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Center for Research and Technology
76TH TSRC, Poster #79
September 24 –27, 2023

on!® PLUS nicotine pouch products (on!® PLUS NPs) are a new type of oral tobacco-derived nicotine (OTDN) pouch product intended for adults aged 21 years or older who use moist smokeless tobacco (MST) or who dual use MST and cigarettes. on!® PLUS NPs have a soft feel and do not contain cut, ground, powdered, or leaf tobacco. To receive market authorization in the United States, the U.S. Food and Drug Administration (FDA) must determine if on!® PLUS NPs are appropriate for the protection of public health (APPH) under section 910(c) of the Food, Drug and Cosmetic Act. To inform an APPH determination, we demonstrated that there are substantial reductions in the levels of harmful and potentially harmful constituents (PHPCs) for on!® PLUS NPs when compared to other tobacco products.

In this study, we measured the HPHCs in three lots of nine on¹® PLUS NPs (three nicotine levels and three flavor varieties) from the FDA Smokeless Tobacco (ST) abbreviated list and compared the results to commercially available tobacco products including cigarettes, smokeless tobacco, and other OTDN pouches. We recognize that on¹® PLUS NPs do not meet the statutory definition of a ST product; however, this approach was considered appropriate as there is no FDA-specific guidance for reporting HPHCs for OTDN products. The HPHCs included in FDA's ST abbreviated list include nicotine, NNN, NNK, B[a]P, acetaldehyde, formaldehyde, crotonaldehyde, cadmium, and arsenic. Among these (apart from nicotine), formaldehyde and acetaldehyde were the only HPHCs that had quantifiable levels in on¹® PLUS NPs, despite the low limit of quantitation for the methods used for the quantitation of these analytes (See note below Table 1). Additionally, a toxicological risk assessment of the HPHCs present at measurable levels in on¹® PLUS NPs were below levels of toxicological

- We demonstrate that on!® PLUS NPs have substantially reduced HPHC levels compared to cigarettes, Moist Smokeless Tobacco (MST), and eight General® snus products FDA previously determined to be modified risk tobacco products.¹
 - The General® snus products included General Portion Original Large, General Mint Portion White Large, General Portion White Large, General Wintergreen Portion White Large, General Loose, General Dry Mint Portion Original Mini, General Classic Blend Portion White Large, and General Nordic Mint Portion White Large.¹
- To establish the reduced risk potential of on!® PLUS NPs compared to other tobacco products, we compared the HPHCs measured in on!® PLUS NPs to cigarette and ST market surveys as well as literature values of other OTDN NP products.^{2,5}

- HPHC testing was conducted by Altria Client Services LLC using ISO 17025 accredited methods that were validated for all matrices.
 - Three lots of the nine varieties of on!® PLUS NP products (three nicotine levels and three flavor varieties) were tested for HPHCs using the FDA's ST list. The averaged HPHC's of the three lots are presented below:
- All HPHCs evaluated were below the limit of quantitation (BLOQ) in on!® PLUS NPs except for acetaldehyde and formaldehyde when compared to the following tobacco categories:
 - MST
 - on!® PLUS NPs demonstrated a >91% reduction for both acetaldehyde and formaldehyde compared to MST.
 - Snus
 - on!® PLUS NPs demonstrated a >92% reduction for acetaldehyde and >96% reduction for formaldehyde compared to General® snus products.
 - Cigarette Smoke
 - The mainstream cigarette smoke yields for acetaldehyde and formaldehyde are 900 and 95 times greater than the maximum amounts determined in on!® PLUS NPs, respectively.⁵
 - Other OTDN NPs
 - A comprehensive survey of the literature indicates that the HPHC levels for on!® PLUS NPs are comparable to or lower than published HPHC results for 18 OTDN NP products.³

- Nicotine, formaldehyde and acetaldehyde were the only HPHCs from the FDA's ST abbreviated list that have quantifiable levels in onit® PLUS NPs.
- A toxicological risk assessment was conducted on formaldehyde and acetaldehyde with an estimated daily lifetime exposure of 14 pouches/day (one can/day) and 100% bioavailability.
- Using established regulatory values developed by the Texas Commission on Environmental Quality (TCEQ), US EPA IRIS, and California EPA (CalEPA), it was determined that:
 - Oral exposure to formaldehyde and acetaldehyde was well below established regulatory values and would not introduce a non-cancer risk.
 - Excess lifetime cancer risk for oral exposure to formaldehyde was estimated to be in the 10⁶ range (1 in 1,000,000) or lower.

