HPHC Market Map Study for US Machine-Made Cigars – Part 1 Physical Properties, Filler, and Smoke HPHC variability

Karl A. Wagner, Lara L. Baker, Michael J. Morton, Raquel M. Olegario, Jennifer H. Smith

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Study Overview

- Part 1: market map overview
  - Discuss the inherent variability of cigars
  - Describe the products
  - Present physical properties and abbreviated HPHCs for filler and smoke[1] under CORESTA, ISO and Intense smoking regimes
  - Compare the physical properties and HPHC variability of cigars and cigarettes
- Part 2: predictive models [2]
  - Compare variability and yields of the three different smoking regimes
  - Examine correlations of TPM, tar, and CO to smoke constituent yields and effect on market mapping prediction intervals
  - Examine cigar filler manufacturing variability

1. 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 (March 2012).
2. TSRC Presentation #62, HPHC Market Map Study for US Machine Made Cigars – Part 2 Predictive Models, Michael Morton.

Cigar Regulatory Landscape

- In May 2016, FDA issued final rule to deem other tobacco products
  - Regulates cigars, pipe tobacco, e-cigarettes and other tobacco products, including dissolvables, gels, and hookah tobacco [1]
- Maryland Federal District Court [2]
  - Ordered FDA to set May 11, 2020, as the deadline for submission of applications for newly deemed tobacco products
- FDA has not published an HPHC list for cigars or specified a smoking regime(s)

1. 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 (May 10, 2016).
2. American Academy of Pediatrics v. FDA, No. PWG-18-883, 2019 U.S. Dist. Westlaw 3067492 (D. Md. July 7, 2019).

Comparison of Sources of HPHC Variability

	Cigarettes	Cigars
Analytical Process	• Uniform product category • Extensive testing experience • Standardized methods • Extensive interlaboratory testing • Well characterized reference products	• Diverse product category • Limited testing experience • Few smoke standardized methods • Limited interlaboratory testing • Reference products recently introduced
Manufacturing Process	• More sophisticated equipment • Often blend over multiple crops • Wrapped in paper	• Less sophisticated equipment • Often blend from single crop • Wrapped in tobacco or tobacco sheet

Cigar Selection

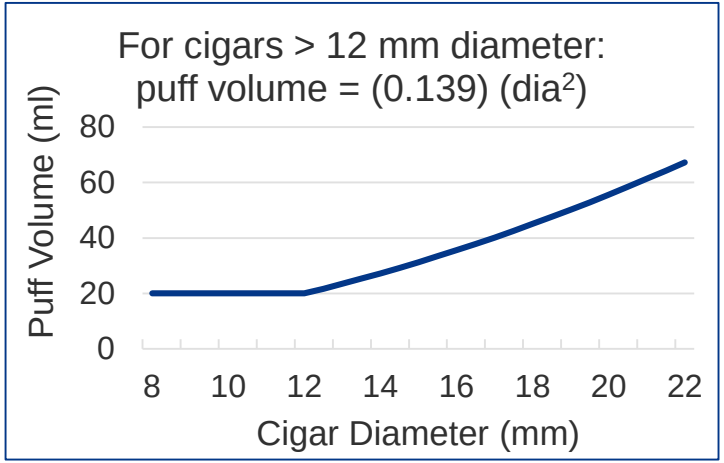
- 24 US machine-made cigars
  - Selection based on:
    - Market share
    - Style (untipped, filter tip, plastic tip, wood tip)
    - Wide range of flavor characteristics
- Includes 9 manufacturers
  - ~38 % market share for cigarillos
  - ~11 % market share for filter tips
- Dimensions and properties
  - 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

Market Map - Machine Made Cigars

Smoking Regimes

- CORESTA Recommended Method No. 64 - Routine Analytical Cigar-Smoking Machine - Specifications, Definitions and Standard Conditions
- ISO 3308:2012, Cigarettes. Routine analytical cigarette-smoking machine — Definitions and standard conditions
- ISO 20778:2018, Cigarettes. Routine analytical cigarette smoking machine. Definitions and standard conditions with an intense smoking regime

	CORESTA CRM #64 [1]	ISO 3308	Intense ISO 20778
Puff volume (ml)	20	35	55
Puff frequency (sec)	40	60	30
Puff duration (sec)	1.5	2	2
Vent blocking (%)	none	none	100



Abbreviated HPHC List for Cigarettes[1]

