

REPORT TO CONGRESS
UNITED STATES TOBACCO PRODUCT EXPORTS THAT DO
NOT CONFORM TO TOBACCO PRODUCT STANDARDS
2018

Submitted Pursuant to
Section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act

U.S. Food and Drug Administration

EXECUTIVE SUMMARY

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted authority to the Food and Drug Administration (FDA or the Agency) to regulate tobacco products, was enacted in 2009. One of the provisions of the Tobacco Control Act requires FDA to report to Congress annually on the export of U.S. tobacco products that do not conform to U.S. tobacco product standards. In addition, the provision requires the Agency to assess the public health impact of these exports and to provide recommendations for mitigating any negative public health impact of such exports.

This is the sixth report submitted to Congress by FDA. The report outlines the Agency's effort to capture data as it relates to the export of tobacco products that do not conform to tobacco product standards. FDA's conclusions in this report are the same as those issued in the 2017 report. Currently, there is only one tobacco product standard applicable: the prohibition on cigarettes or their component parts containing characterizing flavors other than tobacco or menthol. The Agency has no evidence of U.S. exports of tobacco products that do not conform to tobacco product standards established under the FD&C Act, specifically cigarettes or their component parts with prohibited characterizing flavors. Consequently, as FDA concluded in its 2017 report, there is no evidence on which to base analyses of the nature, extent, and destination of tobacco product exports that do not conform to tobacco product standards, public health implications of such exports, and policy alternatives to reduce any negative public health impact of them. Many sources were used to develop this report and confirm that there are no documented instances of the export of tobacco products that do not conform to current applicable tobacco product standards.

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INTRODUCTION

The Tobacco Control Act, which amended the FD&C Act and granted authority to FDA to regulate tobacco products, was enacted in 2009.

This report is in response to section 801(p)(1) of the FD&C Act, which states:

Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

- (A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;*
- (B) the public health implications of such exports, including any evidence of a negative public health impact; and*
- (C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.¹*

TOBACCO PRODUCT STANDARDS

The FD&C Act establishes two tobacco product standard special rules and allows the Secretary of Health and Human Services to revise these standards or adopt additional standards through rulemaking.² The first tobacco product standard states that:

Beginning three months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.³

The second tobacco product standard states that:

Beginning two years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not

¹ FD&C Act Sec. 801(p)(1)

² FD&C Act Sec. 907

³ FD&C Act Sec. 907(a)(1)(A)

*use tobacco, including foreign grown tobacco that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal Law to domestically grown tobacco.*⁴

The FD&C Act does not establish any tolerance limits for pesticide chemical residues that apply to domestically grown tobacco. To determine whether there are pesticide residue tolerance levels applicable to domestic tobacco, FDA previously consulted with the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). According to USDA and EPA, there are currently no established tolerance limits for pesticide chemical residues that apply to domestically grown tobacco.

The Secretary has not finalized any additional tobacco product standards, although, in 2016, FDA finalized a rule to bring additional categories of tobacco products under its authority.⁵ At this time, the only applicable tobacco product standard is the characterizing flavor ban described in section 907(a)(1)(A) of the FD&C Act, which applies only to cigarettes and their component parts.

NATURE AND EXTENT OF U. S. TOBACCO PRODUCT EXPORTS THAT DO NOT CONFORM TO TOBACCO PRODUCT STANDARDS

Section 801(e)(1) of the FD&C Act permits the export of products that do not conform with established tobacco product standards if those exports comply with requirements set forth in that section.⁶ FDA has not found evidence that flavored cigarettes or their component parts are being exported for consumption abroad. The only U.S. tobacco product exports that would not conform to U.S. tobacco product standards would be cigarettes or their component parts (including the tobacco, filters, or paper) that contain a characterizing flavor (other than tobacco or menthol).

