



# SWEDISH MATCH PRESENTATION – TPSAC

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## GOTHIA TEK® SWEDISH MATCH QUALITY STANDARD FOR SNUS

“A voluntary, proprietary standard [that utilizes] acceptable manufacturing processes as confirmed by both application review and on-site inspections. ... The constituent standards set maximum levels that must not be exceeded for selected constituents in the finished products.”<sup>1</sup>

**Based on long-term research and development with product safety and consumer protection as the key targets - made public in year 2000**

**The most important parts of the standard include strict requirements on:**

- Maximum allowable levels of harmful and potentially harmful constituents (HPHC)
- Raw materials; tobacco, ingredients and packaging material
- Manufacturing process
- Consumer information

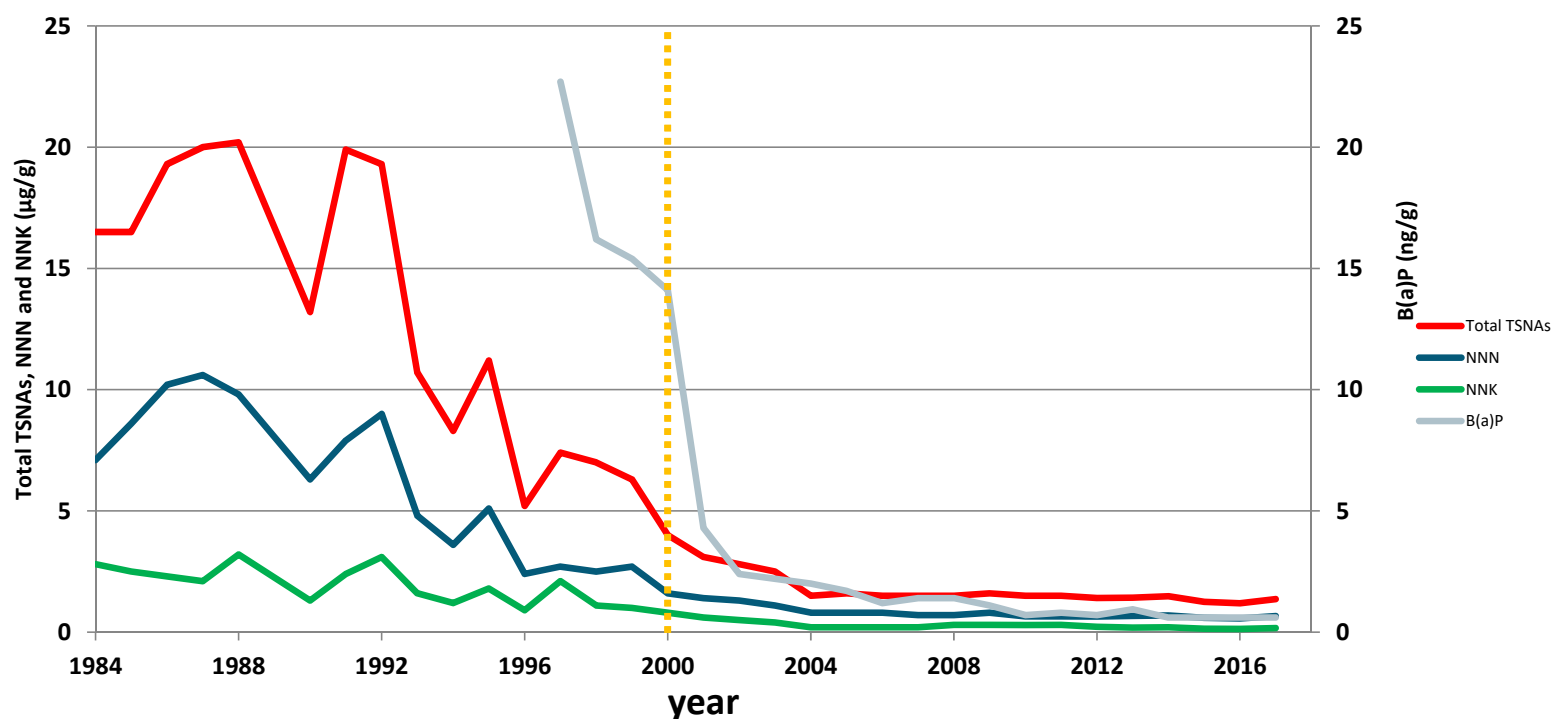


**The standard is not static, but continues to evolve as techniques and processes are improved**

- Maximum levels of HPCH have been reduced in the standard a number of times
- New HPHC have been added

## GOTHIA TEK® HAS CONTRIBUTED TO REDUCTION IN HARMFUL CONSTITUENTS

Levels of NNN, NNK, B(a)P, and total TSNAs have been dramatically reduced.



