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May 4, 2010

**VIA E-MAIL**

New York City Department of Health  
and Mental Hygiene  
Attn: Rena Bryant, Secretary to the Board of Health  
125 Worth Street CN-31  
New York, NY 10013

Re: Comments Submitted on Behalf of Pipe Tobacco Council, Inc. on the Notice of Intention to Amend Title 24 of the Rules of the City of New York to Add a New Chapter 28 (“Restriction on the Sale of Certain Flavored Tobacco Products”)

Dear Ms. Bryant:

Pipe Tobacco Council, Inc. and its members (“PTC”) submit these Comments in response to the Notice of Intention to Amend Title 24 of the Rules of the City of New York to Add a New Chapter 28 (“Restriction on the Sale of Certain Flavored Tobacco Products”), issued by the Department of Health and Mental Hygiene for the City of New York, published in the New York City Record on March 29, 2010.<sup>1</sup> PTC is the national trade association comprised of traditional pipe tobacco manufacturers, importers, distributors and major suppliers to the domestic pipe tobacco industry.

**I. BACKGROUND**

On October 28, 2009, Mayor Michael R. Bloomberg signed into law an ordinance (the “Ordinance”) severely restricting the sale of flavored tobacco products within New York City.<sup>2</sup>

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<sup>1</sup> Available at <http://www.nyc.gov/html/doh/downloads/pdf/notice/2010/amend-title-24.pdf> (last visited April 24, 2010).

<sup>2</sup> See N.Y. City Admin. Code §§ 17-713, *et seq.* (2009).

The Ordinance makes it “unlawful for any person to sell or offer for sale any flavored tobacco product except in a tobacco bar.”<sup>3</sup>

On February 4, 2010, the Cigar Association of America (“CAA”) submitted a letter to the City of New York Departments of Health and Mental Hygiene and Consumer Affairs challenging, *inter alia*, the Departments’ enforcement of the Ordinance until manufacturers, distributors, retailers and consumers are specifically advised as to what products can and cannot be sold under the Ordinance and are given a chance to challenge those determinations.<sup>4</sup> The New York City Law Department responded that the City would not enforce the provisions of the Ordinance “during the pendency of its rule-making process” and until the “enactment of these rules.”<sup>5</sup> The Proposed Rule, described below, followed.

On March 29, 2010, the Department of Health and Mental Hygiene for the City of New York (the “Department”) issued its proposed rule (the “Proposed Rule”)<sup>6</sup> to “define the scope and applicability of the [Ordinance] and provide guidance for sellers of tobacco products about how to determine whether a tobacco product is flavored and therefore subject to restricted sale.”<sup>7</sup> The Proposed Rule fails to provide the required guidance.

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<sup>3</sup> *Id.* at § 17-715 (2009). The Ordinance adopts the definition of “tobacco bar” set forth in section 17-502 of the New York City Administrative Code. *Id.* at § 17-713(i). A “tobacco bar” is a “bar” that “generated ten percent or more of its total annual gross income from the on-site sale of tobacco products and the rental of on-site humidors, not including any sales from vending machines” in the calendar year ending December 31, 2001. N.Y. City Admin. Code § 17-502(jj) (2009). To qualify as a “tobacco bar,” the bar also must: (i) be “registered” as such with the New York City Department of Health and Mental Hygiene; (ii) continue to generate at least “ten percent . . . of its total annual gross income from the on-site sale of tobacco products and the rental of on-site humidors”; and (iii) remain the same size and in the same location as it was on December 31, 2001. *Id.* This standard is nearly impossible to meet and, therefore, currently fewer than ten tobacco bars exist in New York City. *See* Compl., U.S. Smokeless Tobacco Mfg. Co., LLC, v. City of New York, Case No.: 1:2009-cv-10511-CM, ¶ 33 (hereinafter the “Smokeless Tobacco Compl.”). Additionally, most, if not all, tobacco bars do not carry pipe tobacco. Thus, the extremely limited exception to the restriction on the sale of flavored tobacco products is paltry. A more meaningful exception to the ban would permit the sale of flavored tobacco products in retail tobacco shops that restrict entrance to adults.

