



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

January 29, 2020

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.

Chapter 2. General Permitting

SEC 1. Definitions

As used in these Rules, the following words or phrases shall have the meanings set forth below.

"Advertisement" means a written or visual message dedicated to promoting a specific tobacco product(s) inside the Establishment or on the Establishment's storefront, including but not limited to signage, promotional displays, penny trays, shopping baskets, and any other product identification other than the actual Tobacco Product for sale.

"Applicant" means a Business Owner applying for a SFDPH Tobacco Sales Permit to operate in the City and County of San Francisco.

"Bar" means an area, whether a separate, stand-alone business or part of a larger business which is devoted to the serving of alcoholic beverages for consumption by patrons on the premises and in which the serving of food is incidental to the consumption of such beverages.

"Change of Ownership" means a change of 50 percent or more of the ownership of the business within a 12-month period; provided, however, that if the Permittee is a corporation, transfer of 25 percent or more of the stock ownership of the permittee shall be deemed to be a Change of Ownership.

"Characterizing Flavor" means a distinguishable taste or aroma or both, other than the taste or aroma of tobacco, imparted by a Tobacco Product or any byproduct produced by the Tobacco Product. Characterizing Flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. A Tobacco Product shall not be

determined to have a Characterizing Flavor solely because of the use of additives or flavorings or the provision of ingredient information. Rather, it is the presence of a distinguishable taste or aroma or both, as described in the first sentence of this definition that constitutes a Characterizing Flavor.

“Displayed” means in public view.

“Electronic Cigarette” or “E-cigarette” means any device with a heating element, a battery, or an electronic circuit that provides nicotine or other vaporized liquids to the user in a manner that simulates smoking tobacco.

“Employee” means any person who performs work for a Permittee at an Establishment.

“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.

“Labeling” means written, printed, pictorial, or graphic matter upon any Tobacco Product or any of its Packaging.

“Packaging” means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a Tobacco Product is sold or offered for sale to a consumer.

“Permittee” means a person or business entity who holds a Tobacco Sales Permit from the Department for a specific location.

“School” means a public or private preschool, kindergarten, elementary school, middle school, junior high school, high school, or a school combining some or all of the above school grades.

“Self-service Merchandising” means the open display of Tobacco Products to which the public has access without the intervention of the vendor or a store employee.

“Tavern” means cigar or smoking bar.

“Tobacco Products” means (1) any product containing, made, or derived from tobacco or nicotine that is intended for human consumption, whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, or sniffed, or ingested by any other means, including, but not limited to, cigarettes, cigars, little cigars, chewing tobacco, dipping tobacco, pipe tobacco, bidis or snuff; (2) any device or component, part, or accessory that delivers nicotine alone or combined with other substances to the person using the device including but not limited to electronic cigarettes, cigars, or pipes, whether or not the device or component is sold separately. Tobacco Product does not include any product that has been approved by the United States Food and Drug Administration for use as a tobacco cessation product where such product is marketed and sold solely for such an approved purpose.

“Tobacco Sales Permit” means a SFDPH permit issued by the Director under Article 19H.

“Transferable” means conveyable from one person or entity to another person or entity.

SEC. 2. Permit Application

An Applicant may request a consultation meeting with the Department before submitting an application to review requirements set forth in these Rules. The Department's consultation fee is based on the inspector's hourly rate, which can be found at:

https://www.sfdph.org/dph/files/EHSdocs/ehsFees/SF_EHB_Fees.pdf.

A complete Permit Application includes all of the following:

- (a) A Tobacco Sales Permit Pre-Application, Affidavit, and Planning Referral;
- (b) An Application for the Sale of Tobacco Products and/or E-Cigarettes;
- (c) A Copy of the Business Registration Certificate from the San Francisco Office of the Treasurer & Tax Collector;
- (d) A Copy of the California Department of Tax and Fee Administration Retail Tobacco Products License (with a License Number);
- (e) Names of all Owner(s), Principal Officer(s), trust beneficiaries, and Ownership Percentage(s) for each Person identified on the Application;
- (f) Legal documentation listing all the owners of the Establishment;
- (g) Disclosure of any date(s) that the Department suspended or revoked a SFDPH Permit to Operate a Retail Tobacco Establishment issued to any owner or officer disclosed on the application;
- (h) Non-refundable Application Fee;
- (i) A signed copy of the Health and Safety Working Conditions document provided by the Department;
- (j) When applying for an Exception under Article 19H.6, documentation of Direct Negotiations as set forth in Chapter 3, Section 2 of these Rules;
- (k) When applicable, non-refundable Planning Department Zoning Referral Fee; and
- (l) When applicable, Establishment's lease agreement between Establishment's owner and property owner.