- Substantially lower levels of HPHCs in on!® PLUS NPs compared to other tobacco products suggest that adults who use MST products or cigarettes switch to on!® PLUS NPs will reduce their exposure to these constituents.
- The HPHC data consistently demonstrates that on!® PLUS NPs have substantially lower, not detectable, or BLOQ levels of HPHCs compared to General® Snus products that the FDA previously determined to be modified risk tobacco products and comparable or lower levels of HPHCs to other oral NP products.^{1,3}

1. Modified Risk Granted Orders – Risk Modification. FDA Center for Tobacco Products. MR0000020-MR0000022, MR0000024-MR0000025, MR0000027-MR0000029 (October 22, 2019), available at <https://www.fda.gov/media/131922/download>.
2. FDA Draft Guidance 2012: 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. 77 Fed. Reg. 20034 (April 3, 2012).
3. Jablonski JJ, Choetham AG, Martin AM. Market Survey of Modern Oral Nicotine Products: Determination of Select HPHCs and Comparison to Traditional Smokeless Tobacco Products. *Separations*. 2022; 9(3):65.
4. Data source: Summary of 2014 and 2015 Smokeless Market Surveys, RDM JAB 2016 281. 22 most snuff products were sampled in 2014 representing a total of 68% of the snuff market share. 29 snuff most products were sampled in 2015 representing a total of 72% of the snuff market share. The mean values are from Table 1 in FDA Briefing Document: September 13-14, 2018, Meeting of TPSAC on MRTLPA MR0000068-MR0000073 from R.J. Reynolds Tobacco Company. The ranges are from RJRT's MRTLPA MR0000068-MR0000073, Section 6.1.5, Table 6.1.5-13. Data for comparison are in wet weight basis (WWB). The original data was presented in unit/g. We convert the data to unit per portion based on the assumption of a 2-gram portion size for a typical use of MST.
5. Data source: Summary of 2014 and 2015 Cigarette Market Surveys, RDM JAB 2016 306. 45 commercial brand styles were sampled in 2014 representing a total of 51% of the cigarette market share and 50 commercial brand styles were sampled in 2015 representing a total of 60% of the cigarette market share. The mean values are from Table 1 in FDA Briefing Document: September 13-14, 2018, Meeting of TPSAC on MRTLPA MR0000068-MR0000073 from R.J. Reynolds Tobacco Company. The ranges are from RJRT's MRTLPA MR0000068-MR0000073, Section 6.1.5, Table 6.1.5-10. Our comparison is based on the ISO smoking regime (ISO 3308).

Figure 1. Select Products of on!® PLUS NPs



Figure 2. Percent Reduction in HPHCs – Maximum Levels in on!® PLUS NPs Compared to Mean Levels in MST¹⁻³

