

HPHC Market Map Study for US Machine-Made Cigars - Part 1: Description of the Products and the Inherent Variability of Cigars

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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 lacks a thorough and rigorous study of smoke, tobacco chemistry and physical properties of cigars. Market maps or benchmarking studies have been used for many years to aid in the characterization of the cigarette marketplace. Cigars, as a category, are 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 the smoke yields, tobacco chemistry, and physical properties of 24 machine-made cigars from the US marketplace. The goal was to establish HPHC ranges for smoke yields and tobacco chemistry and also to develop marketplace predictive relationships to aid in the evaluation of machine-made cigars not included in this sample of products. Products were smoked using the CORESTA, ISO 3308, and Intense smoking regimes for all of 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. 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.

CIGAR MARKET MAP



Figure 1: 24 US machine-made cigars. The order of the cigars does not represent the order of the data shown in the graphs.

STUDY OVERVIEW

- Evaluate a cross section of the US market for machine-made cigars
- Collect physical properties and abbreviated HPHC data for filler and smoke under CORESTA, ISO 3308 (non-intense) and ISO 220778 (intense) smoking regimes¹⁻⁴
- Compare the cigar physical properties and HPHC variability to commercial cigarettes
- Present examples of analyte ranges for the cigar market map

SOURCES OF HPHC VARIABILITY

	Cigarettes	Cigars
Analytical Process	<ul style="list-style-type: none"> Uniform product category Extensive testing experience Standardized methods Extensive interlaboratory testing Well-characterized reference products 	<ul style="list-style-type: none"> Diverse product category Limited testing experience Few smoke standardized methods Limited interlaboratory testing Reference products recently introduced
Manufacturing Process	<ul style="list-style-type: none"> More sophisticated equipment Often blend over multiple crops Wrapped in paper 	<ul style="list-style-type: none"> Less sophisticated equipment Often blend from single crop Wrapped in tobacco or tobacco sheet

METHODS

- Smoke HPHCs were determined under the three smoking regimes shown in the table below
- CORESTA Recommended Method (CRM) 64 was specifically developed for machine smoking cigars while ISO 3308 and ISO 20778 were developed for cigarettes

	CORESTA Regime: CRM 64 ^{1,2}	Non-intense Regime: ISO 3308 ³	Intense Regime: ISO 20778 ⁴
Puff volume (ml)	20	35	55
Puff frequency (sec)	40	60	30
Puff duration (sec)	1.5	2	2
Vent blocking (%)	none	none	100

¹Cigars greater than 12 mm diameter: puff volume = (cigar diameter)² x 0.139

- Since the FDA has not published an HPHC list specifically for cigars, the abbreviated HPHC list for cigarettes was used¹

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	

CIGAR SELECTION

- Selection based on market share, tip style (untipped, filter tip, plastic tip, wood tip) and inclusion of a wide range of flavor characteristics
- 24 US machine-made cigars
 - 9 manufacturers
 - 38% market share for cigarillos
 - 11% market share for filter tips
- Dimensions
 - Diameter: 7.8 mm - 16 mm
 - Length: 95 mm - 158 mm
 - Weight: 1.1 g - 8.0 g

