



Illicit Trade of Tobacco and Nicotine Products

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ILLICIT TRADE OF TOBACCO AND NICOTINE PRODUCTS

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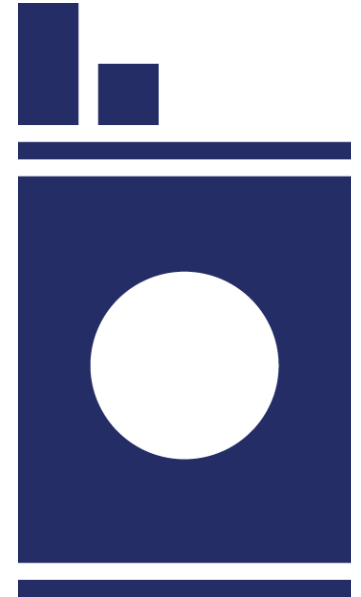


TOBACCO PRODUCT STANDARDS: FDA AUTHORITY

FDA TOBACCO PRODUCT STANDARDS: AUTHORITY



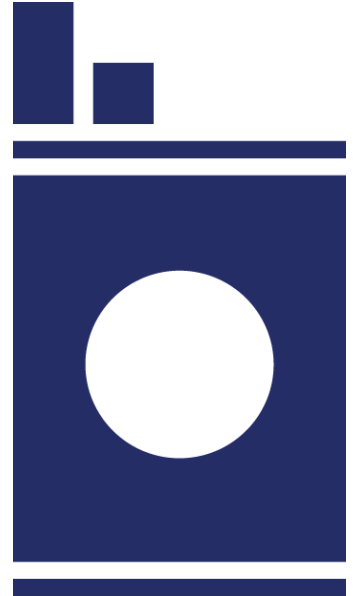
- To establish a tobacco product standard, FDA is required to find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:
 - The risks and benefits of the proposed standard to the population as a whole, including users and nonusers of tobacco products;
 - The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
 - The increased or decreased likelihood that those who do not use tobacco products will start using such products.



FDA TOBACCO PRODUCT STANDARDS: AUTHORITY



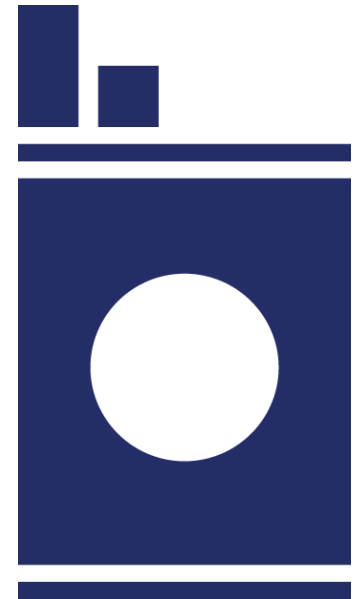
- FDA may establish tobacco product standards that are appropriate for the protection of the public health, including provisions, where appropriate, for the:
 - Reduction or elimination of constituents or harmful components of tobacco products;
 - Construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;
 - Testing of the tobacco product; and
 - Measurement of the tobacco product characteristics of the tobacco product.



FDA TOBACCO PRODUCT STANDARDS: AUTHORITY



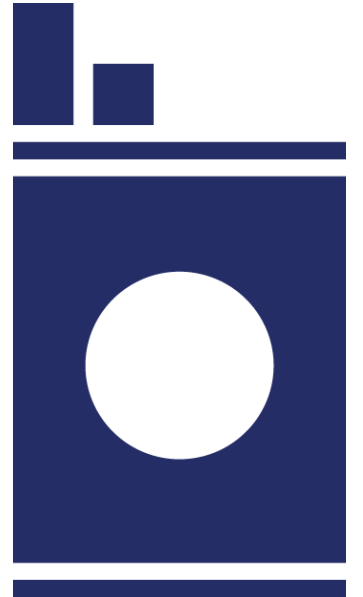
- Additionally, FDA is required to consider other information submitted in connection with a proposed product standard, including information:
 - Regarding the technical achievability of compliance with such standard; and
 - Concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of the product standard and the significance of such demand.
 - *The term “illicit trade” means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.*



FDA TOBACCO PRODUCT STANDARDS: EXAMPLES



- *FDA could establish tobacco product standards that would reduce or eliminate certain harmful constituents in tobacco products;*
- *FDA could establish tobacco product standards that would limit appealing and/or addictive constituents;*
- For example:
- FDA could set a maximum nicotine level for certain products;
- FDA could prohibit the manufacture, sale, and distribution of tobacco products with certain characterizing flavors;



The background of the slide is a dark, swirling smoke or mist pattern in shades of blue and white, creating a sense of movement and depth. A horizontal blue band is overlaid across the middle of the slide, serving as a backdrop for the title text.