## EDUCATION ABOUT MRTP AND SNUS WILL REQUIRE SIGNIFICANT EFFORT

**US smokers are not aware of that snus health risks are lower than other products on the market.**

- Swedish Match's POV: the MRTP process provides an opportunity to correct the US population's beliefs about the risks of use related to different tobacco products.

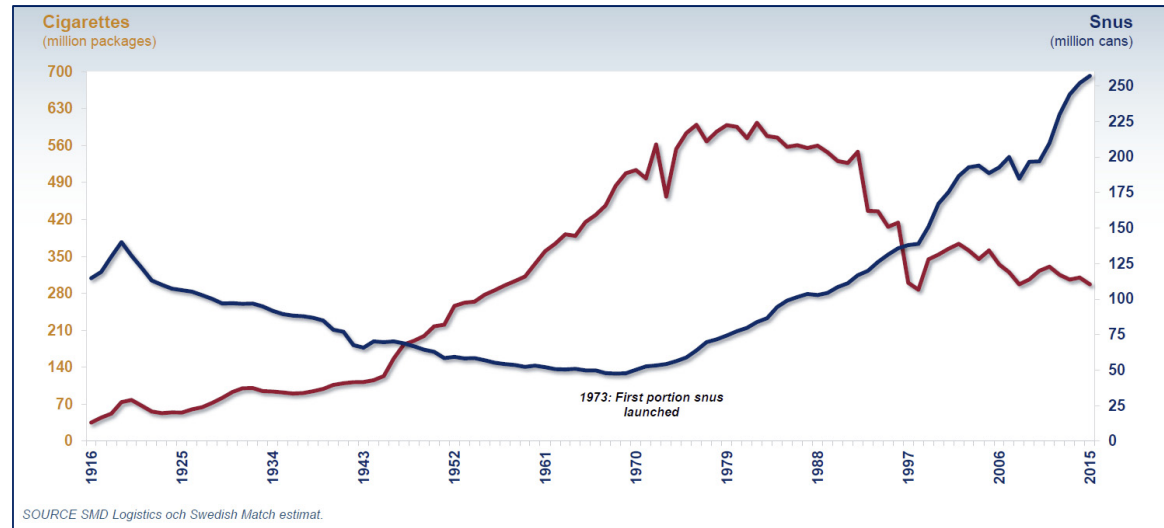
**Population Assessment of Tobacco and Health (PATH) study: adult smokers in the U.S. are misinformed about health effects of using snus vs. cigarettes.**

Data Source	Question	Output	Result
PATH <sup>2</sup> US adult smokers Every day or some days n=9,817	<i>Is using snus pouches less harmful, about the same, or more harmful than smoking cigarettes?</i>	% "less harmful" % "about the same" % "more harmful" % "don't know" % "refused to answer"	<b>8.2%</b> <b>61.5%</b> <b>26.9%</b> 3.1% 0.3%

## SWEDEN DEMONSTRATES VALUE OF AN EDUCATED PUBLIC REGARDING PRODUCT CHOICE

The usage rates of snus and cigarettes in Sweden correlate with a reduction in tobacco-related diseases.

