



August 2, 2022

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **Docket No. FDA-2021-N-1349 (87 Fed. Reg. 26454-26502, May 4, 2022)—Universal Comments on “Tobacco Product Standard for Menthol in Cigarettes”**

I. INTRODUCTION

Universal Leaf Tobacco Company, Inc. (“ULT”), on behalf of itself and its subsidiaries (collectively referred to herein as “Universal”), appreciates the opportunity to submit these comments to the Food and Drug Administration (“FDA” or “Agency”) on the proposed rule entitled *Tobacco Product Standard for Menthol in Cigarettes* (“Proposed Rule”) issued on May 4, 2022.

Universal, headquartered in Richmond, Virginia, is the world’s leading tobacco leaf supplier. Universal conducts its business in 30 countries spanning five continents, employs over 25,000 full-time and seasonal workers, and contracts with nearly 200,000 farmers. Through ULT, Universal procures and processes flue-cured and burley tobacco for manufacturers of, among other products, menthol cigarettes. Universal is a tobacco intermediary (i.e. a facility that receives, processes, blends, and stores leaf tobacco) between tobacco farmers and tobacco product manufacturers. Universal’s processing facilities in the United States also meet the definition of a “Tobacco Warehouse” under the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) and are therefore exempt from regulation under the Food, Drug, and Cosmetic Act (“FD&C Act”).¹

¹ Family Smoking Prevention and Tobacco Control Act § 901(c)(2), 21 U.S.C. § 387 (2011).

On May 4, 2022, the FDA issued the Proposed Rule to prohibit menthol as a characterizing flavor in cigarettes.² Simultaneously, the Agency released the Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and the Unfunded Mandates Reform Act Analysis (collectively referred to herein as “Regulatory Impact Analysis”).³

The Proposed Rule and accompanying Regulatory Impact Analysis solicit comments on the data and assumptions made by FDA in estimating the benefits and costs of the proposed ban. In this comment, Universal intends to provide the Agency direction and guidance to several of these outstanding questions. In doing so, our findings conclude there are considerable unknowns regarding the impact this regulation will have on America’s farmers, rural agricultural communities, local governments, and the public health due to the substantive and procedural insufficiencies in the Agency’s due diligence efforts prior to submitting the Proposed Rule. We therefore believe FDA is inadequately positioned to make an informed decision based on the information provided and suggest a number of alternative regulatory options available to the Agency moving forward.

II. CONTROLLING LEGISLATIVE & REGULATORY AUTHORITY

Introduction. In promulgating a tobacco product standard, FDA must operate within a number of procedural and substantive guardrails to ensure due process is respected and certain considerations are made. In this case, FDA must follow the requirements of: (1) the Tobacco Control Act, (2) Executive Orders 12866 and 13563, (3) the Regulatory Flexibility Act, and (4) the Unfunded Mandates Reform Act of 1995.

Family Smoking Prevention and Tobacco Control Act. In 2009, Congress passed the Tobacco Control Act authorizing FDA to, among other powers, promulgate new tobacco product standards when the Health and Human Services Secretary (“Secretary”) determines that a standard is appropriate for the protection of public health.⁴ In doing so, Congress also expressly prohibited the Agency from banning cigarettes altogether and placed a number of substantive and procedural restrictions on the Agency’s ability to promulgate such rules.⁵ These statutory restrictions on FDA reflect the stated intent of Congress in making tobacco products safer while still preserving an adult consumer’s right to choose to use them.⁶

In determining whether a product standard is appropriate for the protection of public health, the Tobacco Control Act requires the Secretary to make certain substantive considerations, including: (1) the risks and benefits to the population as a whole, (2) the impact on cessation, and (3) the impact on initiation.⁷ Additional considerations by the Secretary must also include the technical achievability of compliance with the standard and information concerning the

² Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26454-26502 (proposed May 4, 2022).

³ Food and Drug Administration, *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* (2022). Available at <https://www.fda.gov/media/158012/download> (last visited July 26, 2022).

⁴ Family Smoking Prevention and Tobacco Control Act § 907(a)(3)(A).

⁵ *Id.* at § 907(d)(3)(A).

⁶ *Id.* at § 3(7).

⁷ *Id.* at § 907(a)(3)(B).

countervailing effects of the tobacco product standard on public health, such as the creation of an illicit market.⁸

The Tobacco Control Act also mandates certain procedural requirements in the promulgation of a tobacco product standard. The notice of proposed rulemaking must specifically seek input from certain interested parties, including the Secretary of Agriculture and those stakeholders that may comment on “structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco”.⁹ In addition, the effective date must not take effect before the one-year anniversary of the rule’s publication date, unless the Secretary determines that an earlier effective date is necessary for the protection of public health. In making that determination, the Secretary must consider a timeline that minimizes economic loss to, and disruption of, domestic and international trade. Furthermore, if the Secretary determines that a product standard can only be met by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of such product standard must be at least two years after date of publication of the final regulation.¹⁰

Executive Orders 12866 and 13563. In 1993, President Clinton issued Executive Order 12866 with the intent to design a regulatory system that (1) advances policies without imposing unacceptable or unreasonable costs on society, (2) recognizes the private sector and private markets as the best engine for economic growth, (3) respects the role of state, local, and tribal governments, and (4) becomes increasingly effective, consistent, sensible, and understandable.¹¹ Specifically, the Executive Order requires agencies to adhere to certain principles in promulgating regulations, including the following relevant requirements:

- (1) *Consideration of Viable Alternatives:* Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior such as user fees or marketable permits, or choosing to not regulate altogether.
- (2) *Cost-Effective Method:* When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve such an objective. In so doing, agencies should select among those approaches that maximize net benefits—including potential economic, environmental, public health and safety, and other advantages such as distributive impacts and equity.
- (3) *Cost/Benefit Analysis:* Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.
- (4) *Evidence-Based Regulation:* Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

⁸ *Id.* at § 907(b).

⁹ *Id.* at § 907(c)(2)(C)-(D).

¹⁰ *Id.* at § 907(d)(2).

¹¹ Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993).

- (5) *Impact on State, Local, & Tribal Entities*: Agencies shall seek the views and assess the effects of federal regulations on state, local, and tribal governments, including the availability of resources to carry out those mandates.
- (6) *Tailored*: Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), taking into account the cost of cumulative regulations.¹²

The Executive Order charges the Office of Information and Regulatory Affairs (“OIRA”) under the Office of Management and Budget (“OMB”) with coordinating a review of agency rulemaking to confirm that regulations are consistent with applicable law, the President’s priorities, and the aforementioned set of principles. OIRA must also ensure that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. Thus, for rules deemed a “significant regulatory action”, agencies must provide OIRA an assessment of the projected benefits, anticipated costs, and why the planned regulatory action is preferable to the identified potential alternatives.¹³ The Executive Order also requires each agency to provide the public with meaningful participation in the regulatory process at this stage. Specifically, “before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation”.¹⁴

In 2011, President Obama issued Executive Order 13563—Improving Regulation and Regulatory Review—to supplement and reaffirm the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866.¹⁵ This Executive Order reiterates the need for agencies to adopt regulation only upon a reasoned determination that its benefits justify its cost, tailor regulations to impose the least burden on society, and select the regulatory approach that maximizes net benefits—including economic, environmental, and public health and safety. It emphasizes the need to consider qualitative impacts, including equity, human dignity, fairness, and distributive effects. Agencies should also “endeavor to provide the public with an opportunity to participate in the regulatory process” and “seek the view of those who are likely to be affected” prior to issuing a notice of proposed rulemaking.¹⁶

Regulatory Flexibility Act. In 1980, Congress passed the Regulatory Flexibility Act stating, “federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public”.¹⁷ Congress was concerned that laws and regulations designed for application to large scale entities were being applied uniformly to small businesses, small organizations, and small governmental jurisdictions, even though the problems that gave rise to government action may not have been caused by those smaller entities.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).

¹⁶ *Id.*

¹⁷ Regulatory Flexibility Act § 2(a)(1), 5 U.S.C. §§ 601-612 (1980).

It was the purpose of the act to establish as a principle of regulatory issuance that agencies should, consistent with objectives of the rule and of applicable statutes, fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their ultimate decision.¹⁸

Agencies are thus required to provide an Initial Regulatory Flexibility Analysis that includes a statement of the rule's need, a succinct statement of the objectives, an estimate of the number of small entities to which the proposed rule will apply, a description of the compliance requirements, and an identification of all duplicate or conflicting rules.¹⁹ They are then required to submit a Final Regulatory Flexibility Analysis ensuring the applicable agency considers the public comments and viable alternatives to minimize the impact on these small entities. This Act also intends to ensure that small entities have been given an opportunity to participate in the rulemaking process.²⁰

Unfunded Mandates Reform Act of 1995. Lastly, the Unfunded Mandates Reform Act intends for each agency to assess the effects of the regulatory action on state, local, and tribal governments, and the private sector.²¹ It requires that prior to issuing a notice of proposed rulemaking for any “significant regulatory action” and prior to issuing any such final rule, an agency must publish a written statement, including:

- (1) *Cost/Benefits Analysis*: A qualitative and quantitative assessment of the anticipated costs and benefits of the federal mandate, including the costs and benefits to state, local, and tribal governments or the private sector, as well as the effect of the federal mandate on health, safety, and environment.
- (2) *Disproportionate Budgetary Impacts*: Estimates by the agency of any disproportionate budgetary effects of the federal mandate upon any particular regions of the nation or particular state, local, or tribal governments, urban or rural, or other types of communities, or particular segments of the private sector.
- (3) *U.S. Economic Impact*: Estimates by the agency of the effect on the national economy, such as the effect on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness of American goods and services.²²

The Act furthermore requires an agency to identify and consider a reasonable number of regulatory alternatives. From those alternatives, the agency must select the least burdensome that achieves the objectives of the rule or provide an explanation why such an option was not preferable.²³

¹⁸ *Id.* at § 2(b).

¹⁹ *Id.* at § 603.

²⁰ *Id.* at § 609.

²¹ Unfunded Mandates Reform Act of 1995 §201, 2 U.S.C. § 1531-1538 (1995).

²² *Id.* at § 202.

²³ *Id.* at § 205(a).

III. INSUFFICIENCIES OF THE PROPOSED RULE

Introduction. As required by the aforementioned legislation and regulations, FDA must submit specific information within a Preliminary Regulatory Impact Analysis, an Initial Regulatory Flexibility Analysis, and an Unfunded Mandates Reform Act Analysis when promulgating a proposed rule the Agency considers a “significant regulatory action”. These studies must include a comprehensive cost/benefit analysis and consideration of the effects on particular small entities and vulnerable communities. In constructing these analyses, FDA must also provide the public with an opportunity to participate and seek the view of those who are likely to be affected prior to issuing a notice of proposed rulemaking.²⁴ FDA did not satisfy such requirements mandated by federal legislation and regulation. Specifically, this section explains the substantive and procedural insufficiencies of the Regulatory Impact Analysis conducted by FDA in promulgating the Proposed Rule.

