# **Rules and Regulations**

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#### **DEPARTMENT OF AGRICULTURE**

### **Food Safety and Inspection Service**

9 CFR Part 327

[Docket No. FSIS-2012-0028]

RIN 0583-AD51

# Eligibility of Namibia To Export Meat Products to the United States

**AGENCY:** Food Safety and Inspection

Service, USDA. **ACTION:** Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to add Namibia to the list of countries eligible to export meat and meat products to the United States. FSIS has reviewed Namibia's laws, regulations, and inspection system as implemented, and has determined that they are equivalent to the Federal Meat Inspection Act (FMIA), the regulations implementing this statute, and the United States food safety system for meat and meat products.

Under this final rule, Namibia will only be able to export to the United States boneless (not ground) raw beef products, such as primal cuts, chuck, blade, and beef trimmings, processed in certified Namibian establishments, because FSIS only assessed Namibia's meat inspection system with respect to these products. Namibia would need to submit additional information for FSIS to review before FSIS would allow Namibia to export other beef product or product from other types of livestock to the United States. All products that Namibia exports to the United States will be subject to reinspection at United States ports-of-entry by FSIS inspectors. DATES: Effective Date: September 12,

FOR FURTHER INFORMATION CONTACT:  $\operatorname{Dr}$ . Daniel L. Engeljohn, Assistant

Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205–0495. SUPPLEMENTARY INFORMATION:

## **Background**

On September 18, 2015, FSIS published a proposed rule in the **Federal Register** (80 FR 56401) to add Namibia to the list of countries eligible to export meat products to the United States (9 CFR 327.2(b)). This final rule is consistent with the proposed rule.

As is explained in the proposed rule, under the FMIA and implementing regulations, meat and meat products imported into the United States must be produced under standards for safety, wholesomeness, and labeling that are equivalent to those of the United States (21 U.S.C. 620). The FMIA also requires that the livestock from which such imports are produced be slaughtered and handled in connection with slaughter in a manner that is consistent with the Humane Methods of Slaughter Act (7 U.S.C. 1901–1906).

Section 327.2 of Title 9 of the Code of Federal Regulations (CFR) sets out the procedures by which foreign countries may become eligible to export meat and meat products to the United States. Paragraph 327.2(a) requires that a foreign country's meat inspection system provide standards equivalent to those of the United States and to provide legal authority for the inspection system and its implementing regulations that is equivalent to that of the United States. Specifically, a country's laws and regulations must impose requirements equivalent to those of the United States with respect to: (1) Ante-mortem inspection, humane methods of slaughter and handling, and post-mortem inspection by, or under the direct supervision of, a veterinarian; (2) official controls by the national government over establishment construction, facilities, and equipment; (3) direct and continuous official supervision of slaughtering and preparation of product by inspectors to ensure that product is not adulterated or misbranded; (4) complete separation of establishments certified to export from those not certified; (5) maintenance of a single standard of inspection and sanitation throughout certified establishments; (6) requirements for sanitation and for sanitary handling of

product at establishments certified to export; (7) official controls over condemned product; (8) a Hazard Analysis and Critical Control Point (HACCP) system; and (9) any other requirements found in the FMIA and its implementing regulations (9 CFR 327.2(a)(2)(ii)).

The country's inspection system must also impose requirements equivalent to those of the United States with respect to: (1) Organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) national government control and supervision over the official activities of employees or licensees; (3) qualified inspectors; (4) enforcement and certification authority; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification and residue standards; and (7) any other inspection requirements (9 CFR 327.2(a)(2)(i)).

## **Evaluation of the Namibian Meat Inspection System**

As explained in the proposed rule, in 2002 and again in 2005, the government of Namibia requested approval to export meat (beef) products to the United States. Namibia stated that, if approved, its immediate intent was to export boneless (not ground) raw beef products such as primal cuts, chuck, blade, and beef trimmings to the United States.

In 2006, FSIS conducted a document review to evaluate the laws, regulations, and other documentation used by Namibia to execute its meat inspection program. FSIS examined the information submitted by Namibia to verify that the following equivalence components were addressed satisfactorily with respect to standards, activities, resources, and enforcement: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Point Systems; (5) Chemical Residue Testing Programs; and (6) Microbiological Testing Programs. The document review was satisfactory to FSIS, and FSIS scheduled an on-site review to evaluate all aspects of Namibia's meat inspection program.

