric motifs, inscriptions, scroll-like handles and/or be ribbed.

3. *Furniture*—In marble and other stone. Types include thrones, tables, and beds. May be funerary, but do not have to be. Approximate date: 1st millennium B.C. to 15th century A.D.

4. *Inscriptions*—Primarily in marble and limestone. Inscribed stone material date from the late 7th century B.C. to 5th century A.D. May include funerary stelae, votive plaques, tombstones, mosaic floors,

and building plaques in Greek, Punic, Latin, or Arabic. Approximate date: 1st millennium B.C. to 1750 A.D.

5 *Tools and Weapons*—In flint, chert, obsidian, and other hard stones. Prehistoric and Protohistoric microliths (small stone tools). Chipped stone types include blades, borers, scrapers, sickles, cores, and arrow heads. Ground stone types include grinders (*e.g.*, mortars, pestles, millstones, whetstones), choppers, axes, hammers, and mace heads. Approximate date: 12,000 B.C. to 1,400 B.C.

6. *Jewelry, Seals, and Beads*—In marble, limestone, and various semi-precious stones, including rock crystal, amethyst, jasper, agate, steatite, and carnelian. Approximate date: 1st millennium B.C. to 12th century A.D.

B. Metal

1. *Sculpture*

a. *Statuary*—Primarily in bronze, iron, silver, or gold, including fragments of statues. Large- and small-scale, including deities, human, and animal figures, as well as groups of figures in the round. Common types are large-scale, free-standing statuary from approximately 3 to 8 ft. in height and life-size busts (head and shoulders of an individual) and statuettes typically 1 to 3 ft. in height. Approximate date: 1st millennium B.C. to 324 A.D.

b. *Reliefs*—Relief sculpture, including plaques, appliques, stelae, and masks. Often in bronze. May include Greek, Punic, Latin, and Arabic inscriptions. Approximate date: 1st millennium B.C. to 324 A.D.

c. *Inscribed or Decorated Sheet*—In bronze or lead. Engraved inscriptions, “curse tablets,” and thin metal sheets with engraved or impressed designs often used as attachments to furniture. Approximate date: 1st millennium B.C. to 15th century A.D.

2. *Vessels and Containers*—In bronze, silver, and gold. These may belong to conventional shapes such as bowls, cups, jars, jugs, strainers, cauldrons, and oil lamps, or may occur in the shape of an animal or part of an animal. Also include scroll and manuscript containers for manuscripts. All can portray deities, humans or animals, as well as floral motifs in relief. Islamic Period objects may be inscribed in Arabic. Approximate date: 1st millennium B.C. to 15th century A.D.

3. *Jewelry and Other Items for Personal Adornment*—In iron, bronze, silver, and gold. Metal can be inlaid (with items such as red coral, colored stones, and glass). Types include necklaces, chokers, pectorals, rings, beads, pendants, belts, belt buckles, earrings, diadems, straight pins and fibulae, bracelets, anklets, girdles, belts, mirrors, wreaths and crowns, make-up accessories and tools, metal

strigils (scrapers), crosses, and lamp-holders. Approximate date: 1st millennium B.C. to 15th century A.D.

4. *Seals*—In lead, tin, copper, bronze, silver, and gold. Types include rings, amulets, and seals with shank. Approximate date: 1st millennium B.C. to 15th century A.D.

5. *Tools*—In copper, bronze and iron. Types include hooks, weights, axes, scrapers, trowels, keys and the tools of crafts persons such as carpenters, masons and metal smiths. Approximate date: 1st millennium B.C. to 15th century A.D.

6. *Weapons and Armor*—Body armor, including helmets, cuirasses, shin guards, and shields, and horse armor often decorated with elaborate engraved, embossed, or perforated designs. Both launching weapons (spears and javelins) and weapons for hand to hand combat (swords, daggers, etc.). Approximate date: 8th century B.C. to 4th century A.D.