Substantive Insufficiencies. FDA’s almost three-hundred page Regulatory Impact Analysis dedicates less than eight pages to the impact a ban on menthol cigarettes will have on the demand for tobacco leaf.²⁵ Within those eight pages, FDA spends half of them discussing historic leaf production in the United States and calculating tobacco volumes. FDA dedicates half a page on international markets and mint/menthol supply chains and finally focuses one page on the reduction in domestic leaf demand.²⁶ In comparison, FDA allocates three pages to describing cost-savings projections in reducing smoking related fires, an issue which the Agency considers in the catch-all category of “other externalities”.²⁷ FDA uses the words “farm”, “farmer”, or “agriculture” a total of 18 times in the entire 288-page Regulatory Impact Analysis and provides five agriculture-related references.²⁸ The word “fire”, alternatively, is used 118 times and FDA provides almost double the number of relevant sources.²⁹ This comparison exposes FDA’s focus on understanding the economic benefits of the Proposed Rule, without extending the same consideration to the potential costs, specifically those to domestic agriculture.

Procedural Insufficiencies. There are also concerns in the method in which FDA collected the data used in constructing the Regulatory Impact Analysis through OIRA. In an effort to inform FDA of the importance of including agriculture in their economic considerations, Universal requested a meeting with OIRA. Upon accepting the request and scheduling the date/time, Universal received notice of the meeting’s cancellation mere hours prior to the scheduled meeting (see Appendix A).

Universal was the only organization from the agricultural private sector to request a meeting with OIRA. Of the 38 representatives that spoke with OIRA, only one, the North Carolina Department of Agriculture and Consumer Services, focused on the economic impact the Proposed Rule would likely have on agriculture.³⁰ While Universal does not manufacture a tobacco product

²⁴ Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).

²⁵ *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at pages 199-206.

²⁶ *Id.*

²⁷ *Id.* at pages 22-25.

²⁸ *Id.* throughout total document.

²⁹ *Id.*

³⁰ Office of Information and Regulatory Affairs, *OIRA Conclusion of EO 12866 Regulatory Review of RIN: 0910-AI60* (2022). Available at: <https://www.reginfo.gov/public/do/eoDetails?rrid=227311> (last visited July 26, 2022).

for retail sale, we chose to engage with OIRA because no other business is as closely aligned to the interests of the farmers as Universal. As such, Universal was in a unique position to explain the impacts the Proposed Rule could have on farmers and agricultural communities prior to the Agency issuing the notice.

Conclusion. The federally required Regulatory Impact Analysis is designed to ensure an agency takes into consideration, *inter alia*, the impact of a significant regulatory action on economic growth, job creation, international competitiveness, distributive burden, equity, small entities, and state, local, and tribal jurisdictions. The required OIRA review for significant regulatory actions further ensures affected stakeholders have notice and opportunity to comment prior to issuing a proposed rule. Executive Order 12866 specifically states, “before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation”.³¹

It is axiomatic that the purpose of the notice and comment period required by the Administrative Procedure Act is for stakeholders to provide FDA with technical information as to better inform the Agency’s decision to proceed or amend a proposed rule. However, it does not absolve the Agency from its statutory and regulatory obligations to seek out reasonably obtainable scientific, technical, and economic information concerning the need for, and consequences of, the intended regulation prior to issuing a notice of proposed rulemaking.³² In this case, FDA spent a negligible amount of resources seeking to understand how the proposed ban on menthol cigarettes will affect agriculture in the United States. FDA’s brief economic analysis neither assigns a value to the reduction in domestic leaf sales, nor does the Agency include this number in the final evaluation of costs. Furthermore, FDA actively chose not to engage the only stakeholder in the agricultural sector that requested a meeting during the OIRA review process.

The remainder of this comment intends to (1) expand upon and supplement FDA’s understanding of the impact on domestic tobacco leaf requirements, (2) introduce FDA to the wider economic impacts not considered by the Agency, and (3) suggest reasonable alternatives to a total ban on menthol cigarettes.

IV. SUPPLEMENTAL REGULATORY IMPACT CONSIDERATIONS

Introduction. FDA’s Regulatory Impact Analysis briefly mentions the direct impact the proposed menthol ban is expected to have on the demand for domestically grown tobacco leaf. FDA requests comments on their estimates and assumptions used in calculating the domestic tobacco leaf used in the production of cigarettes, trends in tobacco production, and the potential effects the Proposed Rule could have on domestic and foreign entities as well as international trade.³³ This section intends to fulfill this request by supplementing the Agency’s assumptions and delineating the risk the Proposed Rule poses to leaf tobacco markets by clearly defining (1) total leaf tobacco volumes necessary to supply the U.S. menthol cigarette market, (2) domestic leaf tobacco requirements by volume, and (3) domestic leaf tobacco requirements by sales value.

³¹ Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993).

³² *Id.*

³³ *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at page 206.

U.S. Affected Tobacco Product Calculation. Euromonitor International Data, cited in the Regulatory Impact Analysis, provides estimates of total and mentholated cigarette, roll-your-own (“RYO”), and heated tobacco product (“HTP”) sales in the United States. As displayed in the table below, menthol accounted for 35% of the total market in 2020 with volumes reaching nearly 78.5 billion sticks and sales revenues of \$33 billion.³⁴

Table 1. Summary of Estimated Sales and Counts for Tobacco Products Affected by the Rule³⁵

Tobacco Product	Total Sales (\$2020, million)	Menthol Sales (\$2020, million)	Total Sales (million sticks)	Menthol Sales (million sticks)
<i>Cigarettes</i>	\$94,173.3	\$32,923.0	222,526.4	77,808.9
<i>RYO</i>	\$333.1	\$25.6	1,861.7	650.9
<i>HTP Cigarettes</i>	\$21.6	\$7.6	41.8	14.6
<i>Total</i>	\$94,528.0	\$32,956.2	224,465.9	78,474.0

The Proposed Rule can therefore expect to directly reduce the demand for tobacco leaf required to produce up to 78,474,000,000 sticks. FDA notes that approximately \$17.7 million in menthol cigarettes were imported into the United States in 2020, with 53% originating in Canada.³⁶ The Agency seemingly concludes that foreign manufactured menthol cigarettes do not use American-grown leaf tobacco and should be excluded from the total sticks affected by the Proposed Rule. However, the United States is the second largest exporter of tobacco leaf in the world with Canada importing \$4,936,371 of leaf in 2020.³⁷ These numbers, combined with adult American consumers’ preferences, suggest it is more likely than not a significant portion of these cigarettes are produced using American-grown tobacco. Regardless, the \$17.7 million in imported menthol cigarettes accounts for only 0.54% of the \$32,956,200,000 billion in total menthol cigarette sales in 2020.

FDA further suggests that because U.S. exports of menthol cigarettes would not be affected by this product standard, some of the available supply of domestically grown tobacco may be used to manufacture tobacco products destined for export.³⁸ Therefore, the Agency asserts the total affected stick count should not include these exported products. FDA, however, notes the 5-year average of cigarettes manufactured in the U.S. for export is approximately 5.8 billion sticks.³⁹ If the Agency were to assume the export market reflected the domestic market and 35% of these exports were menthol, this would account for only 2 billion sticks. It is more likely for a tobacco product manufacturer to terminate production of menthol cigarettes altogether than continue to monopolize production lines to manufacture such *de minimis* volumes. As such, these sticks are included in the total number of affected products and 78,474,000,000 sticks remains a reasonable estimate in the number of products likely to be affected by a U.S. ban on menthol cigarettes.

³⁴ Euromonitor International Limited. (2021). © All rights reserved.

³⁵ Euromonitor International Limited. (2021). © All rights reserved.

³⁶ *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at page 206.

³⁷ TMA, *U.S. Trade Barometer: Exports of Leaf Tobacco*, (December 2020).

³⁸ *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at page 204.

³⁹ *Id.* at 203.

Total Affected Tobacco Leaf Calculation. FDA’s Regulatory Impact Analysis assumes that tobacco filler represents 65-75% of the weight of a cigarette, or approximately 0.7 grams per stick.⁴⁰ Additionally, FDA assumes that 80% of the total weight of a cigarette tobacco filler is comprised of flue-cured and burley tobacco, the types of tobacco leaf used in cigarettes that is also grown in the United States.⁴¹ In alignment with FDA’s assumptions, the average cigarette weighs approximately 1 gram. However, health statistics used in studies by the Organisation for Economic Co-Operation and Development (“OECD”) found a typical cigarette contains a tobacco filler content varying between 65-100% of the weight of the product.⁴² This translates to 0.65 to 1.00 grams of tobacco filler per cigarette, for a slightly higher median weight of 0.83 grams per stick. In regards to the contribution of flue-cured and burley tobacco to the filler weight, there is no reason to believe it is higher or lower than the 80% suggested by FDA. As such, the average weight of flue-cured and burley tobacco in a typical cigarette ranges between 0.52-0.8 grams, or approximately 0.66 grams per stick. This translates to 1.15-1.76 pounds per 1000 cigarettes (“lbs/1000”) for a median of 1.46 lbs/1000 cigarettes.

As noted in Table 1, Euromonitor International Data estimated the U.S. sale of menthol cigarettes in 2020 hit approximately 78,474,000,000 sticks. If, as calculated above, the average cigarette is comprised of 1.15-1.76 lbs/1000 of flue-cured & burley tobacco, the U.S. menthol market’s total requirement for leaf tobacco is between 90,245,100 and 138,114,240 pounds for a median of 114,572,040 pounds.

Affected U.S. Tobacco Leaf Calculation. As noted by FDA, not all leaf tobacco in a menthol cigarette sold in the United States is domestically grown. Furthermore, not all American-grown tobacco is used in a U.S.-manufactured and distributed product. Therefore, understanding the total reduction in demand for domestically grown tobacco leaf requires an understanding of how much domestic leaf a standard cigarette contains in the United States.

Tobacco products are generally comprised of a combination of four main types of leaf tobacco: flue-cured, burley, dark, and oriental. In 2021, farming operations cultivated 218,930 acres of land to produce 477,973,000 pounds of leaf tobacco worth over \$1 billion.⁴³ In the United States, tobacco production is primarily concentrated in rural communities across seven states—Georgia, Kentucky, North Carolina, Pennsylvania, South Carolina, Tennessee, and Virginia.

As noted in the Regulatory Impact Analysis, cigarettes are typically comprised of only three of the four types of tobacco: flue-cured, burley, and oriental.⁴⁴ Flue-cured and burley are grown throughout the United States while oriental tobacco is generally imported due to its soil and climate requirements. Thus, to understand the impact a menthol ban would have on domestic leaf demand, Table 2 provides a five-year overview of flue-cured and burley leaf production in the United States.

⁴⁰ *Id.* at 202.

⁴¹ *Id.*

⁴² Organisation for Economic Co-Operation and Development, *OECD Health Statistics* (2022). Available at: <http://www.oecd.org/health/health-data.htm> (last visited July 23, 2022).

⁴³ U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats*, (2021). Available at <https://quickstats.nass.usda.gov/> (last visited July 26, 2022).

⁴⁴ *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at page 199.

