

**DEPARTMENT OF HOMELAND SECURITY****U.S. Customs and Border Protection****DEPARTMENT OF THE TREASURY****19 CFR Part 12**

[CBP Dec. 21–16]

RIN 1515–AE68

**Extension and Amendment of Import Restrictions Imposed on Archaeological and Ethnological Material of Greece****AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security; Department of Treasury.**ACTION:** Final rule.

**SUMMARY:** This final rule amends the U.S. Customs and Border Protection (CBP) Regulations to reflect an extension and amendment of import restrictions on certain archaeological and ecclesiastical ethnological material of the Hellenic Republic (Greece). The restrictions, which were originally imposed by CBP Dec. 11–25 and last extended in CBP Dec. 16–21, are due to expire on November 21, 2021. The Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has made the requisite determinations for extending the import restrictions that previously existed, and the Government of the United States and the Government of Greece entered into a new agreement to reflect the extension of these import restrictions. The new agreement, which enters into force on November 21, 2021, supersedes the existing Memorandum of Understanding (MOU) that became effective on November 21, 2016, and enabled the promulgation of the existing import restrictions. Accordingly, the import restrictions will remain in effect for an additional five years, and the CBP regulations are being amended to reflect this extension until November 21, 2026. To fulfill the terms of the new MOU, the Designated List of cultural property, which was described in CBP Dec. 11–25, is amended in this document to correct certain typographical errors, to add certain coins from the Byzantine and Medieval periods, to clarify pottery styles, and to include post-Byzantine ethnological material dating up to A.D. 1830.

**DATES:** Effective November 21, 2021.**FOR FURTHER INFORMATION CONTACT:** For legal aspects, W. Richmond Beavers, Chief, Cargo Security, Carriers and Restricted Merchandise Branch,

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**SUPPLEMENTARY INFORMATION:****Background**

Pursuant to the Convention on Cultural Property Implementation Act, Public Law 97–446, 19 U.S.C. 2601 *et seq.* (hereinafter, “the Cultural Property Implementation 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, “the Convention” (823 U.N.T.S. 231 (1972))), the United States entered into a bilateral agreement with Greece on November 21, 2011. The Memorandum of Understanding (MOU) enabled the promulgation of import restrictions on archaeological material representing Greece’s cultural heritage from the Upper Paleolithic (beginning approximately 20,000 B.C.) through the 15th century A.D., and ecclesiastical ethnological material representing Greece’s Byzantine cultural heritage (approximately the 4th century through the 15th century A.D.).

On December 1, 2011, U.S. Customs and Border Protection (CBP) published CBP Dec. 11–25, in the **Federal Register** (76 FR 74691), which amended 19 CFR 12.104g(a) to indicate the imposition of these restrictions and included a list designating the types of archaeological and ecclesiastical ethnological material covered by the restrictions. The restrictions were subsequently extended in 2016. CBP published a final rule (CBP Dec. 16–21) in the **Federal Register** (81 FR 84458), following the exchange of diplomatic notes, extending the import restrictions for a period of five years until November 21, 2021.

Import restrictions listed at 19 CFR 12.104g(a) are effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period may be extended for additional periods of not more than five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists. Since the initial notice was published on December 1, 2011, the import restrictions have been extended once. Following the exchange of diplomatic notes, CBP published a final rule (CBP Dec. 16–21) in the **Federal Register** (81 FR 84458), to

extend the import restrictions for a period of five years to November 21, 2021.

On August 20, 2020, the United States Department of State proposed in the **Federal Register** (85 FR 51544), to extend the MOU between the United States and Greece concerning the import restrictions on certain categories of archeological and ecclesiastical ethnological material of Greece. On March 21, 2021, the Acting Assistant Secretary for Educational and Cultural Affairs, Department of State, after consultation with and recommendations by the Cultural Property Advisory Committee, determined that the cultural heritage of Greece continues to be in jeopardy from pillage of certain archaeological and ecclesiastical ethnological material, and that the import restrictions should be extended for an additional five years.