<sup>4</sup> *See* Letter from Norman F. Sharp, Pres. of Cigar Ass’n of Am., to City of N.Y., Depts. of Health and Mental Hygiene and Consumer Affairs (Feb. 4, 2010).

<sup>5</sup> *See* Letter from Sherrill Kurland, Senior Counsel, City of N.Y. Law Dept., to Hon. Colleen McMahon, U.S. Dist. Judge, U.S. Dist. Ct. S.D.N.Y. (Feb. 10, 2010). Under the New York City Administrative Procedures Act, a final rule is enacted thirty (30) days after it is published in the City Record. *See* 45 N.Y. City Charter § 1043(e).

<sup>6</sup> *See* N.Y. City Admin. Code § 17-718 (providing that the Commissioners of the Department of Health and Mental Hygiene and the Department of Consumer Affairs “shall promulgate any rules as may be necessary for the purposes of carrying out the provisions of this section.”).

<sup>7</sup> Statement of Basis and Purpose, Proposed Rule at 2.

## II. THE PROPOSED RULE

The Proposed Rule primarily addresses the restrictions on the sale of flavored tobacco products,<sup>8</sup> what tobacco products are considered “presumptively flavored tobacco products”<sup>9</sup> and provides a mechanism for tobacco manufacturers to challenge the Department’s determination that a tobacco product that is not presumed to be flavored should be placed on the “Restricted Flavored Tobacco Product List.”<sup>10</sup> It also sets forth enforcement procedures<sup>11</sup> and mandates that all establishments that sell or offer tobacco products for sale outside the original packaging maintain the original packaging until all contents of the package are sold.<sup>12</sup>

Specifically, like the Ordinance, the proposed rule provides that flavored tobacco products “shall only be sold or offered for sale to or in a tobacco bar.”<sup>13</sup> The Proposed Rule adopts the definition set forth in the Ordinance that a “flavored tobacco product” is “any tobacco product or component thereof that contains a constituent that imparts a characterizing flavor.”<sup>14</sup> A “characterizing flavor” is “a distinguishable taste or aroma, other than the taste or aroma of tobacco, menthol, mint or wintergreen, imparted either prior to or during consumption of a tobacco product or component part thereof, including but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice.”<sup>15</sup>

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<sup>8</sup> See Proposed Rule § 28-02.

<sup>9</sup> *Id.* § 28-03.

<sup>10</sup> *Id.* § 28-04.

<sup>11</sup> *Id.* § 28-05.

<sup>12</sup> *Id.* § 28-06. Specifically, the Proposed Rule states that “[e]very owner, operator, manager or other person in control of an establishment that sells or offers for sales tobacco products . . . shall maintain on site the original labels, labeling and packaging provided by the manufacturer” for all products sold outside of the original packaging until the retailer sells “the entire contents of such package.” *Id.* § 28-06(a) (emphasis added). This requirement that retailers maintain such original labels, labeling and packaging for *all* tobacco products, regardless of whether they are flavored or non-flavored, is not contemplated by the Ordinance, is not necessary to carry out the provisions of the Tobacco Product Regulation Act and is unduly burdensome on retailers. This mandate should be removed from the Final Rule.

<sup>13</sup> *Id.* § 28-02(a).

<sup>14</sup> N.Y. City Admin. Code § 17-713(e) (2009); *see also* Proposed Rule § 28-01(h).

<sup>15</sup> N.Y. City Admin. Code § 17-713(b) (2009); *see also* Proposed Rule § 28-01(c).