Table 2. U.S. Flue-Cured & Burley Leaf Tobacco Production (1,000 lbs), 2016-2020⁴⁵

U.S. Flue-Cured (Class 1) Leaf Tobacco Production (1,000 lbs), 2016-2020						
State	2016	2017	2018	2019	2020	5-Year Average
<i>Georgia</i>	28,350	26,250	23,750	18,900	19,355	21,305
<i>North Carolina</i>	330,000	358,600	250,800	234,000	178,200	271,400
<i>South Carolina</i>	24,700	25,200	22,140	15,770	6,600	19,242
<i>Virginia</i>	48,400	50,600	42,000	28,500	23,400	39,180
<i>Total</i>	431,450	460,650	338,690	297,170	227,555	353,127
U.S. Burley (Class 3A, Types 31 & 32) Leaf Tobacco Production (1,000 lbs), 2016-2020						
State	2016	2017	2018	2019	2020	5-Year Average
<i>Kentucky</i>	106,750	129,150	80,000	77,900	68,250	93,190
<i>North Carolina</i>	1,800	1,440	1,125	700	527	1,118
<i>Pennsylvania</i>	16,620	14,670	11,880	8,800	7,920	11,978
<i>Tennessee</i>	16,200	18,000	9,010	6,400	3,875	10,790
<i>Virginia</i>	2,520	2,200	1,500	1,330	680	1,646
<i>Total</i>	143,890	165,460	103,515	95,130	85,617	118,722
Total U.S. Flue-Cured & Burley Tobacco Leaf Production (1,000 lbs), 2016-2020						
	2016	2017	2018	2019	2020	5-Year Average
<i>Total Tobacco Production</i>	628,720	710,161	533,241	467,956	389,413	510,514
<i>Total Flue-Cured & Burley</i>	575,340	626,110	442,205	392,300	323,293	471,850
<i>Flue-Cured & Burley Share</i>	92%	88%	83%	84%	83%	86%

FDA's approach to estimating the share of imported flue-cured and burley tobacco used in the manufacturing of domestically-sold cigarettes is accurate. As Table 3 provides, 40% of the total U.S. supply of flue-cured and burley tobacco used to produce cigarettes was imported.

Table 3. Estimating Net U.S. Supply of Flue-Cured and Burley Tobacco (1,000 lbs), 2016-2020⁴⁶

	2016	2017	2018	2019	2020	5-Year Average
<i>Domestic Production</i>	575,340	626,110	442,205	392,300	323,293	471,850
<i>Exports</i>	236,950	205,394	22,856	136,448	100,914	180,512
<i>Domestic Production Minus Exports</i>	338,390	420,716	419,349	255,852	222,379	291,338
<i>Imports</i>	251,559	202,099	174,167	198,358	153,378	195,912
<i>Total US Supply</i>	589,949	622,815	393,517	454,210	375,757	487,250
<i>Imports Share of Total U.S. Supply</i>	43%	32%	44%	44%	41%	40%
<i>Domestic Share of Total U.S. Supply</i>	57%	68%	56%	56%	59%	60%

⁴⁵ U.S. Department of Agriculture, National Agricultural Statistics Service, *Crop Production Annual Summary* (2016-2021). Available at: <https://usda.library.cornell.edu/concern/publications/k3569432s> (last visited July 26, 2022).

⁴⁶ *Id.*

As such, the five-year average in use of domestically grown flue-cured and burley tobacco in the domestic sale of cigarettes is estimated at approximately 60%.

Conclusion. In this section, we first concluded the total number of cigarettes affected by a U.S. menthol ban is 78,477,400,000 sticks. We determined the average cigarette weight is between 1.15 and 1.76 lbs/1000 of flue-cured and burley tobacco making the U.S. menthol market's total requirement for tobacco leaf between 90,245,100 and 138,114,240 pounds for a median of 114,572,040 pounds. Lastly, we determined that 60% of the flue-cured and burley leaf in a menthol cigarette sold on the U.S. market is grown domestically. With these assumptions taken into consideration, we can conclude FDA's Proposed Rule to ban menthol in cigarettes directly puts between 54,147,060 to 82,868,544 pounds of U.S. grown tobacco at risk, or a median of approximately 68,743,224 pounds. Based on the 2020 average price per pound of tobacco in the United States of \$2.10/pound, this accounts for annual sales of \$113,708,826 to \$174,023,942.⁴⁷

Table 4. Domestic Leaf Volume & Sales Revenue in U.S. Menthol Cigarette Market

	Low Weight Range	High Weight Range	Median
<i>FC/Burley Filler Weight</i>	1.15 lbs/1000	1.76 lbs/1000	1.46 /1000
<i>Total Leaf Requirement</i>	90,245,100	138,114,240	114,572,040
<i>Domestic Leaf (lbs)</i>	54,147,060	82,868,544	68,743,224
<i>Domestic Leaf (\$)</i>	\$113,708,826	\$174,023,942	\$144,360,770

V. ADDITIONAL REGULATORY IMPACT CONSIDERATIONS

Introduction. The previous section expands upon the direct risk, briefly acknowledged by the Regulatory Impact Analysis, to the demand for American-grown tobacco posed by the Proposed Rule. The economic and social impacts of the Proposed Rule, however, extend far beyond this immediate dollar number. This section introduces FDA to important impacts it has not yet considered, including: (1) the impact on the economy of the United States as a whole, (2) the impact on American farmers and their workers, (3) the impact on underserved rural communities, and (4) the impact on small entities, including businesses and governmental jurisdictions.

(1) Impact on the Economy of the United States

Introduction. Tobacco continues to be a critically important crop in the United States. In 2021, American farmers grew 478 million pounds of tobacco leaf across 219,000 acres with farm level receipts of \$1.026 billion.⁴⁸ North Carolina produced approximately 50% of U.S. tobacco with farm level receipts of \$505 million.⁴⁹ Kentucky, the second largest tobacco producing state, saw farm level receipts of \$269 million.⁵⁰

⁴⁷ U.S. Department of Agriculture, National Agricultural Statistics Service, *Agricultural Prices* (2022). Available at: https://www.nass.usda.gov/Publications/Todays_Reports/reports/agpr0522.pdf (last visited July 26, 2022).

⁴⁸ U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021) Available at: <https://quickstats.nass.usda.gov/> (last visited July 26, 2022).

⁴⁹ *Id.*

⁵⁰ *Id.*

Tobacco is produced in 18 states with most being grown in (ranked by production) North Carolina, Kentucky, Virginia, Tennessee, Georgia, South Carolina, and Pennsylvania. Over 90% of U.S. tobacco production is used in cigarette production in the U.S. or exported for foreign cigarette production.⁵¹ This section highlights the role tobacco plays and the larger risk the Proposed Rule poses to the overall economy of the United States.

State of U.S. Tobacco Growing. The Regulatory Impact Analysis notes a decline in tobacco-growing farms and volumes to suggest the importance of tobacco in agriculture is waning. However, the Agency overlooks two important issues related to tobacco volumes in the United States. First, as seen in Table 5 below, there have been two rather significant declines in volumes over the past five years, both due to global market factors.

Table 5. U.S. Leaf Tobacco Production (1,000 lbs), 2016-2020⁵²

State	2016	2017	2018	2019	2020	5-Year Average
Georgia	28,350	26,250	23,750	18,900	19,276	22,805
Kentucky	136,280	183,300	134,370	123,390	107,235	127,129
North Carolina	331,800	360,040	251,925	234,700	184,127	250,895
Pennsylvania	20,460	18,990	17,400	14,300	13,440	16,600
South Carolina	24,700	25,200	22,140	15,770	8,400	18,630
Tennessee	35,690	43,000	39,610	30,490	29,380	34,956
Virginia	51,440	53,381	44,046	30,406	27,555	39,499
TOTAL	628,720	710,161	533,241	467,956	389,413	510,514

Beginning in 2017, the United States and China began a trade dispute culminating in import duties placed on tobacco leaf entering China in 2018 and 2019. Between 2017 and 2020, leaf exports to China dropped from 18,774,623 pounds worth \$162,297,021 to 138,651 pounds valued at \$1,144,890.⁵³ Secondly, the COVID-19 pandemic put stress on supply chains around the world, especially agriculture, resulting in non-market driven declines in production across the board starting in 2020.⁵⁴

In the FDA's economic analysis, the Agency chose not to assign an economic value to the sale of leaf tobacco. The Agricultural Census provided by the USDA, summarized in Table 6 below, shows the sale value of tobacco leaf from the top tobacco-growing states and the 10-year average. The chart indicates that while acreage and production have declined over the years, the efficiency of farms and quality of the U.S. crop has led to 10-year stability in the overall market.

⁵¹ Brown, Blake. "Economic Impact of U.S. Tobacco Farming." Analysis completed with IMPLAN. July 25, 2022.

⁵² U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021). Available at: <https://quickstats.nass.usda.gov/> (last visited July 26, 2022).

⁵³ TMA, *U.S. Trade Barometer: Exports of Leaf Tobacco*, (December 2017, December 2020).

⁵⁴ U.S. Department of Agriculture, Economic Research Service, *Rural America at a Glance* (2021). Available at: <https://www.ers.usda.gov/publications/pub-details/?pubid=102575> (last visited July 26, 2022).

Table 6: Agricultural Census Summary of Tobacco Leaf Sales, 2007-2017⁵⁵

State	2007	2012	2017	10-Year Average
North Carolina	\$549,636,000	\$732,772,000	\$731,657,000	\$671,355,000
Kentucky	\$314,151,000	\$356,603,000	\$351,234,000	\$340,662,667
Virginia	\$68,073,000	\$100,901,000	\$107,620,000	\$92,198,000
Tennessee	\$70,634,000	\$108,224,000	\$99,431,000	\$92,763,000
Georgia	\$56,978,000	\$39,656,000	\$52,676,000	\$49,770,000
South Carolina	\$73,026,000	\$47,984,000	\$46,939,000	\$55,983,000
Pennsylvania	\$28,156,000	\$40,379,000	\$35,994,000	\$34,843,000
US Total	\$1,268,114,000	\$1,491,208,000	\$1,474,376,000	\$1,411,232,667

Economic Impact of Tobacco-Growing. Dr. Blake Brown, Hugh C. Kiger Professor of Agriculture and Resource Economics at NC State University, conducted a high-level study to examine the impact of tobacco growing on the economy of the United States, as well as the specific economies of North Carolina and Virginia (see Appendix B).⁵⁶ The following is a summary of these results, given in terms of direct, indirect, and induced changes with each broken down to changes in employment, labor income, and value-added.

IMPLAN Analysis. IMPLAN is used for the input-output analysis of the economic impacts of tobacco farming. A change in one sector of the economy has multiple impacts in many different associated sectors. IMPLAN divides the impacts of changes in a sector's output into direct, indirect, and induced effects. The direct effects are for a given change in the industry sector in question. For example, if all tobacco production in the U.S. ceases, farm level revenues will decline by \$1.026 billion. Indirect effects are the impacts due to changes in business-to-business transactions of the industry in question with other businesses. For example, if tobacco farms have reduced output, then fertilizer expenditures (and fertilizer industry output) are reduced. Induced effects stem from changes in household spending when the employees in the affected industry have changes in their labor income due to changes in the affected industry. For example, if tobacco farming revenues are reduced then farmers and their employees have less household income to spend which has negative effects on the economy. The sum of direct, indirect, and induced impacts is the total impact on economic output. IMPLAN further divides these three types of impacts into the impact on employment, labor income, and value-added. Employment is the reduction in the number of jobs due to the change in the affected industry. Labor income is thereby reduced. Value-added is defined as the difference in industry output (revenues) and expenditures on intermediate inputs for production in the sector in question.