An application will be deemed abandoned if the Applicant fails to submit all required items within 30 days from the date SFDPH returns the application to the Applicant. After 30 days, the Applicant will be required to submit a new application and non-refundable application fee or request for a one-time 45 day extension to submit all necessary documents to complete the application.

SEC. 3 Change of Ownership

A Tobacco Sales Permit may not be transferred or assigned.

(1) Upon the sale of an Establishment holding a Tobacco Sales Permit, the Tobacco Sales Permit shall be forfeited and considered null and void.

(2) Any Change of Ownership shall be reported to the Department and shall require the new Establishment owner to apply for a Tobacco Sales Permit with the Department within 30 days.

(3) A completed Tobacco Sales Permit Application must be received by the Department within 30 days of a Change of Ownership.

SEC. 4. Grounds for Permit Denial

(1) The Department will deny an application for a Tobacco Sales Permit for any of the following reasons:

- (a) The Establishment is located in a Supervisorial District that has 45 or more Establishments with Tobacco Sales Permits;
- (b) The Establishment is within 500 feet of a School;
- (c) The Establishment is within 500 feet of another Establishment who holds a valid Tobacco Sales Permit;
- (d) The Establishment's whose main purpose is offering food or beverage consumption on the premises, including Bars and Restaurants;
- (e) The Establishment is a Tobacco Shop;
- (f) The Department never issued a Tobacco Sales Permit at the Establishment's specific location;
- (g) The Establishment is a Pharmacy;
- (h) The Applicant has submitted fraudulent or misrepresentative information in their Application;
- (i) The current Permittee for whom the applicant is purchasing the business from is delinquent in paying their Tobacco Sales Permit H-31 license fee; or
- (j) The owner at the Establishment is in violations of SFHC Article 19, Police Code Section 4600.3 (regulating the self-service merchandising of Tobacco Products), or the California Labor Code.

(2) Appeal of School and/or Other Tobacco Sales Permit distance determinations

- (a) The Department shall determine the distance between School and Establishment property lines using the San Francisco Planning Department's online GIS mapping system.
- (b) If the Applicant appeals the denial of a permit application because the applicant disputes SFDPH's 's determination of the property's distance to a School or permitted Establishment, the Applicant may request a 30-day Tobacco Sales Permit application extension from the date of the application denial. The Applicant shall submit a report including the experience of the mapping company, surveyor, or individual conducting the analysis; method(s) used to verify distance between properties and data used; and its contents are submitted under penalty of perjury to the Director for approval.

SEC. 5. Permit Conditions

All Permittees, Permittee's agents, or employees shall comply with all local, state, and federal laws applicable to Tobacco Products and Tobacco Sales.

(1) Permittee shall pay all Tobacco Sales Permit fees.

(a) All annual license fees, including the retail tobacco license issued by the San Francisco Office of the Treasurer and Tax Collector and the tobacco products license fee issued by the State of California, must be paid in full.

(b) File and pay to San Francisco Treasurer and Tax Collector's Office on a quarterly basis the Cigarette Litter Abatement Fee as required by Chapter 105 of the San Francisco Administrative Code.

(2) Permittee shall not sell Tobacco Products to persons under 21 years of age.

Prevent the sales of tobacco products to all persons under 21 years of age by:

(a) Requesting a current and valid government issued photo identification to comply with state and federal laws.

(b) Posting readable San Francisco and California Tobacco 21 signage in a location near the point of sales for Tobacco Products and visible to all customers.

(3) Permittee shall not sell Tobacco Products with a Characterizing Flavor.

(4) Permittee shall properly display packaged Tobacco Products.