7. *Coins*

a. *General*—Examples of many of the coins found in ancient Libya may be found in: A. Burnett and others, *Roman Provincial Coinage*, multiple volumes (British Museum Press and the Bibliothèque Nationale de France, 1992–), R. S. Poole and others, *Catalogue of Greek Coins in the British Museum*, volumes 1–29 (British Museum Trustees 1873–1927) and H. Mattingly and others, *Coins of the Roman Empire in the British Museum*, volumes 1–6 (British Museum Trustees 1923–62). For Byzantine coins, see Grierson, Philip, *Byzantine Coins*, London, 1982. For publication of examples of coins circulating in archaeological sites, see *La moneta di Cirene e della Cirenaica nel Mediterraneo. Problemi e Prospettive*, Atti del V Congresso Internazionale di Numismatica e di Storia Monetaria, Padova, 17–19 marzo 2016, Padova 2016 (Numismatica Patavina, 13).

b. *Greek Bronze Coins*—Struck by city-states of the Pentapolis, Carthage and the Ptolemaic kingdom that operated in territory of the Cyrenaica in eastern Libya. Approximate date: 4th century B.C. to late 1st century B.C.

c. *Greek Silver and Gold Coins*—This category includes coins of the city-states of the Pentapolis in the Cyrenaica and the Ptolemaic Kingdom. Coins from the city-state of Cyrene often bear an image of the silphium plant. Such coins date from the late 6th century B.C. to late 1st century B.C.

d. *Roman Coins*—In silver and bronze, struck at Roman and Roman provincial mints including Apollonia, Barca, Balagrae, Berenice, Cyrene, Ptolemais, Leptis Magna, Oea, and Sabratha. Approximate date: late 3rd century B.C. to 1st century A.D.

e. *Byzantine Coins*—In bronze, silver, and gold by Byzantine emperors. Struck in Constantinople and other mints. From 4th century A.D. through 1396 A.D.

f. *Islamic Coins*—In bronze, silver, and gold. Dinars with Arabic inscriptions inside a circle or square, may be surrounded with symbols. Struck at mints in Libya (Barqa) and adjacent regions. From 642 A.D. to 15th century A.D.

g. *Ottoman*—Struck at mints in Istanbul and Libya's neighboring regions. Approximate date: 1551 A.D. through 1750 A.D.

C. *Ceramic and Clay*

1. *Sculpture*

a. *Architectural Elements*—Baked clay (terracotta) elements used to decorate buildings. Elements include acroteria, antefixes, painted and relief plaques, revetments. Approximate date: 1st millennium B.C. to 30 B.C.

b. *Architectural Decorations*—Including carved and molded brick, and tile wall ornaments and panels.

c. *Statuary*—Large- and small-scale. Subject matter is varied and includes deities, human and animal figures, human body parts, and groups of figures in the round. May be brightly colored. These range from approximately 4 to 40 in. in height. Approximate date: 1st millennium B.C. to 3rd century A.D.

d. *Terracotta Figurines*—Terracotta statues and statuettes, including deities, human, and animal figures, as well as groups of figures in the round. Late 7th century B.C. to 3rd century A.D.

2. *Vessels*

a. *Neolithic Pottery*—Handmade, often decorated with a lustrous burnish, decorated with appliqué and/or incision, sometimes with added paint. These come in a variety of shapes from simple bowls and vases to large storage jars. Approximate date: 10th millennium B.C. to 3rd millennium B.C.

b. *Greek Pottery*—Includes both local and imported fine and coarse wares and amphorae. Also imported Attic Black Figure, Red Figure and White Ground Pottery—these are made in a specific set of shapes (e.g., amphorae, kraters, hydriae, oinochoi, kylikes) decorated with black painted figures on a clear clay ground (Black Figure), decorative elements in reserve with background fired black (Red Figure), and multi-colored figures painted on a white ground (White Ground).
Corinthian Pottery—Imported painted pottery made in Corinth in a specific range of shapes for perfume and unguents and for drinking or pouring liquids. The very characteristic painted and incised designs

depict human and animal figural scenes, rows of animals, and floral decoration. Approximate date: 8th century B.C. to 6th century B.C.

