

**(m) Related Information**

For more information about this AD, contact Jennifer Tsakoumakis, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Blvd., Lakewood, CA 90712-4137; phone: 562-627-5264; fax: 562-627-5210; email: [jennifer.tsakoumakis@faa.gov](mailto:jennifer.tsakoumakis@faa.gov).

**(n) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737-53A1328, dated July 22, 2014.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on March 7, 2016.

**Michael Kaszycki,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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**OFFICE OF THE UNITED STATES  
TRADE REPRESENTATIVE**
**15 CFR Part 2017**

[Docket Number USTR-2016-0002]

RIN 0350-AA07

**Establishment of a Petition Process To  
Review the Eligibility of Countries  
Under the African Growth and  
Opportunity Act (AGOA)**

**AGENCY:** Office of the United States Trade Representative.

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

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**SUMMARY:** The Trade Preferences Extension Act of 2015 (TPEA) requires the President to establish a petition process to review the eligibility of

countries for the benefits of the African Growth and Opportunity Act (AGOA). This authority has been delegated to the Office of the United States Trade Representative (USTR).

**DATES:** The interim final rule is effective on March 18, 2016. USTR will accept comments on the interim final rule in writing on or before April 18, 2016.

**ADDRESSES:** All comments must be submitted electronically at [www.regulations.gov](http://www.regulations.gov), docket number USTR-2016-0002.

**FOR FURTHER INFORMATION CONTACT:** For procedural questions, please contact Yvonne Jamison, Trade Policy Staff Committee, at 202-395-3475. Direct all other questions to Constance Hamilton, Deputy Assistant U.S. Trade Representative for African Affairs, at [Constance\\_Hamilton@ustr.eop.gov](mailto:Constance_Hamilton@ustr.eop.gov) or 202-395-9514.

**SUPPLEMENTARY INFORMATION:****I. Background**

The AGOA (Title I of the Trade and Development Act of 2000, Pub. L. 106-200) (19 U.S.C. 2466a *et seq.*), as amended, contains provisions for enhanced trade benefits for eligible sub-Saharan African countries.

Section 506(c) of the TPEA, which was signed into law on June 29, 2015 (Pub. L. 114-27, sec. 105(d)(3), 129 Stat. 366-367)), requires the President to establish a process to allow any interested person, at any time, to file a petition with USTR concerning the compliance of any sub-Saharan African country listed in section 107 of the AGOA (19 U.S.C. 3706), with the eligibility requirements set forth in section 104 of the AGOA (19 U.S.C. 3703) and the eligibility criteria set forth in section 502 of the Trade Act of 1974 (19 U.S.C. 2462). On February 26, 2016, the President delegated this authority to USTR. *See* E.O. 13720 of Feb. 26, 2016, 81 FR 11087, Mar. 2, 2016.

**II. Analysis of the Interim Final Rule**

The interim final rule adds 15 CFR part 2017. The new Part 2017 establishes a petition process that supplements the annual (normal cycle) request for public comments on whether a beneficiary sub-Saharan African country is meeting the eligibility criteria and requirements of the AGOA program (*see, e.g.*, 80 FR 48951, Aug. 14, 2015).

Section 2017.0 defines acronyms used throughout Part 2017.

Section 2017.1 permits any interested party to submit a petition, at any time, regarding whether a beneficiary sub-Saharan African country meets the eligibility requirements in section 104 of the AGOA and the eligibility criteria in

section 502 of the Trade Act of 1974. It requires that a petition adequately identify the country and the concern. A petition indicating the existence of exceptional circumstances warranting an out-of-cycle review must contain a statement of reasons explaining why an out-of-cycle review is warranted.

Section 2017.2 explains how USTR will process petitions. USTR will consider petitions filed in accordance with the public comment period of the annual (normal cycle) review of all beneficiary countries in conjunction with that review. USTR will consider petitions filed outside of that time frame in the next (normal cycle) annual review. If USTR receives a petition outside of the annual (normal cycle) review process that indicates the existence of exceptional circumstances, the AGOA Implementation Subcommittee will consider whether there is a basis for the initiation of an out-of-cycle review and make recommendations to the Trade Policy Staff Committee, which will, in turn, advise the U.S. Trade Representative. If the U.S. Trade Representative finds that there are exceptional circumstances warranting an out-of-cycle review, within 30 days of that determination USTR will announce a schedule for the review in the **Federal Register**.

