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BACKGROUND

In May 2016, the Federal Food, Drug, and Cosmetic Act was amended to give FDA authority to regulate additional tobacco products, including cigars. Because limited information exists on the composition of cigar filler and chemistry of smoke yields, 60 brands of popular little cigars (filtered sheet-wrapped cigars) (Length: 70-100 mm/Tobacco Weight: 0.7-1.3 g) sold in the US were characterized for physical properties (i.e., tobacco weight, rod length, and rod diameter), tobacco filler nicotine, NNK, NNN, and pH, using validated in-house methods. Nicotine, NNK, NNN and pH of the little cigars were compared to those of 50 popular cigarettes.

METHODS

<u>Physical Properties</u>: Tobacco weight, rod length and diameter of the little cigars were measured with a Cerulean C² and Cerulean PPM.

pH: Calibrated pH meter using standard buffers 4.01 and 7.00.

NNK and NNN: Validated LC/MS/MS method, Waters XBridge BEH C18 column (4.6 mm x 60 mm x 5 μ m), aqueous ammonium acetate mobile phase, isotopically labeled internal standards are used for accurate quantification.

Nicotine: Validated GC/MS method, HP-Ultra column (25m x 0.32mm x 52μm), helium carrier gas are used. Nicotine is extracted by methyl-*tert*-butyl ether (MTBE) + 2N NaOH.

Free Nicotine: Calculated from pH and pKa value of the pyrrolic nitrogen of nicotine using Henderson-Hasselbalch equation.

pH = pKa + log (free NIC/(total NIC – free NIC)) pKa = 8.02

Free (NIC) = ([10pH - 8.02] total NIC) / (1 + [10pH - 8.02])

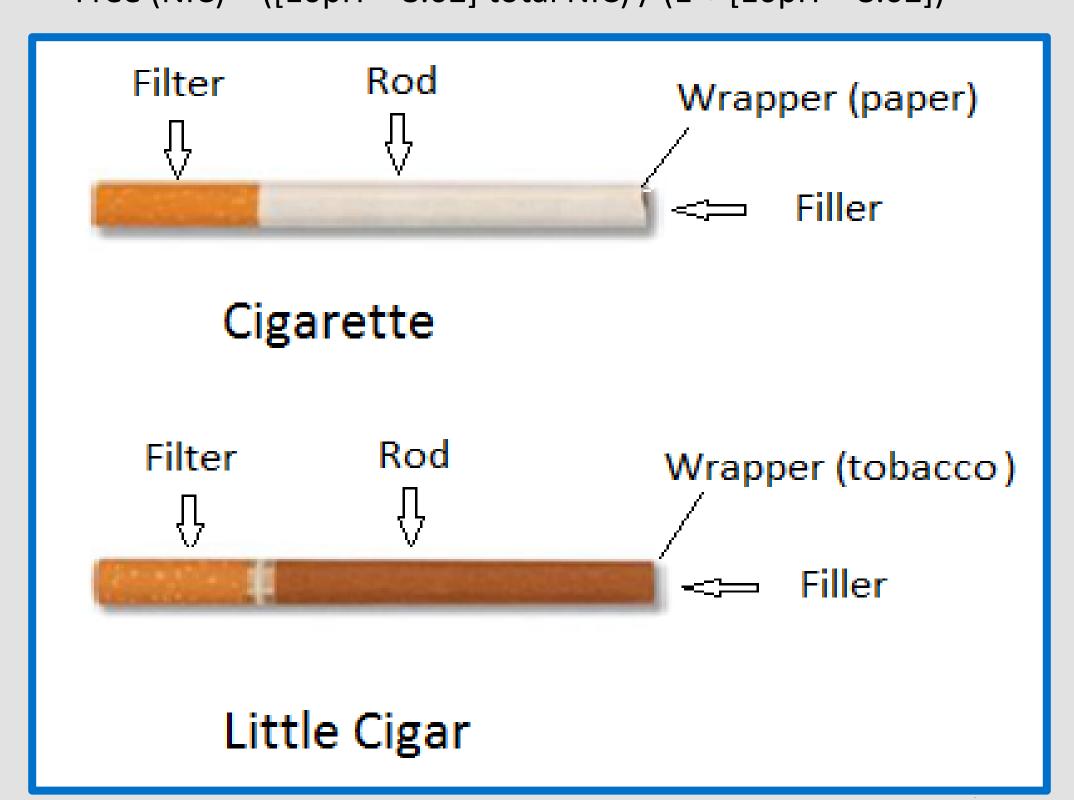


Figure 1. Comparison of a Little Cigar and a Cigarette

Figure 1 illustrates that unlike other types of cigars, little cigars are similar to cigarettes with respect to appearance and size of components including the filter, rod, filler and wrapper. Although the specific ingredients may differ.

