Appendix A: Summary and Response to Comments

45-Day Public Comments and Department of Justice Responses				
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Chapter 11. Unflavored Tobacco List Article 1. General				
§ 942. Definitions				
Applicants, subd. (a)	16-17	The Department of Justice ("Department" or "DOJ") should clarify that either a manufacturer or importer may submit applications for imported products (but both need not) or alternatively, provide a mechanism for coordination to avoid duplicate submissions when both a manufacturer and importer are involved in the distribution chain. The commenter notes that the alleged ambiguity is particularly problematic for imported tobacco products, where both the overseas manufacturer and the U.S. importer could reasonably interpret the regulations as requiring them to submit applications independently.	No changes have been made to the regulations in response to this comment. The regulations are reasonably clear. Proposed Section 942, subdivision (2) defines an "Applicant" to the Unflavored Tobacco List (UTL) as "a Manufacturer *or* Importer." (Emphasis added). A UTL application for a tobacco product's placement on the UTL from either entity is sufficient. If the product manufacturer is not based in the United States, the manufacturer and importer, not the Department, are best suited to determine which entity is better able to apply for the product's placement on the UTL.	278, 280

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What constitutes flavor, subd. (f)	3-3, 20-1, 21-1	The Attorney General should avoid narrowly interpreting what qualifies as an unflavored tobacco product because that would limit legal options for consumers and risk consumers purchasing from illicit channels. Illicit products pose greater risks because of the lack of age verification and other compliance. Legal sales of unflavored tobacco products have decreased, while online, out-of-state, and illicit sales continue; these sources do not collect taxes or verify age. At the wholesale level, fewer lawful products means fewer compliant distribution channels. The result is the creation of an unfair marketplace that harms law-abiding businesses, undermines the policy intent,	No changes have been made in response to this comment, which is interpreted to be an observation rather than a specific recommendation to change the regulations. As provided in the definitions, "[a] Brand Style 'lacks a Characterizing Flavor' if it lacks any Constituent that imparts a Characterizing Flavor." (Proposed Section 942, subd. (g).) A "Characterizing Flavor" has the same meaning as set forth in the authorizing statute, Health and Safety Code section 104559.1, and "means a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco, including, but not limited to, tastes or odors relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice, or a cooling sensation distinguishable by an ordinary consumer during the consumption of a tobacco product." (Proposed Section 942, subd. (g); Health & Saf. Code, §§ 104559.1, subd. (s)(2); 104559.5, subd. (a)(1).) The Attorney General will assess whether brand styles are flavored based on that definition.	015-016, December 23, 2025 Regulatory Hearing Transcript (TR) at 13:18-14:4, 18:10-19:8

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		and increases public health risks. Tax revenue for the state is lost, estimated to be between $0.3 to $1.5 billion by different sources. “A report from the Mackinac Center shows that California now ranks first among states in cigarette smuggling” (emphasis removed). History shows that government mandated prohibition does not eliminate demand, and a more effective approach strives for clarity, responsible retailing, and education, rather than an overly restrictive product list.		
What constitutes flavor, subd. (f)	4-3	When a tobacco product is deemed unflavored “under the statutory and regulatory framework of another state with substantially similar prohibitions on flavored tobacco products,” that	No changes have been made to the regulations in response to this comment. The regulations are consistent with Health and Safety Code, section 104559.1, which requires the Attorney General to establish and maintain a list of “tobacco product brand styles that lack a characterizing flavor,” defines “characterizing	022-023

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		determination constitutes persuasive evidence of the product's conformity with the criteria set forth in Health and Safety Code section 104559.1, subdivision (a), and section 104559.5, subdivision (b)(1). Disregarding such recognition "would impose an arbitrary and duplicative burden upon manufacturers and importers, contravening principles of administrative efficiency and interstate comity." The commenter proposes the Attorney General deem inclusion of a product on another state's unflavored tobacco registry as "prima facie evidence warranting placement on California's UTL, subject to verification of certification requirements."	flavor," and requires the Attorney General to "determin[e] whether or not a brand style has a characterizing flavor" based on the information submitted by a manufacturer or importer, among other factors. (Health & Saf. Code, §§ 104559.1, subds. (a), (c), (s)(2); 104559.5, subd. (a)(1).) The regulations permit applicants to "provide additional information or comments regarding the Brand Style that Applicant considers relevant to the Attorney General's determination as to whether the Brand Style is an unflavored Tobacco Product." (Proposed Section 945, subd. (c)(11).) Applicants shall submit determinations from other jurisdictions as part of their supporting documentation. While the Department will consider such determinations as a factor in its evaluation, they do not dictate or replace the Department's independent review of a brand style's eligibility for the UTL.	
What constitutes, flavor, subd. (f)	11-8, 16-11	The lack of clear criteria for what marketing triggers the presumption that a tobacco	No changes have been made to the regulations in response to this comment. The regulations	275-276, 109, 275-276, 279-280

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		product qualifies as a "flavored tobacco product" invites subjective judgments and inconsistent outcomes. Flavor determinations should not be based on the statutory presumption created by statements of claims regarding flavor. Any flavor determination must be based on the constituents. The presumption based on marketing also violates the First Amendment. This is a burden on speech because manufacturers and importers would not be subject to the same rebuttable presumption about their products if they instead remain silent and did not speak. Further, there are multiple less burdensome alternatives available that are better suited to achieve the statute's purpose, such as imposing a rebuttable presumption when applicants	are consistent with the presumption set forth in the statute. Subdivision (b)(2) of Health and Safety Code section 104559.5 states: "There is a rebuttable presumption that a tobacco product is a flavored tobacco product if a manufacturer or any of the manufacturer's agents or employees, in the course of their agency or employment, 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, images, or all, on the product's labeling or packaging that are used to explicitly or implicitly communicate that the tobacco product has a characterizing flavor." (Health & Saf. Code, § 104559.5, subd. (b)(2).) The statutory provision presumes that when a manufacturer says a brand style tastes like something, it often does. The presumption is triggered when a manufacturer makes statements regarding the brand style's flavor, but the presumption can be rebutted by the applicant. Ultimately, flavor determinations are made based on whether the brand style lacks a characterizing flavor. (*Id*., § 104559.1, subd. (e).)	

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		state that their products include ingredients other than tobacco that impart a characterizing flavor such as a "special blend of herbs and spices added to the product," or having regulations that focus on the inclusion of non-tobacco additives rather than speech about the products. Premium cigar branding often uses artistic designs and descriptions that do not denote flavor. "If DOJ's goal is flavored product enforcement, DOJ should target submissions and evidence requirements to where characterizing flavor risk is real, not impose maximum burden on traditional unflavored cigars. Descriptions of cigars that have not been artificially enhanced should not limit speech of characterizing description."	The proposed "less burdensome" alternatives to the rebuttable presumption fail to satisfy the State's interest in identifying products where the fact that "the tobacco product has or produces a characterizing flavor" is implicitly conveyed. For instance, limiting the presumption to cases where an applicant explicitly discloses ingredients that impart a characterizing flavor is redundant; such a disclosure already confirms the product's disqualification from the UTL. Furthermore, a presumption focused solely on non-tobacco additives is ineffective because: (1) manufacturers often fail to accurately disclose additives, and (2) the mere presence of an additive in a product does not guarantee it reaches the threshold necessary to impart a non-tobacco flavor distinguishable by an ordinary consumer. Furthermore, the court in *Rocky Patel Cigars, Inc.* concluded that plaintiffs would be unlikely to succeed on the merits of the claim that this provision violates the First Amendment because it is "narrowly tailored to serve the State's interest in banning flavored tobacco products." (*Rocky Patel Premium Cigars, Inc.*	

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			v. Bonta (C.D. Cal., Dec. 23, 2025, No. 8:25-CV-02244-MRA(PDX)) 2025 WL 3903972, at *16-18, app. pending, 9th Cir., Dec. 26, 2025, No. 25-8060.)	
Definition of Tobacco Product, subd. (o)	4-1	The proposed regulations appear to treat any product resembling a finished product as subject to UTL listing. However, certain finished products would not be considered a "finished tobacco product," such as additives and ingredients, which are intended solely for further manufacturing: for example, liquid nicotine. "Under Cal. Code Regs. tit. 11, §945(d), UTL listing is required for components or parts that contain nicotine intended for inhalation. Yet, the definition of a 'tobacco product' in Health & Safety Code §104559.5(a)(17) focuses on products 'intended for human consumption.' Ingredients requiring further	No changes have been made in response to this comment. The regulations are reasonably clear. For purposes of inclusion on the UTL, the definition of "tobacco product" includes a product "intended for human consumption" (Health & Saf. Code, § 104559.5, subd. (a)(17)(i)), an electronic device that delivers nicotine or other vaporized liquids "to the person inhaling from the device" (*id*., at subd. (a)(17)(ii)), and an accessory, component, or part that contains nicotine or liquid "intended to be vaporized and inhaled." (*Ibid*); Proposed Section 945, subd. (d).) If an ingredient or additive does not fall within these categories, it is not covered by the UTL.	019-021

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		processing do not meet this criterion." Under federal law, "[i]ngredients and additives of a tobacco product have never been a category of a 'finished tobacco product'" requiring premarket review. *See* 21 U.S.C.A §387(1). The commenter requests clarification that ingredients and additives to a "finished tobacco product" which are intended for further manufacturing, are not considered "a finished tobacco product" under [Section 945] and therefore do not require inclusion on the UTL.		
Definition of Tobacco Product, subd. (o)	4-4	"If California intends to require the listing of ingredients and additives sold for further manufacturing, the rule should specify a simplified mechanism," such	No changes have been made in response to this comment. The regulations are reasonably clear. For purposes of inclusion on the UTL, the definition of "tobacco product" includes a product "intended for human consumption" (Health & Saf. Code, § 104559.5, subd.	023

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		as categorizing them as Other Tobacco Products under Section 945, subdivision (c)(4), with minimal filing requirements. This would prevent unnecessary burdens while maintaining compliance. The commenter asks the Department to clarify definitions where ambiguity exists to avoid unintended inclusion of non-consumer-facing ingredients and additives and seeks clarification as to whether there will be a separate mechanism for manufacturers and importers to submit to the Department a "sister" list of ingredients and additives that are items which are not subject to listing on the UTL.	(a)(17)(i)), an electronic device that delivers nicotine or other vaporized liquids "to the person inhaling from the device" (*id*. at subd. (a)(17)(ii)), and an accessory, component, or part that contains nicotine or liquid "intended to be vaporized and inhaled." (*Ibid*; Proposed Section 945, subd.(d).) If an ingredient or additive does not fall within these categories, it is not covered by the UTL.	
Definition of Tobacco Product, subd. (o)	5-4	Certain products are manufactured solely for further manufacturing and cannot be used as-is without posing significant health risks regardless of whether they are	No changes have been made in response to this comment. This comment raises specific legal questions and seeks legal advice and is therefore irrelevant to the proposed rulemaking. Furthermore, the regulations are reasonably clear. For purposes of inclusion on the UTL,	028-029

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		flavored. "California should not classify products in need of further manufacturing as tobacco products because the CA Health & Safety Code derives tobacco product definitions and regulatory practices from the FFDCA [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.]." Under Cal. Code Regs. tit. 11, §945(d), UTL listing is required for components or parts that contain nicotine intended for inhalation. Yet, the definition of "tobacco product" in Health & Safety Code §104559.5(a)(17) focuses on products "intended for human consumption." Products manufactured for further manufacturing, regardless of flavoring, do not meet this criterion.	the definition of "tobacco product" includes a product "intended for human consumption" (Health & Saf. Code, § 104559.1, subd. (a)(17)(i)), an electronic device that delivers nicotine or other vaporized liquids "to the person inhaling from the device" (*id*. at subd. (a)(17)(ii)), and an accessory, component, or part that contains nicotine or liquid "intended to be vaporized and inhaled." (*Ibid*; Section 945, subd.(d)). If an ingredient or additive does not fall within these categories, it is not covered by the UTL.	

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		The commenter seeks clarification that both flavored and unflavored Electronic Nicotine Delivery Systems (ENDS) intended for further manufacturing may be lawfully sold within the state, and that regardless of flavoring such products may be sold without inclusion on the UTL because they are not considered finished tobacco products under Cal. Code Regs. tit. 11, §945, or any other provision.		
The UTL generally, subd. (p)	15-1, 16-18	Incorporates in this comment all arguments made in judicial challenges to the statute and emergency regulations.	No change has been made in response to this comment. The Attorney General is defending the emergency UTL regulations in litigation arising under the California Administrative Procedure Act in *Rocky Patel Premium Cigars, Inc., et al. v. Bonta*, 25STCV29644 (Cal. Super. Los Angeles); the superior court's denial of plaintiff's motion for a preliminary injunction in that matter is currently before the Second District Court of Appeal in *Rocky Patel Premium Cigars, Inc. v. Bonta* (Apr. 16, 2026, B352839). The Attorney General is also defending the UTL statute and emergency	264, 269

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			regulations against constitutional challenges in *Rocky Patel Premium Cigars, Inc. v. Bonta* (C.D.Cal., No. 8:25-cv-02244); the district court's denial of plaintiff's motion for a preliminary injunction in that case is currently before the Ninth Circuit Court of Appeals in *Rocky Patel Premium Cigars, Inc. v. Bonta* (9th Cir., Jan. 1, 2026, No. 25-8060). For a full statement of the Attorney General's position and arguments in these judicial challenges, please see the Attorney General's publicly-filed briefs for these dockets. For information on accessing these documents, please visit https://pacer.uscourts.gov/ and https://courts.ca.gov/policy-administration/public-records.	
The UTL generally, subd. (p)	9-1	The UTL requirements and structure impose an unfair and disproportionate burden on smaller tobacco product manufacturers, who often lack the financial resources, staff, or infrastructure to comply with the extensive application process, including the $300 initial fee per brand style and subsequent annual	No change has been made in response to this comment. The regulations cannot change the statutory scheme set forth in Assembly Bill 3218. Under Health and Safety Code section 104559.1, subdivision (b)(1), requires "[e]very manufacturer and every importer of tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor." Assembly Bill 3218	095

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		renewals. This creates a significant barrier to entry and operation, effectively creating a market vacuum that allows larger, well-resourced manufacturers to dominate the industry. Requiring manufacturers to register unflavored products on the UTL in order to govern and restrict the broader sale of tobacco products does not make logical sense. Registering one category of products as a means to enforce controls over another introduces unnecessary complexity and inefficiency, further disadvantaging smaller entities that may struggle to navigate such convoluted requirements. The Department should provide exemptions, reduced fees, or streamlined processes for small manufacturers.	provides no exemption for submissions by small manufacturers. The statute also mandates that manufacturers and importers provide a description of each unique brand style, the brand style's status with FDA, and authorizes a fee of up to $1,000 that covers the Department's reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).) Consistent with these mandates, the Attorney General has developed application criteria necessary to distinguish brand styles and evaluate an applicant's certification that a brand style lacks a constituent that imparts a characterizing flavor, as well as a fee structure that covers the Attorney General's costs for operating and maintaining the UTL. The Attorney General declines to exempt small manufacturers from the application process required of other manufacturers, because the information sought is required to evaluate and distinguish products, regardless of the size of the manufacturer. The Attorney General also declines to offer reduced fees for small manufacturers, because their products require similar resources to process as those submitted by other manufacturers.	

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The UTL, subd. (p)	2-2	The UTL and California Business and Professions Code section 22980 "is just illegal" and the "constitutional implications of the search and seizure provisions alone are particularly disturbing."	No change has been made in response to this comment. The Department does not interpret this comment as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). The comment relates to the statutes enacted under Assembly Bill 3218, rather than the regulations, and the commenter does not propose any alternative language for the regulations.	010
The UTL, subd. (p)	2-3	The Department "lacks authority to adopt or otherwise implement the proposed regulatory act" under the Administrative Procedures Act. Assembly Bill 3218 was not a lawful delegation of authority.	No change has been made in response to this comment. The Legislature authorized the Department to promulgate regulations to implement Assembly Bill 3218. (Health & Saf. Code, § 104559.1, subd. (q).) The comment does not relate to any particular regulatory provision or propose any alternative language for the regulations.	011
The UTL, subd. (p)	3-4, 20-2	Enforcement has been inconsistent across the state, which has caused confusion and risk for retailers. The Attorney General's Office should encourage local jurisdictions that have enacted their own flavor bans to adopt the UTL as the standard for	No changes have been made to the regulations in response to these comments. Assembly Bill 3218 explicitly permits local jurisdictions to adopt more restrictive local ordinances, including "standards or definitions for a characterizing flavor that are more restrictive." (Health & Saf. Code, § 104559.1, subd. (r).)	016, TR: 14:4-11

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		enforcement and otherwise promote unform enforcement.		
The UTL, subd. (p)	2-1, 5-1, 8-4, 8-7, 16-13	The UTL "blatantly violates federal law specifically precluding additional premarket review." Assembly Bill 3218 conflicts with and/or is preempted by federal law: the Tobacco Control Act (TCA), 21 U.S.C § 387p. The TCA preempts state requirements that are different from, or in addition to, federal requirements relating to product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing practices, and modified-risk tobacco products. To the extent the UTL requires manufacturers to certify compliance with federal authorization pathways and permits the Attorney General to exclude unauthorized electronic nicotine delivery systems	No change has been made in response to these comments. The Department does not interpret any of the comments as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). The comments appear to relate to the statute, Assembly Bill 3218, rather than the regulations, and they do not propose any alternative language for the regulations. The Preemption Clause of the Tobacco Control Act (TCA) does not extend to the state regulations here because the TCA preempts only state regulations that are "different from, or in addition to, any requirement under the *provisions of [the TCA]* relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." 21 U.S.C. § 387p(a)(2)(A) (emphasis added). The UTL regulations and the statutory authority authorizing those regulations (Health & Saf. Code § 104559.1) do not impose additional or	003-010, 026-027, 045, 047, 276-277, 280

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		from the list, it operates as a state-level premarket screening tied to FDA status. If the Attorney General conditions market access on FDA authorization or imposes documentation that effectively replicates federal premarket review, the UTL risks creating requirements "different from, or in addition to" federal requirements in preempted domains. The UTL regulations operate in parallel with, and in practice replicate, the FDA's premarket tobacco product application framework by conditioning lawful sale on product-specific determinations, evaluating chemical composition and product characteristics, and functioning as a gatekeeper to market access. This state-level framework intrudes into an area occupied by federal law.	different requirements than the TCA's requirements relating to premarket review. Nor does the UTL statute or implementing regulations have any effect on manufacturing tobacco products, or on their introduction into or receipt in interstate commerce. Instead, the UTL applies only to sales of tobacco products in and into the California consumer market. (Health & Saf. Code, § 104559.1, subds. (b)(1), (o).) The TCA includes a Savings Clause, which expressly exempts from preemption state laws, such as the UTL regulations and Health and Safety Code section 104559.1, that "relat[e] to the sale, distribution, possession [of tobacco products], [or] information reporting to the State." (21 U.S.C. § 387p(a)(2)(B).) The TCA leaves states free to "impose[] a sales ban on flavored tobacco products and require[] tobacco companies… to identify whether they are subject to the sales ban or not." (*Rocky Patel Premium Cigars, Inc. v. Bonta* (C.D. Cal., Dec. 23, 2025, No. 8:25-CV-02244-MRA(PDX)) 2025 WL 3903972, at *5, app. pending, 9th Cir., Dec. 26, 2025, No. 25-8060.) The Department therefore declines to delay implementation of the proposed regulations.	