However, a tobacco product cannot be “determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information.”<sup>16</sup>

In determining whether a product constitutes a “flavored tobacco product,” the Proposed Rule sets forth a two-part test. First, the Proposed Rule provides that “[a] tobacco product is presumed to be flavored if its manufacturer, or any person authorized or permitted by its manufacturer to make or disseminate public statements or claims concerning such tobacco product, has made a statement or claim on the tobacco product’s label, labeling or packaging that such tobacco product has or produces a characterizing flavor.”<sup>17</sup> Second, even if a tobacco product is not presumed to be flavored, it may still be deemed a flavored tobacco product “if it has or imparts a characterizing flavor.”<sup>18</sup> Once a product is deemed a flavored tobacco product, the manufacturer will be notified of the Department’s *intent* that such product be placed on the “Restricted Flavored Tobacco Product List.” If the manufacturer either fails to challenge such classification or the challenge is denied, then the product will be placed on the “Restricted Flavored Tobacco Product List” and it can “only be sold or offered for sale to a tobacco bar or in a tobacco bar.”<sup>19</sup> In its exception to the ban of flavored tobacco products, the Proposed Rule impermissibly fails to include as an exception tobacco products that impart a distinguishable taste or aroma of “tobacco.”<sup>20</sup> Because the Ordinance exempts from the ban those products that impart a “distinguishable taste or aroma [of] *tobacco*, menthol, mint or wintergreen” the Proposed Rule must be modified to include an exemption for “tobacco” flavored products within Proposed Rule §§ 28-01(h), 28-02(b) and 28-03(c).<sup>21</sup>

The Proposed Rule fails to provide guidance as to how the Department will determine if a specific tobacco product or specific brand style of a brand family of product has or imparts such a characterizing flavor. The Proposed Rule also fails to provide a timeframe for enforcement of the Ordinance to begin after its effective date, and does not include a product “use-up” period that would prevent financial harm to retailers who already have flavored tobacco products on their shelves that can no longer be sold in New York City under the Ordinance.

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<sup>16</sup> N.Y. City Admin. Code § 17-713(b) (2009); *see also* Proposed Rule § 28-01(c).

<sup>17</sup> Proposed Rule § 28-03(a).

<sup>18</sup> *Id.* § 28-04(a).

<sup>19</sup> *Id.* § 28-04(a).

<sup>20</sup> *See* Proposed Rule §§ 28-01(h), 28-02(b), 28-03(c).

<sup>21</sup> *See* N.Y. City Admin. Code § 17-713(b) (2009) (emphasis added).

PTC submits these comments and requests that the Department modify the Proposed Rule to (1) clearly identify the methodology it will employ and standards it will use to determine whether a tobacco product “has or imparts a characterizing flavor”; (2) set forth a procedure by which a manufacturer can rebut the presumption of a flavored tobacco product within its brand family of products; (3) accept submissions from supporting third parties, including constituent and ingredient manufacturers, when a manufacturer challenges a product’s inclusion on the “Restricted Flavored Tobacco Product List”; (4) increase the time for a manufacturer to challenge its product’s inclusion on the “Restricted Flavored Tobacco Product List” from thirty (30) days to ninety (90) days; (5) add specific language on the method of notice to retailers and manufacturers, including the establishment of a website version of the “Restricted Flavored Tobacco Product List” that clearly distinguishes between individual brand styles to the sub-brand level within a brand family; (6) provide a product “use-up” period of six (6) months from the date the final rule goes into effect for retailers to sell presumptively flavored tobacco products already in stock; (7) provide a “use-up” period of six (6) months from the date a tobacco product that was not presumptively flavored is added to a website displaying the “Restricted Flavored Tobacco Product List”; and (8) provide full assurances of confidentiality to tobacco manufacturers and the manufacturers of its components and ingredients.

### **III. DISCUSSION**

As written, the Proposed Rule is vague, ambiguous, arbitrary and capricious and, therefore, is unenforceable.<sup>22</sup> Immediate enforcement of a Final Rule will also severely harm retailers who have unused product in their inventory that can no longer be sold. Modifying the Proposed Rule to include the specific information and changes requested by PTC in these comments may decrease the likelihood of a legal challenge to the Final Rule.<sup>23</sup> For those reasons, PTC submits these comments.

#### **A. The Proposed Rule Is Contrary to the Statute, Arbitrary and Capricious Because It Fails to Provide A Procedure for Manufacturers to Rebut The Finding of A Presumptively Flavored Tobacco Product**

The Proposed Rule is deficient because it fails to provide any mechanism to rebut the presumption that a tobacco product is a flavored tobacco product. Like the Ordinance, the

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<sup>22</sup> See, e.g., *In re Law Enforcement Officers Union, Dist. Council 82*, 643 N.Y.S.2d 301, 304 (1995) (enjoining enforcement of rule authorizing double occupancy housing units within correctional facilities because rule change was arbitrary and capricious and, therefore, unenforceable).