⁵⁵ U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: <https://www.nass.usda.gov/Publications/AgCensus/2017/index.php> (last visited July 26, 2022).

⁵⁶ Brown, Blake. "Economic Impact of U.S. Tobacco Farming." Analysis completed with IMPLAN. July 25, 2022.

Direct Impacts. Based on 2021 tobacco production, complete elimination of tobacco farming would reduce output by \$1.026 billion. This exogenous change is imposed on the economy and the resulting impacts traced throughout the economy. Such a change could be brought about suddenly by changes in tobacco policy and regulations. Employment in tobacco farming would fall by 15,569 jobs. To state it otherwise, employment in tobacco farming in 2021 is estimated by IMPLAN to be 15,569 and all this would be lost. Consequently, labor income in tobacco farming, all of it, would fall by \$380 million. Value added to the economy by the tobacco farm sector would all be lost equaling \$520 million. The sum of labor income lost plus value-added by tobacco farming plus the cost of intermediate goods purchased for tobacco production equal the direct output loss of \$1.026 billion.

Indirect and Induced Impacts. Lost indirect output to the economy is estimated to be \$828 million. This loss in output is due to a reduction in business that tobacco farms do with supporting and affiliated businesses. For example, tobacco farms will purchase no fertilizer or seeds. As a consequence, those businesses will lose 5,032 jobs and labor income paid by these businesses will decrease by \$262 million. Additionally, these affiliated and supporting industries will reduce the value they add to Gross Domestic Product by \$414 million. The induced impact is a reduction in output of \$952 million. This is a result of people working in tobacco farming having less household income to spend.

Impacts on Affiliated Industries. The indirect and induced effects of the loss of tobacco farming affect a wide range of business and industry sectors as seen in Table 7.

Table 7: Impact on Output from Related Industries

Industry	Impact on Economic Output
<i>Other Real Estate</i>	(\$167,864,348.01)
<i>Support Activities for Agriculture and Forestry</i>	(\$110,154,484.84)
<i>Owner-Occupied Dwellings</i>	(\$74,816,869.77)
<i>Pesticide and other Agricultural Chemical Manufacturing</i>	(\$64,451,852.11)
<i>Wholesale: Other Non-Durable Goods Merchant Wholesalers</i>	(\$55,887,569.54)
<i>Monetary Authorities and Depository Credit Intermediation</i>	(\$43,097,467.24)
<i>Hospitals</i>	(\$41,831,978.64)
<i>Petroleum Refineries</i>	(\$36,473,673.64)
<i>Insurance Carriers, Except Direct Life</i>	(\$33,580,555.08)
<i>Management of Companies and Enterprises</i>	(\$27,865,941.38)

Interestingly, “Other Real Estate” is the affiliated category that is most affected by the elimination of tobacco farming with output in Other Real Estate falling by \$168 million. Other Real Estate includes lessors of non-residential building and operations of residential property managers. Pesticide and other agricultural chemical manufacturing decreases by \$64 million. Petroleum refineries are negatively impacted by \$36 million. Hospitals experience a reduction in economic output of \$42 million.

Geographical Impacts. Tables 8 and 9 give the impacts specific to the North Carolina and Kentucky economies.

Table 8: Impact of Loss of Tobacco Farming on the North Carolina Economy

Impact	Employment	Labor Income	Value Added	Output
<i>Direct</i>	(4422)	(\$179,220,794)	(\$203,546,743)	(\$504,800,000)
<i>Indirect</i>	(2397)	(\$102,781,040)	(\$166,450,565)	(\$326,333,991)
<i>Induced</i>	(1431)	(\$69,447,617)	(\$129,972,558)	(\$226,208,661)
<i>Total</i>	(8250)	(\$351,449,450)	(\$499,969,867)	(\$1,057,342,652)

Table 9: Impact of Loss of Tobacco Farming on the Kentucky Economy

Impact	Employment	Labor Income	Value Added	Output
<i>Direct</i>	(6109)	(\$134,055,249)	(\$174,094,932)	(\$269,268,000)
<i>Indirect</i>	(702)	(\$27,303,419)	(\$38,238,104)	(\$72,697,792)
<i>Induced</i>	(768)	(\$35,924,347)	(\$63,715,813)	(\$114,824,724)
<i>Total</i>	(7578)	(\$197,283,015)	(\$276,048,848)	(\$456,790,516)

North Carolina produces nearly 50% of U.S. tobacco revenues at the farm level with Kentucky producing 26% of farm level receipts. North Carolina loses \$505 million in farm level receipts and Kentucky loses \$269 million. Consequently, 4,422 jobs in tobacco farming are lost in North Carolina and 6,109 in Kentucky. The total reduction in economic output is \$1.057 billion in North Carolina and \$457 million in Kentucky. Employment losses from direct, indirect, and induced impacts total 8,250 in North Carolina and 7,578 in Kentucky.

Total Impacts. The total impact on the economy with a loss of tobacco farming is \$2.8 billion. This includes a reduction in employment of 25,701 jobs, a reduction in labor income of \$944 million, and a reduction in value-added of \$1.467 billion.

Table 10: Impact of Loss of Tobacco Farming on the U.S. Economy

Impact	Employment	Labor Income	Value Added	Output
<i>Direct</i>	(15,549)	(\$380,983,130)	(\$520,206,497)	(\$1,025,874,000)
<i>Indirect</i>	(5,032)	(\$262,123,176)	(\$413,623,092)	(\$828,609,026)
<i>Induced</i>	(5,120)	(\$300,862,962)	(\$533,647,757)	(\$951,936,707)
<i>Total</i>	(25,701)	(\$943,969,267)	(\$1,467,477,346)	(\$2,806,419,733)

Conclusion. America's tobacco-growing operations directly support 15,549 jobs paying \$380,983,130 in labor income and support a total of 25,701 jobs paying nearly one billion dollars in labor income throughout the agricultural sector. Every dollar lost in the sale of tobacco leaf on the farm accounts for \$1.78 lost to the larger economy. Considering the menthol ban risks reducing \$113,708,826 to \$174,023,942 in demand for tobacco leaf, the total annual risk to the United States' economy can be estimated to be between \$316,110,536 and \$483,786,559.

(2) Impact on American Farmers and Workers

Introduction. FDA’s Proposed Rule will have the greatest direct impact on America’s farmers and their workers, yet they are not considered in FDA’s Regulatory Impact Analysis. According to the last Agricultural Census conducted by the USDA, there are 6,237 tobacco-growing farms in the United States.⁵⁷ In 2021, these farmers grew 478 million pounds of tobacco leaf across 219,000 acres with farm level receipts of \$1.026 billion.⁵⁸ The Proposed Rule puts between \$113,708,826 and \$174,023,942 of farm receipts for tobacco leaf at risk. This is the obvious burden FDA’s proposal will have directly on tobacco farmers in the United States. Beyond the loss of this farm revenue, the sale of tobacco also plays an irreplaceable role on the farm in supplying the capital necessary to invest in the infrastructure supporting the cultivation of other crops and compliance with increasing regulations.

Tobacco-Growing Farms in the United States. Small family farms play a key role in tobacco production in the United States. As seen in Table 11, 98.8% of tobacco-growing farms in the top producing states are family/individually owned, partnerships, or held in family-controlled corporations.⁵⁹ Therefore, only 1.2%, or 71 farms, are organized as corporate entities outside of family control.

Table 11: Tobacco-Growing Farm Ownership in Top Tobacco Producing States, 2017⁶⁰

State	Family/Individual	Partnership	Corp/Family Held	Corp/Other
<i>North Carolina</i>	897	184	185	29
<i>Kentucky</i>	2,249	272	74	20
<i>Virginia</i>	244	25	31	6
<i>Tennessee</i>	505	67	19	7
<i>Georgia</i>	71	20	7	8
<i>South Carolina</i>	83	28	5	1
<i>Pennsylvania</i>	746	39	27	0
<i>Total</i>	4,795	635	348	71

Alternatives to Tobacco Growing. Tobacco is considered a “cash crop” as it generates more revenue per acre than most other crops in the United States. Tobacco producers rely on this income to support the production of other crops and to invest in the overall farm. A study of Universal’s contracted operations found 100% of farmers producing flue-cured or burley tobacco for the cigarette market also cultivate a wide variety of complementary crops, the highest among them being corn, soybeans, and wheat in 2021.

⁵⁷ U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: <https://www.nass.usda.gov/Publications/AgCensus/2017/index.php> (last visited July 26, 2022).

⁵⁸ U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021). Available at: <https://quickstats.nass.usda.gov/> (last visited July 26, 2022).

⁵⁹ U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: <https://www.nass.usda.gov/Publications/AgCensus/2017/index.php> (last visited July 26, 2022).

⁶⁰ *Id.*

Figure 1: Percentage of Crops Grown by Universal Farmers in the United States, 2021⁶¹

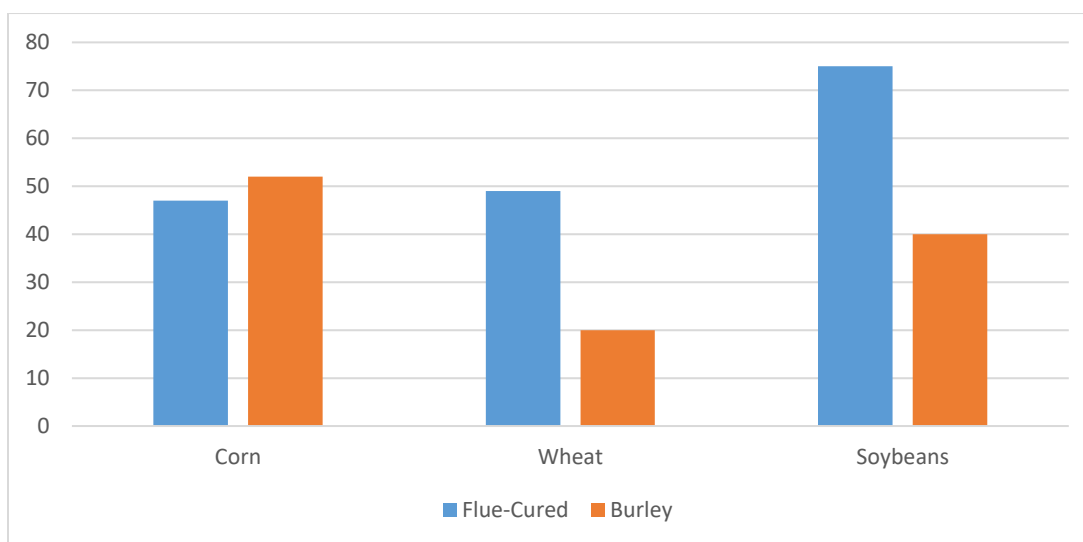
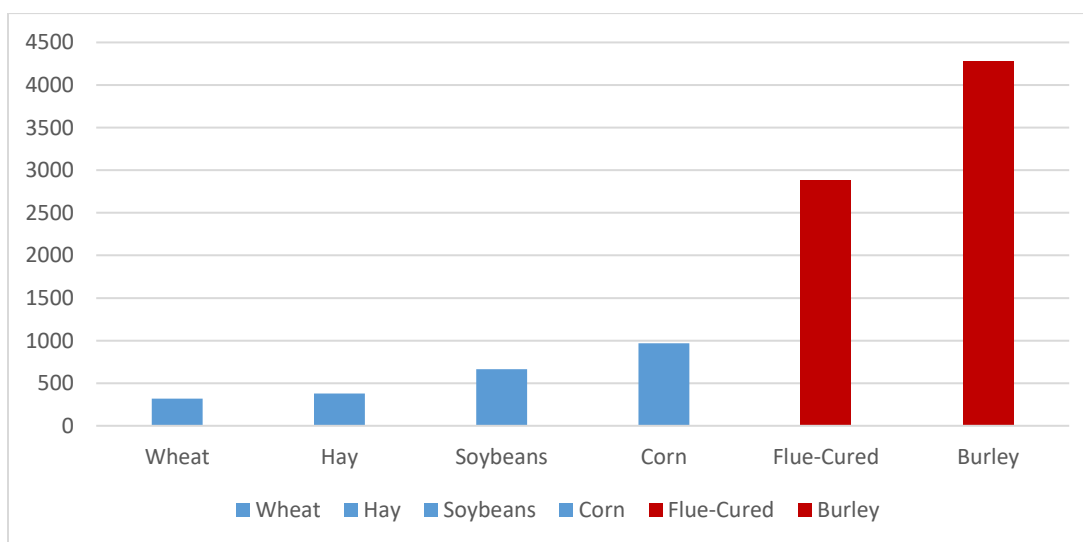


