HPHC Market Map Study for US Machine-Made Cigars – Part 2 Predictive Modeling

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CORESTA Smoke-Techno Conference

6-10 October 2019

Hamburg, Germany

Altria
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Study Overview

- Part 1: market map overview[1]
  - Discuss the inherent variability of cigars
  - Describe the products
  - Present physical properties and abbreviated HPHCs for filler and smoke under CORESTA, ISO and Intense smoking regimes
  - Compare the physical properties and HPHC variability of cigars and cigarettes

- Part 2: predictive models
  - Compare variability and yields of three different smoking regimes: CORESTA, ISO 3308 (ISO), Intense ISO 20778[2] (Intense)
  - Examine correlations of TPM, tar, and CO to smoke constituent yields and effect on market mapping prediction intervals
  - Examine cigar filler manufacturing variability

1. TSRC Presentation #61, HPHC Market Map Study for US Machine Made Cigars – Part 1 Physical Properties, Filler, and Smoke HPHC Variability, Karl Wagner
2. Also known as Health Canada Intense.

Market mapping

- Sampled 24 U.S. machine-made cigars
  - Diameter: 7.8 mm – 16 mm
  - Length: 95 mm – 158 mm
  - Product weight: 1.1 g – 8.0 g
  - 13 Untipped, 8 plastic / wood tipped, 3 filter tip
  - ~38 % market share for cigarillos
  - ~11 % market share for filter tips

- Products tested for smoke and filler HPHCs

Objectives

- Compare three different smoking regimes: CORESTA, ISO, Intense

- Examine correlations of TPM, Tar, and CO to smoke constituent yields and effect on market mapping prediction intervals

- Examine cigar filler manufacturing variability

Comparison of Smoking Regimes

- Short-term relative standard deviations (rep-to-rep variation)
- Overall yield comparisons
- Consistency of constituent smoke yield orderings
  - Are the relative rankings close to the same for the different smoking regimes?

Smoke Chemistry Variability Comparison

- Smoking regimes: CORESTA, ISO, Intense
- 18 constituents on FDA abbreviated constituent list plus tar and TPM
- 7 replicates for each product for each constituent for each regime
- Relative standard deviations were averaged across all 24 products for each constituent and then averaged across constituents

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

1. See figure to the right for cigar diameters > 12 mm.

For cigars > 12 mm diameter:
puff volume = $(0.139)(dia^2)$
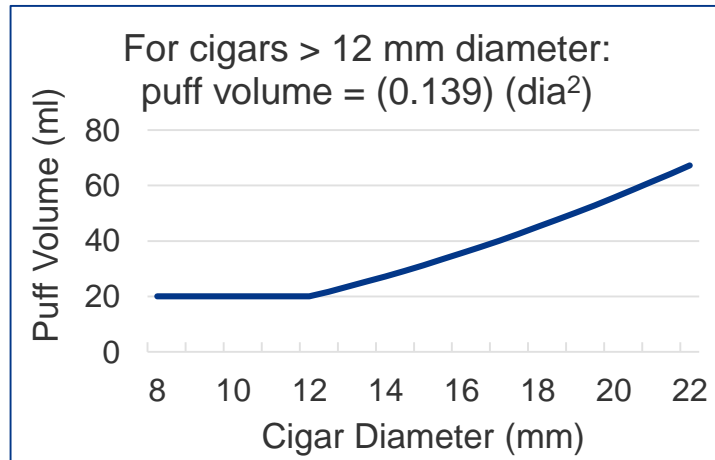
Relative variation (%) averaged across 24 products, 20 analytes

Analyte	Cigars		
	CORESTA	**ISO**	**Intense**
1-Aminonaphthalene	11.8	14.1	11.8
2-Aminonaphthalene	11.2	13.6	11.9
4-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
1,3-Butadiene	12.2	11.6	11.3
CO	13.1	12.6	8.5
Crotonaldehyde	11.7	10.4	8.4
Formaldehyde	22.1	15.9	20.0
Isoprene	13.0	11.8	12.3
NNK	17.9	20.6	17.0
NNN	16.9	18.8	15.9
Nicotine	15.0	14.8	14.6
Tar	12.0	11.4	10.4
Toluene	11.6	10.4	9.3
TPM	19.1	14.7	14.6
AVERAGE	**13.7**	**13.2**	**12.4**

The short-term relative standard deviations are comparable among the three regimes

Measured diameter and associated CORESTA Puff Volume

Product	Diameter mm	CORESTA Puff Volume mL		Product	Diameter mm	CORESTA Puff Volume 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

