December 20, 2024

Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Follow-Up From Meeting Regarding OIRA Review of FDA's Proposed Rule: Tobacco Product Standard for Nicotine Level of Certain Tobacco Products (RIN: 0910-AI76)

To Whom it May Concern:

On behalf of the Coalition of Independent Tobacco Manufacturers of America (CITMA), I write to thank the Office of Information and Regulatory Affairs (OIRA) for the opportunity to meet on December 19, 2024, regarding its review of the Food and Drug Administration's (FDA's) proposed rulemaking entitled, Tobacco Product Standard for Nicotine Level of Certain Tobacco Products (RIN: 0910-AI76), and to provide information in writing regarding the substance of our meeting.

CITMA is a trade coalition group that represents the interests of small tobacco product manufacturers (STPMs),[1] including manufacturers of finished products, their suppliers (e.g., tobacco leaf and blend suppliers), and importers of their products. CITMA provides information and advisory support to its member companies to help them understand the impacts of, and comply with, FDA regulations applicable to the manufacture and distribution of tobacco products. Since the enactment of the Family Smoking Prevention and Tobacco Control Act (TCA), which was supported by CITMA, CITMA has consistently advocated for regulatory approaches that would bring greater consistency, transparency, and efficiency to FDA's regulation of tobacco products.

Legal Standard

In 2009, Congress enacted the TCA, which amended the Federal Food, Drug, and Cosmetic Act (FFDCA) and provided FDA with the authority to regulate tobacco products.[2] The TCA authorizes FDA to adopt new tobacco product standards appropriate for the protection of public health, including setting nicotine yield levels.[3] Of

[1] The Federal Food, Drug, and Cosmetic Act defines "small tobacco product manufacturer" as one that "employs fewer than 350 employees." 21 U.S.C. § 387(16).
[2] Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat, 1776 (2009).
[3] FFDCA § 907(a)(4); 21 U.S.C. § 387g(a)(4).

note, Congress prohibited FDA from banning all cigarettes or requiring the reduction of nicotine yields of a tobacco product to zero.[4]

In setting a new tobacco product standard, FDA must consider information related to:

- Technical achievability of compliance with such standard;[5]
- Scientific evidence concerning risks and benefits to the population as a whole, the likelihood that existing users of tobacco products will stop using such products, and the likelihood that those who do not use tobacco products will start using such products; and[6]
- Countervailing effects of the tobacco product standard on the health of adolescent and adult tobacco users and non-tobacco users, including the creation of a significant demand for contraband or other tobacco products.[7]

CITMA submits that FDA has not satisfied the legal standard for this proposed product standard in multiple ways. First, and most significantly, the substantial negative countervailing effects of implementation of such a standard would undermine any potential public health benefits of the proposal. Second, technical achievability is of particular importance to ensure that it is not impossible for industry to comply with the nicotine standard. The creation of a standard that is not technically achievable would result in a constructive ban of cigarettes, which Congress has expressly prohibited FDA from establishing.

Countervailing Effects

Under the Tobacco Control Act, Congress required FDA to account for "other considerations" including "the creation of a significant demand for contraband . . . that do not meet the requirements of this chapter and the significance of such demand" in developing any product standard.

The contemplated maximum nicotine product standard would effectively ban cigarette products currently preferred by adult tobacco consumers, creating a new demand for unregulated cigarette products from an already sizable illicit cigarette market. The growth of the illicit cigarette market likely would lead to:

1. Higher levels of illegal activity and government expenditures to combat such activity;
2. A significant loss of government tax revenues, which could have a devastating effect on state children's health insurance programs that are funded by taxes collected on cigarette sales;
3. A potential increase in cigarette purchases by minors; and

[4] FFDCA § 907(d)(3); 21 U.S.C. § 387g(d)(3).
[5] FFDCA § 907(b)(1); 21 U.S.C. § 387g(b)(1).
[6] FFDCA § 907(a)(3)(B)(i); 21 U.S.C. § 387(a)(3)(B)(i).
[7] FFDCA § 907(b)(2); 21 U.S.C. § 387g(b)(2).

