



City and County of San Francisco
DEPARTMENT OF PUBLIC HEALTH
ENVIRONMENTAL HEALTH

London N. Breed, Mayor
Grant Colfax, MD, Director of Health
Stephanie K. J. Cushing, MSPH, CHMM, REHS
Director of Environmental Health

Date: December 20, 2019

Re: Review Draft of the Revised Rules and Regulation for the Retail Tobacco Permit Program: Article 19R and 19S of the San Francisco Health Code

Summary

The San Francisco Department of Public Health (SFDPH) is announcing an opportunity for public comment on revised Rules and Regulations governing our program to enforce the prohibition on the sale and distribution of Electronic Cigarettes that require premarket review under the federal Family Smoking Prevention and Tobacco Control ("Tobacco Control Act") but have not received a Premarket Tobacco Product Marketing Order from the U.S. Food and Drug Administration ("FDA") authorizing their sale.

Dates

Submit either electronic or written comments on these draft rules and regulations by January 19, 2020.

Addresses

Submit electronic comments by email to: Jennifer.callewaert@sfdph.org

Submit written comments to: **Jen Callewaert, Tobacco & Smoking Program, San Francisco Department of Public Health, 1390 Market St, Ste 210, San Francisco CA 94102.**

Permits for the Sale of Tobacco Ordinance

On June 25, 2019, the Board of Supervisors passed Ordinance No. 122-19, which amends the SFHC to add new Articles 19R and 19S. These articles prohibit the sale and distribution of Electronic Cigarettes that require premarket review under the Tobacco Control Act but have not received a Premarket Tobacco Product Marketing Order from the FDA authorizing their sale. Information on Articles 19R and 19S, including Rules and Regulations currently in effect, may be found at <https://www.sfdph.org/dph/EH/Tobacco/Ecigarettes.asp>.

Supplementary Information

SFDPH invites comments on these Draft Rules and Regulations, including but not limited to these topics: (1) Whether the Rules and Regulations adequately and accurately describe the conditions under which retail tobacco permittees, manufacturers, and distributors will be granted approval to sell and distribute Electronic Cigarettes in San Francisco as required by the law; and (2) ways to enhance the clarity of the information contained in these rules and regulations.

The current San Francisco Department of Public Health Director's Rules and Regulations for Retail Tobacco Sales (August 16, 2019) may be referenced and found at https://www.sfdph.org/dph/files/EHSdocs/Tobacco/Rules_for_SFHC_19H_Tobacco_Retail_Permits.pdf.



San Francisco Department of Public Health Director's Draft Rules and Regulations for Retail Tobacco Sales

December 20, 2019

Chapter 1. Authority

The San Francisco Health Code (SFHC) sets forth laws regulating the sale, distribution, and use of tobacco and tobacco products. Sections 19H.26, 19Q.5, 19R.3, and 19S.3 authorize the Director of the San Francisco Department of Public Health (SFDPH) to adopt rules and regulations to implement Article 19H (permits for the sale of tobacco), Article 19Q (prohibiting the sale of flavored tobacco products), Article 19R (prohibiting the sale of electronic cigarettes lacking Food and Drug Administration premarket approval), and Article 19S (prohibiting the sale and distribution of tobacco products in San Francisco), respectively.

These Rules and Regulations for Retail Tobacco Sales (Rules) shall apply to all Establishments and Persons that sell or distribute Tobacco Products in the City and shall supersede any existing rules and regulations relating to Article 19H, 19Q, 19R, and 19S. The Director may amend these Rules from time to time.

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Chapter 5. Electronic Cigarettes that Require but Lack Authorization from the U.S. Food and Drug Administration (Articles 19R and 19S of the SFHC)

SEC. 1. Background

On June 25, 2019, the Board of Supervisors passed Ordinance No. 122-19, which amends the SFHC to add new Articles 19R and 19S. These articles prohibit the sale and distribution of Electronic Cigarettes that require premarket review under the federal Family Smoking Prevention and Tobacco Control ("Tobacco Control Act") but have not received a Premarket Tobacco Product Marketing Order from the U.S. Food and Drug Administration ("FDA") authorizing their sale.

In addition, Articles 19Q and 19S of the SFHC prohibit the sale and distribution of Tobacco Products—including Electronic Cigarettes—that contain constituents that impart a characterizing flavor. (See Chapter 4 of these Rules discussing the prohibition on the sale of Flavored Tobacco Products.)

