

Regulations and Procedures Technical Advisory Committee Minutes – March 9, 2021

Open Session

Anne Marie Griffin, chair – Welcome; Vice Chair Andrew Parr called roll of participants. The meeting was held virtually.

There was no overall BIS update.

Presentations by the Public

Bill Root – Public Comment

Bill Root presented a public comment regarding export controls and the COVID-19 pandemic. Copies of the handout and oral remarks summary that he drafted are attached.

Ted Curtin, Director of the Chemical and Biological Controls Division, and Tony Christino, Director of the Foreign Policy Division, and staff members explained BIS controls; a full treatment of their response may be found on the BIS website:

<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 (12/22/20 – 3/8/21). 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

Census continues to review public comments on the impact of removing Electronic Export Information filing requirements for Puerto Rico and the U.S. Virgin Islands. Electronic Export Manifest data from one port is being compared to overall data; carriers report transportation data, so it should be more accurate. Outreach is ongoing to the extent possible. Work at the Census Bureau will be virtual until 2022 due to building renovations. Census receives Voluntary Self Disclosures on paper currently but is looking into creating a secure portal for their submission. Census is working to address technical data questions that have come into them.

Work Groups

Compliance and Enforcement – Janelle Gamble

No specific issues active now.

Practices and Procedures – Laura Molinari

No report.

Technology Controls – Jeff Rittener or Kathleen Gebeau

No report.

Automated Export System (AES) – Adrienne Braumiller

No report (technical difficulties).

Multilateral Controls – Anne Marie Griffin

The group is urging publication of the Wassenaar Arrangement 2019 implementation rule to level the playing field, because the European Union (EU) has already published.

Encryption – Ed Gillespie

Also waiting for publication of Wassenaar rule. Noted a “recast” of European Union export controls [Joint statement by European business on the recast of the EU Regulation on Dual-Use Export Controls | BusinessEurope](#)

Handout fo RPTAC March 9, 2021

From Bill Root, email billroot23@gmail.com; tel. 1 517 333 8707

Subject Vaccine Export Controls

For the health and well-being of every one on the planet, the entire global population must be vaccinated against COVID 19, with no avoidable delays. This is needed to help stop the spread of this pandemic disease. US vaccine export controls constitute such an avoidable delay. Many entire countries now have no COVID 19 vaccines.

Decades ago, at the initiative of the United States, an international Australia Group (AG) was established to coordinate the chemical and biological export controls of its members. The AG agreed, in an Exclusion Note, not to control vaccines. However, the US never included the AG Exclusion Note in its export control regulations. On the contrary, both the US Munitions List and the Commerce Control List have, for many years, controlled vaccine exports, and still do. Most, perhaps all, applications are probably approved. Even so, the license process constitutes an avoidable delay. These US violations of an international obligation with which it has agreed are unconscionable.

I have asked that the next page of this handout be projected on your computer screen. It contains all that you need to know about the “Inconsistent Current Facts” and the minimum required for “Removal of Inconsistencies In Order for US to Comply Fully with the AG Exclusion Note.”

Neither ITAR nor EAR contains a definition of “vaccine.” The AG definition is:

A vaccine is a medicinal product in a pharmaceutical formulation licensed by, or having marketing or clinical trial authorization from, the regulatory authorities of either the country of manufacture or of use, which is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in whom or to which it is administered.

The IEEPA 203(b)(2) except clause permits the President to require a license for such donations; but the ECRA Mandatory Exception includes no 203(b)(2) except clause. Even if the ECRA Mandatory Exception became inapplicable in the future, there are other parts of ECRA supporting US compliance with the AG Exclusion Note, *e.g.*, Section 1752(1)(B) fulfill declared international obligation; (2)(D) protect human rights; and (2)(E) carry out obligations under multilateral export control regimes.

Lack of answers to questions as to whether there is any legislation or Executive Order on the subject of vaccine export controls leads to a belief that vaccine export control inconsistencies can be resolved by State, Defense, and Commerce, without involving either the Congress or the President.

I Inconsistent Current Facts

Australia Group (AG) Exclusion Note:

An agent is covered by this list except when it is in the form of a vaccine. A vaccine is ...

USML XIV(h) controls, to all destinations, vaccines exclusively funded by a Department of Defense contract, as follows: ...

CCL ECCN 1C991.a controls, to AT (Iran, North Korea, or Syria), if not controlled by USML: vaccines contained or designed for use against ECCNs 1C351, 1C353, 1C354

CCL EAR99 controls all toxins and vaccines n.e.s. to Cuba, Iran, North Korea, Syria, or Crimea (including COVID 19 and SARS COV 2 causative agent and vaccines for COVID 19)

No relevant EAR licensing policy for vaccines (742.2(b) biological and chemical irrelevant)

Export Control Reform Act (ECRA) Section 1758(b)(4)(A)(i):

(b) Commerce controls ... (4) Exceptions (A) Mandatory Exceptions (i) described in section 203(b) of IEEPA ...

International Emergency Economic Powers Act (IEEPA) Section 203(b)(2):

(b) The authority ... does not include ... to regulate ...(2) donations ... of articles, such as food, clothing, and medicine ... except ...

II Removal of Inconsistencies In Order for US to Comply Fully with AG Exclusion Note

1 ITAR delete XIV(h); add to XIV(b) decontrol Note 2 AG Exclusion Note and its “vaccine” definition

2 EAR delete 1C991.a; add to 742.2(a) introduction AG Exclusion Note; add to 772.1 AG “vaccine” definition