CIGAR AND CIGARETTE: PHYSICAL PROPERTIES AND HPHC YIELD VARIABILITY

Physical Properties Variability

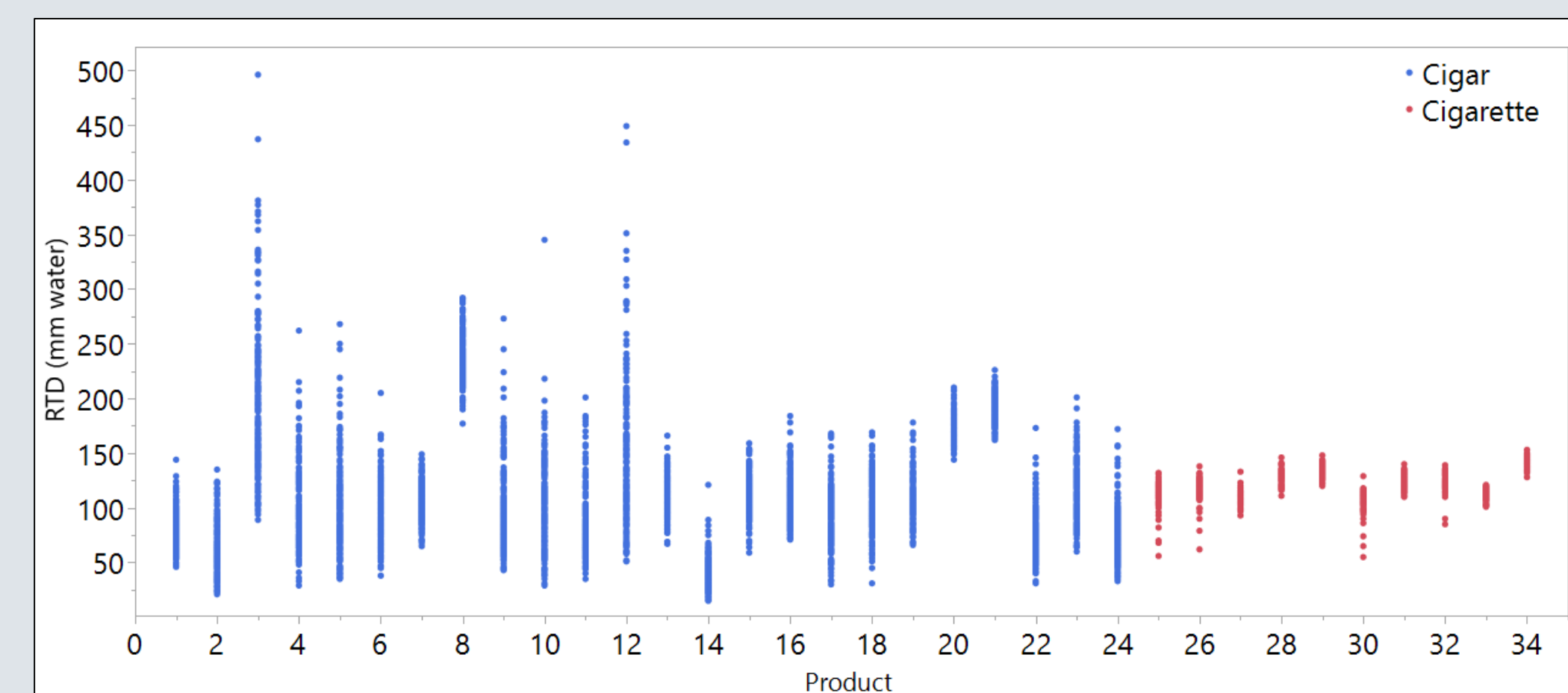


Figure 2: Resistance to draw (RTD) – Cigars and Cigarettes
24 cigar products (220 replicates each) and 10 cigarette products (100 replicates each). The cigars and cigarettes were commercially available in 2018 and 2017, respectively.

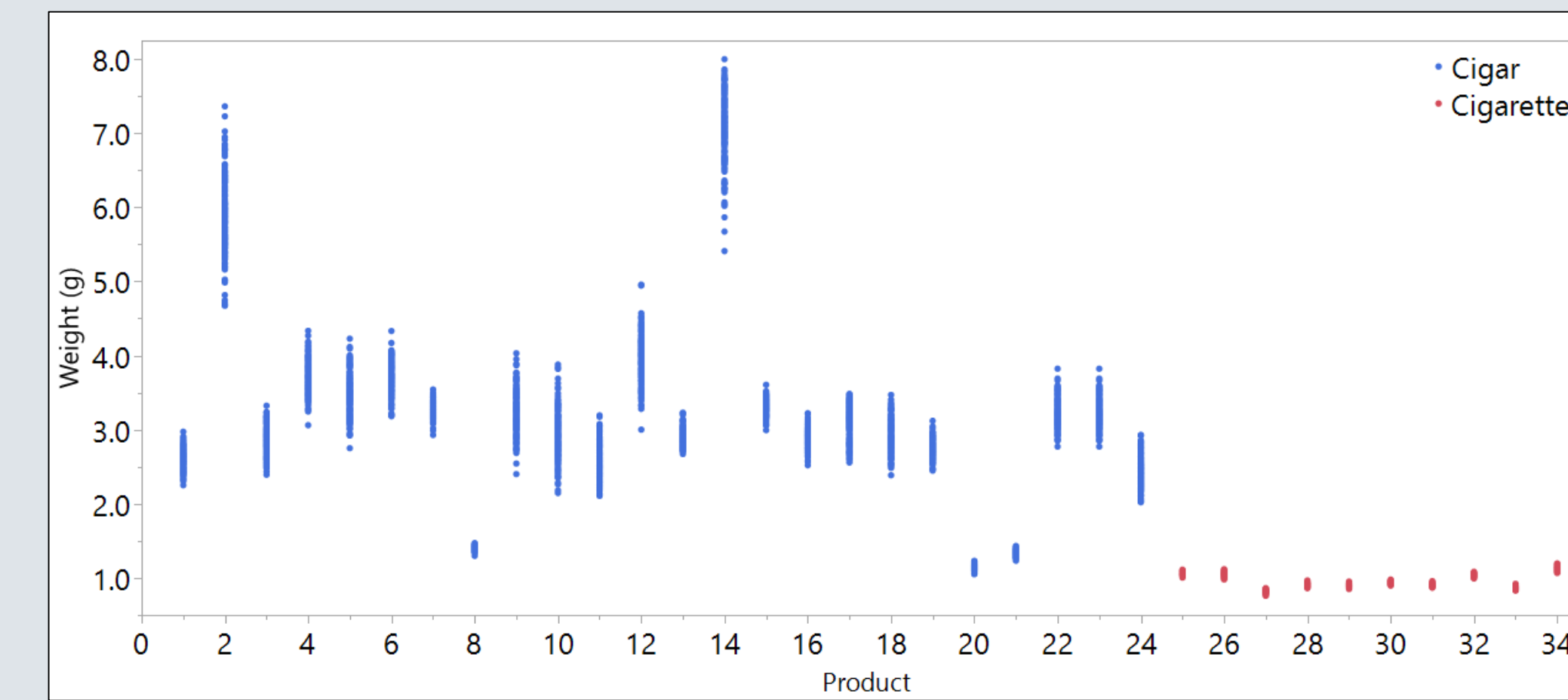


Figure 3: Product Weights
24 cigar products (220 replicates each) and 10 cigarette products (100 replicates each). The cigars and cigarettes were commercially available in 2018 and 2017, respectively.