Figure 2 below shows 2021 crop revenue per acre in the sale of tobacco as compared to those of corn, wheat, soybeans, and hay.

Figure 2: Comparison of Crop Revenue per Acre, 2021⁶²



As Figure 2 represents, a loss of one acre of burley tobacco requires a farmer to grow an additional 13 acres of wheat, 11 acres of hay, six acres of soybeans, or four acres of corn for grain. Similarly, a loss of one acre of flue-cured requires a replacement of approximately nine acres of wheat, eight acres of hay, four acres of soybeans, or three acres of corn for grain. As cropland is limited on the farm, most growers do not have enough land to replace tobacco by simply growing more of another crop of significantly lower value per acre.

⁶¹ Based on Universal Contracted Farmers (2021).

⁶² U.S. Department of Agriculture National Agricultural Statistics Service, *NASS—Quick Stats* (2021). Available at: <https://quickstats.nass.usda.gov/> (last visited July 26, 2022).

The Regulatory Impact Analysis mentions that “some tobacco growers have switched to hemp production as it uses the same equipment and many of the same growing techniques as tobacco”.⁶³ While the cultivation of hemp does share some similarities with tobacco, existing agronomic technology, markets, and federal regulations currently make hemp an ill-suited alternative. First, labor costs are significantly high for hemp compared to tobacco—which is already one of the most labor-intensive crops in the United States. Hemp seeds must be planted by hand rather than using the mechanical planters often used in tobacco. Additionally, no herbicide has been approved for the production of hemp, requiring weeds to be pulled manually. One of the largest obstacles to a farm’s reliance on hemp is the instability of the unregulated cannabidiol (“CBD”) market. The 2018 Farm Bill legalized the production of hemp and gave regulatory authority to FDA over products containing cannabis or cannabis-derived compounds, including CBD.⁶⁴ Since 2018, FDA has approved only one product, a medical grade drug for the treatment of seizures, that contains CBD.⁶⁵ The instability of the market has ultimately led to the instability in pricing of hemp, thus creating great risk to the farmer in dedicating acreage to such a crop. This risk is exasperated as regulations surrounding banking and crop insurance currently remain in their nascent phases.

Conclusion. Tobacco has been, and remains, an unparalleled cash crop on farms in this nation. In 2021, American farms grew 478 million pounds of tobacco across 219,000 acres valued at \$1.026 billion. The vast majority of these farms are small, family held businesses that directly employ 15,549 workers on the farm and support 25,701 jobs across the agricultural sector. Tobacco’s revenues are three to ten times greater than those complementary crops grown alongside tobacco or in the off-season, meaning there is no economically viable alternative to tobacco on the farm. As North Carolina’s Commissioner of Agriculture, Steve Troxler, commented to FDA:

Given the fluctuations of commodity markets, tobacco provides financial stability for many of these farms to remain in production. Without the profitability offered from tobacco, many would not be able to stay in business. If the FDA was to ban menthol cigarettes, we are concerned that the impact on the farm level could lead to many farming operations in our state ceasing to exist (see Appendix C).⁶⁶

Tobacco revenues support grower investment in the farm that makes the production of other crops economically feasible. It also supports farmer investment in compliance with regulatory requirements of, among other things, the Clean Water Act and the Chesapeake Bay Watershed Agreement. Certain emerging agricultural crops, such as hemp, may prove to be an option over the next decade as the market and federal/state regulations continue to mature, but are insufficient as they exist today. Such an impact on the farm should be considered and studied prior to issuing a final regulation.

⁶³ Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis at page 201.

⁶⁴ Food & Drug Administration, *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)* (2021). Available at: <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd> (last visited July 26, 2022).

⁶⁵ *Id.*

⁶⁶ Statement by North Carolina Agricultural Commission Steve Troxler, North Carolina Department of Agriculture and Consumer Services (2022).

(3) Impact on Underserved Rural Communities

Introduction. FDA states its public health equity objective is advanced by addressing how menthol cigarettes disproportionately affect vulnerable populations.⁶⁷ The Agency defines the term “vulnerable populations” to include those “with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQ+, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with behavioral health conditions or substance use disorders.”⁶⁸

In fact, FDA is required to include a consideration of vulnerable populations in its Regulatory Impact Analysis. The Unfunded Mandates Reform Act requires FDA to include estimates of any disproportionate budgetary effects of a federal mandate upon any particular regions of the nation or particular state, local, or tribal governments, urban or rural, or other types of communities.⁶⁹ The Agency is also required by the Tobacco Control Act to consider information submitted on such possible countervailing effects, including among vulnerable populations and other population subgroups.⁷⁰ In selecting among available regulatory alternatives, Executive Orders 12866 and 13563 require an agency choose the option likely to maximize net benefits, including distributive impacts and equity.⁷¹

In the Proposed Rule and Regulatory Impact Analysis, FDA spends considerable time discussing the impact on racial and ethnic populations, individuals who identify as LGBT+, those pregnant or trying to become pregnant, youth, and those with behavioral health conditions or substance use disorders. However, FDA does not include in its analysis the impact on an extremely relevant portion of the “vulnerable population”—underserved rural communities. Therefore, this section of our comment intends to supplement FDA’s conspicuously absent exploration into the impact this Proposed Rule will have on underserved rural populations and communities intrinsically tied to agriculture.

Understanding Rural Populations. The Department of Agriculture defines “rural” or “non-metro” to include some combination of (1) open countryside, (2) rural towns with a population of fewer than 2,500, and (3) urban areas with populations ranging between 2,500-49,999 that are not part of larger labor market areas.⁷² In 2020, approximately 47 million people, 14% of the population, lived in rural areas in the United States.⁷³ A typical rural county contained less than 10% of the population of a typical urban county in 2020—23,000 people compared with 245,000.⁷⁴ According to the USDA, “Residents who live in smaller and more isolated rural settings often face greater difficulties accessing provisions and services or commuting to work, among other economic development challenges. These factors may affect their resiliency to and recovery

⁶⁷ Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26454.

⁶⁸ *Tobacco Product Standard for Menthol in Cigarettes Preliminary Regulatory Impact Analysis* at page 26.

⁶⁹ Unfunded Mandates Reform Act of 1995 §202(a)(3)(B).

⁷⁰ Family Smoking Prevention and Tobacco Control Act § 907(b).

⁷¹ Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993) and Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).

⁷² U.S. Department of Agriculture, Economic Research Service, *What is Rural?* (2021). Available at: <https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/> (last visited July 26, 2022).

⁷³ U.S. Department of Agriculture, Economic Research Service, *Rural America at a Glance* (2021). Available at: <https://www.ers.usda.gov/publications/pub-details/?pubid=102575> (last visited July 26, 2022).

⁷⁴ *Id.*

from shocks, such as the COVID-19 pandemic.”⁷⁵ As seen in Table 12, persistent poverty and unemployment are a disproportionately high in non-metro counties, with 15.2% in persistent poverty as compared to 4.5% of metro counties.⁷⁶

*Table 12: Populations Statistics for Counties by Persistent Poverty, 2010-2020*⁷⁷

	Number of Counties	Population	Population Per County	Population Change (#)	Population Change (%)
<i>Non-Metro</i>	1,976	46,005,635	23,282	-287,771	-0.6
<i>Persistent Poverty</i>	301	5,742,693	19,079	-345,491	-5.7
<i>Not-Persistent Poverty</i>	1,675	40,262,942	24,038	57,720	0.1
<i>Metro</i>	1,166	285,443,646	244,806	22,991,514	8.8
<i>Persistent Poverty</i>	52	11,689,533	224,799	639,584	5.8
<i>Not-Persistent Poverty</i>	1,114	273,754,113	245,740	22,351,930	8.9
<i>United States</i>	3,142	105,490	105,490	22,703,743	7.4

Impact on Rural Communities. America’s rural communities are fundamentally tied to agriculture. Approximately 22.4% of non-metro areas are dependent on the agricultural sector, and, as expected, the vast majority of farms are situated in rural areas.⁷⁸ As delineated above, the loss of tobacco volumes resulting from a menthol ban will have a ripple effect throughout the agricultural sector and therefore rural communities. However, the effect of the Proposed Rule will also have an impact on these communities as related to economic development opportunities.

In 1998, the major cigarette companies entered into a Master Settlement Agreement (“MSA”) with 46 states, the District of Colombia, and certain U.S. territories.⁷⁹ The MSA resulted in perpetual, annual payments from these domestic cigarette manufacturers to the states. Under the MSA, the annual payments are calculated from a base amount of \$9 billion with adjustments made for items including changes in volume and inflation. Whenever the major cigarette companies’ total U.S. sales shipments in any year fall more than two percent lower than their 1997 level, the MSA’s volume adjustment will reduce the companies’ following-year payments to the settling states by 0.98 times the percentage volume decline.⁸⁰ A ban on menthol cigarettes will therefore decrease the revenues derived from these MSA payments to state and local governments.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ U.S. Department of Agriculture, Economic Research Service, *County Typology Codes* (2015). Available at: <https://www.ers.usda.gov/data-products/county-typology-codes/> (last visited July 26, 2022).

⁷⁹ National Association of Attorneys General, *The Master Settlement Agreement* (1999). Available at: <https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/> (last visited July 26, 2022).