(a) Keep Tobacco Products out of reach of customers and behind the counter or in locked display cases at all times.

(b) Permittee may not sell any cigarette except in a sealed manufacturer's package that complies with federal labeling requirements. This prohibits the selling of individual cigarettes or "loosies" which is a violation of Federal law, State law, and the local San Francisco permit.

(5) Permittee shall prohibit indoor smoking.

No Permittee shall allow indoor smoking of tobacco/nicotine products or any other weed or plant in any enclosed building, including all hookah lounges/bars, restaurants, bars, taverns, and tobacco shops

(6) No Smoking signage shall be posted on Establishment's storefront and within the Establishment that is in accordance with Article 19F, Section 1009.22(i).

(7) Permittee shall designate an on-site employee for complaints or inspections.

An on-site employee shall be designated for each shift as the contact person for any complaints or inspections related to Tobacco Product Sales.

(8) Allow inspection.

Any employee or agent of the Department may enter and inspect the premises of a Permittee during Business hours, without prior notice, if the Department staff has reasonable cause to believe that a public nuisance exists. Upon presentation of proper credentials, the Department staff may enter and inspect at any time during regular business hours any Establishment that is engaging in Tobacco Sales, or is suspected by the Director of engaging in such sales.

(9) Permittee shall display permits and licenses.

A Permittee shall display all permits and licenses in a conspicuous place within their Establishment so that the permits and licenses may be readily seen by individuals entering the Establishment.

SEC. 6. Health Inspection

Health Inspections may be conducted with or without an appointment as determined by Department staff. Department staff may perform activities to ensure compliance with these Rules and any other applicable laws including, but not limited to:

- (1) Review valid permits and licenses;
- (2) Review annual tobacco control training records;
- (3) Conduct a walk-through of the Establishment including behind cashier's counter, kitchen, prep areas, storage rooms, cabinets, restrooms, offices and other rooms associated with the Establishment;
- (4) Take photographs and/or video of tobacco products;
- (5) In collaboration with the San Francisco Police Department, use decoy operations to verify compliance with age restrictions or type of products sold to customers;
- (6) Use decoy operations to determine if the Establishment is selling Tobacco Products without a Health Permit or selling Flavored Tobacco Products;
- (7) Interview any person related to the Establishment including but not limited to the Permittee, employees, or customers; and
- (8) Issue educational materials, an Inspection Report, Notice of Violation, Notice of Correction, and/or Notice of Initial Determination.

SEC. 7. Violations and Penalties

The Director may revoke or suspend a Tobacco Sales Permit, or impose administrative penalties if the Director determines that an Applicant, Permittee, Permittee's agent, or Permittee's employee has engaged in any conduct that violates local, state, or federal law applicable to Tobacco Products and/or Tobacco Sales. SFDPH shall issue a Notice of Violation to the Establishment and follow the Enforcement Procedures as set forth in Appendix A of these Rules.

- (1) Suspension Periods: The Director may suspend the Tobacco Sales Permit set forth in Article 19H section 19H.19:
 - (a) Suspension Periods for Sales of Tobacco Products to Persons under the Age of 21 shall result in a suspension of the Tobacco Sales Permit according to Table 1.

Table 1: Tobacco Sales Permit Suspension Periods for sales of Tobacco Products to persons under the age of 21

Number of Times the Violation Occurred	Permit Suspension Period
1 st violation	20 days
2 nd violation within 1 year of 1 st violation	60 days
3 rd violation within 1 year of the 2 nd violation	180 days
4 th violation that occurs within 1 year of 3 rd violation	180 days
2 nd violation that occurs more than 1 year after the 1 st violation	40 days
3 rd violation that occurs more than 1 year after the 2 nd violation	60 days
4 th violation that occurs more than 1 year after the 3 rd violation	90 days

(b) Permit suspension periods shown in Table 1 may be reduced upon written agreement with SFDPH through the mitigation strategies shown in Table 2 which may be amended from time to time:

Table 2: Tobacco Sales Permit Suspension Reduction Mitigations¹ for Violation of sales of Tobacco Products to persons under the age of 21