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		What sets the UTL regulatory scheme apart from otherwise acceptable regulation of tobacco product sales is that it does not operate at the point of sale, but on the manufacturers and importers prior to allowing a product on the market. Unlike general sales restrictions, the UTL compels out-of-state actors to submit to California-specific procedures and timing or be categorically barred, triggering heightened scrutiny of burdens versus benefits established by the Supreme Court under *Pike v. Bruce Church, Inc.* (1970) 97 U.S. 137 (1970) (striking down state law on packaging of cantaloupes.). In *R.J. Reynolds Tobacco Co. v. Bonta* (S.D. Cal. Mar. 15,		

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		2023) 661 F. Supp. 3d 1009, the court upheld Senate Bill 793, which sought a ban on flavored tobacco products, because it was a state retail sales restriction, not a duplicative compliance regime. The UTL introduces additional compliance layers beyond retail enforcement. The Department should delay permanent adoption pending resolution of substantial federal preemption issues.		
The UTL, subd. (p)	2-1, 5-2, 8-4, 16-12	The UTL framework risks violating the Commerce Clause. Assembly Bill 3218 applies facially to products sold in California, but "may impose changes to labeling, marketing, and distribution practices nationwide" and on foreign importers, especially for those selling product into California in order to accommodate California's standards. The compliance	No change has been made in response to these comments. The Department does not interpret any of the comments as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). The comments relate to the enactment of the UTL under Assembly Bill 3218, rather than the regulations, and they do not propose any alternative language for the regulations.	003-010, 027-028, 045, 276, 280

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		costs and logistical hurdles of the UTL could wall off the California market from out-of-state manufacturers and importers. The benefits of duplicative certification beyond existing FDA pathways and enforcement of Senate Bill 792 enforcement are marginal, whereas the burdens on interstate and foreign commerce, including product seizure and civil penalties, are substantial, risking violation of the Commerce Clause. Under the Commerce Clause, a law is invalid if the burdens on interstate commerce are clearly excessive in relation to the local benefits. The burden on interstate commerce will ordinarily be found unreasonable where the state regulation substantially impedes the free flow of	Assembly Bill 3218 penalizes those who possess illicit products for sale in the State or who make illicit sales in the State, rather than reaching out of State to directly regulate the manufacturers or importers of those products. Inclusion on the UTL and UTL application and renewal fees are required only for products "for sale or distribution in or into California." (Health & Saf. Code, § 104559.1, subds. (b)(1), (k)(1).) For any tobacco product not intended for sale or distribution in California, no fees attach; such products cannot be sold downstream into the retail and consumer market in California. (See Health & Saf. Code, § 104559.1, subd. (o).) Finally, neither Assembly Bill 3218 nor the implementing regulations regulate labeling or marketing.	

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		commerce from state to state or governs "those phases of the national commerce which, because of the need of national uniformity, demand their regulation, if any, be prescribed by a single authority." (See *Partee v. San Diego Chargers Football Co.* (1983) 34 Cal. 3d 378, 382-83, quoting *Southern Pacific Co. v. Arizona* (1945) 325 U.S. 761, 767.) The Commerce Clause permits only incidental regulation of interstate commerce by the states; direct regulation is prohibited. The UTL regulations should be presumptively invalid unless the state can demonstrate they are necessary to achieve a legitimate local purpose and that no less discriminatory alternatives exist.		

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The UTL, subd. (p)	5-3	Numerous states and localities maintain distinct tobacco-product registration, certification, or pre-clearance regimes but the UTL regulations further require application packets, fees for initial and renewed placement, samples, and rolling update schedules, with late submissions deferred to future cycles mandating continuous compliance investments to preserve market access. When layered on top of the regimes of other jurisdictions, the obligations under the UTL regulations amount to multiple registrations for products already reviewed, authorized, or deemed by FDA, without demonstrable incremental public-health benefit. "Unless harmonized with federal pathways or streamlined for multi-state	No change has been made in response to this comment. The comment primarily relates to the enactment of the UTL under Assembly Bill 3218, rather than the regulations, and does not propose any alternative language for the regulations. Assembly Bill 3218 and the implementing regulations are permissible as "Congress made an explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products." (*R.J. Reynolds Tobacco Co. v. County of Los Angeles* (9th Cir. 2022) 29 F.4th 542, 550.)	028

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		operators, AB 3218's UTL will remain an outlier that amplifies regulatory fragmentation and invites constitutional scrutiny."		
The UTL, subd. (p)	7-4, 13-4, 14-10, 14-20, 18-4, 19-4	Enforcement of the flavor ban should occur through retail licensing like Massachusetts rather than per-SKU registration. Retail licensing would incur a $0 manufacturer fee versus California's $300-$450 per SKU fee.	No changes have been made to the regulations in response to these comments. The regulations cannot change the statutory scheme set forth in Assembly Bill 3218. Assembly Bill 3218 provides for the Attorney General to create and establish a list of unflavored tobacco products, not enforcement through retail licensing. (Health & Saf. Code, § 104559.1, subd. (a), (g) ["Any brand style not on the UTL shall be deemed a flavored tobacco product under subdivision (b) of Section 104559.5]; see *id.* § 104559.5, subd. (b)(1) ["A tobacco retailer, or any of the tobacco retailer's agents or employees, shall not sell, offer for sale or possess with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer."].) The Department further notes that the benefits of a centralized list of unflavored tobacco products are that anyone may review approved products and that the products are reviewed by the Attorney General's office.	039-040, 118-119, 127-128, 130, 291, 295

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The UTL, subd. (p)	7-4, 11-6, 13-4, 16-10	There should be a retailer sell-through provision for products that were previously lawful. One commenter proposes a retailer sell-through provision that states: (a) A retailer possessing tobacco products purchased prior to January 1, 2026, not on the UTL, may sell such products until June 30, 2026, or until inventory exhausted. (b) Applies only to products lawfully acquired before manufacturer withdrawal. (c) Retailers shall maintain acquisition records available upon Attorney General request.	No changes have been made to the regulations in response to these comments. The regulations cannot change the statutory scheme set forth in Assembly Bill 3218. Assembly Bill 3218 requires the Attorney General to create and establish a list of unflavored tobacco products and further provides that "[a]ny brand style not on the UTL shall be deemed a flavored tobacco product under subdivision (b) of Section 104559.5" and prohibited from retail sale in the state. (Health & Saf. Code, § 104559.1, subd. (a), (g); see *id*. § 104559.5, subd. (b)(1) ["A tobacco retailer, or any of the tobacco retailer's agents or employees, shall not sell, offer for sale or possess with the intent to sell or offer for sale, a flavored tobacco product or a tobacco product flavor enhancer."].) Tobacco products containing a constituent that imparts a characterizing flavor, subject to exceptions, were already illegal for retail sale prior to Assembly Bill 3218 and the publication of the UTL. (Health & Saf. Code, § 104559.5, subds. (a)(1), (a)(6), (b)(1).) Under Assembly Bill 3218 and the implementing regulations, retailers will have 30 days of notice when brand styles are removed from the UTL. Assembly Bill 3218 provides	039-040, 109, 118-119, 274, 279

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			that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Saf. Code, section 104559.1, subds. (d).) (f)(2)(B).) The regulations provide that,"[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).)	
The UTL, subd. (p)	8-1, 8-7	The regulations exceed the statutory authority granted by Assembly Bill 3218, which "authorizes the Attorney General to establish and maintain" an unflavored list. It does not authorize a "discretionary, ongoing product approval regime that conditions lawful market participation on extensive evidentiary submissions, scientific determinations, renewal fees, and continuing compliance obligations beyond those expressly set	No changes have been made to the regulations in response to this comment. The comment contends that the Attorney General lacks authority for 1) requiring evidentiary submissions and scientific determinations, 2) renewal fees, and 3) continuing compliance obligations. Assembly Bill 3218 requires manufacturers to "describe" each brand style. (Health & Saf. Code, § 104559.1, subd. (b)(1)(A).) These regulations specify what is required to describe each brand style. Furthermore, the statute authorizes that, upon the request of the Attorney General, applicants must provide "additional information and factual substantiation regarding a brand style's lack of characterizing flavor" and "additional	044, 047

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		forth by the Legislature." The regulations transform the statutory scheme because rather than implementing a retail sales prohibition, they impose a state-level product gatekeeping framework in which market access depends on the Department's approval and ongoing regulatory discretion. The regulations empower the Department to "evaluate product composition, assess technical characteristics, deny or revoke product eligibility, and condition continued sale on compliance with standards not specified in the statue itself. Because the regulations "enlarge[], alter[], or amend[] the scope of" the statute, they are invalid. The Department should narrow the proposed regulations to conform strictly to statutory authority.	information and documentation regarding tobacco product status, packaging, or marketing of a brand style." (Health & Saf. Code, § 104559.1, subds. (b)(2)(A), (b)(3)(A).) The statute requires the collection of an annual renewal fee. (*Id*., subd. (k)(1).) Beyond the renewal fee and requirements to provide additional information noted above, it also contemplates continued compliance with the requirement to update the Attorney General when manufacture or importation ceases, or when the product becomes flavored. (*Id.*, subds. (f)(1) ["The Attorney General shall remove from the UTL any brand style that the Attorney General determines has a characterizing flavor"], (h).)	

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The UTL, subd. (p)	14-8, 14-25, 16-10, 20-3, 22-4	Because the list was published December 31, 2025, and that day and the next day were holidays, retailers could not possibly comply by removing non-listed products, which raises due process and fairness concerns. The regulations have the effect of retroactively punishing retailers for their possession of products that were legal to possess and offer for sale one day before the publication of the UTL. There should be a grace period to sell through inventory acquired before the initial UTL was published, or realistic transition period so manufacturers can list products, wholesalers distribute them, and retailers can sell them legally without fear of being confiscated.	These comments are focused on the emergency regulations and do not appear to address the effect of the proposed permanent regulations. No changes have been made to the regulations in response to these comments. Flavored tobacco products are illegal in California, regardless of, and before the publication of, the UTL. Further, Assembly Bill 3218 provides that "[a]ny brand style not on the UTL shall be deemed a flavored tobacco product," regardless of the date of publication of the list. (Health & Saf. Code, § 104559.1, subd. (g).) This rulemaking cannot alter the statute. With respect to enforcement, the Department issued an information bulletin that provides in part: "For tobacco products that are not included in the initial publication of the UTL and are not obviously flavored (including hand-rolled leaf cigars), DOJ intends to initially focus on providing manufacturers with education on the statutory requirements and registration process, rather than taking immediate enforcement action. Registration of unflavored tobacco products is conducted on a rolling basis and may be completed at any time at https://utl.doj.ca.gov/. Manufacturers and retailers are warned that, absent registration and inclusion on the UTL, such products are and	127, 130, 274, 279, TR 14:14-15:1, TR 22:11-17

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			will remain subject to seizure and penalties by enforcement agencies. (See, e.g., Bus. & Prof. Code, §§ 22974.2, 22978.3.) This Information Bulletin does not alter or amend applicable law, nor does it contravene manufacturer and retailer responsibility to comply with current laws, rules, and regulations." (Department of Justice, 2025-DLE-17, Enforcement of Flavored Tobacco Products—Unflavored Tobacco List Next Steps, https://oag.ca.gov/system/files/media/2025-dle-17.pdf.)	
The UTL, subd. (p)	14-9, 14-12, 14-27, 22-2	There is no authority for a retailer to register a product on the UTL, but retailers face enforcement risk for products on their shelves. The Department should list products pending review to create a statute-compliant safe harbor by creating a new section 944.5 where complete applications are listed—and therefore eligible for sale—as "pending review" on the UTL. A product designated "Pending Review" would be	No changes have been made to the regulations in response to these comments. Assembly Bill 3218 limits the UTL to those brand styles that "lack a characterizing flavor" and provides that "[a]ny brand style not on the UTL shall be deemed a flavored tobacco product" (Health & Saf. Code, § 104559.1, subds. (a), (g).) Brand styles with pending applications are not eligible for sale during review because the Department must assess the application for completeness and the brand styles associated with that application for eligibility. (See Health and Saf. Code, § 104559.1, subds. (b) [describing information applicants must provide with product submissions], (e) ["The	127, 128, 130, TR 22:17-21

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		listed, and therefore not deemed flavored, while the Department retains the ability to remove products upon final adverse determination. Products that are pending review should not be eligible for penalties. One commenter proposes the following language to establish a safe harbor: "(a) Upon submission of a complete application under Section 947 and payment of the fees required by Section 954, a Brand Style shall be immediately designated as "Pending Review" on the UTL website. (b) A product designated as "Pending Review" shall be subject to enforcement discretion: the Attorney General shall not pursue civil penalties under Section 955 against any retailer, distributor, or delivery seller for the sale of	Attorney General shall decline to include on the UTL any brand style that the Attorney General reasonably determines has a characterizing flavor" and "may decline to include on the UTL any brand style that is adulterated as defined in Section 387b of or misbranded as defined in Section 387c of the FFDCA…"], (b)(2)-(3) [the Attorney General may request "additional information and factual substantiation regarding a brand style's lack of characterizing flavor" and "tobacco product status, packaging, or marketing of a brand style"].) Because brand styles under review are not yet eligible for the UTL and may ultimately be denied, establishing a "Pending Review" safe harbor could result in market confusion and create a false imprimatur with respect to products that may never be authorized for inclusion on the list. Furthermore, applicants have expressed concerns over confidentiality for brand styles that have yet to be officially announced and released in California. For these reasons, the Department declines to create a safe harbor or set an enforcement priority via regulation with respect to brand styles with pending applications.	

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		such product until the Attorney General issues a final determination approving or denying the application. (c) Upon approval, the product shall be transferred to full "Listed" status. Upon denial, and exhaustion of any appeal under Section 949, the "Pending Review" designation shall terminate and enforcement discretion shall no longer apply."		
The UTL, subd. (p)	7-5, 14-14, 14-29	There should be a publicly searchable database with UTL status, including if a product is approved, pending, or denied, available in a .csv download. The commenter proposed the following addition to the regulations: "(a) The Attorney General shall maintain a publicly accessible database, available without charge, that allows any person to verify the UTL	No changes have been made to the regulations in response to these comments. There is a publicly searchable database of all UTL-approved products, including a .csv download option, at https://utl.doj.ca.gov/. The Department does not post brand styles that are pending review. Assembly Bill 3218 limits the UTL to those brand styles that "lack a characterizing flavor" and provides that "[a]ny brand style not on the UTL shall be deemed a flavored tobacco product" (Health & Saf. Code, § 104559.1, subds. (a), (g).)	129, 130

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		registration status of a Tobacco Product by entering one or more of the following: (1) Manufacturer or Importer name; (2) Brand Style name; or (3) Universal Product Code (UPC), if available. (b) The database shall indicate, for each Brand Style: (1) Whether the Brand Style is Listed on the UTL; (2) Whether the Brand Style is designated "Pending Review" under Section 944.5; or (3) Whether an application for the Brand Style has been denied. (c) The database shall be updated within five (5) business days of any approval, denial, or change in status. (d) The database shall be published in a machine-readable format (e.g., CSV or API) to facilitate retailer compliance verification." Finally, there should be publication of aggregate	Brand styles with pending applications are not eligible for sale during review because the Department must assess the application for completeness and the brand styles associated with that application for eligibility. (See Health and Safety Code § 104559.1, subds. (b) [describing information applicants must provide with product submissions], (e) ["The Attorney General shall decline to include on the UTL any brand style that the Attorney General reasonably determines has a characterizing flavor" and "may decline to include on the UTL any brand style that is adulterated as defined in Section 387b of or misbranded as defined in Section 387c of the FFDCA…"], (b)(2)-(3) [the Attorney General may request "additional information and factual substantiation regarding a brand style's lack of characterizing flavor" and "tobacco product status, packaging, or marketing of a brand style"].) Because brand styles under review are not yet eligible for the UTL and may ultimately be denied, creating a mechanism that publicly identifies brand styles submitted for Department review could result in market confusion and create a false imprimatur with respect to products that may never be authorized for inclusion on the list. Furthermore, applicants have expressed	

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		submission data by product category.	concerns over confidentiality for brand styles that have yet to be officially announced and released in California. The Department does not post brand styles that it declines to include on the UTL because doing so would create market confusion, as the UTL functions as a list of approved products. Furthermore, applicants have expressed concerns over confidentiality for brand styles that have yet to be officially announced and released in California. Finally, most submissions are approved and included on the UTL, so there would be little benefit to publishing aggregate submission data. The UTL has standardized names that include product categories and can be searched. For example, if you search "Cigarettes" on the UTL, all cigarettes would appear.	
Inclusion of Cigars, subd. (p)	1-1	"The flavor cigar bill [should be] terminated." Cigars should be allowed to have flavor because "[k]ids don't smoke cigars," and cigars take longer to smoke and are relaxing, not a "nicot[ine] need like cigarettes."	Irrelevant. The comment objects to the statute, not the proposed regulations. No changes have been made to the regulations in response to this comment. The restriction on flavored tobacco products, including cigars, is statutory, pursuant to Health and Safety Code section 104559.5, subdivision (b)(1), and DOJ cannot implement regulations that alter or amend the statute, or	001