LITTLE CIGAR RESULTS

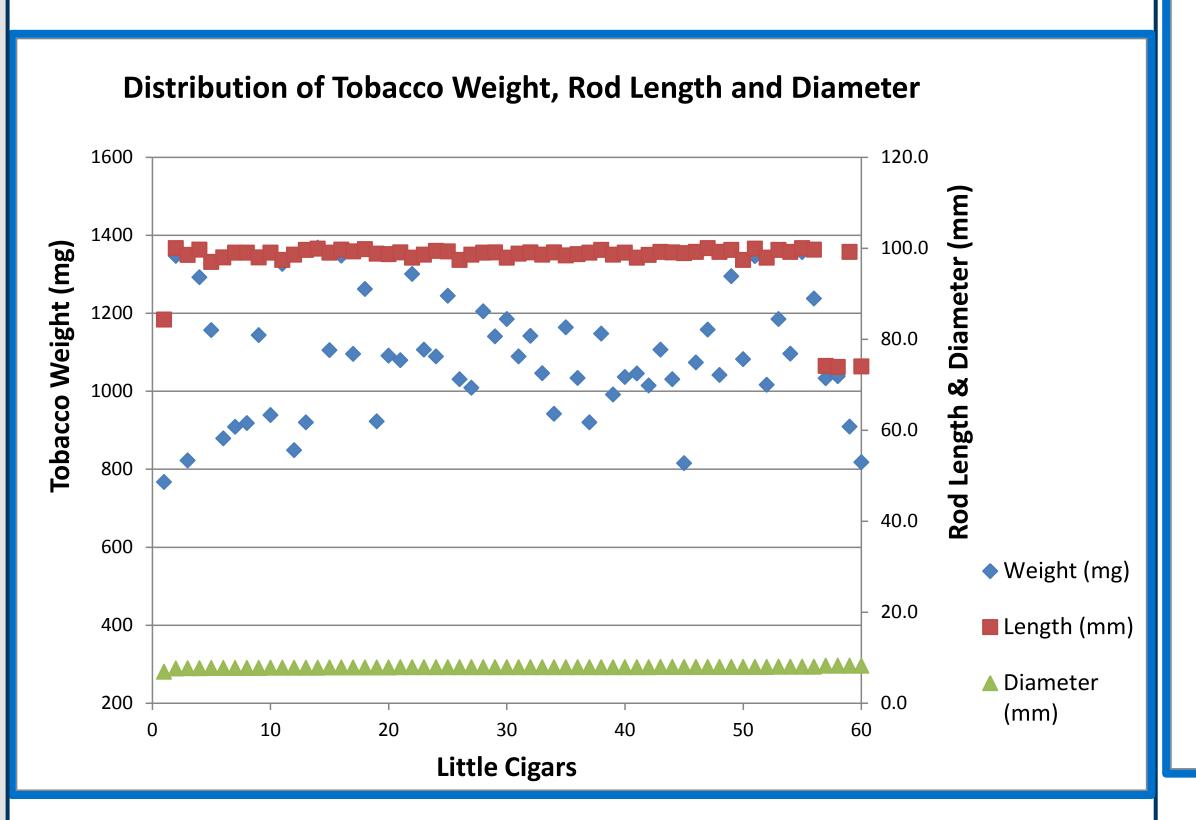


Figure 2. Distribution of tobacco weight, rod length and diameter in the 60 little cigar brands

Figure 2 indicates:

- The tobacco weight (blue diamonds) varies from 767 mg to 1367 mg.
- Most of the little cigars have a rod length (red squares) of approximately 100 mm with a few in a range from 74 mm to 85 mm.
- The rod diameter (green triangles) ranges from 6.8 mm to 8.4 mm.