- All testing was conducted at ISO 17025 accredited laboratories

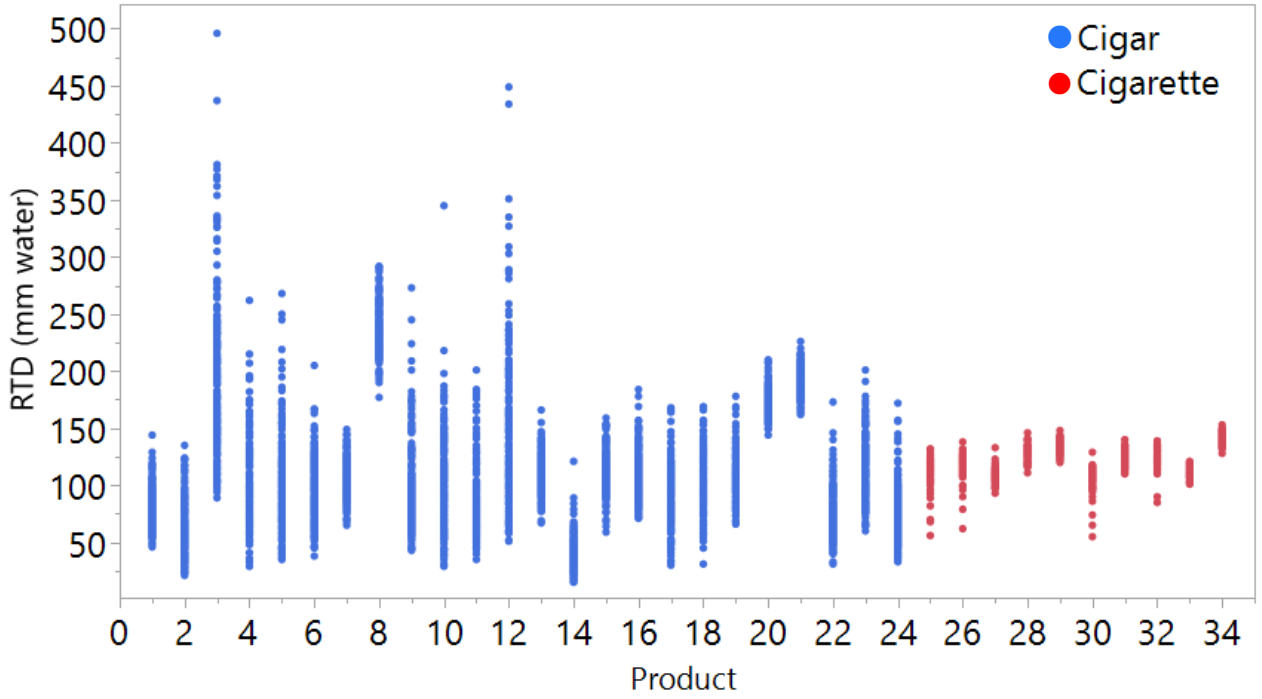
Cigarette Smoke	Roll-your-own Tobacco and Cigarette Filler
Nicotine, Carbon Monoxide	Nicotine
Ammonia	Ammonia
NNK, NNN	NNN, NNK
Formaldehyde, Acetaldehyde, Acrolein, Crotonaldehyde	Arsenic, Cadmium
Benzo[a]pyrene	
1-Aminonaphthalene, 2-Aminonaphthalene, 4-Aminobiphenyl	
1,3-Butadiene, Acrylonitrile, Benzene, Isoprene, Toluene	

1. 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 (March 2012).

Cigar and Cigarette Physical Properties

RTD – Cigars and Cigarettes

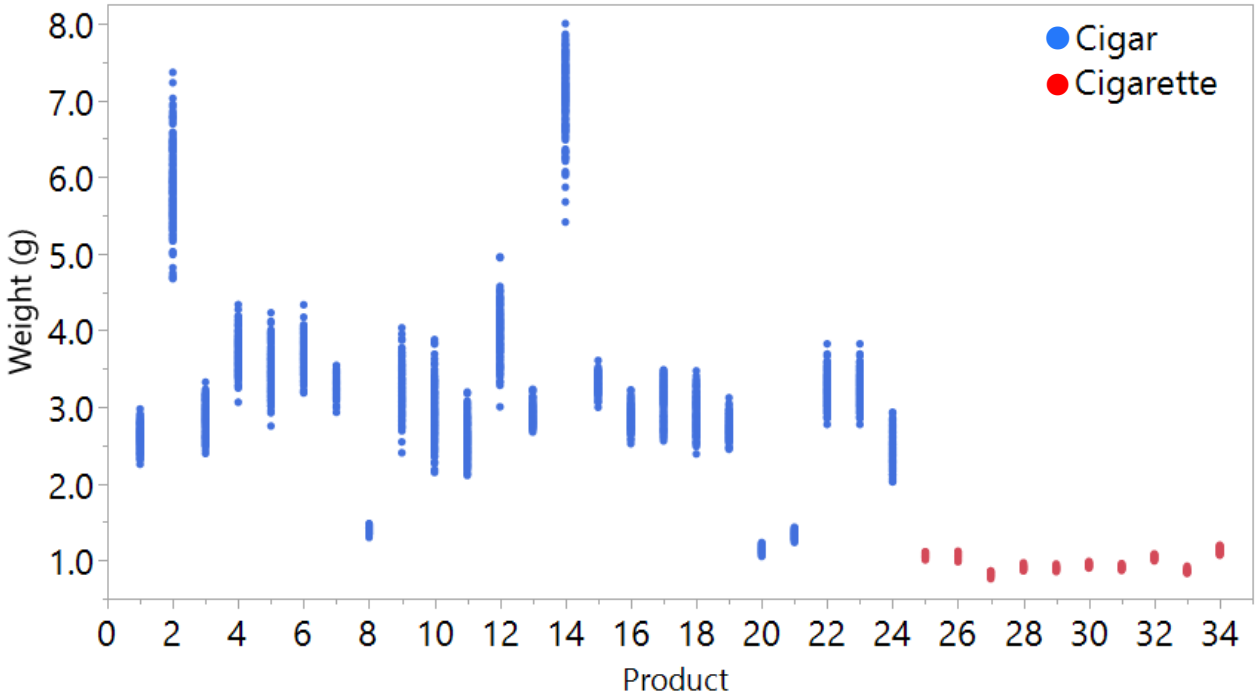
24 cigar products (220 reps each) and 10 cigarette products (100 reps each)



The cigars and cigarettes were commercially available in 2018 and 2017, respectively