4. An influx of unregulated cigarettes with additional potential health and safety risks.

A bi-partisan group of U.S. senators recently highlighted these critical concerns. On August 4, 2023, five senators wrote to U.S. Department of State Secretary Antony Blinken requesting information on how the U.S. Government intends to counter illicit cigarette tracking.[8] In that letter, the senators highlighted that illicit trafficking in tobacco products is a "growing threat to national security" which "encourages a convergence between organized crime, terrorist groups, and other threat networks." The letter notes "financial linkages between Mexican transnational criminal organizations (TCOs) involved in narcotics and fentanyl trafficking, and these tobacco smuggling activities" and that "Mexican TCOs pose a grave threat to American national security and public health." Pointing out that "these TCOs have expanded their operations to include the production and distribution of cigarettes," the senators specifically ask, "whether any domestic efforts to limit tobacco usage—either enacted or proposed—provide an opportunity for transnational criminal organizations to further their illicit trafficking operations."

Based on its members' decades-long experience in this market, CITMA believes that the proposed nicotine product standard would exponentially increase the illicit cigarette trade, amplifying its already devastating consequences. For example, an official from New York City, where tobacco taxes are extremely high, described black market cigarettes as the "principal stoking facility of the engine of organized crime."[9] Some sources have noted that profits from illicit trade in cigarettes in the United States may help fund terrorist organizations, including Hezbollah.[10] An increase in organized crime and violence would, of course, lead to increased federal, state, and local law enforcement burdens and costs as well as decreased public safety.

Moreover, with the greater demand for illicit cigarettes, an increased number of unregulated cigarettes would likely enter the market. Such cigarettes may pose additional potential health and safety concerns because they are unlikely to comply with the current regulatory health standards. Finally, the development of illicit trade channels would threaten to undo the significant gains derived from strictly preventing underage

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[8] See https://www.rubio.senate.gov/wp-content/uploads/_cache/files/998ed5ea-0a04-4f21-9a81-a427bf8290af/08591A3778871FBB3FA57DD14FF1C94A.letter-to-fda-on-tcos-and-tobacco-7.24.23.pdf (accessed December 19, 2024).

[9] Fleenor, Patrick. "Cigarette Taxes, Black Markets, and Crime Lessons from New York's 50-Year Losing Battle." Washington: Cato Institute. Feb. 6, 2003.

[10] Reuter, Peter, and Malay Majmundar (Eds.). Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences. Committee on the Illicit Tobacco Market: Collection and Analysis of the International Experience, National Research Council and Institute of Medicine. Washington, D.C.: The National Academies Press. 2015; Sanderson, Thomas M. "Transnational Terror and Organized Crime: Blurring the Lines." SAIS Review. 24(1):49–61. 2004; Shelley, Louise I., and Sharon A. Melzer. "The Nexus of Organized Crime and Terrorism: Two Case Studies in Cigarette Smuggling." International Journal of Comparative and Applied Criminal Justice. 32(1):43–63. 2008; https://www.ice.gov/news/releases/mohamad-youssef-hammoud-sentenced-30-years-terrorism-financing-case.

access to tobacco products, including those observed following implementation of the T-21 law. If substantial sales of cigarette products go underground, the government would lose some ability to limit access to those of legal age to purchase, thereby undermining public health.

A nicotine standard would impact the entirety of the cigarette market, operating essentially as a ban on cigarettes as they are currently used by adult smokers (in other words, they would still contain all of the harmful constituents, but would not provide the nicotine smokers seek). Without a selection of alternative FDA-authorized nicotine products that are appealing and satisfying to these smokers, they are very likely to seek out illicit products. Unfortunately, however, FDA has not done its Congressionally-mandated job of authorizing potentially lower risk sources of nicotine to help adult smokers move down the continuum of risk.

Based on FDA's own reports, as of March 31, 2024 (the most recent FDA statistics currently available),[11] there were over 26 million premarket tobacco product applications (PMTAs) submitted since approximately September 2020. FDA has refused to accept 19.5 million and refused to file an additional 5.1 million. Thus, based on FDA's own numbers, of approximately 1.26 million remaining applications, the Agency has authorized only 34 electronic nicotine delivery system (ENDS) products, a number of which are no longer available on the market, and zero nicotine pouch products.