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			impair its scope. (See Health & Saf. Code, § 104559.5, subd. (a)(17)(A) [defining "Tobacco product" to include cigars].)	
Inclusion of Cigars, subd. (p)	9-3, 10-1	Hand-rolled cigars should not be included in the flavor ban because of low youth use and health impacts, and because the ban will hurt brick-and-mortar stores, which comply with tax laws. Currently, kids order flavored vape over the internet even though flavored vape is illegal in the state, and when people order online, they rarely pay the state tobacco tax.	No changes have been made to the regulations in response to these comments. The restriction on flavored tobacco products, including cigars, is statutory, pursuant to Health and Safety Code section 104559.5, subdivision (b)(1). "Tobacco product" is defined in statute to include cigars, but to exclude one subset of cigars: "premium cigars." (Health & Saf. Code, §§ 104559.1, subd. (s)(3); 104559.5, subds. (a)(6), (a)(17)(A).) "Premium cigars" are defined by statute as "any cigar that is handmade, is not mass produced by use of mechanization, has a wrapper that is made entirely from whole tobacco leaf, and has a wholesale price of no less than twelve dollars ($12). A premium cigar does not have a filter, tip, or nontobacco mouthpiece and is capped by hand." (Health & Saf. Code, § 104559.5, subd. (a)(13).) Thus, the statutory exemption from the flavor ban provided for "premium cigars" encompasses only a specific subset of hand-rolled cigars. These regulations cannot impair the scope of the statute and exempt all hand-rolled cigars from the statutory ban on flavored tobacco products.	095, 096-097

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			Regarding youth use, the Department also points to a 2018 comment it submitted to FDA, where it, along with other states, noted the following regarding youth use: "'young people . . . , increasingly, consume premium cigars.' In fact, 'younger people actually use premium cigars at higher rates than older people.' Young adults aged 18 to 29 use premium cigars at a rate twice that of adults aged 45 to 64 and six times that of adults aged 65 or older." (Docket No. FDA-2017-N-6107, Regulation of Premium Cigars, https://oag.ca.gov/system/files/attachments/press-docs/premium-cigars-comment-letter.pdf.)	
Inclusion of Cigars, subd. (p)	9-2, 16-1, 16-5	Premium cigars, as defined by federal regulations ("federally defined premium cigars") should not be included in the same regulatory scheme because "by their very nature," they are unflavored, they are less likely to be used by youth, and most users smoke them only occasionally. Because of these factors, FDA does not run federally defined premium	No changes have been made to the regulations in response to these comments. The restriction on flavored tobacco products, including cigars, is statutory, pursuant to Health & Safety Code section 104559.5, subdivision (b)(1). "Tobacco product" is defined in statute to include cigars, but to exclude one subset of cigars, "premium cigars." (Health & Saf. Code, section 104559.1, subd. (s)(3) & 104559.5, subds. (a)(6), (a)(17)(A).) "Premium cigars" are defined as "any cigar that is handmade, is not mass produced by use of mechanization, has a wrapper that is made entirely from whole	095, 270-271, 273, 279

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		cigars through their premarket review process. Federally defined premium cigars must, among other things, be handmade or hand-rolled in whole tobacco leaf with at least 50 percent long filler tobacco, have no filters, contain only tobacco, water, and vegetable gum with no other ingredients or additives, and not have any characterizing flavor other than tobacco. Unlike California's definition of "premium cigar," (see Health & Safety Code § 104559.5(a)(13), the federal definition does not set minimum wholesale cost. The state legislature intended the price difference to allow higher priced cigars to have flavor, not for "how cigars should pass through the Attorney General's	tobacco leaf, and has a wholesale price of no less than twelve dollars ($12). A premium cigar does not have a filter, tip, or nontobacco mouthpiece and is capped by hand." (Health & Saf. Code, § 104559.5, subd. (a)(13).) Thus, the statute does not exclude all federally defined premium cigars, and many would be covered tobacco products by statute. These regulations cannot exempt them from the statute. The Department has established an equitable review process that requires information sufficient to identify products and verify their eligibility for listing on the UTL and declines to grant exemptions or apply more lenient standards to one category of products when all are equally subject to California's flavored tobacco restrictions. Because some federally defined premium cigars are covered under the state's flavored tobacco restrictions, the Department must assess those cigars for eligibility, just as with any other covered tobacco product. Regarding youth use, the Department also points to a 2018 comment it submitted to FDA, where it, along with other states, noted the following regarding youth use: "'young people	

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		unflavored tobacco list process." Premium cigars were never the primary target of California's flavored tobacco ban. However, the proposed regulations would apply to all premium cigars that otherwise meet the federal definition of "premium cigar" but are sold at a wholesale cost of under $12. Imposing regulations on products that are already unflavored and not driving youth addiction is unwarranted and arbitrary and does not serve the state's public health interest. "I respectfully urge the Department to reconsider these regulations, perhaps by providing exemptions, reduced fees, or streamlined processes for small manufacturers, and to differentiate more clearly	. . . , increasingly, consume premium cigars.' In fact, 'younger people actually use premium cigars at higher rates than older people.' Young adults aged 18 to 29 use premium cigars at a rate twice that of adults aged 45 to 64 and six times that of adults aged 65 or older." (Docket No. FDA-2017-N-6107, Regulation of Premium Cigars, https://oag.ca.gov/system/files/attachments/press-docs/premium-cigars-comment-letter.pdf.)	

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		between product categories like premium cigars and other tobacco items. Such adjustments would promote fairness, support economic opportunity, and align more closely with evidence based public health policy."		
Variant, subd. (r)	7-3, 11-5, 11-7, 13-3, 14-3, 14-13, 14-28, 18-3, 19-3, 23-1	Cigars of identical tobacco composition but different sizes require separate $300 product fees instead of the $150 variant fee. Variants should include variations in size dimensions, including length and ring gauge. A size change does not create a characterizing flavor. The Department should adopt a cigar vitola variant pathway with: manufacturer certification that the blend is unchanged, documentation of the vitola dimensions, physical sample only upon request, and "name this ratio blended variants."	No changes have been made to the regulations in response to these comments. The Department's review of a variant for placement on the UTL is based on information submitted via the variant form, as well as the information submitted for the related predicate brand style. For the purposes of the regulations, "Variant" is narrowly defined so that it does not include any differences from the predicate brand style that could create a flavor difference. Variations in size such as length and ring gauge can affect flavor by changing the ratio of filler to wrapper or how quickly a product is smoked. (See, e.g., Online Cigars, Why Do Larger Ring Gauges Offer a Different Taste Profile – Exploring Flavor Dynamics in Larger Cigars, https://online-cigars.com/posts/post/why-do-larger-ring-gauges-offer-a-different-taste-profile; Online Cigars, How Does a Cigar's Size and Shape Impact Its Flavor Profile - A	039, 105, 108, 118, 125, 128-129, 130, 290, 294, TR 27:20-28:16

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		One commenter proposes to add a new subdivision (s): "Cigar Vitola Variant" means a cigar Brand Style that is identical to a Predicate Brand Style in tobacco blend, wrapper, binder, and filler, but differs in length and/or ring gauge (vitola) provided the Applicant certifies under penalty of perjury that no change to the dimensions imparts a Characterizing Flavor. Another proposes the following: "(r)'Variant' means a Tobacco Product that differs from a Brand Style only in packaging quantity, length, ring gauge, or weight, provided the tobacco blend and characterizing flavor status are identical to the Brand Style. For purposes of this subdivision, products differing only in size dimensions shall be presumed	Guide for Connoisseurs, https://online-cigars.com/posts/post/how-does-a-cigars-size-and-shape-impact-its-flavor-profile. Including cigars in the variant definition would be less effective because it would require additional flavor review within the variant process, effectively meaning that a variant fee is charged for a product form level of review. Finally, the Department notes that Submission ID numbers on the UTL portal do not correspond to the number of submissions received by the Department. As of March 31, 2026, the Department has received payment for 7,566 product or variant forms. Regarding staffing, the Department timely processed all submissions completed by the October 9, 2025 deadline and issued a response to each submission.	

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		to have identical characterizing flavor status unless the Attorney General determines otherwise based on specific evidence that the size variation affects flavor. Another commenter states that, based on the assigned Submission ID numbers, it appears that a substantial number of submissions (over 22,000) were received by the Department's October 9, 2025 deadline, that 11,000 staff hours would be required to process this volume of applications, and that staff may not be able to complete processing of the applications before publication and enforcement of the UTL. The commenter proposes that "[o]ne way to lessen this burden is to treat size variations as Variants ($150) rather than new Brand Styles ($300)."		

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Article 2. Applications, List Removal, and Renewals				
§ 944. Service Information and Time Limits				
Time extensions, subd. (c)	17-1	As written, the section will allow the Attorney General's office an unlimited amount of time to initiate the process to remove a product. Section 947(f) gives the Attorney General 90 days following submission to make a determination as to whether the product may be added to the UTL. This should be sufficient time to review. Extending the period further, "essentially without an end date," is unreasonable. A company should be entitled to know if the product will remain on the UTL absent a change in that product. Neither the company nor its customers purchasing the product should be concerned that it might be removed from	No changes have been made to the regulations in response to this comment. Because the Department needs to be able to remove products as it becomes aware of information that would make a product ineligible for the UTL, there is no time limit for initiating removal. This subdivision instead refers to time extensions for other processes, including, for example, responding to additional information provided. The Department also notes that the initial 90-day review timeline in Section 947, subdivision (f), is intentionally fast to minimize market disruption, but may be insufficient when more substantial review and testing is warranted. As noted in the Initial Statement of Reasons, this subdivision is necessary " because depending on the volume and type of information received from Applicants, the Attorney General may require additional time to review such information." Finally, the statute contemplates that the Department may need to remove brand styles from the UTL after they	284-285

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		the UTL after the expiration of the defined review period. Such uncertainty is inconsistent with the purpose of the UTL. This provision should not be included.	are placed on the list. (Health & Saf. Code, § 104559.1, subd. (f).)	
§ 945. Submission of product form				
Carton or roll, subd. (a)	16-15	The proposed regulations lack sufficient clarity regarding the distinction between a "carton or roll" as defined in Section 945(a)(1) and a "Multipack" as defined in Section 942(l), creating uncertainty for manufacturers and importers of cigars sold in bundled or boxed configurations. The regulations should clarify that a bundle or box of cigars containing cigars—each marked and suitable for individual retail sale—qualify as a "carton." "Prior to the Department's issuance of final regulations,	Accept in part. The Department modified the proposed regulation to define "Carton or Roll" as "a package that is marketed for retail sale to consumers." (Proposed Section 942, subd. (e).) If the individual cigar and bundle and/or box (of identical cigars) are each marketed for retail sale, the bundle and/or box would be a "Carton or Roll," under the definition in subdivision (e) of Proposed Section 942. Even prior to this modification, the carton or roll option was an exemption from the requirement to submit the brand style constituting a carton or roll in a separate product or variant form. The exemption previously read that "a carton or roll means a package that is marketed for retail sale to consumers and contains multiple identical Brand Styles that are individually marketed for retail sale to consumers."	277, 280

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		Applicants may submit in error a bundle of premium cigars under a distinct product or variant form (e.g., as a multipack) that would unnecessarily incur both initial submission fees and annual per-Brand Style fees. Accordingly, we urge the Department to establish a process by which Applicants can obtain refunds for fees paid in error and to allow these products to be reclassified accordingly without penalty."	Finally, no other comments have raised similar clarity concerns, and there is no evidence of a need to modify the regulations to include a refund provision to address this theoretical possibility of erroneous submissions. In the event of erroneous submissions, applicants can contact Department staff and appropriate resolution will be based on the facts or error at issue.	
Product form, generally	14-4, 14-21, 22-6	The regulations provide no pathway for lawfully acquired inventory of discontinued products. For example, anniversary releases remain in retailer inventory but manufacturers have no incentive to register the product. Physical samples may no longer exist.	No changes have been made to the regulations in response to these comments. The regulations are consistent with the statutory requirement that information is submitted by a manufacturer or importer. (Health & Saf. Code, § 104559.1, subd. (b)(1).) Distributors or retailers are not expected in the ordinary course of business to possess or be able to independently provide information that may be requested as part of the UTL application process, including, e.g., FDA status records or tobacco product ingredient lists. In the absence of manufacturer or	125-126, 130, TR 22:21-23:6

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			importer participation in the application, then, submissions from other market participants risk incomplete or inaccurate record submission or unreliable detail. If the manufacturer or importer will not register the product and/or a sample does not exist, there is insufficiently reliable detail about the product for the Department to assess it.	
Product form, generally	9-2, 9-3, 15-1, 16-2, 16-5, 16-6, 16-7	As applied to federally defined premium cigars, the UTL application requirements create administrative cost and burden without providing any enforcement benefit. As defined by federal law, premium cigars are unflavored and should be included on the UTL. "As the Attorney General has said, premium cigars as defined by the federal government are almost certain to be included on the list and breeze through the process." Moreover, the "Unflavored Tobacco List statute simply requires a certification that	No changes have been made to the regulations in response to these comments. "Tobacco product" is defined in statute and excludes, in relevant part, "premium cigars." (Health & Saf. Code, section 104559.1, subd. (s)(3).) "Premium cigars" are defined as "any cigar that is handmade, is not mass produced by use of mechanization, has a wrapper that is made entirely from whole tobacco leaf, and has a wholesale price of no less than twelve dollars ($12). A premium cigar does not have a filter, tip, or nontobacco mouthpiece and is capped by hand." (Health & Saf. Code, § 104559.5, subd. (a)(13).) Thus, the statute does not exclude all federally defined premium cigars, and many would be covered tobacco products by statute. These regulations cannot exempt them from the statute. The Department has established an equitable review process that requires information sufficient to identify products and	095, 264-266, 271-273, 273-274, 279

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		(A) '[d]escribes each brand style, brand, and tobacco product category;' (B) describes, for each brand style, if formal FDA authorization has been sought 'and, if so, the status of any request for that authorization;' and (C) '[c]ertifies that each brand style lacks a characterizing flavor.'" (Health & Safety Code, § 104559.1(b)(1).) If the Attorney General then decides, after reviewing said information, that he cannot determine whether the product truly lacks a characterizing flavor, the statute provides that he may request additional information. A streamlined approach should be instituted for federally defined premium cigars, such as requiring manufacturers to send a list of	verify their eligibility for listing on the UTL and declines to grant exemptions or apply more lenient standards to one category of products when all are equally subject to California's flavored tobacco restrictions. Because some federally defined premium cigars are covered under the state's flavored tobacco restrictions, the Department must assess those cigars for eligibility, just as with any other covered tobacco product. The Department never stated that cigars would "breeze through" the process. In the letter cited, the Department stated in relevant part: "I agree that products meeting the definition set forth in your letter are likely to be eligible for listing on the Unflavored Tobacco List when submitted or exempt from that list as 'premium cigars' as defined in California law. See Cal. Health & Saf. Code §§ 104559.1(b)(1), (s)(2), (s)(3); Cal. Health & Saf. Code §§ 104559.5(a)(1), (2), (6), (13). But included among such cigars are products the Legislature specifically included within the definition of covered 'tobacco products,' and both AB 3218 and the implementing emergency regulations provide no carve-out or alternate submission process for	

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		their cigar products, certify that they are not flavored and that they meet the federal definition of premium cigars, and leave it to the Attorney General to follow up with questions in targeted cases.	submitting them to the UTL. Similarly, the application and publication datasets were built together and are interrelated. We are not prepared to accommodate the technical modifications required to create a UTL that includes products submitted under the emergency regulations and through some alternate means."	
Added nicotine, subd. (c)(6)(G)	6-3	The subdivision "requires an applicant to indicate 'whether the product contains added nicotine,'" but does not include a definition of "added nicotine." The commenter proposes modifying the regulation to ask the applicant to identify the "source of nicotine."	No changes have been made to the regulations in response to this comment. The regulation is reasonably clear. A separate definition for "added nicotine" is not needed. Section 945, subdivision (c)(6)(G), which requests information as to whether the tobacco product contains "added nicotine," requires the applicant to identify the type of added nicotine, "including tobacco-derived nicotine, synthetic nicotine, nicotinic alkaloid or nicotine analog, or other type of nicotine."	035
Design files, (c)(7)	6-4	It is not clear what renders a product a variant and whether a manufacturer must submit design files for short-term, limited-time changes to packaging, such as seasonal packaging without flavor information, or a limited-time coupon in the product's shrink	No changes have been made to the regulations in response to this comment. The regulations are reasonably clear. Any new "Brand Style," defined as "a style of tobacco product within a brand that is differentiated from other styles of that brand by weight, volume, size, Universal Product Code, Stock Keeping Unit, nicotine content, characterizing flavor, logo, symbol, motto, labeling, marketing, materials,	035

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		wrap that does not constitute a "true design file change." It would be helpful for the final regulations to confirm that no submissions are required in these circumstances.	packaging, or other indicia of product identification," would require a new UTL application unless it falls under the narrow exceptions contained in Proposed Sections 945, subdivision (a), and 946, subdivision (d). (Health & Saf. Code, § 104559.1, subd. (s)(1).) Proposed Section 945, subdivision (a)(1), excludes cartons and rolls under certain circumstances, while subdivision (a)(2), provides an exception "for variations in a Brand Style caused by changes in manufacturing materials or process that are not distinguishable by an ordinary consumer." Finally, DOJ added Proposed Section 946, subdivision (d), to exclude differences in internal packaging under certain circumstances. Whether the examples listed in the comment would be covered by these exceptions depend on the specific circumstances. Seasonal packaging that differs on the exterior packaging and has a different Universal Product Code, for example, would be a different Brand Style because of the Universal Product Code and packaging difference. It would not fall under any relevant exception as it is not a carton or roll, is distinguishable to the	

