

## Scientific Basis for Concluding the Newly Introduced California “Non-Menthol” Cigarettes Have a Characterizing Flavor

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### Purpose:

Seeking to escape the prohibition of menthol cigarettes from the California market, two transnational tobacco companies (RJ Reynolds, ITG Brands) introduced “non-menthol” cigarettes containing cooling agents, which they marketed as menthol substitutes. These companies claim that their newly introduced products are legal in that cooling agents do not constitute a “characterizing flavor.” This analysis demonstrates that, under California law, the newly introduced “non-menthol” cigarettes deliver a characterizing flavor, and thus are illegal to sell in California.

### Definitions:

**Gustatory Sense:** Specialized chemoreceptors on the tongue for flavor chemicals.

**Olfactory Sense:** Specialized chemoreceptors in the nose for flavor chemical odors.

**Chemesthetic sense:** Somatic chemoreceptors and mechanoreceptors which provide sensitivity of mucosal surfaces in the mouth and nose to flavor chemicals.

**Flavor:** A substance which induces a sensory impression when inhaled or ingested.

**Taste:** Sensation of flavor perceived on contact with a substance when inhaled or ingested. Taste refers to both gustatory and chemesthetic senses.

### Characterizing Flavor:

US FDA: The multisensory experience ( *i.e.*, taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product.<sup>1</sup>

EU: Clearly noticeable smell or taste other than one of tobacco, resulting from an additive or combination of additives.<sup>2</sup>

California: A distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product.<sup>3</sup> Characterizing flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice.

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<sup>1</sup> FDA Proposed Rule, Tobacco Product Standard for Menthol in Cigarettes, 87 FR 26454 at 26455, 26488. <https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes>

<sup>2</sup> Directive 2014/40/EU of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products. Brussels: European Union; 2014 ([http://ec.europa.eu/health/sites/health/files/tobacco/docs/dir\\_201440\\_en.pdf](http://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf), accessed 15 May 2019).

<sup>3</sup> Senate Bill No. 793. [https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill\\_id=201920200SB793](https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB793)

**Physiology of Flavor Sensory Perception (gustatory, olfactory, & somatosensory contributions):**

Many erroneously believe that taste relates only to the sensation induced by a flavor chemical on the chemoreceptors on the tongue (gustatory sense) and nose (olfactory sense). In fact, a third sensory system is an integral contributor to flavor sensory perception: the somatosensory system.<sup>4</sup> A dense array of nerves convey “mouth feel” information regarding temperature, texture, pungency, astringency, and irritation. The oral somatosensory neurological pathway is conveyed primarily by the trigeminal nerve with contributions by the glossopharyngeal nerve and vagal nerve. This system richly innervates the upper aerodigestive tract with a particularly dense concentration in the mouth. It conveys information to the brain pathways which integrate with gustatory and olfactory input to form the perception of flavor. Studies have shown that temperature perception is modulated via two protein receptors TRPM8 (cold) and TRPV1 (hot).<sup>5</sup>

In both the academic literature and in internal tobacco industry documents the somatic sensory component of flavor perception is variably known as chemesthetic, somatosensory, or trigeminal sensation.<sup>6</sup> Together the gustatory, olfactory, and somatosensory components comprise the perceptual gestalt of the flavor stimulus.<sup>7</sup> All three of these systems function as chemical sensors and work in tandem as a multisensory system contributing to taste perception.<sup>8</sup>

In common sensory experience, thermal chemesthetic sensation is important in the enjoyment of hot coffee/tea or cold beverages and ice cream. A hot dish which has turned cold can be displeasing. Aside from direct thermal effects, an additive chemical can trick temperature receptors into perceiving temperature change. For example, chemicals in capsaicin peppers make one’s mouth feel hot while cooling agents such as menthol give a chilling sensation even though neither change mouth temperature.

Chemesthetic sensation also includes mechanical aspects such as perception of food texture and other stimuli such as the tingling of a carbonated beverage.<sup>9</sup> Food scientists are keenly aware of the central role played by the physical properties of food in appreciation of their products. Somatic sensation also encompasses response to chemical stimuli such as irritation induced by peppers and spices (e.g., ginger, cinnamon, cloves). Chemesthetic stimuli are crucial to sensory enjoyment. For example, curry would not be the same without its impactful somatosensory component.