⁸⁰ *Id.*

This will have a disproportionate impact on the economies of rural communities and certain state and local governments. Since its inception, states have received a total of \$145.5 billion in payments from the MSA.⁸¹ Most of the top tobacco-growing states commit large portions of these funds to support the economic development of tobacco-growing regions.

In Virginia, 48% of MSA funds are allocated to economic development of rural communities and assistance to farmers through the Tobacco Region Revitalization Commission.⁸² This Commission has awarded \$1.47 billion in economic development grants and \$309 million to help farmers diversify their production.⁸³ These grants have created more than 27,100 jobs and generated more than \$4.08 billion in private capital investment.⁸⁴ In North Carolina, 50% of the MSA funds, approximately \$1.18 billion, have gone to support economic development in tobacco-dependent communities through the state-sponsored nonprofit organization called the Golden LEAF Foundation.⁸⁵ The Foundation has provided support to tobacco-dependent, economically distressed rural areas of the state by helping create 65,318 jobs, \$695 million in new payrolls, and more than 85,000 workers trained or retrained for higher wages.⁸⁶ In Kentucky, 35.8%, or \$912 million, was used in the Kentucky Agricultural Development Fund supporting rural communities.⁸⁷ Table 13, shows the total distribution of MSA payments to the top tobacco-growing states since its inception.

*Table 13: Distribution of MSA to Tobacco-Growing States, 1999-2022*⁸⁸

State	Total MSA Payments
<i>Georgia</i>	\$3,694,702,699
<i>Kentucky</i>	\$2,548,378,266
<i>North Carolina</i>	\$3,585,195,451
<i>Pennsylvania</i>	\$8,635,599,812
<i>South Carolina</i>	\$1,835,109,331
<i>Tennessee</i>	\$3,666,899,667
<i>Virginia</i>	\$3,076,189,963
<i>Total</i>	\$27,042,075,189

⁸¹ National Association of Attorneys General, *Payments to States Since Inception through April 22, 2021* (2021). Available at: <https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/msa-payment-information/> (last visited July 26, 2022).

⁸² Tobacco Region Revitalization Commission, *2021 Annual Report* (2021). Available at: <https://www.revitalizeva.org/> (last visited July 26, 2022).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Golden Leaf Foundation, *About Section* (2022). Available at: <https://www.goldenleaf.org/about/> (last visited July 26, 2022).

⁸⁶ *Id.*

⁸⁷ Kentucky Agricultural Development, *Tobacco Master Settlement Agreement* (2020). Available at: <https://apps.legislature.ky.gov/CommitteeDocuments/166/13179/Jan%2027%202021%20Tobacco%20Master%20Settlement%20Agreement%20Summary.pdf> (last visited July 26, 2021).

⁸⁸ National Association of Attorneys General, *Payments to States Since Inception through April 22, 2021* (2021). Available at: <https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/msa-payment-information/> (last visited July 26, 2022).

Impact on State Revenues. According to the Tax Foundation, a nationwide ban on menthol cigarettes would result in a federal revenue decline of \$1.9 billion in the first full year after prohibition. In the states, the decline in excise tax revenue would be \$2.6 billion, the decline in sales tax revenue would be \$892 million, and the decline in MSA payments would be \$1.2 billion, for a total state revenue loss of \$4.7 billion.⁸⁹ Table 14 delineates the projected revenue impact of a federal menthol cigarette ban on tobacco-growing states.

Table 14: Revenue Impact of Federal Menthol Cigarette Ban in Tobacco-Growing States⁹⁰

State	Menthol Market Share	Excise Tax Rate/Pack	Total Revenue Loss
<i>Georgia</i>	47%	\$0.37	-\$123,466,776
<i>Kentucky</i>	23%	\$1.10	-\$85,408,770
<i>North Carolina</i>	48%	\$0.45	-\$164,733,092
<i>Pennsylvania</i>	48%	\$2.60	-\$352,089,325
<i>South Carolina</i>	48%	\$0.57	-\$81,979,933
<i>Tennessee</i>	32%	\$0.62	-\$102,194,090
<i>Virginia</i>	45%	\$0.60	-\$121,654,633

The revenue loss to tobacco-producing states alone is therefore estimated at \$1,031,526,619. As rural communities and jurisdictions are less resilient to economic shocks, such as a drastic decline in state revenues, these communities will be disproportionately affected.⁹¹

Conclusion. The Proposed Rule will have a disproportionate impact on local economies and governmental entities situated in rural jurisdictions. The FDA must first understand and study this wider impact prior to issuing its final rule.

(4) Impact on Small Entities (including Businesses and Governmental Jurisdictions)

Introduction. The Regulatory Flexibility Act requires agencies to provide an Initial Regulatory Flexibility Analysis that includes an estimate of the number of small entities to which the proposed rule will apply and consider alternatives to minimize the rule's impact on them.⁹² The Act includes in their consideration governmental jurisdictions and small businesses. A "small governmental jurisdiction" is defined in the Act to mean any locality with a population of less than 50,000.⁹³ The Small Business Administration considers a tobacco farm a "small business" concern if it has annually receipts of less than \$2.25 million.⁹⁴ Currently, FDA's Regulatory Impact Analysis does not include an estimate of the small entities in the agricultural sector likely to be impacted by the Proposed Rule, specifically tobacco-growing farms and small governmental jurisdictions.

⁸⁹ Tax Foundation, *Federal Menthol Cigarette Ban May Cost Governments \$6.6 Billion* (2022). Available at: <https://taxfoundation.org/federal-menthol-cigarette-ban/> (last visited July 26, 2022).

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² Regulatory Flexibility Act § 603(a).

⁹³ Regulatory Flexibility Act § 601(5).

⁹⁴ U.S. Small Business Administration, *Table of Small Business Size Standards* (2017). Available at: https://www.sba.gov/sites/default/files/2022-07/Table%20of%20Size%20Standards_Effective%20July%2014%202022_Final-508.pdf (last visited July 28, 2022).

Small Tobacco-Growing Farms. According to the USDA, family farms remain a key part of United States' agriculture making up 98% of all farms and providing 88% of production.⁹⁵ Most farms are small family farms that operate almost half of U.S. farmland and generate approximately 21% of production.⁹⁶ As seen in Table 11 above, 98.8% of tobacco-growing farms are family controlled. As of 2017, there were 6,237 tobacco-growing farms in the United States, and, as defined above, they will be greatly affected by the Proposed Rule in a number of ways.⁹⁷

Small Governmental Jurisdictions. As delineated in the previous sections, rural communities are tied to the well-being of the agricultural economy with 22.4% of all non-metro areas dependent on the agricultural sector.⁹⁸ By definition, the governments of these rural communities are considered small governmental jurisdictions by the Regulatory Flexibility Act. The Proposed Rule will likely impact these localities in a number of ways, including loss of tax revenue from impacted farms, retail sales, and MSA payments. Furthermore, the burden of enforcement and compliance with the Proposed Rule will ultimately be placed on these small governmental bodies. This includes not only the enforcement at the retail level, but the likely increase to illicit trade that will result from a ban on menthol cigarettes.

Conclusion. FDA is required in its analysis to take into consideration the small businesses and governmental jurisdictions impacted by the Proposed Rule. The Regulatory Impact Analysis at it is currently written overlooks the rural localities and farming operations that supply the majority of tobacco leaf to the U.S. market and should be considered prior to the Agency moving forward with rulemaking.

VI. ALTERNATIVES & RECOMMENDATIONS

Introduction. In promulgating a rule, Executive Orders 12866 and 13563 require agencies to consider viable alternatives to direct regulation, including the alternative of not regulating altogether.⁹⁹ When choosing among the identified options, agencies should select among those approaches that maximize net benefits—including potential economic, environmental, public health and safety, and other advantages such as distributive impacts and equity.¹⁰⁰

The agency must also tailor its regulations to impose the least burden on society, including individuals, businesses, and other entities. The Unfunded Mandates Reform Act likewise requires an agency to identify and consider a reasonable number of regulatory alternatives.¹⁰¹ From those, the agency should select the most cost-effective or least burdensome alternative that achieves the objectives of the rule.

⁹⁵ U.S. Department of Agriculture, Economic Research Service, *A Look at America's Family Farms* (2021). Available at: <https://www.usda.gov/media/blog/2020/01/23/look-americas-family-farms> (last visited July 26, 2022).

⁹⁶ *Id.*

⁹⁷ U.S. Department of Agriculture, National Agricultural Statistics Service, *2017 Census of Agriculture, United States Summary and State Data* (2017). Available at: <https://www.nass.usda.gov/Publications/AgCensus/2017/index.php> (last visited July 26, 2022).

⁹⁸ U.S. Department of Agriculture, Economic Research Service, *County Typology Codes* (2015). Available at: <https://www.ers.usda.gov/data-products/county-typology-codes/> (last visited July 26, 2022).

⁹⁹ Exec. Order No. 12,866, 58 Fed. Reg. 190 (Sep. 30, 1993) and Exec. Order No. 13,563, 76 Fed. Reg. 14 (Jan. 18, 2011).

¹⁰⁰ *Id.*

¹⁰¹ Unfunded Mandates Reform Act of 1995 §205(a).

The following section recommends two alternatives to the Proposed Rule that meet the expectations and obligations required from FDA while imposing a far less burden on society as a whole. We also make suggestions on two alternatives considered by FDA in the Proposed Rule regarding the extension of the effective date and allowing exemptions requests for certain cigarette products.

Agency Objectives. FDA states the intended purpose of the proposed regulation is to reduce the tobacco-related harm associated with menthol cigarette use and mitigate tobacco-related health disparities by advancing health equity. To achieve these objectives, FDA suggests a total ban on the sale of menthol cigarettes.

Like the FDA, Universal and our customers are committed to eliminating youth use of tobacco products. Our customers' youth access prevention policies have contributed to the percentage of youth use of menthol cigarettes dropping to a historic low. A blanket ban on menthol cigarettes, however, will only put unnecessary stress on America's agricultural economy, farmers, state and local governments, and vulnerable communities, including a disproportionate effect on rural populations and small entities. Small businesses and individuals are already burdened by supply chain disruptions, labor shortages, and unparalleled inflation. Additionally, state and local governments will be left to ultimately enforce this rule with less revenue and increased compliance costs from the rise of an illicit market.

The health and equity objectives of FDA and economic well-being of America's agricultural sector are not mutually exclusive. The following proposed alternatives explore two regulatory approaches FDA can take to achieve its objectives while mitigating the harm to agriculture.

Proposed Alternative 1. Universal believes the best means to achieve FDA's health objectives is to establish a well-regulated, legal market for menthol products. The Agency notes combustible cigarette use, both menthol and non-menthol, is declining at a considerable rate. Euromonitor International projects this trend will continue and annual cigarette volume sales will decrease 17.0% between 2021 and 2025.¹⁰² Similarly, the data projects an estimated 10.0% volume decrease for menthol cigarettes between 2021 and 2025 in the absence of the proposed product standard.¹⁰³

Such a market-driven phase out of these products lessens the harm caused by the Proposed Rule's immediate reduction in tobacco leaf and allows the agricultural sector to gradually shift reliance away from tobacco. If the Agency were to additionally harness the regulatory tools already at their disposal to ensure a well-regulated, legal market—such as advertisement restrictions and promulgating and enforcing the rule to increase the legal age of purchase to 21—FDA could achieve greater health equity and reduced overall menthol use while minimizing negative externalities (such as the risk of an illicit market).