<sup>23</sup> By submitting these comments, PTC does not waive its right to challenge the legality of the Ordinance, the Final Rule, inclusion of any product on the “Restricted Flavored Tobacco Product List,” or any enforcement of the restrictions on the sale of certain flavored tobacco products. PTC believes the Ordinance raises significant legal issues that are not addressed herein.

Proposed Rule contains a provision that a tobacco product is presumptively flavored if a “public statement[] or claim[]” is made by its manufacturer or authorized representative “on the tobacco product’s label, labeling or packaging that such tobacco product has or produces a characterizing flavor.”<sup>24</sup> However, there is no procedure in place for a manufacturer to rebut this presumption.

The Ordinance contemplated that the Department would promulgate rules necessary for carrying out enforcement of the Ordinance.<sup>25</sup> It is clear that the Health Committee intended that the above-referenced presumption that a tobacco product is flavored be rebuttable.<sup>26</sup> Despite the intent of the Health Committee, the Department failed to identify in its Proposed Rule any method of rebutting the presumption that a tobacco product is flavored. The Department should modify the Proposed Rule to include such a mechanism.

**B. The Proposed Rule’s Failure to Include Specific Criteria for Determining whether a “Tobacco Product” and Any “Constituent” Impart a “Characterizing Flavor” Render Any Enforcement of The Proposed Rules Arbitrary and Capricious**

The Proposed Rule fails to provide guidance for sellers of tobacco products about how to determine whether a tobacco product that is not presumptively flavored nevertheless has a “characterizing flavor.” The Proposed Rule adopts the definition of “characterizing flavor” set forth in the Ordinance, but does not provide a test that manufacturers, distributors or retailers can use to determine whether a tobacco product (or any component part) “impart[s]” “a distinguishable taste or aroma” that “relat[es] to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice.”<sup>27</sup> It is essential that the Proposed Rule set forth a specific test that the Department will use to determine whether a tobacco product “impart[s]” a “characterizing flavor” so that manufacturers, distributors and retailers -- those who are liable under the Ordinance and Proposed Rule for sales of banned flavored tobacco products -- can determine in advance which products cannot be sold in New York City, and potentially alter the manufacturing of products to conform to the Ordinance.

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<sup>24</sup> Proposed Rule § 28-03(a).

<sup>25</sup> N.Y. City Admin. Code § 17-718 (2009).

<sup>26</sup> The Committee evidenced its intent in the Health Committee Report accompanying the Ordinance, which provided one way of rebutting the presumption: “[e]vidence of the determination by another jurisdiction that a tobacco product does not have or produce a characterizing flavor may be considered in any effort to rebut the presumption that a tobacco product is a flavored tobacco product.” Human Services Division, Committee on Health, *Report on Proposed Int. No. 433-A*, at 10 (Oct. 13, 2009).

<sup>27</sup> N.Y. City Admin. Code § 17-713(b) (2009).

Without advance notice of how the Department will determine whether a product “impart[s]” a “characterizing flavor,” the Ordinance cannot be enforced in a uniform, objective manner. First, the Proposed Rule is ambiguous as to whether the Department will test the tobacco product or its components. Presumably, the result of a smell test of a licorice preservative would impart different results than a similar test of the final tobacco product. Second, the Proposed Rule fails to ensure that the tester of the tobacco products have sufficient qualifications to ensure consistency between testing results of the same products and comparable products. Without stating the criteria, or establishing replicable benchmarks based on publicized standards for determining whether a tobacco product has a “distinguishable taste or aroma,” what smells of vanilla to one tester could simply smell of tobacco to another. Thus, the results of such tests could vary from day to day, and tester to tester. Third, the Proposed Rule fails to provide specific criteria to determine whether a product imparts a “characterizing flavor.” Without providing such specificity to the testers, all test results are purely subjective and non-replicable.

