Report to Congress

U.S. Tobacco Product Exports That Do Not Conform to Tobacco Product Standards 2020

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

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 provision of the Tobacco Control Act requires FDA to report annually to Congress on the export of U.S. tobacco products that do not conform to U.S. tobacco product standards. In addition, this 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 eighth report on this topic submitted to Congress by FDA. This report outlines the Agency's effort to capture data as they relate 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 2019 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 2019 report, there is no evidence on which to base an analysis of the nature, extent, and destination of tobacco product exports that do not conform to tobacco product standards; the public health implications of such exports; and policy alternatives to reduce any negative public health impact of these exports.

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 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.

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 [of Health and Human Services] 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—*
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> *(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:

> *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*

[1] Section 801(p)(1) of the FD&C Act.

[2] See section 907 of the FD&C Act.

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:

Beginning two years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not 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[5] and EPA,[6] 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 tobacco authority.[7] 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 to established tobacco product standards if those exports comply with the requirements set forth in that section.[8] FDA has not found evidence that flavored cigarettes or their component parts are

[3] Section 907(a)(1)(A) of the FD&C Act.

[4] Section 907(a)(1)(B) of the FD&C Act.

[5] See the USDA's Pesticide Data Program Database Search, accessed March 24, 2020, available at https://apps.ams.usda.gov/pdp.

[6] See 40 CFR part 180, accessed March 24, 2020, available at https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol24/xml/CFR-2014-title40-vol24-part180.xml.

[7] See 81 FR 28973 (May 10, 2016).

[8] Section 801(e)(1) of the FD&C Act 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."

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 then includes the information in its inspection report. FDA currently inspects registered establishments to meet the biennial requirement. As of March 1, 2020, the Agency has conducted more than 2,800 inspections of registered establishments, which have included inspections of registered vape shop establishments. Based on the establishment inspection reports that have been finalized, FDA has found no evidence of the exportation of non-conforming flavored cigarettes or their component parts (including the tobacco, filters, or paper).

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 any type of flavored tobacco product. For example, FDA reviewed the Alcohol and Tobacco Tax and Trade Bureau's (TTB's) 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.[9] Further, FDA consulted the USDA's Foreign Agricultural Service (FAS) website database,[10] 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,[11] 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, although exports of cigarettes have been reported under Schedule B, cigarettes and their component parts with characterizing flavors have not been reported separately.[12] 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. This request was sent to the Committee for Statistical Annotation of the Tariff Schedules, composed of the U.S. Customs and Border Protection, the

[9] Email message from the Director, Regulations and Rulings Division, TTB to FDA's Center for Tobacco Products, March 20, 2020.

[10] Accessed March 23, 2020, available at https://www.fas.usda.gov/data.

[11] Accessed March 20, 2020, available at https://www.tma.org/data.

[12] See Chapter 24 of Section B, accessed March 27, 2020, available at https://www.census.gov/foreign-trade/schedules/b/2019/c24.pdf.

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 from August 2010 to July 2011 regarding cigarette tobacco and cigarette paper. Census reviewed export data by specific exporters, 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 have halted their production of flavored cigarettes for export. Consequently, Census has not attempted to obtain information beyond that obtained in their 2011 survey.

VOLUME OF MANUFACTURED TOBACCO PRODUCT EXPORTS

The volume of manufactured tobacco products exported from the United States[13] has declined significantly over recent decades. The total value of exported manufactured tobacco products declined from $3.8 billion in 1999 to $210 million in 2019 (see Table 1).

Table 1. Value of U.S. Exports of Manufactured Tobacco Products in 1999, 2009, and 2019 in Thousands of U.S. Dollars (Nominal)[14, 15]

Product	1999	2009	2019
Cigarettes	3,226,126	412,741	22,535
Other Tobacco Products *(Cigars, Smoking Tobacco, Smokeless Tobacco, Water Pipe Tobacco)*	650,692	76,739	188,116
Total	**3,876,818**	**489,480**	**210,651**

DESTINATION OF U.S. TOBACCO PRODUCT EXPORTS

Although 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's FAS data for 2019 indicate that tobacco products (including unmanufactured tobacco) totaling approximately $943 million[16] were exported from the United

[13] This definition of *manufactured tobacco products* is captured from USDA's FAS data, which captures only 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.

[14] See USDA's FAS, accessed March 23, 2020, available at https://apps.fas.usda.gov/GATS/default.aspx.

[15] *Manufactured tobacco products* consist of cigarettes, cigars, cheroots, smokeless, water pipe, roll-your-own, pipe, and smoking tobaccos, as well as homogenized tobacco products.

[16] Please note that the 2019 figure of $943 million includes $718 million of unmanufactured tobacco. Prior to 2018, the tobacco product export reports to Congress used a figure that did not include unmanufactured tobacco.

States to over 100 countries. These tobacco product exports represented 0.68 percent of all U.S. agricultural exports, which are valued at nearly $137 billion.[17] Of the total amount of U.S.-manufactured tobacco product exports in 2019, $22.5 million were cigarette exports.

As shown in Table 2, Mexico, Sierra Leone, Jamaica, China, and Macau—none of which banned the import or use of flavored cigarettes in 2019—together received 81.8 percent of U.S. cigarette exports.

Table 2. Top Five Recipients of U.S. Cigarette Exports in 2019[18]

Trade Partner	Number of Sticks (Millions)	Percentage
Mexico	419,500	42.36
Sierra Leone	204,916	20.69
Jamaica	67,789	6.85
China	62,173	6.28
Macau	55,353	5.59
Other	180,547	18.23
Total	**990,278**	**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.

[17] USDA's FAS, accessed March 23, 2020, available at https://apps.fas.usda.gov/GATS/default.aspx.

[18] Ibid.

Conclusion

The only currently applicable tobacco product standard is the ban on cigarettes or their component parts (including 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.