SELECTED HPHC RANGES

Filler Ranges

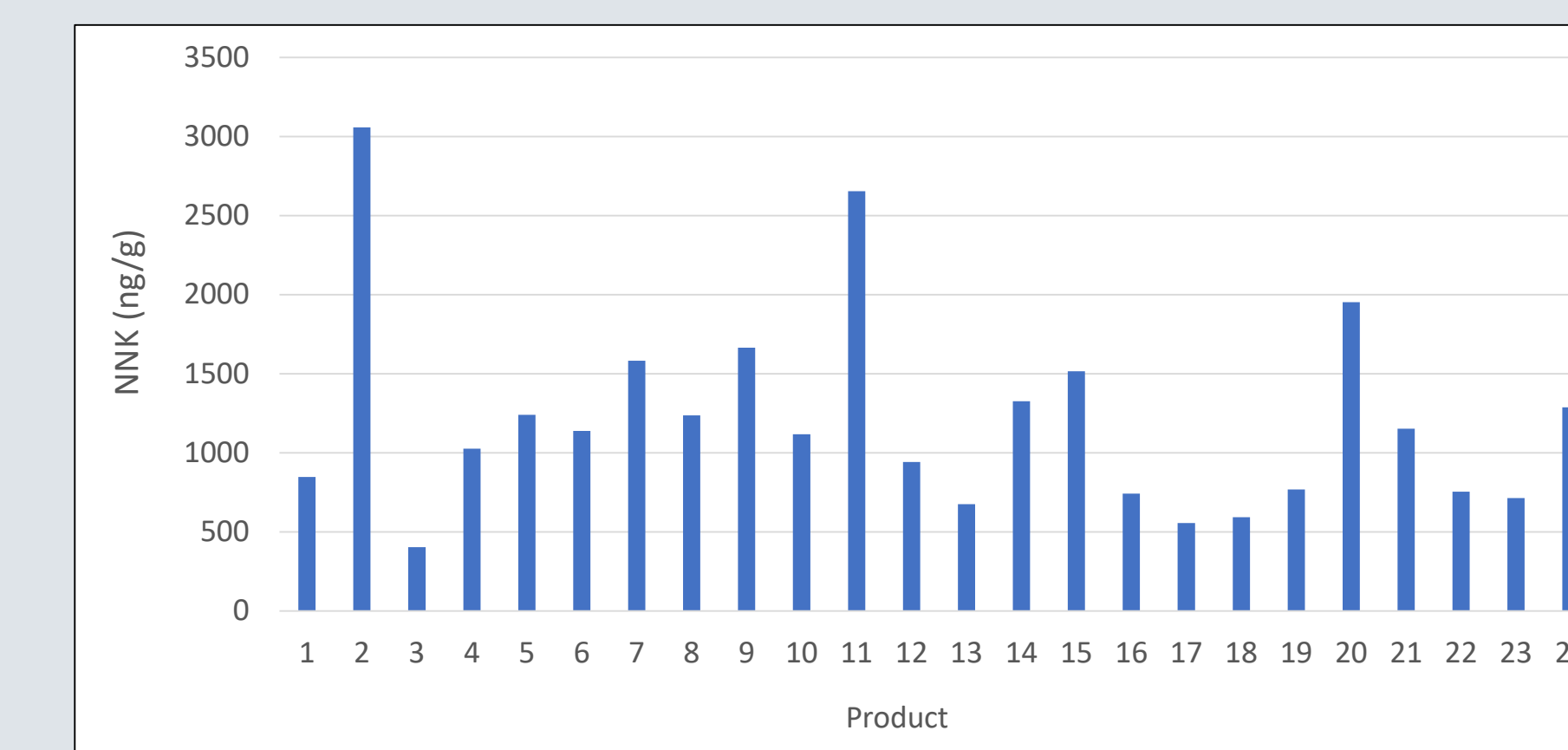


Figure 7: NNK – Ground Cigar

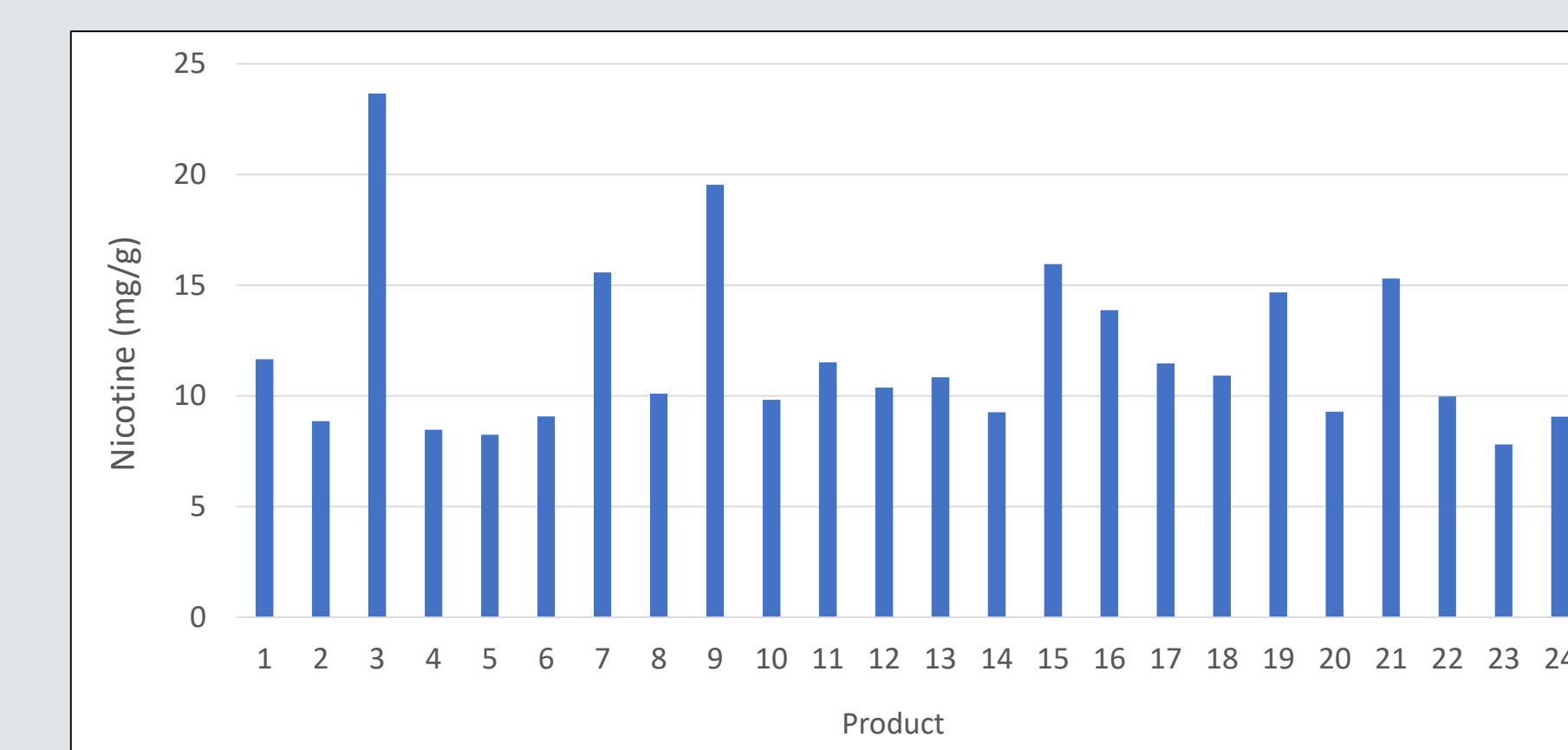


Figure 8: Nicotine – Ground Cigar

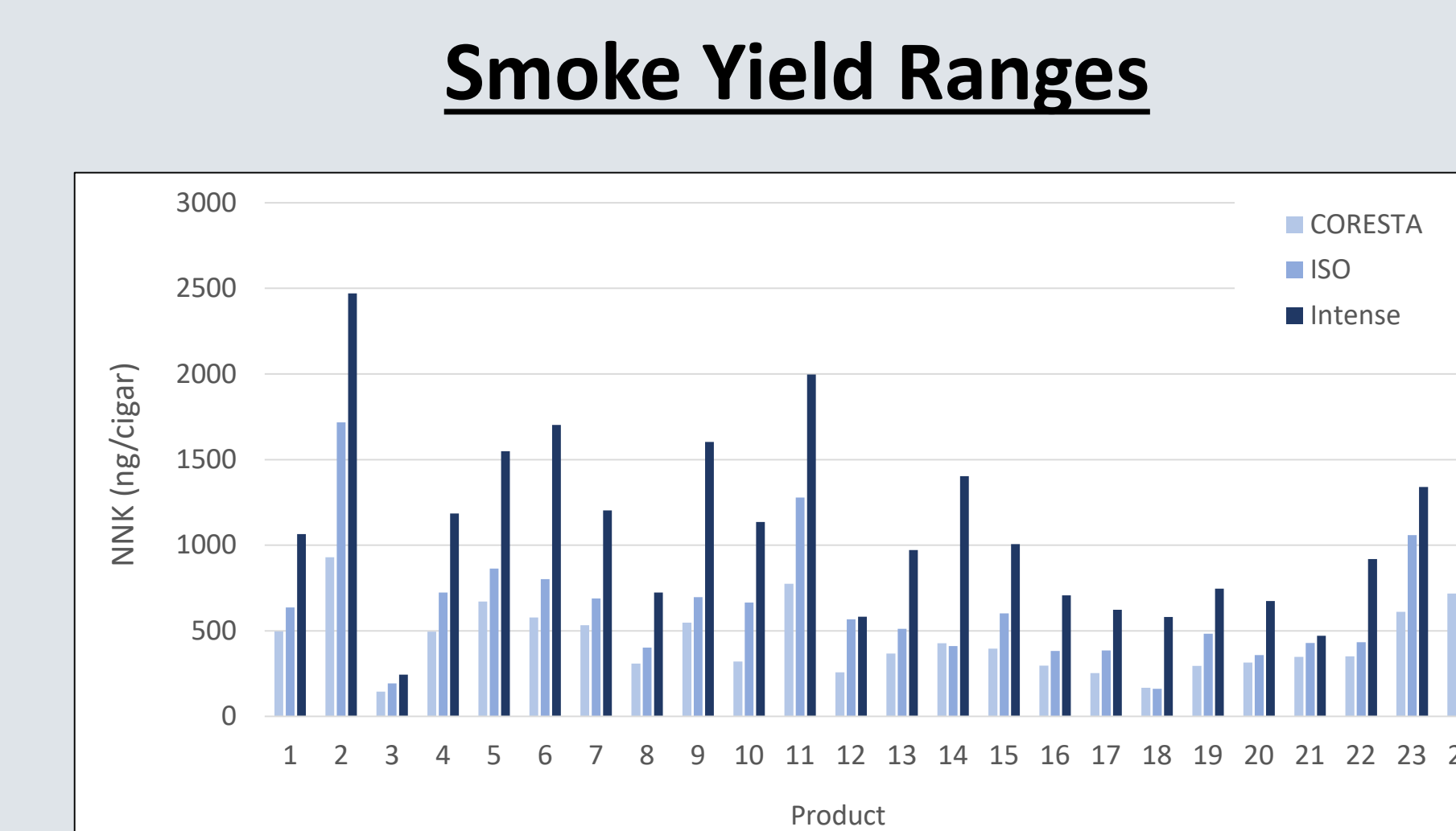


Figure 9: NNK – Cigar Smoke Yields

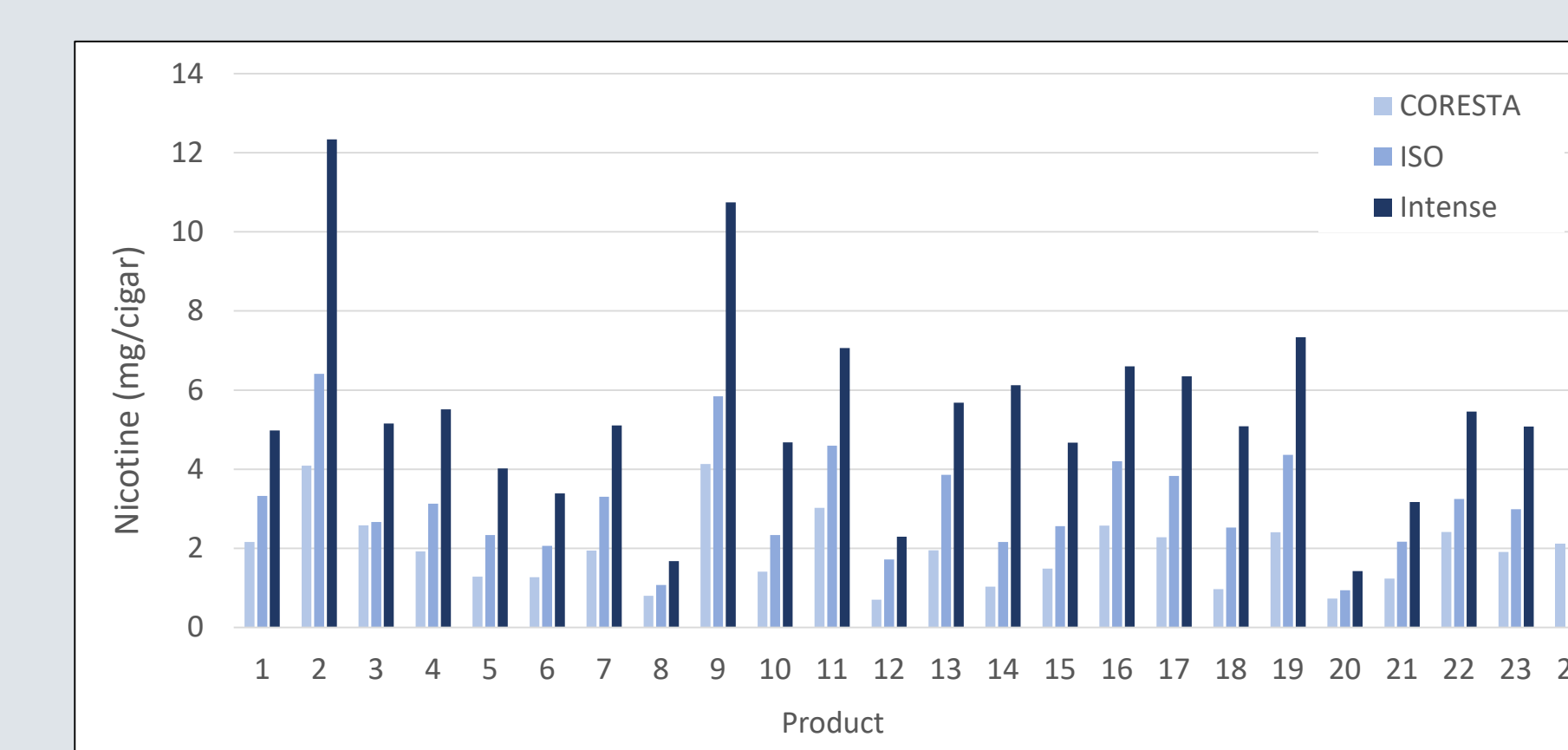


Figure 10: Nicotine – Cigar Smoke Yields

CONCLUSIONS

- Cigars are a more diverse product category than cigarettes
- Smoke yield variability is dependent on the physical properties of the product and is independent of the smoking regime
- Cigar analyte levels differ significantly from product to product
- 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
- Opportunities exist for:
 - Creation of standardized analytical testing methods for smoke HPHCs
 - Establishing laboratory proficiency testing

STRENGTHS & 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.
 - Although this study includes a variety of cigars, it is not representative of the entire cigar category.