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			consumer, and differs in the external packaging. Therefore, it would require a new UTL application using a variant form, unless it imparts flavor, in which case it would require a product form. The Department also declines to implement such an exemption because seasonal packaging may have indications of flavor.	
Written descriptions of images, (c)(8)	6-5	The regulations do not define image. The commenter proposes that the final regulations confirm that no written descriptions are required for "branding elements that are abstract and nonrepresentational shapes."	No changes have been made to the regulations in response to this comment. DOJ has removed the requirement for written descriptions of images in response to other comments, and thus, this comment is now moot. Please see response to comment No. 12-2.	035
Written descriptions of images, (c)(8)	12-2	Written descriptions are duplicative with design files and samples and should be omitted.	Accept. DOJ has removed the requirement for written descriptions of images.	113
FDA status, (c)(9)	12-1	The Department should require less FDA-specific information for products that clearly meet FDA requirements. For products authorized by FDA (e.g., those with Marketing Granted Order, Substantially	No changes have been made to the regulations in response to this comment. The commenter's proposed change is not more effective in carrying out the purpose and intent of the statute; as effective and less burdensome to affected private persons than the adopted regulation; or more cost effective to affected private persons and equally effective in	112-113

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		Equivalent Orders, or Found Exempt Orders), consider removing requirements other than "asking whether the manufacturer has sought 'formal authority, approval, or order from FDA,' and if so, for proof of the application's status." Once FDA has authorized a product, the details of the underlying paperwork become immaterial. Requiring a manufacturer to recite the application's procedural history would impose a burden with no corresponding regulatory benefit.	implementing the statutory policy. If an applicant asserts that a Brand Style is authorized by FDA, all three fields of information required under Section 945, subdivision (c)(9)(A)— (1) identification of the authorization pathway, (2) identification the date of authorization, and (3) documentation establishing that such authorization was received—are necessary in order for DOJ to match the particular Brand Style to an FDA authorized product and verify that authorization for the particular Brand Style at issue was received.	
FDA status, (c)(9)(B)(ii)(III)	6-6	This subdivision "allows an applicant to designate that no marketing authorization has been sought for a product because FDA has issued a rule, guidance, or other formal statement that 'the Brand Style does not require an authorization, approval, or order.'" But "such a rule,	Accepted in part. DOJ has revised the regulations by adding subdivision (c)(8)(B)(i)(VII)(h) to provide that if formal authorization, approval, or order for the Brand Style has been sought under 21 U.S.C. sections 387e(j) or 387j, the applicant may identify a rule, guidance, or other formal statement from FDA that the Brand Style does not require authorization, approval, or order under 21 U.S.C. sections 387e(j) or 387j. The comment	035-036

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		guidance, or statement . . . could be issued *after* the manufacturer has sought a marketing authorization." Subdivision (c)(9)(B)(ii) should allow a manufacturer to make such a designation, or a manufacturer "should be able to make this designation regardless of whether a marketing authorization has or has not been sought." The regulations should allow manufacturers "to designate a product's special marketing authorization status whenever appropriate."	does not provide sufficient support for DOJ to make further modifications to the regulations. The commenter has not identified any other "special marketing authorization status" that is not already captured under the proposed regulations.	
Flavor determinations, (c)(11)	6-7	This subdivision requires an applicant to submit "every determination regarding flavor in the Brand Style made by another government agency and received by Applicant." The commenter seeks clarification "whether this requirement is intended to apply to state or federal government entities."	No changes have been made to the regulations in response to this comment. The regulations are reasonably clear. The regulations state that flavor determinations "made by another government agency" must be provided. The requirement applies to *any* government agency, including federal, state, local, and international entities.	036

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Flavor determinations, (c)(11)	12-4	The requirement for flavor determinations from other jurisdictions should be removed because determinations may not be informative as to whether a product complies with California law because the law is not uniform. Different jurisdictions define "flavor" differently. The Attorney General must make an independent determination based on California's definition. Alternatively, there should be clarification that this requirement only applies to formal and final determinations "issued by government agencies following an adjudicatory process through which the Applicant was provided due process including notice and an opportunity to be heard" because if the Attorney	No changes have been made to the regulations in response to this comment. For the reasons set forth in the Initial Statement of Reasons, the Department has determined that flavor determinations made by another government agency will assist in the Attorney General's review of whether the brand style is eligible for placement on the UTL. Although laws from other jurisdictions may differ, another jurisdiction's analysis of flavor may be persuasive. Flavor determinations from other government agencies are not dispositive. The Department declines to limit the requirement those determinations issued after an adjudicatory process because flavor determinations are required for informational purposes only and are only one factor among many the Department considers when evaluating brand styles submitted to the UTL.	113-114

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		General denies on the basis of another determination without the manufacturer having had a meaningful opportunity to contest the determination in the other jurisdiction, the Attorney General would violate the manufacturer's due process rights. In no circumstance should the Attorney General base his listing determination on another jurisdiction's finding that a product is flavored.		
§ 946. Submission of variant form				
Written descriptions of images, (e)(13)	12-2	Written descriptions are duplicative with design files and samples and should be omitted.	Accept. The requirement for written descriptions of images has been removed from the regulations.	113
Flavor determinations, (f)(14)	12-4	The requirement for flavor determinations from other jurisdictions should be removed because determinations may not be informative as to whether a product complies with California law because the	No changes have been made to the regulations in response to this comment. For the reasons set forth in the Initial Statement of Reasons, the Department has determined that flavor determinations made by another government agency will assist in the Attorney General's review of whether the brand style is eligible for placement on the UTL. Although laws from	113-114

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		law is not uniform. Different jurisdictions define "flavor" differently. The Attorney General must make an independent determination based on California's definition. Alternatively, there should be clarification that this requirement only applies to formal and final determinations "issued by government agencies following an adjudicatory process through which the Applicant was provided due process including notice and an opportunity to be heard" because if the Attorney General denies on the basis of another determination without the manufacturer having had a meaningful opportunity to contest the determination in the other jurisdiction, the Attorney General would	other jurisdictions may differ, another jurisdiction's analysis of flavor may be persuasive. Flavor determinations from other government agencies are not dispositive. The Department declines to limit the requirement those determinations issued after an adjudicatory process because flavor determinations are required for informational purposes only and are only one factor among many the Department considers when evaluating brand styles submitted to the UTL.	

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		violate the manufacturer's due process rights.		
§ 947. Request for Placement on the Unflavored Tobacco List				
Request for UTL placement, generally	11-7, 11-9	A less burdensome alternative that would reduce impact on small businesses is digital-first documentation. "A digital-first pathway reduces cost and improves DOJ processing speed. The system will also need to be available internationally, region locking ID systems (Single Sign On) that require you to be physically located in the United States to begin compliance will not satisfy."	No changes have been made to the regulations in response to this comment. This comment does not provide sufficient specificity for DOJ to consider additional modifications to the text. The UTL application process is in the digital portal available at https://utl.doj.ca.gov. The portal is accessible internationally, though access may be restricted in select locations due to security limitations. Under subdivision (b) of Section 945 of the regulations, "[u]pon a showing of good cause that outweighs the operational needs of the Attorney General, the Attorney General shall permit exceptions from use of the web portal for product forms and/or variant forms."	105, 109
Samples, subd. (b)(5)	6-2, 14-7, 14-22	The sample requirement is not authorized by the statute and was not included in fiscal analyses. Furthermore, it is unnecessary because of the requirement to provide design files. (Proposed Section 945, subd. (c)(7).) The Initial Statement of Reasons stated	No changes have been made to the regulations in response to this comment. Health and Safety Code section 104599.1, subdivision (q) allows the Department to promulgate regulations for the implementation of the UTL. For the reasons set forth in the Initial Statement of Reasons, subdivision (b)(5) of Proposed Section 947, which requires samples unless the brand style has been submitted as a variant, is necessary.	034, 126-127, 130

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		that samples were chosen in lieu of mandating high-resolution photography but did not analyze whether standard photography would achieve equivalent verification at lower cost. Finally, samples cost the Department storage, handling, and processing. One commenter suggests the Department consider digital documentation with specified technical standards, reserving physical sample requests for cause-specific verification.	The regulations do not require design files, as design files are not always available. In recognition of this limitation, the regulations instead provide that "If there is no design file available, photos may be provided of every side of the packaging for the Brand Style that is not blank." (Proposed Section 945, subd. (c)(7); Proposed Section 946, subd. (g)(12).) As explained in the Initial Statement of Reasons, samples allow the Department to create its own photos, ensuring consistent reference photos of approved brand styles to post on the public UTL website. This feature has already been requested by enforcement personnel since the UTL website went live on December 31, 2025, and standard photography would not serve this end. During beta testing, the Department considered providing requests for digital photographs that met design specifications. The Department's experience with that exercise was that it was more cost effective and more consistent to centralize digital capture from sample products than to attempt to enforce consistency across users. And samples, unlike images, permit physical evaluation for indications that the product has (or does not have) a characterizing flavor and	

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			testing. None of these needs can be addressed by standard photography. The utility of and need for samples offsets the storage, handling, and processing costs associated with them. Standard photography would not achieve the ends of samples because it would not allow for adequate photos for enforcement purposes and would not permit product testing. Furthermore, the sample need only include the "the largest packaging unit of the Brand Style marketed for retail sale . . . in assembled packaging" and "the consumable Tobacco Product in the smallest packaging unit marketed for retail sale." Because only the smallest unit of the consumable is required, the sample expense is not substantial. Finally, access to the sample during initial review allows the Department to resolve many questions without needing to trigger additional requests for information, which can add months of additional time to review. The sample requirement is addressed on pages 1-2 of Attachment A to the STD 399.	
Samples, subd. (b)(5)	7-2, 11-4, 13-2, 18-2, 19-2	The sample requirement "create[s] a sequential bottleneck with 90+ day market entry delays." This	No changes have been made to the regulations in response to this comment. In drafting these regulations, the Department has considered the need for physical samples of the product. For	039, 107-108, 118, 290, 294

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		systematically favors large manufacturers who can absorb delays over smaller and new market entrants. A proposed modification is to add to subdivision (b)(5): ". . . provided that an Applicant may satisfy this requirement by providing digital photographic documentation as described in Section 945, subdivision (c)(7). The Attorney General may subsequently request a physical sample within thirty (30) days if digital documentation is insufficient to evaluate for a Characterizing Flavor."	the reasons set forth in the Initial Statement of Reasons, the subdivision (b)(5) of Section 947, requiring samples unless the brand style has been submitted as a variant, is necessary. As explained in the Initial Statement of Reasons, samples allow the Department to create its own photos, ensuring consistent reference photos of approved brand styles to post on the public UTL website. This feature has already been requested by enforcement personnel since the UTL website went live on December 31, 2025, and standard photography would not serve this end. And samples, unlike images, permit physical evaluation for indications that the product has (or does not have) a characterizing flavor and testing. None of these needs can be addressed by standard photography. The utility of and need for samples offsets the storage, handling, and processing costs associated with them. Standard photography would also not achieve the ends of samples because it would not allow for adequate photos for enforcement purposes and would not permit product testing. Furthermore, the sample need only include the "the largest packaging unit of the Brand Style marketed for retail sale . . . in assembled packaging" and "the consumable Tobacco Product in the smallest packaging unit	

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			marketed for retail sale." Because only the smallest unit of the consumable is required, the sample expense is not substantial. Access to the sample during initial review allows the Department to resolve many questions without needing to trigger additional requests for information, which can add months of additional time to review. The Department has established an equitable review process that requires information, including samples, sufficient to identify products and verify their eligibility for listing on the UTL. While small manufacturers expressed concern over market entry delays, the Department maintains that the importance of the sampling process justifies a uniform requirement for applicants both small and large.	
Samples, subd. (b)(5)	11-4, 11-7, 16-3, 17-2	Require physical samples only when needed. Sample requirement forces manufacturers to ship physical product, potentially internationally, before approval and ties up capital in product that cannot be sold.	No changes have been made to the regulations in response to this comment. As explained in the Initial Statement of Reasons, samples allow the Department to create its own photos, ensuring consistent reference photos of approved brand styles to post on the public UTL website. This feature has already been requested by enforcement personnel since the UTL website went live on December 31, 2025, and standard photography would not serve this	105, 107-108, 273, 285-286

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			end. And samples, unlike images, permit physical evaluation for indications that the product has (or does not have) a characterizing flavor and testing. None of these needs can be addressed by standard photography. The utility of and need for samples offsets the storage, handling, and processing costs associated with them. Standard photography would not achieve the ends of samples because it would not allow for adequate photos for enforcement purposes and would not permit product testing. Furthermore, the sample need only include the "the largest packaging unit of the Brand Style marketed for retail sale . . . in assembled packaging" and "the consumable Tobacco Product in the smallest packaging unit marketed for retail sale." Because only the smallest unit of the consumable is required, the sample expense is not substantial. Finally, access to the sample during initial review allows the Department to resolve many questions without needing to trigger additional requests for information, which can add months of time to initial product review.	
Samples, subd. (b)(5)	16-16	The Department should clarify that cigars may satisfy the sample requirement by sending an individual cigar	No changes have been made to the regulations in response to this comment. The regulation is reasonably clear. Whether a cigar applicant may satisfy the sample requirement by sending	277-278, 280

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		and an empty, assembled cigar box, and provide this, or a similar example in the regulation related to cigars.	an individual cigar and an empty package depends on the brand style submitted for placement on the UTL. If the individual cigar is the "smallest packaging unit marketed for retail sale included on the product form," then the individual cigar would satisfy the consumable piece of the sample requirement, and if a box of the cigars was associated as a carton or roll, then an empty box in assembled packaging would satisfy the other piece of the sample requirement. (Proposed Section 947, subd. (b)(5).)	
Pre-existing inventory	14-15, 14-30	Add a new section that civil penalties will not be assessed for one year for products acquired before the UTL was published and have not been affirmatively denied. The commenter proposes the following language: (a) The Attorney General shall not assess civil penalties under Section 955 for the retail sale of a Tobacco Product that does not appear on the UTL through	No changes have been made in response to this comment. Compliance with the statute and the regulations is a fact-specific determination. The comment does not provide substantial evidence or justification that the proposed exception is necessary to effectuate the purpose of the statute. The Department declines to codify a one-year penalty moratorium in the regulations. Instead, enforcement remains within the Department's discretion, with specific priorities communicated through information bulletins. For example, the Department recently issued Information Bulletin 2025-DLE-17, which clarifies that for products not included in the initial UTL and not "obviously flavored," the initial focus will be on manufacturer	129, 130

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		December 31, 2025, if all of the following conditions are met: (1) The retailer acquired the Tobacco Product on or before December 31, 2025; (2) The retailer maintains a purchase invoice, shipping record, or other commercial document demonstrating the date of acquisition; and (3) The Tobacco Product has not been the subject of a final determination by the Attorney General that it contains a characterizing flavor. (b) For purposes of this section, "acquired" means the date the retailer took physical possession of the Tobacco Product or the date appearing on the purchase invoice, whichever is earlier. (c) This section does not apply to Tobacco Products acquired after December 31, 2025. (d) This section establishes enforcement priorities only and does not modify the	education rather than immediate enforcement action. However, the Department emphasizes that registration on the UTL Portal is ongoing, and any unregistered products remain subject to seizure and penalties under Business and Professions Code sections 22974.2 and 22978.3.	

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		determination of "flavored tobacco product" status under Health and Safety Code section 104559.1, subdivision (g).		
§ 948. Impact of FDA Status on Listing and Removal				
FDA Status, generally	16-14	If the Attorney General rejects an application due to noncompliance with federal law, that is impliedly preempted because it takes away enforcement authority from the FDA.	No changes have been made to the regulations in response to this comment. The comment objects to Health and Safety Code section 104559.1, not the proposed regulations. The Department further disagrees with the comment's interpretation of the statute. As a sales restriction, Health and Safety Code section 104559.1 does not reach into the province of FDA, and it neither prohibits (1) the manufacture of any tobacco product or the introduction of any tobacco product into interstate commerce, nor (2) enforces any provision of the Tobacco Control Act (TCA) itself. (21 U.S.C. § 387p.) Instead, the state law uses information related to the TCA (specifically, whether the brand style was required to obtain premarket review but has not received a formal authorization, approval, or order from the FDA) to determine whether tobacco products should be lawful for sale in California. The UTL regulations do not set up a	277, 280

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			separate premarket review process, or impose any additional or different requirements than the FDA process. As the court in *Rocky Patel Cigars, Inc.* explained: …insofar as the Attorney General relies on determinations by the FDA to ascertain which products can be placed on the UTL, the State is merely relying on the "regulatory floor" established by the FDA. This does not implicate any conflict with federal enforcement authority because "[n]oncompliance with the [ ]TCA is not itself an actionable basis for the [State] to" initiate any enforcement proceedings. *Vapor Tech.*, 2025 WL 1787420, at *5. Rather, "a manufacturer or retailer only runs afoul of state law" by selling a banned flavored tobacco product, as determined by the UTL. *See id.* (*Rocky Patel Premium Cigars, Inc. v. Bonta* (C.D. Cal., Dec. 23, 2025, No. 8:25-CV-02244-MRA(PDX)) 2025 WL 3903972, at *7, app. pending, 9th Cir., Dec. 26, 2025, No. 25-8060.)	