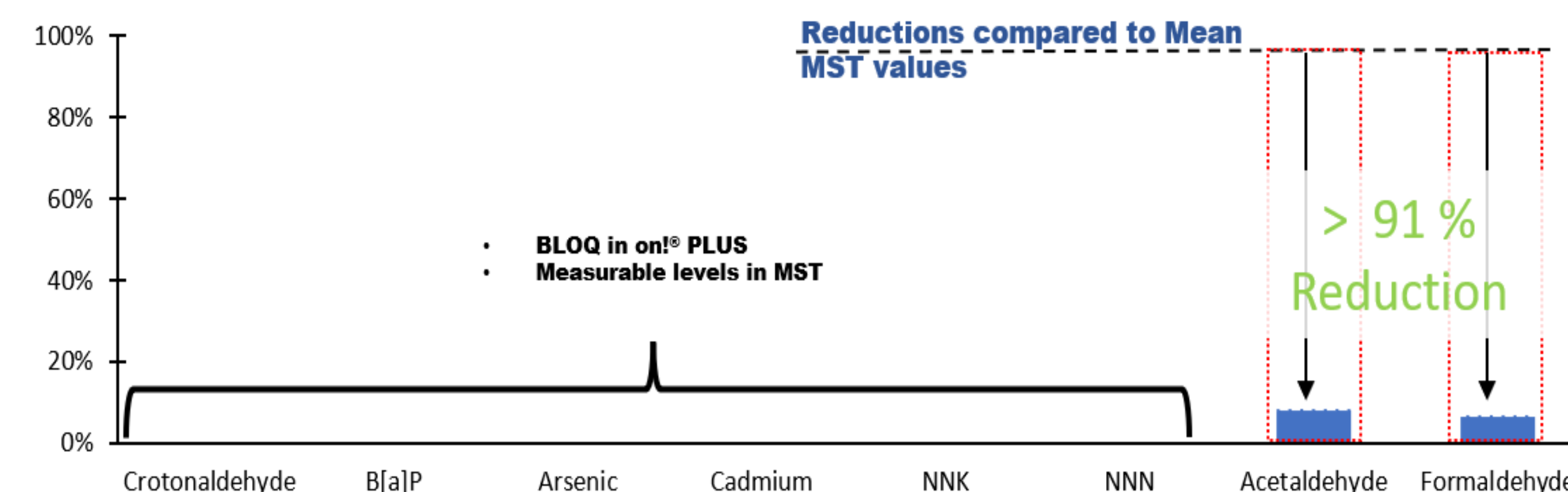


Table 1. Mean Levels of HPHCs in on!® PLUS NPs Compared to Other Oral NP Products, Snus, MST and Cigarettes

Constituent ¹	on ¹ PLUS ² Mean (Min-Max) (unit/portion)	Other NPs ³ Mean (Min-Max) (unit/portion)	General ⁴ Snus ⁴ Mean (Min-Max) (unit/portion)	MST ⁵ Market Survey Mean (Min-Max) (unit/portion)	Mainstream Cigarette Smoke ⁶ , Market Survey Mean (Min-Max) (unit/cigarette)
Acetaldehyde (µg)	0.430 (0.262- 0.774)	BLOQ to 23.5	11 (3-22)	9.22 (1.35-51.89)	615 (81-892)
Arsenic (ng)	BLOQ (<20.00)	BLOQ to 106.0	BLOQ to 32	217 (92-374)	3.0 (0.3-6.2)
B[a]P (ng)	BLOQ (<0.500)	BLOQ to 1.27	BLOQ to 0.27	144 (8-372)	9.0 (3-15)
Cadmium (ng)	BLOQ (<20.00)	BLOQ to 86.0	277 (132-542)	1020 (700-1300)	42 (5-116)
Crotonaldehyde (µg)	BLOQ (<0.10)	BLOQ to 0.0665	BLOQ	1.202 (0.938-1.466)	13 (2-21)
Formaldehyde (µg)	BLOQ- 0.249	1.060 (0.124-5.240)	7.18 (3.77-9.41)	3.66 (1.43-7.46)	24 (2-47)
Nicotine (mg)	8.97 (5.65-12.71)	6.15 (3-8)	8.15 (4.40-14.84)	24.1 (14.8-29.4)	0.9 (0.1-2.1)
Free nicotine (mg)	6.83 (3.81-10.02)	Not Provided	5.8 (1.1-10.2)	8 (1-15)	Not Provided
NNK (ng)	BLOQ (<4.0)	BLOQ to 13.7	108 (41-172)	964 (194-3502)	68 (9-143)
NNN (ng)	BLOQ(<4.0)	BLOQ to 39.4	334 (177-488)	3420 (1104-10444)	90 (11-175)

