CM Galvez

FDA NEWS RELEASE

FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products

Potential Rule Would Propose to Establish a Maximum Level of Nicotine in Cigarettes with the Goal of Reducing Youth Use, Addiction and Death

For Immediate Release:

June 21, 2022

Español (/news-events/press-announcements/la-fda-anuncia-planes-de-norma-propuesta-para-reducir-la-adiccion-de-los-cigarrillos-y-otros)

Today, the Biden-Harris Administration published plans for future potential regulatory actions that include the U.S. Food and Drug Administration's plans to develop a proposed product standard (https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI76) that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other combusted tobacco products. The goal of the potential rule would be to reduce youth use, addiction and death.

Each year, 480,000 people die prematurely from a smoking-attributed disease, making tobacco use the leading cause of preventable disease and death in the United States. Additionally, tobacco use costs nearly $300 billion a year in direct health care and lost productivity.

While nicotine is not what makes smoking cigarettes so toxic, it's the ingredient that makes it very hard to quit smoking. Addiction to nicotine in combusted products is the main driver of sustained use of these products. In fact, more than half of adult cigarette smokers make a serious quit attempt each year (quitting for at least a day), but most do not succeed due to the addictive nature of cigarettes. Such a product standard, if proposed and then finalized after a thorough process, would make those products minimally- or non-addictive.

"Nicotine is powerfully addictive," said FDA Commissioner Robert M. Califf, M.D. "Making cigarettes and other combusted tobacco products minimally addictive or non-addictive would help save lives. The U.S. Surgeon General has reported that 87 percent of adult smokers start smoking before age 18, and about two-thirds of adult daily smokers began smoking daily by 18 years of age. Lowering nicotine

levels to minimally addictive or non-addictive levels would decrease the likelihood that future generations of young people become addicted to cigarettes and help more currently addicted smokers to quit."

A paper published by the FDA in the New England Journal of Medicine (https://www.nejm.org/doi/full/10.1056/NEJMsr1714617) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in 2018 projected that by year 2100, a potential nicotine product standard could result in more than 33 million people not becoming regular smokers, a smoking rate of only 1.4%, and more than 8 million fewer people dying from tobacco-related illnesses. The current smoking rate is 12.5%.

The Spring 2022 Unified Agenda of Regulatory and Deregulatory actions published today provides a report on the actions administrative agencies are considering issuing in the near and long term and currently lists several planned potential regulatory actions related to tobacco products; however, the dates in the Unified Agenda are not intended to be a precise estimate of when the work necessary to complete a proposed rule will be finished nor a final decision regarding whether a rule will be proposed.

The FDA also remains focused on its regulatory oversight of e-cigarettes and other electronic nicotine delivery systems (ENDS). Thus far, FDA has taken action on approximately 99% of the nearly 6.7 million products for which applications were received by the Sept. 9, 2020, deadline, including issuing marketing denial orders for more than 1 million ENDS products. The FDA has also issued warning letters to ENDS product manufacturers and retailers who continue to sell products that are illegally on the market.

The agency is focused on expeditiously completing the review of the remaining applications we received by the Sept. 9 deadline with a focus on those products with large market share. In addition, the FDA has made a significant investment in a multimedia e-cigarette public education campaign aimed at the nearly 10.7 million youth aged 12-17 who have ever used e-cigarettes or are open to trying them highlighting information about the potential risks of e-cigarette use.

Related Information

- Nicotine Is Why Tobacco Products Are Addictive (https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive)
- What Is Nicotine? (https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive#2)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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[c]The US e-cigarette ever use estimate is the median for 18–24 year olds for all US states and DC from the 2017 BRFSS. Sources: US State Prevalence Data: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health. BRFSS Prevalence & Trends Data [online]. 2015. [accessed Sep 9, 2019]. URL: https://www.cdc.gov/brfss/brfssprevalence/; Special Eurobarometer 458: Attitudes of Europeans Toward Tobacco and Electronic Cigarettes [online]. 2017. [accessed Sep 9, 2019]. URL: http://data.europa.eu/euodp/en/data/dataset/S2146_87_1_458_ENG; Canadian Tobacco Alcohol and Drugs (CTADS) Survey: 2017 detailed tables [online]. 2017. [accessed Oct 4, 2019]. URL: https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary/2017-detailed-tables.html.

3.2. European Union

The TPD seeks to reduce the significant public health burden of tobacco use through discouraging youth tobacco use and informing citizens about the health consequences of associated with using tobacco [33]. Many of its primary strategies for achieving these goals are directed specifically toward traditional combusted cigarettes. However, in light of increasing ECIG use, and what the European Commission cited as a lack of evidence thus far in regard to their impact on public health [28], Article 20 of the TPD also includes specific regulations intended to regulate the sale of nicotine-containing ECIGs to consumers (ECIGs without nicotine are not regulated under the TPD). These regulations include setting a maximum concentration of nicotine (20 mg/mL) in ECIG liquid, maximum volume of liquid for tanks and containers that store the liquid (10 mL), and requiring that ECIG devices and storage containers be child-resistant and minimize the risk of accidental exposure [28]. Additionally, vitamins and other additives that create the impression of added health benefits; including caffeine, taurine and other additives and stimulants; colorants and other substances that are harmful to humans, except for nicotine, are not permitted in ECIG liquid. The TPD also requires that consumers be informed about all ECIG ingredients and their nicotine content via mandatory packaging and labelling requirements [27], and that ECIG packaging not contain promotional material.