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FDA Authorization, subd. (a)	4-2	The regulations do not specify what constitutes an "authorization by FDA." California law recognizes that an authorization may be given expressly or impliedly. This is exemplified through the state's data privacy laws. The FDA has both express and implied authorizations. In the context for finished tobacco products an authorization can include the express approval through issuance of a Marketing Granted Orders, as well as of implied approval through a cessation of its enforcement during the Warning Letter process. FDA may imply its approval through a recission of the allegations set forth in a Warning Letter, together with a cessation of enforcement of the originally alleged violations, regardless of whether the agency has opted to issue a Close-Out letter	No changes have been made to the regulations in response to this comment. In drafting these regulations, the Department has considered the implementation of Health and Safety Code 104559.1, sections (e) and (f), which permit the Attorney General to decline to include on, or remove from, the UTL brand styles otherwise required to obtain but have not yet received a formal authorization, approval, or order from the FDA; the Attorney General's exercise of discretion under sections (e) and (f) is reflected in Proposed Section 948, which sufficiently identifies the circumstances in which the Attorney General will exclude a Brand Style from the UTL because a brand style requires, but has not received, a formal authorization, approval, or order from the FDA under 21 U.S.C. section 387e(j) or 387j. The commenter does not identify authority supporting the contention that a tobacco product can be impliedly authorized by FDA when it has not received formal authorization, approval, or a specific order from the FDA under 21 U.S.C. section 387e(j) or 387j, and the Department declines to exercise its discretion to allow products on the UTL under the circumstances identified by the commenter.	021-022

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		following its conclusion of an investigation. The commenter recommends that the Department recognize and accept any FDA issued communication, including a recission of allegations set forth in a Warning Letter coupled with cessation of enforcement of the alleged violations, as sufficient evidence of FDA's "authorization" for UTL purposes. This approach mirrors practices with other state laws, in addition to those in other states, and promotes harmonization with federal law. The commenter requests clarification that the Department recognizes that the FDA may provide an "authorization" that is either explicit or implicit.	Under federal law, the absence of an enforcement action or the withdrawal of an allegation does not constitute an affirmative legal finding of a product's safety or its compliance with premarket requirements. Instead, as explained in the Initial Statement of Reasons, the Department finds that Proposed Section 948 sets forth public health-based criteria for market access in California to tobacco products that require but have not received authorization, approval, or order from the FDA under 21 U.S.C. Secs. 387e(j) or 387j.	
§ 950. List Removal				

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Removal Notice, subd. (b)-(d)	3-1	The draft regulations do not provide "direct notification to retailers—many of whom are small, family-run businesses." This creates a compliance risk because retailers could continue selling products and face penalties. Expecting retailers to monitor the website is "impractical and unreasonable." The Department should establish an opt-in communications system that alerts subscribers of any UTL updates, including list removals or modifications. Creating this type of dedicated mailing list would ensure that all stakeholders, especially independent small business owners, receive immediate notice of any changes, support timely compliance, and protect retailers from inadvertent violations and disproportionate financial harm.	No changes have been made to the regulations in response to this comment. The regulation is consistent with providing public notice to apprise among others, tobacco product retailers and distributors of impending and actual removals. The Department has exercised its discretion to provide in the regulations that notice will be provided on the UTL website. Health and Safety Code section 104599.1 provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Saf. Code, § 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).) Therefore, retailers will have 30 days of notice when brand styles are removed. The Department notes that it has set up a listserv for updates to the UTL, which will send weekly emails identifying brand styles added to the UTL, along with notices regarding	014

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			removals of brand styles from the UTL. Members of the public can sign up for the listserv at https://oag.ca.gov/subscribe.	
Removal Notice, subd. (b)-(d)	3-2	Because retailers often purchase inventory several weeks or months in advance, extend the public notice period to 60 days. This would give retailers time to sell inventory and prevent retailers from having "unsellable stock." The extension would "protect responsible retailers from unintended financial harm and ensure a fair, practical pathway to compliance."	No changes have been made to the regulations in response to this comment. Assembly Bill 3218 provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Saf. Code, § 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).) Therefore, retailers will have 30 days of notice when brand styles are removed. Since that 30-day period a statutory requirement, it is not possible to amend the time by regulation.	015
Removal notice, subd. (b)	8-2, 8-7	The regulations are "vague, unworkable, and violate due process." They do not provide regulated parties with clear, objective, workable standards for determining compliance.	No changes have been made to the regulations in response to this comment. This comment does not provide sufficient specificity for DOJ to consider additional modifications to the text.	044, 047

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		The following are "insufficiently defined and subject to discretionary interpretation": what is a "permissibly unflavored" vape product, the evidentiary burden for placement or continued inclusion on the UTL, and the basis for denial or removal from the UTL. Downstream businesses cannot independently verify compliance and must rely entirely on DOJ determinations. Products can be removed after being lawful, exposing parties to penalties for lawful conduct, making it impossible to comply. The regulations impose strict liability without fair notice, in violation of due process principles. "The absence of objective standards, safe harbors, or meaningful transition provisions renders the	The regulations are reasonably clear. As provided in the definitions, "A Brand Style 'lacks a Characterizing Flavor' if it lacks any Constituent that imparts a Characterizing Flavor." (Proposed Section 942, subd. (g).) A Characterizing Flavor "means a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco, including, but not limited to, tastes or odors relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice, or a cooling sensation distinguishable by an ordinary consumer during the consumption of a tobacco product." (Proposed Section 942, subd. (g); Health & Saf. Code, §§ 104559.1, subd. (s)(2); 104559.5, subd. (a)(1).) Regarding evidentiary burden, UTL applications require a certification that a product is unflavored. (Health & Saf. Code, §104559.1, subd. (b)(1)(C).) Upon request of the Attorney General, an applicant must substantiate that lack of characterizing flavor. (Health & Saf. Code, § 104559.1, subd. (b)(2)(A).)	

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		regulatory framework unworkable in practice and exposes lawful businesses to unpredictable and retroactive enforcement."	The bases for denial and removal laid out in the regulations. (See, e.g., Proposed Section 945, subd. (d), 948(a)-(b) for denial, and Proposed Sections 950(a)-(b), 951, subd. (a).) Health and Safety Code section 104559.1, subdivision (a) requires the UTL to be maintained on the "Attorney General's internet website," and Proposed Section 943, subdivision (a), of the regulations provides the web address for the UTL portal. Downstream businesses can verify compliance by consulting the Unflavored Tobacco List, available at https://utl.doj.ca.gov/. Health and Safety Code section 104559.1 provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Saf. Code, § 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).) Therefore,	

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			retailers will have 30 days of notice when brand styles are removed. Since that 30-day period is a statutory requirement, it is not possible to amend the time by regulation. The commenter's objection to the removal of products from the UTL, purportedly exposing parties to penalties for lawful conduct, is an objection to the statute, not the proposed regulations. Subdivisions (e) and (f)(1) of Health and Safety Code section 104559.1, require the Attorney General to decline to include on the UTL and to remove from the UTL any brand style that the Attorney General determines has a characterizing flavor. (Health & Saf. Code, § 104559.1, subd. (e), (f)(1).) Moreover, the UTL regulations do not make the sale of flavored tobacco unlawful; the sale of flavored tobacco products in the state has been statutorily prohibited prior to the establishment of the UTL. (See Health & Saf. Code, § 104559.5, subd. (b)(1).)	
§ 952. Updates				
Changes in manufacturing materials or	6-1, 12-3	The provision that requires a manufacturer to notify the Attorney General of "[a] change to a Brand Style in	Accepted. Provision removed.	033-034, 113

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process, subd. (b)(5)		manufacturing materials or process that is *not distinguishable* by an ordinary consumer and that does *not alter the flavor in a distinguishable way*" should be removed because it requires information unrelated to product flavor or status. Section 104559.5 of the Health and Safety Code prohibits the sale or distribution in California of tobacco products with a characterizing flavor. A characterizing flavor is defined, in relevant part, as "a taste or odor, *distinguishable by an ordinary* consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco. . . ." (Health & Saf. Code, § 104559.5, subd. (a)(1) (emphasis added).) Also, the UTL does not authorize the Attorney General to regulate aspects of		

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		product manufacturing or specifications, and these provisions pertain to manufacturing and product standard issues governed by federal rather than by state law. Third, the provision is burdensome because the reporting obligation –within only 15 days – is triggered from time of "a change," but it is unclear if this means the time the change is implemented in the manufacturing process or from the time the changed product is shipped into California, or some other time.		
§ 954. Fees				
Fees	11-4, 15-2, 16-4, 16-6, 16-9, 23-1	Because federally defined premium cigars are unflavored, have fewer health impacts, and are otherwise less burdensome to review, they require less extensive review compared to other	No changes have been made in response to this comment. "Tobacco product" is defined in statute and excludes, in relevant part, "premium cigars." (Health & Saf. Code, section 104559.1, subd. (s)(3).) "Premium cigars" are defined as "any cigar that is handmade, is not mass produced by use of mechanization, has a	107-108, 266, 273-274, 279, TR 27:20-28:16.

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		categories and should have a de minimis, nominal, or no fee associated with them. The statute requires that fees be only as high as required to process applications to the list or maintain it. Because of the swift review available for federally defined premium cigars, which lack characterizing flavors by their definition, such fees must be reduced, especially compared to other tobacco products more likely to contain characterizing flavors and requiring strenuous review.	wrapper that is made entirely from whole tobacco leaf, and has a wholesale price of no less than twelve dollars ($12). A premium cigar does not have a filter, tip, or nontobacco mouthpiece and is capped by hand." (Health & Saf. Code, section 104559.5, subd. (a)(6).) Thus, the statute does not exclude all federally defined premium cigars, and many would be covered tobacco products by statute. These regulations cannot exempt them from the statute. The Department has established an equitable review process that requires information sufficient to identify products and verify their eligibility for listing on the UTL and declines to grant exemptions or apply more lenient standards to one category of products when all are equally subject to California's flavored tobacco restrictions. Because some federally defined premium cigars are covered under the state's flavored tobacco restrictions, the Department must assess those cigars for eligibility, just as with any other covered tobacco product.	
Fees	17-3	The fee per SKU should be the cost to establish and administer the UTL program divided by the number of	No changes have been made to the regulations in response to this comment. The January 10, 2025 Budget Change Proposal (BCP), 0820-107-BCP-2025-GB, identifies the costs of the	286

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		submissions. The fees should be lowered now that the Department knows the volume of submissions and because of the cost to manufacturers. Four cigar manufacturers paid $250,000 while the report of the Senate committee considering the legislation said that the estimated cost was "$318,000 in 2024-25 and $603,000 ongoing thereafter for workload." The fees for submissions made to the initial UTL greatly exceeded what the Attorney General's office said was needed in 2024-25 and will be needed going forward. The regulations should align the application and renewal fees with the Attorney General's costs, using real world evidence from the initial submissions.	additional positions required by the Department to operate and maintain the UTL, rather than the full operational and maintenance costs of the program. Attachment A to the STD 399 identifies the Department's estimate of the full operational and maintenance costs of the program, including the costs of positions identified in the BCP and of additional positions within existing Department resources that are expected to be utilized for UTL work. The Department declines to establish lower fees in this rulemaking, as the current fee structure is specifically calculated to align with the Department's operational and maintenance projections. The total program costs for the 2025–26 Fiscal Year, however, is an initial projection and is subject to change as the Department continues to receive and process applications. Projections for Fiscal Years 2026–27 and 2027–28 will be informed by the actual number of products submitted in Fiscal Year 2025–26 and are also subject to change.	
Payment of Fees	12-6	Consider enabling the payment system to accept	No change has been made in response to this comment, which is interpreted to be an	115

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		American Express or ACH transfers because many businesses use these services to facilitate payments for business-related expenses.	observation rather than a specific recommendation to change these regulations. The regulations do not delineate the specific payment options available through the UTL portal and doing so would unnecessarily limit the Department's flexibility in accepting various payment options. The Department notes that it is exploring other potential payment types for use in the UTL portal.	
Article 3. Penalty Citations and Appeals				
§ 955. Penalty Citations				
Penalties generally	8-3, 8-7, 14-2	The regulations authorize penalties against downstream entities that do not manufacture products or control submissions which is "inconsistent with principles of fairness and sound regulatory design." Retailers have no mechanism to ensure product registration, no authority to register products, and no recourse when manufacturers decline to register. Retailers face enforcement for a compliance	No changes have been made to the regulations in response to these comments. The regulation is consistent with the statute, which authorizes penalties against distributors, wholesalers, and delivery sellers. (Health & Saf. Code, § 104559.1, subd. (o)(3).) It is the responsibility of those entities to comply with the UTL, and to review the UTL to ensure products offered appear on the list. The existence of penalties against entities other than the manufacturer is necessary to ensure compliance throughout the supply chain. The comment does not provide substantial evidence or justification that the proposed safe harbor or exception for	044-045, 047, 125

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		status they cannot control, and the regulation should provide meaningful safe harbors for downstream businesses.	downstream entities is necessary to effectuate the purpose of the statute.	
Penalties generally	12-5	The regulations do not address the Department's enforcement discretion to allow retailers, wholesalers, and distributors to possess, store, or hold product that is removed from the UTL. There should be a reasonable opportunity of 60 days for those entities to return the delisted product to the manufacturer, and no penalties should be assessed during that time period. The commenter proposes adding a new Section 955(a)(1) that states: "For 60 days after the Attorney General publishes a notice of removal pursuant to Section 950(e), no penalties shall be assessed under Health and Safety Code section	No changes have been made to the regulations in response to this comment. The proposed change does not fall within any enumerated exception provided in the statute. Subdivision (f)(2)(B) of Health and Safety Code section 104559.1 provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Saf. Code, § 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).) Therefore, retailers will have 30 days of notice when brand styles are removed and may use that time to return to the manufacturer, sell, or otherwise dispose of the products. Furthermore, compliance is a fact-specific determination, and the Department declines to include a provision	114-115

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		104559.1, subdivision (o)(3) against any retailer, wholesaler, or distributor on account of the possession, storage, or holding of inventory of any Brand Style that is the subject of that notice."	in the regulation to limit the Department's enforcement. Moreover, the Department is not the only entity that may enforce the UTL and therefore cannot effectively address enforcement discretion in the regulations. However, the Department has posted information bulletins on the Department's website, such as 2025-DLE-17, Enforcement of Flavored Tobacco Products—Unflavored Tobacco List Next Steps, https://oag.ca.gov/system/files/media/2025-dle-17.pdf, which states that DOJ will exercise enforcement discretion while noting that "State and local law enforcement agencies are authorized to enforce the state's restrictions."	
Economic Analysis				
Economic Analysis	8-5	The Department failed to consider "displacement of lawful commerce into illicit channels, the administrative burden on regulated entities, or the irreversible economic harm that will occur before judicial review is possible." The State of California has experienced an estimated	No change has been made in response to this comment. The comment does not provide sufficient specificity for DOJ to make any modifications to the text. The Department considered the administrative burden and economic impacts on regulated entities (see STD 399 Attachment A, Section B – Estimated Costs) and reasonable alternatives to the proposed regulatory action (see Initial	045-046

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		retail-level tobacco excise tax shortfall of approximately $200 million to $250 million during calendar year 2025 attributable to displacement of lawful vape product sales into unregulated channels; this estimate reflects lost retail excise tax revenue alone. The Department also did not adequately consider "phased implementation, objective testing standards, safe harbors for downstream entities, or other less restrictive alternatives that could advance statutory objectives while minimizing harm to lawful businesses," which "renders the proposed regulations arbitrary and capricious."	Statement of Reasons, p. 32). The Department declines to speculate on the potential secondary impact these regulations may have on retailers that is "attributable to displacement of lawful vape product sales into unregulated channels"; any such impact is too attenuated to estimate. A substantial number of products that retailers cannot sell because they do not appear on the UTL were already unlawful prior to UTL implementation because they are: (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). Moreover, if there are "lawful vape products" that a manufacturer or importer wishes to sell in California, the manufacturer or importer may submit them for inclusion on the UTL. The economic impact on retailers holding prohibited inventory due to the manufacturer or importer declining to register the products is attributable to statutory mandates, not the proposed regulations. Assembly Bill 3218—rather than the implementing regulations—mandates that "[e]very manufacturer and every	

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			importer of tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor," including a description of each unique brand style, the brand style's status with FDA, and a fee of up to $1,000 that covers the Department's reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).) Phased implementation was not feasible in the regulations because Assembly Bill 3218 required the UTL to be published by December 31, 2025. (Health & Saf. Code, § 104559.1, subd. (m).). Regarding the alleged imposition of strict liability for products removed from the UTL without consideration of safe harbors, subdivision (f)(2)(B) of Health and Safety Code section 104559.1 provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Saf. Code, § 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the same day a final notice of removal is	

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			provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).) Therefore, retailers will have 30 days of notice when brand styles are removed and may use that time to return to the manufacturer, sell, or otherwise dispose of the products. Furthermore, compliance is a fact-specific determination, and the Department declines to include a provision in the regulation to limit the Department's enforcement. Similarly, because the Department is not the only entity that may enforce the UTL, enforcement discretion is not included in the regulations. The Department has, however, posted an information bulletin on the Department website, which provides in part: "For tobacco products that are not included in the initial publication of the UTL and are not obviously flavored (including hand-rolled leaf cigars), DOJ intends to initially focus on providing manufacturers with education on the statutory requirements and registration process, rather than taking immediate enforcement action." (Department of Justice, 2025-DLE-17, Enforcement of	

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			Flavored Tobacco Products—Unflavored Tobacco List Next Steps, https://oag.ca.gov/system/files/media/2025-dle-17.pdf.) The regulations do not require testing for every product. The Department declines to require a specific testing method for all products submitted to the UTL because most products will not require that information for a determination, and such evidence could be costly to procure. The Department further declines to mandate specific testing standards, which may vary based on the type of product, the information already submitted by the applicant, and the concerns raised by the Department. The Department does, however, maintain the ability to request additional information and/or conduct independent tests of products.	
Economic analysis	7-1, 11-1, 13-1, 14-1, 14-26, 16-8, 18-1, 19-1	The Department's Initial Statement of Reasons (ISOR) relies on economic projections that appear inconsistent with actual submission data. Documented submission volume from the UTL portal raises questions	No changes have been made to the regulations in response to this comment. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act.	038, 106, 107, 117, 122-125, 289, 293

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		about whether the regulations' economic impact exceeds the $50 million threshold requiring a Standardized Regulatory Impact Assessment (SRIA) under Government Code section 11346.3(c). STD 399 does not account for fees received in different fiscal years in analyzing whether a SRIA is required for the regulation. "DOJ's 'below $10 million' conclusion rests on a 12-month framing that excludes costs businesses must actually pay in the first year." "[T]he STD 399 contains a fiscal year allocation error that further understates first-year impact. The Department allocates Annual Renewal Fees to FY 2026-27, but the first renewal deadline (April	Fees and other business costs identified in the STD 399 are analyzed based on the renewal years they cover, e.g. application fees received prior to March 31, 2026 cover products submitted for inclusion on the UTL in Fiscal Year 2025-2026, and renewal fees received in April 2026 cover products submitted for inclusion on the UTL in Fiscal Year 2026-2027. The Department did not exclude Fiscal Year 2026-27 costs in analyzing the SRIA threshold calculation; even combining all the costs for Fiscal Years 2025-26, 2026-27, and 2027-28, the economic impact does not exceed $10 million or the SRIA threshold. With respect to the comment that the documented submission volume raises questions about Department's economic impact analysis, the Department notes that Submission ID numbers on the UTL portal do not correspond to the number of submissions received by the Department. The Department declines to speculate on the percentage of affected manufacturers or importers that will decline to register tobacco products on the UTL and/or leave the California market; market withdrawal due specifically to the regulations is too attenuated	

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		15, 2026) falls within FY 2025-26 (July 1, 2025 through June 30, 2026). Manufacturers must fund two complete regulatory payment cycles—initial registration (October 9, 2025) and first annual renewal (April 15, 2026)—within 188 days, both in the same fiscal year. This compression understates first-year industry burden and helps explain manufacturer withdrawal risk that results in stranded retailer inventory." Several commenters indicated that the estimated compliance costs would lead them to decide to withdraw, or partially withdraw from the California market, and that these withdrawals are not accounted for in the Department's analysis. For one commenter, costs would lead it to partial withdrawal, reducing its California	to estimate. Following implementation of the UTL, some manufacturers and importers may decline to register products on the UTL and/or leave the California market because those products are: (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). The economic impact on manufacturers or importers that decline to register these prohibited products is attributable to statutory mandates, not the proposed regulations. Finally, the Department notes that Submission ID numbers on the UTL portal do not correspond to the number of submissions received by the Department. As of March 31, 2026, the Department has received payment for 7,566 product or variant forms.	