Although FDA has authorized only these 34 mostly tobacco-flavored ENDS products, vapor market sales are predicted to be $8.8 billion in 2024, indicating that approximately 99% of the ENDS products sold in the United States are illicit. This demonstrates two important points. First, it shows that when FDA limits legal choices, without providing alternatives, the illicit market flourishes. And second, FDA is already struggling to control a thriving illicit marketplace. One that is so difficult to manage that on June 10, 2024, FDA and the Department of Justice announced the formation of a multi-jurisdictional task force to address this widespread and growing problem.[12]

Cigarettes are a much more mature market and no doubt are much more ripe for illicit trade, which already exists due to the significant and varied state taxes applied to the products. If FDA were to implement a cigarette nicotine standard, it must first authorize a wide selection of attractive and satisfying lower risk nicotine products to which adult smokers can switch, as well as communicate clearly to smokers about the continuum of risk. Without such authorized alternatives and clear government communication, a thriving illicit marketplace, with all of the harms to public health and safety as well as national security, is all but guaranteed.

[11] See Tobacco Product Applications: Metrics & Reporting | FDA (accessed December 19, 2024).
[12] See Office of Public Affairs | Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb Distribution and Sale of Illegal E-Cigarettes | United States Department of Justice (accessed December 19, 2024).

Timing for implementation

If FDA were to move forward with implementation of this proposed product standard, it would have to provide a significant amount of time to permit compliance. The implementation of a maximum nicotine level product standard to minimally addictive or non-addictive levels would require substantial changes to the entire industry, beginning with United States tobacco farmers.

FDA should consider the many complexities involved in practically implementing such a standard, including the time for seed development and farmer implementation of the required methods, which could take many years. Because new seed varieties may result in unintended effects to the human body or the environment, FDA should further consider the time needed to assess the potential impacts that use of such seed varieties may implicate. Moreover, as we understand it, in order for farmers to transition to bioengineered tobacco (BE tobacco), the land may have to sit for three to five years before they can make the switch from conventional to BE tobacco crops, for which FDA must account in calculating any appropriate implementation period.

Finally, the Agency must consider the significant amount of capital tobacco warehouses and manufacturers would need to invest in attempting to comply with any standard under consideration. This consideration must include the impacts of industry inventory practices. Because processed tobacco can be stored for up to ten years without quality degradation, and many warehouses and small manufacturers have contracted for eight to ten years of tobacco, FDA should not implement nicotine standards for a time period no less than ten years after establishment and use of a commercially-viable and commercially-scalable tobacco variety or nicotine reduction method to allow companies to sell through their substantial legacy tobacco inventory.

Technical Achievability

Based on CITMA members' extensive experience with tobacco product manufacturing and the production of tobacco leaf, CITMA also has serious questions about the technical feasibility of consistently reducing nicotine levels in cigarettes to minimally addictive or non-addictive levels (i.e., approximately 0.3-0.5 mg of nicotine per gram of tobacco filler) using currently available methods when starting from natural tobacco seeds.

Although use of BE tobacco may allow some growers to achieve these low levels, that approach poses significant economic, legal, and practical concerns. For instance, genetically engineered plant varieties generally require eight to twelve years of research, development, and then prior regulatory approval (in itself a multi-year process) before they can be grown. Further, the logistics and costs presented by use of such patented technology would be monumental, if not unattainable, particularly for those farmers, processors, and manufacturers serving other markets outside the United States and for small farmers, processors, and manufacturers. For example, given the prohibition on BE tobacco in foreign markets, farmers, processors, and manufacturers

would need to maintain two sets of fields and facilities – one for conventional tobacco and one for BE tobacco – and rigorous cross-contamination-prevention processes in order to sell in the United States and in foreign markets.

Moreover, even if these farmers had enormous swaths of farmland, it may still be insufficient to provide the extensive buffer, sometimes up to hundreds or thousands of miles, required by certain jurisdictions to prevent cross contamination. It may therefore be impossible for farmers and processors to serve other markets if BE tobacco is the only option for producing tobacco intended for the United States market.