¹⁰² Euromonitor International Limited. (2021). © All rights reserved.

¹⁰³ *Id.*

Proposed Alternative 2. Should the FDA ultimately determine the only means to achieve their stated objectives is to move forward with a total ban on menthol cigarettes, there are options to achieve a less harmful transition. Universal recommends FDA, in coordination with the Secretary of Agriculture, establish a commission of stakeholders to review and study a menthol ban's impact on the entities discussed in this comment, including farmers, state and local governments, vulnerable rural communities, and other small entities. This has not been part of FDA's multiple scientific reviews, two advance notices of proposed rulemaking, or sponsored research on menthol-related topics.

This commission should consist of government representatives from the Center for Tobacco Products and the USDA, as well as their counterparts in the seven top tobacco-growing states—Georgia, Kentucky, North Carolina, Pennsylvania, South Carolina, Tennessee, and Virginia. It should also include industry and association representatives from the tobacco grower associations, farm worker labor unions, tobacco leaf suppliers, Farm Bureau, Agribusiness Council, and uniquely impacted state, local, and tribal governments. The group should be charged with: (1) conducting a comprehensive study to fully understand the impact a ban on menthol cigarettes will have on the agricultural sector, (2) conducting an economic development study to determine alternative or complimentary crops to tobacco, and (3) suggesting a strategy to mitigate the negative externalities of the Proposed Rule as derived from these studies.

As the mission of the work group requires technical expertise in agriculture, we suggest the USDA leads this effort. These studies and recommendations would then be included in the Secretary of Agriculture's input when the FDA restarts the rulemaking process as required by the Tobacco Control Act.¹⁰⁴ Ultimately, Universal believes that understanding the full economic impact on the agricultural sector is a necessary prerequisite to advancing the Proposed Rule, and FDA should refrain from issuing a final rule until it has completed this due diligence.

Extension of the Effective Date. The effective date in the Proposed Rule allows manufacturers one year after the date of publication to comply with the prohibition of menthol as a characterizing flavor in cigarettes. In the Proposed Rule, the FDA also analyzed an alternative to extend the effective date of the product standard from one year to two years, but concluded one year is sufficient. The Tobacco Control Act typically requires the effective date of a product standard to not take effect before one year after the date of the rule's publication, unless the Secretary determines that an earlier effective date is necessary for the protection of public health.¹⁰⁵ However, it also stipulates that a product standard which can only be met by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer must have an effective date of at least two years after date of publication of the final regulation.¹⁰⁶

All tobacco products are made from the specific, propriety recipe of each tobacco product manufacturer. These recipes consist of decisions regarding ratios of tobacco types, varieties, stalk positions, country of origin, etc. and are what differentiate between cigarette brands. Should adult

¹⁰⁴ Family Smoking Prevention and Tobacco Control Act § 907(c)(2)(D).

¹⁰⁵ Family Smoking Prevention and Tobacco Control Act § 907(d)(2).

¹⁰⁶ *Id.*

consumers switch from menthol cigarettes to non-mentholated products, there could be a shift in tobacco leaf demand. Meeting this new demand could require a substantial change to the type and methods of farming of domestically grown tobacco and require the effective date of the Proposed Rule to be at least two years after date of publication of the final regulation.

The Proposed Rule solicits comments on how to draft the product standard so as not to advantage foreign-grown tobacco over domestically grown tobacco.¹⁰⁷ It is important to note that tobacco leaf suppliers, like Universal, typically contract with farmers on an annual basis. Should the Proposed Rule result in a shift of tobacco requirements during the season, suppliers may be forced to meet market requirements by importing foreign-grown tobacco. The Agency should therefore structure the rule so as to avoid this result by extending the effective date to at least two years.

Ultimately, should FDA decide the only means to achieve their stated objectives is to move forward with a total ban on menthol cigarettes, the Agency should conduct a study on how the ban would impact domestic leaf demand as suggested in Proposed Alternative 2. Regardless of that decision, FDA should extend the effective date to a minimum of two years to ensure the Agency does not run afoul of the procedural restrictions in the Tobacco Control Act or advantage foreign-grown tobacco.

Exemption Request for Cigarette Products. As written, FDA’s proposed product standard would cover all products meeting the definition of “cigarette” in section 900(3) of the FD&C Act.¹⁰⁸ This includes all formulations of cigarettes, cigarette tobacco, and RYO tobacco, as well as HTPs that meet the definition. In the Proposed Rule, FDA solicits comments on “whether the final rule should include a provision that allows firms to request an exemption for specific products of certain types” and what kind of products should be eligible.

In 2017, the FDA announced its comprehensive plan for tobacco and nicotine regulation intended to serve as a multi-year roadmap to better prevent youth access to tobacco products and significantly reduce tobacco-related harm. At the core of FDA’s approach is “demonstrating a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles”, such as those found in products like combustible cigarettes.¹⁰⁹ In the Proposed Rule, the Biden Administration embraces this harm reduction strategy in “recognizing that tobacco products exist on a continuum of risk” and that some products “may pose less risk to individual users or to population health”.¹¹⁰

If FDA ultimately decides to move forward with issuing a final rule banning menthol in cigarettes, the Agency should, at a minimum, exempt those products that fall under the definition of a cigarette, but have received modified risk granted orders. Under the Tobacco Control Act, a product is be considered “modified risk” if an applicant can prove the product, as it is actually used

¹⁰⁷ Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26486.

¹⁰⁸ Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26486.

¹⁰⁹ U.S. Food & Drug Administration, *FDA Announces Comprehensive Regulator Plan to Shift Trajectory of Tobacco-Related Disease, Death* (July 28, 2017). Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm/> (last visited July 26, 2022).

¹¹⁰ Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26486.

by consumers, will (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users, and (2) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.¹¹¹ Considering such products have already proven their health benefit to the user and the population as a whole, this exemption should be automatic rather than require the FDA to spend additional resources to reconsider similar standards.

VII. CONCLUSIONS

In this comment, we have endeavored to expand FDA's understanding of tobacco's significance in agriculture and on the American farm. FDA's exclusion of a sector that could experience a \$484 million annual economic impact—disproportionately incurred by small, family farms located within underserved rural communities—from consideration in the Regulatory Impact Analysis is an abdication of the Agency's due diligence responsibilities under the statutes and regulations designed to ensure such entities are protected.

This notice and comment period is intended for stakeholders to provide FDA with specific, technical information as to better inform the Agency's decision to proceed or amend the Proposed Rule. It is not intended to absolve the Agency of its obligations to seek out reasonably obtainable scientific, technical, and economic information. Considering this, we have not provided FDA an exhaustive study into how this Proposed Rule will impact the agricultural sector. For example, this comment only briefly touches upon the Proposed Rule's likely contribution to the rise in illicit trade and reduction in state/local tax revenues. Instead, we intended to simply expand upon what FDA has acknowledged and introduce the Agency to additional considerations yet to be thoroughly explored.

Universal would like to thank the Food and Drug Administration for its attention and consideration of this comment to the proposed product standard. It is a vastly complex issue with many more questions for the Agency to address. In conclusion, we respectfully recommend FDA consider either of the aforementioned alternatives designed to advance the Agency's objectives while mitigating the harm to agricultural communities.

Sincerely,



Benjamin Dessart
Director, External Affairs
Universal Leaf Tobacco Company, Inc.

¹¹¹ Family Smoking Prevention and Tobacco Control Act § 911(g).

APPENDIX A



April 26, 2022

Dominic Mancini
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget

Dear Acting Administrator Mancini,

We are writing today to inform you of what Universal considers an unacceptable disregard for process by the White House Office of Information and Regulatory Affairs. As you know, the FDA is considering two tobacco product standards intended to (1) ban menthol in cigarettes and (2) ban characterizing flavors in cigars. If adopted, these product standards could have a significant economic impact on not only tobacco product manufacturers, but also agricultural suppliers such as Universal, our contracted farmers, and the rural communities in which we serve.

Our intention was to fulfil the spirit of the Administrative Procedures Act by sharing the attached presentation with your office. Our meeting request was accepted several weeks ago and was posted publicly on the OIRA Rulemaking Dashboard. However, upon accepting our request and scheduling the date/time yourselves, we received notice the morning of the meeting of its cancellation. **Universal was the only organization from the agricultural sector to request a meeting with OIRA.** Our company does not manufacture a tobacco product for retail sale, yet we chose to engage with the government because no other business is as closely aligned to the farmers and growers of tobacco leaf. As such, Universal is in a position to offer your office and the FDA unique insight into the economic impacts these product standards could have on farmers, agricultural communities, and, ultimately, the pocketbooks of every American.

We consider the decision to actively disregard our nuanced perspective to be a disservice to the public, and we are concerned the FDA is subsequently not positioned to make a well-informed decision based on the economic information provided by OIRA. As such, we request you enter the attached presentation into the record and share the relevant information with the FDA prior to their submission of the proposed product standards.

We are happy to discuss with you further and welcome any questions you may have.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Dessart". The signature is fluid and cursive, with a long horizontal stroke at the end.

Benjamin Dessart
Director, External Affairs

APPENDIX B

Economic Impact of Tobacco Farming

Blake Brown, Hugh C. Kiger Professor
July 25, 2022

This study examines the impact on the US, North Carolina and Kentucky economies should tobacco farming cease to exist. Farm level receipts from tobacco leaf were \$1.026 billion in 2021. This was produced on 219,000 acres with 478 million pounds produced. North Carolina produced about one half of US tobacco with farm level receipts of \$505 million. Kentucky, the second largest tobacco producing state, farm level receipts were \$269 million. Tobacco is produced in 19 states with most being produced in (ranked by production) NC, KY, VA, TN, GA, SC and PA. Over 90 percent of US tobacco production is used in cigarette production in the US or exported for cigarette production globally.

IMPLAN

IMPLAN is used for the input-output analysis of the economic impacts of tobacco farming. A change in one sector of the economy has multiple impacts in many different associated sectors. IMPLAN divides the impacts of changes in a sector's output into direct, indirect and induced effects. The direct effects are for a given change in the industry sector in question. For example, if all tobacco production in the US ceases, farm level revenues will decline by \$1.025 billion. Indirect effects are the impacts due to changes in business-to-business transactions of the industry in question with other businesses. For example, if tobacco farms have reduced output, then fertilizer expenditures (and fertilizer industry output) go down. Induced effects stem from changes in household spending when the employees in the affected industry have changes in their labor income due to changes in the affected industry. For example, if tobacco farming revenues are reduced then farmers and their employees have less household income to spend which has negative effects on the economy. The sum of direct, indirect and induced impacts is the total impact on economic output. IMPLAN further divides these three types of impacts into the impact on employment, labor income and value-added. Employment is the reduction in the number of jobs due to the change in the affected industry. Labor income is thereby reduced. Value added is defined as the difference in industry output (revenues) and expenditures on intermediate inputs for production in the sector in question.