c. *Punic and Roman Pottery*—Includes fine and coarse wares, including terra sigillata and other red gloss wares, and cooking wares and mortaria, storage and shipping amphorae.

d. *Byzantine Pottery*—Includes undecorated plain wares, lamps, utilitarian, tableware, serving and storage jars, amphorae, special shapes such as pilgrim flasks. Can be matte painted or glazed, including incised “sgraffitto” and stamped with elaborate polychrome decorations using floral, geometric, human, and animal motifs. Approximate date: 324 A.D. to 15th century A.D.

e. *Islamic and Ottoman Pottery*—Includes plain or utilitarian wares as well as painted wares.

f. *Oil Lamps and Molds*—Rounded bodies with a hole on the top and in the nozzle, handles or lugs and figural motifs (beading, rosette, silphium). Include glazed ceramic mosque lamps, which may have a straight or round bulbous body with flared top, and several branches. Approximate date: 1st millennium B.C. to 15th century A.D.

3. *Objects of Daily Use*—Including game pieces, loom weights, toys, and lamps.

D. Glass, Faience, and Semi-Precious Stone

1. *Architectural Elements*—Mosaics and glass windows.

2. *Vessels*—Shapes include small jars, bowls, animal shaped, goblet, spherical, candle holders, perfume jars (unguentaria), and mosque lamps. Those from prehistory and ancient history may be engraved and/or colorless or blue, green or orange, while those from the Islamic Period may include animal, floral, and/or geometric motifs. Approximate date: 1st millennium B.C. to 15th century A.D.

3. *Beads*—Globular and relief beads. Approximate date: 1st millennium B.C. to 15th century A.D.

4. *Mosque Lamps*—May have a straight or round bulbous body with flared top, and several branches. Approximate date: 642 A.D. to 1750 A.D.

E. Mosaic

1. *Floor Mosaics*—Including landscapes, scenes of deities, humans, or animals, and activities such as hunting and fishing. There may also be vegetative, floral, or geometric motifs and imitations of stone. Often have religious imagery. They are made from stone cut into small bits (tesserae) and laid into a plaster matrix. Approximate date: 5th century B.C. to 4th century A.D.

2. *Wall and Ceiling Mosaics*— Generally portray similar motifs as seen in floor mosaics. Similar technique to floor mosaics, but may include tesserae of both stone and glass. Approximate date: 5th century B.C. to 4th century A.D.

F. Painting

1. *Rock Art*—Painted and incised drawings on natural rock surfaces. There may be human, animal, geometric and/or floral motifs. Include fragments. Approximate date: 12,000 B.C. to 100 A.D.

2. *Wall Painting*—With figurative (deities, humans, animals), floral, and/ or geometric motifs, as well as funerary scenes. These are painted on stone, mud plaster, lime plaster (wet—*buon fresco*—and dry—*secco fresco*), sometimes to imitate marble. May be on domestic or public walls as well as in tombs. Approximate date: 1st millennium B.C. to 1551 A.D.

G. Plaster—Stucco reliefs, plaques, stelae, and inlays or other architectural decoration in stucco.

H. Textiles, Basketry, and Rope

1. *Textiles*—Linen cloth was used in Greco-Roman times for mummy wrapping, shrouds, garments, and sails. Islamic textiles in linen and wool, including garments and hangings.

2. *Basketry*—Plant fibers were used to make baskets and containers in a variety of shapes and sizes, as well as sandals and mats.

3. *Rope*—Rope and string were used for a great variety of purposes, including binding, lifting water for irrigation, fishing nets, measuring, and stringing beads for jewelry and garments.

