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# 1. Introduction

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Products	SKU <sup>1</sup>	Tobacco Recipe <sup>2</sup>	Heat treatment process <sup>3,4</sup>	Can Material Dimension <sup>5</sup> (mm)	Weight/pouch (g)	Pouches per can	Weight/can (g)	Moisture (%)	Nicotine (%)	pH value
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<sup>1</sup> Stock Keeping Unit, Swedish Match Identification Number

<sup>2</sup> Described in more detail in the [section 4](#) “Manufacturing”

<sup>3</sup> PS, Portion Snus

<sup>4</sup> LS, Loose Snus

<sup>5</sup> All lids are of plastic material. Dimension; Diameter x Height (round can), Width x Length x Height (square can)

All data are routine production target values

### 3. Raw tobacco

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## Key activities for production of high quality raw tobacco

The final quality of the raw tobacco is determined by a combination of factors including seed variety, growing and curing conditions, and knowledge/ handling by farmers as well as by suppliers. Swedish Match has developed proprietary procedures to handle and supervise these variables in order to obtain high quality tobacco to ensure consistency, integrity, consumer acceptance, and regulatory compliance of the final products.

Swedish Match longstanding commitment to reduce TSNA's and other undesired constituents in raw tobaccos through research and development and in cooperation with suppliers and growers has resulted in a range of recommendations and instructions.

The production of the tobacco takes place at several locations around the world. The procedures for achievement of tobacco suitable for production of snus according to Swedish Match's standards vary slightly between different areas in the world depending on local conditions, but the main principles are the same.

### Basic actions to secure high quality tobacco for snus production:

- No usage of dark fired tobacco
- No usage of fermented tobaccos
- Increased usage of certified seed varieties with low converter frequency
- Establishment of an "Early Warning System" to assess the quality of a specific crop.
- Removal of stem/midrib from the lamina in *Nicotiana Tabacum* varieties
- Reduction of moisture in the packed raw tobacco from about (b) (4) to reduce formation of TSNA during storage before the manufacturing process
- Control of temperature and relative humidity during storage before the manufacturing process

### Requirements for farmers and suppliers:

- Good sanity during tobacco handling
- Shortest possible lead time between farmer baling and processing of the raw tobacco
- Ability to produce raw tobacco compliant with Swedish Match requirements on an annual basis
- Implementation of Swedish Match's general instructions for packing of tobacco for snus production (b) (4) (b) (4) (b) (4)

**Instructions to farmers and suppliers:**

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### Criteria for choosing supplier

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## Raw tobacco buying process

### The raw tobacco buying process (b) (4)

(b) (4). The initial stage consists of planning. Apart from sales forecasts, storage levels and inventory policy, the chemical results in the previous crops are also considered. Tobacco is procured throughout the calendar year when the tobacco is ready at the source of origin. The suppliers purchase the tobacco directly from the contracted growers. Generally, the supplier provides growers with guidance, fertilizers, agrochemicals and other materials necessary for the production. The supplier is responsible for sorting, threshing, drying and packing the tobacco according to Swedish Match's specifications.

The processing facility is usually located in the region of the growing area. When the farmer bales arrive from the growers to the processing plants it is classified according to the supplier's internal grades, describing the characteristics of the tobacco, such as plant position, maturity, uniformity, cleanliness etc.

In the processing, tobacco grades are blended to meet Swedish Match's quality specifications in terms of organoleptic and chemical properties. The tobacco is threshed and separated into lamina (strips) and stem. Both products undergo a redrying process, before packing into cardboard cartons, in order to obtain adequate conditions for shipment and storing. Only water and heat is added to the tobacco during the processing.

During a tobacco crop season, representatives from Swedish Match are present at different stages of growing, buying and processing. Laboratory tests for quality control are performed throughout the whole process to ensure that the tobacco meets Swedish Match's criteria for approval before a final decision to purchase is made.

**Control of chemical components** - To ensure that the quality of the tobacco meets Swedish Match's standards for constituents in the final product, thorough chemical quality control of the tobacco is performed at different stages of the tobacco procurement process.

- **Early Warning Samples (EWS)**- Swedish Match have implemented an "Early warning system" (b) (4) (b) (4) to obtain an early indication of the chemistry and sanity of the tobacco for a given crop

year. (b) (4)  
(b) (4)

- **Offer samples** - Before buying tobacco from areas where Swedish Match has not previously conducted business, offer samples are collected by the suppliers and sent to Swedish Match for thorough investigation. The tobacco undergoes inspection for physical, chemical and sensory properties as well as the usability for snus production

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- **Packed tobacco samples** - Chemical quality control is performed through the whole tobacco packing process. (b) (4)

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**Shipment & storage** - The tobacco is shipped to Sweden after final approval of the chemical analysis results. Before shipment the tobacco is fumigated against pests according to the Coresta Guide No 2 for fumigation ([http://www.coresta.org/Guides/Guide-No02-Fumigation\\_June09.pdf](http://www.coresta.org/Guides/Guide-No02-Fumigation_June09.pdf)). (b) (4)

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**Inspections at the Swedish Match Warehouse in Sweden** - On arrival in Sweden the quality of the delivered tobacco is inspected (b) (4) ) (4)

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The tobacco is also inspected for the existence of non tobacco related material. The tobacco is stored under controlled conditions until taken out for snus production. The warehouse is tempered throughout the year, the

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## 4. Manufacturing

The production of snus is made in three steps. The first is the **grinding process**, where different types of tobacco are ground and mixed to a tobacco flour batch. In the second step, the mixture is subjected to a computer controlled **heat-treatment/sweating process**, the purpose of which is to improve the flavor and reduce microbial activity which enhances product stability. The snus mixture is cooled and other ingredients such as flavor components and humectants are added. The third step is the **packaging process** where the snus blend is packed into cans.

Swedish Match has two production sites in Sweden; one is located in Gothenburg and the other in Kungälv. (b) (4)

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### **Grinding process**

Raw tobacco for snus production consists of air cured, sun cured and flue-cured (or “bright”) tobacco types of different qualities. Each tobacco blend recipe is specified by a different mixture of the tobacco types. The amount of each type, the share of stem versus lamina tobacco, and the chemical characteristics of the ingoing tobaccos are regulated by specified limits for each individual blend recipe. The exact composition of an individual recipe is updated continuously depending on the supply and chemical properties of available raw tobacco.

Approved recipes are used for ordering tobacco blends from the raw tobacco storage. (b) (4)

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Swedish Match’s process for blending tobacco according to the recipes adheres to the following specifications:

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**Tobacco grinding flow chart**

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- **Start-up** - (b) (4)  
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- **Pre grinding** - (b) (4)  
(b) (4)

- **Drying** - (b) (4)  
(b) (4)

- **Grinding and sieving** - (b) (4)  
(b) (4)

- (b) (4)

- (b) (4)

- **Quality assurance** - (b) (4)  
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- **Chemical quality confirmation:**

- (b) (4)

**Storage of tobacco blends -** (b) (4)  
(b) (4)

The grinding procedure (b) (4)  
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**Heat-treatment/sweating process**

Several different computer controlled heat-treatment/sweating processes are used by Swedish Match th (b) (4)  
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The processes used for the products marketed in the US are: (1) (b) (4)  
(b) (4), (2) (b) (4), and (3) (b) (4)  
(b) (4). Each process comprises:

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**Snus process flow chart:**



(b) (4)

**Batching (all processes)** - (b) (4)  
(b) (4)

**Heating (all processes)** - (b) (4)  
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**Sweating (all processes)** - (b) (4)  
(b) (4)

**Process 1 & 2** (b) (4)  
(b) (4)

(b) (4) (Figure 4:1)

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*Figure 4:1. Temperature over time during the short term sweating process used for production of loose snus and portion snus (White).*

**Process 3** (b) (4)

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(Figure 4:2).

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**Figure 4:2.** (b) (4)



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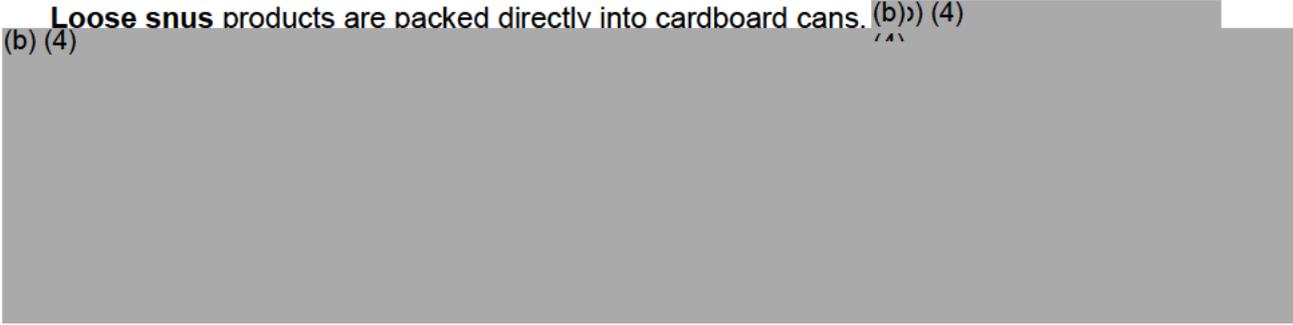


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**Packaging process**

Loose snus products are packed directly into cardboard cans. (b) (4)  
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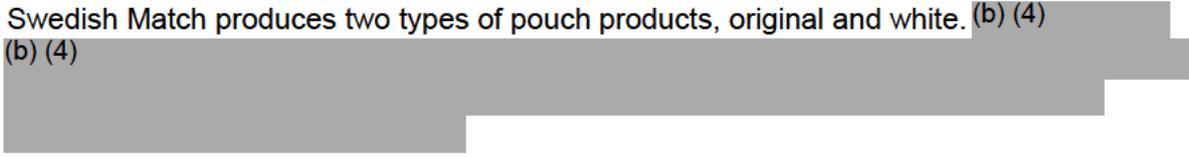
**Loose snus packaging flow chart:**

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**Pouched snus packaging**

Swedish Match produces two types of pouch products, original and white. (b) (4)  
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**Portion snus packaging flow chart:**

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**Original pouch - (b) (4)**  
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**White pouch** - (b) (4)

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**Cold storage and shipping** - (b) (4)

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## **Appendices**

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### 5. Hygiene

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## 6. Ingredients

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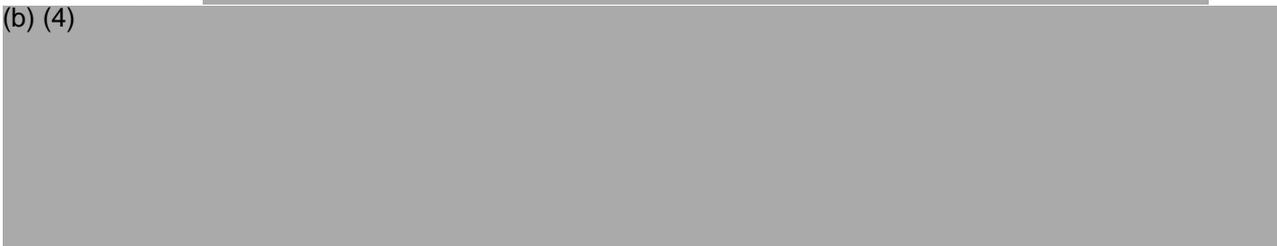
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### Short description of methods

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	Method	Analyte	Comments
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**Method 1** (b) (4) (b) (4)

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**References:**

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Analyte:

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Validation parameters:

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Analyte:

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Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b) (4)

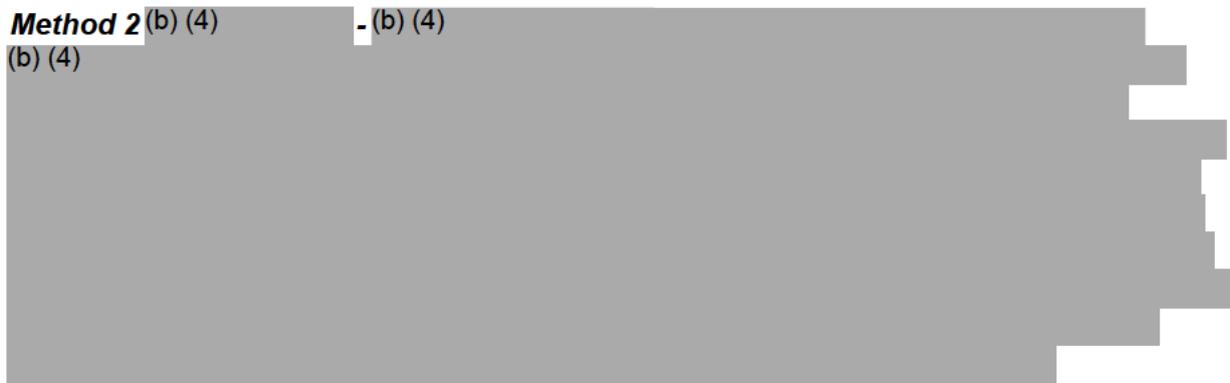
Relative standard deviation under within laboratory reproducibility condition (RSD<sub>R</sub>)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)
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**Method 2** (b) (4) - (b) (4)  
(b) (4)



