HPHC Market Map Study for US Machine-made Cigars - Part 2: Predictive Modeling

ABSTRACT

In May 2016, the U.S. Food and Drug Administration (FDA) issued a final rule to deem cigars to be subject to the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). As part of this regulation, the FDA will require manufacturers to report the quantities of Harmful and Potentially Harmful Constituents (HPHCs) in cigar filler and smoke. However, there have been few, if any, thorough and rigorous studies of smoke and tobacco chemistry and physical properties of cigars. Market maps or benchmarking studies have been used in the cigarette industry for many years to aid in the characterization of the marketplace. Cigars, as a category, have been little-studied as compared to cigarettes. Market map studies provide comparative values and predictive models for aiding in the assessment of other marketplace products. This study examined cigar smoke yields, tobacco chemistry, and physical properties of 24 machine-made cigars from the US marketplace to develop marketplace predictive relationships to aid in the evaluation of machine-made cigars not included in this sample of products. Cigars show much greater variability in weight and resistance to draw than cigarettes and that variation is reflected in much greater smoke yield variability than is seen with cigarettes. Products were smoked using the CORESTA, ISO, and Health Canada Intense smoking regimes for all the constituents on the FDA abbreviated HPHC list for cigarettes. The cigars were also tested for each of the tobacco filler constituents on the FDA abbreviated HPHC list for cigarettes. The market map approach facilitates comparison of smoke yields within the broader market perspective rather than one-to-one cigar comparisons. Many of the smoke yield correlations are further improved by incorporating the tobacco characteristics into predictive models.

MARKET MAPPING

► 24 US machine-made cigars

- Diameter: 7.8 mm 16 mm
- Length: 95 mm 158 mm
- Weight: 1.1 g 8.0 g
- 13 untipped, 3 filter tip, 8 plastic/wood tipped

Products were tested for physical properties and smoke and filler HPHCs

- Smoking regimes: CORESTA, ISO, Intense
- 18 constituents on FDA's abbreviated constituent list, plus tar and total particulate matter (TPM)
- 7 replicates for each product for each constituent for each regime

STUDY OUTLINE

- Compare variability and yields of three different smoking regimes: CORESTA, ISO 3308 (ISO), Intense ISO 20778 (Intense)
- Examine correlations of TPM, tar, and CO to smoke constituent yields and effect on market mapping prediction intervals
- Examine cigar filler temporal manufacturing variability

SMOKING REGIMES

CORESTA CRM #64 ¹	ISO 3308 ²	Intense ISO 20778 ³
20	35	55
40	60	60
1.5	2	2
none	none	100
	CORESTA CRM #641 20 40 1.5 None	CORESTA CRM #641ISO 33082203540601.52Nonenone

See figure to the right for CORESTA puff volume for cigar diameters > 12 mm.



RESULTS

Comparison of Smoking Regimes Relative Variation (RSD) of the Three Smoking Regimes by Analyte

	Cigars		
Analyte	CORESTA	ISO	Intense
-Aminonapthalene	11.8	14.1	11.8
2-Aminonapthalene	11.2	13.6	11.9
-Aminobiphenyl	10.5	13.1	11.2
Acetaldehyde	10.9	9.3	8.4
Acrolein	12.4	11.0	10.8
Acrylonitrile	12.0	11.8	10.1
Ammonia	20.3	19.0	22.0
Benzene	10.3	9.2	8.9
Benzo[a]pyrene	9.3	9.2	9.5
,3-Butadiene	12.2	11.6	11.3
00	13.1	12.6	8.5
Crotonaldehyde	11.7	10.4	8.4
Formaldehyde	22.1	15.9	20.0
soprene	13.0	11.8	12.3
INK	17.9	20.6	17.0
INN	16.9	18.8	15.9
licotine	15.0	14.8	14.6
ar	12.0	11.4	10.4
oluene	11.6	10.4	9.3
PM	19.1	14.7	14.6
VERAGE	13.7	13.2	12.4

Average Measured Diameters and Calculated Puff Volumes Under **CORESTA Regime**

Product	Diameter	CORESTA Puff Volume	Product	Diameter	CORESTA Puff Volume
		mL			mL
1	10.7	20	13	10.7	20
2	12.7	22	14	15.7	34
3	10.7	20	15	9.4	20
4	9.6	20	16	10.4	20
5	9.6	20	17	10.4	20
6	9.6	20	18	10.6	20
7	9.5	20	19	10.3	20
8	7.9	20	20	7.9	20
9	11.2	20	21	7.9	20
10	11.0	20	22	10.1	20
11	10.1	20	23	10.3	20
12	11.2	20	24	10.2	20

Tar Yield Comparison Under the Three Smoking Regimes







- Commonly indexed by Tar, TPM, or CO



compounds were better correlated to tar or TPM



NNN Prediction Intervals Using TPM Alone





Prediction Intervals

Common outputs from market maps or benchmarking studies are prediction intervals giving ranges within which future results are expected to lie.

- May incorporate filler analyte concentration

NNN Prediction Intervals Including Filler NNN



R² for the Analytes Examined to Determine Where Including Filler HPHCs in Prediction Intervals was Beneficial

Smoke Analyte	Regime	Tar or TPM Only	Tar or TPM and
			Tobacco
NNN	CORESTA	0.464	0.843
(with TPM)	ISO	0.293	0.842
	Intense	0.511	0.871
NNK	CORESTA	0.402	0.634
(with TPM)	ISO	0.271	0.757
	Intense	0.471	0.706
Nicotine	CORESTA	0.552	0.706
(with Tar)	ISO	0.622	0.715
	Intense	0.588	0.579
Formaldehyde	CORESTA	0.225	0.767
(with Tar)	ISO	0.269	0.700
	Intense	0.141	0.559
Ammonia	CORESTA	0.305	0.332
(with TPM)	ISO	0.255	0.274
	Intense	0.002	0.215

NNN, NNK, and formaldehyde prediction intervals were noticeably improved by including filler HPHCs. NNN and NNK are improved because of the

Results from different production batches were often quite different in measured filler NNN value, indicating that there is considerable variability in NNN content with different batches of products.

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CONCLUSIONS

- Cigars are a more diverse product category than cigarettes.
- All three smoking regimes gave similar levels of variability and generally ranked the smoke yields comparably.
- Smoke yields can be benchmarked with prediction intervals using TPM, Tar, or CO yield, and, for some analytes, incorporating filler analyte concentration.
- Because of the variability in cigars the prediction intervals were still quite wide.
- Tobacco filler constituents (particularly TSNAs) can show considerable differences over time.

STRENGTHS AND LIMITATIONS

Strength

Our study includes physical property data, abbreviated list HPHC data for filler and for smoke generated under three smoking regimes, and example prediction intervals for cigars.

Limitations

- Our results represent a point-in-time analysis and do not represent long term manufacturing variability.
- Additionally, the cigar category is diverse and includes a wide variety of product styles, sizes, and manufacturing methods and although this study includes a variety of cigars, it is not representative of the entire cigar category.

REFERENCES

- . CORESTA Recommended Method No. 64-Routine Analytical Cigar-Smoking Machine-Specifications, Definitions, and Standard Conditions
- 2. ISO 3308:2012, Cigarettes. Routine Analytical Cigarette-Smoking Machine-Definitions, and Standard Conditions
- 3. ISO 20778:2018, Cigarettes. Routine Analytical Cigarette-Smoking Machine-Definitions, and Standard Conditions with an Intense Smoking Regime.
- 4. Guidance for Industry, Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (3/2012).
- 5. Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (5/10/2016).