I. Bone, Ivory, Shell, and Other Organics

1. *Small Statuary and Figurines*— Subject matter includes human, animal, and hybrid figures, and parts thereof as well as groups of figures in the round. These range from approximately 4 to 40 in. in height. Approximate date: 1st millennium B.C. to 15th century A.D.

2. *Reliefs, Plaques, Stelae, and Inlays*—Carved and sculpted. May have figurative, floral and/or geometric motifs.

3. *Personal Ornaments and Objects of Daily Use*—In bone, ivory, and spondylus shell. Types include amulets, combs, pins, spoons, small containers, bracelets, buckles, and beads. Approximate date: 1st millennium B.C. to 15th century A.D.

4. *Seals and Stamps*—Small devices with at least one side engraved with a design for stamping or sealing; they can be discoid, cuboid,

conoid, or in the shape of animals or fantastic creatures (*e.g.*, a scarab). Approximate date: 1st millennium B.C. to 2nd millennium B.C.

5. *Luxury Objects*—Ivory, bone, and shell were used either alone or as inlays in luxury objects including furniture, chests and boxes, writing and painting equipment, musical instruments, games, cosmetic containers, combs, jewelry, amulets, seals, and vessels made of ostrich egg shell.

J. Wood—Items such as tablets (*tabulae*), sometimes pierced with holes on the borders and with text written in ink on one or both faces, typically small in size (4 to 12 in. in length), recording sales of property (such as slaves, animals, grain) and other legal documents such as testaments. Approximate date: late 2nd to 4th centuries A.D.

II. Ottoman Ethnological Material

A. Stone

1. *Architectural Elements*—The most common stones are marble, limestone, and sandstone. From sites such as forts, palaces, mosques, shrines, tombs, and monuments, including doors, door frames, window fittings, columns, capitals, bases, lintels, jambs, friezes, pilasters, engaged columns, altars, mihrabs (prayer niches), screens, fountains, mosaics, inlays, and blocks from walls, floors, and ceilings. Often decorated in relief with religious motifs.

2. *Architectural and Non-architectural Relief Sculpture*—In marble, limestone, and sandstone. Types include carved slabs with religious, figural, floral, or geometric motifs, as well as plaques and stelae, sometimes inscribed.

3. *Statuary*—Primarily in marble, but also in limestone and sandstone. Large and small-scale, such as human (including historical portraits or busts) and animal figures.

4. *Sepulchers*—In marble, limestone, and other kinds of stone. Types of burial containers include sarcophagi, caskets, coffins, and chest urns. May be plain or have figural, geometric, or floral motifs painted on them, be carved in relief, and/or have decorative moldings.

5. *Inscriptions, Memorial Stones, and Tombstones*—Primarily in marble, most frequently engraved with Arabic script.

6. *Vessels and Containers*—Include stone lamps and containers such as those used in religious services, as well as smaller funerary urns.

B. Metal

1. *Architectural Elements*—Primarily copper, brass, lead, and alloys. From sites such as forts, palaces, mosques, shrines, tombs, and monuments, including doors, door fixtures, other lathes, chandeliers, screens, and sheets to protect domes.

2. *Architectural and Non-architectural Relief Sculpture*—Primarily bronze and brass. Includes appliques, plaques, and stelae. Often with religious, figural, floral, or geometric motifs. May have inscriptions in Arabic.

3. *Vessels and Containers*—In brass, copper, silver, or gold, plain, engraved, or hammered. Types include jugs, pitchers, plates, cups, lamps, and containers used for religious services (like Qur'an boxes). Often engraved or otherwise decorated.

4. *Jewelry and Personal Adornments*—In a wide variety of metals such as iron, brass, copper, silver, and gold. Includes rings and ring seals, head ornaments, earrings, pendants, amulets, bracelets, talismans, and belt buckles. May be adorned with inlaid beads, gemstones, and leather.