The Department should therefore provide a specific set of criteria that would guide its testers in making its determinations and, likewise, guide manufacturers in creating products that do not unintentionally impart a “characterizing flavor” that lands them on the “Restricted Flavored Tobacco Product List.”

**C. The Current Procedures and Thirty Day Time Period for a Manufacturer to Challenge the Department’s Determination that a Product Is a Flavored Tobacco Product Are Unworkable**

The proposed procedures for objecting to the Department’s notice of intent to include a product on the “Restricted Flavored Tobacco Product List” are unreasonable and unworkable. The Proposed Rule states that if the Department determines that a tobacco product imparts a characterizing flavor, it shall notify the manufacturer and state the basis for its determination.<sup>28</sup> Yet, it does not state with sufficient specificity what information should be included in that notice. The Proposed Rule then provides that “[a] manufacturer may within thirty (30) days of service of the notification described . . . object to the inclusion of its product on the Restricted Flavored Tobacco Product List.”<sup>29</sup> It also mandates that the objection be in writing and “include *all* information and evidence a manufacturer deems relevant to a determination of whether a product has or imparts a characterizing flavor.”<sup>30</sup> As discussed below, the requirement that manufacturers gather and submit, in writing, all relevant information within thirty (30) days after receipt of notification is simply not feasible.

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<sup>28</sup> Proposed Rule § 28-04(b)(1).

<sup>29</sup> *Id.* § 28-04(b)(2).

<sup>30</sup> *Id.* (emphasis added).

**1. *The Proposed Rule should state with specificity the basis for its determination that a product has or imparts a “characterizing flavor”***

To ensure that the manufacturer is given sufficient information to understand how the Department determined that a product imparts a “characterizing flavor,” the Proposed Rule should be modified to mandate what specific information be included in the Department’s notice. First and foremost, the notice should clearly include a statement as to what “characterizing flavor” the Department found the product to have. Additionally, the notice should provide a detailed summary of how the product was tested, who tested it, the results of any scientific test (if any), and the results of any smell or taste test. The results of the smell or taste test ought to include the methodology of the testing (e.g. the ambient conditions under which the product was tested and whether the tester smelled or tasted a characterizing flavor either (i) when the product was lit, (ii) when the product was not lit, or (iii) when the product was being smoked). Such specificity and replicable methods will ensure that the manufacturer has the information it needs in order to challenge the Department’s findings.

**2. *The Proposed Rule should include a mechanism for confidential third party submissions or joint submissions***

The Proposed Rule does not provide any means for a third party to submit documentation in support of a manufacturer’s objection to a product’s proposed inclusion on the “Restricted Flavored Tobacco Product List.” However, it is very unlikely that the manufacturer has all information or evidence “relevant to a determination of whether the product has or imparts a characterizing flavor.” In fact, much of this data may reside with third parties—including constituent manufacturers, distributors or retailers—and a manufacturer would not have the ability to access it.

The fact that third party constituent manufacturers likely possess relevant information greatly complicates the acquisition and submission of evidence in support of a challenge. A manufacturer may deem its constituent’s ingredients “relevant to a determination of whether the tobacco product has or imparts a characterizing flavor.” However, this belief presents practical problems because this information includes trade secrets that will likely be owned by entities other than the tobacco product manufacturer. These entities vigorously guard their formulas and would not provide such information to the manufacturer for its submission to the Department. Thus, the Proposed Rule should be modified to provide a mechanism for confidential third-party submissions or joint submissions between the tobacco manufacturers and constituent manufacturers, distributors and/or retailers.