Overall tar yield comparison

Generally Intense > ISO > CORESTA
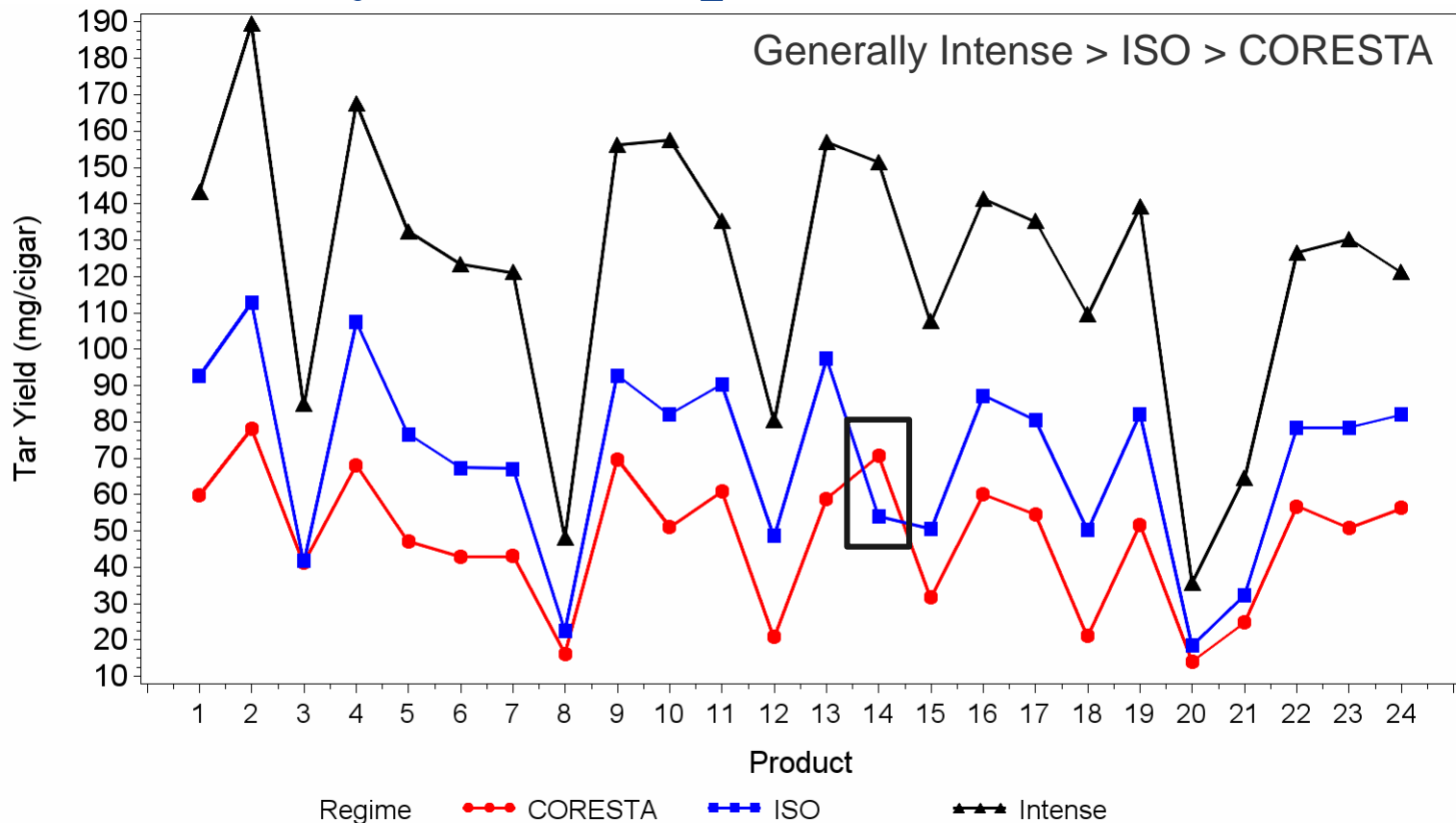
Yield ratios can be different for analytes

Ratio of Intense/CORESTA

Ratio of ISO/CORESTA
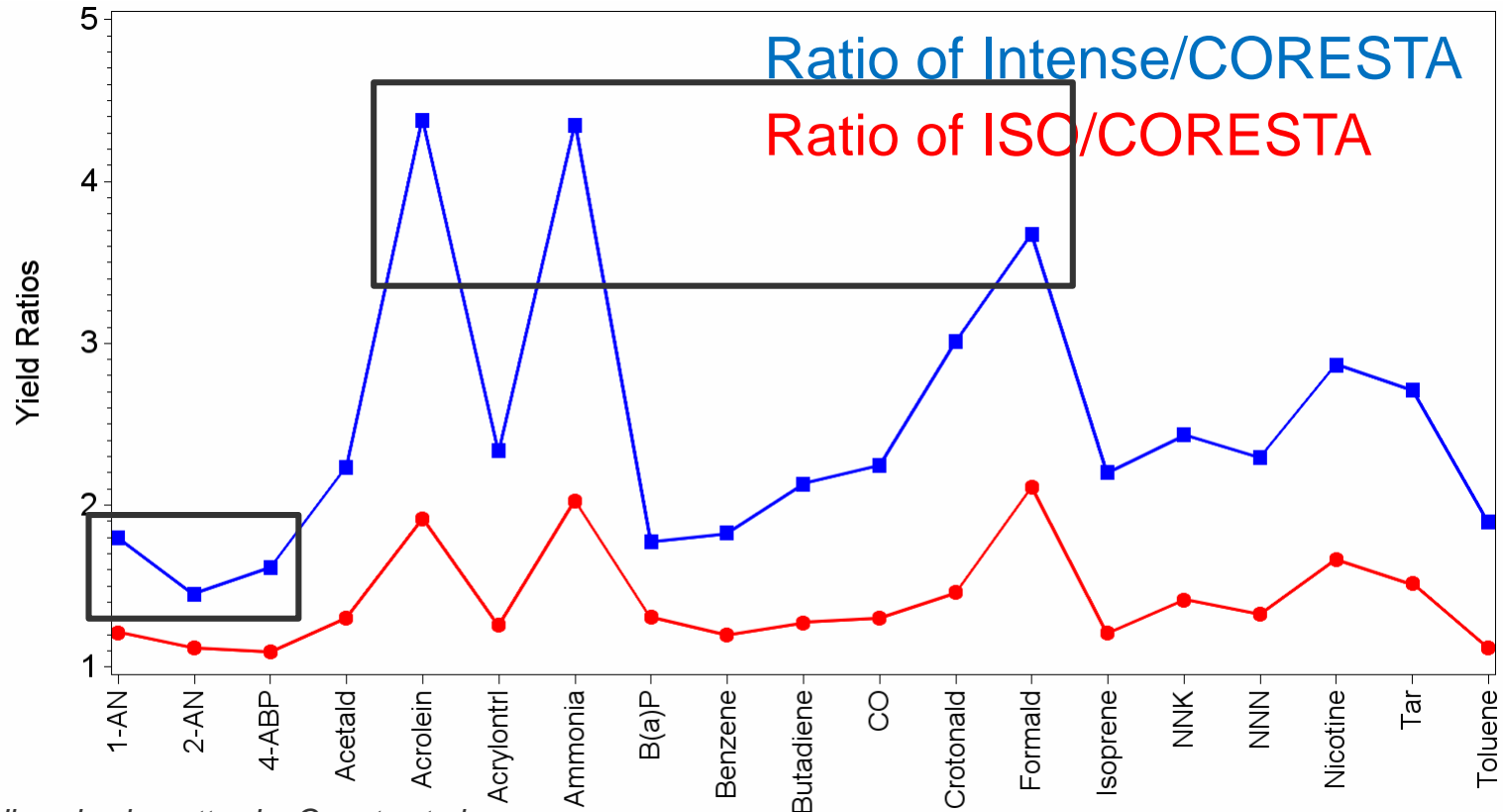
Similar to findings in cigarettes by Counts et al.
Reg Tox Pharm 41 (2005) pp 185-227