Weight – Cigars and Cigarettes

24 cigar products (220 reps each) and 10 cigarette products (100 reps each)



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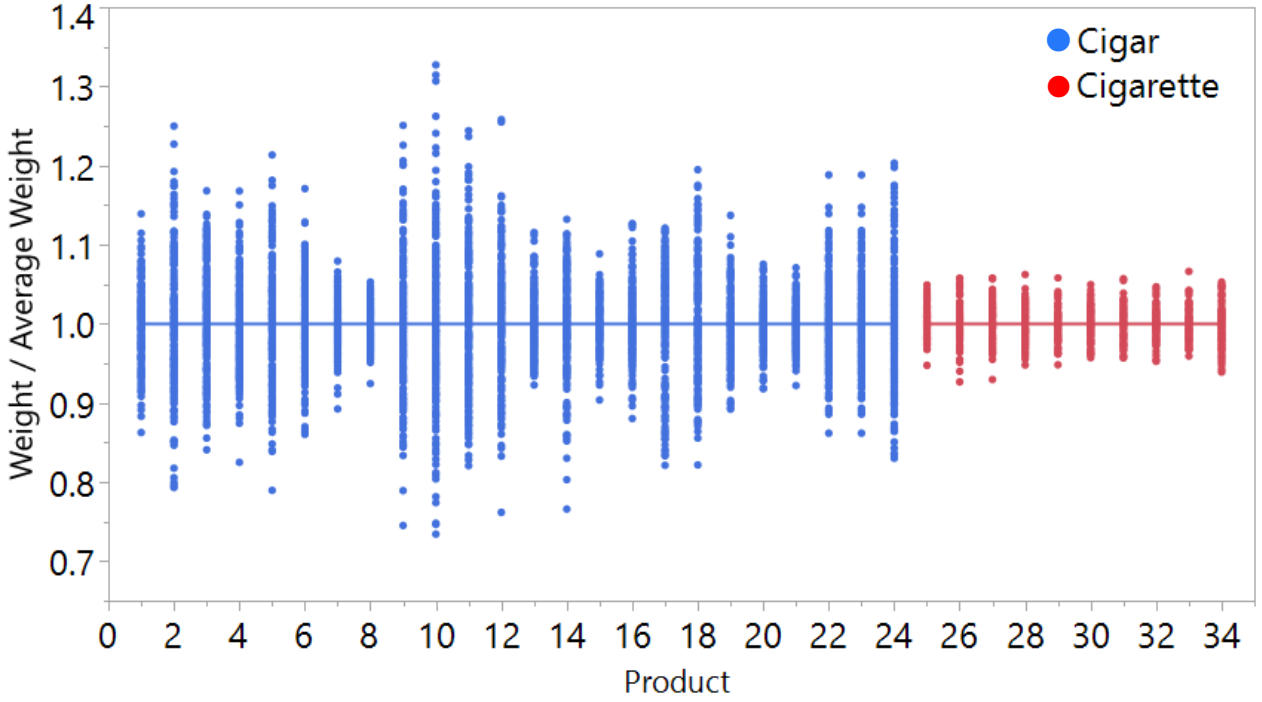
Relative Weight – Cigars and Cigarettes

24 cigar products (220 reps each) and 10 cigarette products (100 reps each)