Note: Acetaldehyde LOQ = 0.10 µg/portion, formaldehyde LOQ= 0.10 µg/portion

Data Source: FDA Draft Document 2017: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke (Under Section 904(a) of the Federal Food, Drug, and Cosmetic Act; 77 Fed. Reg. 20034 (April 3, 2012). BfAP – Benz[a]anthracene; NNK – 4-(methylnitrosamino)-1-(pyridin-1-yl)-1-pyrone; nitroNN – N-nitroso-N-methyl-4-aminobenzonitrile; Federal Food, Drug, and Cosmetic Act; 77 Fed. Reg. 20034

Data Source: We use the mean value for any constituent with quantifiable levels in 3 bits of 9 varieties of the e-cigarette PLUS Nic (three nicotine levels and three flavor varieties); BLOD – below the limit of quantification. A value next to “–” sign indicates the limit of detection.

Data Source: J. Jablonski, J.J. Cheetham, A.G. Martin, A.M. Market Survey of Modern Oral Nicotine Products: Determination of Selected HPHCs and Comparison to Traditional Smoking Mixtures. *Toxicology & Tobacco Products*. Separations 2019, 65. <https://doi.org/10.3390/separations2019065>

The nicotine data is a risk labeled and measure nicotine values. The pH and Free nicotine was not provided.

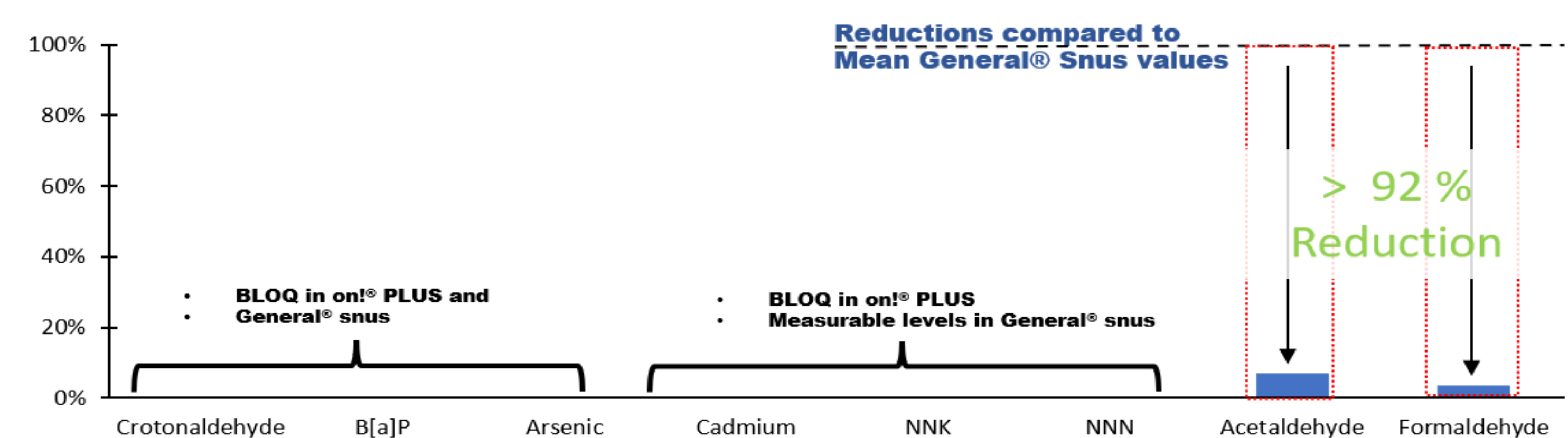
Data source: FDA review notes: “Chemistry Review of Pre-market Tobacco Applications (PMTAs) Submitted by Swedish Match North America for Smoos Smokables Tobacco Product, 10/28/2015 (obtained by Freedom of Information Act requests). Data used for comparison are mean values of 10 cigarettes per pack or one weight portion. For the case group (PMTOO0007), we convert the values from units to uniform based on a 2 gram portion size per use. One of the eight products (PMTOO0008) has no quantifiable values of arsenic and B[a]P; levels of arsenic and B[a]P are RLOB in other seven products. The LOOs were not provided.

