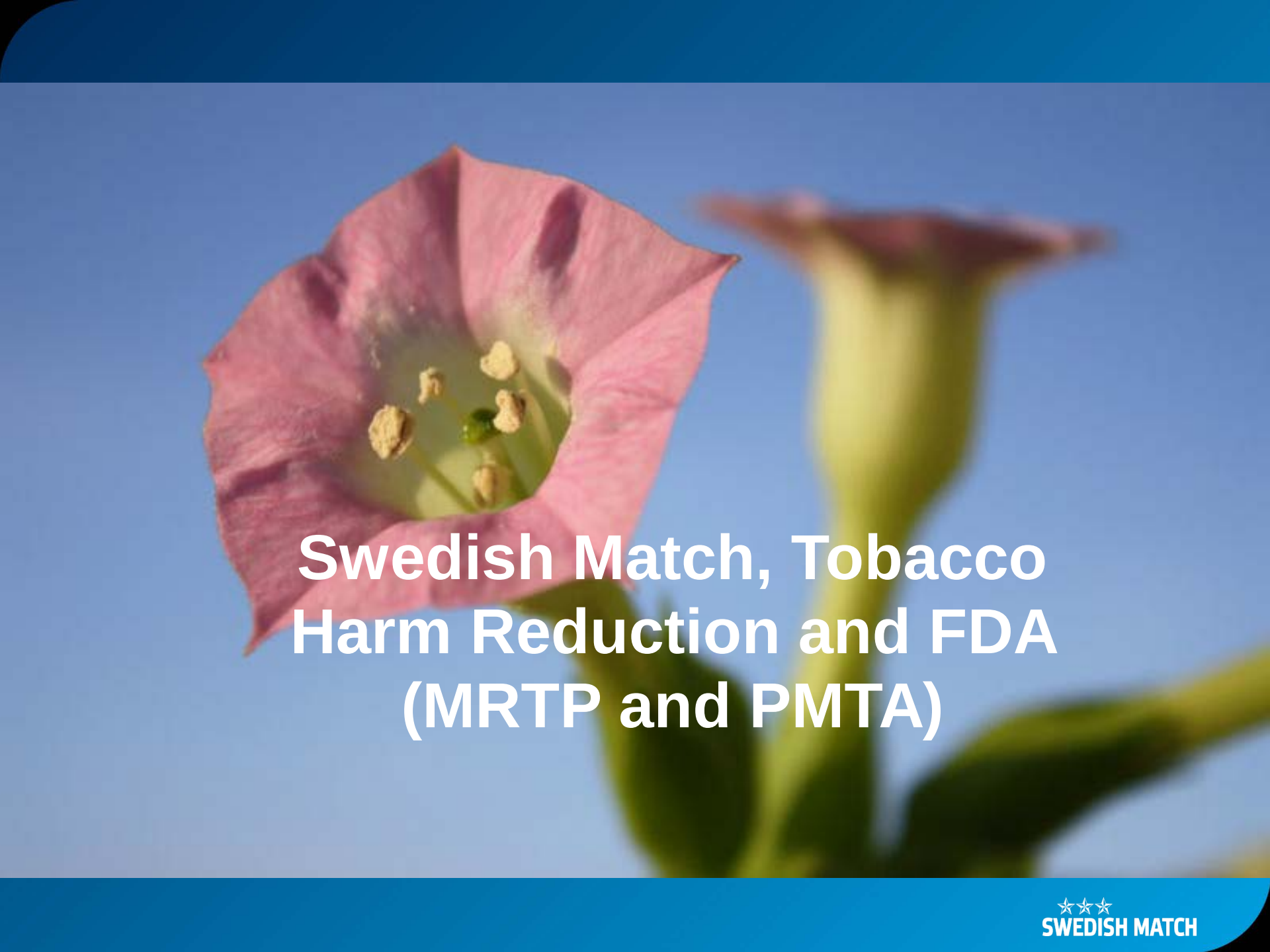


Swedish Match, Tobacco Harm Reduction and FDA (MRTP and PMTA)

SWEDISH MATCH

"A world without cigarettes"

We create shareholder value by offering tobacco consumers enjoyable products of superior quality in a responsible way. By providing products that are recognized as safer alternatives to cigarettes, we can contribute significantly to improved public health.