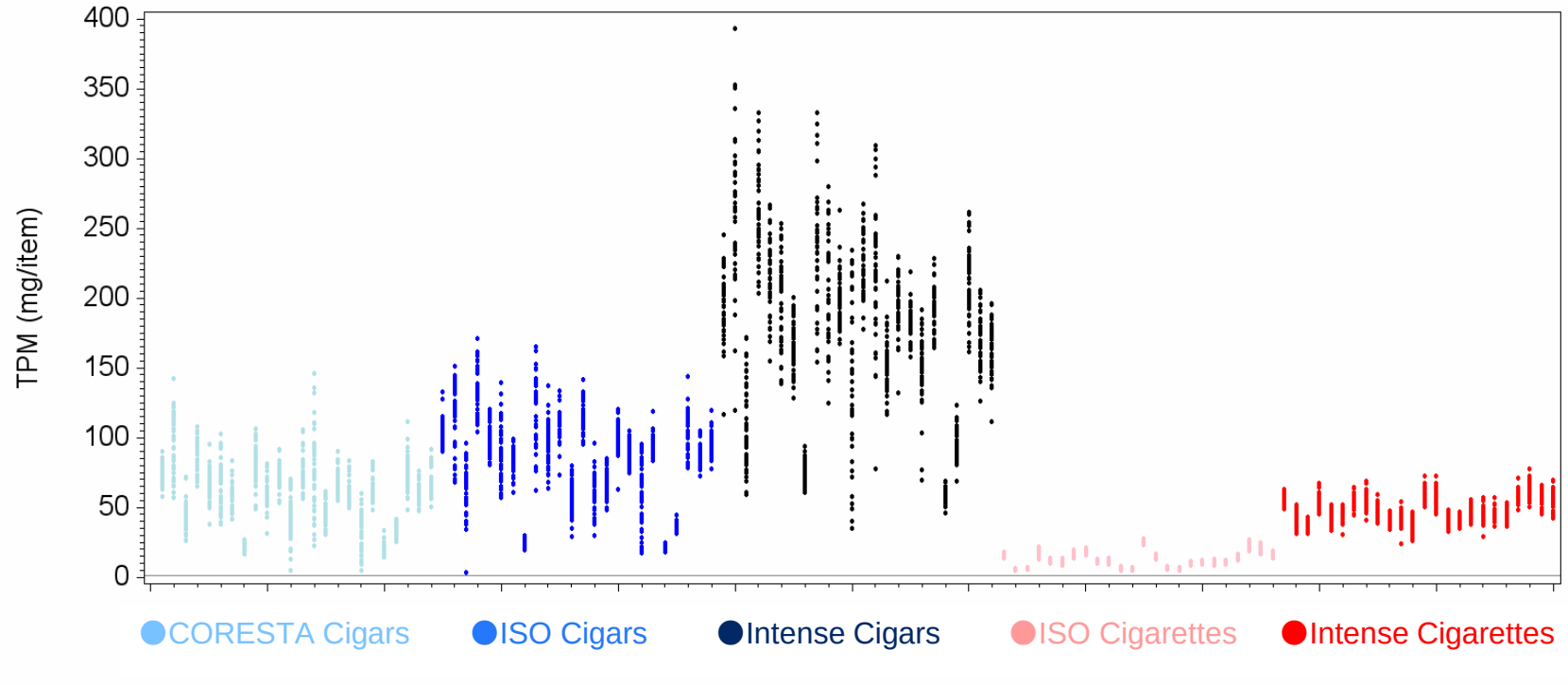


The cigars and cigarettes were commercially available in 2018 and 2017 respectively

Cigar and Cigarette HPHC Yields and Variability

TPM Variability Across Categories and Regimes

24 cigar products (42 reps each) and 25 cigarette products (55 reps each)