In 2006, FSIS conducted an on-site audit of Namibia's meat inspection system and identified systemic deficiencies within the six equivalence components. In response to this audit, Namibia submitted a corrective action plan that addressed FSIS's findings. In

2009, FSIS conducted a follow-up onsite audit to verify that all outstanding issues identified during the previous audit had been resolved and that Namibia had satisfactorily implemented all the laws, regulations, and instructions to the field that FSIS found to be equivalent during the document review and previous audit. Nonetheless, the new audit identified new systemic deficiencies within the equivalence components of government oversight, sanitation, HACCP, chemical residue, and microbiological testing programs.

Following the 2009 on-site audit, Namibia again provided a comprehensive corrective action plan that addressed the findings identified. In 2013, FSIS proceeded with a follow-up on-site audit of Namibia's meat inspection system and verified that Namibia had satisfactorily implemented the corrective actions taken in response to the 2009 on-site audit. The 2013 audit identified new findings within the equivalence components of government oversight, statutory authority and food safety regulations, sanitation, and chemical residue testing programs.

In response to the 2013 audit findings, Namibia implemented immediate corrective actions and submitted another corrective action plan that addressed the findings identified during the audit of its food safety system. FSIS conducted another on-site audit in 2014 to verify that Namibia had effectively implemented those corrective actions.

FSIS concluded, on the basis of the 2014 audit, that Namibia had fully implemented the corrective action plan that it submitted in response to the 2013 audit. FSIS did not find any significant problems during the 2014 on-site audit. Furthermore, through the audit, FSIS found that Namibia had implemented a sampling and testing program for Shiga toxin-producing Escherichia coli (STEC) that is equivalent to FSIS's program. Industry in Namibia is required to control for or address STEC so that it is at a non-detectable level, and government testing in Namibia verifies that industry has the necessary controls

For more detailed information on FSIS's evaluation of the Namibian meat inspection system, see the proposed rule (80 FR 56401) and for the full audit reports, go to: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.

### **Final Rule**

After considering the comments received on the proposed rule, discussed below, FSIS concludes that Namibia's meat inspection system is equivalent to the United States' inspection system for meat and meat products. Therefore, FSIS is amending its meat inspection regulations to add Namibia to the list of countries eligible to export meat and meat products to the United States (9 CFR 327.2(b)). Under FSIS's import regulations, the government of Namibia must certify to FSIS that those establishments that wish to export meat and meat products to the United States are operating under requirements equivalent to those of the United States (9 CFR 327.2(a)).

FSIS will verify that the establishments certified by Namibia's government meet the United States requirements through periodic and regularly scheduled audits of Namibia's meat inspection system. In the future, if Namibia wants to export other beef products (e.g., ground beef) or other meat products to this country (e.g., pork products), it will need to notify FSIS and submit information about its requirements and inspection program for these products. FSIS would then review the information and determine whether the Agency needs to audit the operations in Namibia producing these products to determine whether the requirements and inspection program for these products is equivalent to those in the United States. Namibia would not be allowed to export additional products to the United States until FSIS determines that the country's requirements and inspection program for the products are equivalent to FSIS's

Although a foreign country may be listed in FSIS's regulations as eligible to export meat and meat products to the United States, the exporting country's products must also comply with all other applicable requirements of the United States, including those of the Animal and Plant Health Inspection Service (APHIS). These requirements include restrictions under 9 CFR part 94 of the APHIS regulations, which regulate the importation of meat and meat products from countries into the United States to control the spread of specific animal diseases. According to 9 CFR 94.1, APHIS listed Namibia as a country free of rinderpest and foot-andmouth disease (excluding the region north of the Veterinary Cordon Fence).

Also, under this final rule, all meat and meat products exported to the United States from Namibia will be subject to reinspection by FSIS at United States ports of entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count.

