

California has demonstrated that the State meets the criteria for accredited-free status as set forth in the definition of *accredited-free State or zone* in § 77.5 of the regulations.

Based on our evaluation of California's request, we are classifying the entire State of California as accredited-free.

#### Immediate Action

Immediate action is warranted to relieve restrictions on the interstate movement of cattle and bison from the State of California. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

#### Executive Order 12866 and Regulatory Flexibility Act

This interim rule is subject to Executive Order 12866. However, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. The full analysis may be viewed on the *Regulations.gov* Web site (see **ADDRESSES** above for instructions for accessing *Regulations.gov*) or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Tuberculosis testing, including veterinary fees, costs approximately \$10 to \$15 per head. Approximately 100,000 tuberculosis tests were conducted in California in 2015, to meet the import requirements imposed by other States. Based on this information, the annual cost savings associated with advancing the tuberculosis status of California from modified accredited advanced to accredited-free will range from \$1 million to \$1.5 million. We note that Federal interstate movement testing requirements for modified accredited advanced States were suspended by a Federal Order issued in April 2010. The \$1 million to \$1.5 million in savings that will be realized represents less than

0.02 percent of the approximately \$10 billion earned from California's cattle and milk sales.

Entities that may be affected by the interim rule fall into various categories of the North American Industry Classification System. The majority of the affected businesses are small entities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

#### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule has no retroactive effect and does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

Accordingly, we are amending 9 CFR part 77 as follows:

#### PART 77—TUBERCULOSIS

- 1. The authority citation for part 77 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

##### 77.7 [Amended]

- 2. In § 77.7, paragraph (a) is amended by adding the word “California,” after the word “Arkansas.”

##### 77.9 [Amended]

- 3. In § 77.9, paragraph (a) is amended by removing the word “California” and adding the word “None” in its place.

Done in Washington, DC, this 29th day of July 2016.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2016–18428 Filed 8–5–16; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Part 774

[Docket No. 160303184–6184–01]

RIN 0694–AG90

#### Amendment to the Export Administration Regulations To Add Targets for the Production of Tritium and Related Development and Production Technology to the List of OY521 Series

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** In this interim final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to make certain items subject to the EAR and to impose on those items a license requirement for export and reexport to all destinations, except Canada. Specifically, this rule classifies certain specified targets “specially designed” for the production of tritium and related “development” and “production” technology under Export Control Classification Numbers (ECCNs) 0A521 and 0E521, respectively, on the Commerce Control List (CCL). As described in the final rule that established the OY521 series and that was published in the **Federal Register** on April 13, 2012, items are added to the OY521 series upon a determination by the Department of Commerce, with the concurrence of the Departments of Defense and State, and other agencies as appropriate, that the items should be controlled for export because the items provide at least a significant military or intelligence advantage to the United States or foreign policy reasons justify control. In this matter, the Department of Energy also concurred in the control imposed. The items identified in this rule are controlled for regional stability (RS) Column 1 reasons. The only license exception available for these items is for exports, reexports, and transfers (in-country) made by or consigned to a department or agency of the U.S. Government.

**DATES:** This rule is effective August 8, 2016. Comments must be received by October 7, 2016.

**ADDRESSES:** You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. The identification number for this rulemaking is BIS–2016–0027.

- *By email directly to:* [publiccomments@bis.doc.gov](mailto:publiccomments@bis.doc.gov). Include RIN 0694–AG90 in the subject line.

- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Refer to RIN 0694–AG90.

**FOR FURTHER INFORMATION CONTACT:**

Steven Clagett, Director, Nuclear and Missile Technology Controls Division, Office of Nonproliferation and Treaty Compliance, by phone at (202) 482–1641, or by email at [Steven.Clagett@bis.doc.gov](mailto:Steven.Clagett@bis.doc.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

BIS established the ECCN 0Y521 series to identify items that warrant control on the CCL but are not yet identified in an existing ECCN (77 FR 22191, April 13, 2012). Items are added to the ECCN 0Y521 series by the Department of Commerce, with the concurrence of the Departments of Defense and State, and other agencies as appropriate, 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. In this matter, the Department of Energy also concurred in the control imposed. 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), in this case the Nuclear Suppliers Group, to determine an appropriate longer-term control over the item, or that the item does not warrant control on the CCL.