Regarding health warning statements, "This product contains nicotine which is a highly addictive substance" must appear in the national language of the country in which the ECIGs are sold, with the warning label covering at least 30 % of the two largest surfaces of packaging of nicotine-containing pre-filled ECIGs and refill containers. Further, packaging must include a list of all ingredients (in descending order of their share of weight), nicotine content, nicotine emission per dose, and a notice that the product is not allowed to be accessed by children. ECIG manufacturers are also required to provide the European Commission and EU member states with information on new products they intend to introduce to the market, including ingredients, emissions, nicotine content, and production, as well as reporting on annual sales, demographics of their users, and product preferences [28]. This information, as well as monitoring by member state regulatory authorities, may be used to inform future regulatory action by member states

youth, and in broadcast media or publications geared toward youth [38]. As Canadian health authorities seek to reduce the appeal of ECIGs to youth while also allowing legal sale, they have placed significant restrictions on manufacturers and retailers at the federal level, and continue to amend TVPA to clarify and promulgate further regulations [[37], [38], [39]].

3.4. United States

As part of the Family Smoking Prevention and Tobacco Control Act in 2009, the US Food and Drug Administration's Center for Tobacco Products was granted regulatory authority over the manufacture, sale, and marketing of traditional tobacco products. Effective in August 2016, the FDA's deeming rule designated ECIGs as a tobacco product granting the agency regulatory authority [40]. Under federal regulations, ECIGs may not be sold to individuals under the federal minimum purchase age of 21 [41], nor be sold in vending machines in places where youth are allowed, and retailers are legally responsible for requiring photo identification age verification for individuals under age 27 intending to purchase ECIGs. Beginning in 2018, nicotine-containing ECIG devices and liquid must contain warning statements about the addictive qualities of nicotine that read "WARNING: This product contains nicotine. Nicotine is an addictive chemical" [42]. FDA also sponsors national surveys on ECIG and other tobacco use and tobacco regulatory science to produce evidence relevant to developing regulations that advance its public health standard.

As of June 2019, all manufacturers of ECIG devices and liquids currently on the market must submit a list of all ECIG products, ingredients, labelling and advertising to FDA. After FDA's evaluation of the list is completed, products FDA allows to be marketed are said to be granted "premarket authorization" [43,44]. Further, all ECIGs on the market as of August 2016 are subject to FDA compliance policies, but enforcement has been deferred, particularly for not obtaining premarket authorization. As part of its enforcement duties for ECIGs in violation of marketing authorization, FDA has sent letters to approximately 90 companies seeking information to determine if tobacco products are being marketed illegally and has issued warning letters to six companies notifying them of the need to remove a combined 71 products from the market [44]. Cited violations of marketing authorization include actions such as advertising online and via social media without using required nicotine warning statements, using modified risk messaging to imply ECIGs are less harmful than combusted cigarettes, and not providing FDA with lists of ingredients, among others [45,46]. However, citing concerns over the protracted pace of FDA's implementation and enforcement of ECIG manufacturer regulations, a US District Court ordered that preauthorization documents be submitted to FDA by ECIG manufacturers by May 2020 [47].

The FDA has signaled it is taking several additional steps in its Youth Tobacco Prevention Plan to regulate tobacco products further, many involving ECIGs [48]. Increased age verification will be required for online sales. Additionally, marketing for ECIG products targeting children will be removed. This regulation includes eliminating animation, as well as popular youth flavors like candy. Reacting to hundreds of vaping-related illnesses, and new evidence from 2019 national

survey data that ECIG use among adolescents continues to increase, the Trump administration directed the FDA in September 2019 to clear the US market of all non-tobacco flavored ECIG products [17]. A partial flavor ban was enacted in early 2020 to reduce the appeal of ECIGs to youth by banning the sale of fruit and mint flavors in cartridge-based products (like JUUL) popular among youth [49]. However, the White House and FDA have since retreated from making any decisions regarding ECIG flavors. In addition to federal regulations regarding ECIGs, many US states and localities have passed additional restrictions on ECIGs, discussed in the coming sections [50,51].

3.5. Summary

The EU, Canada, and the US each have federal-level frameworks for regulating ECIGs. While all three approaches regulate packaging and labeling, though to varying degrees, several differences in federal regulatory strategies are noteworthy. The EU's TPD is distinguished by the limits it places on nicotine concentration in e-liquid and on e-liquid volume. In Canada, a broad and restrictive federal regulatory approach for ECIGs was only recently enacted after most provinces already had fairly comprehensive ECIG policies. US federal action on ECIGs is arguably the weakest of the three with many regulations slow to be enacted or enforced (e.g., premarket authorization), with others announced but not implemented (e.g., flavor ban). Nonetheless, states in the US, and likewise members states in the EU, and provinces in Canada have leveraged federalism to enact ECIG policies that extend beyond federal regulatory frameworks. These member state-, province-, and state-level ECIG policies and the prevalence of ECIG use in these regions are discussed next.