Consistency of yield rankings
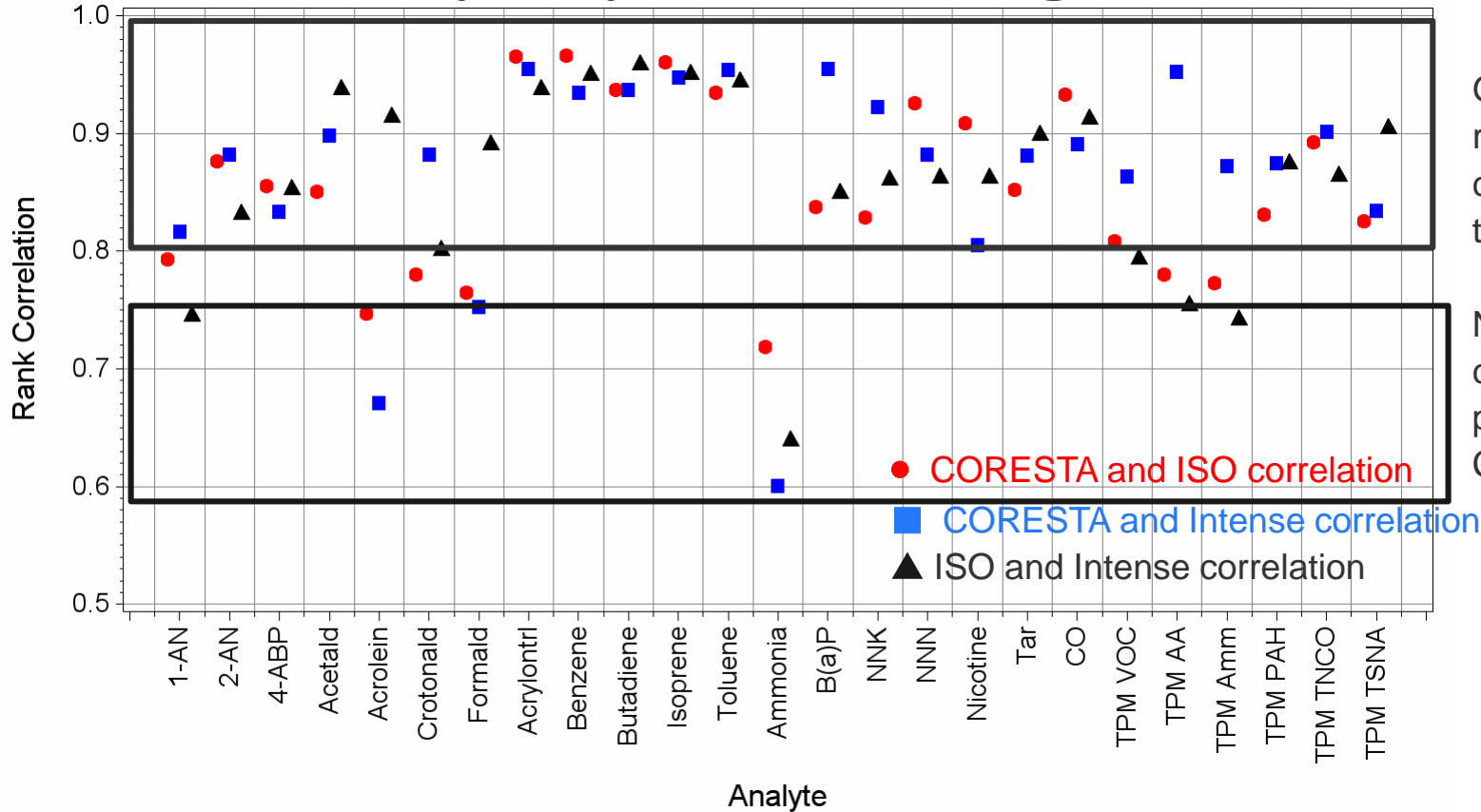
Generally the rankings are consistent between the methods.