5. *Weapons and Armor*—Often in iron or steel. Includes daggers, swords, saifs, scimitars, other blades, with or without sheaths, as well as spears, firearms, and cannons. Ottoman types may be inlaid with gemstones, embellished with silver or gold, or engraved with floral or geometric motifs and inscriptions. Grips or hilts may be made of metal, wood, or even semi-precious stones such as agate, and bound with leather. Armor consisting of small metal scales, originally sewn to a backing of cloth or leather, and augmented by helmets, body armor, shields, and horse armor.

6. *Ceremonial Paraphernalia*—Including boxes (such as Qur'an boxes), plaques, pendants, candelabra, stamp and seal rings.

7. *Musical Instruments*—In a wide variety of metals. Includes cymbals and trumpets.

C. Ceramic and Clay

1. *Architectural Decorations*—Including carved and molded brick, and engraved and/or painted tile wall ornaments and panels, sometimes with Arabic script. May be from forts, palaces, mosques, shrines, tombs, or monuments.

2. *Vessels and Containers*—Includes glazed, molded, and painted ceramics. Types include boxes, plates, lamps, jars, and flasks. May be plain or decorated with floral or geometric patterns, or Arabic script, primarily using blue, green, brown, black, or yellow colors.

D. Wood

1. *Architectural Elements*—From sites such as forts, palaces, mosques, shrines, tombs, monuments, and madrassas, including doors, door fixtures, panels, beams, balconies, stages, screens, ceilings, and tent posts. Types include doors, door frames, windows, window frames, walls, panels, beams, ceilings, and balconies. May be decorated with religious, geometric or floral motifs or Arabic script.

2. *Architectural and Non-architectural Relief Sculpture*—Carved and inlaid wood panels, rooms, beams, balconies, stages, panels, ceilings, and doors, frequently decorated with religious, floral, or geometric motifs. May have script in Arabic or other languages.

3. *Qur'an Boxes*—May be carved and inlaid, with decorations in religious, floral, or geometric motifs, or Arabic script.

4. *Study Tablets*—Arabic inscribed training boards for teaching the Qur'an.

E. Bone and Ivory

1. *Ceremonial Paraphernalia*—Types include boxes, reliquaries (and their contents), plaques, pendants, candelabra, stamp and seal rings.

2. *Inlays*—For religious decorative and architectural elements.

F. Glass—Vessels and containers in glass from mosques, shrines, tombs, and monuments, including glass and enamel mosque lamps and ritual vessels.

G. Textiles—In linen, silk, and wool. Religious textiles and fragments from mosques, shrines, tombs, and monuments, including garments, hangings, prayer rugs, and shrine covers.

H. Leather and Parchment

1. *Books and Manuscripts*—Either as sheets or bound volumes. Text is often written on vellum or other parchment (cattle, sheep, goat, or camel) and then gathered in leather bindings. Paper may also be used. Types include the Qur'an and other Islamic books and manuscripts, often written in brown ink, and then further embellished with colorful floral or geometric motifs.

2. *Musical Instruments*—Leather drums of various sizes (e.g., bendir drums used in Sufi rituals, wedding processions and Mal'uf performances).

I. Painting and Drawing—Ottoman Period paintings may depict courtly themes (*e.g.*, rulers, musicians, riders on horses) and city views, among other topics.

Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Orders 12866 and 13771

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 or Executive Order 13771 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866 and section 4(a) of Executive Order 13771.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1), pertaining to the Secretary of the Treasury's authority (or that of his/her delegate) to approve regulations related to customs revenue functions.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12) is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g:

■ a. The table in paragraph (a) is amended by adding the entry for Libya in appropriate alphabetical order; and

■ b. The table in paragraph (b) is amended by removing the entry for “Libya” in its entirety, but retaining the table headings.

The addition reads as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

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(a) * * *

State party	Cultural property	Decision No.
* * * * *		
Libya.....	Archaeological and ethnological material from Libya.....	CBP Dec. 18–07..
* * * * *		

Dated: July 3, 2018.