Mitigation Strategy		Suspension Reduction Period
1.	Training	
1a.	The Permittee trains all employees regarding state and local tobacco laws and provides SFDPH proof of training through a sign-in sheet.	-5 days
2.	Equipment and Display(s)	
2a.	Install a scanner or other age verification device (only applicable for an Establishment without an age verification device when violation occurred).	-5 days
2.	Equipment and Display(s) Continued	
2b.	Remove all Displayed Tobacco Product advertisements for as long as the Permittee owns the Establishment (only applicable for an Establishment that currently has Tobacco Product Advertisements in the public view prior to when violation occurred).	-10 days

2c.	Cover all Tobacco Products with Permanently Installed Opaque Covering which means a built-in cabinet, shelf, or storage container which cannot be removed easily and does not display tobacco to the public when a tobacco sale is not in progress (only applicable for an Establishment that currently has Tobacco Products in the public view prior to when violation occurred).	-10 days
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¹ The Permittee shall be offered mitigation strategies to reduce a permit suspension only once per year. Each suspension reduction mitigation strategy is available to Permittees once in the lifetime of their Tobacco Sales Permit.

The Equipment and Display Mitigation Strategies shall remain in effect permanently for the life of the Tobacco Sales Permit.

The written agreement will put the Permittee on notice that failure to comply with the agreed upon mitigation strategies will result in a 20-day minimum suspension.

The Permittee shall pay a reinspection fee based on the inspector's hourly rate as noted in Section 1 of these Rules, above, for all inspections and trainings conducted by the Department resulting from any violations.

SEC. 8. Permit Decisions: Right to Appeal

Decisions regarding a permit denial, suspension, revocation, and penalties are subject to appeal under Section 19H.24.

Chapter 3. Density Cap Exception

SEC 1. Definitions

For the purposes of the Density Cap Exceptions in Section 19H.6, the following words or phrases shall have the meanings set forth below.

"Density Cap Exception" means the exceptions defined in Article 19 SFHC Section 19H.6.

"Direct Negotiations" means an Original Owner is in direct negotiations with a New Buyer OR a New Buyer is in direct negotiations with aimed at reaching an agreement for the sale of the Original Owner's Retail Food Store Establishment, Tobacco Shop, Bar, or Tavern to the New Buyer.

"Effective Date" of Section 19H.6 means January 18, 2015.

"Five Years as of the Effective Date" means since January 18, 2010.

"New Buyer" means an individual or entity who is purchasing or acquiring an Establishment from the Original Owner and is applying for a SFDPH Tobacco Sales Permit seeking to continue the sales of tobacco at the Establishment's specific location.

"Original Owner" means an individual or entity who owned an Establishment and was the holder of the SFDPH Tobacco Sales Permit on January 18, 2015 and was in business at the specific location from January 18, 2010 to January 18, 2015.

“Retail Food Store Establishment” means an Establishment that sells foods, such as beverages, dairy, dry goods, fresh produce, other perishable items, beer, wine, and/or liquor sales for consumption.

“Subsequent Buyer” means an individual or entity who is purchasing an Establishment from a New Buyer and is applying for a SFDPH Tobacco Sales Permit seeking to continue the sales of tobacco at the Establishment’s specific location.

“Tobacco Shop” means any tobacco retailer whose principal business is selling Tobacco Products, tobacco paraphernalia, or both, as evidenced by any of the following: 50% or more of floor area and display area is devoted to the sale or exchange of Tobacco Products, tobacco paraphernalia, or both; 70% or more of gross sales receipts are derived from the sale or exchange of Tobacco Products, tobacco paraphernalia, or both; or 50% or more of completed sales transactions include a Tobacco Product or tobacco paraphernalia.

SEC 2. Exceptions for Certain New Permits

The Department will deny an application for a Tobacco Sales Permit for any of the reasons listed in Sections 19H.4(f) and 19.H5. (See Grounds for Permit Denial in Chapter 2, Section 4 of these Rules.)

