Report to Congress

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

2019

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

U.S. Food and Drug Administration

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

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, the Tobacco Control Act 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 seventh annual report on this topic submitted to Congress by FDA. The report outlines the Agency's effort to capture data that relates to the export of U.S. tobacco products that do not conform to tobacco product standards. FDA's conclusions in this report are the same as those detailed in the 2018 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. Consequently, as FDA concluded in its 2018 report, there is no evidence on which to base analyses of the (1) nature, extent, and destination of tobacco product exports that do not conform to tobacco product standards; (2) public health implications of such exports; and (3) 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 U.S. tobacco products that do not conform to current applicable tobacco product standards. Therefore, the impact on public health of such exports cannot be assessed.

TABLE OF CONTENTS

INTRODUCTION

This report is in response to section 801(p)(1) of the Federal Food, Drug, and Cosmetic Act (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—*
>
> *(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]

The Family Smoking Prevention and Tobacco Control Act, which amended the FD&C Act and granted authority to the Food and Drug Administration (FDA or the Agency) to regulate tobacco products, was enacted in 2009.

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 sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.*[3]

---

[1] Section 801(p)(1) of the FD&C Act.
[2] Section 907 of the FD&C Act.
[3] Section 907(a)(1)(A) of the FD&C Act.

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 U.S. Environmental Protection Agency (EPA). According to USDA[5] and EPA,[6] there are 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 (including the tobacco, filters, or paper).

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 U.S. tobacco products that do not conform with established tobacco product standards if those exports comply with requirements set forth in that section.[8] 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 that contain a characterizing flavor (other than tobacco or menthol).

Under its authority under the FD&C Act, FDA began, in October 2011, conducting biennial inspections of registered tobacco product manufacturers. As part of this inspection process, FDA requests information from manufacturers on tobacco products being exported and includes that information in its inspection report. FDA currently inspects approximately 50 percent of

---

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

[5] USDA Pesticide Data Program, accessed September 4, 2019, from https://apps.ams.usda.gov/pdp.

[6] 40 CFR part 180, accessed September 4, 2019, from https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol24/xml/CFR-2014-title40-vol24-part180.xml.

[7] 81 FR 28974 (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.*

registered establishments each fiscal year to meet the biennial inspection requirement. As of August 1, 2019, the Agency has conducted more than 1,300 inspections of registered establishments, which includes inspections of registered vape shop establishments. Based on the establishment inspection reports that have been finalized this year, FDA has found no evidence of the exportation of non-conforming flavored cigarettes or their component parts.

In addition, FDA queried other government entities to help document the extent of U.S. 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. For example, FDA reviewed the reporting requirements of the Alcohol and Tobacco Tax and Trade Bureau (TTB) and found that flavored cigarettes and their component parts are not separately reported from cigarettes in general. As FDA has done for its previous reports, FDA contacted TTB this year, and TTB again confirmed this finding.[9] Similarly, 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] which is 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 are reported under Schedule B, cigarettes and their component parts with characterizing flavors are not separately reported. 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 (484(f) Committee), which is composed of the U.S. Customs and Border Protection, the U.S. International Trade Commission, and Census. The 484(f) Committee 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. 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 halted their production of flavored cigarettes for export. Consequently, Census has not attempted to obtain information beyond that obtained in their 2011 survey.

---

[9] Email message from Director, Regulations and Rulings Division, TTB to FDA's Center for Tobacco Products, September 16, 2019.

[10] USDA FAS, accessed August 5, 2019, from https://www.fas.usda.gov/data.

[11] Tobacco Merchants Association, accessed August 6, 2019, from https://www.tma.org/data.

BACKGROUND ON U.S. TOBACCO PRODUCT EXPORTS

The volume of manufactured tobacco products exported from the United States[12] has significantly declined over recent decades. Specifically, the total value of exported manufactured tobacco products declined from $3.8 billion in 1999 to $184 million in 2018 (Table 1).

Table 1. Value of U.S. Exports of Manufactured Tobacco Products in 1999, 2009, and 2018 in Thousands of U.S. Dollars (nominal)[13, 14]

Product	1999	2009	2018
Cigarettes	3,226,126	412,741	18,702
Other Tobacco Products *(Cigars, Smoking Tobacco, Smokeless Tobacco, Water Pipe Tobacco)*	650,692	76,739	166,075
Total	**3,876,818**	**489,480**	**184,777**

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.*[15]

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 FAS data for 2018 indicate that tobacco products (including

[12] This definition of *manufactured tobacco products* is captured from USDA FAS data, which captures only agricultural products. Electronic cigarettes and other non-agricultural tobacco products and their component parts are not included in this data, and a source has yet to be identified to track exports of these products.
[13] USDA FAS, accessed August 6, 2019, from https://apps.fas.usda.gov/GATS/default.aspx.
[14] *Manufactured tobacco products* consist of cigarettes, cigars, cheroots, smokeless, water pipe, roll-your-own, pipe and smoking tobaccos, and homogenized tobacco products.
[15] GAO, GAO-11-313, Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees (2011). The GAO report named only Reynolds American as a U.S. manufacturer that currently exports cigarettes. FDA was unable to locate any export data about other manufacturers' brands.

unmanufactured tobacco) totaling approximately $1.2 billion[16] are exported from the United States to over 100 countries. These tobacco product exports represent 0.88 percent of all U.S. agricultural exports, which are valued at $140 billion.[17] Of the total amount of U.S.-manufactured tobacco product exports in 2018, $18.7 million were cigarette exports. As shown in Table 2, Mexico, United Arab Emirates, Jamaica, Marshall Islands, and Taiwan—none of which banned the import or use of flavored tobacco products in 2018—receive 64.9 percent of U.S. cigarette exports.

Table 2. Top Five Recipients of U.S. Cigarette Exports in 2018[18]

Trade Partner	Number of Sticks (Millions)	Percentage
Mexico	173,869	33.07
United Arab Emirates	48,993	9.32
Jamaica	75,519	14.37
Marshall Islands	25,806	4.91
Taiwan	16,875	3.21
Other	184,604	35.12
Total	**525,666**	**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 U.S. TOBACCO PRODUCT STANDARDS

FDA continues to have no evidence that flavored cigarettes or their component parts 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 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 that contain a characterizing flavor (other than tobacco or menthol). FDA has no evidence that these products are being exported from the United States.

---

[16] Please note that the current figure of $1.2 billion includes $1 billion of unmanufactured tobacco. Prior to 2018, tobacco product export reports to Congress used a figure that did not include unmanufactured tobacco.
[17] USDA FAS, accessed August 6, 2019, from https://apps.fas.usda.gov/GATS/default.aspx.
[18] Ibid.