REFERENCES

- 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 Cosmetics Act (3/2012).
- 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.

Smoke Yield Variability

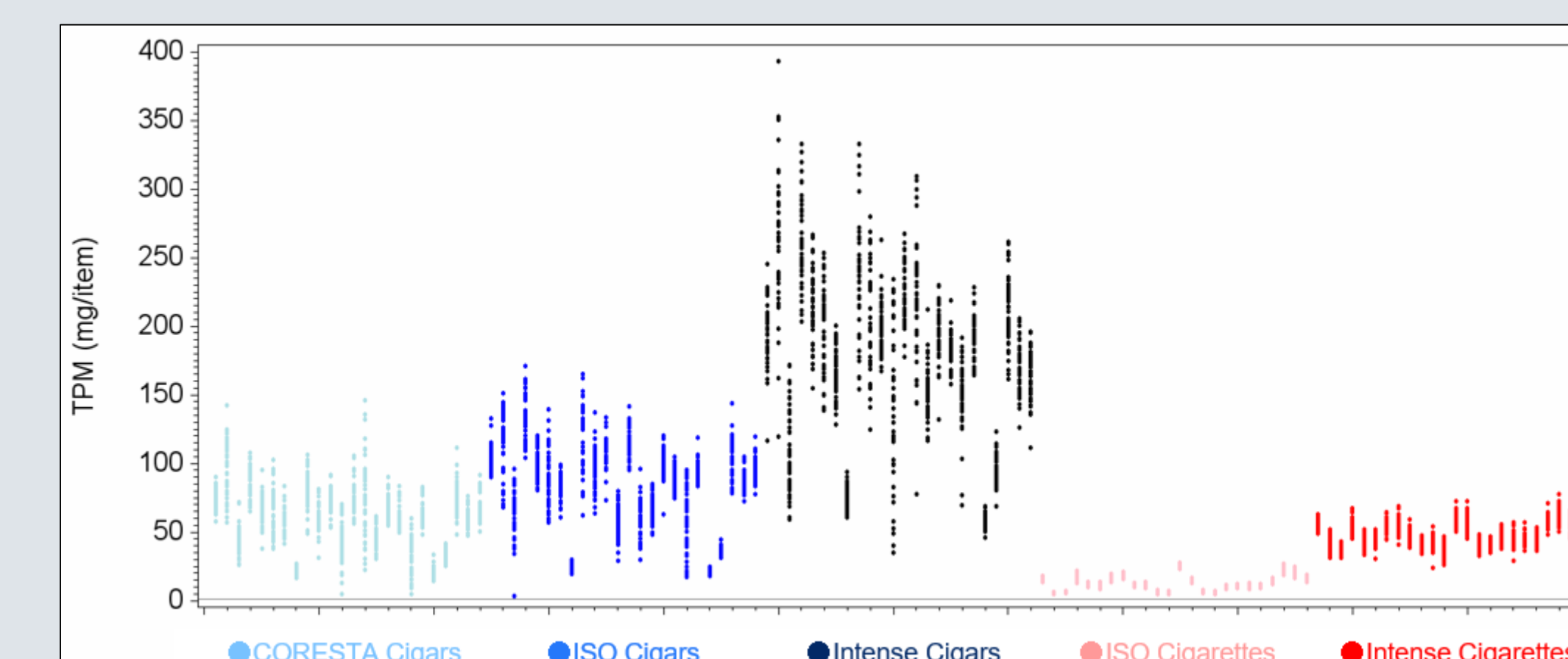


Figure 4a: Total Particulate Matter (TPM) Variability Across Categories and Smoking Regimes
24 cigar products (42 replicates each) and 24 cigarette products (55 reps each). The cigars and cigarettes were commercially available in 2018 and 2012, respectively.