Subsequently, on September 22, 2021, the Governments of the United States and Greece entered into a new agreement, titled “Memorandum of Understanding between the Government of the United States of America and the Government of the Hellenic Republic Concerning the Imposition of Import Restrictions on Categories of Certain Archaeological and Ethnological Materials of the Hellenic Republic,” which is effective on November 21, 2021. The new MOU supersedes the existing MOU that first entered into force on November 21, 2011. Pursuant to the new MOU, the import restrictions will remain in effect for an additional five years.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions. The restrictions are to continue in effect until November 21, 2026. Importation of such material of Greece, as described in the Designated List below, shall be restricted through that date unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

The Designated List and additional information may also be found at the following website address: <https://eca.state.gov/cultural-heritage-center/cultural-property-advisory-committee/current-import-restrictions> by selecting the material for “Greece.”

**Designated List of Archaeological and Ecclesiastical Ethnological Material of Greece**

The Designated List contained in CBP Dec. 11–25, which describes the types of articles to which the import restrictions apply, is amended to reflect the addition of certain archaeological and ecclesiastical ethnological material to the Designated List. To fulfill the terms

of the new MOU, the Designated List of cultural property is amended in this document to add certain coins from the Byzantine and Medieval periods, to clarify pottery styles, and to include post-Byzantine ethnological material dating up to A.D. 1830, as well as clarify certain provisions of the Designated List contained in CBP Dec. 11–25 by making minor revisions to the language, organization, and numbering of the Designated List. For the reader's convenience, CBP is reproducing the Designated List contained in CBP Dec. 11–25 in its entirety, with the changes, below.

The Designated List includes archaeological material from Greece ranging in date from approximately the 3rd millennium B.C. to 15th century A.D., and ecclesiastical ethnological material from Greece from the Early Christian, Byzantine, and post-Byzantine periods, including objects made from A.D. 324 through 1830.

### Categories of Archaeological and Ethnological Ecclesiastical Material

- I. Archaeological Material
  - A. Stone
  - B. Metal
  - C. Ceramic
  - D. Bone, Ivory, Wood and Other Organics
  - E. Glass and Faience
  - F. Textile
  - G. Papyrus Documents
  - H. Paintings
  - I. Mosaics
- II. Ecclesiastical Ethnological Material
  - A. Stone
  - B. Metal
  - C. Ceramic
  - D. Bone and Ivory Objects
  - E. Wood
  - F. Glass
  - G. Textile
  - H. Parchment and Paper
  - I. Painting
  - J. Mosaics

### I. Archaeological Material

The archaeological materials represent the following periods, styles, and cultures: Upper Paleolithic, Neolithic, Minoan, Cycladic, Helladic, Mycenaean, Submycenaean, Geometric, Orientalizing, Archaic, Classical, Hellenistic, Roman, Byzantine, and Medieval.

#### A. Stone

##### 1. Sculpture

a. Architectural Elements—In marble, limestone, gypsum, and other kinds of stone. Types include acroteria, antefixes, architrave, base, basin, capital, caryatid, coffer, column, crowning, fountain, frieze, pediment, pilaster, mask, metope, mosaic and inlay, jamb, tile, triglyph, tympanum, wellhead, revetment, cut stone paving,

tiles. Approximate date: 3rd millennium B.C. to 15th century A.D.

b. Monuments—In marble, limestone, and other kinds of stone. Types include menhir, “horns of consecration,” votive statues, funerary and votive stelae, and bases and base revetments, and columnar grave monuments. These may be painted, carved with relief sculpture, and/or carry dedicatory or funerary inscriptions. Approximate date: 3rd millennium B.C. to 15th century A.D.

c. Sarcophagi—In marble, limestone, and other kinds of stone. Some have figural scenes painted on them, others have figural scenes carved in relief, and some just have decorative moldings. Approximate date: 3rd millennium B.C. to 15th century A.D.

d. Large Statuary—Primarily in marble, also in limestone and sandstone, including fragments of statues. Subject matter includes human and animal figures and groups of figures in the round. Common types are large-scale, free-standing statuary from approximately 1 m to 2.5 m in height and life-size busts (head and shoulders of an individual). The style may be naturalistic, as in the Classical Period, highly stylized, as in the Bronze Age culture of the Cyclades, or somewhere in between. Approximate date: 4th millennium B.C. to 15th century A.D.