FSIS will conduct other types of reinspection activities, such as incubation of canned products to ensure product safety and taking product samples for laboratory analysis to detect any drug or chemical residues or pathogens that may render the product unsafe or any species or product composition violations that would render the product economically adulterated. Products that pass reinspection will be stamped with the official mark of inspection and allowed to enter United States commerce. If they do not meet this country's requirements, they will be refused entry and within 45 days will have to be returned to the country of origin, destroyed, or converted to animal food (subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import reinspection activities can be found on the FSIS Web site at: http://www.fsis.usda.gov/wps/ portal/fsis/topics/international-affairs/ importing-products/port-of-entryprocedures.

In addition, Namibian meat and meat products will be eligible for importation into the United States only if they are from animals slaughtered on or after the effective date of this final rule.

#### **Summary of Comments and Responses**

FSIS received 92 comments on the proposed rule. Eighty-one of the comments were received from individuals; 10 of the comments were received from trade associations representing American cattlemen and the beef industry, pork producers, milk producers, and farmers; and one comment was from a consumer advocacy group. Of the 92 comments, 87 were against the proposed rule, including those from all of the trade associations. Four individuals and one advocate on the behalf of the Namibian Meat Board were in support of the proposed rule.

The following is a discussion of the relevant issues raised in the comments.

Comments: Almost all of the comments expressed concern about the recent outbreaks of foot and mouth disease (FMD) in the areas north of the Veterinary Cordon Fence (VCF), a fence separating Northern Namibia and neighboring countries from the central and southern parts of Namibia that is designed to contain FMD outbreaks north of the fence. The majority of the individuals and various trade associations stated that the prevalence of FMD in the region presents a threat to the security of U.S. cattle and food safety. The commenters stated that Namibia cannot guarantee that FMDinfected animals will stay out of the

region in Namibia south of the VCF. Several trade associations also expressed concern about deficiencies found in a 2013 European Commission audit of Namibia's animal health control system. One trade association concluded that these deficiencies would result in commingling of contaminated cattle with cattle from the FMD-free zone south of the VCF. A few commenters were also concerned that the proposed rule did not address what steps FSIS would take to ensure that such commingling does not occur.

Several trade associations also expressed concern in their comments about the future of the VCF.

Commenters cited recent statements made by the Namibian Agricultural Minister who, according to the commenters, has expressed a desire to have the fence removed. Additional commenters pointed to the lack of structural integrity of the VCF. Those commenters stated that the VCF is frequently breached by the country's elephant and buffalo population, which raises the possibility of other wildlife traveling through carrying FMD.

Furthermore, one trade association expressed concern over a 30-kilometer section of the VCF dismantled by the authorities. The trade association argued that this places southern Namibia at risk of becoming re-infected with FMD, because it allows buffaloes and elephants to re-enter the FMD-free zone. Additionally, some commenters expressed concern about the lack of a recent APHIS audit, and requested that FSIS delay any further action on the proposed rule until APHIS conducts an audit and publishes a formal risk assessment.

Response: Although Namibia may be listed in FSIS's regulations as eligible to export poultry products to the United States, the products must also comply with all other applicable requirements of the United States, including those of USDA's APHIS, before any products can enter the United States.

APHIS is responsible for preventing the entry of foreign animal diseases into the livestock population of the United States. APHIS determines the animal health status of foreign countries or regions for certain diseases, and this process is outlined in Title 9 CFR part 92. These animal health status determinations help establish the import requirements for livestock and products derived from them.

In 2006, APHIS recognized the region of Namibia south of the VCF as free of FMD and rinderpest (71 FR 62198). This regulation relieved certain restrictions due to FMD and rinderpest on the importation into the United States of certain live animals and animal products from all regions of Namibia except the region north of the VCF. APHIS is developing a prioritization process for conducting reviews of countries or regions that have received animal health status recognition, such as the FMD freedom recognition granted to a region of Namibia. FSIS has provided the concerns identified in the comments on the proposed rule to APHIS, and APHIS will consider these as they finalize and implement their prioritization process. Therefore, at this time, APHIS rules allow beef from the region of Namibia south of the VCF to be exported to the United States.