KEVIN K. McALEENAN,
*Commissioner, U.S. Customs and
Border Protection.*

TIMOTHY E. SKUD,
Deputy Assistant Secretary of the Treasury.

[Published in the Federal Register, July 9, 2018 (83 FR 31654)]

NOTICE OF ISSUANCE OF FINAL DETERMINATION CONCERNING MALARONE TABLETS

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of Malarone tablets. Based upon the facts presented, CBP has concluded that the country of origin of the Malarone tablets is Canada for purposes of U.S. Government procurement.

DATES: This final determination was issued on July 2, 2018. A copy of the final determination is attached. Any party-at-interest may seek judicial review of this final determination within August 8, 2018.

FOR FURTHER INFORMATION CONTACT: M. Cunningham, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325–0034.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on July 2, 2018, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued one final determination concerning the country of origin of Malarone tablets, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination (HQ H290684) was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the processing in Canada will result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the Malarone tablets is Canada.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: July 2, 2018.

ALICE A. KIPEL,
Executive Director,
Regulations and Rulings, Office of Trade.

HQ H290684

July 2, 2018

OT:RR:CTF:VS H290684 RMC

CATEGORY: Origin

NICOLAS GUZMAN
DRINKER BIDDLE & REATH LLP
1500 K STREET NW
SUITE 1100
WASHINGTON, DC 20005-1209

Re: U.S. Government Procurement; Country of Origin of Malarone Tablets;
Substantial Transformation

DEAR MR. GUZMAN:

This is in response to your letter, dated September 13, 2017, requesting a final determination on behalf of GlaxoSmithKline LLP (“GSK”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). A teleconference was held with counsel for GSK on June 8, 2018.

This final determination concerns the country of origin of Malarone tablets. As a U.S. importer, GSK is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

GSK is a global healthcare company that researches, develops, and manufactures pharmaceutical medicines, vaccines, and consumer healthcare products. At issue in this case are tablets sold under the brand name Malarone, which are indicated for the prevention and treatment of acute, uncomplicated *Plasmodium falciparum* malaria. GSK states that Malarone tablets have been shown to be effective in regions where other malaria drugs such as chloroquine, halofantrine, mefloquine, and amodiaquine may have unacceptable failure rates, presumably due to drug resistance.

According to the FDA prescribing information, Malarone is a fixed-dose combination of atovaquone and proguanil hydrochloride. See Prescribing Information, https://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4089b1_05_05_atovaquone.pdf (last visited Dec. 11, 2017). The chemical name of atovaquone 11 is trans-2-[4-(4 chlorophenyl)cyclohexyl]-3-hydroxy-1,4-naphthalenedione and the molecular formula for atovaquone is C₂₂H₁₉ClO₃. The chemical name of proguanil hydrochloride is 1-(4-chlorophenyl)-5-isopropyl-biguanide hydrochloride and the chemical formula for proguanil hydrochloride is C₁₁H₁₆ClN₅•HCl. Each Malarone Tablet contains 250 milligrams of atovaquone and 100 milligrams of proguanil hydrochloride.

The FDA prescribing information also describes the microbiology or “mechanism of action” of atovaquone and proguanil hydrochloride. It states that atovaquone and proguanil hydrochloride “interfere with 2 different pathways involved in the biosynthesis of pyrimidines required for nucleic acid replication. Atovaquone is a selective inhibitor of parasite mitochondrial electron transport. Proguanil hydrochloride primarily exerts its effect by means of the metabolite cycloguanil, a dihydrofolate reductase inhibitor. Inhibition of dihydrofolate reductase in the malaria parasite disrupts deoxythymidylate synthesis.”

GSK notes that atovaquone by itself is not indicated for the prevention or treatment of malaria. By itself, atovaquone is used for other purposes, such as the treatment of acute pneumocystis carinii pneumonia and cerebral toxoplasmosis. In contrast, proguanil hydrochloride can be used to treat malaria. However, GSK cites to several academic studies that conclude that the combination of atovaquone and proguanil hydrochloride provides a more effective treatment compared to taking proguanil hydrochloride alone. GSK therefore states that atovaquone and proguanil are “synergistic in their mechanisms of action,” resulting in the increased effectiveness of Malarone tablets compared to taking atovaquone or proguanil hydrochloride alone.