e. Small Statuary and Figurines—In marble and other stone. Subject matter includes human and animal figures and groups of figures in the round. These range from approximately 10 cm to 1 m in height. The style may be naturalistic, as in the Classical Period, highly stylized, as in the Bronze Age culture of the Cyclades, or somewhere in between. Approximate date: 20,000 B.C. to 15th century A.D.

f. Reliefs—In marble and other stone. Types include carved slabs with figural, vegetative, floral, or decorative motifs, sometimes inscribed, and carved relief vases. Used for architectural decoration, funerary, votive, or commemorative monuments. Approximate date: 3rd millennium B.C. to 15th century A.D.

g. Furniture—In marble and other stone. Types include tables; thrones; beds; and altars, round or rectangular. Approximate date: 12th century B.C. to 15th century A.D.

2. Vessels—In marble, steatite, rock crystal, and other stone. These may belong to conventional shapes such as bowls, cups, jars, jugs, and lamps, or may occur in the shape of an animal or human, or part of an animal or human. Approximate date: 7th millennium B.C. to 15th century A.D.

3. Tools and Weapons—In flint/chert, obsidian, and other hard stones. Chipped stone types include blades,

small blades, borers, scrapers, sickles, cores, arrow heads, and spindle whorls. Ground stone types include grinders (e.g., mortars, pestles, millstones, whetstones), choppers, axes, hammers, and mace heads. Approximate date: 20,000 B.C. to 15th century A.D.

4. Seals and Beads—In marble, limestone, and various semiprecious stones including rock crystal, amethyst, jasper, agate, steatite, and carnelian. Approximate date: 6th millennium B.C. to 15th century A.D.

#### B. Metal

##### 1. Sculpture

a. Large Statuary—Primarily in bronze, including fragments of statues. Subject matter includes human and animal figures and groups of figures in the round. Common types are large-scale, free-standing statuary from approximately 1 m to 2.5 m in height and life-size busts (head and shoulders of an individual). Approximate date: 2nd millennium B.C. to A.D. 324.

b. Small Statuary and Figurines—Subject matter includes human and animal figures, groups of figures in the round, masks, and plaques. These range from approximately 10 cm to 1 m in height. Approximate date: 3rd millennium B.C. to A.D. 324.

c. Inscribed or Decorated Sheet Metal—In bronze, lead, and gold. Engraved inscriptions, “curse tablets,” “Orphic/Dionysiac tablets,” and thin metal sheets with engraved or impressed designs often used as attachments to furniture and clothing. Approximate date: 4th millennium B.C. to 15th century A.D.

2. Vessels—In bronze, gold, and silver. These may belong to conventional shapes such as bowls, cups, jars, jugs, strainers, cauldrons, and lamps, or may occur in the shape of an animal or part of an animal. Approximate date: 5th millennium B.C. to 15th century A.D.

3. Personal Ornaments—In bronze, gold, and silver. Types include rings, beads, pendants, belts, belt buckles, earrings, diadems, spangles, straight and safety pins (fibulae), necklaces, mirrors, wreaths, cuffs, and funerary masks. Approximate date: 7th millennium B.C. to 15th century A.D.

4. Tools—In copper, bronze, iron, and lead. Types include hooks, weights, axes, scrapers, (strigils), trowels, keys; the tools of craftspersons such as carpenters, masons and metal smiths; and medical tools such as needles, spoons, lancets, and forceps. Approximate date: 4th millennium B.C. to 15th century A.D.

5. Weapons and Armor—In copper, bronze, iron and lead. Types include

both launching weapons (spears and javelins) and weapons for hand-to-hand combat (swords, daggers, etc.). Armor includes body armor, such as helmets, cuirasses, shin guards, and shields, and horse armor often decorated with elaborate engraved, embossed, or perforated designs. Approximate date: 6th millennium B.C. to 30 B.C.