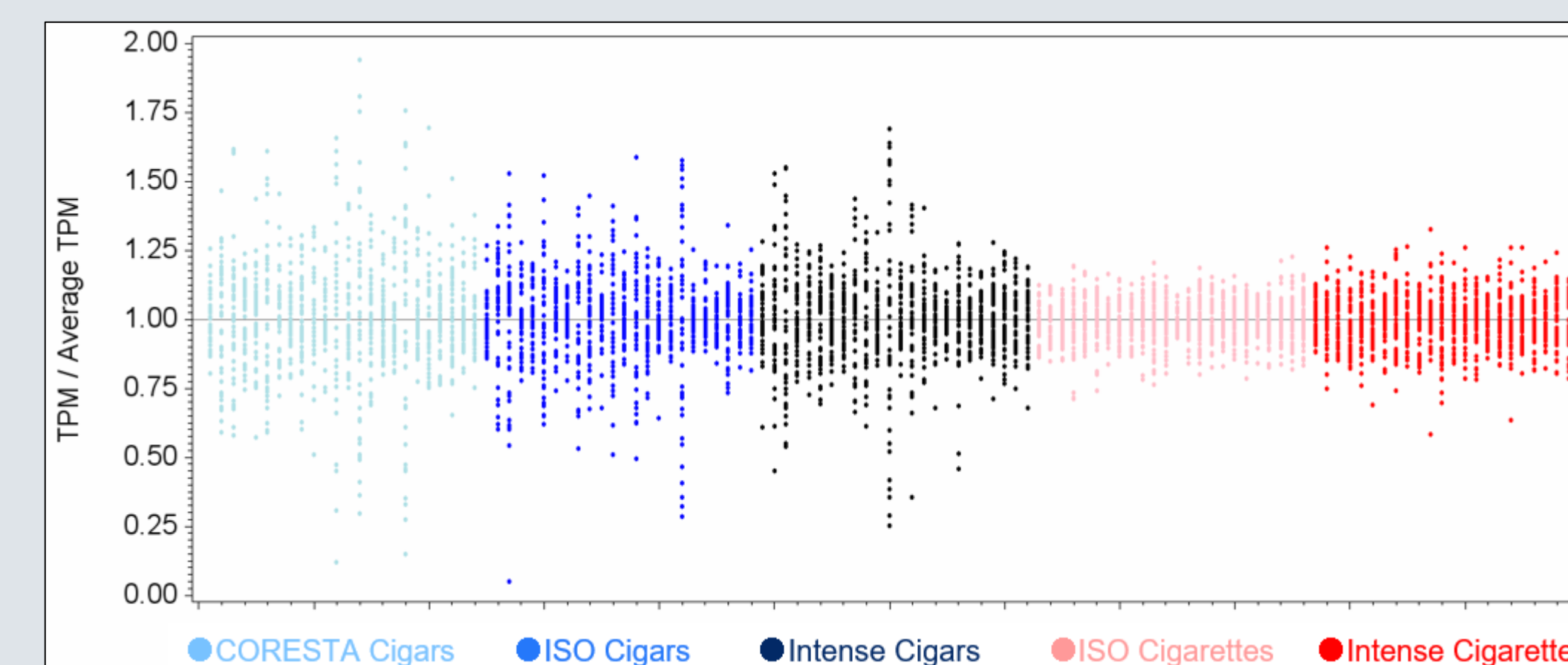


Figure 4b: Relative Total Particulate Matter (TPM) Variability Across Categories and Smoking Regimes
24 cigar products (42 replicates each) and 24 cigarette products (55 reps each). The cigars and cigarettes were commercially available in 2018 and 2012, respectively.

