That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Winters Municipal Airport, and 1 mile each side of the 352° bearing from the airport extending from the 6.6-mile radius to 9.3 miles north of the airport, and within 2 miles each side of the 180° bearing from the airport from the 6.6-mile radius to 9.6 miles south of the airport.

Issued in Fort Worth, Texas, on August 17, 2016.

Christopher L. Southerland,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2016–20152 Filed 8–24–16; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

19 CFR Part 351

[Docket Number 160815742–6742–01]

RIN 0625–AB08

Modification of Regulations Regarding Basis for Normal Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Proposed rule and request for comments.

SUMMARY: The Department of Commerce (''the Department'') proposes to modify the regulations pertaining to the use of constructed value or third country sales for purposes of determining normal value, where the exporting country does not constitute a viable market, and is seeking comments from parties. This modification, if adopted, will specify that, where the exporting country does not constitute a viable market, the Department normally will calculate normal value based upon constructed value. This modification would invert the preexisting order of preference that, where the exporting country does not constitute a viable market, the Department normally calculates normal value based on sales in a viable third country. The Department proposes this modification in light of certain advantages of constructed value over third country sales, such as availability of cost of production information and comparability to U.S. prices.

DATES: To be assured of consideration, written comments must be received no later than September 26, 2016.

ADDRESSES: All comments must be submitted through the Federal eRulemaking Portal at *http://www.regulations.gov,* Docket No. ITA–2016–0009, unless the commenter does not have access to the internet. Commenters that do not have access to the internet may submit the original and one electronic copy on CD–ROM of each set of comments by mail or hand delivery/courier. All comments should be addressed to Paul Piquado, Assistant Secretary for Enforcement & Compliance, Room 1870, Department of Commerce, 14th Street and Constitution Ave. NW., Washington, DC 20230. Comments submitted to the Department will be uploaded to the eRulemaking Portal at *www.Regulations.gov*.

The Department will consider all comments received before the close of the comment period. All comments responding to this notice will be a matter of public record and will be available on the Federal eRulemaking Portal at www.*Regulations.gov*. The Department will not accept comments accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason.

Any questions concerning file formatting, document conversion, access on the Internet, or other electronic filing issues should be addressed to Moustapha Sylla, Enforcement and Compliance, at (202) 482–4685 or email address: *webmaster-support@ita.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Zachary Simmons at (202) 482–4044 or Abdelali Elouaradia at (202) 482–1374.

SUPPLEMENTARY INFORMATION:

Background

In general terms, section 731 of the Tariff Act of 1930, as amended (the Act), provides that when a company is selling foreign merchandise in the United States at less than fair value, and the International Trade Commission determines that an industry is materially injured or threatened with material injury by reason of such sales or imports, the Department shall impose an antidumping duty. Furthermore, section 751 of the Act provides that the Department shall periodically review and determine, upon request, the amount of any antidumping duty. Pursuant to section 773(a) of the Act, the Department's analysis involves a comparison between a company's sales price to, or in, the United States (defined either as export price or constructed export price) with the normal value. *See* 19 CFR 351.401(a); *see also* section 772 of the Act (defining export price and constructed export price); section 773 of the Act (defining normal value). Although in most circumstances, sales in the exporting country provide the most appropriate basis for normal value, section 773 of the Act also permits the use of third country sales or constructed value as the basis for normal value. *See also* 19 CFR 351.404(a).

The Department's regulations identify circumstances in which it may rely upon another basis for normal value. The Department may use a basis other than sales in the exporting country where, pursuant to 19 CFR 351.404(b), the Department determines that the exporting country does not constitute a viable market. 19 CFR 351.404(c). In addition, the Department may use a basis other than sales in the exporting country where a proper comparison between sales in the exporting country and sales in the United States is not possible. 19 CFR 351.404(c)(2)(i).[1]

In those circumstances where the Department determines that sales in the exporting country do not permit an appropriate comparison to United States sales, ''[t]he Secretary normally will calculate normal value based on sales to a third country rather than on constructed value if adequate information is available and verifiable . . .'' 19 CFR 351.404(f). Thus, although § 404(f) of the Department's regulations contemplates both sales in a third country and constructed value as bases to calculate normal value, it establishes an order of preference in which the Department ''normally'' will use sales in a third country. Section 404(f) establishes sales in a third country as the preferred basis to calculate normal value where (1) there are no sales of the foreign like product in the exporting country, (2) there are insufficient sales of the foreign like product in the exporting country and thus the market is not viable, or (3) the Department has otherwise determined it cannot use such sales for purposes of determining normal value pursuant to section 773(a)(1)(B)(i) of the Act.

However, the Department has identified some factors in favor of inverting the current order of preference to use, normally, constructed value rather than sales in a third country. First, the proposed preference for constructed value accords with the

[1] The Department has exercised this discretion in the past. *See, e.g., Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, from Japan,* 65 FR 62700, 62702 (Dep't of Commerce Oct. 19, 2000) (prelim. results) (basing normal value on constructed value because ''the unique, custom-built nature of each LNPP sold does not permit proper price-to-price comparisons'') unchanged in *Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, from Japan,* 66 FR 11555 (Dep't of Commerce Feb. 26, 2001) (final results).