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

7. Coins—Many of the mints of the listed coins can be found in B.V. Head, *Historia Numorum: A Manual of Greek Numismatics* (London, 1911) and C.M. Kraay, *Archaic and Classical Greek Coins* (London, 1976). Many of the Roman provincial mints in Greece are listed in A. Burnett *et al.*, *Roman Provincial Coinage I: From the Death of Caesar to the Death of Vitellius (44 BC–AD 69)* (London, 1992) and *id.*, *Roman Provincial Coinage II: From Vespasian to Domitian (AD 69–96)* (London, 1999).

a. Greek Bronze Coins—Struck by city-states, leagues, and kingdoms that operated in the territory of the modern Greek state (including the ancient territories of the Peloponnese, Central Greece, Thessaly, Epirus, Crete and those parts of the territories of ancient Macedonia, Thrace and the Aegean islands that lay within the boundaries of the modern Greek state). Approximate date: 5th century B.C. to late 1st century B.C.

b. Greek Silver Coins—This category includes the small denomination coins of the city-states of Aegina, Athens, and Corinth, and the Kingdom of Macedonia under Philip II and Alexander the Great. Such coins weigh less than approximately 10 grams and are known as obols, diobols, triobols, hemidrachms, and drachms. Also included are all denominations of coins struck by the other city-states, leagues, and kingdoms that operated in the territory of the modern Greek state (including the ancient territories of the Peloponnese, Central Greece, Thessaly, Epirus, Crete, and those parts of the territories of ancient Macedonia, Thrace and the Aegean islands that lie within the boundaries of the modern Greek state). Approximate date: 6th century B.C. to late 1st century B.C.

c. *Roman Coins Struck in Greece*—In silver and bronze, struck at Roman and Roman provincial mints that operated in the territory of the modern Greek state (including the ancient territories of the Peloponnese, Central Greece, Thessaly, Epirus, Crete, and those parts of the territories of ancient Macedonia, Thrace and the Aegean islands that lie within

the boundaries of the modern Greek state). Approximate date: late 2nd century B.C. to 3rd century A.D.

d. *Coins from the Byzantine and Medieval Periods*—This category includes coin types such as those of the Byzantine and medieval Frankish and Venetian states that circulated primarily in Greece, ranging in date from approximately the 3rd century A.D. to the 15th century A.D.

### C. Ceramic

#### 1. Sculpture

a. Architectural Elements—Baked clay (terracotta) elements used to decorate buildings. Elements include acroteria, antefixes, painted and relief plaques, metopes, cornices, roof tiles, revetments, and brick. Approximate date: 3rd millennium B.C. to 30 B.C.

b. Large Statuary—Subject matter includes human and animal figures and groups of figures in the round. Common types are large-scale, free-standing statuary from approximately 1 m to 2.5 m in height and life-size busts (head and shoulders of an individual). Approximate date: 3rd millennium B.C. to 30 B.C.

c. Small Statuary—Subject matter is varied and includes human and animal figures, human body parts, groups of figures in the round, shrines, houses, and chariots. Includes Mycenaean and later Tanagra figurines. These range from approximately 10 cm to 1 m in height. Approximate date: 7th millennium B.C. to A.D. 324.

d. *Sarcophagi*—Block- or tub-shaped chests, often painted, known as *larnax* (plural, *larnakes*). Approximate date: 3rd millennium B.C. to 30 B.C.

#### 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 with three or four legs to handled scoops and large storage jars. Approximate date: 7th millennium B.C. to 3rd millennium B.C.

b. Minoan, Cycladic, and Mycenaean Pottery—Handmade and wheelmade pottery in shapes for tableware, serving, storing, and processing, with lustrous burnished, matte, appliqué, incised, and painted decoration; includes local styles such as Kamares ware, Pictorial Style, and extraordinary shapes such as “frying pans” and “kernois.” Approximate dates: 4th millennium B.C. to 12th century B.C.

c. “Submycenaean” and Pottery of the Geometric Period (including “sub-Geometric”)—Handmade and wheelmade pottery that succeeds the styles of the Late Bronze Age and is

produced in decorated and undecorated styles, often reflecting that of the Late Bronze Age but predominately using compasses for circles and linear “geometric” decoration, as well as schematic representations of humans, animals and birds. This category also includes Proto-Attic Black and White style pottery. Approximate dates: 12th century B.C. to 7th century B.C.

d. Attic Black Glaze, 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). Approximate date: 6th century B.C. to 4th century B.C.

e. Corinthian Pottery—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.

f. West Slope Ware—This ware is named after a type of pottery from the west slope of the Athenian Acropolis. It has a black-glaze with relief and polychrome decoration and was produced first in Athens in the fourth century B.C., but the style is also manufactured elsewhere, such as at Corinth, Macedonia and Crete down to the first century B.C. Approximate date: 4th century B.C. to 1st century B.C.