**References:**

- (b) (4)

Analyte:

(b) (4)

Validation parameters:

Method measurement interval

- (bb) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)
- (b) (4)

Analyte:

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Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)
- (b) (4)

**Method 3 (NDMA) - (b) (4)**

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**Reference:**

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Analyte:

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Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)
- (b) (4)

**Method 4** (b) (4)

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**References:**

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- (b) (4)

Analyte:

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Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition (RSD<sub>R</sub>)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

Analyte:

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Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

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**Method 5** (b) (4)

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**References:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

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Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 6** (b) (4)

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**References:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 7** (b) (4)

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**References:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability conditions ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 8** (b) (4)

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**Reference:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ):

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Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

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Relative standard deviation under within laboratory reproducibility condition (RSD<sub>R</sub>)

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Total relative measurement uncertainty with a coverage factor of 2

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**Method** (b) (4)

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**References:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 10** (b) (4)

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**References:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 11** (b) (4)

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**Reference:**

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**Analyte:**

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**Validation parameters:**

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Analyte:**

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**Validation parameters:**

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Analyte:**

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**Validation parameters:**

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2:

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 12** (b) (4)

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**Reference:**

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**Analyte:**

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**Validation parameters:**

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

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Relative standard deviation under within laboratory reproducibility condition (RSD<sub>R</sub>)

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 13** (b) (4)

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**References:**

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**Analyte:**

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**Validation parameters:**

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

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Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2

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**Method 14** (b) (4)

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**References:**

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition ( $RSD_r$ )

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Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

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Total relative measurement uncertainty with a coverage factor of 2:

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**Method 15** (b) (4)

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Analyte:

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Validation parameters:

Method measurement interval

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Limit of quantification (LOQ)

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Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b) (4)

Reproducibility, within laboratory relative standard deviation (RSD<sub>R</sub>)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

**Method 16** (b) (4)

(b) (4)

**References:**

- (b) (4)
- (b) (4)

- (b) (4) [redacted]

Analyte:

(b) (4) [redacted]

Validation parameters:

Method measurement interval

- (b) (4) [redacted]

Limit of quantification (LOQ):

- (b) (4) [redacted]

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b) (4) [redacted]
- (b) (4) [redacted]

Reproducibility, within laboratory relative standard deviation (RSD<sub>R</sub>)

- (b) (4) [redacted]

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4) [redacted]
- (b) (4) [redacted]

**Method 17** (b) (4) [redacted]

(b) (4) [redacted]

**References:**

- (b) (4) [redacted]
- (b) (4) [redacted]
- (b) (4) [redacted]

Analyte

(b) (4) [redacted]

Validation parameters:

Method measurement interval

- [redacted] (b) (4) [redacted]

Limit of quantification (LOQ):

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

Analyte

(b) (4)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ):

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

Analyte

(b) (4)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ):

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Reproducibility, within laboratory relative standard deviation ( $RSD_R$ )

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

Analyte

(b) (4)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ):

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b) (4)

Reproducibility, within laboratory relative standard deviation (RSD<sub>R</sub>)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

**Chemical analyses** (b) (4)

(b) (4)

(Table 7:3), (b) (4) The analytical methods are described below.

**Table 7:3. Chemical analyses** (b) (4)

#	Method	Analyte	Comments	Laboratory
(b) (4)				

(b) (4)



**Method 18** (b) (4)

(b) (4)



**References:**

- (b) (4)   
  

- (b) (4) 

Analyte

(b) (4) 

Validation Parameters:

Method measurement interval

- (b) (4) 

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b)

Analyte

(b) (4)

Validation Parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b)

Analyte

(b) (4)

Validation Parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b)

Analyte

(b) (4)

Validation Parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4) (b)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>)

- (b)

**Method 19** (b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

**Reference:**

- (b) (4)
- [Redacted]

Analyte:

(b) (4)

Validation parameters:

Method measurement interval:

- (b) (4)

Limit of quantification (LOQ):

- (b) (4)

Relative standard deviation under repeatability condition (RSD<sub>r</sub>):

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

**Method 20** (b) (4)

(b) (4)

Analytes:

(b) (4)

Validation Parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2:

- (b) (4)
- (b) (4)

**Method 21** (b) (4)

(b) (4)

of quantification are shown in [Table 7.4](#).

**References:**

- (b) (4)

- (b) (4) [redacted]

Analytes:  
See Table 4.

Validation parameters:  
Method measurement interval

- (b) (4) [redacted]
- Total relative measurement uncertainty with a coverage factor of 2
- (b) (4) [redacted]

**Table 7:4. Limit of quantification (LOQ) for agrochemicals.**

Analyte	LOQ microg/g
(b) (4)	[redacted]

Analyte	LOQ microg/g
(b) (4)	[redacted]

Analyte	LOQ microg/g
(b) (4)	

Analyte	LOQ microg/g
(b) (4)	

Analyte	LOQ microg/g
(b) (4)	

Analyte	LOQ microg/g
(b) (4)	

Analyte	LOQ microg/g
(b) (4)	

Analyte	LOQ microg/g
(b) (4)	

Analyte	LOQ microg/g
(b) (4)	

**Method 22** (b) (4)

(b) (4)

**Reference:**

- (b) (4)

Analyte:

(b) (4)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of Quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability conditions (RSD<sub>r</sub>)

- (b) (4)

Relative standard deviation under within laboratory reproducibility conditions (RSD<sub>R</sub>)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2

- (b) (4)

**Method 22** (b) (4)

(b) (4)

**References:**

- (b) (4)
- (b) (4)

Analyte:

(b) (4)

Validation Parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Total relative measurement uncertainty with a coverage factor of 2:

- (b) (4)

**Method 23** (b) (4)

**References:**

- (b) (4)
- (b) (4)

Analyte:

(b) (4)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Relative standard deviation under repeatability condition ( $RSD_r$ )

- (b)

Relative standard deviation under within laboratory reproducibility condition ( $RSD_R$ )

- (b)

Total relative measurement uncertainty with a coverage factor of 2

- (b)

**Method** (b) (4)

**References:**

- (b) (4) [redacted]
- (b) (4) [redacted]
- (b) (4) [redacted]

Analyte:

(b)

Validation parameters:

Method measurement interval

- (b) (4) [redacted]

Limit of quantification (LOQ)

- [redacted]

Measurement uncertainty

- (b) [redacted]

Analyte:

(

Validation parameters:

Method measurement interval

- (b) (4) [redacted]

Limit of quantification (LOQ)

- (b) (4) [redacted]

Measurement uncertainty

- (b) [redacted]

Analyte:

(b)

Validation parameters:

Method measurement interval

- (b) (4) [redacted]

Limit of quantification (LOQ)

- (b) (4) [redacted]

Measurement uncertainty

- (b) [redacted]

Analyte:

(b)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification

- (b) (4)

Measurement uncertainty

- (b) (4)

**Method 26** (b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

**Reference:**

- (b) (4)
- [Redacted]

Analyte:

(b)

Validation parameters:

Method measurement interval

- (b) (4)

Limit of quantification (LOQ)

- (b) (4)

Measurement (b) (4)

(b)

**Method 27** (b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

**Method 28** (b) (4)

[Redacted]

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

**Method 29** (b) (4)

[Redacted]

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

**Method 30** (b) (4)

[Redacted]

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

**Method 31** (b) (4)

[Redacted]

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

Analyte:

(b) (4)

Limit of quantification (LOQ)

- (b) (4)

**Method 32** (b) (4)

[Redacted]

Analytes:

(b) (4)

Limit of detection

- (b) (4)

**Chemical Quality Control Program - Tobacco Blends**

(b) (4) [Redacted]

**Chemical Quality Control Program in 2011 -** (b) (4) [Redacted]  
 ) (Table 7:5). (b) (4) [Redacted]

**Table 7:5. Number of exceptions (slightly out of the tolerance limits in 2011)**

Compound	TL	Unit	All
(b) (4) [Redacted]			
<b>Total</b>			

1) Valid for R1, 2) Valid for R15

The snus products marketed by Swedish Match in the US are shown in [Table 7:6](#) together with the corresponding tobacco blend numbers. [Table 7:7](#) shows the number of tested tobacco blend batches (n), minimum, arithmetic mean, maximum and median result values for the year 2011. The results are summarized and commented upon in the internal report (b) (4) [Redacted]

**Table 7:6. US products with corresponding tobacco blend number**

SKU	Product name	Tobacco Blend Number
4877	General Classic Blend PSWL	(b) (4)
4800	General Dry Mint PSOM	(b) (4)
4880	General PSOL	(b) (4)
4852	General Lös	(b) (4)
4352	General Mint PSWL	(b) (4)
4876	General Nordic Mint PSWL	(b) (4)
4881	General PSWL	(b) (4)
4882	General Wintergreen PSWL	(b) (4)

**Table 7:7. Chemical results for the tobacco blends produced and analyzed in 2011. Values in bold are above the tolerance limit.**

		(b) (4)					(b) (4)				
<b>Compound</b>	<b>Unit</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>
(b) (4)											

(b) (4)



**Table 7:7, cont'd**

		(b) (4)					(b) (4)				
<b>Compound</b>	<b>Unit</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>

(b) (4)



(b) (4)

**Table 7:7, cont'd**

		(b) (4)					(b) (4)				
<b>Compound</b>	<b>Unit</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>

(b) (4)

**Table 7:7, cont'd**

		(b) (4)					(b) (4)				
<b>Compound</b>	<b>Unit</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>
(b) (4)											

**Table 7:7. cont'd**

		(b) (4)				
<b>Compound</b>	<b>Unit</b>	<b>n</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Median</b>
(b) (4)						

(b) (4)



**Historical Data on Tobacco Blends** - Chemical data for tobacco blends collected during 2002 – 2011, from the Chemical Quality Control Program are summarized below. The average nicotine content in the tobacco blends has been almost constant over the years (Figure 7:1). The content of nitrate ion has varied over the years (b) (4)

(Figure 7:2).