Data source: Summary of data and 2015 SmokesMarket Research: RDMJ 1A10 2015: 22 moist snuff products were sampled in 2014 representing a total of 6% of the moist snuff market share. 29 moist snuff products were sampled in 2015 representing a total of 14% of the moist snuff market share. The mean values and error bars are shown in Figure 1. The mean values and error bars are shown in Figure 1. The mean values and error bars are shown in Figure 1.

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Data source: Summary of data and 2015 Cigarette Market Research: RDMJ 1A10 2015: 36 commercial brand types of smoking were sampled in 2014 representing a total of 51% of the cigarette market share and 50 commercial brand types were sampled in 2015 representing a total of 44% of the cigarette market share. The mean values and error bars are shown in Table 1 in ESI-Briefing Document. September 13, 14, 2016. Meeting of ITSGAC on RTMTPAS/MKTMA000006. MARKET000007 from R.J. Reynolds Tobacco Company. The ranges are from RUTS/RTMTPAS/MKTMA000006. MARKET000007: Summary of data and 2015 Cigarette Market Research: RDMJ 1A10 2015: 36 commercial brand types of smoking were sampled in 2014 representing a total of 51% of the cigarette market share and 50 commercial brand types were sampled in 2015 representing a total of 44% of the cigarette market share. The mean values and error bars are shown in Table 1 in ESI-Briefing Document. September 13, 14, 2016. Meeting of ITSGAC on RTMTPAS/MKTMA000006. 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Figure 3. Percent Reduction in HPHCs – Maximum Levels in on!® PLUS NPs Compared to Mean Levels in General® Snus¹⁻³



1. Source: FDA Draft Guidance 2012. Report on Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act; 77 Fed. Reg. 20034 (April 3, 2012). HPHC = Harmful and Potentially Harmful Constituents. Constituents described in the abbreviated list of HPHCs in smokeless from the 2012 Draft Guidance; 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 (FDCA). Nicotine data are not shown.
2. Data Source: We use the maximum value for any constituent with quantifiable levels in 3 lots of 9 varieties of the on[†] PLUS NP (three nicotine levels and three flavor varieties). BLOQ = below the limit of quantification.
3. Data source: Summary of 2014 and 2015 Smokeless Market Surveys, RDM JAB 2016 281. 22 moist snuff products were sampled in 2014 representing a total of 68% of the moist snuff market share. 29 moist snuff products were sampled in 2015 representing a total of 72% of the moist snuff market share. The mean values are from Table 1 in FDA Briefing Document: September 13, 2014, Meeting of TPSCAC on MTRTPAs MR0000066- MR0000073 from R.J. Reynolds Tobacco Company. The ranges are from RJRT's MTRTPAs MR0000066- MR0000073, Section 6.1.5, Table 6.1.5-13. Data for comparison are in wet weight basis (WWB). The original data was presented in unit/g. We convert the data to unit per portion based on the assumption of a 2-gram portion size for a typical use of MST.

1. Source: FDA Draft Guidance 2012: 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, 77 Fed. Reg. 20034 (April 3, 2012). PHHC = Harmful and Potentially Harmful Constituents. Constituents described in the abbreviated list of PHHCs in smokeless from the 2012 Draft Guidance, 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 (FDCA). Nicotine levels are not shown.

2. Data Source: We use the maximum value for any constituent with quantifiable levels in 3 lots of 9 varieties of the on! PLUS NP (three nicotine levels and three flavor varieties). BLOQ = below the limit of quantification.

3. Data source: FDA reviewer notes - Chemistry Review of Pre-market Tobacco Applications (PMTAs) Submitted by Swedish Match North America for Snus Smoked Tobacco Product, 10/30/2015 (obtained by Freedom of Information Act request). Data used for comparison are mean values of 8 General® snus products on a wet weight basis. For the sole loose product (PM0000010), we convert the values from unit/g to unit/portion based on a 2-gram portion size per use. One of the 8 products (PM0000011) has quantifiable values of arsenic and B[a]P; levels of arsenic and B[a]P are BLOQ in other 7 products. The LOQs were not provided.