**3. *The period of time to object to the proposed inclusion of a product on the “Restricted Flavored Tobacco Product List” should be extended to ninety (90) days***

It is clear that a manufacturer may need to provide voluminous support for its objection to the proposed inclusion of its product on the “Restricted Flavored Tobacco Product List.” In order to gather this information, the manufacturers likely will need to reach out to constituent manufacturers, if not also to distributors and retailers to gather “*all*” relevant information. Such a process takes time and would require a coordinated submittal by multiple parties to the Department. It is not feasible for this process to take place within thirty (30) days of service of the notification that the Department determined that a tobacco product has or produces a characterizing flavor. Because of the complexities of gathering and submitting the information necessary to respond to the Department’s decision, and the need for manufacturers to have time to replicate the Department’s test methodology, PTC suggests that the manufacturers be given ninety (90) days to respond to the Department’s decision to include its product on the “Restricted Flavored Tobacco Product List.” In any event, manufacturers should be given *at least* as much time to object as the Department has to rule on the objection (i.e. at least sixty days).<sup>31</sup>

**D. *The Proposed Rule Should Include a Procedure to Notify Retailers that a Product Has Been Added to the “Restricted Flavored Tobacco Product List” and a “Use-Up” Period for Retailers to Clear Out Existing Inventory of Restricted Products***

The Proposed Rule does not identify a mechanism to notify retailers and distributors -- those entities most at risk for violating the Ordinance -- that a product has been added to the “Restricted Flavored Tobacco Product List.” Further, the Proposed Rule does not address tobacco retailer’s financial need to sell restricted flavored tobacco products that it already purchased and has in stock. The Proposed Rule should be modified to set forth a workable procedure to provide electronic notice to retailers and distributors of a product’s restricted status. Additionally, the Department should include a “use-up” period that would allow retailers to sell restricted product for a pre-determined number of days after (1) the final rule goes into effect and (2) a product that was not presumptively flavored appears on the website version of the “Restricted Flavored Tobacco Product List.”

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<sup>31</sup> Proposed Rule § 28-04(b)(4) (prescribing that the Department shall either grant or deny a manufacturer’s request to exclude the tobacco product from the Restricted Flavored Tobacco Product List within sixty (60) days of receipt of a manufacturer’s objection).

***1. The Proposed Rule should provide a specific mechanism to notify distributors and retailers that a product has been placed on the “Restricted Flavored Tobacco Product List”***

Easily-accessible and timely notice that a product has been added to the “Restricted Flavored Tobacco Product List” must be provided to retailers and distributors because they are financially liable for violations of the Ordinance. Without such notice, these entities could unwittingly offer for sale or sell banned products and be subjected to the harsh penalties set forth in the Proposed Rule. Adding a product to “Appendix A” of Chapter 28 of Title 24 of the Rules of the City of New York through the process set forth in the New York City Administrative Procedures Act is insufficient and unlikely to place retailers and distributors on notice that a product is banned for sale outside of a tobacco bar.<sup>32</sup>

The burden of notifying retailers and distributors that a product has been added to the “Restricted Flavored Tobacco Product List” rests with the Department, given that the Department generates and maintains the list. Manufacturers of pipe tobacco products do not have a direct line of communication with most retailers in New York City. Because of this lack of communication, manufacturers cannot be charged with notifying these entities that its specific tobacco products have been banned from sale outside of tobacco bars.

Therefore, in order to provide notice to retailers and distributors that a specific flavored product has been banned from sale in New York City, PTC suggests that the Department add a link to the Restricted Flavored Tobacco Product List to its website. The list should be organized by specific product name to the sub-brand level, state the date that the product was added to the website and, as discussed below, include the “use-up” date for existing product. The effective date of the ban should be ninety (90) days after the product is listed on the website, to ensure that distributors and retailers are sufficiently on notice of a product’s banned status.

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<sup>32</sup> Additionally, inclusion of the “Restricted Flavored Tobacco Product List” as Appendix A to the Rules may require the Department to follow the formal rule-making procedure set forth in the New York City Administrative Procedures Act (the “Act”) each time a product is added to the “Restricted Flavored Tobacco Product List.” See 45 N.Y. City Charter § 1043(a) (mandating that “[n]o agency shall adopt a rule except pursuant to this section” and requiring notice and comment prior to a rule becoming effective). Under the Act, a “Rule” means “the whole or part of any statement or communication of general applicability that . . . implements or applies law or policy . . . .” *Id.* at § 1041(5). A “Rule” includes, but is not limited to “any statement or communication which prescribes . . . standards which, if violated, may result in a sanction or penalty.” *Id.* at § 1041(5)(a). Under this definition, it is possible that including the “Restricted Flavored Tobacco Product List” as Appendix A constitutes a “Rule” under the Act and is subject to the specific rule-making procedures set forth in 45 N.Y. City Charter §§ 1041, *et seq.*