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<sup>4</sup> Small DM, Green BG. A Proposed Model of a Flavor Modality. In: Murray MM, Wallace MT, editors. *The Neural Bases of Multisensory Processes*. Boca Raton (FL): CRC Press/Taylor & Francis; 2012. Chapter 36. PMID: 22593893. (<https://www.ncbi.nlm.nih.gov/books/NBK92876/>)

<sup>5</sup> Running CA. Oral sensations and secretions. *Physiol Behav*. 2018 Sep 1;193(Pt B):234-237. doi: 10.1016/j.physbeh.2018.04.011. Epub 2018 Apr 10. PMID: 29653113.

<sup>6</sup> Krishnan-Sarin S, O'Malley SS, Green BG, Jordt SE. The science of flavour in tobacco products. *World Health Organ Tech Rep Ser*. 2019 Oct 24;1015:125-142. PMID: 36743396; PMCID: PMC9896977.

<sup>7</sup> Delwiche J. The impact of perceptual interactions on perceived flavor. *Food Quality and Preference*. 2004; 15: 137-146.

<sup>8</sup> Spence C. Multisensory flavour perception. *Curr Biol*. 2013 May 6;23(9):R365-9. doi: 10.1016/j.cub.2013.01.028..

<sup>9</sup> Saint-Eve A, Deleris I, Feron G, et al. How trigeminal, taste and aroma perceptions are affected in mint-flavored carbonated beverages. *Food Quality and Preference*. 2010; 21: 1026-1033.

### Studies of Oral and Nasal Chemesthetic Sensation:

The contribution of the somatosensory system to flavor perception has been extensively studied by the tobacco industry as well as academic researchers. The three primary taste sensory systems -- gustatory (tongue), olfactory (nose), and chemesthetic (feel) -- interact with each capable of modulating the others.<sup>10</sup> For example, addition of a chemesthetic agent can act to enhance the perception of flavors.<sup>11 12</sup> Neural wiring supports this cross sensory modulation in that oral somatosensory projections have robust connections to the central gustatory nuclei.<sup>13</sup> Thermal activation of somatosensory sensors act to modulate the neural circuits in both the gustatory nervous system and tongue taste receptors.<sup>14 15</sup> Across individuals, the acuity of taste varies widely. This is also true for oral chemesthesia.<sup>16</sup> Evidence shows that that cooling agents also induce a somatosensory response in the nasal lining analogous to that in the oral cavity.<sup>17</sup>

### Tobacco Industry Research Into Flavor Sensory Perception:

The tobacco industry has long conducted intensive research into the sensory perception of tobacco smoke, with a particular focus upon menthol.<sup>18 19</sup> Menthol possesses a minty flavor (gustatory) and also induces a notable cooling effect (somatosensory). During the 1980s and 1990s, major companies like R.J. Reynolds and Philip Morris were spending between \$14 and \$20 million per year in chemosensory research.<sup>20</sup> This research focused on somatosensory as well as gustatory and olfactory senses. In internal tobacco documents, the somatosensory contribution is often referred to as the “trigeminal” sense. A search of the Truth Tobacco

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<sup>10</sup> Slack, J.P. Molecular Pharmacology of Chemesthesia. In Chemosensory Transduction; Zufall, F., Munger, S.D., Eds.; Academic Press: Cambridge, MA, USA, 2016; Chapter 21, pp. 375–391, ISBN 978-0-12-801694-7.

<sup>11</sup> Kim EH, Paredes D, Motoi L, Eckert M, Wadamori Y, Tartaglia J, Wade C, Green C, Hedderley DH, Morgenstern MP. Subthreshold chemesthetic stimulation can enhance flavor lastingness of a soft chewable candy. *Food Res Int.* 2021 Feb;140:109883. doi: 10.1016/j.foodres.2020.109883. Epub 2020 Nov 10. PMID: 33648200.

