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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 140711578-4578-01]

RIN 0694 – AG23

Technical Amendments to the Export Administration Regulations: Update of Export Control Classification Number 0Y521 Series Supplement - Biosensor Systems and Related Software and Technology

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final Rule; technical amendment.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by removing certain entries from the supplement that identifies those items subject to the EAR that are not listed elsewhere in the Commerce Control List (CCL), but which the Department of Commerce, with the concurrence of the Departments of Defense and State, has determined should be controlled for export for foreign policy reasons or because the items provide a significant military or intelligence advantage to the United States. Within one calendar year from the date that such items are listed in the supplement, BIS must publish a rule reclassifying the items under an entry on the CCL. Otherwise, such items automatically become designated as EAR99 items, unless BIS publishes a rule amending the supplement to extend the period in which the items will be listed therein. In accordance with this requirement, this rule removes references to biosensor systems and related “software” and “technology” from the supplement, because these items automatically became designated as EAR99 items on March 28, 2014, and the references to them in the supplement are now obsolete.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Scott Hubinger, Senior Chemist and General Engineer, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance by phone 202-482-5223 or by email at scott.hubinger@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

ECCN 0Y521 Series

BIS established the ECCN 0Y521 series in a final rule published April 13, 2012 (72 FR 22191) (hereinafter “April 13 rule”) to identify items that warrant control on the Commerce Control List (CCL) but are not yet identified in an existing ECCN. Items are added to the ECCN 0Y521 series by the Department of Commerce, with the concurrence of the Departments of Defense and State, upon a determination that an item should be controlled because it provides at least a significant military or intelligence advantage to the United States or because foreign policy reasons justify such control. The ECCN 0Y521 series is a temporary holding classification with a limitation that while an item is temporarily classified under ECCN 0Y521, the U.S. Government works to adopt a control through the relevant multilateral regime(s), to determine an appropriate longer-term control over the item, or that the item does not warrant control on the CCL.

Under the procedures established in the April 13 rule and codified at §742.6(a)(7)(iii) of the EAR, items classified under ECCN 0Y521 remain so-classified for one year from the date a

final rule identifying the item is published in the *Federal Register* amending the EAR, unless the item is re-classified under a different ECCN, under an EAR99 designation, or the 0Y521 classification is extended. During this time, the U.S. Government determines whether it is appropriate to submit a proposed control to the applicable export control regime (e.g., the Wassenaar Arrangement) for potential multilateral control, with the understanding that multilateral controls are preferable when practical.

Technical Amendments Updating Supplement No. 5 to Part 774: Removal of References to Biosensor Systems and Related “Software” and “Technology”

On March 28, 2013 (78 FR 18814), BIS imposed 0Y521 license requirements on biosensor systems and related “software” and “technology” for export and reexport to all destinations, except Canada. Under the procedures established in the April 13 rule and as described in Supplement No. 5 to Part 774, the effective date of the initial classification was the date of that rule’s publication, March 28, 2013, and the date the items would be designated EAR99, unless reclassified in another ECCN or the 0Y521 classification was reissued, was one year later, March 28, 2014. In the interim, BIS, on behalf of the U.S. Government, submitted a proposal to the Australia Group (a multilateral regime of which the United States is a member) for control of the items for nonproliferation reasons. The Australia Group decided that it would not impose controls on the items, and the U.S. Government did not seek further consideration of multilateral controls, nor did BIS re-classify the items under a different ECCN or reissue the 0Y521 classification. In accordance with §742.6(a)(7)(iii) of the EAR, as of March 28, 2014, the 0Y521 classification of the biosensor systems and related “software” and “technology” expired, meaning the items were no longer classified in the 0Y521 series and became designated

EAR99. By removing the items from the list of items classified in the 0Y521 series in Supplement No. 5 to Part, this rule removes text that imposes no license requirement but has potential to confuse readers about the items' EAR99 status.

Further, BIS received two comments in response to the March 28, 2013 interim final rule. One commenter stated that designating the Biosensor System No. 1 0A521 without license exception options other than License Exception GOV section 740.11(b)(2)(ii) may result in regulating the item more restrictively than it would under the ITAR and may result in “chilling effects toward academic research and thereby diminish innovation.” Another commenter raised concerns that the scope of what is covered by the No.1 0E521 “Technology” might be overly broad without a reference to the General Technology Note and that BIS should provide guidance on how to interpret the scope. The change of status of the biosensor systems and related “software” and “technology” to EAR99 renders the comments moot.

Therefore, in this rule, BIS amends the EAR to update certain entries in Supplement No. 5 to Part 774— Items Classified Under Export Control Classification Numbers (ECCNs) 0A521, 0B521, 0C521, 0D521 and 0E521—according to the procedure set forth in the April 13 rule that established the 0Y521 series. Specifically, in this rule, BIS removes references to biosensor systems and related “software” and “technology” under ECCNs 0A521 No. 1, 0D521 No. 1 and 0E521 No. 1, respectively, from Supplement No. 5 to Part 774 of the EAR to conform with the current legal status of those items under the EAR and rid the Supplement of obsolete references. The items are EAR99 and the 0Y521 series license requirements do not apply. This is a technical amendment that only updates Supplement No. 5 to Part 774 of the EAR. It does not alter any right, obligation or prohibition under the EAR.

Export Administration Act

Since August 21, 2001, the Export Administration Act has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., 783 (2002)), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and extended most recently by the Notice of August 8, 2013, 78 FR 49107 (August 12, 2013), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined to be not significant for purposes of Executive Order 12866.
2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule does not involve any collection of information.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(3)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates Supplement No. 5 to Part 774 to the EAR by removing references to certain items to make the Supplement conform to the current legal status of those items under the EAR. These revisions are merely technical and reflect what already is in effect under the EAR in accordance with established procedure, and the procedure itself was proposed to the public and the subject of public comment. This rule clarifies information, which serves to avoid confusing readers about the items' EAR99 status. It does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, Part 774 of the Export Administration Regulations (15 CFR Parts 730 – 774) is amended as follows:

PART 774 – [AMENDED]

1. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

2. Supplement No. 5 to Part 774 – Items Classified Under ECCNs Items Classified Under Export Control Classification Numbers (ECCNs) 0A521, 0B521, 0C521, 0D521 and 0E521 - is amended by:
 - a. Removing and reserving the entire entry for item “*No. 1* Biosensor systems and dedicated detecting components” under the section “0A521. Systems, Equipment and Components”;
 - b. Removing and reserving the entire entry for item “*No. 1* 0D521 “Software” for the function of Biosensor Systems controlled by ECCN 0A521.” under section “0D521. Software”; and

- c. Removing and reserving the entire entry for item “*No. 1* 0E521 “Technology for the “development” or “production” of Biosensor Systems controlled by ECCN 0A521.” under section “0E521. Technology”.

DATED: July 25, 2014

Kevin J. Wolf

Assistant Secretary for Export Administration

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