WHO estimated death rates (per 100,000) and proportion attributable to tobacco, 2004, male only<sup>3</sup>



		All Cause	Malignant Neoplasms	Cardiovascular Disease	Respiratory Disease
Sweden	Total	1,516	378	688	61
	Attributable to tobacco	<b>152</b>	<b>74</b>	<b>40</b>	<b>30</b>
USA	Total	1,394	357	511	102
	Attributable to tobacco	<b>320</b>	<b>145</b>	<b>91</b>	<b>67</b>

## SCIENTIFICALLY ACCURATE AND IMPROVED CONSUMER UNDERSTANDING OF RISK

***Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis.***

### Conclusions on Swedish Match's proposed MRTP claim for General Snus.<sup>4</sup>

- The evidence *"supports the revised modified risk claim as scientifically accurate."*
- *"(Swedish Match's) new consumer perceptions and intentions research provides evidence that the proposed modified risk claim would improve U.S. consumers' understanding of the products' health risks relative to cigarettes, smokeless tobacco, and dual use of the products with cigarettes."*
- *"The proposed modified risk claim is likely to increase use of General Snus among adult tobacco consumers who could benefit their health by switching."*
- *"The claim is not likely to impact use among never and former users."*



## SCIENTIFIC DATA SUPPORTS REDUCED RISK OF CONDITIONS INCLUDED IN CLAIM

Results from published studies of health effects of Swedish snus use or smoking compared to non-users of tobacco for:<sup>5</sup>

- Mouth cancer,
- Heart disease,
- Stroke,
- Lung cancer,
- Emphysema and
- Chronic bronchitis

Reference	Tobacco Product Used	Mouth Cancer	Heart Disease	Stroke	Lung Cancer	Emphysema and Chronic Bronchitis
		RR (95% CI), n	RR (95% CI), n	RR (95% CI), n	RR (95% CI), n	RR (95% CI)
Boffetta et al. 2008	Swedish snus	1.0 (0.7-1.3), n=4	n/a	n/a	0.8 (0.6-1.0), n=2	n/a
Lee & Hamling 2009; Lee 2011	Swedish snus	1.01 (0.71-1.45) <sup>†</sup> , n=4	n/a	n/a	0.82 (0.52-1.28) <sup>†</sup> , n=2	n/a
Rostron et al. 2018	Swedish snus	n/a	1.04 (0.93-1.16) <sup>†§</sup> , n=3	1.04 (0.92-1.17) <sup>†  </sup> , n=1	n/a	n/a
Boffetta & Straif 2009	Swedish snus	n/a	Any MI: 0.87 (0.75-1.02), n=6 Fatal MI: 1.27 (1.07-1.52), n=5	Any stroke: 1.02 (0.93-1.13), n=3 Fatal stroke: 1.25 (0.91-1.70), n=2	n/a	n/a
Lee 2011	Swedish snus	n/a	0.99 (0.85-1.14) <sup>†</sup> , n=9	1.06 (0.96-1.17) <sup>†</sup> , n=6	n/a	n/a
Roosaar et al. 2008	Swedish snus	n/a	n/a	n/a	n/a	0.8 (0.2-3.0) <sup>††</sup> (<80 years old) 2.0 (1.2-3.4) <sup>††</sup> (80+ years old)
CPS II Population 1982-1988*	Smoking	10.89	2.80 (35-64 years old) 1.51 (64+ years old)	3.27 (35-64 years old) 1.63 (64+ years old)	23.26	Bronchitis, Emphysema: 17.1 Chronic Airway Obstruction: 10.58

Abbreviations: RR=relative risk; CI=confidence interval; n=number of risk estimates for meta-analysis; n/a=not applicable; MI=myocardial infarction

<sup>1</sup>All but one study (Roosaar et al. 2008) are meta-analyses

\*Male current smokers

<sup>†</sup>RR estimate is for never smokers

<sup>‡</sup>Nonmalignant respiratory disease death (which includes chronic obstructive pulmonary disease (COPD), bronchitis, emphysema, pneumonia, and influenza)

<sup>§</sup>RR estimate includes a pooled study of 8 cohorts from Hansson et al. 2012

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## M RTP CLAIM DEEMED SCIENTIFICALLY ACCURATE BY FDA

*Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.*

**Scientific literature served as the foundation for development of the claim, in addition to:**

- Technical Project Review Letters from PMTA and initial MRTP application;
- Qualitative consumer research.

**Claims designed to minimize reading grade-level, as measured by Flesch-Kincaid Readability Scores.**

- Inclusion of term “exclusively” raised reading academic reading level.
- Qualitative research: “instead of” was most natural descriptor based on respondent’s verbatim answers.