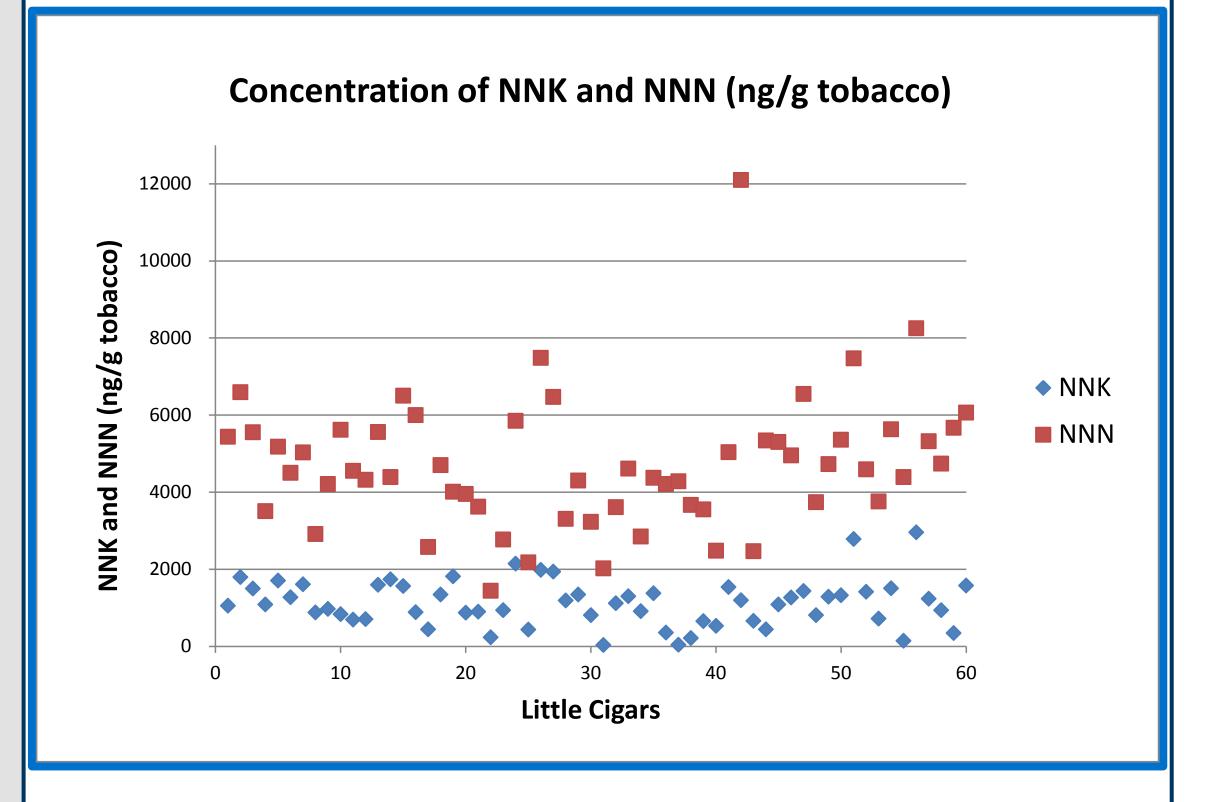


Figure 3. Distribution of NNK and NNN concentrations (ng/g tobacco) in the 60 little cigar brands

Figure 3 indicates:

- NNK (blue diamonds) varies from 26 to 2950 ng/g tobacco.
- NNN (red squares) varies from 1440 to 12100 ng/g tobacco.
- Both NNN and NNK concentrations have a wide range and NNN is higher than NNK.