Items classified under ECCN 0Y521, including the items identified in this interim final rule as 0A521 and 0E521 items, 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 Nuclear Suppliers Group) for potential multilateral control, with the understanding that multilateral controls are preferable when practical. An item's ECCN 0Y521 classification may be extended for two one-year periods to provide time for the U.S. Government and multilateral regime(s) to reach agreement on controls for the item, and provided that the U.S. Government has submitted a proposal to obtain multilateral controls over the item. Further extension beyond three years may occur only if the Under Secretary for Industry and Security makes a determination that such extension is in the national security or foreign policy interests of the United States. An extension or re-extension, including a determination by the Under Secretary for Industry and Security, will be published in the **Federal Register**.

*License Requirements, Policies and Exceptions*

The license requirements and policies for the ECCN 0Y521 series appear in § 742.6(a)(7) of the EAR. ECCN 0Y521 items are subject to a nearly worldwide license requirement (*i.e.*, for every country except Canada) with a case-by-case license review policy, through regional stability (RS Column 1) controls. The description and status of ECCN 0Y521 items appear in Supplement No. 5 to part 774 of the EAR, along with any item-specific license exceptions, where applicable. Unless otherwise indicated, License Exception GOV is the only license exception available and is applicable to all ECCN 0Y521 series items, including those items identified in this notice, if the item is within the scope of § 740.11(b)(2)(ii) (Exports, reexports, and transfers (in-country) made by or consigned to a department or agency of the U.S. Government), as provided in § 740.2(a)(14).

*Addition of ECCN 0A521 and 0E521 Items: Targets for the Production of Tritium and Related “Development” and “Production” Technology*

In this rule, BIS amends the EAR to make targets made of or containing lithium “specially designed” for the production of tritium by insertion in the core of a nuclear reactor and related “development” and “production” technology subject to the EAR and imposes a license requirement on the items. These items are being added to the 0Y521 series pursuant to a determination by the Department of Commerce, with the concurrence of the Departments of Defense, State and

Energy, that the items should be controlled because they provide a significant military or intelligence advantage to the United States or because foreign policy reasons justify such controls.

ECCN 0A521 No. 1, which appears in the table found in Supplement No. 5 to part 774 of the EAR, covers targets made of or containing lithium “specially designed” for the production of tritium by insertion in the core of a nuclear reactor.

ECCN 0E521 No. 1 covers technology required for the “development” or “production” of items classified under ECCN 0A521 No. 1.

*License Applications for the New ECCN 0A521 and 0E521 Items*

License applications for these items may be submitted through SNAP–R in accordance with § 748.6 of the EAR. Exporters are directed to include detailed descriptions and technical specifications with the license application, and identify the item's ECCN.

The rule is being issued in interim final form because while the government believes that it is in the national security interests of the United States to immediately implement these controls, it also wants to provide the interested public with an opportunity to comment on the new controls of the items. Comments may be submitted in accordance with the **DATES** and **ADDRESSES** sections of this rule. BIS will review and, if appropriate, address such comments through rulemaking consistent with the process described in the April 13, 2012 final rule creating the ECCN 0Y521 series (77 FR 22191).

**Export Administration Act**

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2015, 80 FR 48233 (August 11, 2015), has continued the Export Administration Regulations 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 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 is 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 OMB control number. This rule affects two approved collections: (1) The Simplified Network Application Processing + System (control number 0694–0088), which carries a burden hour estimate of 43.8 minutes, including the time necessary to submit license applications, among other things, as well as miscellaneous and other recordkeeping activities that account for 12 minutes per submission; and (2) License Exceptions and Exclusions (0694–0137). BIS does not believe that this rule will materially increase the number of submissions under these collections.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring prior notice, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States (*See* 5 U.S.C. 553(a)(1)). BIS, with the concurrence of the U.S. Departments of Defense and State, is implementing this rule because the items identified for the ECCN 0Y521 series in this rule provide a significant

military or intelligence advantage to the United States. Immediate imposition of a license requirement is necessary to effect the national security and foreign policy goals of this rule. Immediate implementation will allow BIS to prevent exports of these items to users and for uses that pose a national security threat to the United States or its allies. If BIS delayed this rule to allow for prior notice and opportunity for public comment, the resulting delay in implementation would afford an opportunity for the export of these items to users and uses that pose such a national security threat, thereby undermining the purpose of the rule. In addition, if parties receive notice of the U.S. Government’s intention to control these items under 0Y521 once a final rule was published, they might have an incentive to either accelerate orders of these items or attempt to have the items exported prior to the imposition of the control.

Further, BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3). Immediate implementation of these changes will allow BIS to prevent exports of these items to users and for uses that pose a national security threat to the United States or its allies. If BIS delayed this rule to allow for a 30-day delay in effectiveness, the resulting delay in implementation would afford an opportunity for the export of these items to users and uses that pose such a national security threat, thereby undermining the purpose of the rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared. Although notice and opportunity for comment are not required, BIS is issuing this rule as an interim final rule with a request for comments. All comments must be in

writing and submitted via one or more of the methods listed under the **ADDRESSES** caption to this notice. All comments (including any personal identifiable information) will be available for public inspection and copying. Those wishing to comment anonymously may do so by submitting their comment via *regulations.gov* and leaving the fields for identifying information blank.