Notwithstanding Sections 19H.4(f)(3), (4), (5), and (7) and Section 19H.5, the Director is authorized to issue a Tobacco Sales Permit on a one-time basis in the following limited circumstances under Section 19H.6:

- (1) **New Buyer of a Retail Food Store or Tobacco Shop.** A Retail Food Store Establishment or Tobacco Shop Permittee since January 18, 2010, may submit an affidavit to the Director attesting to: (a) their ownership of the Establishment; (b) under the same Tobacco Sale Permit; (c) for at least five (5) consecutive years immediately before the submission of the affidavit; and (d) Direct Negotiations. Upon submission of the Permittee’s affidavit, a New Buyer may apply for a Tobacco Sales Permit for the Permittee’s Retail Food Store Establishment or Tobacco Shop.
- (2) **Subsequent Buyer of a Retail Food Store or Tobacco Shop.** A Retail Food Store Establishment or Tobacco Shop New Buyer may submit an affidavit to the Director attesting to: (a) their ownership of the Establishment; (b) under the same Tobacco Sales Permit; and (c) for at least ten (10) years. Upon submission of the New Buyer’s affidavit, a Subsequent Buyer may apply for a Tobacco Sales Permit for the New Buyer’s Retail Food Store Establishment or Tobacco Shop. A Subsequent Buyer applying for a new Tobacco Sales Permit must acquire a 100% ownership interest in the Establishment.
- (3) **Child of Permittee.** A child of a Retail Food Store Establishment or Tobacco Shop Permittee may apply for a Tobacco Sales Permit for their parent’s Establishment if their parent holds a Tobacco Sales Permit as of January 18, 2015. The child applying for a new Tobacco Sales Permit must have a 100% ownership interest in the Establishment.
- (4) **Seismic Retrofitting Relocation.** A Retail Food Store Establishment or Tobacco Shop Permittee as of January 18, 2015, which must relocate from their Establishment due to seismic retrofitting under Chapter 34B of the Building Code may apply for a Tobacco

Sales Permit for their Establishment. The Permittee's application is subject to further review including confirmation of seismic retrofitting by the Department of Building Inspection.

- (5) **New Buyer of a Tavern.** A Tavern Permittee since January 18, 2010, that seeks to demonstrate previous compliance with Section 1009.23(d) of Article 19F of SFHC (prohibition against smoking in enclosed areas), shall submit a copy of their previously approved SFDPH application which establishes that an area within the Tavern is a historically compliant semi-enclosed smoking room. Additionally, the Tavern Permittee may submit an affidavit to the Director attesting to: (a) their ownership of the Establishment; (b) under the same Tobacco Sale Permit; (c) for at least five (5) consecutive years immediately before the submission of the affidavit; and (d) Direct Negotiations. Upon submission of the Tavern Permittee's affidavit, a New Buyer may apply for a Tobacco Sales Permit for the Permittee's Tavern.
- (6) **Subsequent Buyer of a Tavern.** A New Buyer of a Tavern may submit an affidavit to the Director attesting to: (a) their continuous ownership of the Establishment; (b) under the same Tobacco Sales Permit; and (c) for at least ten (10) years. Upon submission of a New Buyer's affidavit, a Subsequent Buyer may apply for a Tobacco Sales Permit for the New Buyer's Tavern. A Subsequent Buyer applying for a new Tobacco Sales Permit must acquire 100% ownership of the Establishment.
- (7) **Death or Divorce.** A spouse or domestic partner may acquire the ownership from the Permittee of an Establishment through the death or divorce. The spouse or domestic partner applying for a new Tobacco Sales Permit must have a 100% ownership interest in the Establishment.

If an owner or entity is applying for an Exception set forth in 19H.6, proof of documentation of a Direct Negotiation is required and shall be submitted with the Permit Application, including but not limited to: escrow documents, notarized letter regarding sale of the business with the Permittee and New Buyer or Subsequent Buyer, and/or alcohol license sales contract. Other documentation may be required by the Department in order to confirm any Exceptions for Certain New Permits listed in Chapter 3, Sec 2.

Chapter 4. Favored Tobacco Products (Article 19Q of the SFHC)

SEC 1. Definitions

As used in these Rules, the following words or phrases shall have the meanings set forth below.

"Marketing" means the process or technique of promoting, selling, and distributing a product or service.

SEC 2. Penalties for Violation of Article 19Q

- (1) Abatement opportunity.