Note most of these cigars had the same puff volume under CORESTA.

● CORESTA and ISO correlation

■ CORESTA and Intense correlation

▲ ISO and Intense correlation

Objectives

- Compare three different smoking regimes: CORESTA, 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 manufacturing variability

Correlations between analyte and TPM, Tar, CO
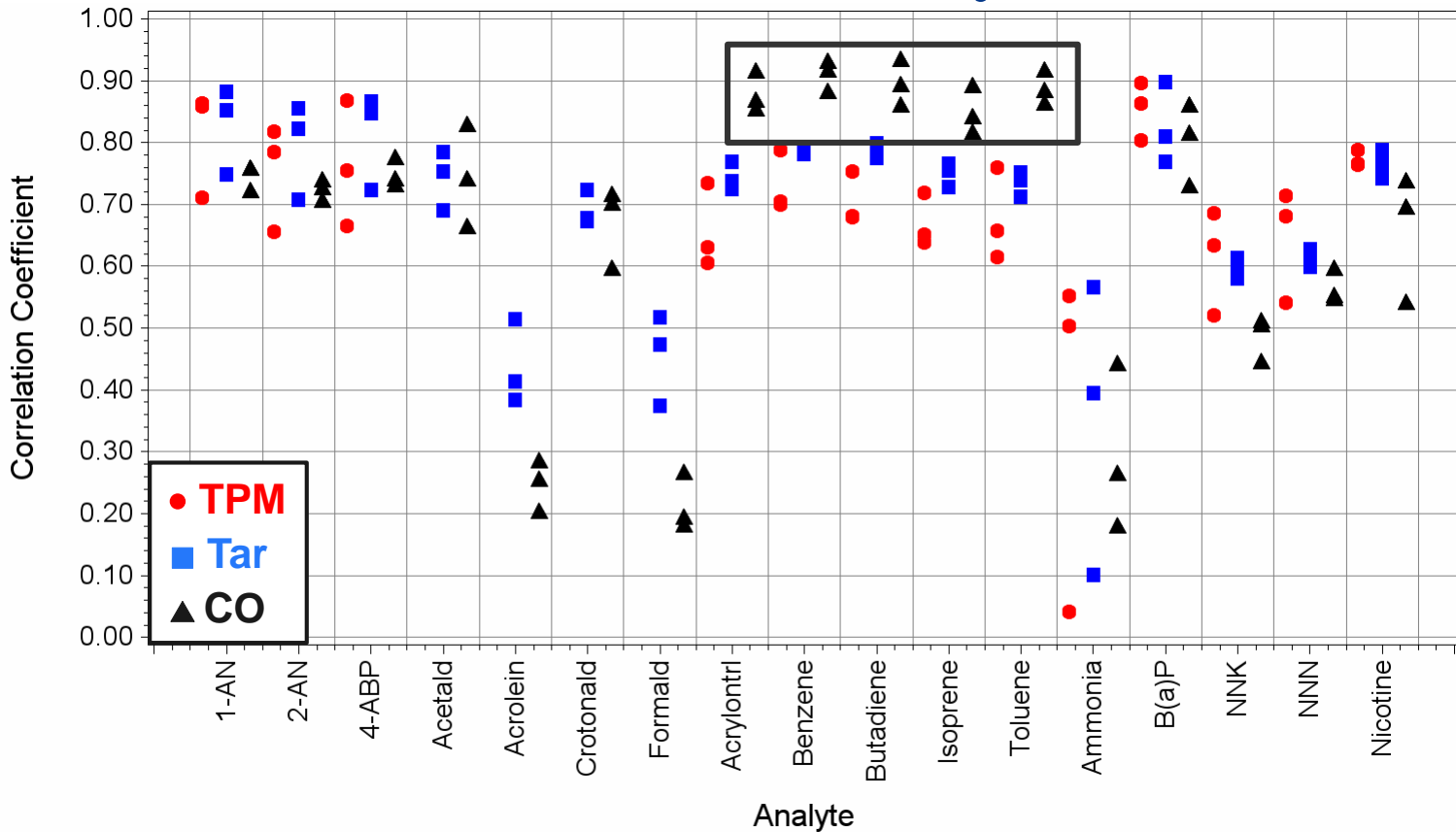
Gas phase compounds often better correlated to CO. Particulate phase typically better correlated to tar or TPM.