FDA'S DRAFT CONCEPT PAPER

DRAFT CONCEPT PAPER: PROCESS AND TIMELINE



- Draft Concept Paper
 - Multi-discipline participation
 - Began in 2014 as an internal, informal, information collection exercise
 - Discussed utility of making it public
 - Not all-encompassing; not conclusory

DRAFT CONCEPT PAPER: PUBLIC DOCKET



- Public Docket
 - March 16th Federal Register Notice
 - Comment period ended July 16th
 - Requested information and analysis
 - Currently reviewing submissions and deciding next steps

DRAFT CONCEPT PAPER: CONTENT OVERVIEW



- Elements of illicit trade
 - Sources of tobacco
 - Manufacturing of illicit products
 - Other products used to evade product standards
 - Distribution of illicit products
 - Development of consumer awareness
 - Sales of illicit tobacco products

DRAFT CONCEPT PAPER: CONTENT OVERVIEW



- Potential consumer behaviors
 - Overall behaviors
 - Illicit market buying behavior
 - Research on VLNC cigarettes
 - Comparators: prisons and prohibition

DRAFT CONCEPT PAPER: CONTENT OVERVIEW



- Pricing
 - Factors impacting price
 - Data comparing legal and illegal products
 - Potential impacts of difference in price between products
- Enforcement and other controls

NEXT STEPS

- Continue to review submissions to the docket
- Consider information and potential impact of illicit trade when promulgating tobacco product standards



QUESTIONS?



THANK YOU

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Eric N. Heyer

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- Section 907(b) requires FDA to consider “all other information submitted in connection with a proposed [tobacco product] standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband”

- Tobacco Control Act House Report (H.R. Rep. No. 111-58 at 38 (2009)): Section 907(a)(1) characterizing flavor ban for cigarettes justified, in part, by low overall and irregular use by adult smokers:

“In addition, the sudden removal of a legal source for [a tobacco product used regularly by a large number of heavily addicted adult users] without the type of consideration and review that FDA will be able to conduct might unnecessarily increase the illegal black market risk, which could also pose a health hazard to users.”

- Even as of 2014, some 10.2 million U.S. adults had used non-tobacco flavors in the last 30 days.*

*Bonhomme, MG, et al., Flavoured non-cigarette tobacco product use among US adults: 2013-2014. Tob Control. 2016 Nov;25(Suppl 2):ii4-ii13. doi: 10.1136/tobaccocontrol-2016-053373. Epub 2016 Oct 28.

- Concerns regarding DIY e-liquids include the following:
 - (1) Accurate labeling and quality controls for DIY ingredients
 - (2) Safety of users and non-users
 - (3) Broad undermining of FDA's regulatory authority
- Would the propensity for flavored e-liquid users to turn to DIY make a proposed flavor product standard self-defeating?

Accurate Labeling and Quality Controls

- Google search for “DIY e-liquid” finds over 7,000,000 hits, including instructional YouTube videos and websites selling DIY e-liquid supplies, including:
 - ✓ flavor extracts / additives
 - ✓ “starter kits”
 - ✓ vegetable glycerin
 - ✓ propylene glycol
 - ✓ nicotine
 - ✓ pre-mixed “bases”
- One lab analysis* of 30 “nicotine free” flavor additives for DIY e-liquids found flavor additives containing nicotine concentrations of 14.2 mg/mL and 95.4 mg/mL.
- Under and undiluted nicotine solutions of 250 - 990 mg / mL concentrations readily available.