Today's vision is closely linked to the vision of the past

- **During the 80's and the 90's Swedish Match developed the GothiaTek® standard**

"We shall make our Swedish snus accepted by consumers as well as the society and authorities. Snus should not have a negative impact on the user's health." **Stefan Gelkner, CEO Swedish Match North Europe Division, 1985**

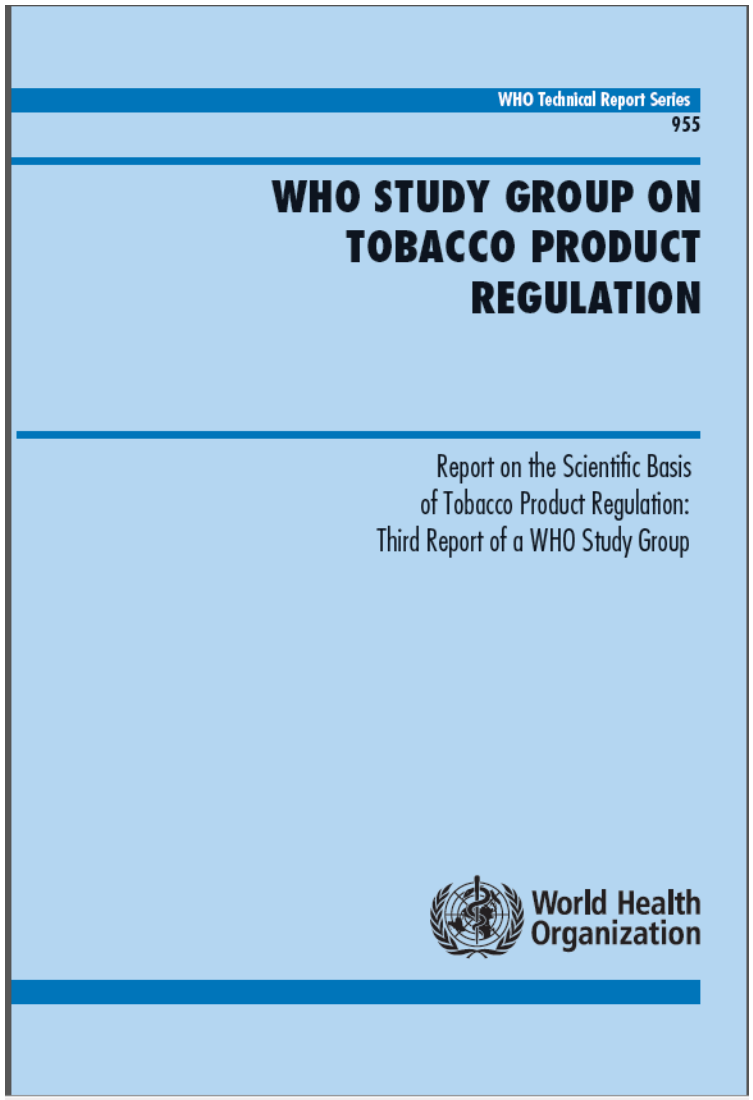
- **In 1999 Swedish Match sold its cigarette business**

"The sale of Swedish Match's cigarette operations should be seen against the background of the company's strategy of concentrating the major portion of its resources and future investments toward smokeless products and cigars" **Lennart Sundén, President and CEO of Swedish Match, 1999.**

Snus

- **Snus is pasteurized and regulated product that has been used in Nordic countries for over 200 years**
- **The manufacturing process is constantly evolving with a focus on product quality and consumer safety**
- **This non-combustible product that has been subject to most extensive science since the 1970ties, and is associated with a low relative risk**
- **Swedish smoking prevalence is now at 10% and Norway is following suit – it shows in the public health statistics**

Recommended regulation



- whether understanding about the hazard of the remaining products is influencing initiation or cessation rates.

Regulators should pursue whatever corrective action is necessary to prevent consumers from being misled. These monitoring and surveillance concerns are described in more detail in the WHO report, *Evaluation of new or modified tobacco products* (*18*).

3.9 Recommendations

- All products that deliver nicotine for human consumption should be regulated.
- Smokeless tobacco products should be regulated by controlling the contents of the products.
- The metric for measuring toxicants in smokeless tobacco should be the amount per gram of dry weight of tobacco.
- Initially, upper limits should be set for two nitrosamines N′-nitrosonornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and one polycyclic aromatic hydrocarbon, benzo[*a*]pyrene.
- The combined concentration of NNN plus NNK in smokeless tobacco should be limited to 2 µg/g dry weight of tobacco.
- The concentration of benzo[a]pyrene in smokeless tobacco should be limited to 5 ng/g dry weight of tobacco.
- Regulation of the distribution and sale of smokeless tobacco products should include a requirement for affixation of the date by which the product must be sold or returned to the manufacturer and a requirement for refrigeration of the product before sale in order to limit the increase in the concentration of nitrosamines that occurs over time of storage.

3.10 Acknowledgement

This report was prepared on the basis of a discussion paper written for TobReg by Stephen S. Hecht, Ph.D., American Cancer Society Research Professor and Wallin Land Grant Professor of Cancer Prevention at the University of Minnesota Masonic Cancer Center, Minneapolis, Minnesota.