Prediction Intervals

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

  - Commonly indexed by Tar, TPM, or CO

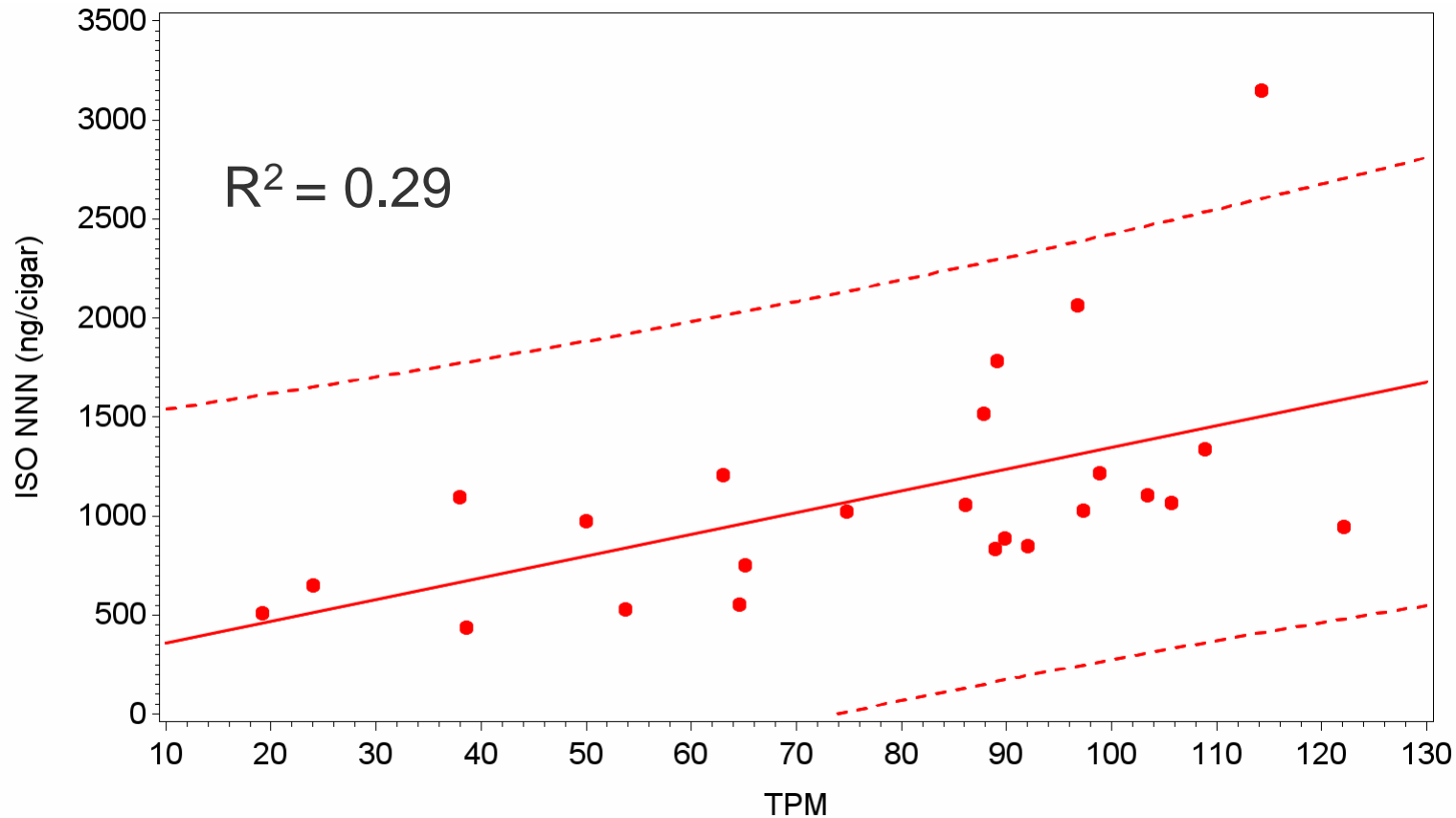 - May incorporate filler analyte concentration
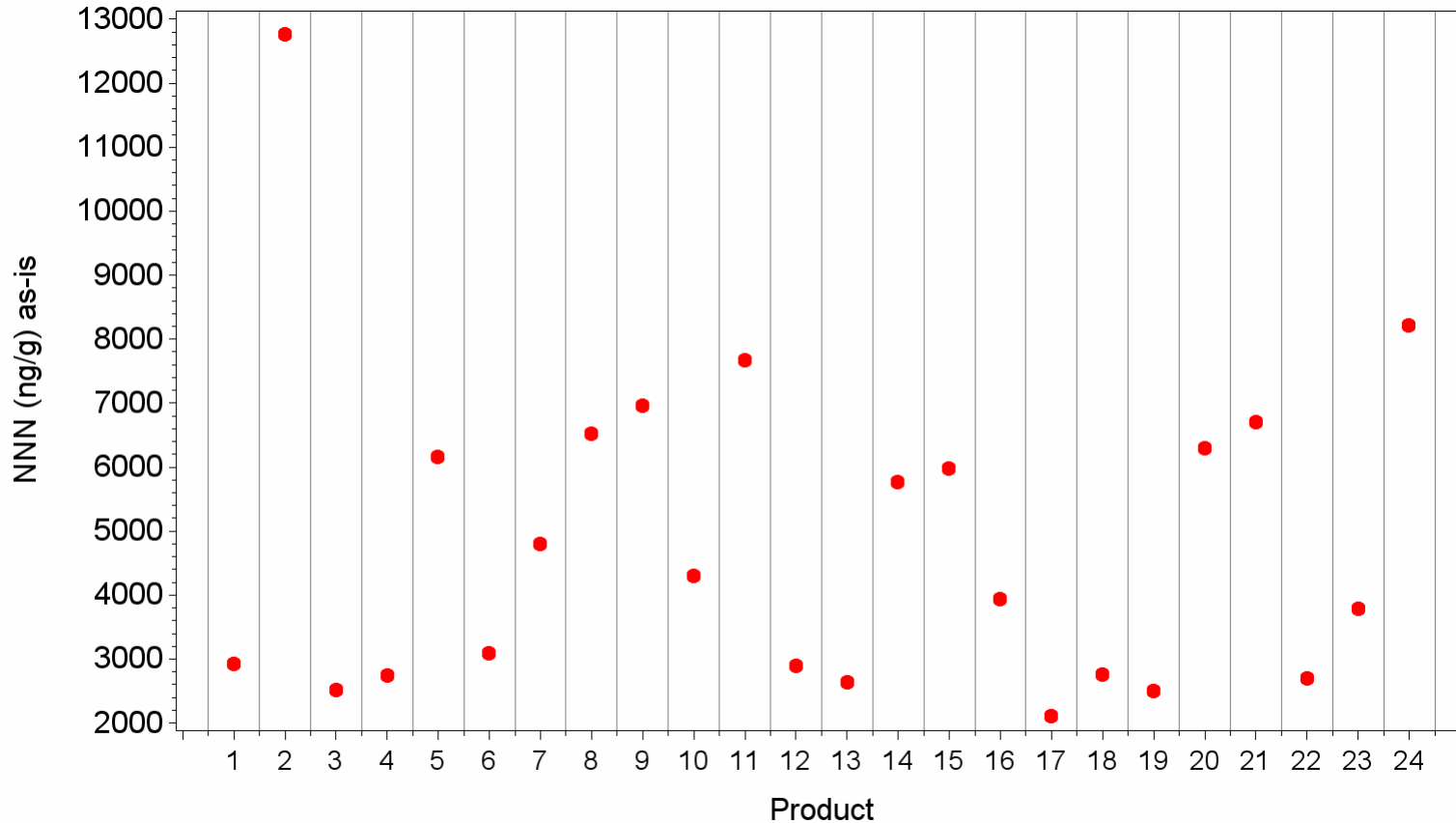