<sup>12</sup> Green BG, Nachtigal D. Somatosensory factors in taste perception: effects of active tasting and solution temperature. *Physiol Behav.* 2012 Nov 5;107(4):488-95. doi: 10.1016/j.physbeh.2012.05.010. Epub 2012 May 17. PMID: 22609629; PMCID: PMC3513519

<sup>13</sup> Green BG, Alvarez-Reeves M, George P, Akirav C. Chemesthesia and taste: evidence of independent processing of sensation intensity. *Physiol Behav.* 2005 Nov 15;86(4):526-37. doi: 10.1016/j.physbeh.2005.08.038. Epub 2005 Sep 30. PMID: 16199067.

<sup>14</sup> Lemon CH. Modulation of taste processing by temperature. *Am J Physiol Regul Integr Comp Physiol.* 2017 Oct 1;313(4):R305-R321. doi: 10.1152/ajpregu.00089.2017. Epub 2017 Aug 9. PMID: 28794101; PMCID: PMC5668616.

<sup>15</sup> Green BG, Nachtigal D. Temperature Affects Human Sweet Taste via At Least Two Mechanisms. *Chem Senses.* 2015 Jul;40(6):391-9. doi: 10.1093/chemse/bjv021. Epub 2015 May 10. PMID: 25963040; PMCID: PMC4542652.

<sup>16</sup> Roukka S, Puputti S, Aisala H, Hoppu U, Seppä L, Sandell MA. The Individual Differences in the Perception of Oral Chemesthesia Are Linked to Taste Sensitivity. *Foods.* 2021 Nov 8;10(11):2730. doi: 10.3390/foods10112730. PMID: 34829011; PMCID: PMC8618882.

<sup>17</sup> Renner B, Schreiber K. Olfactory and trigeminal interaction of menthol and nicotine in humans. *Exp Brain Res.* 2012 May;219(1):13-26. doi: 10.1007/s00221-012-3063-2. Epub 2012 Mar 21. PMID: 22434343; PMCID: PMC3338917.

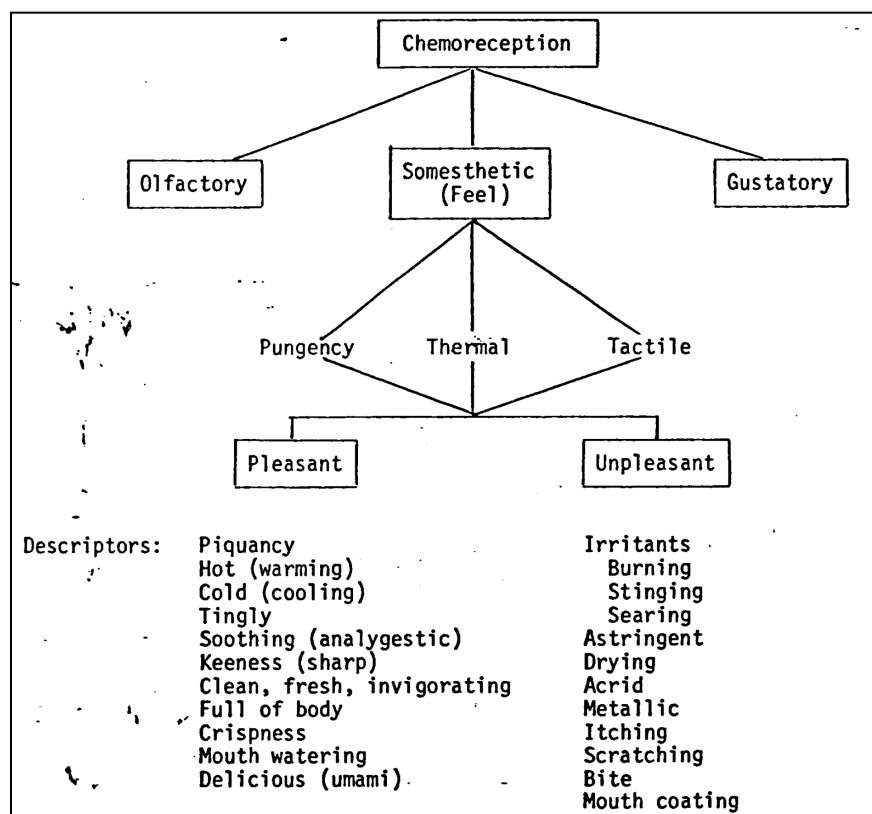
<sup>18</sup> Kreslake JM, Wayne GF, Connolly GN. The menthol smoker: tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior. *Nicotine Tob Res.* 2008 Apr;10(4):705-15. doi: 10.1080/14622200801979134. PMID: 18418792.