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Relative TPM Variability Across Categories and Regimes

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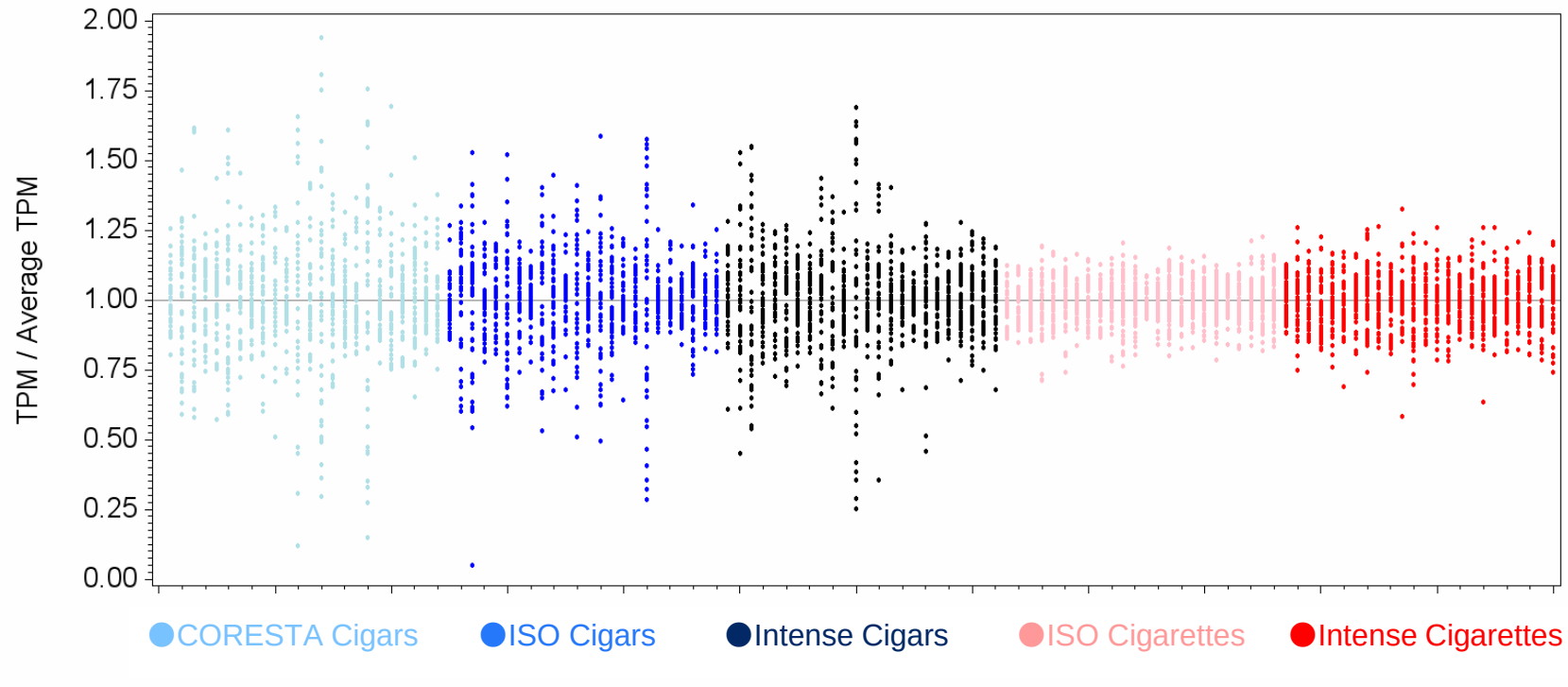
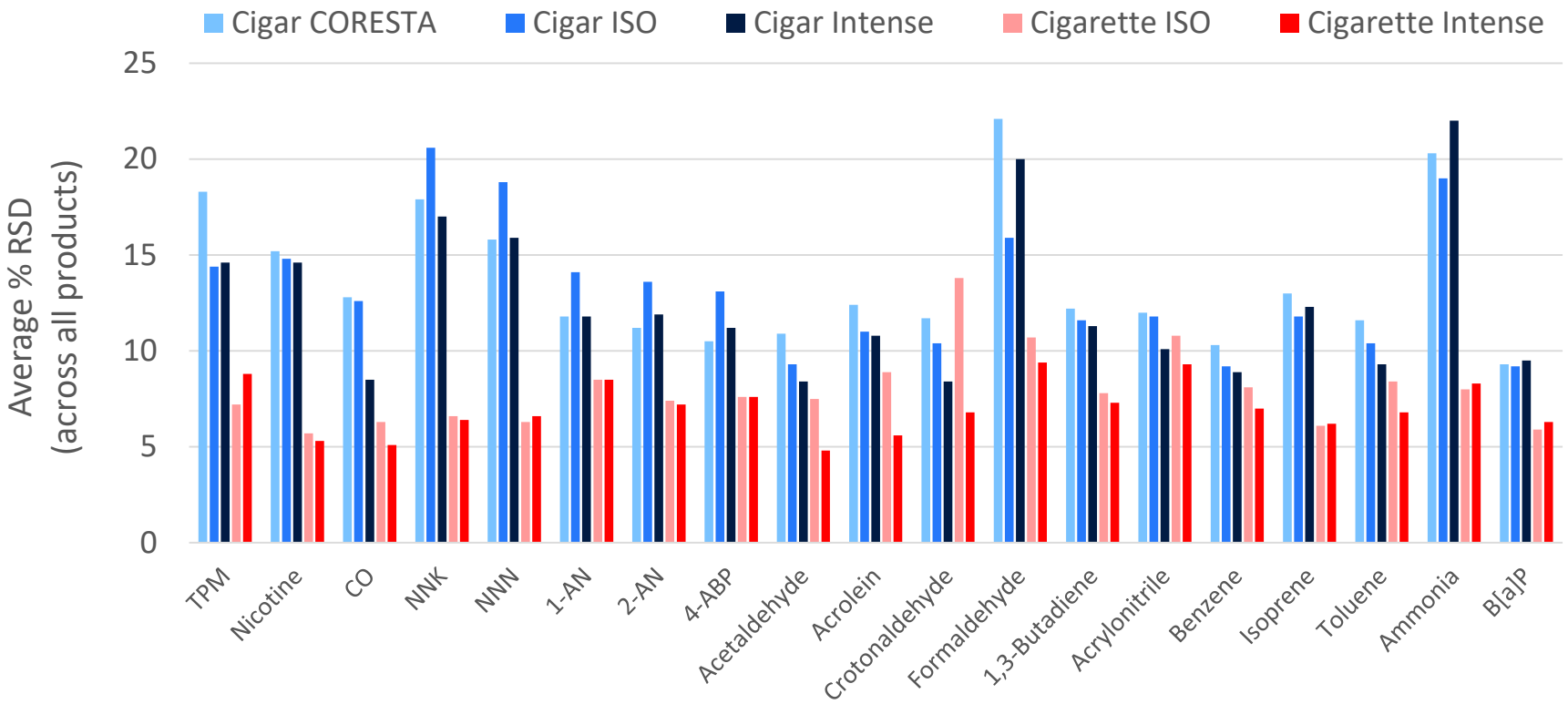