Section 2017.3 requires USTR to publish a summary of the actions taken in response to petitions in the **Federal Register**. The notice also will include a list of pending petitions upon which no decision has been made.

Section 2017.4 provides that all submitted materials will be made available for public inspection at [www.regulations.gov](http://www.regulations.gov) other than appropriately designated confidential business information.

The TPEA extended the AGOA until September 30, 2025. *See* Pub. L. 114-27, sec. 103, 129 Stat. 364, June 29, 2015. Section 2017.5 provides that the AGOA petition process will expire on that date unless extended by statute.

**III. Requirements for Submission**

All submissions must be in English and must be submitted electronically via <http://www.regulations.gov>. USTR will not accept hand-delivered submissions. To make a submission using <http://www.regulations.gov>, enter the docket number USTR-2016-0002 in the "Search for" field on the home page and click "Search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice by selecting "Notice" under "Document Type" in the "Filter Results by" section on the left side of the screen and click

on the link entitled “Comment Now.” The <http://www.regulations.gov> Web site offers the option of providing comments by filling in a “Type Comment” field or by attaching a document using the “Upload file(s)” field. (For further information on using the <http://www.regulations.gov> Web site, please consult the resources provided on the Web site by clicking on “How to Use This Site” on the left side of the home page.) The <http://www.regulations.gov> Web site allows users to provide comments by filling in a “Type Comment” field or by attaching a document using the “Upload file(s)” field. The AGOA Implementation Subcommittee prefers that submissions be provided in an attached document.

#### *Business Confidential Submissions*

USTR will grant business confidential status to information you submit if you certify that you would not customarily release the information to the public and clearly designate it as confidential business information. You must mark your submission “BUSINESS CONFIDENTIAL” at the top and bottom of the cover page and on each succeeding page, and the submission should indicate, via brackets, the specific information that is confidential. Additionally, you must include “Business Confidential” in the “Type Comment” field. If you submit a comment containing business confidential information, you also must submit a separate non-confidential version that is not a part of the same submission as the confidential version, indicating where confidential information has been redacted. The non-confidential version will be placed in the docket and open to public inspection.

#### *Public Inspection*

All comments we receive, except for information granted “business confidential” status, will be available for public viewing without change, including any personal information you provide, such as your name and address. You can find the comments by entering docket number USTR–2016–0002 in the search field at [www.regulations.gov](http://www.regulations.gov).

#### **IV. Notice and Public Participation**

USTR is promulgating these changes as an interim final rule in order to meet the statutory deadline for establishment of a petition process. Accordingly, USTR for good cause finds that the notice and publication requirements of the Administrative Procedure Act are unnecessary. See 5 U.S.C. 553(b)(3)(B). However, because this type of

rulemaking generally requires notice and receipt of public comment, USTR will accept written comments on the interim final rule on or before April 18, 2016.

#### **V. Effective Date**

For the reasons stated in part IV above, USTR for good cause finds that the interim final rule should become effective on March 18, 2016. See 5 U.S.C. 553(d)(3).

#### **VI. Regulatory Flexibility Act**

USTR is adopting 15 CFR part 2017 in the form of an interim final rule and not as a proposed rule. Therefore, the provisions of the Regulatory Flexibility Act do not apply. See 5 U.S.C. 601(2), 603(a).

#### **VII. Paperwork Reduction Act**

The interim final rule does not contain any collections of information under the Paperwork Reduction Act of 1995. See 44 U.S.C. 3501 *et seq.* Consequently, USTR has not submitted any information to the Office of Management and Budget for review.

#### **List of Subjects in 15 CFR Part 2017**

Administrative practice and procedure, Confidential business information, Foreign trade.