(b) (4)

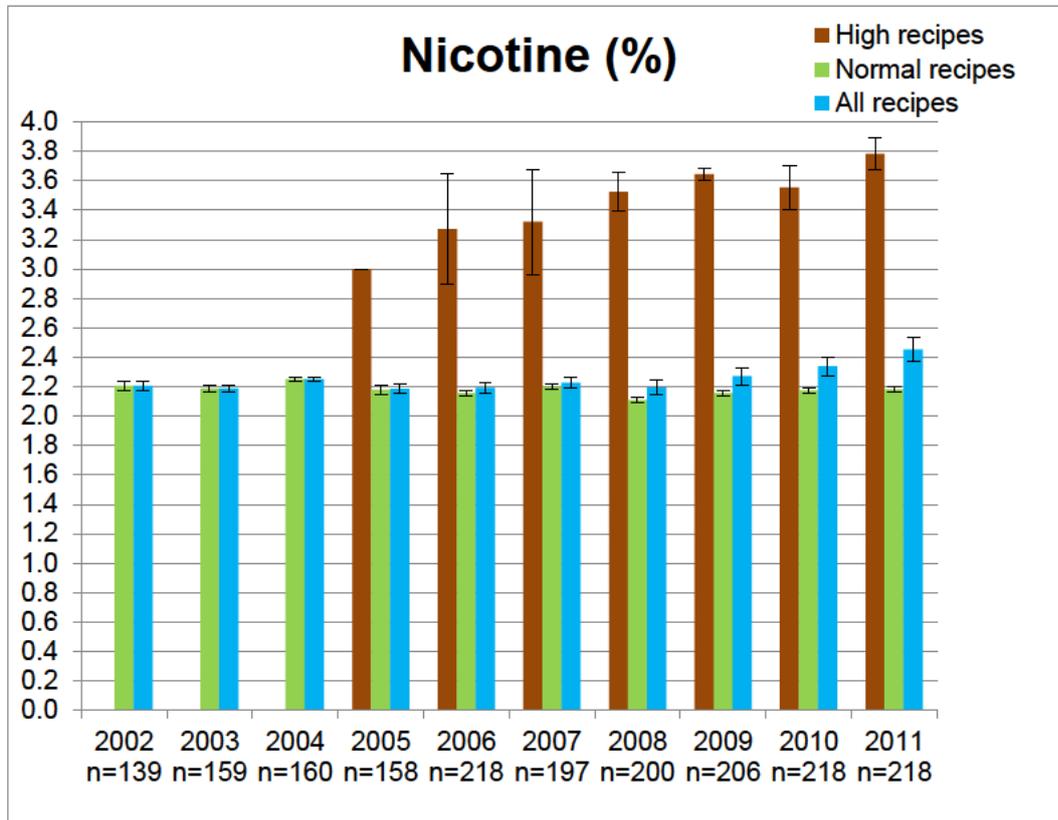
(Figure 7:3). The content of nitrite ion has varied slightly over the years (Figure 7:4). The average level of TSNA has decreased over the years and has reached a stable level of c. 1.7 microg/g. The same apply for the sum of NNN+NNK level, which has stabilized just over 1 microg/g (Figure 7:5) (b) (4)

(b) (4)

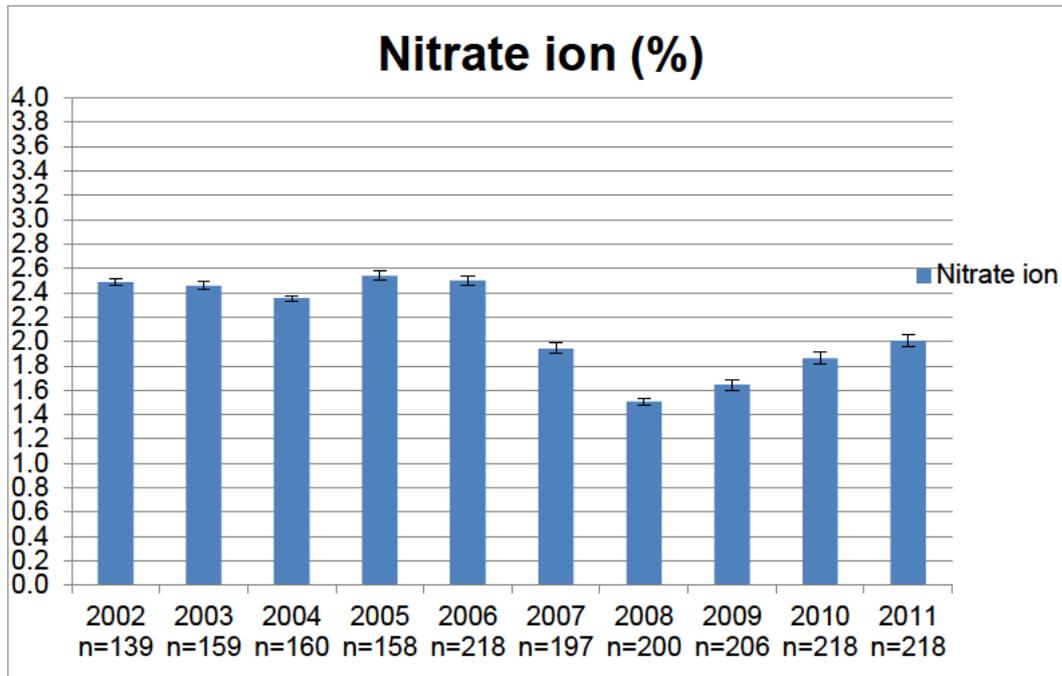
(b) (4) (Figure 7:6). (b) (4)

(b) (4) (Figure 7:7).

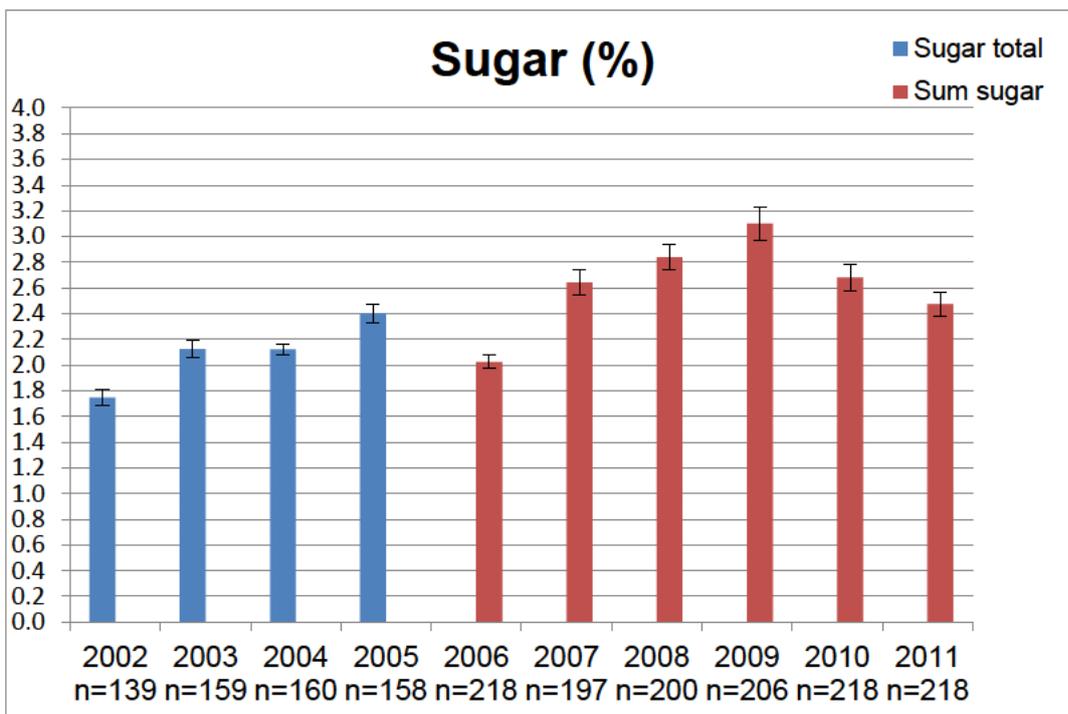
**Figure 7:1. The average nicotine content together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.**



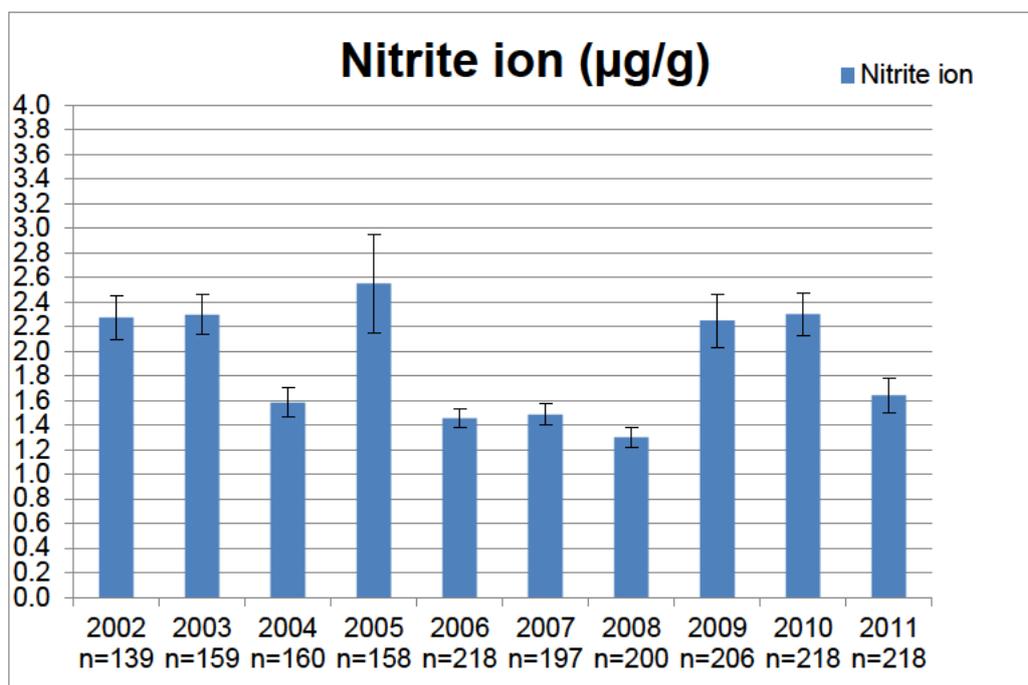
**Figure 7:2.** The average nitrate ion content together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.



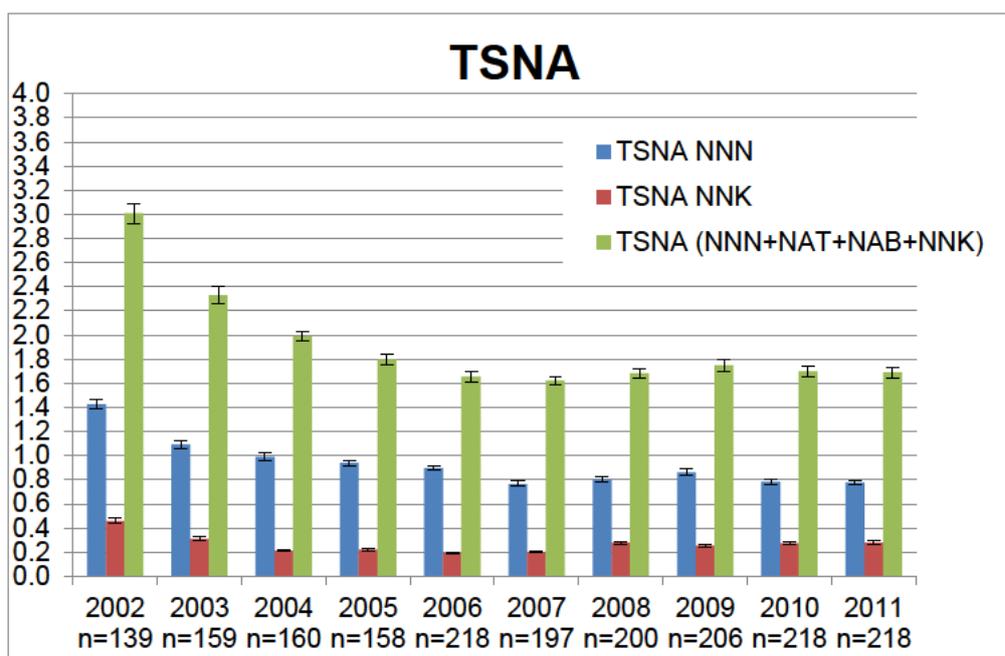
**Figure 7:3.** The average sugar content together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.



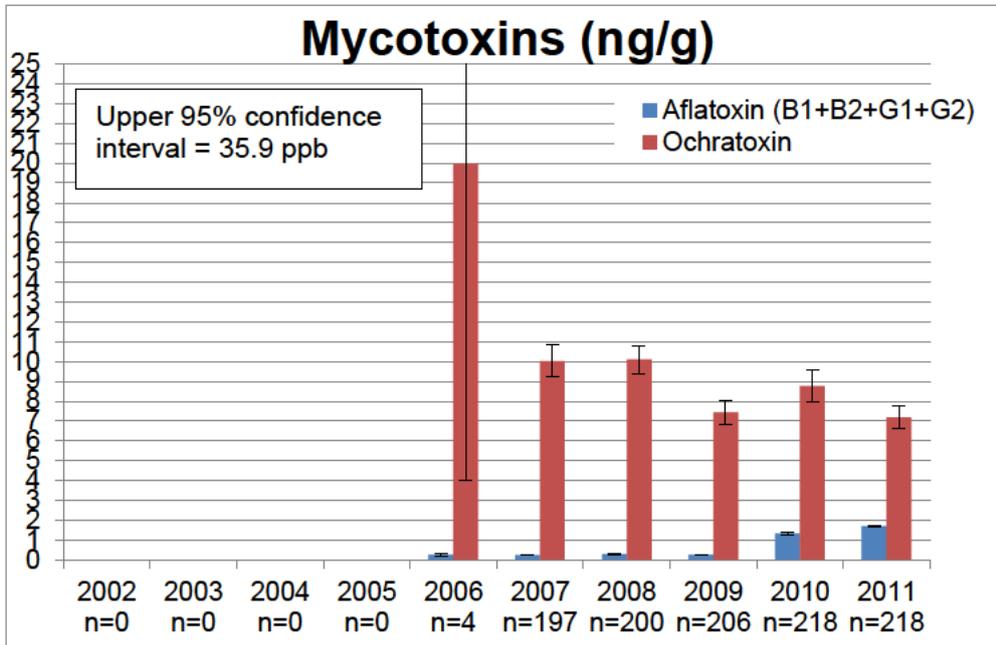
**Figure 7:4.** The average nitrite ion content together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.