The cigars and cigarettes were commercially available in 2018 and 2012, respectively

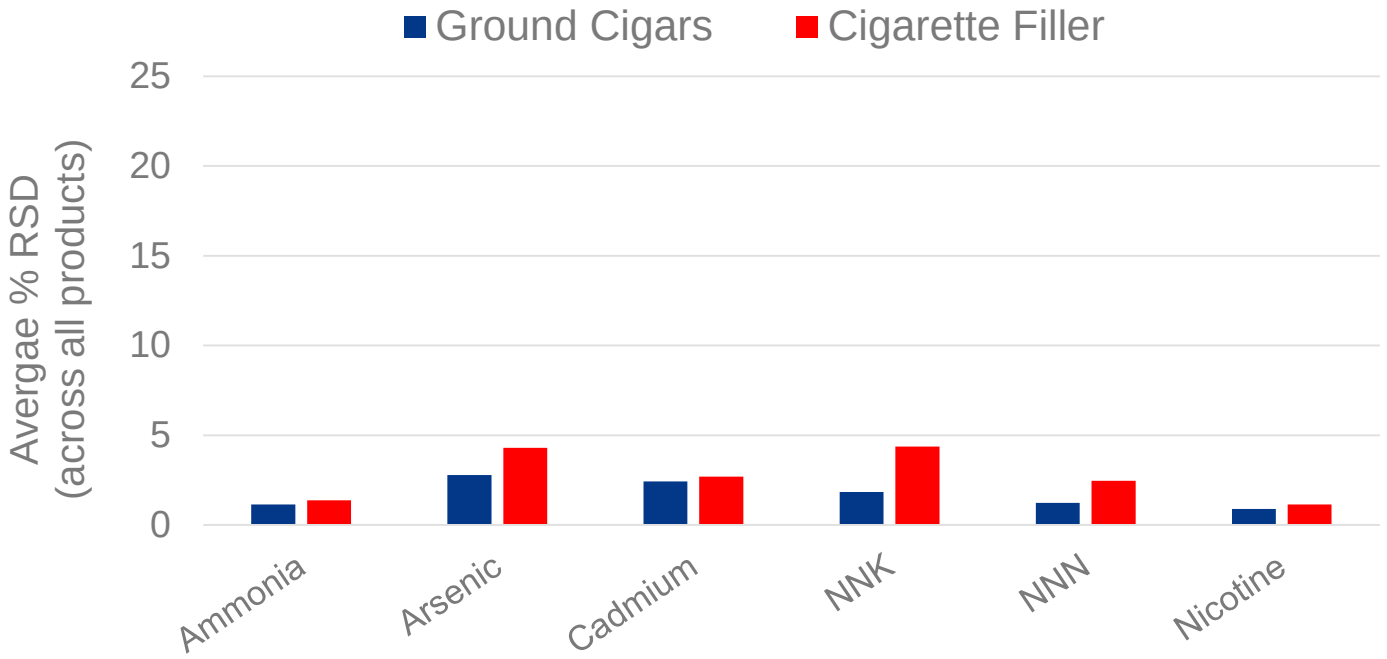
Short-term Variability – Smoke

24 cigar products, 146 cigarette products, 7 replicates per brand

