Regulations and Procedures Technical Advisory Committee Minutes –
June 8, 2021

Open Session

Anne Marie Griffin, chair – Welcome, roll call of RPTAC members. The meeting was held virtually.

There was no overall BIS update, but Regulatory Policy Division Director Hillary Hess noted that the BIS Annual Conference would be held virtually September 2, 2021, and that frequently asked questions (FAQs) regarding Foreign Military Sales (FMS) and firearms had been posted on the BIS website.

Presentations by the Public

Jimmy Goodrich – Semiconductor Industry Association (SIA)

Jimmy Goodrich of SIA gave a presentation entitled "Strengthening the Global Semiconductor Supply Chain in an Uncertain Era." A copy of the presentation is posted with these minutes.

Juhi Tariq, Tina Termei – CompTIA

Juhi Tariq and Tina Termei of CompTIA gave a presentation entitled "Export Control Priorities for the Tech Industry." A copy of the presentation is posted with these minutes.

Bill Root – Public Comment

Bill Root presented a public comment regarding COVID-19 Frequently Asked Questions (FAQs). A copy of his written submission is attached. BIS FAQs are posted here:

https://www.bis.doc.gov/index.php/documents/pdfs/2532-severe-acute-respiratory-syndrome-coronavirus-2-sars-cov-2-faq/file

Hillary Hess, BIS Regulatory Policy Division – Published Regulations

Enumerated rules published since last meeting (3/16/21 – 6/1/21). The Wassenaar Arrangement 2019 implementation rule the interim final rule revising part 744 of the EAR as a result of the Export Control Reform Act were both subject to the regulatory freeze; decisions on the disposition of these rules are pending.

Shannon Barley – Census Bureau

Work proceeds on rules proposing revisions to routed export provisions and filing requirements for the U.S. Virgin Islands and Puerto Rico. Census plans to remove an unneeded exemption for

technical data (filing for a tangible item that "contains" intangible technology – filing is not required for the technology; only the laptop is to be reported).

Work Groups

Encryption – Ed Gillespie

Work on a paper regarding European cybersecurity rules.

Compliance and Enforcement – Janelle Gamble

No update.

Practices and Procedures – Naomi LaBonte and Laura Molinari

No report.

Multilateral Controls – Curtis Dombek

Organizing presentation on new European Union dual-use regulations. Work on Wassenaar Arrangement issues.

Technology Controls – Kathleen Gebeau

Work on Trusted Deemed Exporter proposal.

Automated Export System (AES) – Adrienne Braumiller

Waiting for further progress on the draft rules regarding routed transactions.

Recordkeeping – Andrew Parr

No report.

May 29, 2021

To: RPTAC
From: Bill Root, email billroot23@gmail.com; tel. 1 517 333 870g7

Subject: COVID 19 Frequently Asked Questions (FAQs)

The following FAQ excerpts are from an article by Robert Woodward published on the BIS website 2/25/20 and modified 3/24/21. My Comments follow the Background and each of the six Questions and Answers, which I have numbered, although Woodward does not.

This May 29 document is for use in the event that BIS refers to the Woodward document during the discussion of vaccines at the June 8 RPTAC meeting. Neither the Woodward document nor my Comments change my Handout or my recommended texts of EAR revisions re vaccines.

Background and FAQ Guidance:

ICTV officially named SARS-CoV-2 as causing the current outbreak.
While the official nomenclature of the species exactly matches the entry for SARS-CoV on the CCL (1C351a37), SARS-CoV-2 is genetically distinct from SARS-CoV. Existing entry was intended to capture only the virus causing SARS after etiology, pathogenacity, and epidemiology was well established. In contrast, the disease transmission, progressions, and lethality of SARS-CoV-2 is not yet fully elucidated.
Comment: It is hard to imagine now how any virus could have been more fully elucidated than the one causing COVID 19. Since official nomenclature "exactly matches" the CCL entry, why bother to make the distinction between SARS-CoV and SARS-CoV-2. If vaccines for the latter were construed to be on the CCL, they would fall under 1C991a, which is identified as being in Country Chart Column AT 1. After the recent removal of Sudan from AT1, that Column now is completely blank. Probably E:1 (terrorist support countries Iran, North Korea, and Syria) was intended. These are three of the four countries for which licenses are normally required by "not elsewhere specified" in EAR99, without being specified anywhere. Too include Cuba, add E:2.