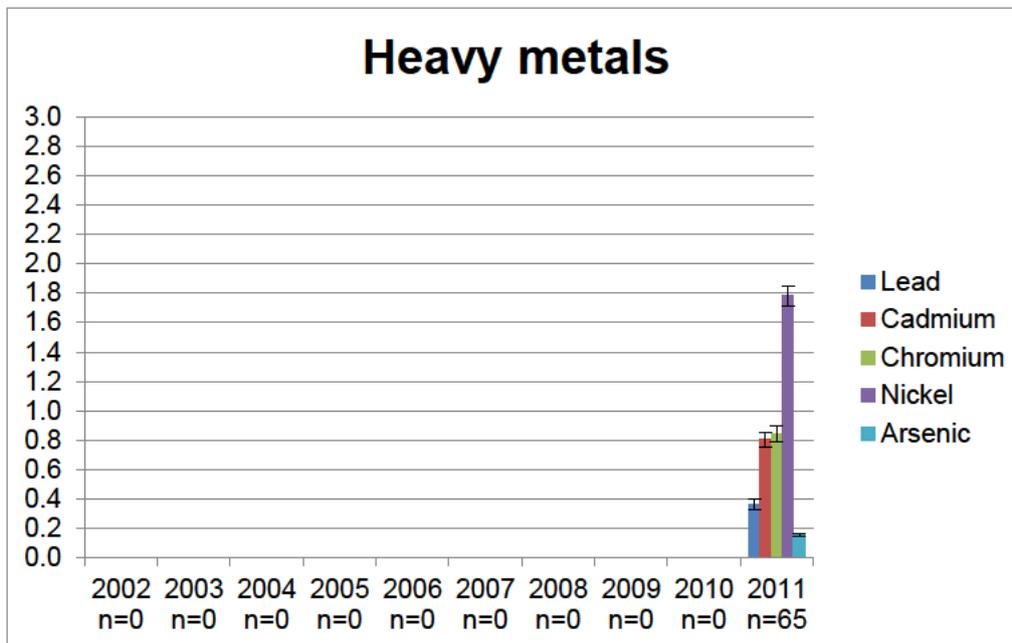
**Figure 7:5.** The average TSNA content (microg/g) together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.



**Figure 7:6. The average content of mycotoxins together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.**



**Figure 7:7. The average content of heavy metals (microg/g) together with 95% confidence intervals for the total number of tobacco blends (n) tested per year.**



**Chemical Quality Control Program – finished products**

(b) (4)  
[Redacted]  
(b) (4) 4)  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

**Sampling procedure - (b) (4)**  
[Redacted]. The products are stored in a refrigerator or freezer according to [CORESTA Guide N° 11 – Technical Guideline for Sample Handling of Smokeless Tobacco and Smokeless Tobacco Products](#), until analyzed. (b) (4)  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]  
[Redacted]

**Selection of analytes to be tested - (b) (4)**  
[Redacted]  
[Redacted] Table 7:8(b) (4)  
[Redacted].

**Table 7:8. Reasons for inclusion of analytes in the 2011 analytical battery**

Analyte	Reason for inclusion
(b) (4)	[Redacted]

(b) (4)



(b) (4)

\*TPSAC proposed list dated 07/07/2010

<b>International Agency for Research on Cancer (IARC) Classification</b>		
IARC 1	Sufficient evidence in humans or sufficient evidence in animals and strong mechanistic data in humans	Carcinogenic to humans
IARC 2A	Limited evidence in humans and sufficient evidence in animals	Probably carcinogenic to humans
IARC 2B	Limited evidence in humans and less than sufficient evidence in animals	Possibly carcinogenic to humans

<b>National Toxicology Program (NTP) Carcinogen Classification Abbreviations</b>	
KHC	Known human carcinogen
RAHC	Reasonably anticipated to be a human carcinogen

<b>US Environmental Protection Agency (EPA) Carcinogen Classification Abbreviation</b>	
PrHC	Probable human carcinogen
PoHC	Possible human carcinogen
LC	Likely to be carcinogenic

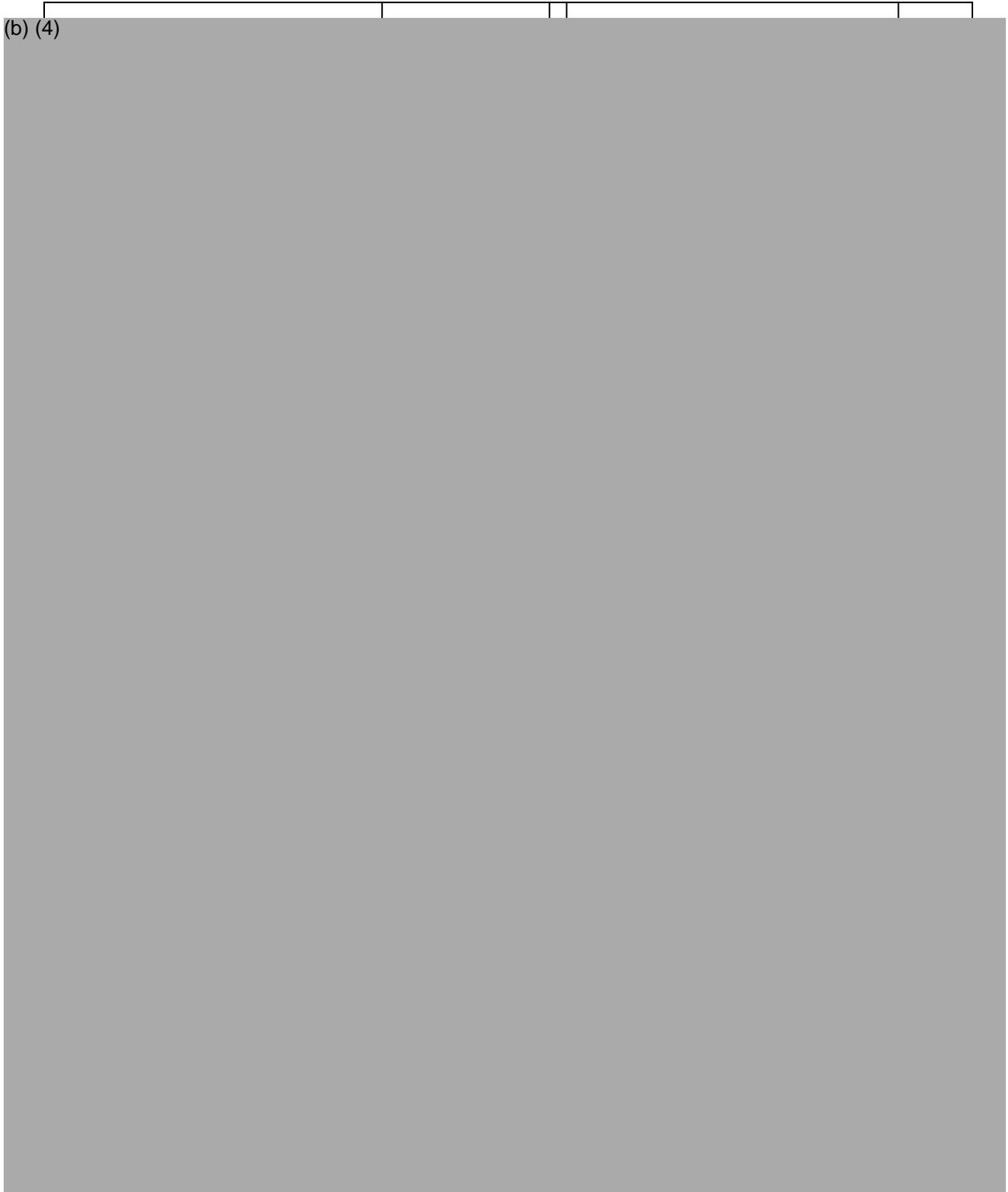
**Upper internal constituent limits** - In 2001, Swedish Match introduced the GothiaTek® standard for snus products which includes limits for certain controversial compounds in finished products. As a complement, Swedish Match has on several occasions since 2001 introduced stricter internal tolerance limits for some constituents and additives (see [Table 7:9](#)). The Gothiatek® limits and the internal tolerance limits are based on dry weight (b) (4)

(b) (4)



**Table 7:10. Snus products (n=76) tested in the Chemical Quality Program 2011**

(b) (4)



**Table 7:11. Number of tested samples, minimum, maximum and median values of selected analytes for all products tested in 2011, together with the arithmetic mean value  $\pm$  2 standard deviations for all products analyzed in 2010 and 2011. Gothiatek® limits (GT-2001) and Swedish Match internal tolerance limits are shown. All results are on dry weight when not otherwise indicated.**

Compound	n	Min 2011	Mean 2011 (Mv $\pm$ 2 stdev)	Mean 2010 (Mv $\pm$ 2 stdev)	Max 2011	Median 2011	GT-2001	Internal limits	
TSNA-NNN (microg/g)	(b) (4)								
TSNA-NAT (microg/g)									
TSNA-NAB (microg/g)									
TSNA-NNK (microg/g)									
TSNA tot (microg/g)									
Nitrite (microg/g)									
NDMA (ng/g) (SM)									
B(a)P (ng/g)									
Lead (microg/g)									
Arsenic (microg/g)									
Cadmium (microg/g)									
Chromium (microg/g)									
Nickel (microg/g)									
Nicotine (%)									
Nornicotine (microg/g)									
Anatabine (microg/g)									
Nitrate (%)									
Glycerol (% as is)									
PG (% as is)									
Ammonia (mg/g)									
Water activity									
Moisture (%)									
Bacteria (log cfu/g. as is)									
Aflatoxin B1, B2, G1, G2 (ng/g)									
Ochratoxin (ng/g)									

Compound	n	Min 2011	Mean 2011 (Mv ± 2 stdev)	Mean 2010 (Mv ± 2 stdev)	Max 2011	Median 2011	GT-2001	Internal limits
pH	(b) (4)							
Ethanol (%)								
Ethyl Carbamate (ng/g)								
Formaldehyde (microg/g)								
Acrylamide (ng/g)								
Sum Carcinogenic PAHs (ng/g)								
Sum Other PAHs (ng/g)								

Products tested in 2011 had in most cases stable levels of the tested compounds. The compound levels were in general well below the Gothiatek® limits and have been so for many years.

The nicotine, pH and moisture levels are well within the specifications set by Swedish Match.

All products had levels of the Gothiatek® compounds below the limits at all testing occasions except three products, which had cadmium levels slightly above the limit. The internal tolerance limit for cadmium was exceeded in nine products.

(b) (4)

In the ambition to successively lower the levels of undesired compounds in snus products, Swedish Match has introduced internal tolerance limits for the Gothiatek® compounds, some additional questionable compounds and additives. The snus products tested in the 2011 Chemical Quality Control Program had in most cases levels of these undesired compounds and additives below the internal limits, but there were some exemptions.

(b) (4)

(b) (4)

**Chemical Quality Control of snus products marketed in the US** - Results for the products marketed in the US are presented in Table 7:12. These data thus refer to a subset of the products included in Table 7:11. The results were in general similar to those presented in Table 7:11. Specifically, all of the US products had levels below the Gothiatek® limits. (b) (4)

The US products were also screened at one occasion for (b) (4) agrochemicals. The products were tested according to Swedish Match Agrochemical Management Program. The results are presented below under the heading “Agrochemical Residues in Tobacco and Snus Products”.

