Background

As described in the FAQs below, BIS currently considers SARS-CoV-2 to be distinct from SARS-CoV and MERS-CoV, and as such, will continue to classify SARS-CoV-2 and its specific genetic elements as EAR99. The mRNA vaccines against COVID-19, as well as adenovirus chimeric SARS-CoV-2 spike protein vaccines already in distribution, are classified as EAR99. An export license is generally not required for export of this virus, it's genetic elements, or vaccines against COVID-19 to most destinations.

FAQ Guidance

Since the International Committee on Taxonomy of Viruses (ICTV) officially named the virus causing the current outbreak of coronavirus disease "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and a member of the severe acute respiratory syndrome-related coronavirus species, does BIS consider this pathogen now controlled under Export Control Classification Number (ECCN) 1C351.a.47?

The ICTV is the international body responsible for official classification and taxonomy of viruses. In a report published on February 7, 2020, the organization classified the causative agent of COVID-19 respiratory disease as SARS-CoV-2 virus. It further noted that the virus is a variant belonging to the species *severe acute respiratory syndrome-related coronavirus.* The Commerce Control List (CCL) currently controls the export of SARS-CoV under the ECCN 1C351.a.47, "severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus)."

While the official nomenclature of the species exactly matches the entry for SARS-CoV on the CCL, SARS-CoV-2 is a genetically distinct virus from SARS-CoV and causes a clinically distinct disease, COVID-19, from the severe acute respiratory syndrome-related coronavirus caused by SARS-CoV. The existing SARS entry was intended to capture only the virus causing severe acute respiratory syndrome, after the etiology, pathogenicity, and epidemiology were well established in the public health community. In contrast, the disease transmission, progression, and lethality of SARS-CoV-2 virus are not yet fully elucidated.

Therefore, BIS currently considers SARS-CoV-2 virus to be distinct from the SARS-CoV virus and as such will continue to classify the SARS-CoV-2 and its specific genetic elements as EAR99. An export license is generally not required for export of this virus or its genetic elements to most destinations. However, exporters are reminded that certain end-users, end-uses, and destinations may require a license for the export of EAR99 items. Exporters should continue to screen all requests in accordance with Supplement No. 3 to Part 732 of the Export Administration Regulations (EAR), the General Prohibitions in Part 736 of the EAR, the Consolidated Screening List, and the end-user and end-use-based controls in Part 744 of the EAR.

BIS recently updated the vaccine control, ECCN 1C991. Are the COVID-19 vaccines captured under this final rule?

There are two general categories of COVID-19 vaccines that are seeking or have received FDA approval for distribution in the U.S.: 1) mRNA vaccines that deliver mRNA that produces the SARS-CoV-2 spike protein in the host cell; and 2) chimeric viruses that express the spike protein.

As stated previously, BIS currently considers SARS-CoV-2 and its genetic elements to be EAR99, therefore the SARS-CoV-2 spike protein is considered to be EAR99. The mRNA vaccines currently distributed in the United States are considered to be EAR99. An export license is generally not required for export of mRNA COVID-19 vaccines to most destinations. However, exporters are reminded that certain end-users, end-uses, and destinations may require a license for the export of EAR99 items.

The chimeric virus based COVID-19 vaccines incorporate an additional virus that may or may not be a controlled agent. If the viral agent is not controlled (e.g. adenovirus and measles), then the vaccine is considered to be EAR99. An export license is generally not required for export of these COVID-19 vaccines to most destinations. However, exporters are reminded that certain end-users, end-uses, and destinations may require a license for the export of EAR99 items.

As a result of the January 7, 2021 update to ECCN 1C991 vaccines designed for use against COVID-19 that incorporate controlled agents (e.g. Newcastle disease virus and Vesicular stomatitis virus) or their genetic elements are controlled under ECCN 1C991 for anti-terrorism (AT1) reasons. Therefore, a license is required to export these vaccines to certain destinations in accordance with the embargoes and other special controls described in Part 746 of the EAR. Prior to this update to the EAR, these chimeric vaccines were controlled under ECCN 1C353 for chemical and biological weapons (CB1) and AT1 reasons with worldwide licensing requirements.

Please note that the ECCN 1C991 classification applies only to the finished vaccine formulated for direct patient use. Bulk drug products containing controlled genetically modified organisms or genetic elements are controlled under ECCN 1C353.

Does an EAR99 COVID-19 vaccine require a license for export or reexport to Cuba, Iran, North Korea, or Syria?

Pursuant to Sec. 746.2 of the Export Administration Regulations (EAR), in most circumstances, EAR99 COVID-19 vaccine requires a license for export or reexport to Cuba, which is subject to a comprehensive embargo codified in U.S. law. In some cases, donations of COVID-19 vaccine may be authorized under License Exception GFT, if the terms and conditions of 15 C.F.R. § 740.12(b) are met.

Pursuant to Sec. 746.7 of the EAR, EAR99 COVID-19 vaccine does not require a BIS license for export or reexport to Iran, other than in specific circumstances such as the involvement of a denied party. However, no person may export or reexport any item that is subject to the EAR, including EAR99 items, if such transaction is prohibited by the Iranian Transactions and

Sanctions Regulations (31 CFR part 560) and not authorized by the Department of the Treasury's Office of Foreign Assets Control (OFAC). Please consult OFAC for license requirements and the availability of general licenses pursuant to the Iranian Transactions and Sanctions Transactions. For questions regarding OFAC-administered sanctions against Iran, please visit OFAC's website or call (800) 540-6322.