<sup>19</sup> Ferris Wayne G, Connolly GN. Application, function, and effects of menthol in cigarettes: a survey of tobacco industry documents. *Nicotine Tob Res.* 2004 Feb;6 Suppl 1:S43-54. doi: 10.1080/14622203310001649513. PMID: 14982708.

<sup>20</sup> Patten T, De Biasi M. History repeats itself: Role of characterizing flavors on nicotine use and abuse. *Neuropharmacology.* 2020 Oct 15;177:108162. doi: 10.1016/j.neuropharm.2020.108162. Epub 2020 Jun 1. PMID: 32497589; PMCID: PMC7814940.

Industry Documents Library for “somatosensory OR trigeminal OR ‘cooling agents’” on March 1, 2023 yielded 15,547 documents.<sup>21</sup> Because RJ Reynolds is the purveyor of two newly introduced “non-menthol” cigarette brands (Camel and Newport) a few of the company’s internal documents relating to “cooling agents” is used as an illustration.

A 1981 RJ Reynolds report, “The Trigeminal Effect as It Relates to Sensory Attributes of Tobacco Products” was authored by Quality Assurance Manager Gerald Boles.<sup>22</sup> The analysis was motivated by the appearance of competitive brands, such as Philip Morris’s Northwind, which contained cooling chemicals rather than menthol. Boles cites then recent academic research which he describes as necessitating: “a complete revision of the concept of taste chemistry.”<sup>23</sup> Regarding the somatosensory impact, which he described as the “feel” of tobacco, Boles concluded: “It is my contention that a very positive effect upon the trigeminal system is responsible for a large part of the widespread acceptance of tobacco products.” He cited research which deemphasized the importance of gustatory and olfactory senses and suggested that the trigeminal sensation is a primary driver of the “wide usage” of tobacco products.



From Boles, RJ Reynolds 1981

<sup>21</sup><https://www.industrydocuments.ucsf.edu/tobacco/results/#q=somatosensory%20OR%20trigeminal&h=%7B%22hideDuplicates%22%3Afalse%2C%22hideFolders%22%3Atrue%7D&subsite=tobacco&cache=true&count=14705>

<sup>22</sup> Boles G; Quality Assurance. The Trigeminal Effect As It Relates To Sensory Attributes Of Tobacco Products. (Feel, As Opposed To Taste And Aroma, As A Smoking Satisfaction Factor).. 1981 July 28. RJ Reynolds Records; Master Settlement Agreement. <https://www.industrydocuments.ucsf.edu/docs/nrjl0095>

<sup>23</sup> Cain W S. Yale University. Sensory Attributes Of Cigarette Smoking. 1980. Brown & Williamson Records; Branbury report. Master Settlement Agreement. <https://www.industrydocuments.ucsf.edu/docs/pfgm0178>

In a 1984 report authored by RJ Reynolds employee Cindy Stewart, titled “trigeminal stimulation produced by cigarette smoke” concluded: “Trigeminal Stimulation and its interaction with other sensory perceptions is necessary before one can understand the basic sensation of cigarette smoke.”<sup>24</sup> The Reynolds report goes on to explain: “The fifth cranial nerve (Trigeminal) mediates common chemical sensation in the nasal cavities and a large portion of the mouth. The generally accepted purely trigeminal chemical sensations include pungency, tingly, harshness, sting, burn, clean, fresh, soothing, cool, warmth, pain and various other somesthetic qualities such as piquancy, acidity, and astringency.” The 1984 Reynolds report goes on to characterize that the trigeminal (chemesthetic sense) makes an important contribution to flavor: “The sense of smell seems also to play only a secondary role in the enjoyment of smoking. If one chemosensory attribute predominates over others, it is that derived through (trigeminal) stimulation of common chemical senses. The common chemical modality *has generally received little acknowledgment for its contribution to flavor*. Yet the modality mediates the important sensation of pungency, warmth, cold, pain, and various to her somesthetic qualities.” (emphasis added)

A 1986 research paper produced while under contract with RJ Reynolds by Dr. Wayne Silver of Wake Forest University titled “The common chemical sense” describes the role of somatosensory perception in taste in great detail.<sup>25</sup> In sum, for 4 decades RJ Reynolds has understood the central importance of somatosensory component of tobacco flavor and taste perception.