Q1 Are COVID 19 vaccines under the final rule for 1C991?
Both the two (mRNA and chimeric) categories of COVID 19 are EAR99 (*i.e.*, not 1C991).
Chimeric includes additives that may, or may not, be a controlled agent.
Prior to the 1/7/21 final rule, chimeric Newcastle or Vesicular-stomatitis were 1C353 with worldwide licensing.

Comment: The 1/7/21 final rule did not revise 1C353. Prior to that rule, vaccines "against", *inter alia,* Newcastle or Vesicular-stomatitis viruses (1C351a33 or a56) or for their genetically modified organisms (1C353) were controlled by 1C991a. That rule increased (not decreased as implied by the FAQ reply) coverage by inserting "containing,
or" before "designed for use against". The statements in that rule that the 1C991a changes were to match similar changes agreed in an AG 2019 plenary are puzzling for two reasons:

(1) why should control parameters track parameters for exclusion from control? and
(2) why are the final rule, the AG and BIS websites, and the press statement by the AG describing the 2019 plenary all silent concerning the actual 2019 changes in AG exclusions?

Q2 Does EAR99 COVID 19 require licenses to Cuba, Iran, North Korea, and Syria?
Cuba: In most cases yes. May be authorized under GFT.
Iran: Yes, by OFAC. BIS license required only in special cases, such as denied parties.
North Korea: Not required per 746.4.
Syria: Not required per 746.9
Q3 Does 1C991 COVID vaccine require licenses to Cuba, Iran, North Korea, or Syria
Yes. See OFAC re Iran

Comment: Re Q2, nobody would want to export this virus, unless it was contained in a vaccine. The Yes answer to Q3 is wrong. As stated by Woodward in Background, the SARS-CoV-2 causative agent for COVID 19 is not included in 1C351, 1C353, or 1C354. Therefore, COVID 19 vaccines are regulated (but not controlled) in EAR99, rather than by 1C991a. The Yes answer for Cuba unless GFT applies is wrong. A license is not required, because of the ECRA references to the relevance of IEEPA Section 230(b).
The Yes, by OFAC, answer is also wrong. OFAC reg 560.210(b) states:

> Prohibitions at 560.204 and 560.206 do not apply to donations by US persons of articles such as food, clothing, and medicine intended to be used to relieve human suffering.

Vaccines are clearly medicines.
The no answers for North Korea and Syria are correct, but for the wrong reasons. ECRA references to IEEPA 203(b) are more current than the cited references for North Korea in 746.4 to EAA, which expired in 2001, and for Syria in 746.9 to a 2003 law relevant to Syria.

Q4 Do EAR medical items related to COVID 19 testing and treatment require licenses to Cuba, Iran, North Korea, or Syria?

Cuba, North Korea, and Syria: Yes, EAR99 requires licenses for all medical items.

Iran: Yes, by OFAC. BIS license only for specific situations, such as denied parties.

Comment: The responses to this testing and treatment FAQ do not provided guidance on the following more relevant question:

> Are items related to COVID 19 testing and treatment regarded as medicines not requiring a license under EAR99 because of applicability of IEEPA 203(b)?

The word "medical" in Q4 suggests a positive answer to that alternative question, in which case licenses would not be required for testing and treatment items.

But the Q4 Yes answers for all four countries suggests a negative answer to the more relevant question.

This unresolved issue is not relevant to whether COVID 19 vaccines require a license.

Q5 Will BIS process license applications for COVID 19 vaccines and medical items to test or treat COVID 19 on an expedited basis?

Yes

Comment: Licenses for COVID 19 vaccines are not required because of ECRA references to IEEPA 203(b). Q5 becomes relevant to items to test or treat COVID 19 only if the response to the more relevant question under Q4 is negative.

Q6 How do MERS and SARS (1C351a30 and a47) impact research using them?

Both MERS and SARS and their genetically modified organisms, require licenses to most destinations.

Both are impacted by the 1/7/21 final rule to revise 1C991a.

SARS-CoV-2 is EAR99.

Comment: Neither MERS nor SARS were impacted by the 1/7/21 final rule to revise 1C991a unless there are vaccines against them which also contain them. As described by Woodward in the Background, such vaccines would not be relevant to COVID 19.

The answers describing license requirements for export do not fully respond to the question, because most research does not involve an export.