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		portfolio by 35 percent; another to reducing its California portfolio by 85 percent; and another to reducing its California portfolio by 30 percent. For another, compliance costs would exceed its California profit margin, leading to full market withdrawal. Another commenter stated that premium cigar manufacturers will incur "millions of dollars in regulatory costs" from under the current fee system and that "many companies have indicated they may cease offering certain cigars in California or withdraw from the California market entirely." One commenter also stated that while the "Department's economic analysis assumed the entire UTL program would generate 7,415 total product submissions		

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		statewide," according to the sequentially assigned Submission ID numbers, the Department received approximately 22,212 submissions.		
Economic analysis	7-1, 11-1, 11-2, 13-1, 14-1, 14-16, 14-19, 18-1, 19-1, 22-1	Several commenters state that, based on industry data and sequencing of Department-assigned Submission ID numbers, the STD 399 underestimated the total number of product or variant forms submitted for inclusion on the UTL. "The Department's economic analysis assumed the entire UTL program would generate 7,415 total product submissions statewide (STD 399 Attachment A, Page 5). Actual submission data from the Department's own portal appears inconsistent with this projection."	No change has been made in response to this comment. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. The Submission ID numbers on the UTL portal do not correspond to the number of submissions received by the Department. As of March 31, 2026, the Department has received payment for 7,566 product or variant forms.	038-039, 106, 107, 117, 122-125, 129, TR 21:5-16

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		"Based on submission ID sequencing, the portal has received over 22,000 submissions as of October 2025—three times projected." "Based on these figures, compliance costs appear to exceed the Department's 'Below $10 million' determination. This calculation represents a conservative minimum based solely on documented submission volume and DOJ's own cost estimates." "How did the Department arrive at 7,415 total submissions when actual submissions by October 9 (Submission ID #22,212) exceeded this by 3x?"		
Economic analysis	7-1, 8-6, 11-1, 13-1, 14-6, 14-17, 14-19, 14-26, 14-31, 14-32,	The STD 399 should analyze downstream impacts on retailers. One commenter observed that "[o]nly 92 cigar	No change has been made in response to this comment. The Department does not interpret these comments as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government	038-039, 046-047, 106, 107, 117, 126, 129, 130, TR 21:5-16

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	18-1, 19-1, 22-1	manufacturers have registered" for the UTL, which is "a fraction of the nationally active cigar manufacturers," and that "the STD 399 economic analysis does not account for downstream impacts on retail licensees at all—the 23,523 retail licensees identified through CDTFA data represent an entirely unaccounted category in the Department's economic impact analysis." Another comment asked: "Why were over 23,000+ California tobacco retailers excluded from the STD 399 economic impact analysis when they bear stranded inventory risk?" Relatedly, the commenter asked: "Did the Department evaluate whether the $50 million SRIA threshold was exceeded when	Code section 11346.9, subdivision (a)(3). Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. The Department declines to speculate on the potential secondary impact these regulations may have on 23,000+ California retailers; any such impact is too attenuated to estimate. A substantial number of products that retailers cannot sell because they do not appear on the UTL were already unlawful prior to UTL implementation because they are: (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). Moreover, the economic impact on retailers holding prohibited inventory is attributable to statutory mandates, not the proposed regulations.	

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		applying actual submission volume (22,000+) rather than projected volume (7,415)?" Another commenter disagreed with the Department's conclusion that the proposed regulations will not result in economic harm or employment losses in California, arguing instead that the "proposed regulatory framework is likely to result in widespread business closures, particularly among small and independently owned establishments." Several commenters also stated that a "survey of five California retailers identified over $3 million in at-risk inventory. . . if 1% hold comparable inventory, aggregate stranded value exceeds $138 million—nearly 3x the $50 million SRIA threshold."	The Department recognizes that, following implementation of the UTL, California retailers may no longer be able to sell some unflavored tobacco products because the manufacturers and importers of those products failed to register them for inclusion on the UTL. But Assembly Bill 3218—rather than the implementing regulations—mandates that "[e]very manufacturer and every importer of tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor," including a description of each unique brand style, the brand style's status with FDA, and a fee of up to $1,000 that covers the Department's reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).) Finally, the Department notes that Submission ID numbers on the UTL portal do not correspond to the number of submissions received by the Department. As of March 31, 2026, the Department has received payment for 7,566 product or variant forms.	

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		Another commenter stated that of the 14 members of its association hold $4.6 million in at-risk inventory, with a zero sell-through period. No transitional costs were analyzed for existing in-state, tax-paid inventory.		
Economic analysis	14-6, 14-23, 22-3, 22-6	Commenters request the Department address in the Final Statement of Reasons what percentage of affected manufacturers it anticipates will not register products, and whether potential market withdrawal was factored into the economic impact analysis. The Department's analysis did not include products that	The Department does not interpret this comment as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). No changes have been made to the regulations in response to this comment. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department	126, 130, TR 21:21-22-10

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		will not or cannot be registered. This is orphan inventory, including limited editions, past seasonal releases, and discontinued items. Manufacturers are also selectively registering only high-volume SKUs, and there is no ability to confirm what any manufacturer has actually submitted. The inventory that the manufacturer no longer has incentives to register, or physical samples of, then becomes unsellable due to no action of the retailer.	complied with DOF's guidelines and the Administrative Procedure Act. The Department declines to speculate on the percentage of affected manufacturers or importers that will decline to register tobacco products on the UTL; market withdrawal due specifically to the regulations is too attenuated to estimate. Following implementation of the UTL, some manufacturers and importers may decline to register products on the UTL because they are: (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). The economic impact on manufacturers or importers that decline to register these prohibited products is attributable to statutory mandates, not the proposed regulations. Manufacturers and importers may also decline to register products on the UTL because Assembly Bill 3218—rather than the implementing regulations—mandates that "[e]very manufacturer and every importer of	

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			tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor," including a description of each unique brand style, the brand style's status with FDA, and a fee of up to $1,000 that covers the Department's reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).)	
Economic Analysis	8-6, 14-18, 22-3	The unaccounted for impact on California's small businesses is significantly larger than what the STD 399 reflects. Explain evidentiary support for the determination of zero business eliminations and zero job losses while acknowledging 90 percent small business impact. Commenters disagreed with the Department's conclusion, as reflected in the Initial Statement of Reasons, that the	The Department does not interpret this comment as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). No changes have been made to the regulations in response to this comment. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. The Department finds that the proposed regulations will neither lead to the creation or elimination of any jobs or businesses. Some	046-047, 129, TR 21:21-22:10

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		proposed Unflavored Tobacco List regulations will not result in economic harm or employment losses in California. That conclusion is not supported by current market conditions or by observable tax collection data. Commenters using publicly available tax rates and conservative consumption estimates, estimate that the state has already experienced a retail-level tobacco excise tax shortfall of approximately $200 million to $250 million during calendar year 2025 attributable to displacement of lawful vape product sales into unregulated channels. This estimate reflects lost retail excise tax revenue alone and does not include additional losses associated with distributor-level taxes, sales taxes, income taxes, or related economic activity.	jobs or businesses may be eliminated following implementation of the UTL because the UTL makes it more difficult to sell products that were already (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). This economic impact is attributable to statutory mandates, not the proposed regulations. Some jobs or businesses may also be eliminated following implementation of the UTL because manufacturers and importers may decline to comply with the statutory mandates of Assembly Bill 3218, which requires that "[e]very manufacturer and every importer of tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor," including a description of each unique brand style, the brand style's status with FDA, and a fee of up to $1,000 that covers the Department's	

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		Outreach to licensed smoke shops and vape retailers across California indicate that approximately 50 to as much as 85 percent of gross retail revenue at these establishments is derived from vape product sales. Where the vast majority of lawfully sold vape products are rendered unsellable due to list-based exclusion or regulatory uncertainty, store closures are not speculative—they are economically inevitable. As a direct consequence, the proposed regulatory framework is likely to result in widespread business closures, particularly among small and independently owned establishments. These closures will lead to significant job losses throughout the vape product	reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).) Any job or business creation or elimination specifically attributable to the implementing regulations is too attenuated to estimate.	

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		supply chain. The scale of the affected sector suggests that job losses will reach into the tens of thousands statewide. These economic harms are not offset by increased compliance or lawful substitution. Instead, demand for vape products persists and is increasingly met through illicit, untaxed, and unregulated channels. This outcome not only undermines public health objectives but also exacerbates revenue losses to the State while eroding lawful employment.		
Economic analysis	11-3, 14-5, 14-24	The Department estimates compliance costs at $365-$525 per Brand Style submission (STD 399 Attachment A, Page 2). However, this estimate rests on assumptions that may significantly understate actual burden.	No changes have been made to the regulations in response to these comments. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. All or nearly all of the information required to complete the UTL product and variant forms overlaps with information used by a	107, 126, 130

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		Registration per SKU requires more than 30 minutes, as assumed by the Department, and is a multi-hour task, which may require 2 to 4 hours. Per-SKU compliance for an out-of-state manufacturer includes: document preparation and verification; label, packaging, and carton review; translation and coordination across production teams; international shipping coordination and tracking; and internal approvals, recordkeeping, and renewal planning. Furthermore, the Department's labor estimate did not include photography as a separate line item and did not address that review by compliance officers or legal counsel will be required before executing applications under penalty of perjury.	manufacturer in the routine marketing of such tobacco products. Further, as one applicant observed, "each application takes about 10 minutes, 20 for me because I'm slow." (HBTC Live Episode 304 with special guest Pete Johnson, https://www.youtube.com/watch?v=KvKCgskPXMA (accessed April 28, 2026.) The applicant's observation is consistent with the Department staff observations interacting with numerous applicants regarding application preparation. The Department also notes that: photography is not required if a product design file is provided; the Department has removed the requirement to provide a written description of the package image; the electronic attestation—presumably made by a person familiar with the product familiar with the product they are attesting to—should not take more than a minute to complete; and the UTL portal is designed for ease of use, featuring electronic forms with drop-down menus and streamlined online submission. Furthermore, companies have the discretion to choose who is authorized to execute applications. There is no regulatory requirement that the individual executing the application be a compliance officer or legal counsel. Finally, the	

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		The Department assumes $50 per hour for labor but rates for legal counsel or a compliance officer typically exceed $100 per hour. Using more realistic labor assumptions (3 hours at $100 per hour = $300, versus the Department's $25), actual costs may approach $640-$800 per Brand Style. Based on supplier communications, some manufacturers have indicated they will decline to register rather than absorb these costs.	Department's estimate that it will take approximately 30 minutes to complete an application for a product submitted on the product form includes time that may be necessary—if no design file is available—to photograph and upload the non-blank sides of the brand style.	
Economic analysis	14-7	"The ISOR states the Department previously considered a regulation mandating high-resolution photographs but rejected it due to "inconsistent image quality." The Department provides no analysis of whether standardized photography specifications	No changes have been made to the regulations in response to this comment. The STD 399 published on November 7, 2025, provides that the Department "previously considered a regulation mandating high-resolution photographs of all tobacco product sides as an alternative to requiring that Manufacturers and Importers submit a physical product sample." The commenter does not identify alternative "standardized photography specifications" the	126-127

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		would achieve equivalent verification at lower cost."	Department should have considered. Nevertheless, the Department notes that applicant photography has not always been adequate to assess brand styles, and the Department must frequently consult submitted physical samples when conducting product review.	
Economic analysis	14-11	California imposes tobacco taxes including excise and sales taxes on tobacco products. To the extent that manufacturer withdrawal occurs due to compliance costs, the resulting reduction in legal tobacco sales would produce corresponding reductions in state and local tax revenue. The STD 399 does not appear to account for this potential fiscal impact.	The Department does not interpret this comment as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). No changes have been made to the regulations in response to this comment. Government Code section 11357 requires a state agency to follow the Department of Finance's (DOF) instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. The Department declines to speculate on the potential secondary impact these regulations may have on state and local tax revenues resulting from non-registration of products by manufacturers and importers because any such impact is too attenuated to estimate. Following	128

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			implementation of the UTL, some manufacturers and importers may decline to register products on the UTL because they are: (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). This economic impact is attributable to statutory mandates, not the proposed regulations. Manufacturers and importers may also decline to register products on the UTL because Assembly Bill 3218—rather than the implementing regulations—mandates that "[e]very manufacturer and every importer of tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor," including a description of each unique brand style, the brand style's status with FDA, and a fee of up to $1,000 that covers the Department's reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).)	

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Economic analysis	22-5	"The Standard 399 also projected 10 products per business, whereas one of our coalition stores carries over stores carries over 3,000 different SKUs."	The Department does not interpret this comment as an "objection or recommendation made regarding the specific adoption, amendment, or repeal proposed" of the proposed regulations under Government Code section 11346.9, subdivision (a)(3). No changes have been made to the regulations in response to this comment. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. The STD 399 did not project the submission of ten products per retailer, as suggested by the commenter. While the Department estimated an average of ten unique tobacco products submitted *per manufacturer or importer* for inclusion on the UTL in Fiscal Year 2025–26, it estimated program costs based on its estimate that it would receive approximately 7,415 unique tobacco products for listing on the UTL in Fiscal Year 2025-26. (See Health & Saf. Code § 104559.1, subd. (k) [manufacturers and importers "shall be accompanied by an initial application fee" of up to $1,000 per brand style "to offset the costs incurred by the Attorney	TR 21:17-21.

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			General for processing the submissions and operating the UTL"].) As of March 31, 2026, the Department has received payment for 7,566 product or variant forms.	

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Chapter 11. Unflavored Tobacco List Article 1. General				
§ 942. Definitions				
Applicants, subd. (a)	29-3	To make the UTL requirements more specific to simplify and improve compliance and enforcement, "[m]odify the definition of 'applicant' in §942(a) to explicitly include vape shops that make their own flavors,	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulations are reasonably clear. Vape shops that make their own flavors are covered by the definition of "Manufacturer" in the regulations.	360

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		which means they essentially become 'manufacturers.'"	Under Proposed Section 942, subdivision (a), "Applicant" is defined as a "Manufacturer or Importer." "Manufacturer" is defined in subdivision (k) of Proposed Section 942 as "any person who manufactures, fabricates, assembles, processes, or labels a finished Tobacco Product and any other person licensed as a manufacturer by the California Department of Tax and Fee Administration under Business and Professions Code sections 22979 or 22979.21."	
What constitutes flavor, subd. (f)	29-1	To make the UTL requirements more specific and to simplify and improve compliance and enforcement, prohibit products that have been deemed by FDA to have a "characterizing flavor" from inclusion on the UTL.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. California law has its own definition and standard for characterizing flavor. "A Brand Style 'lacks a Characterizing Flavor' if it lacks any Constituent that imparts a Characterizing Flavor." (Proposed Section 942, subd. (g).) A Characterizing Flavor "means a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco, including, but not limited to, tastes or odors relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert,	345, 359

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			alcoholic beverage, menthol, mint, wintergreen, herb, or spice, or a cooling sensation distinguishable by an ordinary consumer during the consumption of a tobacco product." (Proposed Section 942, subd. (g); Health & Saf. Code, §§ 104559.1, subd. (s)(2); 104559.5, subd. (a)(1).) If FDA has stated that a brand style has a characterizing flavor, that is relevant evidence for the Department's flavor determination but is not dispositive because the FDA standard is not identical to that articulated under the Health and Safety Code.	
What constitutes flavor, subd. (f)	29-2	To make the UTL requirements more specific and to simplify and improve compliance and enforcement, prohibit products that have added ingredients such as sweeteners and/or cooling agents from being included in the UTL.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. California law has its own definition and standard for characterizing flavor. "A Brand Style 'lacks a Characterizing Flavor' if it lacks any Constituent that imparts a Characterizing Flavor." (Proposed Section 942(g).) A Characterizing Flavor "means a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco, including, but not limited to, tastes or	354, 359-360

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			odors relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice, or a cooling sensation distinguishable by an ordinary consumer during the consumption of a tobacco product." (Proposed Section 942, subd. (g); Health & Saf. Code, §§ 104559.1, subd. (s)(2); 104559.5, subd. (a)(1).) The mere presence of an ingredient such as a sweetener or cooling agent does not mean that an ordinary consumer can distinguish a taste, odor, or cooling sensation from the tobacco product Therefore, the Department declines to add this modification.	
What constitutes flavor, subd. (f)	29-9	To strengthen enforcement of the prohibition on tobacco product flavor enhancers, "prohibit flavoring agents that can be added to packaging since these substances can diffuse into the tobacco product."	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulations do not address flavor enhancers or other products sold separately from registered products to produce a flavor that is not found in the marketed product itself. The Department declines to prohibit the mere presence of a flavoring agent in a packaging because the mere presence of such ingredients does not mean that an ordinary consumer can	361

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			distinguish a taste, odor, or cooling sensation from the brand style. The regulations are consistent with the statute, and the Department has exercised its discretion to implement Health and Safety Code section 104559.1 by defining characterizing flavor as stated in Section 942, subdivision (f).	
What constitutes flavor, subd. (f)	27-1	Include clear flavored vape products to the list of permitted products. "[T]he clear, unflavored products I had been purchasing for personal use are no longer meaningfully available." Forcing adults toward heavily formulated tobacco flavored products may not be a better public health result than allowing access to genuinely unflavored alternatives.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulation is consistent with the definition of "characterizing flavor" provided by statute. A "characterizing flavor" is "a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco, including, but not limited to, tastes or odors relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice, or a cooling sensation distinguishable by an ordinary consumer during the consumption of a tobacco product." (Health & Saf. Code, section 104559.5, subd. (a)(1).) An unflavored tobacco product, including an unflavored vape, would not have a	023

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			distinguishable flavor other than that of tobacco since it has no flavor. (See Section 945(c)(4) (listing "E-Cigarettes, Vapes, and E-Liquids" as a category) The Department notes that the label "clear" sometimes indicates that a product has flavor (see Department of Justice, 2024-DLE-18, Restrictions on Flavored Tobacco Products, https://oag.ca.gov/system/files/media/2024-dle-18.pdf.), but even if labeled "clear," a product that lacks a characterizing flavor would be eligible for placement on the UTL.	
The UTL generally, subd. (p)	29-13	The implementing regulations and proposed modifications will greatly simplify compliance with and enforcement of California's expansive flavor ban because: a. The law applies not only to cigarettes and cigars, but also to e-cigarettes, nicotine pouches, and other nicotine products, and explicitly applies to synthetic as well as tobacco-derived nicotine products.	The Department appreciates this comment of support. No change has been made in response to this comment. The comment concurred with the proposed regulations, so no further response is required.	