**2. *The Department should add a use-up period to the Proposed Rule to protect retailers from unnecessary financial harm***

The Proposed Rule also should include a “use-up” period that would reduce the negative financial impact on retailers who have restricted product in stock. Retailers that sell pipe tobacco are most likely to suffer financial harm from immediate enforcement of the ban after the final rule goes into effect or a product is added to the “Restricted Flavored Tobacco Product List.” At any given time, a manufacturer or bonded warehouse could have at least six (6) months of product in inventory. In addition, it is not unusual for a retail establishment to have a supply of pipe tobacco on its shelf for over a year.

The inclusion of a use-up period is common when agencies have in the past mandated changes to the production, labeling and/or packaging of tobacco products. For instance, the Alcohol and Tobacco Tax and Trade Bureau (“TTB”) and the Bureau of Alcohol, Tobacco, Firearms and Explosives (“ATF”) both have provided for use-up periods when requiring the industry to change labels and packages of tobacco products, including pipe tobacco. In Treasury Decision ATF-424, issued December 22, 1999, ATF issued temporary regulations requiring manufacturers and importers to mark packages of roll-your-own tobacco as either “roll-your-own tobacco” or “Tax Class J.”<sup>33</sup> The temporary regulations provided a use-up period through April 1, 2000 for manufacturers who used packages that did not meet the marking requirements, provided they used the packages before January 1, 2000.<sup>34</sup> On June 29, 2000, ATF extended the use-up period for six additional months at the PTC’s request.<sup>35</sup> PTC requested that ATF extend the use-up period based on reasons similar to those set forth in these Comments. In addition, in TTB Ruling 2004-1, issued April 7, 2004, TTB gave holders of certificates of label approval until September 1, 2004 to voluntarily surrender non-compliant labels containing calorie and carbohydrate content in alcoholic beverages. Also, in Industry Circular 74-8 (Oct. 22, 1974), ATF gave a one-year use-up period for inventory of stickers, labels and packaging materials on cigars and cigarettes removed for export without payment of tax.

Because of the potential for substantial financial harm to retailers, PTC suggests that the Proposed Rule be modified to include a “use-up” period that would provide a six (6) month stay of enforcement of the Ordinance and final rule in two circumstances. First, retailers should be given six (6) months after the effective date of the final rule to sell presumptively flavored

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<sup>33</sup> See Implementation of Public Law 105-33, Section 9302, Relating to the Imposition of Permit Requirements on the Manufacturer of Roll-Your-Own Tobacco, 64 Fed. Reg. 71,929 (Dec. 22, 1999).

<sup>34</sup> *Id.*

<sup>35</sup> See Extension of Package Use-Up Rule for Roll-Your-Own Tobacco Manufacturers and Importers, 65 Fed. Reg. 40,050 (June 29, 2000).

tobacco already in stock.<sup>36</sup> Second, once a product appears on the website version of the “Restricted Flavored Tobacco Product List,” described *supra*, a retailer should be allowed six (6) months from the date the product appears on that list to sell its existing inventory of the restricted product.

The harm that would result from the postponed enforcement of the Ordinance and Proposed Rule through an established “use-up” date is far outweighed by the harm that retailers would experience if they were prohibited from selling flavored tobacco products already in their inventory. Thus, the Department should create a “use-up” period of six (6) months to allow all non-tobacco bar retailers sufficient time to sell all noncompliant inventory already in stock.<sup>37</sup> During such use-up periods, it is essential that City enforcement officials be provided with regularly updated lists and real-time access to the “Restricted Flavored Tobacco Product List.” The Department should follow well-established government practices related to maintaining the confidentiality of manufacturer trade secrets.