**Table 7:12. Chemical results from 2011 for snus products marketed by Swedish Match in the US. All values except glycerol, propylene glycol, water activity and bacteria are given on dry matter basis.**

		General Classic Blend PSWL, n=3	General Dry Mint PSOM, n=4	General PSOL, n=4	General Loose, n=4	General Mint PSWL, n=4	General Nordic Mint PSWL, n=4	General PSWL, n=4	General Wintergreen PSWL, n=6
		4877	4800	4880	4852	4352	4876	4881	4882

(b) (4)

			eneral Classic Blend SWL, n=3	eneral Dry Mint PSOM, =4	eneral SOL, n=4	eneral oose, n=4	eneral Mint SWL, n=4	eneral Nordic Mint SWL, n=4	eneral SWL, n=4	eneral Wintergreen SWL, n=6
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(b) (4)



**Reporting of Harmful and Potentially Harmful Constituents to FDA in 2012** - In March 2012 FDA/CTP requested reporting of nine constituents of the HPHCs on FDA’s established list for smokeless tobacco products. Quantities of these constituents in the eight Swedish Match US snus products were reported prior to September 22, 2012.

(b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (4)

All analyses were performed by Swedish Match, R&D, Chemical Analysis in Stockholm, which is a laboratory accredited for most of the HPHC analytes.

**Table 7:13. Levels of selected HPHCs in snus products marketed by Swedish Match in the US according to a report submitted to the FDA-CTP in 2012. Mean values with standard deviations within parentheses.**

	Pouch snus products								Loose snus product	
	Unit	General Mint PSWL, n=12	General Dry Mint PSOM, n=18	General Nordic Mint PSWL, n=18	General Classic Blend PSWL, n=18	General PSOL, n=18	General PSWL, n=18	General Wintergreen PSWL, n=18	Unit	General Loose, n=12
<b>SKU</b>		<b>4352</b>	<b>4800</b>	<b>4876</b>	<b>4877</b>	<b>4880</b>	<b>4881</b>	<b>4882</b>		<b>4852</b>
<b>Pouch weight</b>	g	0.999 (0.0477)	0.335 (0.0136)	0.900 (0.0141)	0.870 (0.0746)	0.981 (0.0189)	0.966 (0.0523)	0.977 (0.0524)		
<b>Acetaldehyde</b>	microg/unit of use	16.9 (5.39)	2.50 (0.709)	10.5 (1.84)	11.6 (1.40)	13.9 (2.24)	17.3 (4.84)	13.4 (2.60)	µg/g	12.6 (1.42)
<b>Arsenic</b>	microg/unit of use	<0.10 (0.00)	<0.10 (0.00)	<0.10 (0.00)	<0.10 (0.00)	<0.10 (0.00)	<0.10 (0.00)	<0.10 (0.00)	µg/g	<0.10 (0.00)
<b>B(a)P</b>	ng/unit of use	<0.6 (0.218)	<0.6 (0.00)	<0.6 (0.00)	<0.6 0.199	<0.6 (0.00)	<0.6 (0.00)	<0.6 (0.00)	ng/g	<0.6 (0.0953)
<b>Cadmium</b>	microg/unit of use	0.210 (0.0175)	0.107 (0.00923)	0.231 (0.0225)	0.243 (0.0274)	0.197 (0.0110)	0.229 (0.0159)	0.235 (0.0241)	µg/g	0.190 (0.0387)
<b>Crotonaldehyde</b>	microg/unit of use	<0.25 (0.00)	<0.25 (0.00)	<0.25 (0.00)	<0.25 (0.0485)	<0.25 (0.00)	<0.25 (0.00)	<0.25 (0.00)	µg/g	<0.25 (0.00)
<b>Formaldehyde</b>	microg/unit of use	6.56 (0.853)	3.31 (0.582)	6.1 (1.26)	6.92 (0.765)	6.33 (0.883)	6.03 (0.750)	4.99 (0.663)	µg/g	4.89 (0.369)
<b>Nicotine (Free)</b>	mg/unit of use	6.39 (0.346)	0.973 (0.269)	5.66 (0.252)	5.69 (0.433)	6.21 (0.295)	6.37 (0.402)	6.43 (0.374)	mg/g	5.64 (0.107)
<b>Nicotine (Total)</b>	mg/unit of use	7.16 (0.441)	4.95 (0.205)	6.85 (0.305)	6.66 (0.540)	7.54 (0.240)	7.37 (0.426)	7.62 (0.436)	mg/g	7.04 (0.116)

<b>NNK</b>	microg/unit of use	0.142 (0.00635)	0.0923 (0.0639)	0.162 (0.0188)	0.144 (0.0147)	0.106 (0.0130)	0.143 (0.0155)	0.151 (0.0186)	µg/g	0.0911 (0.00902)
<b>NNN</b>	microg/unit of use	0.301 (0.0200)	0.332 (0.213)	0.315 (0.0250)	0.291 (0.0225)	0.273 (0.0145)	0.313 (0.0207)	0.336 (0.0332)	µg/g	0.215 (0.0109)

**Historical Data** - Chemical data collected during 2002 – 2011 from the Chemical Quality Control Program are shown in [Figures 7:8-14](#).

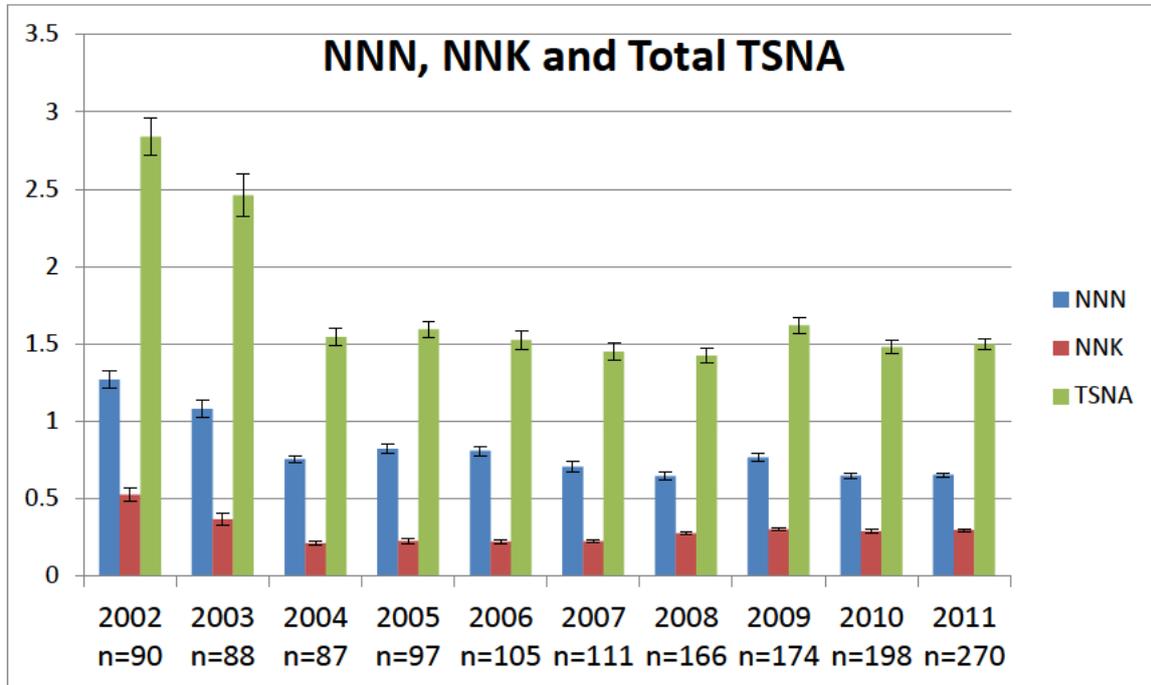
A long term strategy to continuously reduce the level of TSNA has resulted in low and a stable TSNA level (<2 microg/g) since 2003-2004 ([Graph 7:8](#)). The level of B(a)P has been low since the the late 1990s when use of fire-cured tobacco was discontinued (Rutqvist et al, 2011). (b) (4)

(b) (4) ([Figure 7:9](#)). (b) (4) t ([Figure 7:10](#)).

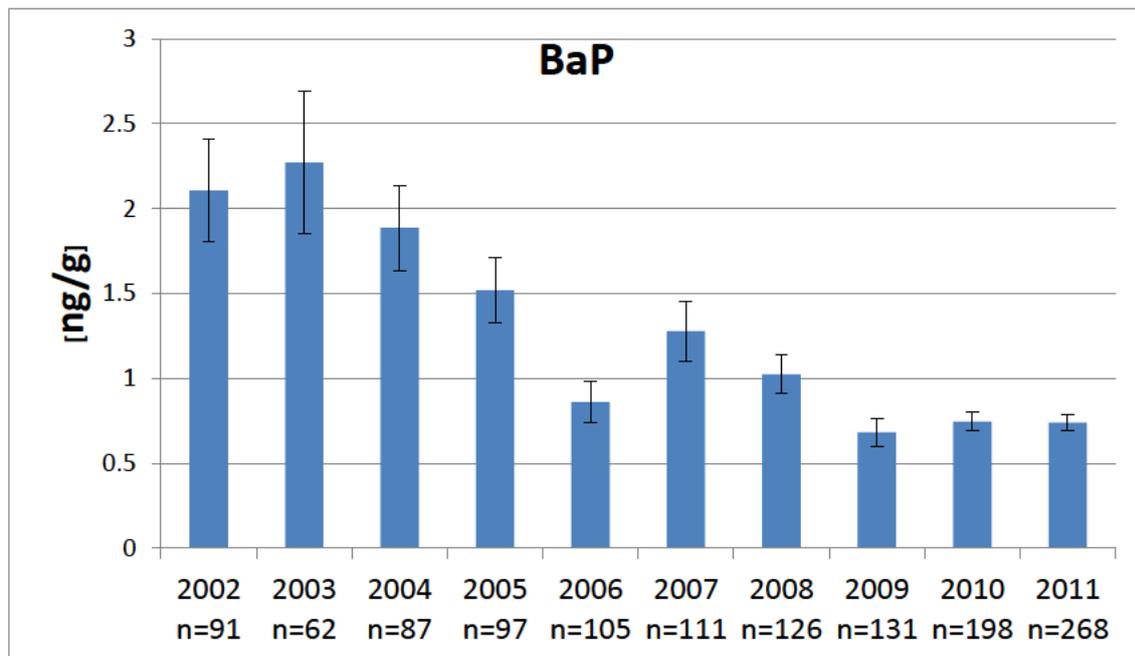
The levels of the five Gothiatek® metals have remained stable over the past decade, and all values are below the Gothiatek® limits ([Figure 7:11](#)). The content of NDMA has consistently been below 1 ng/g ([Figure 7:12](#)).

The average nicotine content and pH value in all Swedish Match snus products has been constant over the past decade ([Figure 7:13, 7:14](#)).

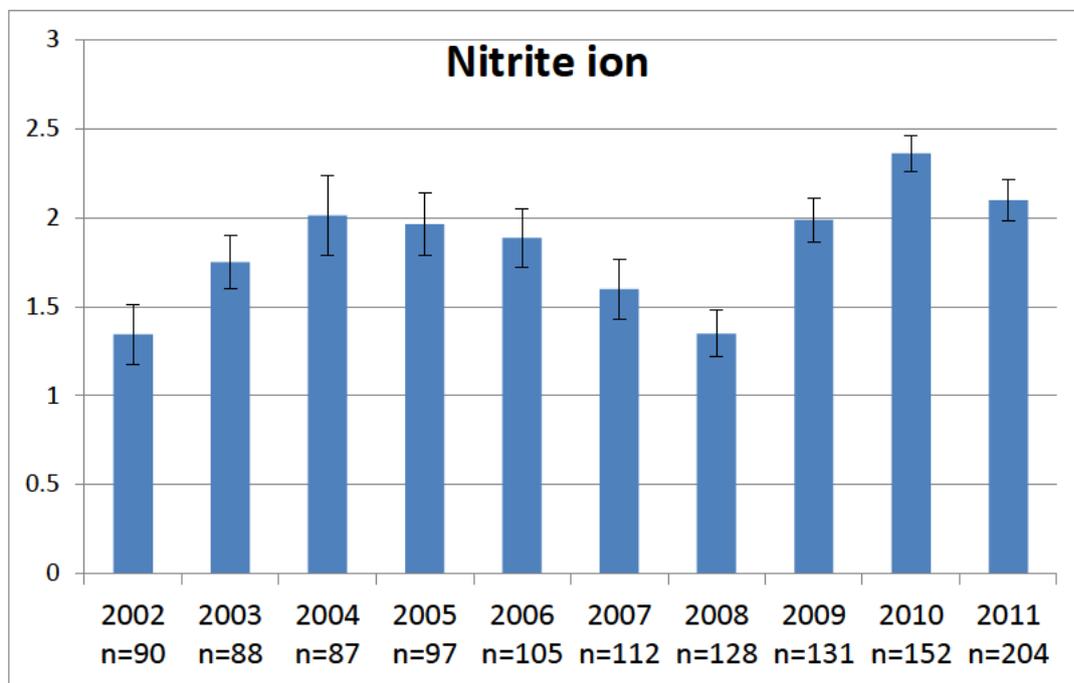
**Figure 7:8. The average content (microg/g) of TSNAs (NNN, NNK, and total TSNAs) in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



