Market Survey of Modern Oral Nicotine Products: Determination of Select HPHCs and Comparison to Traditional Smokeless Tobacco Products

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Introduction

- Family Smoking Prevention and Tobacco Control Act gave regulatory oversight to the US Food and Drug Administration (FDA).

- Specific requirements were set for language to be included on warning labels and for scientific rigor when making claims of modified risk profiles.

- To claim modified risk, scientific evidence must be provided to the FDA to receive permission to market products as modified or reduced risk.

Efforts to Modify/Reduce Risk

- Combustion is a significant source of many harmful or potentially harmful constituents (HPHCs).
- Recent development aims at reducing consumer's exposure to HPHCs while still delivering nicotine.
- Products being promoted as an alternative to traditional cigarettes/smokeless tobacco:
  - Electronic Nicotine Delivery Systems (ENDS)
  - Heated Tobacco Products (HTP)
  - Modern Oral Nicotine Products (MONP)

What are Modern Oral Nicotine Products?

- Modern oral nicotine products (MONP) are a novel class of nicotine-containing products aimed at reducing HPHC exposure.
- Intended to be consumed in a similar way to smokeless tobacco products.
- Various products currently available, but to date, none have received FDA authorization to be classified as modified risk.
- Products can be divided into two general classes based on filler composition
  - White granular powder – comes in pouches
  - Plant material – comes in pouches or long cut

Study Design

- Twenty-five (25) products from nine manufacturers were assessed.
  - Included in this are CRP1.1 and CRP2.1, and two commercial products.
- Compounds to be analyzed were selected based upon FDA HPHC list for smokeless tobacco.
  - Including TSNAs, nitrite, BaP, carbonyls, metals.
- All products extracted in triplicate for all assays and reported on a per gram basis.

Code	Form	Base	Flavor
A1	Pouch	powder	Wintergreen
A2	Pouch	powder	Black Cherry
A3	Pouch	powder	Mint
A4	Pouch	powder	Citrus
B1	Pouch	powder	Wintergreen
B2	Pouch	powder	Citrus
B3	Pouch	powder	Berry
C1	Pouch	powder	Mango
C2	Pouch	powder	Honey Lemon
C3	Pouch	powder	Wintergreen
D1	Pouch	powder	Lush
E1	Pouch	powder	Citrus
E2	Pouch	powder	Wintergreen
F1	Pouch	plant	Wintergreen
F2	Pouch	plant	Straight
F3	Long Cut	plant	Peach
F4	Long Cut	plant	Berry
G1	Long Cut	plant	Blood Orange
G2	Long Cut	plant	Peach
G3	Pouch	plant	Straight
G4	Pouch	plant	Wintergreen
Snus	Pouch	tobacco	Wintergreen
Long Cut	Long Cut	tobacco	Wintergreen
CRP1.1	Pouch	tobacco	Straight
CRP2.1	Long Cut	tobacco	Straight

Study Design

- All assays used in this study have been fully validated and are based upon corresponding CORESTA methods
  - Exceptions being BaP and nitrite
- For pouched products, an integer number of whole pouches were extracted. Amount of long cut product based on established tobacco methods.
  - TSNAs: 1.0 to 1.7 grams
  - Nitrite: 1.5 to 2.2 grams
  - BaP: 0.9 to 1.7 grams
  - Carbonyls: 0.8 to 1.6 grams
  - Metals: 0.5 to 1.7 grams