SEC. 2. Definitions

For purposes of enforcement of Articles 19R and 19S, the following terms shall have the following meanings:

"Director" means the Director of Health, or the Director's designee.

"Distributor" means any Person other than a common carrier who transfers an Electronic Cigarette or Flavored Tobacco Product, whether domestic or imported, at any point from

the original place of manufacture to the Person who sells or distributes the Electronic Cigarette or Flavored Tobacco Product to individuals for personal consumption.

“Electronic Cigarette” has the meaning set forth in Section 30121 of the California Revenue and Taxation Code, as may be amended from time to time. As of the date these Rules were last updated (noted on Page 1), Section 30121 defined the term “Electronic Cigarette” to mean:

“any device or delivery system sold in combination with nicotine which can be used to deliver to a person nicotine in aerosolized or vaporized form, including, but not limited to, an e-cigarette, e-cigar, e-pipe, vape pen, or e-hookah. Electronic cigarettes include any component, part, or accessory of such a device that is used during the operation of the device when sold in combination with any liquid or substance containing nicotine. Electronic cigarettes also include any liquid or substance containing nicotine, whether sold separately or sold in combination with any device that could be used to deliver to a person nicotine in aerosolized or vaporized form. Electronic cigarettes do not include any device not sold in combination with any liquid or substance containing nicotine, or any battery, battery charger, carrying case, or other accessory not used in the operation of the device if sold separately. Electronic cigarettes shall not include any product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where that product is marketed and sold solely for such approved use. As used in this subdivision, nicotine does not include any food products as that term is defined pursuant to Section 6359.”

“Establishment” means any store, stand, booth, concession or any other enterprise that engages in the retail sale of tobacco products, including stores engaging in the retail sale of food items.

“Exemption from Substantial Equivalence Marketing Order” means an order issued by the FDA under the authority of 21 U.S.C. § 387j(a)(2)(A)(ii) that a tobacco product is exempt from the requirements of 21 U.S.C. § 387(e) or pursuant to a regulation issued under 21 U.S.C. § 3873e(j)(3).

“Flavored Tobacco Product” shall have the meaning set forth in SFHC Section 19Q.2.

“List of Approved Electronic Cigarettes Pending FDA Posting” means a list to be maintained by SFDPH of tobacco products that are the subject of a Tobacco Product Marketing Order that has been issued by the FDA, but that has not yet been posted on the FDA’s website.

“Manufacturer” means any Person who manufactures, fabricates, assembles, processes, or labels an Electronic Cigarette or imports a finished Electronic Cigarette for sale or distribution in the United States.

“New Tobacco Product” has the meaning set forth in 21 U.S.C. § 387j(a)(1), as may be amended from time to time. As of the date these Rules were last updated (noted on Page 1), Section 387j defined the term “new tobacco product” to mean:

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the

modified product was commercially marketed in the United States after February 15, 2007.

“Permittee” means a Person who holds a Tobacco Sales Permit from the Department for a specific location.

“Person” means any individual, partnership, cooperative association, private corporation, personal representative, receiver, trustee, assignee, or any other legal entity.

“Premarket Tobacco Product Marketing Order” means an order issued by the FDA under the authority of 21 U.S.C. § 387j(c)(1)(A)(i) that a tobacco product may be introduced or delivered for introduction into interstate commerce.

“Substantial Equivalence Marketing Order” means an order issued by the FDA under the authority of 21 U.S.C. § 387j(a)(2)(A)(i) that a tobacco product is substantially equivalent to an eligible predicate tobacco product and in compliance with the requirements of the Tobacco Control Act.

“Tobacco Product Marketing Order” means a Substantial Equivalence Marketing Order, an Exemption from Substantial Equivalence Marketing Order, or a Premarket Tobacco Product Marketing Order.

SEC. 3. Electronic cigarettes that may lawfully be sold in San Francisco

Articles 19R and 19S prohibit the sale of Electronic Cigarettes that: (1) are New Tobacco Products; (2) require premarket review under 21 U.S.C. § 387j; and (3) do not have a premarket review order under 21 U.S.C. § 387j(c)(1)(A)(i).

According to the FDA, there are no Electronic Cigarettes on the market today that do not qualify as New Tobacco Products.