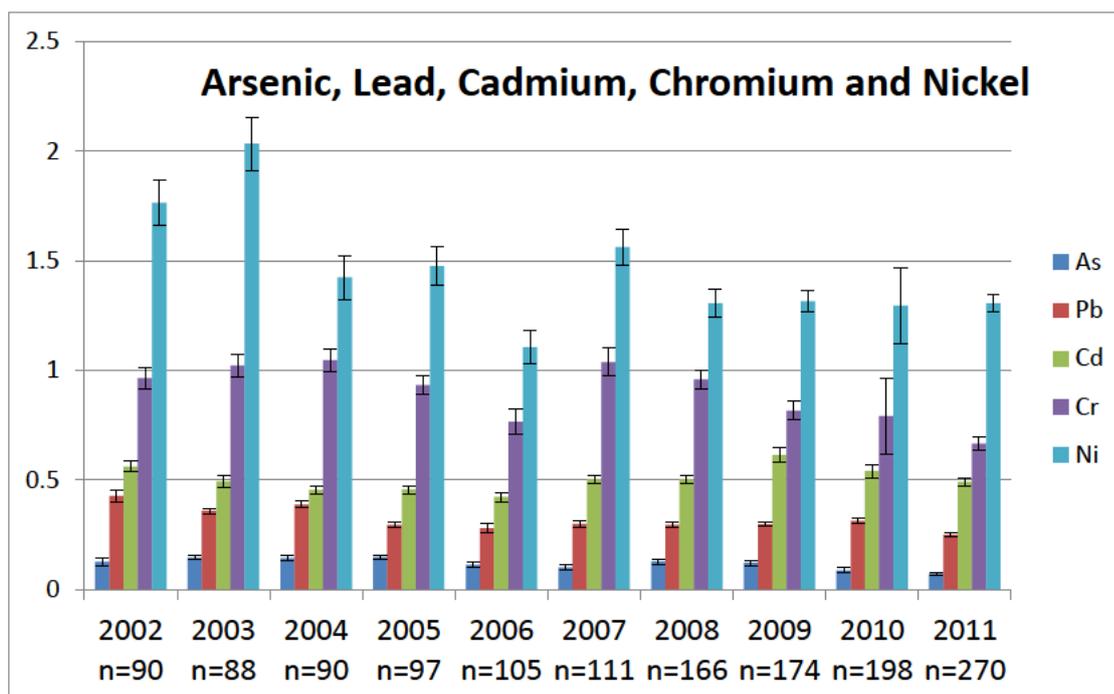
**Figure 7:9. The average content of B(a)P in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



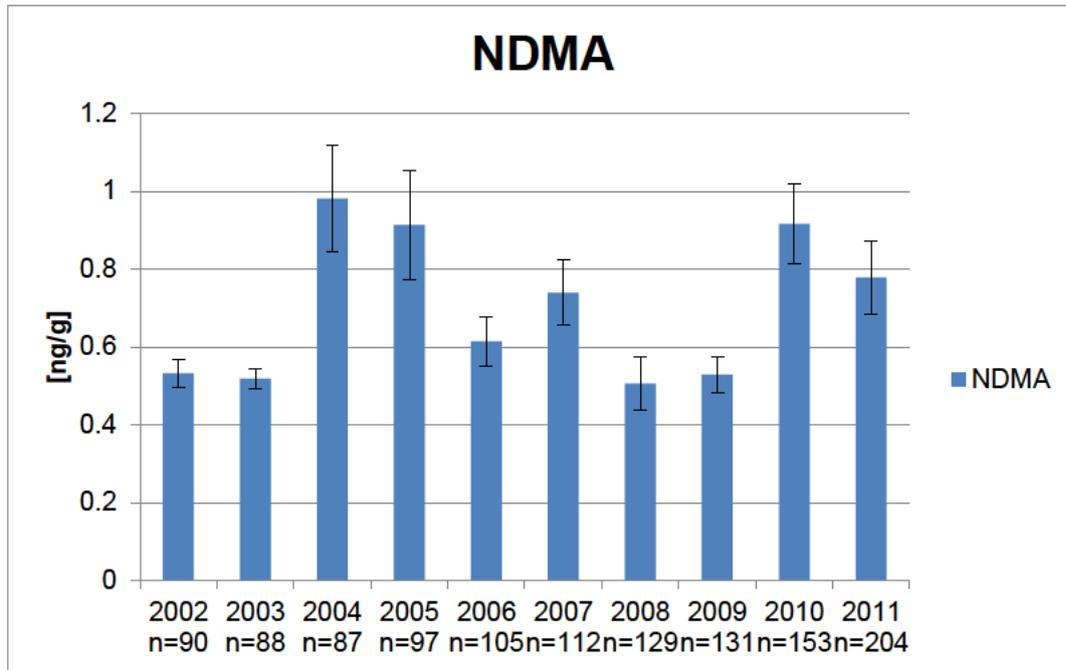
**Figure 7:10. The average content of nitrite ion (microg/g) in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



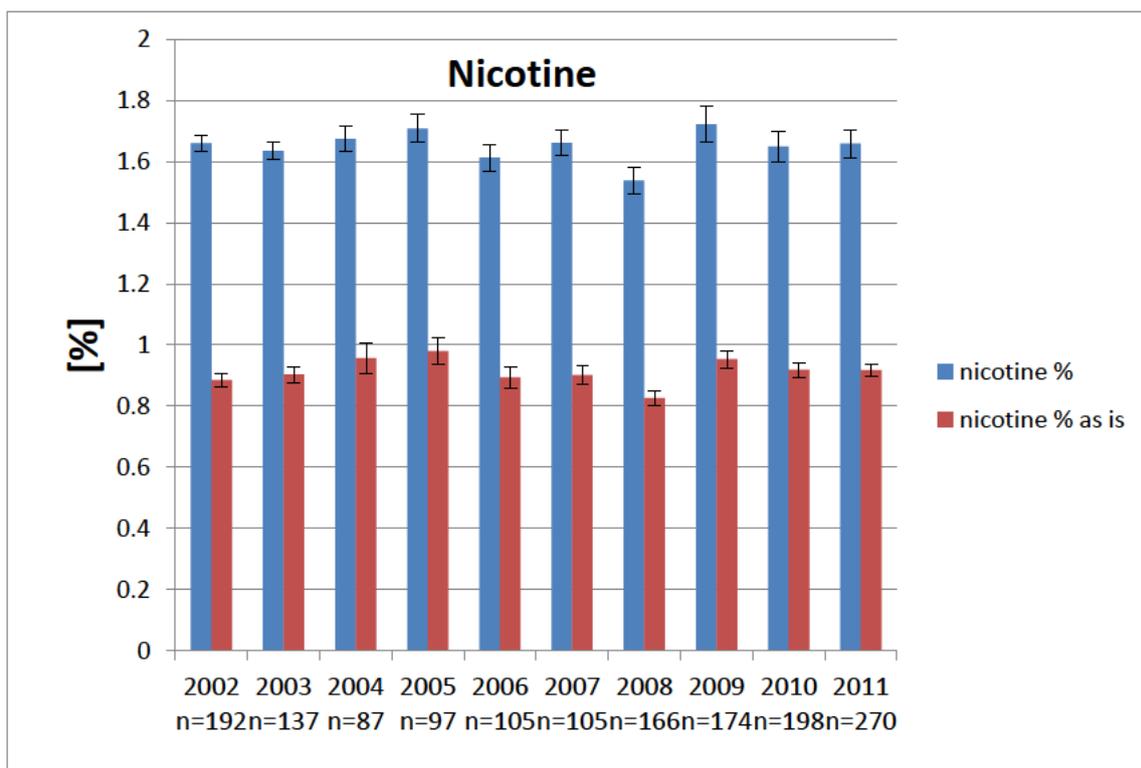
**Figure 7:11. The average content of selected metals (microg/g) in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



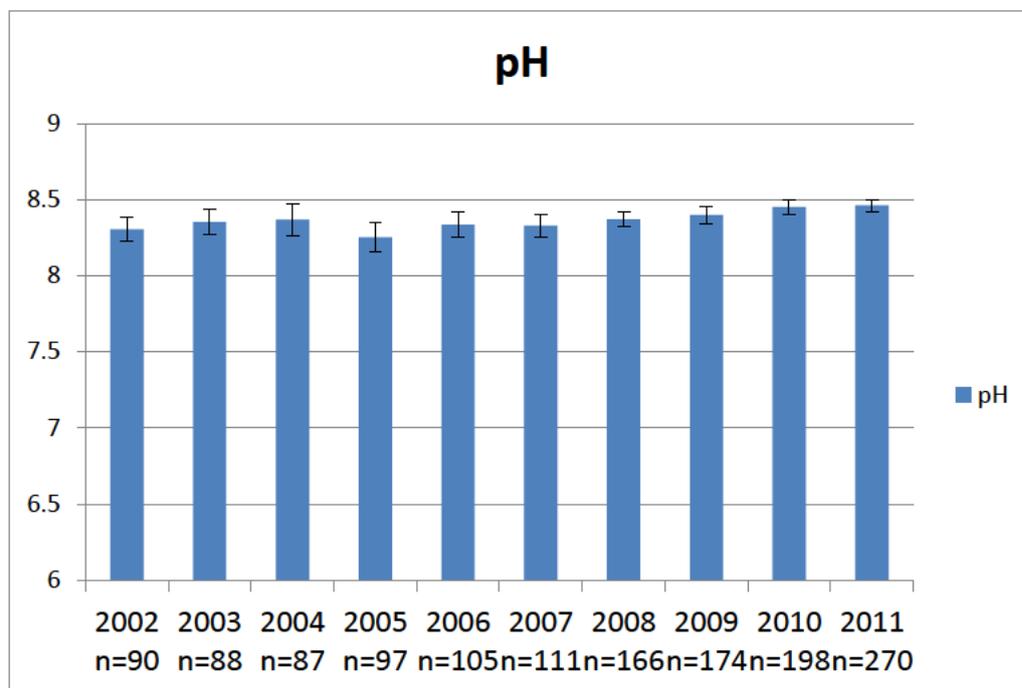
**Figure 7:12. The average content of NDMA in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



**Figure 7:13. The average content of nicotine in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



**Figure 7:14. The average pH level in all snus products included in Swedish Match's Chemical Quality Program during 2002-2011. Number of tested products (n), and 95% confidence intervals are indicated.**



**Product stability during storage**

**Storage of snus at ambient conditions** - The recommended shelf life in cool storage for snus products is different according to product category: (b) (4)

(b) (4) . (b) (4)

The testing is part of the Chemical Quality Analysis Program.