## Cooling Agents

Cooling agents induce a sensation of reduced temperature without actually altering it. They are commonly used in the flavor (e.g. confectionaries), oral care, and fragrance industries. Their cooling sensation is perceived by many consumers as connoting freshness and cleanliness. The natural mint extract menthol is the best-known cooling agent in tobacco products. During the 1970s, Wilkinson Sword Research Laboratories introduced a series of synthetic cooling agents in the menthane carboxamide family which cool without menthol’s minty flavor.<sup>26</sup> These compounds are commonly referred to as WS (e.g. WS-3, WS-5, WS-23) and may have a cooling intensity up to four times that of menthol.<sup>27</sup> Cooling flavors can boost the intensity of other flavors.<sup>28</sup> A cooling-flavor mixture can also extend the lasting capacity of the flavor. Cooling agents can also have the effect of masking unpleasant tobacco flavors, such as bitterness,

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<sup>24</sup> Stewart C. Trigeminal Stimulation Produced By Cigarette Smoke. 1984. RJ Reynolds Records; Master Settlement Agreement. <https://www.industrydocuments.ucsf.edu/docs/yhgd0087>

<sup>25</sup> Silver Wl. Wake Forest Univ. The Common Chemical Sense. 1986. RJ Reynolds Records; Master Settlement Agreement. <https://www.industrydocuments.ucsf.edu/docs/hzpm0093>, <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=lfwn0092>

<sup>26</sup> Furrer, S.M., Slack, J.P., McCluskey, S.T. et al. New Developments in the Chemistry of Cooling Compounds. *Chem. Percept.* 1, 119–126 (2008). <https://doi.org/10.1007/s12078-008-9023-3>

<sup>27</sup> Johnson S, Tian M, Sheldon G, Dowd E. Trigeminal Receptor Study of High-Intensity Cooling Agents. *J Agric Food Chem.* 2018 Mar 14;66(10):2319-2323. doi: 10.1021/acs.jafc.6b04838. Epub 2017 Jan 11. PMID: 28042937.

<sup>28</sup> DeLaura C. Perception interaction between cooling and flavors. Thesis. 2014 <https://rucore.libraries.rutgers.edu/rutgers-lib/42376/PDF/1/play/>

including diminishing aftertaste.<sup>29 30</sup> While generally considered safe for ingestion, the inhalational toxicity of synthetic cooling agents has not been thoroughly investigated.<sup>31</sup>

### Cooling Agents in Cigarettes:

The tobacco industry has long been interested in cooling agents. RJ Reynold’s interest in cooling compounds began as early as 1972 when they received and taste tested a series of Wilkinson Sword cooling compounds.<sup>32</sup> By 1990, RJ Reynolds was exploring WS-3 as a “top dressing” for their menthol product lines.<sup>33</sup> Top dressings are flavorings applied toward the end of the manufacturing, using an alcohol solution where the alcohol evaporates and leaves flavoring behind. Emphasizing the role of cooling agents in taste, the study was titled: “Sensory evaluation of WS-3 flavor compound study.” Other tobacco companies including British American Tobacco, Philip Morris, Brown & Williamson, and Lorillard also showed interest in cooling agents.<sup>34 35 36 37</sup> Recently, cooling agents have become common in e-cigarette liquids, especially “ice” flavors which are typically combined with fruit flavors.<sup>38 39 40 41 42</sup>