Pursuant to Sec. 746.4 of the EAR, EAR99 COVID-19 vaccine does not require a license for export or reexport to North Korea, as EAR99 medicine receives license-free treatment to that country.

Pursuant to Sec. 746.9 of the EAR, EAR99 COVID-19 vaccine does not require a license for export or reexport to Syria, as EAR99 medicine receives license-free treatment to that country.

As with any export or reexport, transactions involving certain restricted end-users or for restricted end-uses, as described in parts 744 and 746 of the EAR, may trigger additional license requirements. Please consult BIS at Foreign.Policy@bis.doc.gov if you know or have reason to believe a denied or otherwise restricted party is involved in your transaction or to discuss other specific circumstances.

Does 1C991 COVID-19 vaccine require a license for export or reexport to Cuba, Iran, North Korea, or Syria?

1C991 COVID-19 vaccine requires a license for export or reexport to Cuba, North Korea and Syria. Please see the references to the appropriate sections of the EAR noted above.

For export or reexport of 1C991 COVID-19 vaccine to Iran, please consult the Department of the Treasury's Office of Foreign Assets Control (OFAC) for license requirements and the availability of general licenses pursuant to the Iranian Transactions and Sanctions Regulations (31 CFR part 560). As stated in the EAR, to avoid duplication, exporters or reexporters are not required to seek separate authorization from BIS for an export or reexport subject both to the EAR and to OFAC's Iranian Transactions and Sanctions Regulations. Therefore, if OFAC authorizes an export or reexport of 1C991 COVID-19 vaccine to Iran, such authorization is considered authorization for purposes of the EAR as well. For questions regarding OFAC-administered sanctions against Iran, please visit OFAC's website or call (800) 540-6322.

Please consult BIS at Foreign.Policy@bis.doc.gov for export or reexport to denied or otherwise restricted parties or to discuss other specific circumstances.

Do EAR99 medical items related to COVID-19 testing and treatment require a license for export or reexport to Cuba, Iran, North Korea, and Syria?

Pursuant to Sec. 746.2 of the Export Administration Regulations (EAR), all EAR99 medical items related to COVID-19 testing and treatment require a license for export or reexport to Cuba, which is subject to a comprehensive embargo codified in U.S. law.

Pursuant to Sec. 746.7 of the EAR, EAR99 COVID-19 medical items for COVID-19 testing and treatment do not require a BIS license for export or reexport to Iran, other than in specific circumstances such as the involvement of a denied party. However, no person may export or reexport any item that is subject to the EAR, including EAR99 items, if such transaction is prohibited by the Iranian Transactions and Sanctions Regulations (31 CFR part 560) and not authorized by the Department of the Treasury's Office of Foreign Assets Control (OFAC). Please consult OFAC for license requirements and the availability of general licenses pursuant to the Iranian Transactions and Sanctions Transactions. For questions regarding OFAC-administered sanctions against Iran, please visit OFAC's website or call (800) 540-6322.

Pursuant to Sec. 746.4 of the EAR, EAR99 medical items for COVID-19 testing and treatment do require a license for export or reexport to North Korea.

Pursuant to Sec. 746.9 of the EAR, EAR99 medical items for COVID-19 testing and treatment do require a license for export or reexport to Syria.

As with any export or reexport, transactions involving certain restricted end-users or for restricted end-uses, as described in parts 744 and 746 of the EAR, may trigger additional license requirements. Please consult BIS at Foreign.Policy@bis.doc.gov if you know or have reason to believe a denied or otherwise restricted party is involved in your transaction or to discuss other specific circumstances.

Will BIS process license applications for the export or reexport of COVID-19 vaccine and medical items to test for and treat COVID-19 on an expedited basis?

Yes; BIS will process license applications for the export or reexport of COVID-19 vaccine and medical items to test for and treat COVID-19 on an expedited basis.

Middle East respiratory syndrome related coronavirus (MERS-related coronavirus) has recently been added to the CCL, and is currently controlled under ECCN 1C351.a.30, in addition to SARS-related coronavirus under ECCN 1C351.a.47, how does this impact COVID-19 research that use these two controlled viruses?

Both MERS-CoV and SARS-CoV are on the CCL under ECCN 1C351.a.30, and 1C351.a.47, respectively, with their genetic elements controlled under ECCN 1C353 for CB1 and AT1 reasons. Therefore, a license is required to export these viruses or their genetic elements to most destinations.

As a result of the January 7, 2021 update to ECCN 1C991 vaccines designed for use against COVID-19 that incorporate controlled agents (e.g. MERS-CoV or SARS-CoV) or their genetic elements are controlled under ECCN 1C991 for AT1 reasons. Therefore, a license is required to export these vaccines to certain destinations in accordance with the embargoes and other special controls described in part 746 of the EAR.

BIS currently considers SARS-CoV-2 to be distinct from the SARS-CoV and MERS-CoV, and as such, will continue to classify the SARS-CoV-2 and its specific genetic elements as EAR99. An export license is generally not required for export of this virus or its genetic elements to most destinations. However, exporters are reminded that certain end-users, end-uses, and destination countries may require a license for the export of EAR99 items. Exporters should continue to screen all requests in accordance with Supplement No. 3 to Part 732 of the EAR, the General Prohibitions in Part 736 of the EAR, the Consolidated Screening List, and the end-user and end-use-based controls in Part 744 of the EAR.