(b) (4)

All products tested for product stability in 2011 are listed in [Tables 7:14](#) and [7:15](#) below (b) (4)

(b) (4)

**Table 7:14. Water content , pH level and nicotine content in selected snus products during storage until best before date (in refrigerator during 3 weeks, thereafter at ambient room temperature and relative humidity). Analytical results for products sampled during 2011. The nicotine values are given as dry weight.**

(b) (4)



(b) (4)

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***Table 7:15. Content of TSNA, nitrite ions, NDMA, and bacterial activity in selected snus products during storage until best before date (in refrigerator during 3 weeks, thereafter at ambient room temperature and relative humidity). Analytical results for products sampled during 2011. The values on TSNA, NDMA and nitrite ion are given as dry weight.***

(b) (4)

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(b) (4)



*Historical data* - The corresponding results from the years 2007 through 2011 for selected snus products stored at ambient conditions are shown in Tables 7:16 and 7:17. (b) (4)



***Table 7:16. Analytical results from the years 2007 to 2011 showing the pH value and the content of water and nicotine in snus products stored in refrigerator for 3 weeks and at ambient room temperature and relative humidity until best before date.***

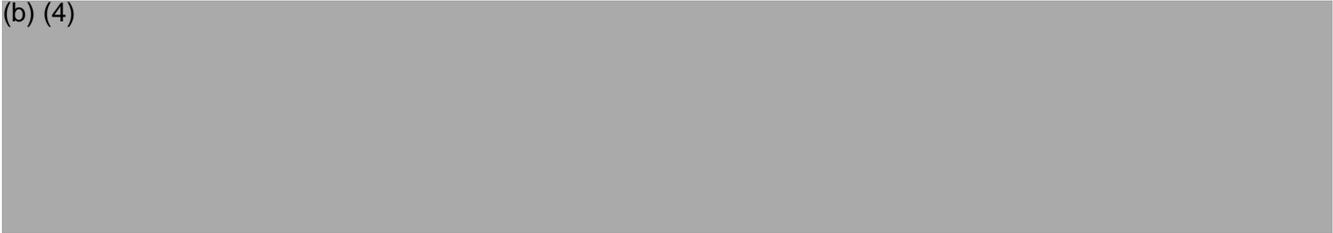
(b) (4)



(b) (4)



(b) (4)

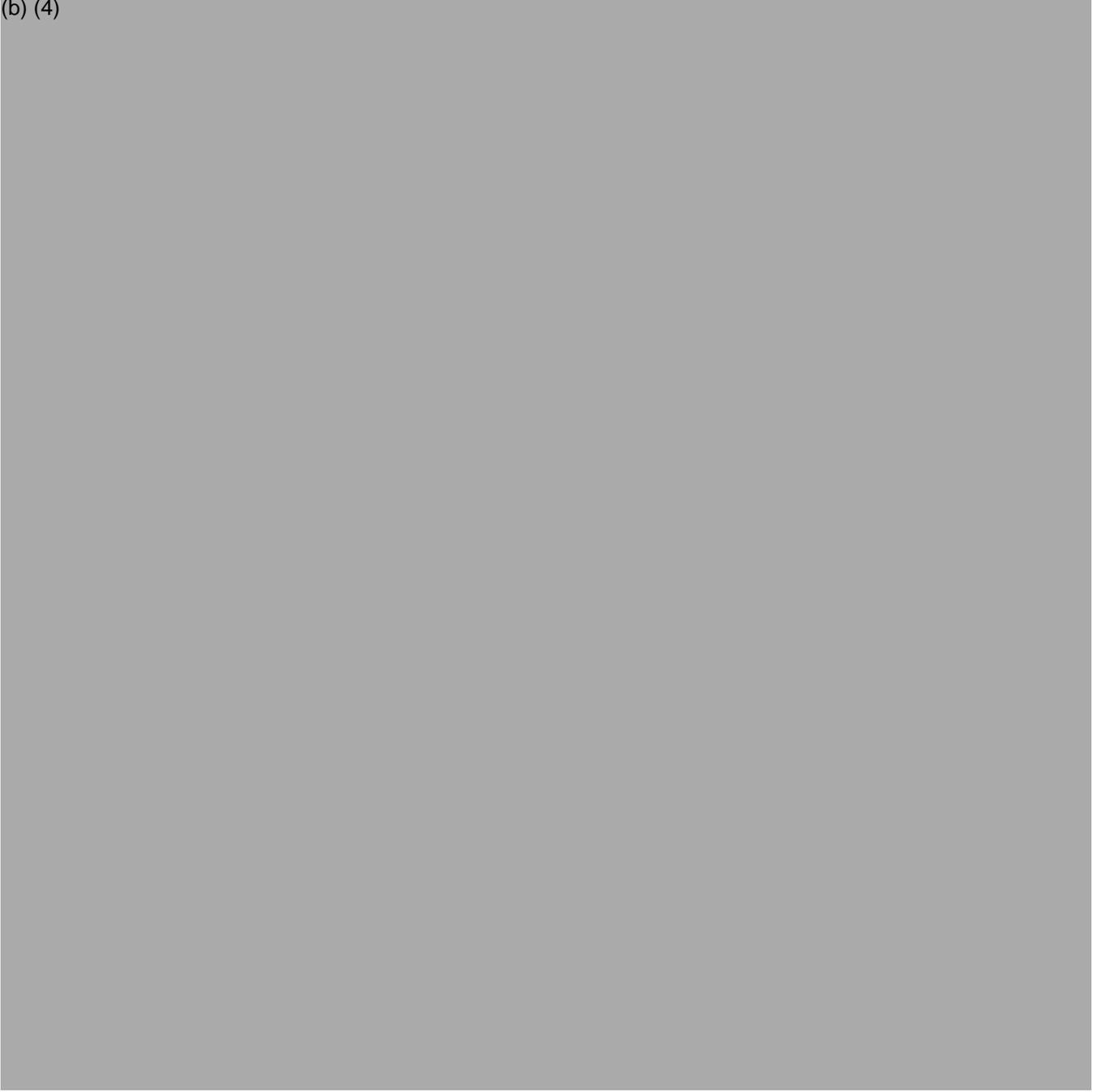
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**Table 7:16. Analytical results from the year 2011 showing the content of TSNA, nitrite ion, NDMA and colony forming bacteria count in snus products stored in refrigerator for 3 weeks and at ambient room temperature and relative humidity until best before date.**

(b) (4)

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(b) (4)



**Storage of snus at ambient and cold conditions – (b) (4)**

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(b) (4)

[Redacted text]. The results for the eight snus product currently marketed in the US are shown in [Tables 7:18](#) and [7:19](#). (b) (4)

[Redacted text block]

(b) (4)

[Redacted text block]

**Table 7:18. Analytical results from the year 2012 showing the pH and  $a_w$  values and the content of water, moisture, nicotine and colony forming bacteria count for products marketed in the US stored both in refrigerator and at ambient room temperature and relative humidity until best before date.**

(b) (4)



**Table 7.18, cont'd.**

(b) (4)



**Table 7:19. Analytical results from the year 2012 showing the content of acrylamide, TSNA, NDMA, nitrite ion and ethyl carbamate for products marketed in the US stored both in refrigerator and at ambient room temperature and relative humidity until best before date.**

(b) (4)



**Table 7:19, cont'd.**

(b) (4)



**Brands Testing Program of snus products**

Brands Testing of Swedish Match snus products has been performed annually since 1988.

(b) (4) [Redacted text block]

(b) (4) [Redacted text block]

**2011 Brands Testing Program of Swedish Match snus products**

**Products** (b) (4) [Redacted text block]

**Test battery** - (b) (4) [Redacted text block]

(b) (4) [Redacted text block]

**Chemical results** (b) (4) [Redacted text block], [Table 7:20..](#)

**Table 7:20.** (b) (4)

Analyte	Min	Mean	Max	n
(b) (4)				

(b) (4)



**2012 Brands Testing of Swedish Match snus products on the US market**

As of 2012, all Swedish Match snus products currently marketed in the US were included in the Brands Testing Program. Table 7:21 summarizes the results for these eight products. All of them had levels below the GothiaTek® limits as well as the internal tolerance limits.

**Table 7:21. Chemical data on the snus products on the US market derived from the Brands Testing Program in 2012.**

Analyte	Unit	General Mint, PSWL	General Dry Mint, PSOM	General LS	General Nordic Mint, PSWL	General Classic Blend, PSWL	General PSOL	General PSWL	General Wintergreen, PSWL
SKU		4352	4800	4852	4876	4877	4880	4881	4882

(b) (4)

Analyte	Unit	General Mint, PSWL	General Dry Mint, PSOM	General LS	General Nordic Mint, PSWL	General Classic Blend, PSWL	General PSOL	General PSWL	General Wintergreen, PSWL
SKU		4352	4800	4852	4876	4877	4880	4881	4882

(b) (4)



Analyte	Unit	General Mint, PSWL	General Dry Mint, PSOM	General LS	General Nordic Mint, PSWL	General Classic Blend, PSWL	General PSOL	General PSWL	General Wintergreen, PSWL
SKU		4352	4800	4852	4876	4877	4880	4881	4882

(b) (4)



Analyte	Unit	General Mint, PSWL	General Dry Mint, PSOM	General LS	General Nordic Mint, PSWL	General Classic Blend, PSWL	General PSOL	General PSWL	General Wintergreen, PSWL
SKU		4352	4800	4852	4876	4877	4880	4881	4882

(b) (4)

All values are given on dry matter basis unless otherwise stated.

### **Swedish Match Agrochemical Residue Management program**

Swedish Match has established an Agrochemical Residue Management Program, which includes a formalized process for inclusion of agrochemicals to be tested, decisions about Guidance Residue Levels (GRLs), and procedures concerning the company's stewardship of dealing with agrochemical residues in raw tobacco and snus products.

Swedish Match performs agrochemical residue testing of raw tobacco shipments prior to their release for snus manufacture. (b) (4)

Analytical testing is done by a certified laboratory. Individual results are documented and stored. Results are reviewed on a monthly basis. Upon acceptable results, the tobacco will be released for use in the production. Swedish Match also performs agrochemical residue testing on finished snus products. This is performed annually under the Brands Testing Program.

(b) (4)

### **Guidance Residue Levels (GRLs) for Agrochemicals in Tobacco and Oral Smokeless Tobacco Products**

The included agrochemicals (pesticides, fungicides, and herbicides) are either:

- (b) (4)
- 
- 
- 

(b) (4)

### **Procedure to set SM GRLs for agrochemicals** (b) (4)

(b) (4)

- (b) (4)

- 

- 

- 

(b) (4)

(b) (4)

(b) (4)

**Agrochemical residue levels in raw tobacco - (b) (4)**

[Redacted]

Testing of agrochemical residues in raw tobacco (as well as in finished products) is done at the Swedish consultant laboratory “Eurofins AB” in Lidköping, Sweden. Eurofins AB is a certified laboratory contracted by the National Food Agency in Sweden to perform testing in food products. Eurofins AB uses methods approved by the Swedish National Food Agency. These methods are developed and validated for agrochemical analyses of food, and have been modified for analysis of tobacco and tobacco products.

(b) (4)

[Redacted]

**Agrochemical residue levels** are annually checked in all Swedish Match snus products in the Brands Testing Program. (b) (4)

[Redacted]

(b) (4)

[Redacted]

**Agrochemical Residues in 2011 - (b) (4)**

(Table 7:22). (b) (4)

[Redacted]

**Table 7:22. Frequency of agrochemicals found in (b) snus products tested in 2011.**

Agrochemical residue	Found	
	Frequency	Freq. > GRL

(b) (4)

**Agrochemical residue levels in Swedish Match snus products on the US market** - The snus products marketed in the US were tested in 2011 at one occasion for approximately 340 agrochemical residues. The results are presented in Table 7:23. All of the detected agrochemicals had levels below Swedish Match internal GRLs. (b) (4)

**Table 7:23. Agrochemical residues found in 2011 in snus products marketed in the US.**

SKU	Product	Agrochemical	Amount microg/g	SM GRL (snus) microg/g
4352	General Mint PSWL	(b) (4)		





SKU	Product	Agrochemical	Amount microg/g	SM GRL (snus) microg/g
4882	General Wintergreen PSWL	(b) (4)		

All values are given on wet basis.  
 \* GRL:Endosulfan + metab.  
 \*\* GRL: Triadimefon+Triadimenol

**Historical data** - Over the years new agrochemicals have been introduced on the market while use of others has been discontinued. The number of available analytical test methods has increased and the sensitivity of the methods has been improved. Despite these circumstances, the total number as well as amount of residue does not appear to have increased over the last ten years (Table 7:24).

**Table 7:24. Frequency of detected residues and total residue amount in two snus products during 2002-2011.**

SKU Product	Year	No. of found residues	No. of analyzed residues	Total amount of residue (microg/g)
804 Ettan LS	(b) (4)			
875 Ettan PSOL				

**References**

(b) (4) [Redacted]  
[Redacted]

(b) (4) [Redacted]  
[Redacted]

(b) (4) [Redacted]

(b) (4) [Redacted]  
[Redacted]  
[Redacted]

(b  
)  
(4)

Rutqvist, L.E., Curvall, M., Hassler, T., Ringberger, T., Wahlberg, I. (2011) Swedish snus and the GothiaTek standard. Harm Reduction Journal, 8, 11

**Appendices:**

1. (b) (4)
2. (b) (4)
3. (b) (4)
4. (b) (4)
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9. (b) (4)
10. (b) (4)
11. (b) (4)
12. (b) (4)
13. (b) (4)

- 14. (b) (4) [Redacted]
- 15. (b) (4) [Redacted]
- 16. (b) (4) [Redacted]
- 17. (b) (4) [Redacted]
- 18. (b) (4) [Redacted]
- 19. (b) (4) [Redacted]
- 20. (b) (4) [Redacted]
- 21. (b) (4) [Redacted]
- 22. (b) (4) [Redacted]

## 8. Packaging

### **Pouch material - (b) (4)**

[Redacted text block]

### **Can material - (b) (4)**

[Redacted text block]

### **Selection and approval of suppliers - (b) (4)**

[Redacted text block]

Swedish Match suppliers of current packaging materials, such as cans, lids, labels and pouch material are listed in Table 8:1.