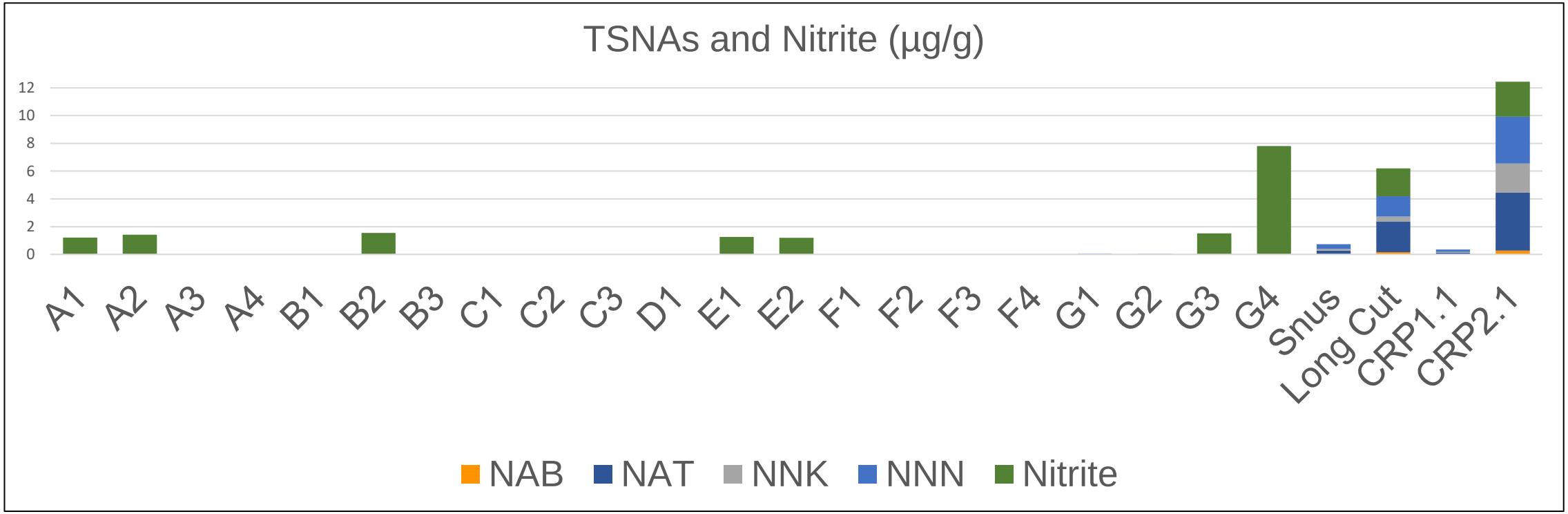
		In-house	CORESTA		IARC
Compound	**Units**	**LOQ**	**LOQ**	**Method No**	**Class**
NAB	ng/g	3.3	3.8	CRM-72	3
NAT	ng/g	13	15	CRM-72	3
NNK	ng/g	13	15	CRM-72	1
NNN	ng/g	13	15	CRM-72	1
Nitrite	µg/g	1.0	-	*	2A
BaP	ng/g	0.18	0.15	CRM-82	1
Acetaldehyde	µg/g	0.09	0.1	CRM-86	2B
Crotonaldehyde	µg/g	0.04	0.05	CRM-86	2B
Formaldehyde	µg/g	0.09	0.1	CRM-86	1
Arsenic	ng/g	7.4	200	CRM-93	1
Beryllium	ng/g	3.7	200	CRM-93	1
Cadmium	ng/g	3.7	200	CRM-93	1
Chromium	ng/g	15	200	CRM-93	3
Cobalt	ng/g	3.7	200	CRM-93	2B
Lead	ng/g	3.7	200	CRM-93	2B
Nickel	ng/g	37	200	CRM-93	2B
Selenium	ng/g	15	200	CRM-93	3

*** Astoria Pacific Method A181**

Results: BaP

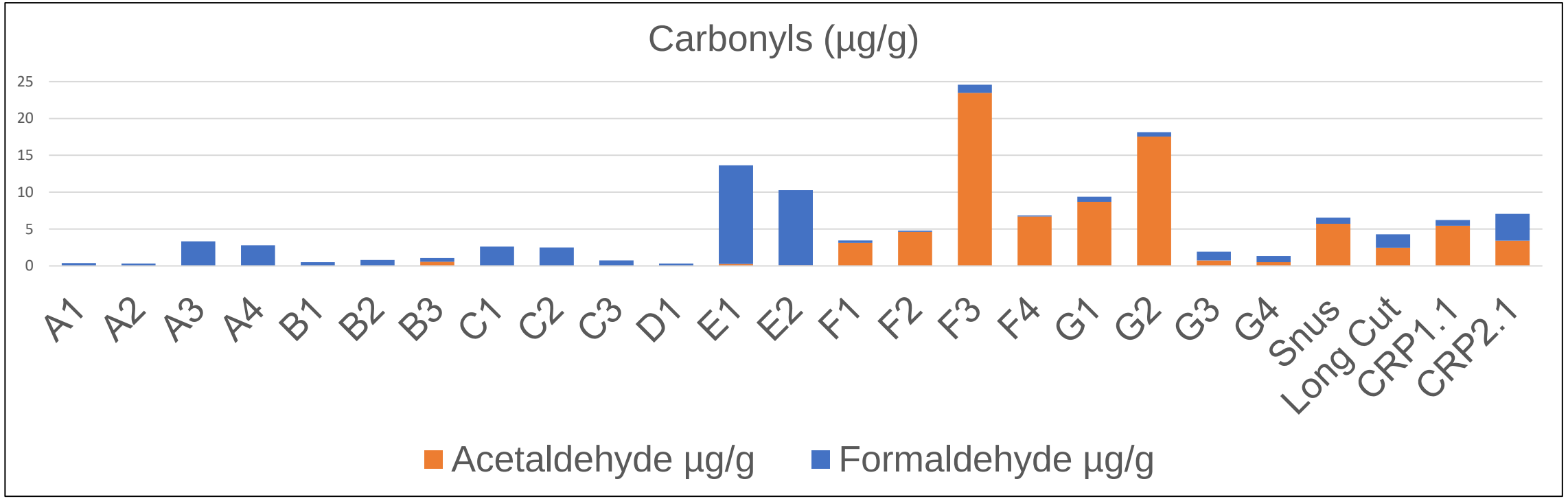
- BaP typically produced during combustion.
- Depending on manufacturing process, BaP may be produced for plant-based products.
- Only one MONP (plant-based) resulted in detectable levels of BaP (1.27 ± 0.04 ng/g).
- Smokeless products examined had substantially higher levels of BaP (77.2 ± 2 ng/g and 151 ± 3 ng/g)