Prediction Intervals Benzene in Smoke
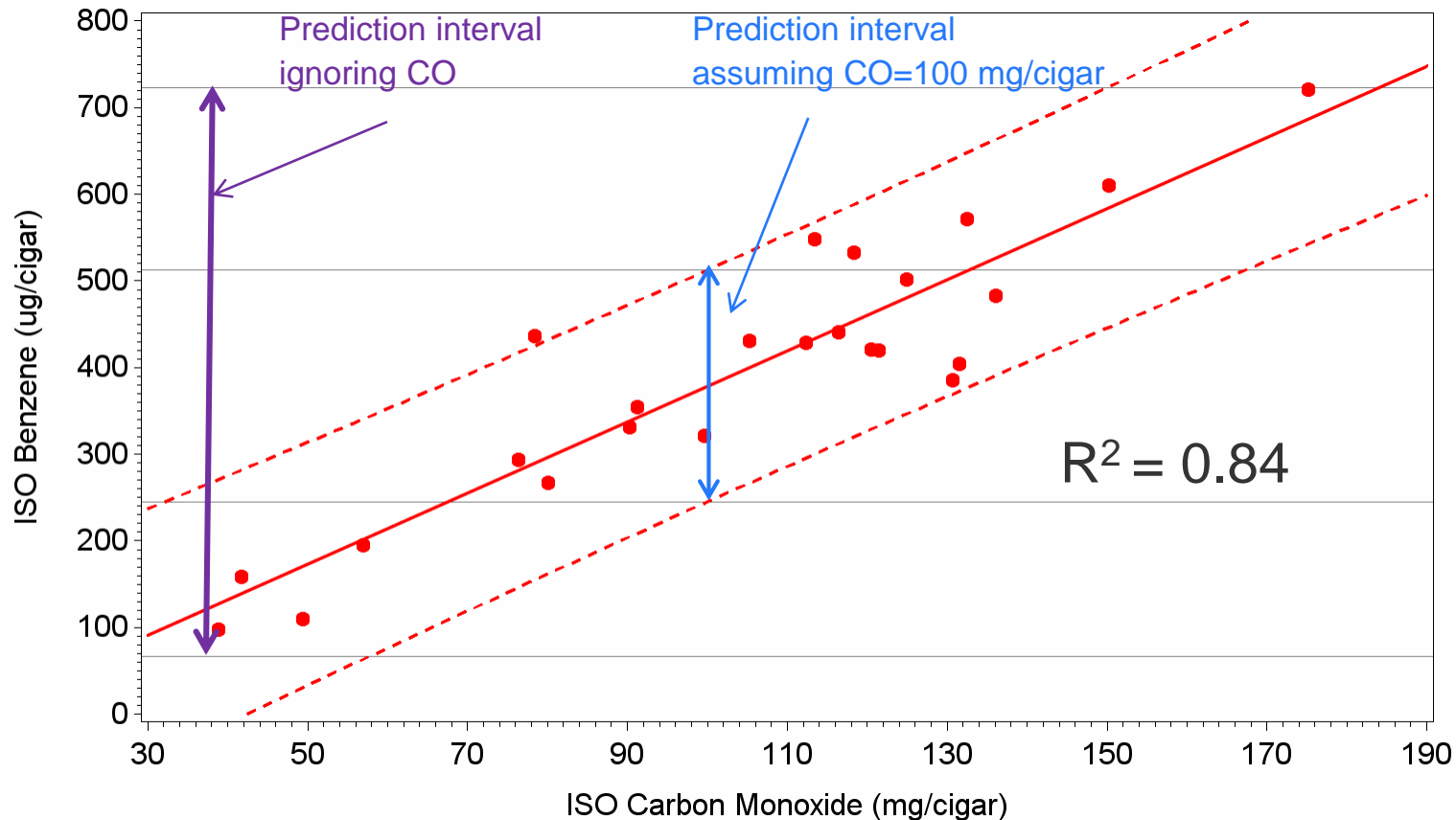
Prediction intervals are narrower with knowledge of CO. The better the correlation of CO to the constituent yield, the more the narrowing.