g. Moldmade Bowls—These bowls with relief decoration were developed in Athens in the late third century B.C. and soon manufactured elsewhere, such as in Corinth and Argos. Patterns include pine-cone scales, leaves, petals, or figural scenes. They have black glaze, often with a metallic sheen. Approximate date: 3rd century B.C. to 1st century B.C.

h. Utilitarian Ware—Includes undecorated plates, cooking pots, water jars (plain and incised), plain perfume jars (unguentaria), and transport amphorae (often with stamped handles). Approximate date: 6th century B.C. to A.D. 324.

i. Byzantine Pottery—Includes undecorated plain wares, utilitarian, tableware, serving and storage jars, special shapes such as pilgrim flasks, and can be matte painted or glazed, including incised “sgraffito” and stamped with elaborate polychrome decorations using floral, geometric, human, and animal motifs; it is generally locally manufactured, though

places like Corinth were major producers. Approximate date: 324 A.D. to 15th century A.D.

3. Inscriptions—These are typically unbaked and should be handled with extreme care, even when hard-fired through accidental burning. They typically take the form of tablets shaped like leaves of rectangular or square shape and they are often lined, with incised, and sometimes stamped, characters known as “Linear A” and “Linear B.” Approximate date: 2nd millennium B.C. to 12th century B.C.

4. Lamps—Can be handmade, wheelmade, or moldmade. Shapes include open with a pinched nozzle, partially enclosed with a rim, or covered with a decorated disc. Athens and Corinth were major producers. Approximate date: 7th century B.C. to A.D. 324.

5. Loom Weights—Shapes include conical, pyramidal, disc or rings. Can be stamped, incised, or glazed. Approximate date: 7th millennium B.C. to 15th century A.D.

#### D. Bone, Ivory, Wood and Other Organics

1. Small Statuary and Figurines—Subject matter includes human and animal figures and groups of figures in the round. These range from approximately 10 cm to 1 m in height. Approximate date: 7th millennium B.C. to 15th century A.D.

2. Personal Ornaments—In bone, ivory, and spondylus shell. Types include amulets, combs, pins, spoons, small containers, bracelets, buckles, and beads. Approximate date: 7th millennium B.C. to 15th century A.D.

3. 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: 7th millennium B.C. to 2nd millennium B.C.

4. Musical Instruments—In bone, ivory and tortoise shell. Types include pipe and flute. Approximate date: 3rd millennium B.C. to 15th century A.D.

5. Ostrich Egg Vessels—Often decorated with an incised scene (e.g., geometric, animal, human, etc.). Approximate date: 3rd millennium B.C. to 2nd millennium B.C.

6. Furniture—Bone and ivory furniture inlays and veneers. Approximate date: 2nd millennium B.C. to 15th century A.D.

#### E. Glass and Faience

1. Vessels—Shapes include small jars, bowls, animal shaped, goblet, spherical, candle holders, perfume jars

(unguentaria). Approximate date: 2nd millennium B.C. to 15th century A.D.

2. Beads—Globular and relief beads. Approximate date: beginning in 2nd millennium B.C.

3. Small Statuary—Includes human and animal figures in the round, scarabs, and other imitations of eastern themes. These range from approximately 3 to 20 cm in height. Approximate date: 2nd millennium to 7th century B.C.

#### F. Textiles

Clothing or fragments of clothing or carpets or cloth for hanging. Approximate date: 1100 B.C. to 15th century A.D.

#### G. Papyrus Documents

Documents made from papyrus and written upon in ink; these are often rolled, fragmentary, and should be handled with extreme care. Approximately 7th century B.C. to A.D. 324.

#### H. Paintings

1. Domestic and Public Wall Painting—These are painted on mudplaster, lime plaster (wet—buon fresco—and dry—secco fresco); types include simple applied color, bands and borders, landscapes, scenes of people and/or animals in natural or built settings. Approximate date: 3rd millennium B.C. to A.D. 324.

2. Tomb Paintings—Paintings on plaster or stone, sometimes geometric or floral but usually depicting gods, goddesses, or funerary scenes. Approximate date: 2nd millennium B.C. to A.D. 500.