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		b. The UTL will contain only tobacco products that lack characterizing flavors, so any product that is not on the UTL would be deemed a prohibited flavored tobacco product and illegal for sale in California. This makes it easier for retailers to understand and comply with the law and makes it easier for enforcement efforts. c. Requiring manufacturers and importers to apply for inclusion on the UTL may reduce opportunities to evade the flavor ban. d. Publishing a list of products that are legal to sell makes it easier for retailers to know what they may legally sell. e. By authorizing civil penalties against sellers and making products not on the UTL subject to seizure, the regulations help ensure compliance with the flavored		

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		tobacco ban and aids enforcement efforts. f. The UTL states which products are permitted to be sold. This framing is important because it: (1) makes it more difficult for the industry to come up with new products not specifically identified on a prohibited list (under previous law, anything which was not forbidden was allowed, which made it easier to evade); and (2) makes it easier for retailers to understand and comply.		
The UTL, subd. (p)	26-4	There should be a predictable update schedule to the UTL instead of continuous updates. Under the current framework, products may be added or removed at any time, requiring retailers, distributors, and enforcement officials to continuously monitor the list. Establishing a standard update schedule,	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. Assembly Bill 3218 provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health and Safety Code section 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the	021-022

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		such as twice-annual publication dates with allowances for true emergencies, would provide greater clarity and consistency for regulated businesses and enforcement agencies, improving compliance and reducing inadvertent violations.	same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Section 950, subd. (d).) Therefore, retailers will have 30 days of notice when brand styles are removed. The Department has set up a listserv for updates to the UTL, which will send weekly emails identifying brand styles added to the UTL, along with notices regarding removals of brand styles from the UTL. Members of the public can sign up for the listserv at https://oag.ca.gov/subscribe. The Department declines to eliminate the continuous update schedule because it receives new brand style applications throughout the year and a limited update schedule would cause applicants longer wait times to sell those brand styles. Furthermore, pursuant to statute, once a product is not eligible for the UTL for any of the enumerated removal reasons, the brand style must be removed to maintain the accuracy of the UTL. (Health & Saf. Code, § 104559.1, subd. (f)(1).)	

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The UTL, subd. (p)	24-1	The state should be focusing on efforts to stop minors from vaping, smoking, or purchasing vapes, and making sure people are not selling vapes or smoking products to minors, rather than punishing adults. The ban on flavored tobacco is not nationwide, so many can buy flavored products, and many smoke shops still sell flavored products. The time and money spent on enforcing the flavor ban could be spent on training people better and/or holding them more accountable for selling to minors	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The restriction on flavored tobacco products is statutory (Health & Safety Code, § 104559.5, subd. (b)(1)), and the Department cannot implement regulations that alter the statute, or impair its scope. If any member of the public wishes to report sales of flavored products, the Department's public reporter form is available at https://utl.doj.ca.gov/public-reporter-form.	001
The UTL, subd. (p)	27-2	Commenter requests that the Department "require retailers that sell vape products to offer nicotine free options, so that adults trying to reduce dependence or quit altogether have a practical for quitting	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. Assembly Bill 3218	023

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		support rather than being pushed toward more harmful alternatives, including combustible cigarettes." The current system may be producing worse outcomes by taking away what many adults viewed as the least objectionable option.	does not authorize the Department to require retailers to affirmatively sell products.	
The UTL, subd. (p)	28-11, 28-17	Establish a submission-ID verification mechanism returning limited status only (received/pending/approved/ denied) so retailers can verify whether a product has been submitted for Department review, reducing compliance uncertainty that currently exposes retailers to seizure and civil-penalty exposure for products not yet listed on the UTL. This comment is related to the modifications to sections 945 and 946 because the modifications reduce compliance friction and	The Department notes that this comment is not limited to the modifications because the minor changes to sections 945 and 946 do not impact the necessity of a verification mechanism. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. First, products with pending applications are not eligible for sale during review because the Department has not yet determined whether such products are unflavored and otherwise eligible for the list. (See Health and Saf. Code § 104559.1, subds. (a) "The Attorney General shall establish and maintain . . . a list of tobacco product brand styles that lack a characterizing flavor"], (b)(1) ["The Attorney General may deem each [submission of a brand style] to be a request that the brand style be	034-036

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		"those revised procedures are what give rise to the transparency gap described above." This lack of transparency creates business uncertainty. Retailers cannot verify if a submission is pending or never submitted while it decides to pull products from sale pending approval. "Procedures in which enforcement risk depends on non-public information about pending administrative approvals raise an APA clarity and administrability concern—persons directly affected cannot 'easily understand' their compliance obligations when compliance depends on information the Department does not make available. (Gov. Code § 11349.1(a)(3).)."	included on the UTL."].) Because brand styles under review are not yet eligible for the UTL and may ultimately be denied, creating a mechanism that publicly identifies brand styles submitted for Department review could result in market confusion and create a false imprimatur with respect to products that may never be authorized for inclusion on the list. Furthermore, applicants have expressed concerns over confidentiality for brand styles that have yet to be officially announced and released in California.	

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		This transparency need is demonstrated by the fact that 517 products were approved between January 5, 2026 and March 2, 2026, and the Department's own enforcement bulletin, stating that it would focus on education while cautioning that unregistered products are subject to seizure "underscores an administrability and implementation gap not addressed in the modified text."		
Variant, subd. (r)	28-3, 28-4, 28-5, 28-6, 28-7, 28-14, 28-15	Variants should include variations in size dimensions, including length and ring gauge. The addition of section 945(a)(2) shows that the Department "recognizes that certain limited manufacturing variations—including minor dimensional inconsistencies in hand-wrapped cigars—do not	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to these comments. "Variant" is narrowly defined so that it does not include any effects that could create a flavor difference. Variations in size such as length and ring gauge can affect flavor by changing the ratio of filler to wrapper or how quickly a product is smoked.	029-032, 035-036

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		require separate product or variant forms." Small size differences do not "introduce new constituents or flavoring additives." Requiring a full submission, including fees, increases costs "without a corresponding increase in the information the Department needs to evaluate characterizing-flavor risk." The concern is particularly acute when tobacco composition is identical and "packaging differs only in the vitola name and printed dimensions—physical descriptors that convey size, not flavor." The incremental characterizing flavor risk is zero. Even if submission is required, the fee should not be required. The commenter "does not dispute that certain product-form fields—such as physical dimensions, universal	(See, e.g., Online Cigars, Why Do Larger Ring Gauges Offer a Different Taste Profile – Exploring Flavor Dynamics in Larger Cigars, https://online-cigars.com/posts/post/why-do-larger-ring-gauges-offer-a-different-taste-profile; Online Cigars, How Does a Cigar's Size and Shape Impact Its Flavor Profile - A Guide for Connoisseurs, https://online-cigars.com/posts/post/how-does-a-cigars-size-and-shape-impact-its-flavor-profile.) Therefore, the Department's review of a product that differs in size does not qualify for the discounted fee under the variant process, because that process is intended to eliminate the need for redundant administrative review by linking variations of a tobacco product that should not alter its flavor to an underlying product submitted on the product form. It is true that the Department clarified that small manufacturing inconsistencies do not require flavor review because those inconsistencies, by the Department's definition, are "not distinguishable by an ordinary consumer." (Proposed Section 945(a)(2).) This means that the flavor cannot be distinguishable from the base product. (See Health & Saf. Code, § 104559.5, subd. (a)(1) [defining "Characterizing flavor" as	

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		product codes, and photographs—would differ between vitolas. The Necessity concern is specific: the Department has not identified what additional information bearing on characterizing-flavor risk—the sole statutory basis for UTL eligibility under Health and Safety Code § 104559.1—is gained from a separate full-fee evaluation of an identically composed product." The administrative burden on cigar manufacturers has led to low participation by those manufacturers in the UTL process. Accordingly, the commenter requests a dimension-only supplemental brand style pathway "with streamlined submissions and a reduced incremental fee" or, "[i]f the	"a taste or odor, distinguishable by an ordinary consumer."].)	

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		Department believes statutory constraints require separate full product-form treatment for each dimension-defined Brand Style, an FSOR explanation grounded in Health & Safety Code § 104559.1(s)(1)/(k)(1) and the Necessity standard explaining why identical-composition products require duplicative flavor evaluations at full cost. (Gov. Code §§ 11346.2(b)(4), 11346.9(a)(3).)"		
Article 2. Applications, List Removal, and Renewals				
§ 945. Submission of product form				
Minor variations, subd. (a)(2)	28-1, 28-2, 28-12, 28-13, 28-14	The modified § 945(a)(2) exempts manufacturers from filing separate product or variant forms for manufacturing variations in a Brand Style that are "not distinguishable by an ordinary consumer." The provision further references	No changes have been made to the regulations in response to these comments. The regulations are reasonably clear. Proposed subdivision (a)(2) removes the requirement for a separate product form or variant form for "variations in a Brand Style caused by changes in manufacturing materials or process that are not distinguishable by an ordinary consumer, where a product form or variant form for the Brand Style has already	028-029, 035

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		"minor changes resulting from a Brand Style being manufactured by hand, such as minor inconsistencies in the dimensions of a hand wrapped cigar." This is a practical addition, particularly for handmade cigar manufacturers whose products inherently vary from one unit to the next. However,"[n]ot distinguishable by an ordinary consumer" is unclear, and should be objectively defined with sufficient specificity for manufacturers to determine compliance and retailers to assess their enforcement risk. The regulation needs to specify who makes the determination (e.g., if the manufacturer self-certifies that a variation is indistinguishable or the Department evaluates this	been submitted." As explained in the Final Statement of Reasons, this new subdivision reflects the Department's acknowledgement that certain manufacturing changes that are not marketed differently and would not be distinguishable by an ordinary consumer do not constitute a new Brand Style that would require any new review from the Department through the submission of a new product or variant form. This standard also ensures that there are no flavor changes that would be distinguishable by an ordinary consumer, mirroring the language from the definition of characterizing flavor, which prohibits a constituent with a "a taste or odor, distinguishable by an ordinary consumer either prior to or during the consumption of a tobacco product, other than the taste or odor of tobacco . . . ." (Health & Safety Code, § 104559.5, subd. (a)(1).) The "ordinary consumer" standard is reasonably clear benchmark that relies on common perception rather than technical criteria. Manufacturers and importers are responsible for submitting every eligible brand style that is intended for sale or distribution in or into the state for inclusion on the UTL. The Department has provided examples of brand style variations stemming from changes in manufacturing	

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		after submission); the applicable evidentiary standard (e.g., what the manufacturer must produce to the Department); and when the determination is made (e.g., time of submission, the Department's review, or upon enforcement). Timing affects how manufacturers structure their compliance programs. The phrases "minor inconsistencies" and "minor changes" require clarification and objective definition with sufficient specificity for manufacturers to determine compliance and retailers to assess their enforcement risk. Federally defined premium hand-rolled cigars are "agricultural products measured by length and ring gauge." It is unclear if a minor inconsistency would encompass a variant of 1	materials or processes that may be considered "not distinguishable by an ordinary consumer." These include the replacement of tipping paper with a substantially identical version from a new source, minor adjustments in cigarette length (e.g., 84 mm to 83.8 mm) that are not marketed differently, or minor inconsistencies in the dimensions of a hand-wrapped cigar. As the parties possessing the most direct information regarding their products, manufacturers and importers must determine whether a change is "distinguishable by an ordinary consumer" and submit their products to the UTL accordingly. This aligns with their existing duty to certify that a product lacks a constituent that imparts a "characterizing flavor"—a standard which itself relies on whether a flavor is distinguishable by an ordinary consumer—confirming that manufacturers are best positioned to evaluate and provide this information. As noted in Information Bulletin 2025-DLE-17, if a covered product (including hand-rolled leaf cigars) that is not obviously unflavored is brought to the Department's attention, the Department intends to initially focus on providing manufacturers with education on the statutory requirements and registration	

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		millimeter, a quarter inch, or two ring gauge points. Manufacturers cannot base their compliance on an undefined metric, nor can retailers evaluate their enforcement risk for products not yet appearing on the UTL without knowing where the line is drawn. The lack of clarity violates the Administrative Procedure Act. Commenter proposes the following definition: "For purposes of this subdivision, 'not distinguishable by an ordinary consumer' means the variation would not be apparent to a reasonable consumer through visual inspection of the product and its external packaging and labeling at the point of retail sale. The manufacturer shall make this determination in good faith at the time of	process, rather than taking immediate enforcement action. (Cal. Dept. Justice, Information Bull. No. 2025-DLE-17, Enforcement of Flavored Tobacco Products Restrictions (Nov. 10, 2025) https://oag.ca.gov/system/files/media/2025-dle-17.pdf.) The Department notes that changes to a cigar in the magnitude of a quarter inch or two ring gauge points are generally marketed differently (see Health & Saf. Code, § 104559.1, subd. (s)(1) [providing that "brand style" includes "a brand that is differentiated from other styles of that brand by … marketing"] and would therefore require submission a separate product form. Similarly, significant variations in size, for example two cigars that differ in size by a quarter inch, are "distinguishable by an ordinary consumer" and would require separate product forms.	

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		submission. 'Minor inconsistencies in the dimensions' means variations in length of two millimeters or less, or ring gauge of two ring-gauge points (2/64 inch, ≈ 0.8 mm in diameter) or less, from the dimensions stated on the product form."		
Added nicotine, subd. (c)(6)(G)	29-4	Require UTL applicants to provide proof of the actual nicotine strength under §945(c)(6)(G), since often labels do not accurately reflect the nicotine content.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. Section 945, subdivision (c)(6)(G), requires applicants to provide "the concentration or strength of nicotine in the product," not the labeled concentration or strength. Applicants must certify under penalty of perjury that all provided information is correct. (Proposed Section 947, subd. (c).) The Department can also test provided samples if necessary. (*Id.*, subd. (b)(5).)	360
FDA status, (c)(9)	29-5	"Remove the term 'approval' in all instances of the proposed regulations where it is used in the context of FDA	This comment is not limited to the modifications. Nevertheless, the Department provides a response below.	360

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		authorization of new tobacco products. (E.g., §945(c)(9)). FDA never 'approves' tobacco products; rather, it grants manufacturers permission to market tobacco products." This term should be eliminated because a product deemed "FDA-approved" often leads consumers, especially youth, to misbelieve that the FDA has determined that the product is "safe."	No changes have been made to the regulations in response to this comment. The regulations are reasonably clear. The regulations refer to FDA "authorization, approval, or order" to maintain consistency with the enabling statute, which provides that the Attorney General may decline to include in UTL or remove from the UTL and brand style that is "required to obtain and has not received a formal authorization, approval, or order under Section 387e(j) or 387j" of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 301 et seq. (Health & Saf. Code, § 104559.1, subd. (e).)	
§ 946. Submission of variant form				
Variant form exception, (d)	28-9	Adopt objective criteria for "implicitly convey" as used in this subdivision. "The new § 946(d) sensibly exempts variant forms when internal packaging differs but external packaging is identical—unless statements on the internal packaging 'implicitly or explicitly	No changes have been made to the regulations in response to this comment. The regulations are reasonably clear. The Department declines to incorporate the proposed language. The Department makes this determination on a case-by-case basis. A brand style with a descriptor that implies flavor—regardless of the language of the descriptor or the date descriptor was developed—require separate submission on a variant form under Section 946, as the brand style	033-034

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		convey the presence of a characterizing flavor.'" The implicit standard is unclear, particularly in the context of the packaging of federally defined premium cigars, which include "heritage-based text," geographical indicators of tobacco origin, and "traditional Spanish-language descriptors" such as Maduro, Habano, and Corojo. Under a subjective "implicitly convey" standard, a manufacturer cannot predict how the Department will interpret a foreign-language term recognized in the cigar trade or a brand slogan that predate the regulations. This uncertainty may cause manufacturers to file unnecessary variant forms, defeating the purpose of the exemption. Commenter proposes the following safe harbor: "For	would not qualify for the exemption under subdivision (d).) Based on the provided example, internal packaging only referring to "geographical indicators of tobacco origin" or varietal such as the provided examples of Habano and Corojo, would not implicitly convey flavor. In the example provided, internal packaging only referring to Maduro, a type of tobacco wrapper, would also not implicitly convey flavor.	