The manufacturing process for GSK’s Malarone tablets begins in India, where the Malarone tablets’ two active pharmaceutical ingredients (“APIs”), atovaquone and proguanil hydrochloride, are manufactured. After the two APIs are manufactured in India, they are imported into Canada for further processing at GSK’s Mississauga, Ontario facility (“GSK Canada”). At GSK Canada, the two APIs are combined in a process that begins by producing a dry mix of the APIs, low-substituted hydroxypropyl cellulose NF, microcrystalline cellulose NF, and sodium starch glycolate NF. The dry mix is then combined with the following inactive ingredients, which are each sourced from the United States or a TAA-eligible country, to produce granules:

- Povidone K30 USP
- Polaxamer 188 NF
- Sofium Starch Glycolate NF
- Hydroxy Propyl Cellulose NF
- Purified Water USP
- Microcrystalline Cellulose NF
- Alcohol USP

Next, the granules are dried, milled into a dry powder, blended with magnesium stearate NF, and compressed into tablets. Finally, a film coat mix is added and the tablets are polished.

Once the manufacturing process is complete, the finished Malarone tablets are exported to a GSK facility in Zebulon, North Carolina. There, the tablets are packaged and labeled for sale to Prasco Laboratories, which markets and distributes the tablets under their own labeling as an authorized generic product under an agreement with GSK.

ISSUE:

What is the country of origin of the Malarone tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002. However, where the processing from bulk form into measured doses involves the combination of two or more APIs, and the resulting combination offers additional medicinal benefits compared to taking each API alone, CBP has held that a substantial transformation occurred. *See, e.g.*, HQ 563207, dated June 1, 2005.

For example, in HQ 563207, CBP held that the combination of two APIs to form Actoplus Met, an alternative treatment for type 2 diabetes, constituted a substantial transformation. The first API, Pioglitazone HCl sourced from Japan or other countries, functioned as an insulin sensitizer that targets insulin resistance in the body. The second API, biguanide sourced from Japan, Spain, and other countries, functioned to decrease the amount of glucose produced by the liver and make muscle tissue more sensitive to insulin so glucose can be absorbed. In Japan, the two APIs were mixed together to form a fixed-combination drug called Actoplus Met. In holding that a substantial transformation occurred when the APIs were combined in Japan to produce Actoplus Met, CBP emphasized that “[w]hile we note that pioglitazone and metformin may be prescribed separately, the final product, Actoplus Met, increases the individual effectiveness of pioglitazone and metformin in treating type 2 diabetes patients.”

Similarly, in HQ H253443, dated March 13, 2015, CBP held that the combination of two APIs in China to produce Prepopik, “a dual-acting osmotic and stimulant laxative bowel preparation for a colonoscopy in adults,” constituted a substantial transformation. Although the importer claimed that Country A-origin sodium picosulfate was the only API in Prepopik, CBP found that the Country B-origin magnesium oxide ingredient also qualified as an API. CBP further found that taking Prepopik had “a more stimulative

laxative effect” than taking each of the APIs individually and therefore held that a substantial transformation occurred when the APIs were combined in China.

Here, as in HQ 563207 and HQ H253443, two separate APIs are mixed to create a fixed combination drug that offers additional medicinal benefits compared to taking each API alone. The first API, atovaquone, is not indicated for the prevention or treatment of malaria. The second API, proguanil hydrochloride, is used to treat malaria, but is less effective than Malarone. This is because of the “synergies in [the APIs’] method of action,” which result in a product that “interfere[s] with 2 different pathways” to prevent and treat malaria. Under these circumstances, the combination of atovaquone, proguanil hydrochloride, and inactive ingredients to form Malarone tablets in Canada results in a substantial transformation. The country of origin of the Malarone tablets is therefore Canada.