3. Panel Paintings on wood depicting gods, goddesses, or funerary scenes. Approximate date: 1st millennium B.C. to A.D. 324.

#### I. Mosaics

Floor mosaics including landscapes, scenes of humans or gods, and activities such as hunting and fishing. They are made from stone, tile, or glass cut into small bits (tesserae) and laid into a plaster matrix. They may also be vegetative, floral, or decorative motifs. Approximate date: 5th century B.C. to A.D. 500.

## II. Ecclesiastical Ethnological Material

The ecclesiastical ethnological materials represent the Early Christian and Byzantine, and post-Byzantine periods and include objects made from A.D. 324 through 1830.

#### A. Stone

1. Architectural Elements—In marble and other stone, including upright

“closure” slabs, circular marking slabs *omphalion*, which may be decorated with crosses, human, or animal figures.

2. Monuments—In marble and other stone; types such as funerary inscriptions.

3. Vessels—Containers for holy water.

4. Reliefs—In marble and other stone, used for architectural decoration. May be carved as icons in which religious figures predominate in the figural decoration.

5. Furniture—In marble and other stone. Types include thrones and altars.

#### B. Metal

1. Reliefs—Cast as icons in which religious figures predominate in the figural decoration.

2. Boxes—Containers of gold and silver, used as reliquaries for sacred human remains. Carved and engraved decoration includes religious figures, scenes from the Bible, floral and geometric designs.

3. Vessels—Containers of lead, which carried aromatic oils and are called “pilgrim flasks.”

4. Ceremonial paraphernalia—In bronze, silver, and gold including asterisks, censers (incense burners), communion chalices and disks, book covers, lances, liturgical items like ciborium (*artophorion*), book covers, benediction or processional crosses, bishop’s crowns, buckles, and chests. These are often decorated with molded or incised geometric motifs or scenes from the Bible, inscriptions in Greek, and encrusted with semi-precious or precious stones. The gems themselves may be engraved with religious figures or inscriptions. Ecclesiastical treasure may include all of the above, as well as rings, earrings, and necklaces (some decorated with ecclesiastical themes) and other implements (e.g., spoons).

#### C. Ceramic

Vessels which carried aromatic oils and are called “pilgrim flasks.”

#### D. Bone and Ivory Objects

Ceremonial paraphernalia including boxes, reliquaries (and their contents), plaques, pendants, candelabra, stamp rings, crosses. Carved and engraved decoration includes religious figures, scenes from the Bible, and floral and geometric designs.

#### E. Wood

Wooden objects include architectural elements such as painted wood screens (iconostasis) and *lypira*; carved doors, crosses, painted wooden beams from churches or monasteries, and monastery seals; furniture such as thrones, pulpit bases (*proskinitaria*), lecturns

(*analogia*); chests, and other objects, including musical instruments. Religious figures predominate in the painted and carved figural decoration. Ecclesiastical furniture and architectural elements may also be decorated with geometric or floral designs and/or inlaid with glass or other material.

**F. Glass**

Vessels of glass include lamps, candle sticks, and other ritual vessels.

**G. Textile**

Ecclesiastical garments and other ritual textiles, including robes, vestments (*sakkos, phelonion, omophorion, epitachelion, epigonation*), and altar clothes. They are often of a fine fabric and richly embroidered in silver and gold. Embroidered designs include religious motifs and figures, floral, and geometric designs.

**H. Parchment and Paper**

Documents such as illuminated manuscripts occur in single leaves or bound as a book or “codex” and are written or painted on animal skins (cattle, sheep/goat, camel) known as parchment. Illuminated manuscripts, printed books used for religious/ritual purposes, and icons may also be printed on paper in the post-Byzantine period.

**I. Paintings**

1. Wall paintings—On various kinds of plaster and which generally portray religious images and scenes of Biblical events. Surrounding paintings may contain animal, floral, or geometric designs, including borders and bands.

2. Panel Paintings (Icons)—Smaller versions of the scenes on wall paintings, and may be partially covered with gold or silver, sometimes encrusted with

semi-precious or precious stones and are usually painted on a wooden panel, often for inclusion in a wooden screen (iconostasis).