As well, even if it were technically feasible to reduce the nicotine levels to 0.3-0.5 mg/g in a small, controlled setting, it would be difficult if not impossible to consistently implement such methods to produce commercially adequate quantities of such tobacco in a real-world setting. External field and environmental factors such as rainfall, climate conditions, soil, and altitude considerably impact nicotine levels in tobacco. Thus, identical tobacco varieties grown in different locations or at different time points can result in significantly varying nicotine levels. Accordingly, even if a low-nicotine tobacco variety can be grown on a small scale in a greenhouse or a laboratory, it may be impossible to scale up such operations and consistently stay within the proposed Nicotine Standard given the lack of control and predictability over such factors in the field. Further, even if such low-nicotine tobacco varieties can be grown in certain environments, it may not be technically achievable in others.

Farmers can also utilize certain techniques to impact nicotine levels, but each has its own potential limitations and drawbacks. These include:

- Increasing the number of tobacco seedlings planted in the field to minimally decrease the total alkaloid (including nicotine) levels, but with risks to lowering yield, depletion of soil nutrients, and nonconformity of current machinery.
- Decreasing the amount of nitrogen fertilization to decrease the total alkaloid (including nicotine) levels, but with risks to lowering yield.
- Reducing topping[13] and/or suckering[14] of tobacco plants to reduce nicotine accumulation, but with risks related to poor yield and tobacco quality, increased buildup of insects, and decreasing root development.[15]
- Once-over harvesting – the process of harvesting tobacco stalk all at once (primarily used for burley tobacco) – that reduces the accumulation of nicotine

[13] "Topping" is the process of removing the budding part of the tobacco plant, which can result in a tobacco leaf that matures more uniformly with better quality and increased nicotine accumulation. See, e.g., Lewis, R.S., K.E. Drake-Stowe, and R.E. Dewey (2018) Evaluation of Mutation-Derived Flue-Cured and Burley Tobacco Lines for Reduced Nicotine Accumulation. 48th Tobacco Workers Conference, Myrtle Beach, SC, Jan. 15-18.]

[14] "Suckering" is the pruning of leaves and new buds to help improve leaf development, which can result in an increased nicotine accumulation. See, e.g., Lewis, R.S., K.E. Drake-Stowe, and R.E. Dewey (2018) Evaluation of Mutation-Derived Flue-Cured and Burley Tobacco Lines for Reduced Nicotine Accumulation. 48th Tobacco Workers Conference, Myrtle Beach, SC, Jan. 15-18.]

[15] Loren R. Fisher et al., *Topping, Managing Suckers, and Using Ethephon in* 2018 Flue-Cured Tobacco Guide 97 (N.C. State Univ., 2018).

that naturally occurs when tobacco is harvested in stages instead of all at once. Once-over harvesting can result in lower yields and lower quality of the finished tobacco product.

Cross-breeding may be used to achieve lower levels of nicotine content in tobacco, but it may result in significant negative impacts to tobacco yields and quality.[16] Some breeding techniques may also increase nornicotine, which is a recognized addictive component of tobacco products that may reinforce addictive properties of nicotine at lower levels and can be converted to a toxic Group 1 carcinogen.[17]

FDA must thoroughly consider all of these factors before proceeding with a rulemaking of this significance.

Thank you again for taking the time to meet with us to discuss our concerns. If you have any questions or require additional information, please contact me at aka8015@msn.com.

Sincerely,

Kevin Altman
Coalition of Independent Tobacco Manufacturers of America

[16] See, e.g., Chaplin JF, Weeks WW. Association Between Percent Total Alkaloids and Other Traits in Flue-Cured Tobacco. Crop Sci. 1976; 16:416-418; Lewis RS, Jack Am, Morris JW, et al. RNAi-Induced Suppression of Nicotine Demethylase Activity Reduces Levels of a Key Carcinogen in Cured Tobacco Leaves. Plant Biotechnol J. 2008; 6(4): 346-354; Ramsey S. Lewis, *Potential Mandated Lowering of Nicotine Levels in Cigarettes: A Plant Perspective,* Nicotine & Tobacco Research, 2018, at 3; Christie D. Fowler et al., *Basic Science and Public Policy: Informed Regulation for Nicotine and Tobacco Products*, 20 Nicotine & Tobacco Research 789 (2018).

[17] *Id.*