Results: TSNAs & Nitrite



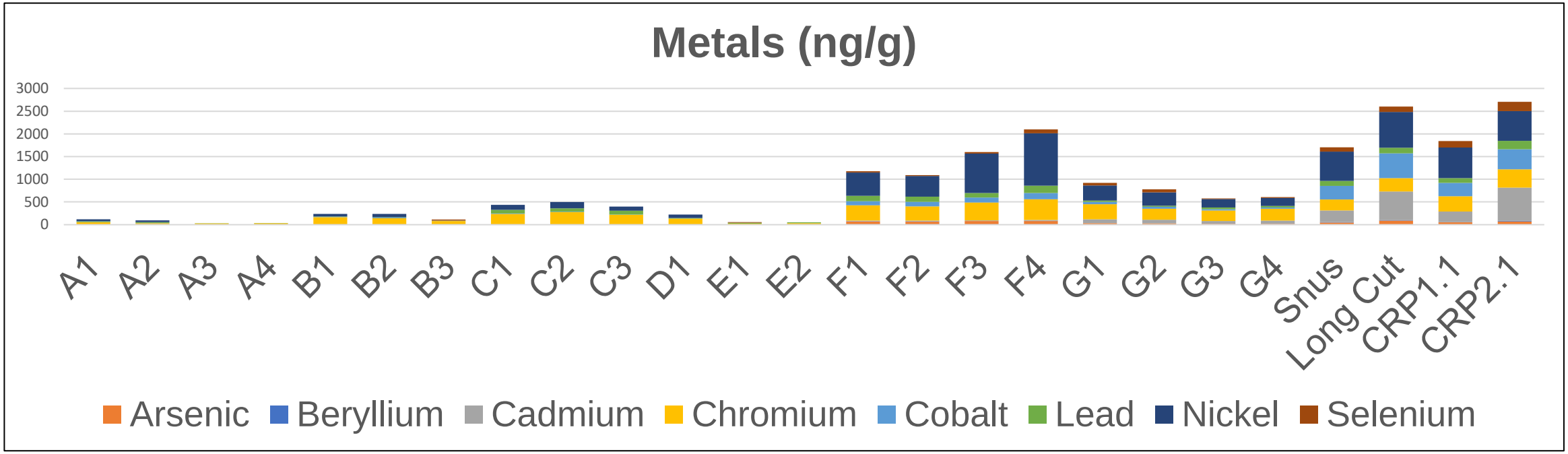
- In most MONP, nitrite was found below LOQ. When present, nitrite was at levels below those found in tobacco, except for test article G4.
- TSNAs examined were either non-detect or below LOQ for all MONP for all but two products (low levels of NAT, NNN, and NNK).

Results: Carbonyls



- Formaldehyde in MONP was comparable to levels seen in tobacco products (levels in powder-based products higher than plant-based products).
- Average acetaldehyde levels in powder-based MONP pouches were lower than those seen in all plant-based products (including tobacco).
- Plant-based MONP Ranged from lower to significantly higher than in tobacco products.

Results: Metals



- Metals were generally present in higher levels in plant-based products (MONP and tobacco) than powder-based MONP.
- Products C1, C2, and C3 had chromium levels at or higher than those observed in plant-based MONP and comparable to tobacco products.
- Products F1, F2, F3, F4 had levels of nickel comparable or greater than those observed in smokeless tobacco products.

Conclusions

- Modern oral nicotine products (MONP) are being produced as an alternative to traditional smokeless tobacco products.
- Generally, the observed analyte levels in powder-based MONP were lower than plant-based MONP.
- The average levels of most analytes measured in MONP were lower than those measured in smokeless tobacco products.
  - Exceptions: carbonyls, select metals
- The LOQs of the methods used for analysis were acceptable and are suitable for the analysis of MONP.
  - Possible exception: TSNAs

Thank you for your attention!

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