Pursuant to its authority under the FD&C Act, FDA began conducting biennial inspections of registered tobacco product manufacturers in October 2011. As part of this inspection process, FDA requests information from manufacturers on tobacco products being exported and includes the information in its inspection report. FDA currently inspects 50 percent of registered establishments each fiscal year to meet the biennial requirement. As of February 1, 2018, the Agency has conducted 658 inspections of registered establishments, which includes inspections of registered vape shop establishments. Based on those establishment inspection reports that have been finalized, FDA has found no evidence, through its inspections, of the exportation of non-conforming flavored cigarettes or their component parts (including the tobacco, filters, or paper).

⁴ FD&C Act Sec. 907(a)(1)(B)

⁵ 81 FR 28973

⁶ FD&C Act Sec. 801(e)(1) states that “[a] food, drug, device, tobacco product, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act, and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a), if it—(A) accords to the specifications of the foreign purchaser, (B) is not in conflict with the laws of the country to which it is intended for export, (C) is labeled on the outside of the shipping package that it is intended for export, and (D) is not sold or offered for sale in domestic commerce.”

In addition, FDA queried other government entities to help document the extent of tobacco product exports that do not conform to tobacco product standards. However, FDA was unable to identify any U.S. government agency that required exporters to keep or report records of their shipments in a manner that would identify a flavored tobacco product of any type.

FDA reviewed the Alcohol and Tobacco Tax and Trade Bureau's (TTB) reporting requirements and found that flavored cigarettes and their component parts are not reported separately from cigarettes in general. As it did for the previous reports, FDA contacted TTB, and TTB again confirmed this finding.

FDA again consulted the USDA's Foreign Agricultural Service (FAS) website database, which reports the amount of U.S. tobacco product exports, and found that the database does not indicate whether any of the tobacco product exports contain characterizing flavors.

The Agency also examined the Tobacco Information Service database on the website of the Tobacco Merchants Association, a non-governmental agency, and found no data on cigarettes or their component parts with characterizing flavors. Additionally, FDA reviewed the data collected by the U.S. Census Bureau (Census) under Schedule B, a numbering system administered by Census that classifies all exported products, and found that, while exports of cigarettes are reported under Schedule B, cigarettes and their component parts with characterizing flavors are not reported separately. FDA has confirmed that this remains the case.

As stated in the previous reports that were submitted to Congress, FDA requested a change to the exporting codes used by Census that would allow the Agency to identify exports of flavored cigarettes or their component parts. The request was sent to the Committee for Statistical Annotation of the Tariff Schedules (484(f) Committee), comprised of the U.S. Customs and Border Protection, the U.S. International Trade Commission, and Census. This is an interagency committee that reviews requests for changes to the statistical reporting requirements of Schedule B for exports. FDA's request was denied in November 2011 because Census determined that there were not significant exports of flavored cigarettes or cigarette paper. Census made this determination based on its review of export data regarding cigarette tobacco and cigarette paper from August 2010 to July 2011. Census reviewed export data by specific exporter, surveying companies responsible for 94.8 percent of the cigarette trade and 96.4 percent of the cigarette paper trade. Census asked whether the companies were exporting any flavored cigarettes or cigarette papers. The companies responded that, as a result of the domestic ban on characterizing flavors, they halted their production of flavored cigarettes for export. Consequently, Census has not attempted to obtain information beyond that obtained in their 2011 survey.

BACKGROUND ON TOBACCO PRODUCT EXPORTS

The volume of manufactured tobacco products exported from the United States⁷ has declined significantly over recent decades. The total value of exported manufactured tobacco products declined from \$3.8 billion in 1999 to \$408 million in 2016 (Table 1). As noted in FDA’s previous reports to Congress, this decline was primarily a result of large U.S. manufacturers selling off their international businesses or forming subsidiaries located in foreign countries.