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- <sup>29</sup> Vummaneni, Vishnumurthy, and Dheeraj Nagpal. "Taste masking technologies: an overview and recent updates." *International Journal of Research in Pharmaceutical and Biomedical Sciences* 3.2 (2012): 510-524.
- <sup>30</sup> Harmik Sohi, Yasmin Sultana & Roop K. Khar (2004) Taste Masking Technologies in Oral Pharmaceuticals: Recent Developments and Approaches, *Drug Development and Industrial Pharmacy*, 30:5, 429-448, DOI: 10.1081/DDC-120037477
- <sup>31</sup> Leventhal AM, Tackett AP, Whitted L, Jordt SE, Jabba SV. Ice flavours and non-menthol synthetic cooling agents in e-cigarette products: a review. *Tob Control*. 2022 Apr 28;tobaccocontrol-2021-057073. doi: 10.1136/tobaccocontrol-2021-057073. Epub ahead of print. PMID: 35483721; PMCID: PMC9613790.
- <sup>32</sup> Swicegood Kw; Rjr. An Interim Summary Of " An Interim Summary Of "The Evaluation Of Wilkinson Sword Cooling Without Menthol Material". Project No 2908.; . Project No 2908.. 1974 August 01. RJ Reynolds Records; Master Settlement Agreement. Unknown. <https://www.industrydocuments.ucsf.edu/docs/zscy0046>
- <sup>33</sup> Gignac J; Product & Applied Technology; Savoca M. Rdm1990 060. Sensory Evaluation of Ws-3 Flavor Compound Study - SALEM 85MF. 1990 March 20. RJ Reynolds Records; Master Settlement Agreement. <https://www.industrydocuments.ucsf.edu/docs/qlwd0152>
- <sup>34</sup> Souza Cruz. Cooling Agent 10. 3-I-Menthoxo propan-1,2-diol (MPD). As an excellent cooling agent. 1993 July 07. Brown & Williamson Records; Master Settlement Agreement. <https://www.industrydocuments.ucsf.edu/docs/mqmn0225>
- <sup>35</sup> Viso ME Synthesis Of 3-Hydroxymethyl-P-Menthyl Levulinate, A Reported Cooling Agent For Use In Mentholated Cigarettes (Project B484, Syn). 1994 May 31. Lorillard Records; Master Settlement Agreement. Unknown. <https://www.industrydocuments.ucsf.edu/docs/fsyf0063>
- <sup>36</sup> BAT Group Research and Development Centre; Wood, DJ. Wilkinson Sword Coolants. 1980 October 02. British American Tobacco Records. <https://www.industrydocuments.ucsf.edu/docs/qfb0195>
- <sup>37</sup> Biswell Ea; Marketing Development Dept. Northwind Historical Review. 1987 February 27. RJ Reynolds Records; Master Settlement Agreement. Unknown. <https://www.industrydocuments.ucsf.edu/docs/jqyv0185>
- <sup>38</sup> Jabba SV, Erythropel HC, Torres DG, Delgado LA, Woodrow JG, Anastas PT, Zimmerman JB, Jordt SE. Synthetic Cooling Agents in US-marketed E-cigarette Refill Liquids and Popular Disposable E-cigarettes: Chemical Analysis and Risk Assessment. *Nicotine Tob Res*. 2022 Jun 15;24(7):1037-1046. doi: 10.1093/ntr/ntac046. PMID: 35167696; PMCID: PMC9199944.
- <sup>39</sup> Leventhal AM, Tackett AP, Whitted L, Jordt SE, Jabba SV. Ice flavours and non-menthol synthetic cooling agents in e-cigarette products: a review. *Tob Control*. 2022 Apr 28;tobaccocontrol-2021-057073. doi: 10.1136/tobaccocontrol-2021-057073. Epub ahead of print. PMID: 35483721; PMCID: PMC9613790.
- <sup>40</sup> Omaiye EE, Luo W, McWhirter KJ, Pankow JF, Talbot P. Flavour chemicals, synthetic coolants and pulegone in popular mint-flavoured and menthol-flavoured e-cigarettes. *Tob Control*. 2022 Aug;31(e1):e3-e9. doi: 10.1136/tobaccocontrol-2021-056582. Epub 2021 Jun 30. PMID: 34193607; PMCID: PMC8716610.
- <sup>41</sup> Omaiye EE, Luo W, McWhirter KJ, Pankow JF, Talbot P. Disposable Puff Bar Electronic Cigarettes: Chemical Composition and Toxicity of E-liquids and a Synthetic Coolant. *Chem Res Toxicol*. 2022 Aug 15;35(8):1344-1358. doi: 10.1021/acs.chemrestox.1c00423. Epub 2022 Jul 18. PMID: 35849830; PMCID: PMC9382667.
- <sup>42</sup> Reger, Lea, Moß, Julia, Hahn, Harald and Hahn, Jürgen. "Analysis of Menthol, Menthol-Like, and Other Tobacco Flavoring Compounds in Cigarettes and in Electrically Heated Tobacco Products" *Contributions to Tobacco & Nicotine Research*, vol.28, no.2, 2018, pp.93-102. <https://doi.org/10.2478/cttr-2018-0010>