FSIS and APHIS work closely together to ensure that all meat and meat products imported into the United States comply with the regulatory requirements of both agencies. In 1985, FSIS and APHIS signed a memorandum of understanding (MOU) in which both agencies agreed to cooperate in meeting their respective needs relative to information exchange of disease surveillance, diagnostic testing, investigations, trace backs, and animal and public health emergencies to achieve their related objectives of reducing the spread of animal diseases, and of providing a wholesome and economical food supply. The MOU is updated periodically to ensure that it addresses matters of importance to both agencies. The MOU was last updated November 20, 2014. In accord with this MOU. FSIS and APHIS established procedures for communication between the two agencies regarding the inspection, handling, and disposition of imported meat products. APHIS and FSIS communicate regularly to ensure that products APHIS has restricted from entering the United States because of animal disease concerns are not imported into the United States.

Comments: A majority of the trade associations and the consumer advocacy group comments expressed concern about the deficiencies found in the 2006, 2009, and 2013 FSIS audits, particularly with respect to problems FSIS found in the Namibian food-safety system, the lack of collaboration FSIS found between the Namibian ministries, and staffing problems FSIS identified in the ministries.

Response: FSIS assesses a country's food regulatory system in terms of six equivalence components and uses its findings from the assessment in deciding whether or not to grant eligibility to the country for the importation of its meat or meat food products into the United States. On the basis of the 2014 follow-up on-site audit, FSIS determined that Namibia fully met the criteria within those six equivalence components, in accordance with 9 CFR 327.2. Specifically, FSIS found that Namibia had a system in place to verify and enforce HACCP requirements. FSIS also found that Namibia had an effective strategy for implementing sample collection for chemical residue monitoring. Regarding staffing problems found during the 2009 on-site audit within the government oversight component, Namibia implemented corrective action plans for relief inspection personnel. FSIS concluded that Namibia had satisfactorily addressed the findings in this component. FSIS found Namibia to have remedied all deficiencies regarding the components that the Agency had uncovered in past audits, and determined that, as implemented, Namibia's inspection system (slaughter and processing) for beef is equivalent to the United States' meat inspection system. The details of Namibia's compliance with those components can all be found on the FSIS Web site at: http://www.fsis.usda.gov/wps/portal/ fsis/topics/international-affairs/ importing-products/eligible-countriesproducts-foreign-establishments/ foreign-audit-reports.

Additionally, regarding deficiencies noted during past FSIS audits of the Namibian food-safety system, the history, background and verification of corrective actions are documented in the 2009, 2013, and 2014 final audit reports.

Namibia has established its equivalence and when this final rule is effective, Namibia will be eligible to export certain beef products to the United States. FSIS ensures that countries maintain equivalence through a three-part process, involving: (1) Recurring equivalence reviews (e.g., through use of the country Self Reporting Tool or other documentation from the Central Competent Authority) of the exporting country's applicable laws and regulations; (2) periodic onsite equivalence verification audits in the exporting country; and (3) ongoing point-of-entry (POE) re-inspection of shipments received from the exporting country. These POE activities include examination of products for defects,

<sup>&</sup>lt;sup>1</sup>Final Report of an audit, carried out in Namibia, from 19 February to 01 March 2013, in order to evaluate the animal health control system in place, in particular relation to controls on foot-and-mouth disease. The audit found insufficient implementation and documentation of actions following the incursion of FMD positive buffalo in the disease-free zone. An Audit conducted by the European Commission, Health and Consumers Directorate—General, September 7, 2013.

container examinations, and laboratory analysis of product samples.

For all these reasons, therefore, concerns about deficiencies found in past FSIS audits are unwarranted. The deficiencies have been remedied and the Namibian inspection system will be subject to ongoing verification to ensure that it continues to maintain standards equivalent to those of the United States.

Comments: Some comments from individuals and trade associations expressed concern over the economic effect that the rule would have on American ranchers. These commenters stated that the importation of Namibian beef would lower the price of beef overall and cause a decline in sales and job loss for the American beef industry. Two individuals supported the proposed rule and agreed with FSIS's economic analysis.

Response: FSIS estimates that the expected amount of imported Namibian beef is only 0.008 <sup>2</sup> to 0.05 percent of the United States beef production; therefore, there will be no significant impact on sales and the United States economy.