TPEA, which amended section 773(b)(2) of the Act, regarding the importance of the cost of production in the Department's analysis of unfair trading behavior. Specifically, the TPEA amended section 773(b)(2) of the Act to require that the Department request cost information from individually examined respondent companies in antidumping proceedings. *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015). As a consequence, the Department, in all segments of its antidumping duty proceedings for which the complete initial questionnaire was not issued as of August 6, 2015, now requires that parties provide cost of production information, which is necessary information for the use of constructed value. *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793, 46794 (August 6, 2015). Therefore, obtaining constructed value information will not generally impose an additional burden upon the Department or respondent parties. By comparison, the Department would not necessarily already have requested the information necessary to calculate normal value based upon sales in a third country.

Second, constructed value normally may be preferable to sales in a third country because it provides a more appropriate comparison to U.S. prices. Based upon the Department's experience, third country sales sometimes involve products that are similar, but not identical, to the products sold in the United States. *See* 19 CFR 351.404(e). However, as delineated under sections 773(e) and (f) of the Act, constructed value reflects the costs associated with the production and sale of the merchandise.

Given the foregoing considerations, the Department is issuing this proposed rule to modify the regulations at issue pursuant to Administrative Procedure Act (5 U.S.C. 553) notice and comment procedures; the Department invites comments from all parties.

Proposed Modification

The Department proposes to modify 19 CFR 351.404(f) and 19 CFR 351.405(a) as indicated below. These modifications, if adopted, are intended to establish an order of preference in which, where the exporting country does not constitute a viable market, the Department normally will calculate normal value using constructed value. Although sales in a third country remain an appropriate basis for normal value in certain circumstances, constructed value would represent the approach ''normally'' used by the Department.

Proposed Effective Date

The Department proposes to make this rulemaking effective for segments of antidumping duty proceedings initiated on or after 30 days following the date of publication of the final rule.

Comments

The Department invites parties to comment on this proposed rule and the proposed effective date. Further, any party may submit comments expressing its disagreement with the Department's proposal and may propose an alternative approach.

Classifications

Executive Order 12866

It has been determined that this proposed rule is not significant for purposes of Executive Order 12866.

Paperwork Reduction Act

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. chapter 35.

Executive Order 13132

This proposed rule does not contain policies with federalism implications as that term is defined in section 1(a) of Executive Order 13132, dated August 4, 1999 (64 FR 43255 (August 10, 1999)).

Regulatory Flexibility Act

The Chief Counsel for Regulation has certified to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that the proposed rule would not have a significant economic impact on a substantial number of small business entities.

The entities upon which this rulemaking could have an impact include foreign exporters and producers, some of whom are affiliated with U.S. companies, and U.S. importers. Enforcement & Compliance currently does not have information on the number of entities that would be considered small under the Small Business Administration's size standards for small businesses in the relevant industries. However, some of these entities may be considered small entities under the appropriate industry size standards. Although this proposed rule may indirectly impact small entities that are parties to individual antidumping duty proceedings, it will not have a significant economic impact on any entities.

The proposed action alters the Department's approach in instances where the exporting country does not constitute a viable market or, pursuant to 19 CFR 351.404(c)(2), the Department declines to calculate normal value on the basis of exporting country sales. In particular, it would direct the Department normally to rely upon constructed value, rather than sales in a third country, as the basis for normal value. However, if the proposed rule is implemented, no entities would be required to undertake additional compliance measures or expenditures. Specifically, section 773(b)(2) of the Act now requires that the Department request cost of production information from each examined respondent in every segment of an antidumping duty proceeding. As a result, for those individually examined respondents whose exporting country is not viable or where the Department cannot otherwise use the sales in the exporting country, the Department will already have required submission of the information necessary to calculate normal value based upon constructed value, thus obviating the need to request information on sales in a viable third country. Therefore, the proposed rule would not have a significant economic impact upon a substantial number of small business entities. For this reason, an Initial Regulatory Flexibility Analysis is not required and one has not been prepared.

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping, Business and industry, Cheese, Confidential business information, Countervailing duties, Freedom of information, Investigations, Reporting and recordkeeping requirements.

Dated: August 19, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

For the reasons stated, 19 CFR part 351 is proposed to be amended as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

■ 1. The authority citation for 19 CFR part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

■ 2. In § 351.404, revise paragraph (f) to read as follows:

§ 351.404 Selection of the market to be used as the basis for normal value.

* * * * *

(f) *Constructed value and third country sales.* The Secretary normally will calculate normal value based on constructed value (*see* section 773(a)(4) of the Act (Use of Constructed Value)) rather than on third country sales.

■ 3. In § 351.405, revise paragraph (a) to read as follows:

§ 351.405 Calculation of normal value based on constructed value.

(a) *Introduction.* In certain circumstances, the Secretary may determine normal value by constructing a value based on the cost of manufacture, selling general and administrative expenses, and profit. The Secretary may use constructed value as the basis for normal value where: The exporting country is not viable; sales below the cost of production are disregarded; sales outside the ordinary course of trade, or sales the prices of which are otherwise unrepresentative, are disregarded; sales used to establish a fictitious market are disregarded; no contemporaneous sales of comparable merchandise are available; or in other circumstances where the Secretary determines that exporting country sales are inappropriate. (*See* section 773(e) and section 773(f) of the Act.) This section clarifies the meaning of certain terms relating to constructed value.

* * * * *

[FR Doc. 2016–20417 Filed 8–24–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket No. FDA–2016–D–2373]

Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry.'' The draft guidance, when finalized, will help food establishments determine whether the activities that they perform are within the ''farm'' definition established in our regulation for Registration of Food Facilities. Determining whether the activities a food establishment performs are within the ''farm'' definition plays a key role in determining whether its business is exempt from our regulations for Registration of Food Facilities, and from certain requirements in our regulations for ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' and ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2017.

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 identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2373 for ''Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts