Report to Congress

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

Calendar Year 2023

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 U.S. Food and Drug Administration (FDA or Agency) to regulate tobacco products, was enacted in 2009. Section 801(p)(1) of the FD&C 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, assess the public health impact of these exports, and provide recommendations for mitigating any negative public health impact of such exports through the submission of a specified report to Congress.

This is the twelfth report on this topic submitted to Congress by FDA and covers calendar year 2023. This report outlines the Agency's effort to capture information from 2023 related to the export of U.S. tobacco products that do not conform to U.S. tobacco product standards. FDA's conclusions in this report are the same as those issued in the calendar year 2022 report to Congress.

Currently, there is only one tobacco product standard applicable to the export of tobacco products: the prohibition on cigarettes or their component parts containing characterizing flavors other than tobacco or menthol. The Agency has found no evidence of any U.S. exports of tobacco products in 2023 that did 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 report covering calendar year 2022, there is no evidence on which to base an analysis of the following:

(1) The nature, extent, and destination of tobacco product exports that do not conform to tobacco product standards;
(2) The public health implications of such exports; and
(3) Policy alternatives to reduce any negative public health impact of these exports.

Many sources were used to develop this report and confirm that, in 2023, there also were no documented instances of the export of U.S. tobacco products that did not conform to current applicable tobacco product standards.

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Acronym List

CENSUS	U.S. Census Bureau
EPA	Environmental Protection Agency
FAS	USDA's Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
Tobacco Control Act	The Family Smoking Prevention and Tobacco Control Act
TTB	Alcohol and Tobacco Tax and Trade Bureau
USDA	U.S. Department of Agriculture

I. 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 U.S. Food and Drug Administration (FDA or Agency) to regulate tobacco products, was enacted in 2009.

This report to Congress is in response to the reporting requirement in 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.

II. 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.[1] 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.[2]

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.[3]

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 consulted resources from the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). According to USDA[4] and EPA[5] resources, there are currently no established tolerance limits for pesticide chemical residues that apply to domestically grown tobacco.

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[1] See section 907 of the FD&C Act.
[2] Section 907(a)(1)(A) of the FD&C Act.
[3] Section 907(a)(1)(B) of the FD&C Act.
[4] See USDA's Pesticide Data Program Database Search, accessed May 1, 2024, available at https://apps.ams.usda.gov/pdp.
[5] See 40 CFR part 180, accessed May 1, 2024, available at https://www.govinfo.gov/app/details/CFR-2022-title40-vol26/CFR-2022-title40-vol26-part180.

The Secretary has not yet finalized any additional tobacco product standards, although FDA, on May 4, 2022, published the following two proposed product standards in the *Federal Register*, one to prohibit menthol as a characterizing flavor in cigarettes,[6] and one to prohibit characterizing flavors (other than tobacco flavor) in cigars.[7] FDA is committed to completing the rulemaking process. At this time, the only enforceable tobacco product standard is the characterizing flavor prohibition described in section 907(a)(1)(A) of the FD&C Act, which applies only to cigarettes and their component parts.

[6] Tobacco Product Standard for Menthol in Cigarettes. 87 FR 26454 (May 4, 2022).
[7] Tobacco Product Standard for Characterizing Flavors in Cigars. 87 FR 26396 (May 4, 2022).

III. 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] 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. FDA has not yet found evidence that flavored cigarettes or their component parts are being exported for consumption abroad.

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. In calendar year 2023, the Agency conducted more than 830 inspections and investigations of tobacco product manufacturers, which included inspections of registered vape shop establishments.[9] 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) through these inspections.

In addition, FDA queried other federal 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 had done for the previous reports, FDA contacted TTB for this report, and TTB again confirmed this finding.[10] Further, FDA consulted the website database of USDA's Foreign Agricultural Service (FAS),[11]

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

[9] Vape shops are often regulated as both a retailer and manufacturer when they, for example, mix e-liquids, make or modify vaporizers, or mix loose tobacco and then sell these products.

[10] Email message from the Tobacco Products Regulations and Rulings Division of the TTB to FDA's Center for Tobacco Products, April 4, 2024.

[11] Accessed May 14, 2024, available at https://www.fas.usda.gov/data.

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,[12] a non-governmental agency, and found no data on cigarettes or their component parts with characterizing flavors (excluding tobacco and menthol).

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.[13] FDA has confirmed that this remains the case.

As stated in previous reports on this subject 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 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, because of the domestic ban on characterizing flavors (excluding tobacco and menthol), they have halted their production of flavored cigarettes for export. Consequently, Census has not attempted to obtain information beyond that obtained in its 2011 survey.[14]

[12] Accessed May 14, 2024, available at https://www.tma.org/data.
[13] See Chapter 24 of Schedule B, accessed June 23, 2024, available at https://www.census.gov/foreign-trade/schedules/b/2022/c24.html.
[14] See the 2013 report to Congress entitled *United States Tobacco Product Exports That Do Not Conform to Tobacco Product Standards* for more information on FDA's request to the U.S. Census Bureau and see correspondence related to this report, available at https://www.fda.gov/media/85859/download.

A. Volume of Manufactured Tobacco Product Exports

The volume of manufactured tobacco products exported from the United States[15] has declined significantly over recent decades. The total value of exported manufactured tobacco products declined from nearly $3.9 billion in 1999 to $241 million in 2023 (see Table 1).

Table 1. Value of U.S. Exports of Manufactured Tobacco Products in 1999, 2009, and 2023 in Thousands of U.S. Dollars (Nominal)[16,17]

Product	1999	2009	2023
Cigarettes	3,226,126	412,741	71,754
Other Tobacco Products*	650,692	76,739	169,507
Total	**3,876,818**	**489,480**	**241,262**

* (Includes cigars, smoking tobacco, smokeless tobacco, water pipe tobacco)

B. 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 2023 indicate that tobacco products (including unmanufactured tobacco) totaling approximately $1.3 billion[18] were exported from the United States to over 100 countries. These tobacco product exports in 2023 represented 0.74 percent of all U.S. agricultural exports, which are valued at $175 billion.[19] Of the total amount of U.S.-manufactured tobacco product exports in 2023, $71.8 million were cigarette exports.

As shown in Table 2, a total of 3,734,328,000 cigarette sticks were exported in 2023. Aruba, United Arab Emirates, Libya, Canada, and Panama together received 67 percent of U.S. cigarette exports. Of these countries, only Canada has banned the

[15] 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.
[16] See USDA's FAS database, accessed May 14, 2024, available at https://apps.fas.usda.gov/GATS/default.aspx.
[17] Manufactured tobacco products consist of cigarettes, cigars, cheroots, smokeless, water pipe, roll-your-own, pipe, and smoking tobaccos, as well as homogenized tobacco products.
[18] Please note that the 2022 figure of $1.3 billion includes $969.9 million of unmanufactured tobacco.
[19] USDA's FAS database, accessed May 2, 2024, available at https://apps.fas.usda.gov/GATS/default.aspx.

import or use of flavored cigarettes.[20]

Table 2. Top Five Recipients of U.S. Cigarette Exports in 2023[21]

Trade Partner	Number of Sticks (Thousands)	Percentage
Aruba	1,057,035	28.31
United Arab Emirates	451,653	12.09
Libya	378,000	10.12
Canada	351,996	9.43
Panama	247,734	6.63
Other	1,247,910	33.42
Total	**3,734,328**	**100.00**

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

[20] In 2010, federal legislation in Canada banned flavors (except menthol) in cigarettes, little cigars/cigarillos, and blunt wraps. In 2015, amendments extended this legislation to other types of cigars, with an exception for "traditional alcohol flavours." The exception for menthol in these products was removed effective 2017. See https://uwaterloo.ca/tobacco-use-canada/adult-tobacco-use/other-tobacco-use/flavoured-tobacco-products

[21] USDA's FAS database, accessed May 2, 2024, available at https://apps.fas.usda.gov/GATS/default.aspx.

IV. Public Health Impact of Exports That Do Not Conform to Tobacco Product Standards

FDA continues to have no evidence that flavored cigarettes (excluding tobacco and menthol) 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.

V. Policy Alternatives

As noted above, FDA currently has no evidence that flavored cigarettes (excluding tobacco and menthol) 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.

VI. Conclusion

The only currently applicable tobacco product standard is the prohibition 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.

This report was prepared by FDA's Center for Tobacco Products. For further information, please contact:

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