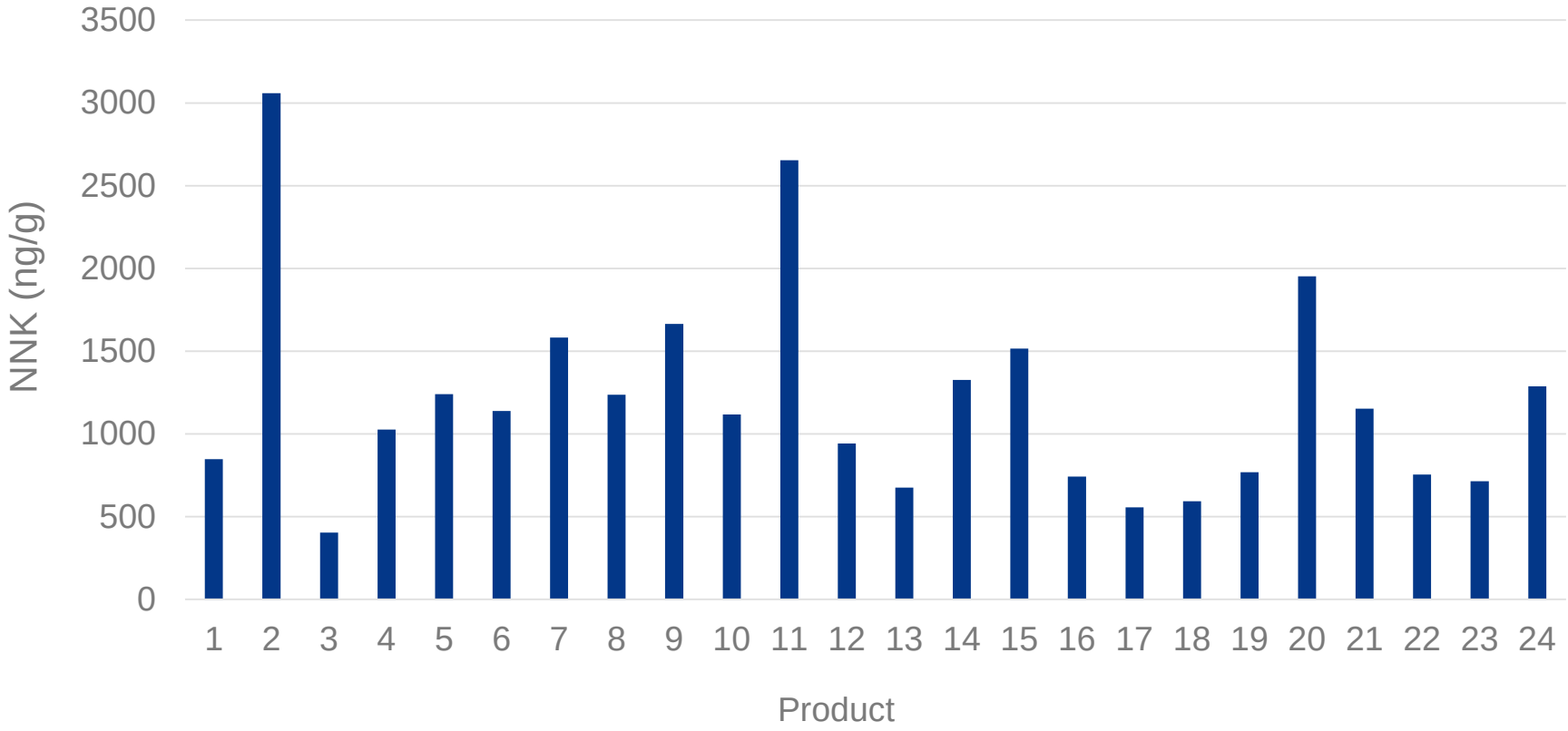


Short-term Variability – Filler

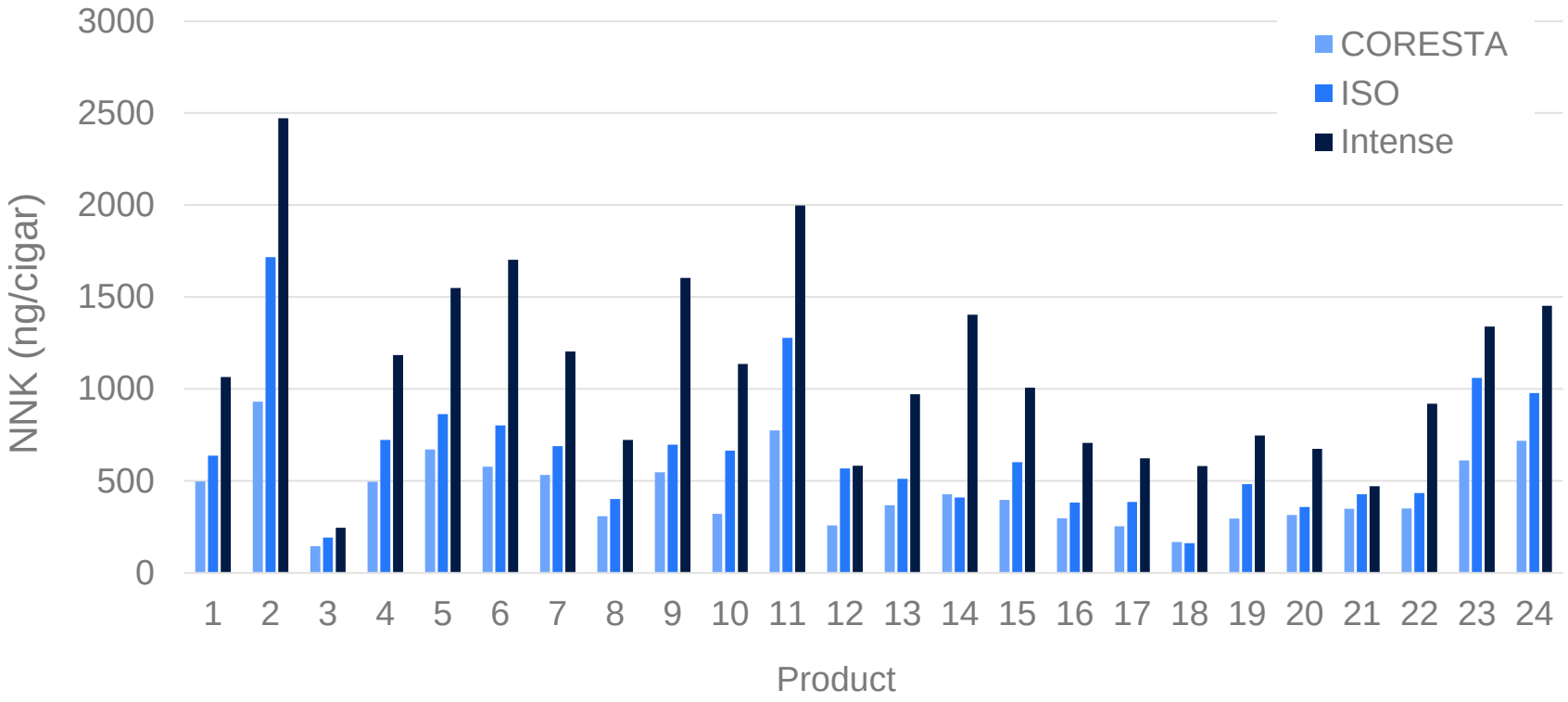
24 cigar products, 146 cigarette products, 7 replicates per brand