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		purposes of this subdivision, statements on internal packaging do not 'implicitly convey' the presence of a characterizing flavor solely on the basis of (a) branding or slogans established prior to the effective date of this regulation, (b) geographical indicators of tobacco origin, or (c) Spanish-language cigar-industry descriptors recognized in the trade prior to the effective date of this regulation that do not explicitly reference a specific non-tobacco flavoring ingredient." Otherwise, the commenter requests that the Department clarify what meets the standard in the Final Statement of Reasons.		
§ 947. Request for Placement on the Unflavored Tobacco List				

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Certification, subd. (c)	29-6	In addition to the certification under penalty of perjury that the product does not have a characterizing flavor, this section should require applicants to provide "rigorous scientific evidence that their products are not flavored as a condition of placement on the UTL" and make it clear that the burden is on the applicant to demonstrate that the product is unflavored and therefore legal to sell, not on the Attorney General to prove that the product is flavored and therefore illegal to sell.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The proposed changes are neither more effective in carrying out the purpose and intent of the statute; as effective and less burdensome to affected applicants than the adopted regulation; nor more cost effective for applicants and equally effective in implementing the statutory policy. Regarding evidentiary burden, as noted in the comment, UTL applications require a certification that a product is unflavored. (Health & Saf. Code, §104559.1, subd. (b)(1)(C).) And, upon request of the Attorney General, an applicant must substantiate that lack of characterizing flavor. (Health and Saf. Code, section 104559.1, subd. (b)(2)(A).) The Department declines to require scientific evidence that products are not flavored for every submission since most products will not require that information for an accurate determination as to whether the product is flavored and such scientific evidence may be costly for companies. However, the Department does maintain the	360-361

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			ability to request additional information, as noted above.	
§ 948. Impact of FDA Status on Listing and Removal				
FDA Status, generally	29-7	Section 948 should follow the example of San Francisco Health Code sections 19R and 19S, and prohibit products that have not obtained FDA marketing authorization from inclusion on the UTL.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. In drafting these regulations, the Department has considered the implementation of Health and Safety Code, section 104559.1, subdivisions (e) and (f), which permit the Attorney General to decline to include on, or remove from, the UTL brand styles otherwise required to obtain but have not yet received a formal authorization, approval, or order from the FDA and has exercised its discretion to implement sections (e) and (f) as described in Section 948. For the reasons identified in the Initial Statement of Reasons, the Department finds that Section 948 sets forth public health-based criteria for market access in California to tobacco products that require but have not received authorization, approval, or order from the FDA under 21 U.S.C. Secs. 387e(j) or 387j.	361
§ 949. Requests for Additional Information				

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Additional information on packaging, marketing, or FDA status, subd. (b)	29-8	"Require all applicants to submit examples of packaging under §949(b) as a condition of placement on the UTL."	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The proposed change is neither more effective in carrying out the purpose and intent of the statute; as effective and less burdensome to affected applicants than the adopted regulation; nor more cost effective for applicants and equally effective in implementing the statutory policy.. Examples of packaging are required under the sample requirement of Section 947, subdivision (b)(5). The regulations do not require samples of variant packaging because variants are brand styles that are already approved, and the application process requires submission of a design file or detailed photos of the brand style as well as the variant. (See Proposed Section 945, subd. (c)(7); Section 946, subd. (g)(12).) Furthermore, the variant definition excludes brand styles with a "packaging differences that imparts flavor." (Proposed Section 942, subd. (s).)	361
§ 950. List Removal				

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Removal, generally	26-2	A clear and reasonable sell-through period should be established when previously approved products are later removed from the UTL to avoid unintentional financial harm and ensure a fair transition when a product's regulatory status changes. Wholesalers and retailers should not be penalized when products are removed with "little or no advance warning and immediately become illegal."	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulation is consistent with Health and Safety Code, section 104559.1, which provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Safety Code, § 104559.1, subd. (f)(2)(B).) The regulations provide that, "[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Proposed Section 950, subd. (d).) Therefore, wholesalers and retailers will have 30 days of notice when brand styles are removed.	021
Removal, generally	26-3	Under California's tobacco tax system, licensed distributors must prepay the excise tax by purchasing and affixing state-issued stamps to cigarette packages prior to distribution. Once a product	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The comment falls outside of the scope of the Department's	021

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		is stamped, the stamp cannot be reused. There should be a refund mechanism for distributors that have stamped products that are subsequently removed from the UTL because the tax was paid in reliance of the product's lawful status and stamps cannot be reused.	rulemaking authority. The collection and remittance of tobacco excise taxes falls within the purview of the California Department of Tax and Fee Administration, and is not addressed by the enabling statute or these implementing regulations.	
Removal notice, subd. (b)	26-1	The regulations should require direct, timely notice to downstream distributors whenever a product is under review for removal or is ultimately removed from the UTL. The current regulations only require notice to applicants, while other market participants must rely on the postings to the Attorney General's website. This approach is insufficient for businesses that make purchasing and inventory decisions based on what	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulation provides public notice to apprise among others, tobacco product retailers and distributors of impending and actual removals. The Department has exercised its discretion to provide in the regulations that notice will be provided on the UTL website. The statute provides that "[r]emoval of a brand style from the UTL will be effective 30 days after the manufacturer or importer is given notice." (Health & Safety Code, § 104559.1, subd. (f)(2)(B).) The regulations	020-021

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		products are on the UTL, and distributors face liability. Without direct notice, distributors may face liability for selling products that were legal at the time of purchase but became unlawful without their knowledge. Strengthening notice requirements to require direct communications to downstream entities, e.g., subscription-based email alerts, at all stages of the removal process would promote a well-informed marketplace, protect reasonable reliance interests, and enhance confidence in the UTL as a reliable compliance tool.	provide that, "[o]n the same day a final notice of removal is provided to Applicant, a public notice will be posted on the Attorney General's website at https://utl.doj.ca.gov communicating the Attorney General's intention to remove the Brand Style from the UTL in thirty (30) days." (Section 950, subd. (d).) Therefore, retailers and distributors will have 30 days of notice when brand styles are removed. The Department notes that it has set up a listserv for updates to the UTL, which will send weekly emails identifying Brand Styles added to the UTL, along with notices regarding removals of Brand Styles from the UTL. Members of the public can sign up for the listserv at https://oag.ca.gov/subscribe.	
Removal notice, subd. (e)	29-10	"In addition to posting a public notice on the AG's website that a product has been removed from the UTL under §950(e), send notices that products are removed from	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulation provides public notice to apprise, among others,	361

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		the UTL to all licensed tobacco product retailers."	tobacco product retailers of removals, so that they may stay compliant with the restrictions on sales of products not appearing on the UTL. The Department has exercised its discretion to provide in the regulations that notice will be provided on the UTL website. The Department notes that it has set up a listserv for updates to the UTL, which will send weekly emails identifying Brand Styles added to the UTL, along with notices regarding removals of Brand Styles from the UTL. Members of the public can sign up for the listserv at https://oag.ca.gov/subscribe.	
§ 951. Renewals				
Renewals, generally	25-1	Revise Section 951(a) to align the renewal date with a December 31 annual publication date, or with the October 9 initial application deadline from the emergency regulations, and provide prorated fee relief to initial applications, if the April 15 date is retained. The requirement of a renewal application by April 15,	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made in response to this comment. The April 15 renewal deadline and the $150 renewal fee are consistent with the language, structure, and intent of Health and Safety Code, section 104559.1, subdivision (k)(1). Subdivision (k)(1) requires that the Department collect an annual renewal fee and further provides that "[t]he fee shall be for the fiscal year ending June 30 and shall not be	004-005

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		2026, for brand styles on the UTL as of March 31, 2026, combined with the fee of $150 and lack of proration, produces an inequitable result for applicants, particularly for federally defined premium cigar manufacturers and small businesses that disproportionately bear the burden of the UTL regulations. The emergency regulations provided that UTL applications submitted by October 9, 2025, would receive a response and be considered for inclusion in the initial UTL published on or before December 31, 2025. The application fees, $300 per brand style and $150 per variant, applied to the fiscal year ending June 30, 2026. But under Section 951(a), the same applicants must submit renewal	prorated." (Health & Saf. Code, § 104559.1, subd. (k)(1).) Because of this statutory requirement, the Department cannot prorate fees. Furthermore, the closeness of the October 9 deadline to the renewal timeline only applies in the first year. The Department disagrees that the UTL fees do not reflect the costs related to the UTL. The April 15 deadline ensures compliance with the statutory requirement that fees align with the fiscal year. Under Health and Safety Code section 104559.1, subd. (k)(1), this renewal fee covers the costs of maintaining the UTL for the *following* fiscal year (beginning July 1). Collecting these funds in advance allows the Department to process payments by the June 30 year-end, ensuring the UTL is fully funded and maintained for the duration of the upcoming fiscal year. The commenter has not provided substantive evidence or justification that the proposed renewal deadlines are necessary to effectuate the purpose of the statute.	

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		applications and pay the $150 per brand style renewal fee by April 15, for the next fiscal year running July 1, 2026 to June 30, 2027. The closeness of the April 15, 2026 deadline to October 9, 2025 creates a compressed fee cycle that imposes financial hardship on small business. It is also inconsistent with the statutory mandate that UTL fees reflect the cost of implementing and maintaining the UTL. The deadline has no basis in the statute and does not advance public health objectives. The commenter proposes the following alternatives: 1) an annual deadline of December 31 to align with the publication date in the statute, 2) an annual deadline of October 9 to align with the initial		

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		publication deadline, 3) if the deadline is unchanged, a prorated credit for timely applications.		
§ 952. Updates				
Changes in FDA information and documents, subd. (b)(2), (b)(3)	30-1	The modified text of subdivision (a)(2) in section 945 could be read as inconsistent with subdivisions (b)(2) and (b)(3) of section 952. Subdivision (a)(2) of section 945 exempts "variations in a Brand Style caused by changes in manufacturing materials . . . [e]xamples of such changes include replacement of a cigarette's tipping paper with substantially identical tipping paper from a new source." However, subdivisions (b)(2) and (b)(3) of section 952 require updates submitted to the Attorney General for certain changes to FDA	No changes have been made to the regulations in response to this comment. The regulation is reasonably clear and internally consistent. Under subdivision (a)(2) of section 945 a manufacturer or importer is not required to submit a new product or variant form for "changes in manufacturing materials or process that are not distinguishable by an ordinary consumer," but, if a change in manufacturing materials or process triggers changes to previously submitted FDA information under subdivision (c)(8) of section 945 or FDA documents under subdivision (c)(9) of section 945, then an update is required under subdivisions (b)(2) and/or (b)(3) of section 952. These updates are necessary to verify a brand style's status with the FDA and whether that status renders the brand style ineligible for listing on the UTL under Proposed Section 948 of the regulations.	364-366

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		documents and information. A minor modification such as a change in tipping paper would necessarily generate additional FDA documents and information, and those documents would arguably fall within the scope of subdivisions (b)(2) and (b)(3) of section 952. Consider removing (b)(2) and (b)(3) of section 952 or appending the following clarifying language to the end of the sections: "Minor changes to a product that would otherwise require the issuance of an exemption from the Substantial Equivalence requirement by FDA under Section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act do not require updates under this section."		
Changes in manufacturing	28-8	Since section 945(c)(8) was deleted, the cross references	Accept. The Department notes that these corrections are non-substantive.	032-033

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materials or process, subd. (b)(5)		in section 952(b)(2)-(4) need to be updated.		
§ 953. Designation of Confidential Information				
Confidentiality of additional information and factual substantiation, subd. (d)	29-11	Make scientific information submitted by applicants under Section 953(7)(d) as additional information available (with confidential proprietary information redacted) for transparency and the ability of scientists and researchers to confirm the unflavored determination.	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The Department cannot implement regulations that alter or amend a statute or enlarge or impair its scope. ("[A]n agency does not have discretion to promulgate regulations that are inconsistent with the governing statute, alter or amend the statute, or enlarge its scope." (*California Sch. Bds. Assn. v. State Bd. of Educ.* (2010) 191 Cal. App. 4th 530, 544.) Health and Safety Code 104559.1, subdivision (b)(2) provides that "additional information and factual substantiation regarding a brand style's lack of characterizing flavor . . . shall be considered confidential and corporate proprietary information." (Health & Saf. Code, § 104559.1, subd. (b)(2).) These regulations cannot make information public that is confidential by statute.	361-362
Article 3. Penalty Citations and Appeals				

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§ 955. Penalty Citations				
Penalty amount, subd. (b)	29-12	"Provide a starting point and/or range for determining the amount assessed for penalty citations and violations under §955(b)."	This comment is not limited to the modifications. Nevertheless, the Department provides a response below. No changes have been made to the regulations in response to this comment. The regulation is consistent with the authorizing statute, which provides maximum penalties. (Health & Saf. Code, section 104559.1, subd. (o)(3).) The Department declines to adopt regulatory penalty benchmarks or ranges for violations of penalties issued under Health and Safety Code section 104559.1, subdivision (o). Maintaining the broad discretionary authority granted by statute allows the Department to tailor enforcement actions to the unique facts of each case, ensuring that penalties remain proportional to the nature and severity of the violation.	362
Economic Analysis				
Economic analysis; Samples, § 947, subd. (b)(5)	28-6, 28-14, 28-15	Because the Department utilized the § 945(a)(2) modification to create a dimensional-variation exemption framework, the	This comment is not limited to the modifications. The Department refers to its response to Nos. 7-1, 8-6 11-1, 11-2, 13-1, 14-2 14-6, 14-17, 14-19, 14-26, 14-31, 14-32, 18-1, 19-1, 22-1, 22-4 from the 45-day comment period.	031-036

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		Department's choice to limit that framework to incidental manufacturing variations—while leaving in place the per-product cost structure for identical-composition vitolas—is the specific regulatory mechanism perpetuating the economic impact on small business/cigar manufacturers, which were not fully accounted for in the Department's economic analysis. A SRIA concern is raised because the February 19 modifications—particularly § 945(a)(2)'s revised submission framework and § 947(b)(5)'s assembled-packaging requirement—change participation and cost assumptions underlying the Department's economic analysis and estimates regarding the economic	The commenter asserts that the Department's decision not to provide a reduced fee for cigars of varying sizes—notwithstanding identical filling and wrapping materials—is the "specific regulatory mechanism perpetuating" non-participation by manufacturers and importers and therefore causing a downstream effect on retailers. The Department complied with DOF's guidelines and the Administrative Procedure Act. The Department declines to speculate on the potential secondary impact these regulations may have on retailers; any such impact is too attenuated to estimate. A substantial number of products that retailers cannot sell because they do not appear on the UTL were already unlawful prior to UTL implementation because they are: (1) impermissibly flavored under Senate Bill 793 (effective December 22, 2022); or (2) adulterated and/or misbranded and were therefore prohibited under federal law (see 21 U.S.C. § 331(a) [prohibiting the introduction into interstate commerce of any tobacco product that is adulterated or misbranded]). Moreover, the economic impact on retailers holding prohibited	

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		impact of the regulations. Commenter raises this data in the context of the modified text itself. The UTL currently lists 4,827 cigar products from 92 manufacturers—approximately 9.4% of the premium cigar SKUs documented in that dataset. The SBA Office of Advocacy has stated in testimony that small businesses dominate the premium cigar industry, and emphasized that compliance costs can fall disproportionately on small manufacturers. This data confirms that the per-product registration framework has not achieved broad manufacturer participation, particularly among the small, independent producers who account for a substantial share of premium cigar production and brand variety	inventory is attributable to statutory mandates, not the proposed regulations The Department recognizes that, following implementation of the UTL, California retailers may no longer be able to sell some unflavored tobacco products because the manufacturers and importers of those products failed to register them for inclusion on the UTL. But Assembly Bill 3218—rather than the implementing regulations—mandates that "[e]very manufacturer and every importer of tobacco products shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor," including a description of each unique brand style, the brand style's status with FDA, and a fee of up to $1,000 that covers the Department's reasonable costs of operating and maintaining the UTL. (See Health & Saf. Code, §104559.1, subds. (b), (k).) Furthermore, the commenter's failure to quantify the specific fiscal impact on retailers resulting from manufacturers or importers declining to register cigars solely due to the lack of a size-based fee reduction reinforces the Department's	

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		and whose products are disproportionately sold by commenter's members. The commenter's updated analysis, based on CDTFA retailer license data and inventory surveys of members, estimates that the UTL's regulatory impact on California's traditional premium cigar retail sector alone approaches the $50 million threshold requiring a SRIA under Government Code § 11346.3(c). Specifically: of 23,523 licensed tobacco retailers statewide (CDTFA data, February 2, 2026), the commenter identified 144–199 traditional premium cigar retailers through a web-validated filtering methodology. Commenter's members' inventory data shows a median non-exempt	position that any claimed economic harm is speculative. Finally, the Department notes that differences in the size of a cigar (such as length and ring gauge) can affect flavor by changing the ratio of filler to wrapper or how quickly a product is smoked. (See, e.g., Online Cigars, Why Do Larger Ring Gauges Offer a Different Taste Profile – Exploring Flavor Dynamics in Larger Cigars, https://online-cigars.com/posts/post/why-do-larger-ring-gauges-offer-a-different-taste-profile; Online Cigars, How Does a Cigar's Size and Shape Impact Its Flavor Profile - A Guide for Connoisseurs, https://online-cigars.com/posts/post/how-does-a-cigars-size-and-shape-impact-its-flavor-profile.) Therefore, the Department's review of a product that differs in size does not qualify for the discounted fee under the variant process, because that process is intended to eliminate the need for redundant administrative review by linking variations of a tobacco product that should not alter its flavor to an underlying product submitted on the product form.	

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		inventory exposure of $161,375 per retailer (trimmed-mean: $245,652). Extrapolated across the confirmed retailer population, statewide inventory exposure ranges from $35.4 million to $48.9 million—before accounting for manufacturer registration costs, compliance labor, or retailers not captured by the commenter's filtering methodology. The Department's STD 399 (Exhibit D) estimated economic impact "Below $10 million" and projected zero business eliminations. The observed manufacturer registration rate of 19.9% relative to the STD 399 projection—and the significant gap between projected and actual manufacturer participation across all product categories—suggest this		

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		estimate requires reassessment. Notably, the STD 399 economic analysis does not account for downstream impacts on retail licensees at all—the 23,523 retail licensees identified through CDTFA data represent an entirely unaccounted category in the Department's economic impact analysis.		
Economic analysis; Samples, § 947, subd. (b)(5)	28-10, 28-16	The revised § 947(b)(5) specifies three options for physical sample submission. The new requirement that samples include "assembled packaging (not flat packed)" has a direct cost impact on out-of-state manufacturers. Shipping assembled cigar boxes incurs a high cost, which are incurred per brand style, per submission. Since the STD 399 was prepared before the requirement to submit assembled packaging	No changes have been made to the regulations in response to this comment. Government Code section 11357 requires a state agency to follow DOF's instructions for estimating a regulation's fiscal and economic impact. The Department complied with DOF's guidelines and the Administrative Procedure Act. The regulations proposed on November 7, 2025 specified that sample packages need to be assembled, and the Department's cost estimates identified in the STD 399 published on November 7, 2025—$10 for manufacturing and $30 for shipping individual products, and $100 for manufacturing and $60 for shipping cartons—were based on the use of assembled packaging for UTL samples.	034, 036

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		existed, the commenter requests confirmation the STD 399 has been updated or, if not, requests that it is updated.		