**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; 42 U.S.C. 2139a; 42 U.S.C. 6212; 15 U.S.C. 1824a; 50 U.S.C. 4305; 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 7, 2015, 80 FR 48233 (August 11, 2015).

- 2. Amend Supplement No. 5 to Part 774 by:
  - A. In the table, remove the reserved entry under 0A521 and add in its place entry No. 1.
  - B. In the table, remove the reserved entry under 0E521 and add in its place entry No. 1.

The additions read as follows:

**Supplement No. 5 to Part 774—Items Classified Under ECCNS 0A521, 0B521, 0C521, 0D521 AND 0E521**

The following table lists items subject to the EAR that are not listed elsewhere in the CCL, but which the Department of Commerce, with the concurrence of the Departments of Defense and State, has identified warrant control for export or reexport because the items provide at least a significant military or intelligence advantage to the United States or for foreign policy reasons.

Item descriptor <i>Note:</i> The description must match by model number or a broader descriptor that does not necessarily need to be company specific	Date of initial or subsequent BIS classification (ID = initial date; SD = subsequent date)	Date when the item will be designated EAR99, unless reclassified in another ECCN or the 0Y521 classification is reissued	Item-specific license exception eligibility
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**0A521. Systems, Equipment and Components.**

No. 1 Targets made of or containing lithium “specially designed” for the production of tritium by insertion in the core of a nuclear reactor.	August 8, 2016 (ID) ...	August 8, 2017 .....	License Exception § 740.11(b)(2)(ii) only.	GOV	under
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Item descriptor <i>Note:</i> The description must match by model number or a broader descriptor that does not necessarily need to be company specific	Date of initial or subsequent BIS classification (ID = initial date; SD = subsequent date)	Date when the item will be designated EAR99, unless reclassified in another ECCN or the 0Y521 classification is reissued	Item-specific license exception eligibility			
<b>0E521. Technology.</b>						
No. 1 "Technology" required for the "development" or "production" of 0A521 No. 1 items.	August 8, 2016 (ID) ...	August 8, 2017 .....	License	Exception	GOV	under
			§ 740.11(b)(2)(ii) only.			

Dated: July 25, 2016.

**Matthew S. Borman,**

*Deputy Assistant Secretary for Export Administration.*

[FR Doc. 2016-18070 Filed 8-5-16; 8:45 am]

**BILLING CODE 3510-33-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 610

[Docket No. FDA-2016-N-1170]

#### Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products; Confirmation of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of September 16, 2016, for the final rule that appeared in the *Federal Register* of May 4, 2016. The direct final rule amends the general biological products standards relating to dating periods and removes certain standards relating to standard preparations and limits of potency. FDA is taking this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities without diminishing public health concerns. This action is part of FDA's retrospective review of its regulations in response to an Executive order. This document confirms the effective date of the direct final rule.

**DATES:** Effective date of final rule published in the *Federal Register* of May 4, 2016 (81 FR 26687), confirmed: September 16, 2016.

**FOR FURTHER INFORMATION CONTACT:** Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301,

Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of May 4, 2016 (81 FR 26687), FDA solicited comments concerning the direct final rule for a 75-day period ending July 18, 2016. FDA stated that the effective date of the direct final rule would be on September 16, 2016, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

**Authority:** Therefore, under the biological products provisions of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended. Accordingly, the amendments issued thereby are effective.

Dated: August 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-18584 Filed 8-5-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1105

[Docket No. FDA-2016-N-1555]

#### Refuse To Accept Procedures for Premarket Tobacco Product Submissions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a rule describing when FDA will refuse to accept a tobacco product submission (or application) because the application has

not met a minimum threshold for acceptability for FDA review. Under the rule, FDA will refuse to accept a tobacco product submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the type of submission. By refusing to accept submissions that have the deficiencies identified in the rule, FDA will be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions. FDA is issuing this action directly as a final rule because we believe there is little likelihood that we will receive any significant adverse comments opposing the rule given the specific deficiencies identified that will result in FDA's refusal to accept the submission.

**DATES:** This rule is effective December 21, 2016. Submit either electronic or written comments on this direct final rule by October 24, 2016. If we receive no significant adverse comments during the specified comment period, we intend to publish a confirmation document on or before the effective date by publication of a document in the *Federal Register*.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that