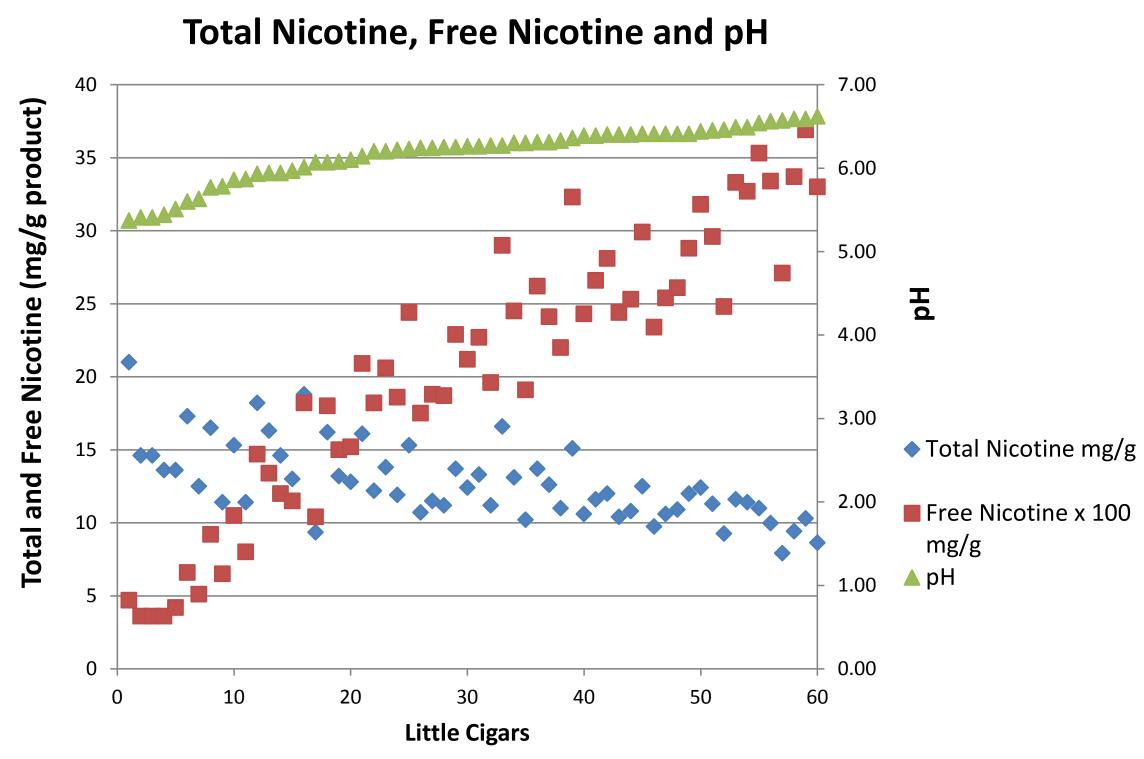


Figure 4. Distribution of total and free nicotine concentrations and pH of the 60 little cigar brands

Figure 4 indicates:

- The total nicotine concentrations have a range of 7.9 21.0 mg/g tobacco (blue diamonds).
- The free nicotine concentrations have a range of 0.05 -0.33 mg/g tobacco (red squares).
- The pH ranges from 5.4 to 6.6 (green triangles). It is noted that the free nicotine concentration increases rapidly with the increase of pH value.

Summary Results for Little Cigars

- Mean tobacco weight at 1085 (range 767 1367) mg
- Mean rod length at 97.4 (range 73.9 100) mm
- Mean rod diameter at 7.8 (range 6.8 8.4) mm
- Mean NNK at 1118 (range 26 2950) ng/g tobacco
- Mean NNN at 4714 (range 1440 12100) ng/g tobacco
- Mean total nicotine at 12.7 (range 7.9 21.0) mg/g tobacco
- Mean free nicotine at 0.21 (range 0.05 0.33) mg/g tobacco
- Mean pH at 6.2 (range 5.4 6.6)

COMPARISON OF LITTLE CIGARS WITH POPULAR CIGARETTES

Nicotine, NNK, NNN, and pH in 50 popular cigarettes (top-selling cigarettes) in US have been studied and published by T. S. Lawler, *et al.*¹ and S. H. Edwards, *et al.*² Unlike other types of cigars, little cigars are similar to cigarettes with respect to size and components. A preliminary comparison of 60 common little cigars with 50 popular cigarettes shows differences between these product categories (See Table 1).

Table 1. Comparison of pH, Nicotine, NNK and NNN between 60 Little Cigars and 50 Popular Cigarettes

Tobacco Product		рН	Total Nicotine (mg/g)	Free Nicotine (mg/g)	% Free Nicotine	NNK (ng/g)	NNN (ng/g)
Little Cigar	Mean	6.2	12.7	0.21	1.7	1118	4714
	Range	5.4 - 6.6	7.9 - 21.0	0.05 - 0.33	0.2 - 3.8	26 - 2950	1440 - 12100
Cigarette	Mean	5.5	19.2	0.05	0.3	523	1901
	Range	5.1 - 5.6	16.2 - 26.3	0.032 - 0.082	0.12 – 0.38	194 - 1903	306 - 2970
Difference		个13%	↓34%	个320%	个467%	个114%	个148%

Note: Cigarette rod length is approximately 100 mm or 84 mm and rod diameter is approximately 8 mm or 6 mm; Little cigar rod length is approximately 100 mm with a few in a range from 74 mm to 85 mm and rod diameter ranges from 6.8 mm to 8.4 mm.

Summary Results of the Comparison

- Little cigars and cigarettes have similar physical dimensions and appearance.
- Mean NNK amount of little cigars is higher than that of cigarettes (1118 vs 523 ng/g tobacco).
- Mean NNN amount of little cigars is higher than that of cigarettes (4714 vs 1901 ng/g tobacco).
- Mean total nicotine amount of little cigars is lower than that of cigarettes (12.7 vs. 19.2 mg/g tobacco).
- Mean pH of the little cigars is greater than that of cigarettes (pH 6.2 versus pH 5.5), resulting in a higher mean free nicotine amount in the little cigars than in the cigarettes (0.21 vs. 0.05 mg/g tobacco free nicotine concentration; 1.7% vs. 0.3% percent free nicotine).

CONCLUSIONS

 The data suggests that despite the similarities to cigarettes, little cigars may deliver more free nicotine and expose users to more harmful chemicals.

REFERENCES

T. S. Lawler, et al. (2017). Surveillance of Nicotine and pH in Cigarette and Cigar Filler. Tob. Regul. Sci. 3(2 Suppl 1), S91-S106.
 S. H. Edwards, et al. (2017). Tobacco-Specific Nitrosamines in the Tobacco and Mainstream Smoke of U.S. Commercial Cigarettes. Chemical Research in Toxicology. 30 (2), 540-55.

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2048(72) - Document not peer-reviewed