■ For the reasons stated in the preamble, USTR amends 15 CFR by adding part 2017 to read as follows:

#### **PART 2017—PETITION PROCESS TO REVIEW ELIGIBILITY OF COUNTRIES UNDER THE AFRICAN GROWTH AND OPPORTUNITY ACT (AGOA)**

Sec.

2017.0 Definitions.

2017.1 Petition for review.

2017.2 Action following receipt of a petition.

2017.3 Publication regarding petitions.

2017.4 Public inspection.

2017.5 Expiration.

**Authority:** 19 U.S.C. 2466a *et seq.*; Pub. L. 114–27, sec. 105(d)(3), 129 Stat. 366–367, June 29, 2015; E.O. 13720 of Feb. 26, 2016, 81 FR 11087, Mar. 2, 2016

#### **§ 2017.0 Definitions.**

For purposes of this part:  
**AGOA** means the African Growth and Opportunity Act, as amended (Title I of the Trade and Development Act of 2000, Pub. L. 106–200) (19 U.S.C. 2466a *et seq.*).

**TPC** means the Trade Policy Committee.

**TPRG** means the Trade Policy Review Group.

**TPSC** means the Trade Policy Staff Committee.

**USTR** means the Office of the United States Trade Representative.

#### **§ 2017.1 Petition for review.**

(a) Any person may submit a petition to USTR in accordance with this section with respect to the compliance of any country listed in section 107 of the AGOA (19 U.S.C. 3706), with the eligibility requirements set forth in section 104 of the AGOA (19 U.S.C. 3703) and the eligibility criteria set forth in section 502 of the Trade Act of 1974 (19 U.S.C. 2462).

(b) A petition must:

(1) Identify the sub-Saharan African country that would be subject to the review;

(2) Indicate the specific eligibility requirement or criterion that the petitioner believes warrants review; and

(3) Include all available supporting arguments and information to explain why review is warranted.

(c) A petition requesting an out-of-cycle review under section 111(d)(4) of the AGOA (19 U.S.C. 2466a(d)(4)) must contain a statement indicating the existence of exceptional circumstances warranting the out-of-cycle review.

(d) The TPSC may request additional information.

#### **§ 2017.2 Action following receipt of a petition.**

(a) USTR will consider a petition received in accordance with the schedule published in the **Federal Register** for the annual (normal cycle) AGOA review process under section 111 of the AGOA (19 U.S.C. 2466a) in conjunction with that annual review.

(b) Except as provided in paragraph (c) of this section, USTR will consider a petition received at any time other than the time described in paragraph (a) of this section, in accordance with the schedule published in the **Federal Register** for the next annual (normal cycle) AGOA review process.

(c)(1) If a petition received at any time other than the time described in paragraph (a), requests an out-of-cycle review under section 111(d)(4) of the AGOA (19 U.S.C. 2466a(d)(4)), within 60 days:

(i) The AGOA Implementation Subcommittee will review the petition and report to the TPSC whether there are exceptional circumstances warranting an out-of-cycle review;

(ii) The TPSC will conduct further review as necessary;

(iii) The TPSC Chair will report the results of the TPSC review to the U.S. Trade Representative; and

(iv) The U.S. Trade Representative may convene the TPRG or the TPC for further review of the TPSC recommendations and other decisions.

(2) If the U.S. Trade Representative finds that there are exceptional

circumstances warranting an out-of-cycle review, within 30 days of that determination USTR will announce a schedule for the review in the **Federal Register**. The schedule will include the deadline and guidelines for any party to submit written comments supporting, opposing or otherwise commenting on any proposed action.

(3) For any out-of-cycle review initiated under this paragraph (c), the AGOA Implementation Subcommittee will consider public input received by the applicable deadline and any other relevant information and report to the TPSC. The TPSC will conduct further review as necessary and prepare recommendations for the U.S. Trade Representative. The U.S. Trade Representative may convene the TPRG or the TPC for further review of recommendations and other decisions. The U.S. Trade Representative will make recommendations to the President, which may include a recommendation that no action be taken.

### **§ 2017.3 Publication regarding petitions.**

USTR will publish in the **Federal Register**:

(a) A list of actions taken in response to a petition, such as the publication of a Presidential proclamation modifying the designation of a country or the application of duty-free treatment with respect to articles from a country pursuant to the AGOA; and

(b) A list of petitions upon which no decision was made, and thus which are pending further review.