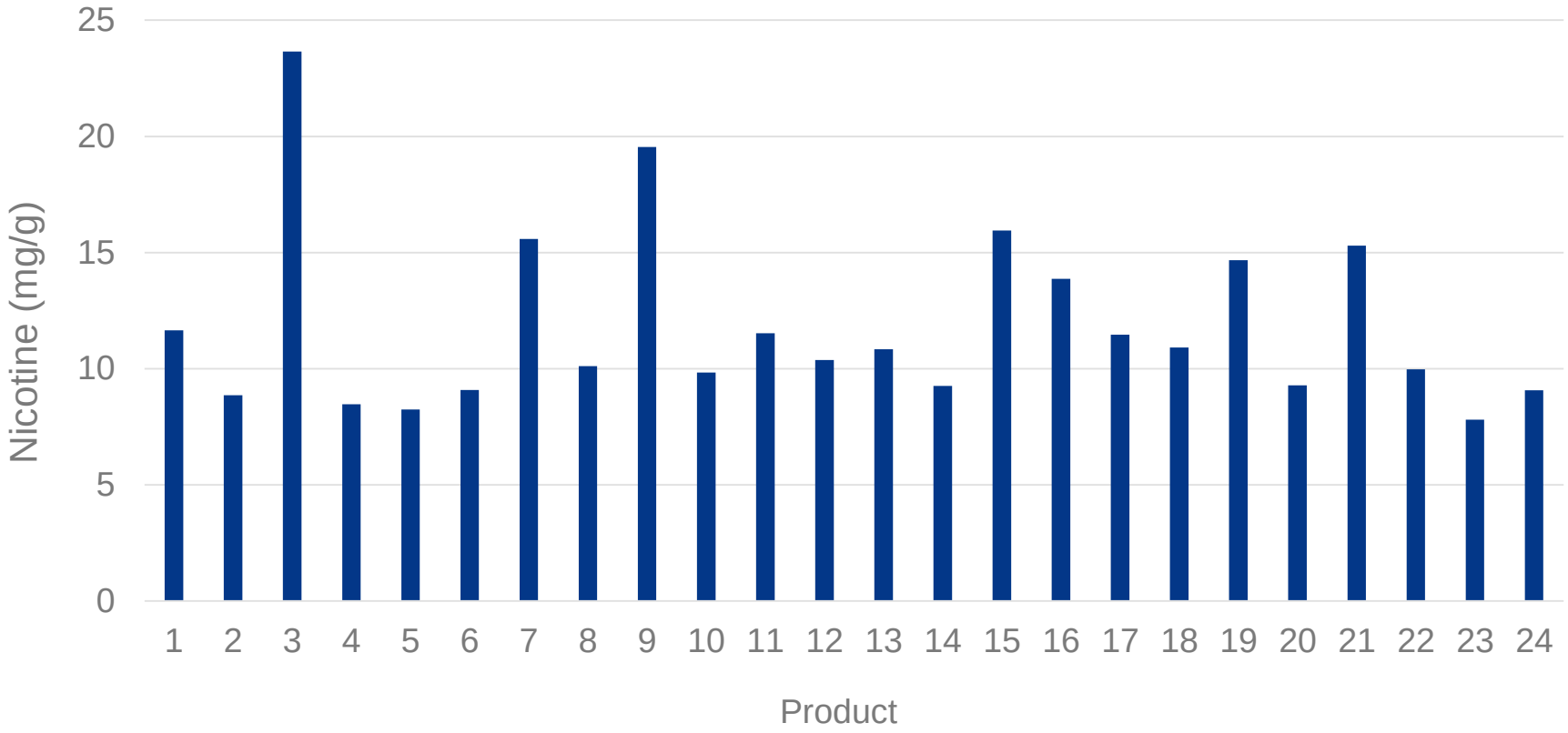
NNK – Ground Cigar



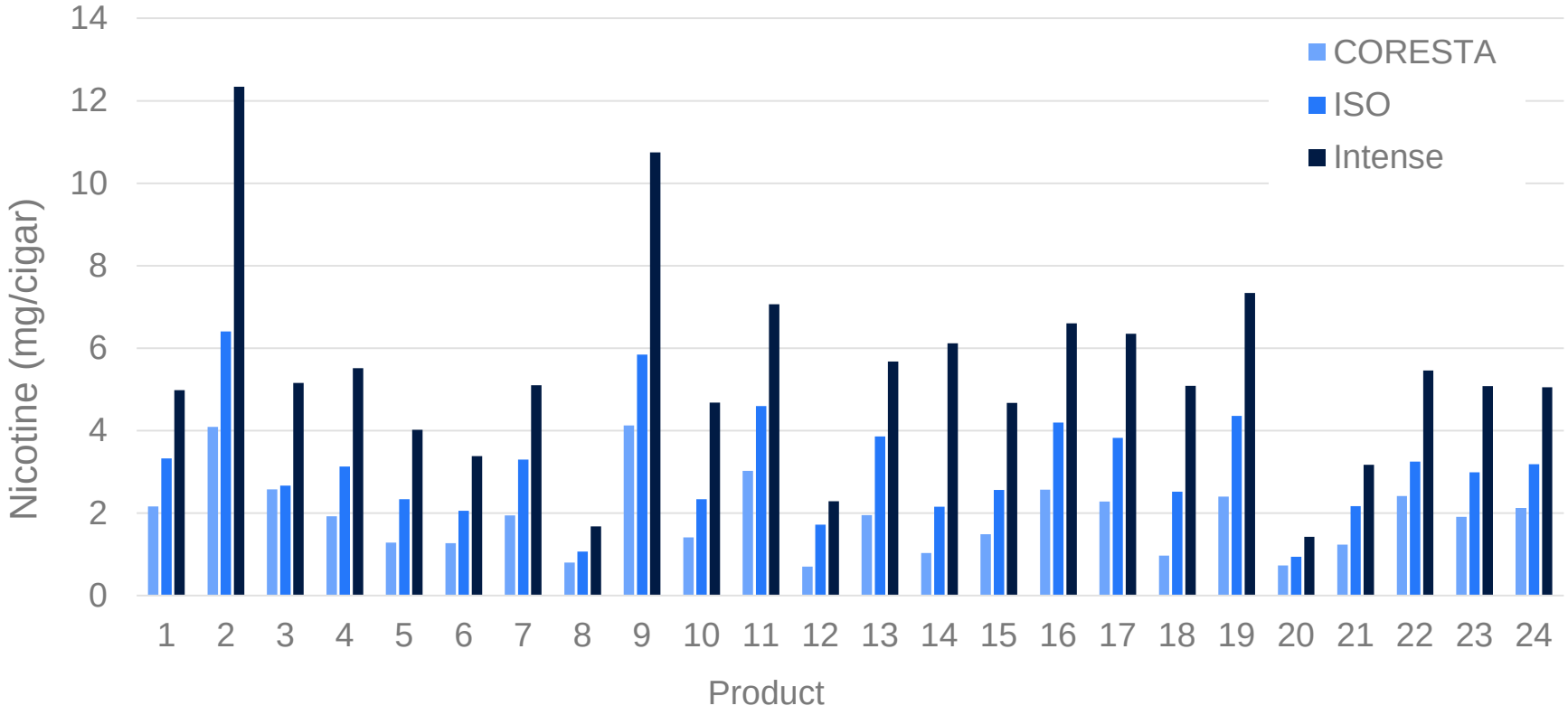
NNK – Cigar Smoke Yields



Nicotine – Ground Cigar



Nicotine – Cigar Smoke Yields



Key Takeaways

- Cigars are a more diverse product category than cigarettes
- Cigar physical properties and smoke yields are significantly more variable than cigarettes
- Cigar filler HPHCs show significantly less variability than cigar smoke HPHCs and may be useful for comparative purposes
- In the cigar analytical testing space, opportunities exist for:
  - Creation of standardized methods for smoke HPHCs
  - Establishing proficiency testing
  - Characterization of the University of Kentucky cigar reference products

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