#### **E. The Proposed Rule Does Not Provide Adequate Assurances of Confidentiality**

As discussed above, in order to challenge a determination that a product is a flavored tobacco product, the Proposed Rule requires that a manufacturer object in writing and “include *all* information and evidence that a manufacturer deems relevant to a determination of whether a tobacco product has or imparts a characterizing flavor.”<sup>38</sup> This requirement clearly requires manufacturers to consider submission of information that is confidential or proprietary. As with most consumer products, the ingredients, including flavorings or other constituents, are proprietary to the manufacturer of the ingredient and include valuable trade secret information. The Proposed Rule contains very ambiguous provisions regarding treatment of confidential information. The Proposed Rule states that a manufacturer “may request” that information it submits in accordance with the objection procedures “be designated as confidential.”<sup>39</sup> Further, the Proposed Rule does not ensure that the confidential information will be protected from disclosure, but simply states that “[a]ny portion of a manufacturer’s submission for which such [confidential] privilege is asserted shall be treated as confidential *until such time* as a Freedom of

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<sup>36</sup> Under the New York City Administrative Procedures Act, the effective date of a final rule is thirty (30) days after the rule is published in the City Record. See 45 N.Y. City Charter § 1043(e).

<sup>37</sup> The Proposed Rule should further be modified to ensure that retailers are not cited for violations of the Ordinance until a reasonable period of time elapses after the product first appears on the link to the “Restricted Flavored Tobacco Products List” on the Department’s website, as described in Section II(D)(1), *supra*.

<sup>38</sup> Proposed Rule § 28-04(b)(2) (emphasis added).

<sup>39</sup> *Id.* § 28-04(b)(3).

Information Law Request is made for that information.”<sup>40</sup> Such protection does not extend to any third party submissions, including those of constituent manufacturers. Neither the manufacturers of pipe tobacco nor the constituent manufacturers should have to rely on such a vague promise. The City should abide by the well-established government practices that protect manufacturer trade secrets.

In addition, the New York Freedom of Information Law protects from disclosure “trade secrets” or other records that are “submitted to an agency by a commercial enterprise or derived from information obtained from a commercial enterprise and which if disclosed would cause substantial injury to the competitive position of the subject enterprise” and not simply “confidential” business information as stated in the Proposed Rule.<sup>41</sup> Thus, the Proposed Rule should be modified to mirror the exact language in the Freedom of Information Law to ensure that a manufacturer’s trade secrets and other competition-sensitive data is protected from disclosure *even when* a Freedom of Information Law Request is made for that information. Further, such information should also be protected from disclosure pursuant to a subpoena for agency records. Without such modifications, the provisions of the Proposed Rule are wholly inadequate and unreasonable.

#### **IV. CONCLUSION**

PTC respectfully requests that the New York City Department of Health and Mental Hygiene modify its Proposed Rule immediately to (1) clearly identify the methodology it will employ and standards it will use to determine whether a tobacco product “has or imparts a characterizing flavor”; (2) set forth a procedure by which a manufacturer can rebut the presumption of a flavored tobacco product within its brand family of products; (3) accept submissions from supporting third parties, including constituent and ingredient manufacturers, when a manufacturer challenges a product’s inclusion on the “Restricted Flavored Tobacco Product List”; (4) increase the time for a manufacturer to challenge its product’s inclusion on the “Restricted Flavored Tobacco Product List” from thirty (30) days to ninety (90) days; (5) add specific language on the method of notice to retailers and manufacturers, including the establishment of a website version of the “Restricted Flavored Tobacco Product List” that clearly distinguishes between individual brand styles to the sub-brand level within a brand family; (6) provide a product “use-up” period of six (6) months from the date the final rule goes into effect for retailers to sell presumptively flavored tobacco products already in stock; (7) provide a “use-up” period of six (6) months from the date a tobacco product that was not presumptively flavored is added to a website displaying the “Restricted Flavored Tobacco Product List”; and (8) provide

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<sup>40</sup> *Id.* (emphasis added).

<sup>41</sup> *See* N.Y. Pub. Off. Law § 87(2)(d).

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full assurances of confidentiality to tobacco manufacturers and the manufacturers of its components and ingredients.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kellie L. Newton". The signature is written in a cursive, flowing style.

Kellie L. Newton, Esq.  
Counsel for Pipe Tobacco Council, Inc.