Therefore, the only Electronic Cigarettes that may lawfully be sold in San Francisco or to a Person in San Francisco consistent with Articles 19R and 19S of the SFHC are: (1) Electronic Cigarettes that do not require premarket review, as evidenced by the fact that they are the subject of a Substantial Equivalence Marketing Order or an Exemption from Substantial Equivalence Marketing Order; and (2) Electronic Cigarettes that are the subject of a Premarket Tobacco Product Marketing Order.

The FDA posts on its website:

- (1) A list of Substantial Equivalence Marketing Orders issued by the FDA. <https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se>
- (2) A list of Exemption from Substantial Equivalence Marketing Orders issued by the FDA. <https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se>
- (3) A list of Premarket Tobacco Product Marketing Orders issued by the FDA. <https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders>

In some instances, there may be a delay between the date that the FDA issues a Tobacco Product Marketing Order to a Manufacturer and its posting of such order on the FDA website. A Manufacturer or Distributor that possesses a Tobacco Product Marketing Order that has been issued by the FDA—but that has not yet posted on the FDA’s website—may send a true and correct copy of such Tobacco Product Marketing Order to SFDPH. Upon receipt and confirmation that the Tobacco Product Marketing Order is valid, SFDPH shall

add the name of the Electronic Cigarette to the List of Approved Electronic Cigarettes Pending FDA Posting. SFDPH will post such list on its website at <https://www.sfdph.org/ecigs>.

Electronic Cigarettes that do not appear on any one of the FDA’s three Marketing Order lists, or on SFPDH’s List of Approved Electronic Cigarettes Pending FDA Posting, may not lawfully be sold in San Francisco or to a Person in San Francisco.

Distributors, retailers, and consumers seeking to confirm whether an Electronic Cigarette may lawfully be sold in San Francisco, or to a Person in San Francisco, must consult these lists.

In addition, Articles 19Q and 19S of the SFHC prohibit the sale of Tobacco Products, including Electronic Cigarettes, that have a characterizing flavor. So, even if an Electronic Cigarette appears on one of the three FDA lists or on the List of Approved Electronic Cigarettes Pending FDA Posting, it may not lawfully be sold or distributed in San Francisco if it has a Characterizing Flavor. (For more information about Flavored Tobacco Products, see Section 4 of these Rules.)

SEC 4. Penalties for Violation of Article 19R

(1) Abatement opportunity.

For a first time violation of Article 19R (Prohibiting the Sale of Electronic Cigarettes Lacking FDA Pre-Market Approval), a Permittee will be afforded the opportunity to remove from its Establishment all Electronic Cigarettes that may not lawfully be sold in San Francisco, in lieu of a permit suspension. Failure to remove such products within 72 hours shall result in the suspension of the Tobacco Sales Permit for 10 days. SFDPH shall issue a Notice of Violation to the Establishment and follow the Enforcement Procedures as set forth in Appendix A of these Rules prior to the imposition of such suspension.

(2) Violations of Article 19R (Prohibiting the Sale of Electronic Cigarettes Lacking FDA Pre-Market Approval) shall result in a suspension of the Tobacco Sales Permit according to Table 4.

Table 4: Tobacco Sales Permit Suspension Periods for Sales or Distribution of Electronic Cigarette in Violation of Article 19R

Number of Times the Violation Occurred	Permit Suspension Period*
1 st violation	10 days (unless product(s) have been removed within 72 hours)
2 nd violation	20 Days
3 rd violation	40 Days
4 th and each violation afterwards	90 Days

SEC 5. Penalties for Violation of Article 19S

SFDPH shall issue administrative penalties for violations of Article 19S consistent with Chapter 100 of the Administrative Code. Prior to issuing a citation for a first violation of Article 19S, SFDPH shall issue a Notice of Correction advising the Person of the violation and affording them the opportunity to recall all Electronic Cigarettes and/or Flavored

Tobacco Products that they sold or distributed in violation of Article 19S, in lieu of an administrative penalty. If the violator chooses to recall all such Electronic Cigarettes and/or Flavored Tobacco Products, the violator shall submit to SFPD an affidavit declaring that it has recalled all of the Electronic Cigarettes that it sold or distributed to Persons in San Francisco in violation of Article 19S and will not engage in any future sales or distributions of such products to Persons in San Francisco. If the violator fails or refuses to recall all Electronic Cigarettes and/or Flavored Tobacco Products sold in violation of Article 19S, SFPD shall issue a citation for administrative penalties and shall make a referral to the City Attorney for enforcement.

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