**J. Mosaics**

Wall mosaics generally portray religious images and scenes of Biblical events. Surrounding panels may contain animal, floral, or geometric designs. They are made from stone and glass cut into small bits (tesserae) and laid into a plaster matrix.

**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; see 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 Order 12866**

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 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.

**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.

Troy A. Miller, Acting Commissioner, U.S. Customs and Border Protection, having reviewed and approved this document, is delegating the authority to electronically sign this document to Robert F. Altneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

**List of Subjects in 19 CFR Part 12**

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, Reporting and recordkeeping requirements.

**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, the table in paragraph (a) is amended by revising the entry for Greece (Hellenic Republic) to read as follows:

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

(a) \* \* \*

State party	Cultural property	Decision No.
*	*	*
Greece (Hellenic Republic)	Archeological materials representing Greece’s cultural heritage ranging in date from approximately 3rd millennium B.C. to 15th century A.D., and ecclesiastical ethnological material from Greece from the early Christian, Byzantine, and post-Byzantine periods, including objects made from A.D. 324 through 1830.	CBP Dec. 21–16.
*	*	*

\* \* \* \* \*

**Robert F. Altneu,**

*Director, Regulations & Disclosure Law  
Division, Regulations & Rulings, Office of  
Trade U.S. Customs and Border Protection.*

Approved: November 17, 2021.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. FDA-2020-N-1088]

#### **Microbiology Devices; Reclassification of Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Assay Devices, Renamed to Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Tests**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify nucleic acid-based hepatitis C virus (HCV) ribonucleic acid (RNA) devices intended for the qualitative or quantitative detection or genotyping of HCV RNA, postamendments class III devices (product codes MZP and OBF), into class II (general controls and special controls), subject to premarket notification. FDA is renaming and codifying these devices under the classification regulation named “nucleic acid-based hepatitis C virus (HCV) ribonucleic acid tests.” FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of these devices.

**DATES:** This order is effective December 22, 2021.

**FOR FURTHER INFORMATION CONTACT:**

Silke Schlottmann, Division of Microbiology Devices, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3258, Silver Spring, MD 20993-0002, 301-796-9551, [Silke.Schlottmann@fda.hhs.gov](mailto:Silke.Schlottmann@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### **I. Background—Regulatory Authorities**

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended

for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (general and special controls), and class III (general controls and premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until: (1) FDA reclassifies the device into class I or II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807, subpart E (21 CFR part 807, subpart E).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

FDA relies upon “valid scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2), in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))). Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA) (see section 520(c) of the FD&C Act).

FDA published a proposed order in the **Federal Register** of April 2, 2020 (85 FR 18483), to reclassify nucleic acid-

based HCV RNA devices intended for the qualitative or quantitative detection or genotyping of HCV RNA, postamendment class III devices, into class II (general controls and special controls), subject to premarket notification. FDA has considered the information available to the Agency, including the deliberations of the March 22, 2018, Microbiology Devices Panel (2018 Panel), and comments from the public docket and has determined that there is sufficient information to establish special controls to effectively mitigate the risks to health identified in section V of the proposed order, and that these special controls, together with general controls, provide a reasonable assurance of safety and effectiveness when applied to nucleic acid-based HCV RNA devices intended for the qualitative or quantitative detection or genotyping of HCV RNA.

Therefore, in accordance with section 513(f)(3) of the FD&C Act, FDA, on its own initiative, is issuing this final order to reclassify nucleic acid-based HCV RNA devices intended for the qualitative or quantitative detection or genotyping of HCV RNA from class III to class II (general and special controls).<sup>1</sup>

#### **II. Comments on the Proposed Order**

On April 2, 2020, FDA published in the **Federal Register** a proposed order to reclassify nucleic acid-based HCV RNA devices intended for the qualitative or quantitative detection or genotyping of HCV RNA from class III to class II, subject to premarket notification. The comment period on the proposed order closed on June 1, 2020. In response to the proposed order, FDA received comments from industry, healthcare associations, public health departments, and individual consumers by the close of the comment period, some of which contained one or more comments on one or more issues. We describe and respond to the comments in this section of the document. Certain comments are grouped based on common themes; we grouped similar comments together under the same number and listed them numerically.

<sup>1</sup> FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of **Federal Register**'s (OFR) interpretation of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22) and the Document Drafting Handbook.