In 2011, the U.S. Government Accountability Office (GAO) completed a report to Congress on illicit trade that noted “the leading U.S. cigarette manufacturers have split or sold their international businesses and now sell almost exclusively in the U.S. market. Reynolds American is the one exception among the leading tobacco companies, and manufactures its Natural American Spirit brand cigarettes for export to Asian markets.”⁸

Table 1. Value of U.S. Exports of Manufactured Tobacco Products in 1999, 2009, and 2016 in Thousands of U.S. Dollars (nominal)^{9, 10}

| Product | 1999 | 2009 | 2016 |
|---|-----------|---------|---------|
| Cigarettes | 3,226,126 | 412,741 | 256,969 |
| Other Tobacco Products (Cigars, Smoking Tobacco, Smokeless Tobacco, Water Pipe Tobacco) | 650,692 | 76,739 | 151,368 |
| Total | 3,876,818 | 489,480 | 408,337 |

DESTINATION OF U.S. TOBACCO PRODUCT EXPORTS

While there is no evidence of regulated exports of U.S. tobacco products that do not conform to tobacco product standards, there are data documenting the destination of U.S. tobacco product exports in general. USDA FAS data for 2016 indicate that tobacco products (including unmanufactured tobacco) totaling approximately \$1.5 billion¹¹ are exported from the United States to over 100 countries. These tobacco product exports represent 1.11 percent of all U.S.

⁷ This definition of manufactured tobacco products is captured from USDA FAS data, which only captures agricultural products. Electronic cigarettes and other non-agricultural tobacco products and their component parts are not included, and a source has yet to be identified to track exports of these products.

⁸ U.S. Gov’t Accountability Off., GAO-11-313, *Illicit Tobacco: Various Schemes are Used to Evade Taxes and Fees* 8 (2011). The GAO report named only RAI as a U.S. manufacturer that currently exports cigarettes. FDA was unable to locate any export data about other manufacturers’ brands.

⁹ USDA FAS, accessed December 1, 2017, from www.fas.usda.gov/GATS/default.aspx.

¹⁰ *Manufactured tobacco products* consist of cigarettes, cigars, cheroots, smokeless, water pipe, roll-your-own, pipe and smoking tobaccos, and homogenized tobacco products.

¹¹ Please note that the current figure of 1.5 billion includes 1 billion of unmanufactured tobacco. The previous export Reports to Congress used a figure that did not include unmanufactured tobacco.

agricultural exports, which are valued at \$135 billion.¹² Of the total amount of U.S.-manufactured tobacco product exports in 2016, \$256.9 million were cigarette exports. As shown in Table 2, Japan, Netherlands, Russia, United Arab Emirates, and Jamaica—none of which banned the import or use of flavored tobacco products in 2016—receive 97.1 percent of U.S. cigarette exports combined.

Table 2. Top Five Recipients of U.S. Cigarette Exports in 2016¹³

| Trade Partner | Number of Sticks (Millions) | Percentage |
|----------------------|-----------------------------|------------|
| Japan | 15,622.77 | 93.14 |
| Netherlands | 239.31 | 1.43 |
| Russia | 173.92 | 1.04 |
| United Arab Emirates | 167.11 | 1.00 |
| Jamaica | 81.63 | 0.49 |
| Other | 486.70 | 2.90 |
| Total | 16,771.44 | 100.00 |

As previously noted, FDA has no evidence that any of these exported cigarettes had characterizing flavors (other than tobacco or menthol).

PUBLIC HEALTH IMPACT OF EXPORTS THAT DO NOT CONFORM TO TOBACCO PRODUCT STANDARDS

FDA continues to have no evidence that flavored cigarettes or their component parts (including the tobacco, filters, or paper) are being exported from the United States. Therefore, the impact on public health of such exports cannot be assessed.

POLICY ALTERNATIVES

As noted above, FDA currently has no evidence that flavored cigarettes or their component parts (including the tobacco, filters, or paper) are being exported. Consequently, at this time, FDA cannot assess the impact on public health of such exports or provide policy alternatives to reduce any negative impact on public health.

CONCLUSION

The only currently applicable tobacco product standard is the ban on cigarettes or their component parts (the tobacco, filters, or paper) that contain a characterizing flavor (other than tobacco or menthol). FDA has no evidence that these products are being exported from the United States.

¹² USDA FAS accessed December 1, 2017, from <http://apps.fas.usda.gov/gats/default.aspx>

¹³ Ibid.