4. Comparisons of E-cigarette regulations and tobacco use in EU Member States, US States, and Canadian Provinces

4.1. Overview

To understand the motivations for EU member state-specific, Canadian province-specific, and US state-specific regulatory action on ECIGs beyond federal-level policies, we first report differences in ECIG ever use among adults 18–24 in selected EU member countries, Canadian provinces, and US states that recently reformed how these products are regulated. Using data from the 2017 Eurobarometer [14], the 2017 Behavioral Risk Factor Surveillance System (BRFSS) [52], and the 2017 Canadian Alcohol, Tobacco and Drugs Survey [53] we find that 56 % of young adults in Estonia and 40 % in Lithuania reported ever using and ECIG, compared to 15 % in Italy and 3% in Malta (Fig. 1). We found that in the Netherlands, 33 % of young adults reported ECIG ever use, similar to the 31 % prevalence of ever use among young adults in Finland, Germany and Greece, while reports of ECIG ever use were lower in Slovenia (21 %), Slovakia (20 %), and Ireland (20 %).

Container e-liquid means "a container of liquid nicotine or other liquid where the liquid is marketed, sold, or intended for use in an electronic smoking device, but does not include a prefilled cartridge or other container where the cartridge or container is marketed, sold, or intended for use as, or as a part of, an electronic smoking device."
N.J. Stat. Ann. § 54:40B-2 (2022) (http://njlaw.rutgers.edu/cgi-bin/njstats/showsect.cgi?section=54%3A40b-2&actn=getsect)

Tobacco product means "any product containing, made, or derived from any tobacco, nicotine, or other chemicals or substances for consumption by a person, including, but not limited to, cigars, little cigars, cigarillos, chewing tobacco, pipe tobacco, smoking tobacco and their dsubstitutes, dry and moist snuff, and liquid nicotine, but does not include cigarette . . . ."
N.J. Stat. Ann. § 54:40B-2 (2022) (http://njlaw.rutgers.edu/cgi-bin/njstats/showsect.cgi?section=54%3A40b-2&actn=getsect)

NJ Nicotine Level Tax for E-Cigs

IS THERE A STATE EXCISE OR SPECIAL TAX (NON-SALES TAX) PLACED ON E-CIGARETTES?

Liquid nicotine taxed at rate of $0.10 per fluid milliliter by volume, and a proportionate rate on all fractional parts of fluid milliliter (except container e-liquid).
N.J. Stat. Ann. § 54:40B-3.2(a), (d) (2022) (http://njlaw.rutgers.edu/cgi-bin/njstats/showsect.cgi?section=54%3A40b-3.2&actn=getsect)

Container e-liquid taxed at rate of 10% of the listed retail sale price.
N.J. Stat. Ann. § 54:40B-3.4(a) (2022) (http://njlaw.rutgers.edu/cgi-bin/njstats/showsect.cgi?section=54%3A40b-3.4&actn=getsect)

WHAT REGULATIONS ARE IN PLACE FOR E-CIGARETTE PACKAGING?

Liquid nicotine container means "a bottle or other container of liquid, wax, gel, or other substance containing nicotine, where the liquid or other contained substance is sold, marketed or intended for use in a vapor product [but] does not include [containers] prefilled and sealed by the manufacturer [and] not intended to be opened by the consumer."

N.J. Stat. Ann. § 2A:170-51.9(a)(3) (2022) (https://codes.findlaw.com/nj/title-2a-administration-of-civil-and-criminal-justice/nj-st-sect-2a-170-51-9.html)

Vapor product means "any non-combustible product containing nicotine that employs a heating element, power source, electronic circuit, or other electronic, chemical, or mechanical means, regardless of shape or size, to produce vapor from nicotine in a solution or any form [including] any electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or similar product or device, and any vapor cartridge or other container of nicotine in a solution or other form intended to be used with, or in, any such device."

N.J. Stat. Ann. § 2A:170-51.9(a)(4) (2022) (https://codes.findlaw.com/nj/title-2a-administration-of-civil-and-criminal-justice/nj-st-sect-2a-170-51-9.html)

Tax

Electronic smoking device means "a nonlighted, noncombustible device that may be used to simulate smoking and that employs a mechanical heating element, battery, or circuit, regardless of shape or size, to produce aerosolized or vaporized nicotine or other substance for inhalation into the body of a person, [including devices marketed as] an e-cigarette, e-cigar, e-pipe, e-hookah, vape pen, or any other similar product with any other product name or descriptor."

N.J. Stat. Ann. § 54:40B-2 (2022) (http://njlaw.rutgers.edu/cgi-bin/njstats/showsect.cgi?section=54%3A40b-2&actn=getsect)

Liquid nicotine means "any solution containing nicotine that is designed or sold for use with an electronic smoking device."

N.J. Stat. Ann. § 54:40B-2 (2022) (http://njlaw.rutgers.edu/cgi-bin/njstats/showsect.cgi?section=54%3A40b-2&actn=getsect)