*Davis, B, et al., Unexpected nicotine in Do-it-Yourself electronic cigarette flavourings, Tob Control. 2016 Apr;25(e1):e67-8. doi: 10.1136/tobaccocontrol-2015-052468. Epub 2015 Jul 27.

Safety of Users and Non-users

- One website's warning: "This concentrate cannot be used directly. It must be mixed with VG or PG base to a safe rate. Please do some research before handling this."
- Augmented risk of accidental poisoning to children.
- Augmented risk of use of contaminated or mislabeled ingredients by users of DIY e-liquids.

Broad Undermining of FDA Regulatory Authority

- Availability of DIY components contributes to unregulated manufacturing and unauthorized “new” tobacco products.
- Studies from other jurisdictions very limited, yet still remarkable:
 - Wong, LP, et al. (2017)*: cross-sectional survey of 851 Malaysian ENDS users
 - ❖ ban on sales of nicotine-containing e-liquid in several states in Malaysia other than through pharmacies or registered medical practitioners
 - ❖ 44.2% of respondents reported plans to continue same e-cigarette use
 - ❖ 63.1% of respondents reported being able to obtain nicotine-containing e-liquid through online purchase
 - ❖ 30.8% of respondents fabricated own e-liquid on DIY basis; many from lower income group
 - ❖ extrapolated to U.S. market, 3 million consumers could be manufacturing on a DIY basis in their homes

*Wong, LP, et al. (2017), E-Cigarette Users' Attitudes on the Banning of Sales of Nicotine E-Liquid, Its Implications on E-Cigarette Use Behaviors and Alternative Sources of E-Liquid. J Comm Health 42(6):1225-1232.

Broad Undermining of FDA Regulatory Authority

- Studies from other jurisdictions very limited, yet still remarkable:
 - In 2013, Brazil banned all non-tobacco flavors, including menthol, in tobacco products.
 - Part of multi-pronged tobacco control plan that also included health warnings, a national smoke-free law, point-of-sale advertising ban, and tobacco tax increases.
 - From 2013 to 2014, the number of illicit cigarettes seized nearly tripled, from just over 370,000,000 pieces in 183 in 2013 to over 1,311,000,000 pieces in 269 seizures in 2014. (WCO Illicit Trade Reports for 2013, 2014.)

Conclusion

- More robust data on the countervailing effects of any proposed tobacco product standard limiting e-liquid flavors is needed before product standards can be imposed.



Emerging Illicit Markets in light of the ANPRM

Clarissa Manning, MPP

BOTEC Analysis

October 26, 2018

Cigarette and e-cigarette use damages health

47.1%

Individuals believing VLNC cigarettes are less likely to cause cancer (Byron *et al*)

E-cigarettes are less harmful than traditional cigarettes (Public Health England)

95%

96%

Former smokers reporting that e-cigarette flavors were important in their attempt to quit smoking

Current Illicit Market

- Illicit cigarettes make up 13% – 25% of the total US market (Joossens 2010)
- Counterfeit cigarettes and “cheap whites” are less common in the US
- 25% of smokers use price minimization strategies
- \$5 billion in lost revenue from unpaid excise taxes

How might smokers respond to regulation?

- Quit tobacco products entirely
- Cross borders to purchase product
- Switch to other nicotine-delivery devices
- Purchase products on the illicit market

Enforcement Options

Cease & Desist Letters; Civil Penalties

- Requires little regulatory effort
- Work well in legal markets or with largely legal actors

Increased Arrests and Incarceration

- Society not likely to tolerate more incarceration
- Costs of regulations transferred to state and local jurisdictions
- Long sentences may not be a deterrent

Unintended Consequences of Enforcement

- Inadequate enforcement of regulations
- Enforcement swamping
- Increased violence
- Widespread use of illicit products
- Transnational organized crime influence

Comparable Markets

- Cannabis – low violence; wide-spread use
- Cocaine – high violence; high incarceration
- Opioids – high enforcement costs; escalating public health crisis
- Alcohol – A legal product becoming illegal; high-violence; high enforcement costs



What Do We Need to Know?

- How big could the market get?
- How much enforcement will be required at that market size?
- Is that enforcement capacity available now? Can it be made available?
- Are the costs of that enforcement tolerable relative to the reduction in smoking?