RESULTS

The question posed by this study is "What are the economic impacts of eliminating tobacco farming in the United States?" This can also be interpreted as the economic impact that tobacco farming has on the U.S. economy. The results are given in terms of direct, indirect and induced changes with each broken down to changes in employment, labor income and value-added. Results for the US economy from such a change as well as changes in the economies of the two largest tobacco producing states, NC and KY, are given in Tables 1-3. The total impact on the economy of a loss of tobacco farming is \$2.8 billion (Table 1). This means that \$1 generated at the farm level by tobacco production generates an additional \$1.78 in the general economy. As a result of the elimination of tobacco farming, reductions occur in employment of 25,701 jobs, labor income of \$944 million and value-added of \$1.467 billion.

Direct Impacts

Based on 2021 tobacco production, complete elimination of tobacco farming would reduce output by \$1.025 billion. This exogenous change is imposed on the economy and the resulting impacts traced

throughout the economy. Such a change could be brought about suddenly by changes in tobacco policy and regulations. Employment in tobacco farming would fall by 15,569. To state it otherwise employment in tobacco farming in 2021 is estimated by IMPLAN to be 15,569 and all this would be lost. Consequently, labor income in tobacco farming, all of it, would fall by \$380 million. Value added to the economy by the tobacco farm sector would all be lost equaling \$520 million. The sum of labor income lost plus value-added by tobacco farming plus the cost of intermediate goods purchased for tobacco production equal the direct output loss of \$1.025 billion.

Indirect and Induced Impacts

Lost indirect output to the economy is estimated to be \$828 million. This loss in output is due a reduction in business that tobacco farms do with supporting and affiliated businesses. For example, tobacco farms will purchase no fertilizer, seed or chemicals. As a consequence, those businesses will lose 5,032 jobs and labor income paid by these businesses will decrease by \$262 million. Additionally, these affiliated and supporting industries will reduce the value they add to Gross Domestic Product by \$414 million. The induced impact is a reduction in output of \$952 million. This is result of people working in tobacco farming having less household income to spend.

Impacts on Affiliated Industries

The indirect and induced effects of the loss of tobacco farming affect a wide range of business and industry sectors (Table 4). Interestingly, “Other Real Estate” is the affiliated category that is most affected by the elimination of tobacco farming with output in Other Real Estate falling by \$168 million. Other Real Estate includes lessors of non-residential building, operations of residential property managers. Pesticide and other agricultural chemical manufacturing decreases by \$64 million. Petroleum refineries are negatively impacted by \$36 million. Hospitals experience a reduction in economic output of \$42 million.

Geographical Impacts

Tables 2 and 3 give the impacts on the NC and KY economies. North Carolina produces almost 50 percent of US tobacco revenues at the farm level with Kentucky producing 26 percent of farm level receipts. NC loses \$505 million in farm level receipts and Kentucky loses \$269 million. Consequently 4,422 jobs in tobacco farming are lost in NC and 6,109 in KY. The total reduction in economic output is \$1.057 billion in NC and \$457 million in KY. Employment losses from direct, indirect and induced impacts total 8,250 in NC and 7,578 in KY.

Tax Impacts

Federal, state, county and municipal taxes collected decrease due to elimination of tobacco farming. At the US level \$280 million in taxes are lost. This includes losses in county, state and federal taxes of \$7, \$49 and \$202 million, respectively. North Carolina alone accounts for losses of county taxes of \$3 million, state taxes of \$14 million, and federal taxes of \$71 million. This impact will be highest in rural counties that produce the most tobacco.

Table 1. Impact of Loss of Tobacco Farming on the US Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(15,549)	(\$380,983,130)	(\$520,206,497)	(\$1,025,874,000)
Indirect	(5,032)	(\$262,123,176)	(\$413,623,092)	(\$828,609,026)
Induced	(5,120)	(\$300,862,962)	(\$533,647,757)	(\$951,936,707)
Total	(25,701)	(\$943,969,267)	(\$1,467,477,346)	(\$2,806,419,733)

Table 2. Impact of Loss of Tobacco Farming on the North Carolina Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(4422)	(\$179,220,794)	(\$203,546,743)	(\$504,800,000)
Indirect	(2397)	(\$102,781,040)	(\$166,450,565)	(\$326,333,991)
Induced	(1431)	(\$69,447,617)	(\$129,972,558)	(\$226,208,661)
Total	(8250)	(\$351,449,450)	(\$499,969,867)	(\$1,057,342,652)

Table 3. Impact of Loss of Tobacco Farming on the Kentucky Economy

Impact	Employment	Labor Income	Value Added	Output
Direct	(6109)	(\$134,055,249)	(\$174,094,932)	(\$269,268,000)
Indirect	(702)	(\$27,303,419)	(\$38,238,104)	(\$72,697,792)
Induced	(768)	(\$35,924,347)	(\$63,715,813)	(\$114,824,724)
Total	(7578)	(\$197,283,015)	(\$276,048,848)	(\$456,790,516)

Table 4. Impact on Output from Related Industries

Industry	Impact on Economic Output
Other real estate	(\$167,864,348.01)
Support activities for agriculture and forestry	(\$110,154,484.84)
Owner-occupied dwellings	(\$74,816,869.77)
Pesticide and other agricultural chemical manufacturing	(\$64,451,852.11)
Wholesale - Other nondurable goods merchant wholesalers	(\$55,887,569.54)
Monetary authorities and depository credit intermediation	(\$43,097,467.24)
Hospitals	(\$41,831,978.64)
Petroleum refineries	(\$36,473,673.64)
Insurance carriers, except direct life	(\$33,580,555.08)
Management of companies and enterprises	(\$27,865,941.38)

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APPENDIX C



Steven W. Troxler
Commissioner

North Carolina Department of Agriculture and Consumer Services

July 22, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: Docket ID FDA-2021-N-1349

Dear Dr. Califf:

I am writing to express my concern about the negative impacts a menthol cigarette ban would have on the agricultural economy in North Carolina. Specifically, that a highly traceable, compliant and quality U.S. produced tobacco utilized in domestic manufacturing would be replaced by an increased illicit trade centered around mentholated cigarettes. These products would not be held to the same high standards regarding production and manufacturing that currently exists in the marketplace.

As a North Carolina native, raised in Browns Summit, I am proud that agriculture has been and continues to be the foundation of our state's economy. Today, agriculture and agribusiness contribute \$92.9 billion annually to our state's economy, or almost 16% of the gross state product. This leading economic driver also employs over 15% of the state's workforce through 668,000 jobs.

I have worked hard as the founder, owner and operator of Troxler Farms to build a successful business. Drawing from that experience, I have been elected to serve five terms as North Carolina Commissioner of Agriculture since 2005 and understand the challenges farmers face daily.

I have dedicated my life to preserving, promoting and developing North Carolina agriculture and agribusiness to ensure we can continue to provide food, fiber and fuel for our state, nation and world. I believe the success of agriculture is paramount to our national security and I want to ensure North Carolina farmers can continue to meet the needs of consumers domestically and abroad.

While our farmers produce a diversity of crops and livestock, no discussion of North Carolina agriculture would be complete without including the significance of tobacco to our state. Every stage of tobacco production takes place in North Carolina, from farming and harvesting to

processing, manufacturing and packaging. In fact, our state has been one of the centers of the U.S. tobacco industry for well over 100 years. The crop remains just as significant today.

Tobacco is vitally important to North Carolina's agricultural sector and broader state economy. North Carolina leads the nation in the production and sale of flue-cured tobacco. Nearly 80% of the flue-cured tobacco grown in the U.S. and half of the total U.S. tobacco crop originates in fields across our state. The total production value of tobacco in North Carolina in 2021 was \$504.8 million with 252.4 million pounds harvested.

Money generated from the sale of tobacco trickles down through the economy, especially in rural North Carolina, supporting families and small business across the state. I can tell you that tobacco money has put many rural young people through higher education, including my own two sons.

As the global state of agriculture continues to transition, the tobacco industry faces new challenges at home and abroad. International tariffs, unpredictable extreme weather, a decline in the number of adult smokers, competition from foreign tobacco growers and the COVID-19 pandemic's disruption to rural farm operations and manufacturing all threaten the industry, and as a result, the state's revenue from tobacco production.

Tobacco is not the only crop grown on a "tobacco farm." These farms also grow sweet potatoes, soybeans, corn, cotton, cucumbers, and other commodities in addition to many having livestock operations. These farms produce tobacco that is the most traceable, compliantly produced tobacco in the world. Through Good Agricultural Practices, including a third-party verification process, tobacco grown in the US is held to certification standards that are often more stringent than state or federal laws regarding crop production, environmental stewardship and labor.

Given the fluctuations of commodity markets, tobacco provides financial stability for many of these farms to remain in production. Without the profitability offered from tobacco, many would not be able to stay in business. If the FDA was to ban menthol cigarettes, we are concerned that the impacts on the farm level could lead to many farming operations in our state ceasing to exist.

Even with all these challenges and uncertainties, farmers and industry representatives I talk with share a strong, common concern about the effort to ban menthol cigarettes. While I am not a scientist, I would expect any such ban by the FDA would need to be supported by scientific evidence. Much of this scientific support seems to be unclear, and the stated rationale has been to protect youth from smoking, which I believe has already been addressed by the Federal Tobacco 21 legislation. I also believe that adults are capable of making their own decisions regarding the use of a legal product.

I strongly support keeping our young people from smoking, as does the entire grower community. In fact, the use of traditional tobacco products, such as cigarettes, has been in decline for years and is at an all-time low among youth as noted in a report from the Centers for Disease Control and Prevention indicating that from 2011 to 2021, the percentage of middle school students who reported using cigarettes in the past 30 days decreased from 4.3% to 1%, and the percentage of high school students who reported smoking cigarettes in the past 30 days decreased from 15.8% to 1.9%.

It seems that measures such as the Federal Tobacco 21 legislation are addressing the concern regarding youth smoking. A menthol ban based on youth usage seems misguided and could cause significant damage to North Carolina's economy, farmers, and manufacturers.

The devastating economic consequences of a menthol ban are easy to predict and include significant job losses across North Carolina and the nation from farms to convenience stores. Further negative economic impact will be seen through reduced tax revenues (\$240 million in NC alone) from tobacco products and reduced payments to states under the tobacco settlement agreements. Less obvious are the unintended consequences that removing menthol cigarettes from the market could trigger including expansion of an illegal cigarette market and organized crime activity.

Tobacco grown and manufactured in the United States is traceable, compliant and highly regulated – this higher standard also leads it to be the most expensive tobacco produced and sold in the world. An illicit market would utilize foreign tobacco that is not produced in compliance to the same high standards regarding crop production practices, environmental stewardship or human rights. This includes subjecting the public to illegal pesticide residues as well as a product that may be grown and/or manufactured under child, forced or unregulated labor. Additionally, FDA through statute has regulatory authority over domestic cigarette production; this oversight for public health would be lost through expansion of an illicit market.

While I am confident that North Carolinians will continue to uphold the state's reputation of being the world's most compliant and best leaf tobacco, I urge you to advocate for these hardworking farmers, families, manufacturers, and employees by opposing an economically devastating menthol ban.

Thank you for your attention to this critical matter and for all that you do on behalf of America's agricultural community.

Sincerely,



Steven W. Troxler
Commissioner