## M RTP CLAIM TO BE ADDED TO EXISTING AND FUTURE GENERAL SNUS ADVERTISING,

The example advertisement reflects the content of stimuli shown in related consumer research.

### Rotated government warning statements.

- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is addictive.

*A TOBACCO EXPERIENCE*  
**LIKE NO OTHER**



*Using General Snus instead of cigarettes  
puts you at a lower risk of mouth cancer,  
heart disease, lung cancer, stroke,  
emphysema, and chronic bronchitis.*

[LEARN MORE AT GENERALSNU.S.COM](http://Generalsnus.com)

General Snus is for adult-tobacco users. If you do not currently use tobacco, General Snus is not for you. If you use tobacco and would like to quit, discuss with your physician or visit [BeTobaccoFree.gov](http://BeTobaccoFree.gov) for more information.

**WARNING: This product  
can cause mouth cancer.**

## CONSUMER RESEARCH STUDY DESIGN AND METHODOLOGY

- **Consumer intentions and opinions study included over 10,000 respondents.**
- **Test v. control study design.**
- **Outcomes of interest in the research:**
  - Effect on understanding of the risks of using General Snus.
  - Absolute risk;
  - Relative to cigarettes;
  - Relative to dual use.
- **Effect on intention to use General Snus.**
  - Among current tobacco users;
  - Among non-users, including never and former users.

## CLAIM IMPROVED CONSUMER UNDERSTANDING OF RISK <sup>6</sup>

### Overall perception of health risk

*“The (Swedish Match Consumer) Study provides evidence that the proposed modified risk claim would improve consumers’ understanding of the health risks of using General Snus.” (p. 22)*

### Perception of absolute risk

*“Consumers continued to perceive daily General Snus use as presenting substantial health risks, particularly for mouth cancer and gum disease.” (p. 22)*

### Perception of relative risk

*“Adding the proposed claim to the video advertisement for General Snus substantially increased the percentage of smokers who perceived General Snus as lower in health risks than cigarettes.” (p. 22)*

### Dual Use:

*“The proposed claim improved consumers’ understanding that dual use of General Snus with cigarettes is more harmful than exclusively using General Snus.” (p. 23)*

## RESULTS: SWITCHING AND INTENTION (CURRENT USERS)

Older adult smokers in the test group were statistically significantly more likely to express interest in trying General Snus vs. control; younger group, directionally more likely.

Table 7. Intentions to buy General Snus among participants in the applicant's PBI Study <sup>7</sup>	Mean Intentions to Buy General Snus (0-10 scale, 10= "Certain, practically certain [99+ in 100]")	
	Control (Claim Absent)	Test (Claim Present)
<b>Tobacco User Group</b>		
Young Adult Cigarette Smokers	1.85	2.19
Older Adult Cigarette Smokers	1.49*	2.04*
Adult Smokeless Tobacco Users	3.41	3.71
Young Adult Never Tobacco Users	0.37	0.34
Older Adult Never Tobacco Users	0.29	0.23
Adult Former Cigarette Smokers	0.20	0.31

Note: The study item asked, "How likely are you to buy General Snus for yourself if sold in a store where you usually shop?" The response scale ranged from 0 ("No chance, almost none [1 in 100]") to 10 ("Certain, practically certain [99+ in 100]").

\* p = .001.