For a first time violation of Article 19Q (Prohibiting the Sale of Flavored Tobacco Products), a Permittee will be afforded the opportunity to remove Tobacco Products with a Characterizing Flavor from their Establishment in lieu of a permit suspension or

administrative penalty. 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.

- (2) Violations of Article 19Q (Prohibiting the Sale of Flavored Tobacco Products) shall result in a suspension of the Tobacco Sales Permit according to Table 3.

Table 3: Tobacco Sales Permit Suspension Periods for Sales or Distribution of Tobacco Products with a Characterizing Flavor: second or subsequent violations

Number of Times the Violation Occurred	Permit Suspension Period
1 st violation	10 days
2 nd violation	20 Days
3 rd violation	40 Days
4 th and each violation afterwards	90 Days

SEC 3. Flavored Tobacco Products List

- (1) SFDPH will develop and maintain a non-exhaustive Flavored Tobacco Products List to facilitate compliance with and enforcement of Article 19Q. The Flavored Tobacco Products List will be maintained on SFDPH's website:

<https://www.sfdph.org/dph/EH/Tobacco/flavoredtobacco.asp>

- (2) The Flavored Tobacco Products List will include:

- (a) Tobacco Products that SFDPH has determined to be Flavored Tobacco Products based on their taste or aroma.
- (b) Tobacco Products SFDPH presumes to be Flavored Tobacco Products based on their Labeling, Packaging, or Marketing. SFDPH will presume that a Tobacco Product is a Flavored Tobacco Product if the Manufacturer or any of the Manufacturer's agents or employees has made a statement or claim directed to consumers or to the public that the Tobacco Product has or produces a Characterizing Flavor, including, but not limited to, text, color, and/or images on the product's Labeling or Packaging that are used to explicitly or implicitly communicate that the Tobacco Product has a Characterizing Flavor. SFDPH will presume that a Tobacco Product is flavored if its Labeling, Packaging, or Marketing include descriptive terms such as "spicy" and "sweet" that imply or evoke Characterizing Flavors. SFDPH will not presume that a Tobacco Product is a Flavored Tobacco Product if the only descriptors that appear on its Labeling, Packaging, or Marketing are "strong," "mild," or "plain," where those descriptors appear to be referring to the taste of tobacco.
- (c) Tobacco Products that have been found by an administrative law judge to be Flavored Tobacco Products, following an administrative hearing. SFDPH will

update the Flavored Tobacco Products List to include such products within 14 days of the issuance of an administrative decision.

SEC 4. Permittee Inquiry about Flavored Tobacco Products

A Permittee may inquire of SFDPH whether a Tobacco Product is a Flavored Tobacco Product for purposes of Article 19Q by sending an inquiry to 1390 Market Street, Suite 210, San Francisco, CA 94102 or SF-FlavoredTobacco@sfdph.org. Such inquiry must include the brand, product name, product type, and either (1) a photocopy, photograph, or digital image of the products packaging and labeling, or (2) a web link to digital images of the product's packing and labeling. If SFDPH determines that the Tobacco Product is Flavored based on its aroma or taste, or that it is presumed to be flavored based on its Packaging, Labeling, or Marketing, SFDPH will update the Flavored Tobacco Products List within 45 days of the receipt of the inquiry, and will advise the Permittee of its conclusions within the same time frame.

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.”

Electronic Cigarette includes any device or delivery system sold in combination with nicotine for a single price.

"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.

“Sell,” “Sale,” and “to Sell” means any transaction, including but not limited to transactions over the phone, in person, or online, where, for any consideration, ownership of a Tobacco Product is transferred from one Person to another, including but not limited to any transfer of title or possession for consideration, exchange, or barter, in any manner or by any means.

“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 SFDPH’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 and distribution of any and all Tobacco Products that have a Characterizing Flavor as defined in Chapter 2 of these Rules. 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 Chapters 2 and 4 of these Rules.)

SEC 4. Penalties for Violation of Article 19R

(2) 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 display and/or 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.

(3) 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 SFDPH 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, SFDPH shall issue a citation for administrative penalties and shall make a referral to the City Attorney for enforcement.