Comment: The one trade association that disputed FSIS's economic analysis specifically stated that applying multipliers from a paper by VanSickle,<sup>3</sup> Namibia's beef import of 1.9 million pound in the first year (after the rule is finalized) and 12.5 million pounds in the 5th year will likely result in a negative impact on the United States economy of \$14.9 million and \$96 million, respectively; and the United States will suffer 127 job losses in the first year and 837.5 job losses in the 5th year.

Response: The multipliers the commenter used, i.e. \$3.87 impact on total United States economic output per \$1 decline in sales for the cattle ranching and farming sector and 67 United States job losses per 1 million pounds of additional beef imports, are from a paper that has not been peerreviewed. The multipliers in the VanSickle paper were results from an input-output model (I–O model) named IMPLAN. However, the paper did not describe the model or the input data,

nor specify the assumptions of the model. Therefore, there is no way to validate the model's accuracy in depicting the linkage from beef imports to total economic output and job loss. As a consequence, the credibility of the multipliers lacks support. All economic projection models and estimations are based on assumptions. To properly interpret a model's projections, it is important to understand and evaluate the accuracy of its assumptions every step of the way. Neither the VanSickle paper nor the commenter ever addressed any of these issues.

In fact, the use of an I-O model such as IMPLAN has been considered problematic in economic research. In addition to the lack of transparency inherent in the software-generated calculations, peer-reviewed journal articles have also suggested that inaccurate production functions are one of IMPLAN's weakest links, and that an I–O model has the potential to overcalculate impact.4 In addition, in a review of several studies that used methodology similar to IMPLAN, Kinnaman (2011) found the studies to be based on questionable assumptions that likely overstate the economic impact.<sup>5</sup> Furthermore, Brown and Munasib & Rickman (2014) also found studies using I-O models over-estimated actual economic impact of natural gas extraction. Because of the difficulty in using the I-O model appropriately and correctly, there are hardly any relevant studies based on such models for agriculture imports that have gone through the peer review process of an economic journal.6

There are other economic impact models that are more comprehensive and more robust than I–O models, such as econometric simulation models (ESMs) or computable general equilibrium (CGE) models. It is quite an undertaking to use these models, for modelers have to collect data and adjust assumptions in the models before

running estimations. It is only sensible to use these models when the size of expected imports is significant. Because the projected amount of beef imports from Namibia is very small, only 0.07 to 0.44 percent of total United States imports, FSIS believes it does not need a model to tell that it is very unlikely to have a noticeable impact on beef prices and other economic measures.

# Executive Order 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders (E.O.) 12866 and 13563 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, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule was designated a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, this rule was not reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

# **Economic Impact Analysis for Namibia Export Equivalence**

This final rule adds Namibia to the list of countries eligible to export meat products into the United States. The government of Namibia intends to certify only one Namibian establishment as eligible to export boneless raw beef products to the United States. Given this establishment's beef production capacity and the projected export volume, FSIS projects that this final rule will not have a significant impact on the United States economy. The annual boneless beef production of this establishment averaged 21.4 million pounds from 2008 to 2014. The projected volume of exports to the United States is about 1.9 million pounds in the first year, increasing to about 12.5 million pounds in five years.7 The average annual United States domestic beef production in 2012–2015 was 24.9 billion pounds, projected to be 24.6 billion pounds in 2016.8 The total United States import of beef averages 2.70 billion pounds per year for 2012–2015, projected to be 2.85

<sup>&</sup>lt;sup>2</sup> In the proposed rule, FSIS used 2012–2014 U.S. beef production data to estimate the expected amount of imported Namibian beef would be .007 to .05 percent of the United States beef production. In the final rule, FSIS used U.S. beef production data from 2012–2015 to update the estimated expected amount of imported Namibian beef to be .008 to .05 percent of the United States beef production.

<sup>&</sup>lt;sup>3</sup> The VanSickle paper is a comment paper submitted to APHIS in 2004 by John VanSickle on the economic analysis in the APHIS proposed rule for Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities. The commenter attached a copy of the paper.