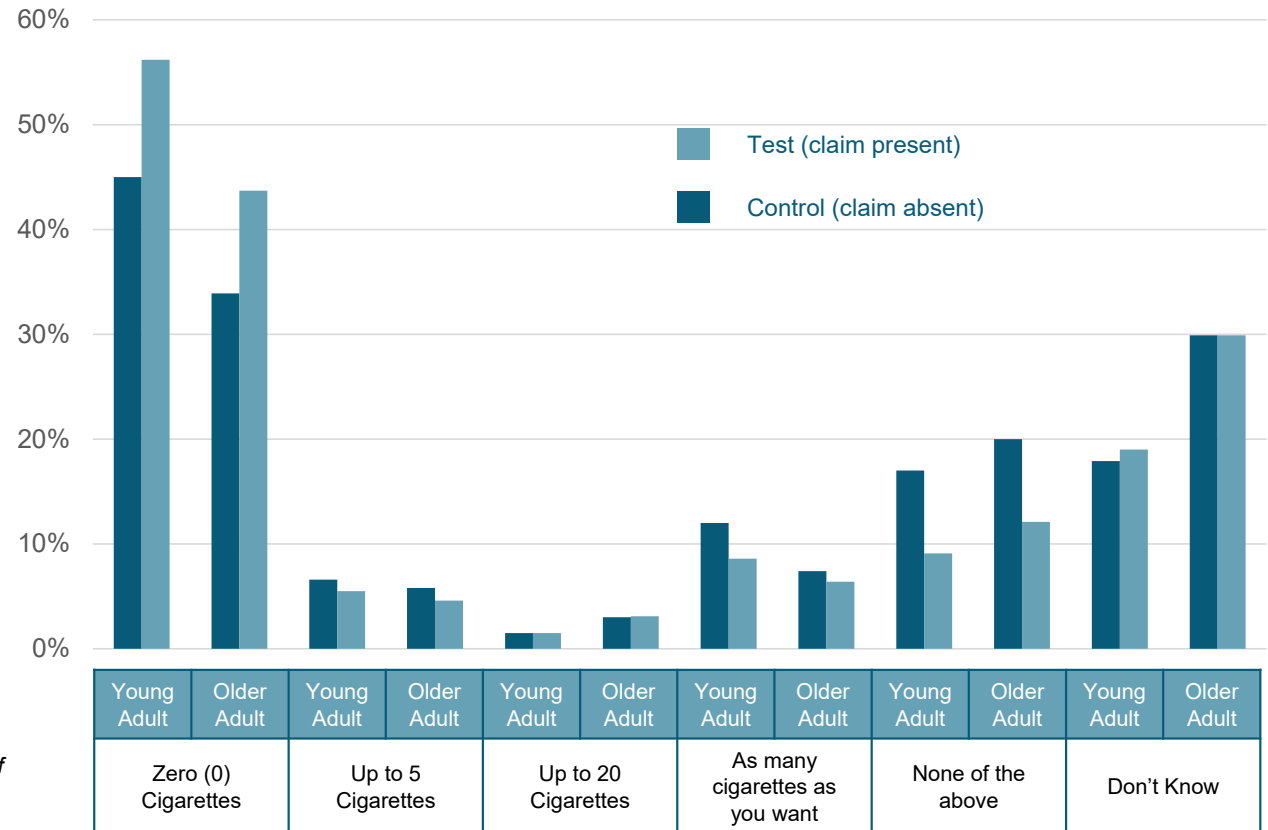
† Note: Young adult refers to participants of legal age to use tobacco products to 24 years old. Older adult refers to participants over 24 years old. Adult refers to participants of legal age to use tobacco products or older.

## REDUCED THE NUMBER OF SMOKERS WHO BELIEVE THAT PARTIAL SUBSTITUTION WOULD REDUCE DISEASE RISK

### Adding the MRTTP claim:

- Increased the proportion of smokers who responded “Zero (0)” cigarettes
- Did not increase the proportions of smokers who responded “Up to 5 cigarettes,” “Up to 20 cigarettes,” or “As many as you want to smoke,”

Smokers' perceived # cig they can smoke on a day when using General Snus, to put them at lower risk of disease (%)



Note: The study item asked, “For General Snus to put you at a lower risk of disease, how many cigarettes can you smoke on a day when you also use General Snus?” The applicant defined “Zero (0) cigarettes” as correct.

† Note: Young adult refers to participants of legal age to use tobacco products to 24 years old. Older adult refers to participants over 24 years old.

## IN SUMMARY: GENERAL SNUS MEETS CRITERIA FOR MRTTP

*Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.*

**General Snus, and the marketing thereof, is appropriate for the protection of the public health.**

- Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users
- Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

### **Reduced harm to individual users**

- Reduced risk for a number of disease endpoints

### **Benefit to the population as a whole**

- Improved comprehension and perception of relative risks snus vs cigarettes
- Continued understanding of absolute health risks for snus
- Improved understanding that health risks require complete switching
- Increased interest in buying General Snus among current smokers.
- No increase in the likelihood of initiation by non-users of tobacco.