### **§ 2017.4 Public inspection.**

USTR will make publicly available at [www.regulations.gov](http://www.regulations.gov):

(a) Any written request, brief or similar submission of information made pursuant to this part; and

(b) Any stenographic record of any public hearing that may be held pursuant to this part.

(c)(1) USTR will grant business confidential status and withhold from public disclosure the information submitted if the petitioner certifies that the information customarily would not be released to the public and clearly designates the information as confidential business information.

(2) To request business confidential status the petitioner must mark the submission "BUSINESS CONFIDENTIAL" at the top and bottom of the cover page and on each succeeding page, and the submission should indicate, via brackets, the specific information that is confidential.

(3) If the submission contains business confidential information, the

petitioner also must submit a non-confidential version or summary, indicating where confidential information has been redacted, and a written explanation of why the material should be protected.

(4) The non-confidential version or summary will be made publicly available at [www.regulations.gov](http://www.regulations.gov).

(5) A request for exemption of any particular information may be denied if it is determined that such information is not entitled to exemption under law. In the event of such a denial, the information will be returned to the person who submitted it, with a statement of the reasons for the denial.

### **§ 2017.5 Expiration.**

The Trade Preferences Extension Act of 2015 extended the AGOA until September 30, 2025 (Pub. L. 114–27, sec. 103, 129 Stat. 364). Accordingly, this Part will expire on that date unless extended by statute.

**Florizelle Liser,**

*Assistant U.S. Trade Representative for African Affairs.*

[FR Doc. 2016–06127 Filed 3–17–16; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Parts 189 and 700**

**[Docket No. FDA–2004–N–0188; (Formerly 2004N–0081)]**

**RIN 0910–AF47**

#### **Use of Materials Derived From Cattle in Human Food and Cosmetics**

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

**ACTION:** Final rule; adoption of interim final rule as final with amendments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is issuing a final rule prohibiting the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. We have designated the following items as prohibited cattle materials: Specified risk materials (SRMs), the small intestine from all cattle (unless the distal ileum has been removed), material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef). We are taking this action to minimize human exposure to

certain cattle material that could potentially contain the BSE agent.

**DATES:** This final rule is effective on April 18, 2016.

**FOR FURTHER INFORMATION CONTACT:** Johnny Braddy, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1709.

### **SUPPLEMENTARY INFORMATION:**

#### **Executive Summary**

##### *A. Purpose of the Rule*

BSE is a fatal neurological disorder of cattle that has a long incubation period (2 to 8 years). It is transmitted when cattle ingest protein meal containing the BSE infectious agent. Cattle affected by BSE are usually apart from the herd and will show progressively deteriorating behavioral and neurological signs. Cattle will react excessively to noise or touch and will eventually stumble, fall, and experience seizures, coma, and death. Studies have linked variant Creutzfeldt-Jakob disease (vCJD) in humans to exposure to the BSE agent, most likely through human consumption of beef products contaminated with the BSE agent. There is no known treatment of vCJD, and it is invariably fatal.

The final rule completes a rulemaking process that began with an interim final rule (IFR) in 2004 and was followed by IFRs in 2005 and 2008. The final rule establishes measures to prohibit the use of certain cattle material in FDA-regulated human food and cosmetics to address the potential risk of BSE. Because the United States has had measures in place to prevent the introduction and spread of BSE, including those affirmed in this rule, the risk of human exposure to the BSE agent from FDA-regulated human food and cosmetics is negligible.

##### *B. Legal Authority*

We are issuing these regulations under the adulteration provisions in sections 402, 409, 601, and under section 701 (21 U.S.C. 342, 348, 361, and 371) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

##### *C. Summary of the Major Provisions of the Rule*

The final rule provides definitions for prohibited cattle materials and prohibits their use in human food, dietary supplements, and cosmetics, to address the potential risk of BSE. We designate the following items as prohibited cattle materials: SRMs, the small intestine from all cattle unless the distal ileum has been properly removed, material from nonambulatory disabled cattle,