### Professional Flavor Organizations Definition of Flavor includes the Chemesthetic Sense

As we have explained above, a scientific consensus exists concerning the integral role of the chemesthetic sense, such as that induced by cooling agents, in flavor perception. Professional societies of flavoring manufacturers and scientific researchers have endorsed this role and incorporate it in their technical definition of the term flavor.

- The **Flavor and Extract Manufacturers Association** of the United States (FEMA) is comprised of flavor manufacturers, flavor users, flavor ingredient suppliers, and others with an interest in the U.S. flavor industry. FEMA defines flavor as: “Flavor is the entire range of sensations that we perceive when we eat a food or drink a beverage. Flavor encompasses a substance’s taste, smell, and any physical traits we perceive in our mouths, such as “heat” (for example, cinnamon) or “cold” (for example, spearmint).”<sup>43</sup>
- The **Society of Sensory Professionals** is a nonprofit organization dedicated to developing and promoting the field of sensory science. Membership is open to anyone anywhere in the world who holds an interest in sensory or consumer science. The society defines flavor as: “perception resulting from stimulating a combination of the taste buds, the olfactory organs, and chemesthetic receptors within the oral cavity; the combined effect of taste sensations, aromatics, and chemical feeling factors evoked by a substance in the oral cavity.”<sup>44</sup>

### US Food and Drug Administration Definition of Characterizing Flavors in Tobacco Products:

The highlighted text below states that among the factors FDA considers relevant in determining whether a cigarette has a “characterizing flavor” is: “The multisensory experience (i.e., taste, aroma, and cooling and burning sensations in the mouth and throat).”<sup>45</sup> While the text comes from a proposed federal product standard that would prohibit menthol in cigarettes, which has yet to be implemented, it does indicate the FDA’s present interpretation of the term, and it includes the chemesthetic sense.

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<sup>43</sup> Flavor and Extract Manufacturers Association of the United States (FEMA) Glossary of terms:  
<https://www.femaflavor.org/flavor-glossary-terms>

<sup>44</sup> Society of Sensory Professionals definition of flavor.  
<https://www.sensorysociety.org/knowledge/sspwiki/Pages/Flavor%20Flavour.aspx>

<sup>45</sup> Tobacco Product Standard for Menthol in Cigarettes (Proposed Rule 5/4/2022). 87 FR 26454 at 26455, 26488. <https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes>

Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience ( i.e., taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products; and
- Any other means that impart flavor or represent that the tobacco products has a characterizing flavor.

FDA 2022 definition of characterizing flavor.

### California Senate Bill No. 793 (Removal of Flavored Tobacco Products from the Market) Definition of Characterizing Flavors

SB No. 793 defines a characterizing flavor as: “a distinguishable **taste** or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproduct produced by the tobacco product. Characterizing flavors include, **but are not limited to**, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice.<sup>46</sup>

**The newly introduced Camel, Newport, and Kool cigarettes induce a strongly perceived cooling sensation caused by the addition of synthetic cooling agents. As there is broad consensus among sensory scientists, the tobacco industry, and flavor industry professional organizations that the chemesthetic sense is an integral component of flavor perception, these “non-menthol” cigarettes have a characterizing flavor as defined in SB No.793.**

Clarifying the characterizing flavor applicability to cooling agents is much more than merely a California issue. The tobacco industry likely views its California launch of “Non-Menthol” cigarettes as a test case for a national roll out should the FDA, as expected, prohibit sale of menthol cigarettes nationally.

<sup>46</sup> Senate Bill No. 793. [https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill\\_id=201920200SB793](https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB793)