HPHC Variability

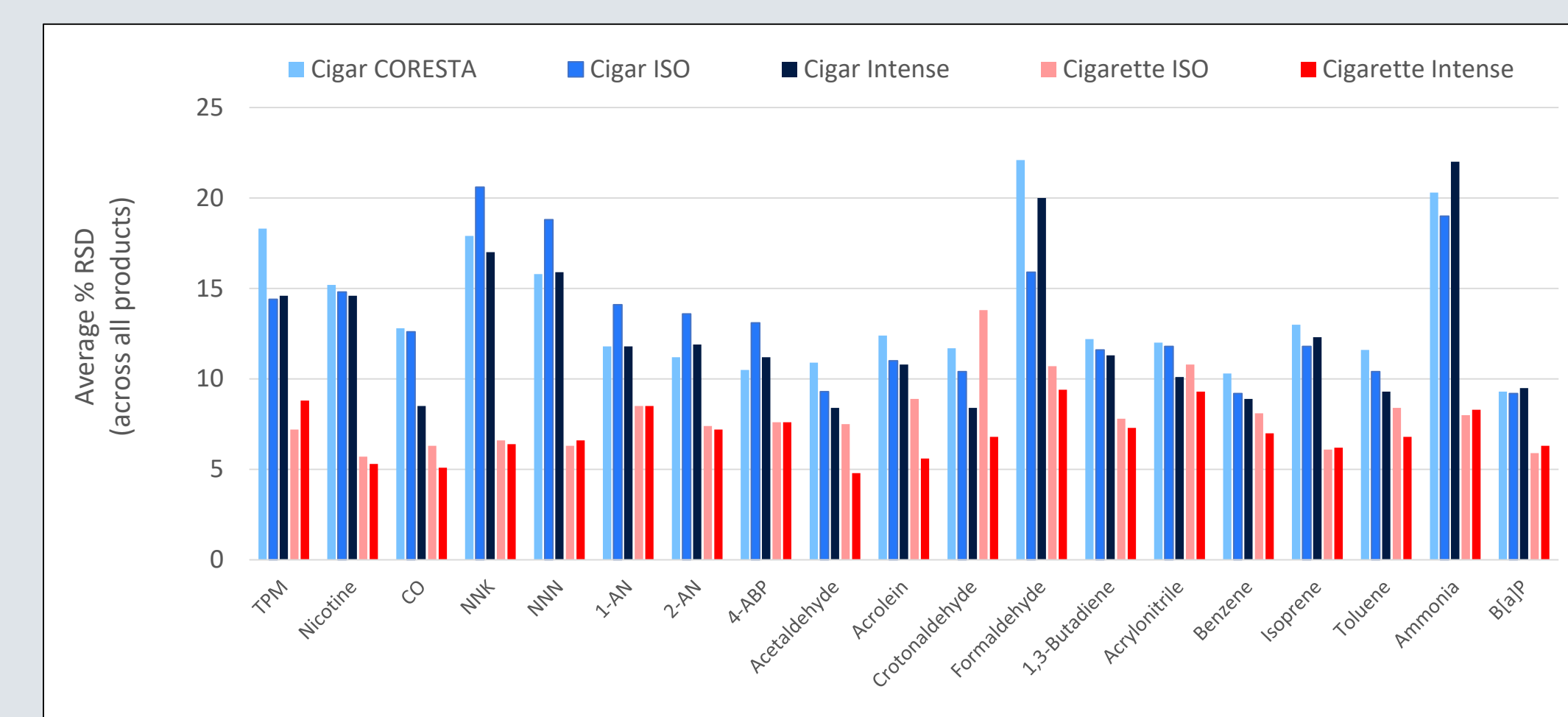


Figure 5: Short-term Variability for the Abbreviated List Smoke HPHCs¹
24 cigar products and 146 cigarette products, 7 replicates per brand. The cigars and cigarettes were commercially available in 2018 and 2012, respectively.

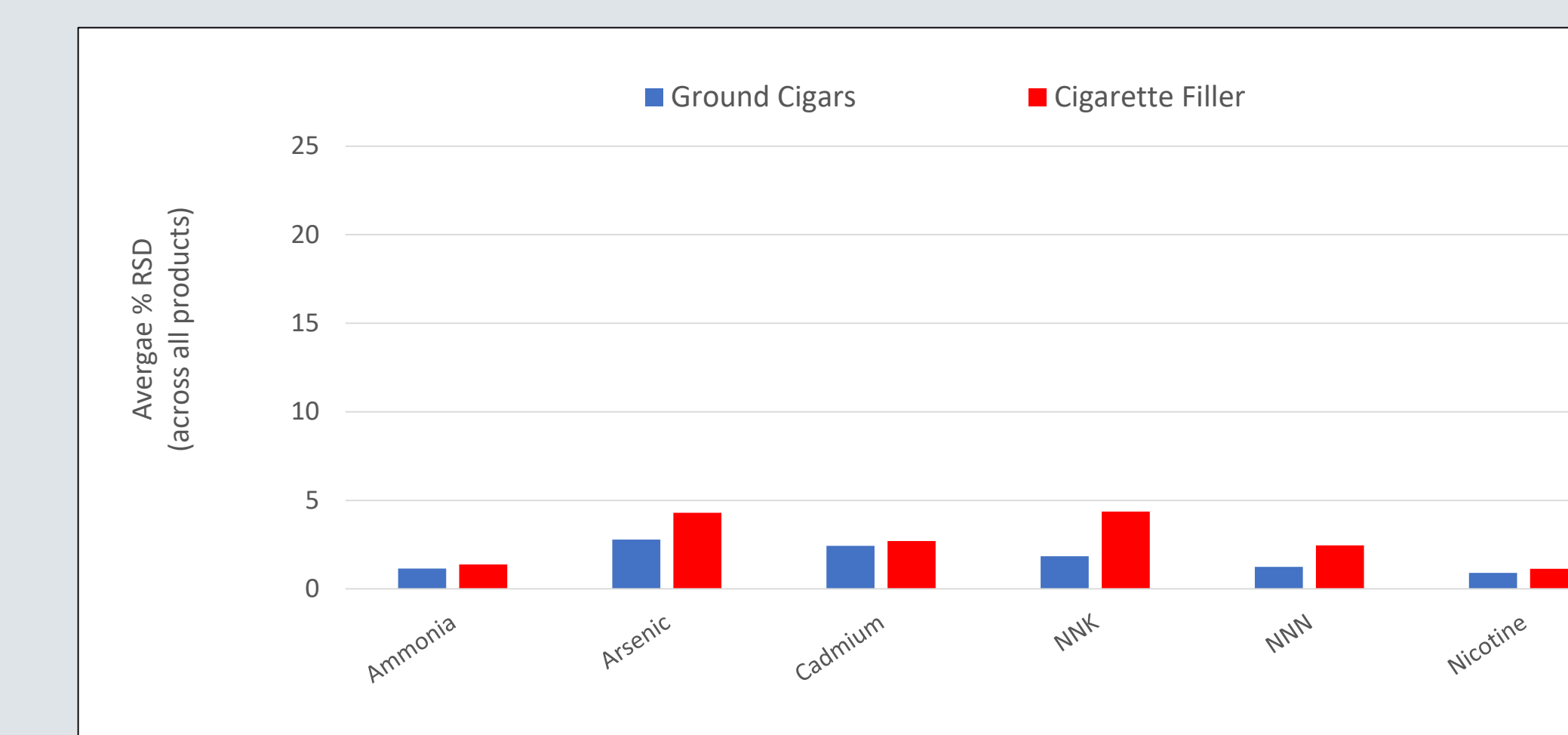


Figure 6: Short-term Variability for the Abbreviated List Filler HPHCs¹
24 cigar products and 146 cigarette products, 7 replicates per brand. The cigars and cigarettes were commercially available in 2018 and 2012, respectively.