<sup>&</sup>lt;sup>4</sup>Lazarus, W.F., D.E. Platas, and G.W. Morse, 2002. IMPLAN's Weakest Link: Production Functions or Regional Purchase Coefficients? *Journal of Regional Analysis and Policy*, 32 (2002): 33–48:; Brown, J.P., Goetz, S.J., Ahearn, M.C., & Liang, C. (2014) Linkages between Community-Focused Agriculture, Farm Sales, and Regional Growth. *Economic Development Quarterly*, 28(1), 5–16.

<sup>&</sup>lt;sup>5</sup> Kinnaman, T.C., 2011. The Economic Impact of Shale Gas Extraction: A Review of Existing Studies. *Ecol. Econ.* 70: 1243–1249.

<sup>&</sup>lt;sup>6</sup> Brown, J.P., Goetz, S.J., Ahearn, M.C., & Liang, C. (2014) Linkages between Community-Focused Agriculture, Farm Sales, and Regional Growth. *Economic Development Quarterly*, 28(1), 5–16; Munasib, A. and D.S. Rickman, 2015. Regional Economic Impacts of the Shale Gas and Tight Oil Boom: A Synthetic Control Analysis. *Regional Science and Urban Economics*, 50:1–17.

<sup>&</sup>lt;sup>7</sup> According to Namibia, this is the "optimistic" projection they wish to achieve. Market conditions will affect actual results.

<sup>&</sup>lt;sup>8</sup> http://www.ers.usda.gov/media/2009937/ldp-m-260.pdf, accessed on April 7, 2016; part of Livestock, Dairy, & Poultry Outlook by Economic Research Service, USDA.

billion pounds in 2016.9 Therefore, the projected Namibian beef imports in the first year would only be about 0.008 percent of total United States production, and 0.07 percent of total United States imports. If Namibia achieves the projected export goal in five years, and assuming that United States beef production and import volume stay about the same, the projected beef imports from Namibia would still only be about 0.05 percent of total United States production, and 0.44 percent of total United States imports.

Ålthough Namibia indicates that, for now, it is seeking to export boneless beef products only, this final rule would not preclude their exporting other meat products in the future, if the products meet all other applicable requirements of the United States, including those of USDA's APHIS, and any additional requirements that FSIS might have in place with regard to the products. Therefore, the long-term economic impact could be larger than what FSIS can assess right now.

# Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), this final rule will not have a significant impact on a substantial number of small entities in the United States. As mentioned above, the expected trade volume is very small. Therefore, the action should have no significant impact on small entities that produce beef products domestically.

### Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

### **Paperwork Reduction Act**

No new paperwork requirements are associated with this rule. Foreign countries wanting to export meat and meat products to the United States are required to provide information to FSIS certifying that their inspection systems provide standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are equivalent to those of the United States. This

information collection was approved under OMB number 0583–0153. The rule contains no other paperwork requirements.

#### **E-Government Act**

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

#### Additional Public Notification

FSIS will officially notify the World Trade Organization's Committee on Sanitary and Phytosanitary Measures (WTO/SPS Committee) in Geneva, Switzerland, of this rule and will announce it online through the FSIS Web page located at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules.

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register.

FSÍS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

#### **USDA Non-Discrimination Statement**

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in,

deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

# How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program
Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain\_combined\_6\_8\_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email: *Mail:* U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW.,

Washington, DC 20250–9410. Fax: (202) 690–7442.

Email: program.intake@usda.gov. Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

#### List of Subjects in 9 CFR Part 327

Food labeling, Food packaging, Imports, Meat inspection.

For the reasons set out in the preamble, FSIS amends 9 CFR part 327 as follows:

## **PART 327—IMPORTED PRODUCTS**

■ 1. The authority citation for part 327 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.18, 2.53

#### § 327.2 [Amended]

■ 2. Amend § 327.2(b) by adding "Namibia" in alphabetical order to the list of countries.

Done at Washington, DC, on July 1, 2016. **Alfred V. Almanza**,

Acting Administrator.

[FR Doc. 2016-16546 Filed 7-12-16; 8:45 am]

BILLING CODE 3410-DM-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Food and Drug Administration**

### 21 CFR Part 876

[Docket No. FDA-2016-N-1813]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Metallic Biliary Stent System for Benign Strictures

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