Because of the variability of cigars both prediction intervals are quite wide

$R^2 = 0.84$

Prediction interval ignoring CO

Prediction interval assuming CO=100 mg/cigar

ISO Benzene (ug/cigar)

ISO Carbon Monoxide (mg/cigar)

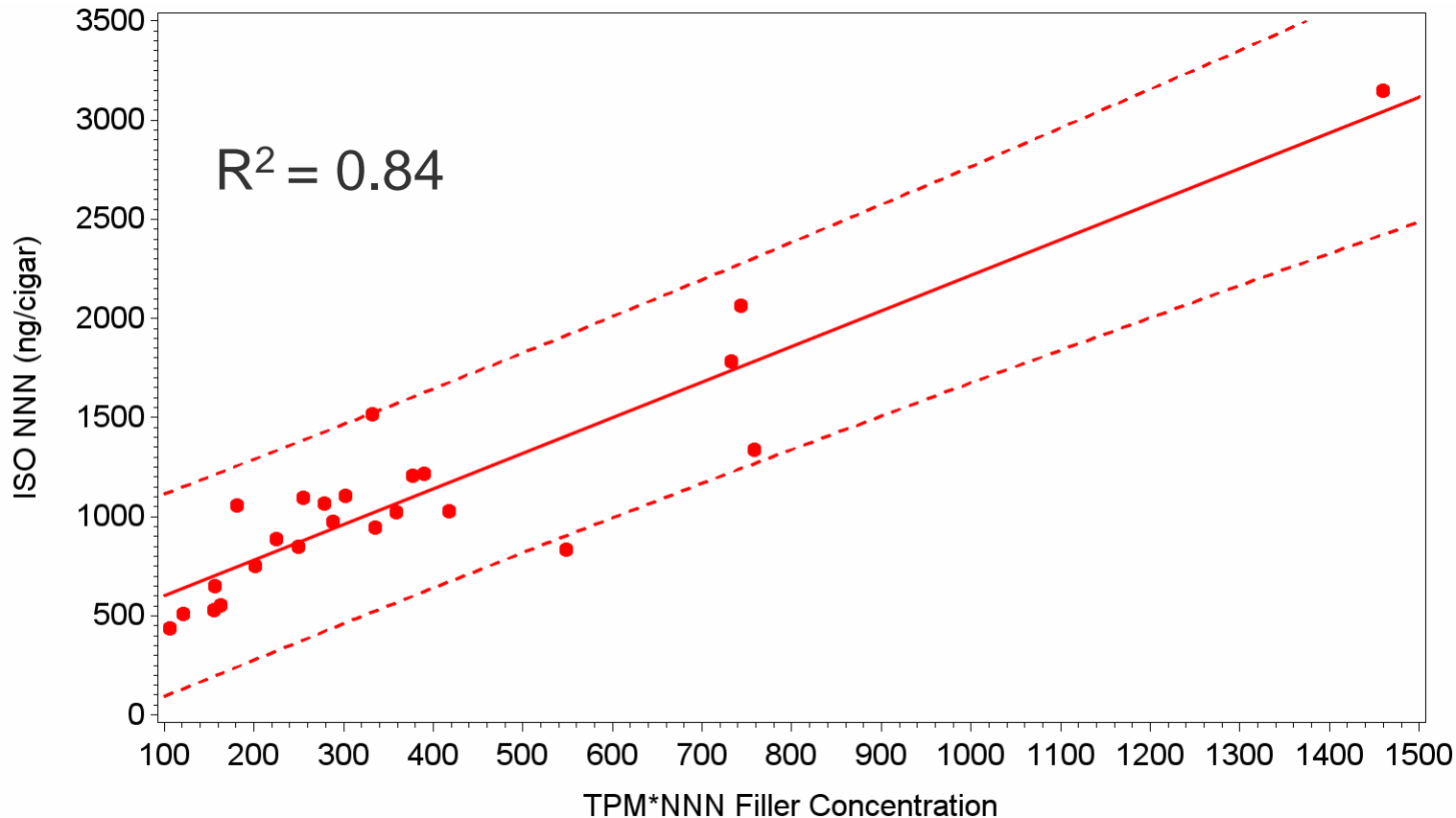# Prediction Intervals NNN in Smoke

$R^2 = 0.29$

Tobacco NNN varies from product to product

Alternative Model

- Intuitively, because of the large product-to-product NNN differences, one would expect the tobacco NNN to affect NNN smoke yields in addition to TPM

- Simple Model Incorporating TPM and Filler Analyte Concentration:
  $NNN = a + b(TobNNN * TPM)$, where TobNNN is the concentration per gram of NNN in the cigar filler.

