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, 2011 and extended in CBP Dec. 16–21, and enables 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.


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SUPPLEMENTARY INFORMATION:

Background


On December 1, 2011, U.S. Customs and Border Protection (CBP) published CBP Dec. 11–25, in the Federal Register (76 FR 74091), which amended 19 CFR 12.104(g) 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 12.104(g) 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 twice. 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 archeological 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 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 12.104(g) 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
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, gyspum, and other kinds of
   stone. Types include acroteria,
antefixes, architrave, base, basin,
capital, caryatid, eoff, 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 statury 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 decoratoin,
   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
   part of an animal. Approximate date:
   5th millennium B.C. to 15th century A.D.

2. Tools—In flint/chert, obsidian, and other hard stones.
Chipped stone types include blades,
small blades, borers, scrapers, sickles,
cores, arrow heads, and spindie whors.
Ground stone types include grinders
(e.g., mortars, pesties, 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 semi-precious
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,
wraths, 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], tweels, keys;
   the tools of craftpersons 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 B.C.–AD 69) (London, 1992) and id., Roman Provincial Coinage II: From Vespasian to D-operator (London, 1996). In Greek, the coin includes the ancient territories of the Peloponnese, Greece, Thessaly, Epirus, Crete, 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 the Aegean islands that lie within the boundaries of the modern Greek state). Approximate date: 6th millennium B.C. to 30 B.C.

Approximate date: 6th millennium 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. Sarkophagi—Block- or tub-shaped chests, often named after a type of pottery from the 1st century B.C. to the 1st century B.C.

e. Moldmade Bowls—These bowls with relief decoration were developed in Athens in the late third century B.C. and soon 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.

f. Organic 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. There 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...
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.
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(f) 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).1

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.

1 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.