HOLDING:

The country of origin of the Malarone tablets for purposes of U.S. Government procurement is Canada.

Notice of this final determination will be given in the **Federal Register**, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

ALICE A. KIPPEL,
*Executive Director,
Regulations & Rulings
Office of Trade.*

[Published in the Federal Register, July 9, 2018 (83 FR 31764)]

COMMERCIAL CUSTOMS OPERATIONS ADVISORY COMMITTEE (COAC) CHARTER RENEWAL

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Charter Renewal.

SUMMARY: The Secretaries of the Department of the Treasury and the Department of Homeland Security approved the renewal of the charter for the Commercial Customs Operations Advisory Committee (COAC). The committee's charter is effective May 15, 2018, and expires May 15, 2020. Section 109 of the Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA) established the COAC. The committee operates in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. App.), except as otherwise provided for in section 109 of TFTEA. The COAC is a statutory advisory committee that provides the Department of the Treasury and the Department of Homeland Security with the perspectives and advice of the private sector.

ADDRESSES: If you desire to submit comments on this action, they must be submitted by September 10, 2018. Comments must be identified by (Docket No. USCBP-2018-0020) and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* (Tradeevents@dhs.gov). Include the docket number in the subject line of the message.
- *Fax:* (202) 325-4290.
- *Mail:* Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229.
- *Instructions:* All submissions received must include the words "Department of Homeland Security" and USCBP-2018-0020, the docket number for this action. Comments received will be posted without alteration at <https://www.regulations.gov> including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and search for Docket Number USCBP-2018-0020. To submit a com-

ment, see the link on the *Regulations.gov* website for “How do I submit a comment?” located on the right hand side of the main site page.

FOR FURTHER INFORMATION CONTACT: Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344-1440; facsimile (202) 325-4290.

Purpose and Objective: In accordance with section 109 of TFTEA, the COAC provides advice to the Secretary of the Treasury and the Secretary of Homeland Security with respect to all matters involving the commercial operations of U.S. Customs and Border Protection (CBP), including advising with respect to significant changes that are proposed with respect to regulations, policies, or practices of CBP; provides recommendations to the Secretary of the Treasury and the Secretary of Homeland Security on improvements to the commercial operations of CBP; collaborates in developing the agenda for Advisory Committee meetings; and performs such other functions relating to the commercial operations of CBP as prescribed by law or as the Secretary of the Treasury and the Secretary of Homeland Security jointly direct.

The COAC charter can be found at <http://www.cbp.gov/sites/default/files/documents/COAC%20Charter%20Filed%203.23.15.pdf>.

Responsible CBP Officials: Mr. Bradley F. Hayes, Executive Director, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344-1440.

Dated: July 3, 2018.

BRADLEY F. HAYES,
Executive Director,
Office of Trade Relations.

[Published in the Federal Register, July 10, 2018 (83 FR 31974)]

**ACCREDITATION AND APPROVAL OF SAYBOLT LP
(NEDERLAND, TX) AS A COMMERCIAL GAUGER AND
LABORATORY**

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP (Nederland, TX) as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Saybolt LP (Nederland, TX) has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 8, 2017.

DATES: Saybolt LP (Nederland, TX) was approved and accredited as a commercial gauger and laboratory as of August 8, 2017. The next triennial inspection date will be scheduled for August 2020.

FOR FURTHER INFORMATION CONTACT: Christopher J. Mocella, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt LP, 4144 N Twin City Hwy., Nederland, TX 77627, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt LP (Nederland, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Saybolt LP (Nederland, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27-03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27-05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27-06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27-13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27-48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
Pending.....	D4007	Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.

Dated: July 2, 2018.

DAVE FLUTY,
Executive Director,
Laboratories and Scientific Services.

[Published in the Federal Register, July 12, 2018 (83 FR 32313)]