Prediction Intervals NNN in Smoke

Prediction Intervals

- The better the correlation, the narrower are the prediction intervals.

- The prediction intervals incorporating tobacco NNN concentration are roughly half the width of the intervals using TPM alone

- Because of the very high variation in cigar smoke yields, the prediction intervals are still quite wide

R² Values Incorporating Tobacco Characteristics

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

The model for formaldehyde is
$y=a + b1*Tar + b2*(TobAmm*Tar)$
(TPM not captured with carbonyls)

The b2 coefficient
is negative, showing that for
formaldehyde higher filler ammonia
reduces the formaldehyde
yields.

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Filler Temporal Variation

- Most products in this market map were tested twice for filler analytes
  - Some products from the same production batch and some from two different production batches

Percentage Difference in Two NNN Filler Results
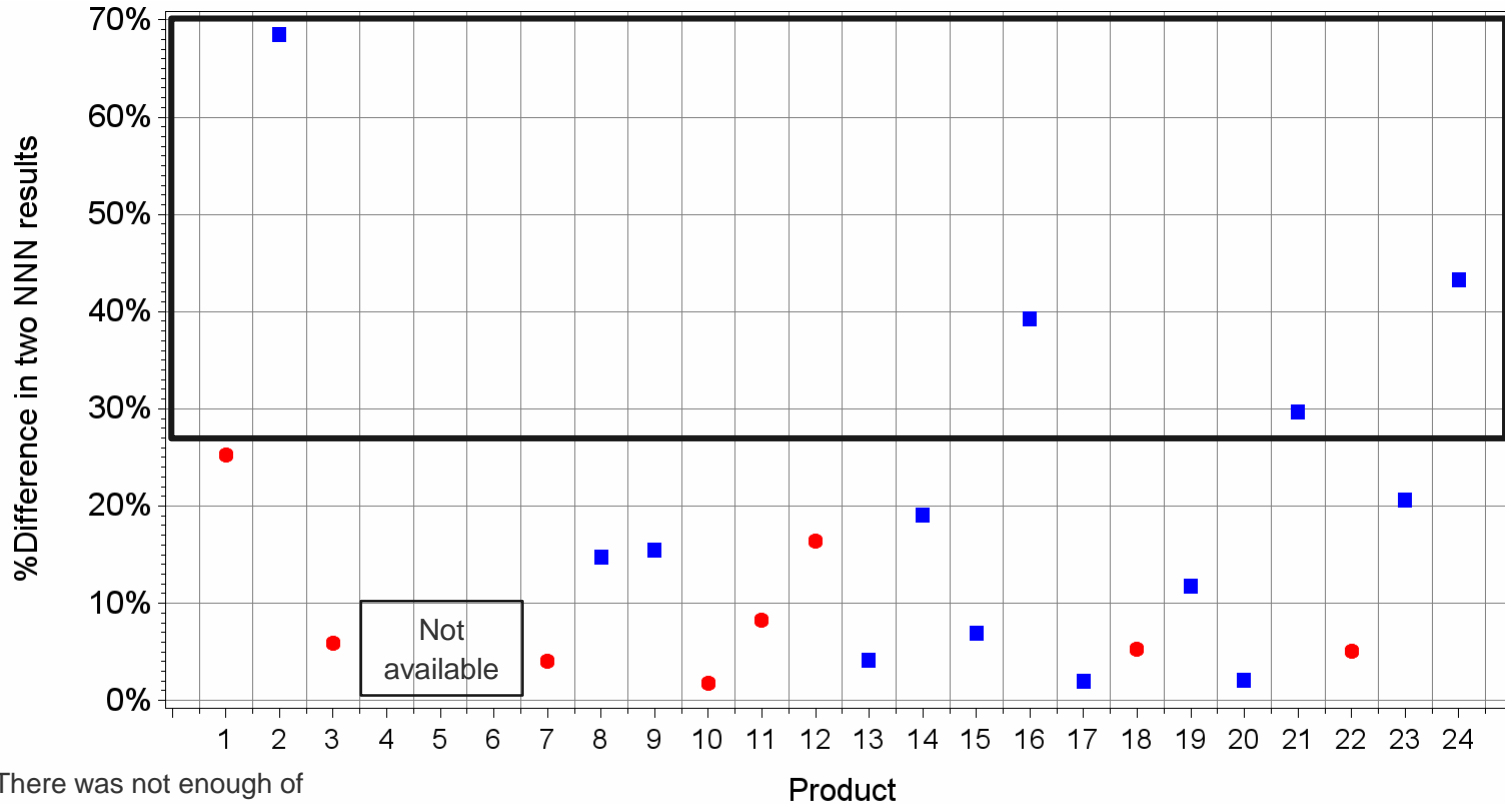
This shows moderate differences when the same batch is tested at different times and often much larger differences when testing different batches

There was not enough of products 4, 5, and 6 remaining for filler re-testing

Same Product Batch   Different Product Batch

Summary and 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

Thank You

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