Regulatory approaches – one product, three geographies

Sweden

- Manufacturing regulated in the Swedish food law, only food approved additives allowed.
- NNN, NNK & BaP regulated according to WHO TobReg 2009 recommendations plus max levels of aflatoxin and mercury

European Union (minus SE)

- Banned from placing on the market since 1992
- No serious attempt to understand risk, scientific evaluation questionable
- All other smokeless tobacco products virtually unregulated from a quality/consumer safety perspective
- No quality requirements for new products

USA

- Allowed on the market, ingredients reporting required, including according to HPHC
- Innovation/improvements must have scientific underpinning (SE, PMTA & MRTP)

US smokeless regulatory framework

The Comprehensive Smokeless Tobacco Health Education Act (CSTHEA)

- Ingredients reporting
- Current warning labels etc

Family Smoking Prevision and Tobacco Control Act of 2009, which in effect 'froze' the market on the 15 Feb 2007;

- 2 pathways to market for new products
  - SE – for 'minor' adjustments of products already on the market by Feb 2007
  - PMTA – show proof that marketing of the new product would be appropriate for the protection of the public health
- 1 pathway for reduced risk communication
  - MRTP – if approved it gives authorization to market a product with claims of reduced risk or reduced exposure

Swedish Match - MRTPA

- **Health warning required by CSTHEA conflict with extensive scientific evidence related to the health effects of SNUS**
  - Gum disease
  - Tooth loss
  - Mouth cancer
- **Filing of MRTPA under Section 911(g)(1) is appropriate vehicle for labeling changes, rather than rulemaking under CSTHEA**
- **The MRTPAs for ten General snus products request:**
  - Removal of warning labels citing mouth cancer, gum disease, and tooth loss
  - Amend “Not a safe alternative to cigarettes” to “No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes”
  - Retain “addiction” warning
- **No other claims are changes in marketing, other than the modified warning statements**

Applying for an MRTP – What did we need

- **A reduced risk product**
- **“An Experience”: human health evidence from decades of marketing and consumption in Sweden (and Norway)**
- **Data from clinical trials on the effectiveness of snus in smoking cessation**
- **Data from clinical study on impact of warning statements on consumer comprehension and perception**

Standard for Approval

FDA must determine whether an MRTP will significantly reduce harm and the risk of tobacco-related disease to individuals and benefit the health of the population as a whole, taking into account:

- the relative health risks to individuals of the MRTP;
- the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the MRTP;
- the increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP;
- the risks and benefits to persons from the use of the MRTP as compared to the use of smoking cessation drug or device products approved to treat nicotine dependence (e.g., nicotine replacement therapies (NRTs)); and,
- comments, data and information submitted by interested persons.

Lessons Learned from MRTPA Process

- In preparing an MRTP application draw from the language in Section 911 of the Tobacco Control Act, the FDA Draft Guidance for Industry document, and the Institute of Medicine MRTP Committee report.
- Use the limited meetings with FDA wisely. Be prepared to explain your approach but don't expect FDA to "approve" or even comment. (CTP has set limits on how often it will meet with a company)
- Once FDA determines the application is "complete" all information, other than proprietary information, is made publicly available, so applicant must be prepared.
- Be prepared to respond to Additional Information Requests (AIRs) from FDA; the responses will also be publicly available.

PMTA - Background

- A new tobacco product, including a tobacco product modified in any way after February 15, 2007 requires premarket review and an order from FDA authorizing the marketing of the product.
- FDA will deny a PMTA and issue a no marketing authorization order that the product may not be introduced or delivered for introduction into interstate commerce where FDA finds that, among other things, there is a lack of a showing that marketing the product is appropriate for the protection of the public health

Swedish Match was granted a PMTA for 8 new General products in November 2015

SM had to demonstrate that these products **are appropriate for the protection of the public health**. The assessment was based on, among other things:

- the risks and benefits to the population as a whole, including users and non -users of tobacco products,
- Evidence showing that these products, marketed as described in the application, would result in a low likelihood of new initiation, delayed cessation or relapse.

Policy based evidence vs. Evidence based policy

Clear legislative objectives, married with rigorous, scientific requirements, articulated guidelines and clear requirements may:

- save us from future trench wars
  - Lights
  - Filters
- save us from discriminatory and disproportionate behaviour from the regulators
  - Brexit
- provide the consumer with a better perception of risk

An open and non-discriminatory engagement with all stakeholders promotes treatment based on merit.

Legislation based on flawed scientific foundation equals bad regulation

Thank you

SWEDISH MATCH

Toxins in food (100g) and snus – a perspective of risk

Arsenic

= 7,5x

Ochratoxin

= 5x

Quicksilver

= 54x

Cadmium

= 3x

BaP

= 18x

Nitrite

= 15x

Chrome

= 3,5x

Acetaldehyd

= 5,5x

Nickel

= 2x

Mercury

= 1x

Formaldehyd

= 47x

N-Nitrosodimethylamine (NDMA),

= 17x