**Table 8:1. Current suppliers of packaging materials for Swedish Match US products**

	Supplier name	Products produced
(b) (4)	[Redacted]	[Redacted]

## **Selection and approval of materials in pouches and cans**

**Regulatory compliance pouch materials** - The pouch material is considered as a packaging and shall, therefore, according to Swedish Match policy, comply with legislation concerning materials and articles intended to come in contact with food. (b) (4)

There is no EU legislation on pouch materials used in smokeless tobacco products. Some ingredients in the pouch material are considered as plastic materials and must therefore fulfill the EU-regulation 10/2011, which concerns plastic materials and articles intended to come in contact with food. Also, there are regulations concerning pouch materials issued by FDA as well as recommendations from the BfR Federal Institute for Risk Assessment in Germany.

Swedish Match requires that the pouch paper supplier certifies that the paper and all in-going components conform to relevant EU and FDA regulations. The pouch material and its ingredients must thus fulfill the requirements in the following directives:

- [US FDA CFR 21 176.170](#) Components of paper and paperboard in contact with aqueous and fatty foods.
- [US FDA CFR 21 176.180](#) Components of paper and paperboard in contact with dry foods.
- [US FDA CFR 21 173.340](#) Secondary direct food additives permitted in food for human consumption (Defoaming agents).
- [US FDA CFR 21 175.105](#) Indirect Food Additives: Adhesives and components of coatings (Adhesives).
- Bundesinstitute für Risikobewertung, BfR; BfR XXXVI paper and board for food contact.
- Regulation [\(EC\)1333/2008](#) OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 16 December 2008 on food additives
- LIVSFS 2012:6, Livsmedelsverkets föreskrifter om snus och tuggtobak (Swedish National Food Agency's directive on snus and chewing tobacco).
- COMMISSION REGULATION [\(EU\) No 10/2011](#) of 14 January 2011 on plastic materials and articles intended to come into contact with food (replaces 2002/72/EG).
- [Color Additive Status](#)  
Listing: <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm106626.htm>

(b) (4)

**Selection and regulatory compliance can materials** - Material selection for the can and plastic lids are determined by the following quality requirements:

- (b) (4)

- (b) (4)
- 
- 

(b) (4)

A list of materials and food contact compliance for Swedish Match snus cans for the US market is provided in Table8: 2.

**Table 8:2. Material description and regulatory compliance for can components.**

Product*	Compliance for can & lid	Can/Lid color	Compliance for colorant
(b) (4)			

(b) (4)



**Technical specifications**

**Pouch material** - (b) (4)

[Redacted text]

**Table 8:3. Technical specifications of pouch material.**

	Supplier Test Method	EDANA Method	Unit	Target	Tolerance
<b>For all widths</b>					
<b>Base Unit Weight</b>	(b) (4)				
<b>Thickness (E)</b>	(b) (4)				
<b>Dry MD Tensile</b>	(b) (4)				
<b>Wet MD Tensile</b>	(b) (4)				
<b>Wet TD Tensile</b>	(b) (4)				
<b>Heat seal</b>	(b) (4)				
<b>Web quality</b>	(b) (4)				

**Cans and lids** - (b) (4)

[Redacted text]

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[Redacted text]

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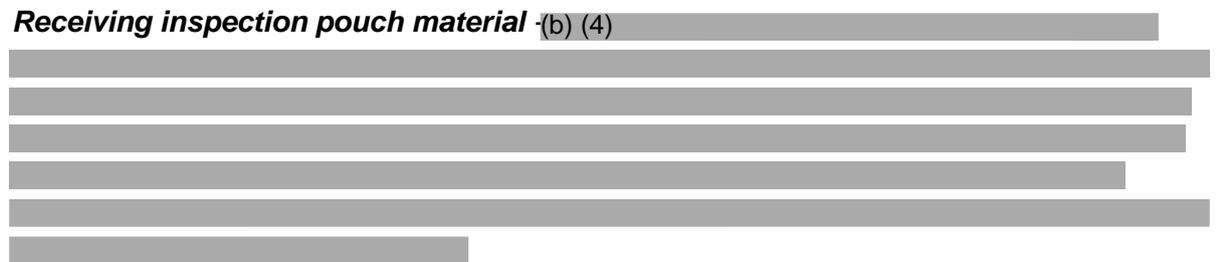
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(b) (4)

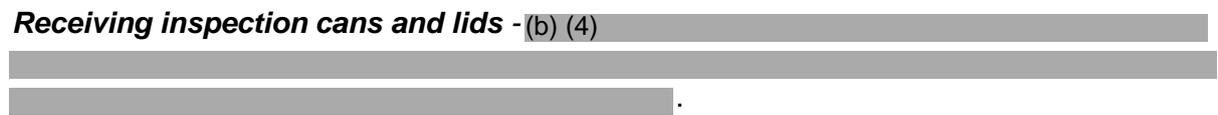
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**Quality control**

**Receiving inspection pouch material** (b) (4)

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**Receiving inspection cans and lids** - (b) (4)

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Other testing parameters are:

- (b) (4)
  - 
  - 
  - 
  -
- 
- The list items are redacted with a solid grey bar.

If all tests are approved, the materials are released for use in the production.

## **Microbiology**

**Pouch material, lids and cans** - (b) (4)

[REDACTED]  
[REDACTED]  
[REDACTED]  
(b)

(b) (4)

[REDACTED]  
[REDACTED]

## **Traceability**

**Traceability of pouch material** - (b) (4)

[REDACTED]  
[REDACTED]  
[REDACTED]

**Traceability of cans and lids** - (b) (4)

[REDACTED]

## **Hygiene and environment**

**Supplier** - (b) (4)

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

**Storage facility for packaging** - Hazards in this area includes flying insects and high microbiological presence. All packaging materials are well sealed until ready to use in production. In order to prevent contamination of the hygiene zone, the storage areas are kept free from vermins. The following precautions are taken:

- Daily removal of dust and mechanical cleaning of floor surfaces
- Halogen traps for flying insects
- Mouse traps
- Microbiological tests of equipment and packaging materials intended to come in close contact with the product
- Microbiological tests of room air

All passageways for trucks in the production and storage areas are cleaned daily (b) (4)

(b) (4)

[REDACTED] to prevent contamination of packaging materials and hygiene areas.

Microbiological tests are done twice a year of the air in the production and storage areas to

determine the level of microbiological presence (b) (4)

(b) (4)

**References:**

Bundesinstitute für Risikobewertung, BfR; BfR XXXVI paper and board for food contact.  
<http://bfr.zadi.de/kse/faces/resources/pdf/360-english.pdf;jsessionid=45481F4092486B312247E3CFFB88D2A>

Color Additive Status

List, <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm106626.htm>

Commission regulation (EU) No 10/2011 of January 2011 on plastic materials and articles intended to come in contact with food. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>

Commission Directive 2002/72/EC of August 2002 relating to "Plastic materials and articles intended to come into contact with foodstuffs", <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:220:0018:0018:EN:PDF>

Harmonized Test Methods for the Nonwovens and Related Industries, Edition 2012, [http://www.edana.org/newsroom/reports-publications/publication/2013/01/28/standard-test-methods-for-the-nonwovens-industry-\(edition-2012\)](http://www.edana.org/newsroom/reports-publications/publication/2013/01/28/standard-test-methods-for-the-nonwovens-industry-(edition-2012))

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF>).

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come in contact with food and repealing Directives 80/590/EEC and 89/109/EEC, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:en:PDF>

Swedish National Food Agency Directive on Snus and Chewing Tobacco, LIVSFS 2012:6, ([http://www.slv.se/upload/dokument/lagstiftning/2012/2012\\_6\\_snus.pdf](http://www.slv.se/upload/dokument/lagstiftning/2012/2012_6_snus.pdf)).

US FDA 21 CFR 173.340 Secondary direct food additives permitted in food for human consumption (Defoaming agents).

US FDA 21 CFR 175.105 Indirect Food Additives: Adhesives and components of coatings (Adhesives).

US FDA 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

US FDA 21 CFR 176.180 Components of paper and paperboard in contact with dry foods.

**Appendices:**

1. (b) (4) [Redacted]
2. (b) (4) [Redacted]
3. (b) (4) [Redacted]
4. (b) (4) [Redacted]
5. (b) (4) [Redacted]
6. (b) (4) [Redacted]
7. (b) (4) [Redacted]
8. (b) (4) [Redacted]

Production approval of the manufacturing, packaging and labelling are documented and records stored.

*Swedish snus according to Gothiatek®*

## 9. Trace and Recall

Regulatory requirements for traceability typically stipulate that suppliers, manufactures, and distributors have product traceability one step forward and one step backward in the supply chain. These requirements are met through trading partners contributing essential pieces of information that are collected, documented and recorded by Swedish Match. This chapter describes the company's traceability of internal, external, disposition and recall processes.

**Regulations** - Swedish Match snus traceability processes are in compliance with the Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002, Chapter II General Food Law, Section 4, General Requirements of Food Law, Article 18, Traceability and the Swedish Food Agency directives on snus and chewing tobacco LIVSFS 2012:6, §12 Traceability. The Gothiatek® standard stipulates that the manufacturing process must comply with Swedish laws on food production and must meet the requirements of the quality standard ISO 9001:2000.

**Internal traceability at the Gothenburg and Kungälv manufacturing facilities** – Swedish Match has internal processes and inventory management controls that track ingredients, components, packaging, and labels through their receiving, manufacturing and holding activities. Ingredients are defined as raw materials and additives per Directive 2000/12/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling presentation and advertising of foodstuffs. Various functional units such as procurement, regulatory affairs, R&D, engineering, production, quality control, logistics, storage and affiliate companies work together to ensure internal traceability.

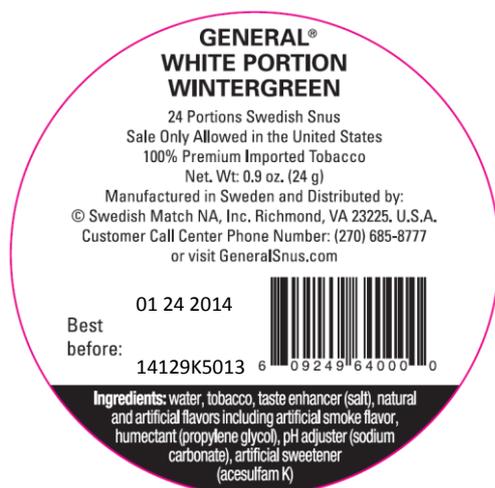
The Swedish general food law requires a manufacturer to follow “Codex Alimentarius, General Principles of Food Hygiene CAC/RCP 1-1969”, which is an internationally recognized process for food safety. The Hazard Analysis Critical Control Point, HACCP based quality assurance system ensures that employees are HACCP qualified, each critical control point of the production chain is identified, and the critical control limits are determined, monitored and recorded. Swedish Match's HACCP program addresses microbiological, chemical and physical potential hazards and has established appropriate controls for hazards identified as reasonably likely to occur when manufacturing. Furthermore, hygiene procedures stipulate pre- and post processing contamination prevention activities. Control measures for metal fragments are established and involve the use of on-line metal detection equipment and daily equipment checks. After heat treatment, contamination is prevented by the use of a closed tubing system. Production approval of the manufacturing, packaging and labelling are documented and records stored.

**Product Identifier** – The minimum requirement for traceability is that each traceable unit has been uniquely labeled so that it can be identified. Swedish Match uses a standardized graphic that is machine- and human-readable, and which conforms to recognized international standards, has a batch identification number, and displays the best before date. The batch identification number represents the product with the information Swedish Match considers relevant for traceability of the final tobacco product and would be used in the event of a recall. This batch number references the tobacco product itself and the items contained in it. (b) (4)

**Labels** - Below are example labels of the can, the roll and the case representing the brand General Wintergreen Portion White Large.

**Can Label** - The batch number is affixed via a round, paper adhesive sticker to the bottom of each can (b) (4). The label inks and adhesives are approved for indirect food contact. Furthermore, the adhesives are self-adhesive, have size requirements, and some are synthetic to withstand moisture. These markings are used as part of the traceability process.

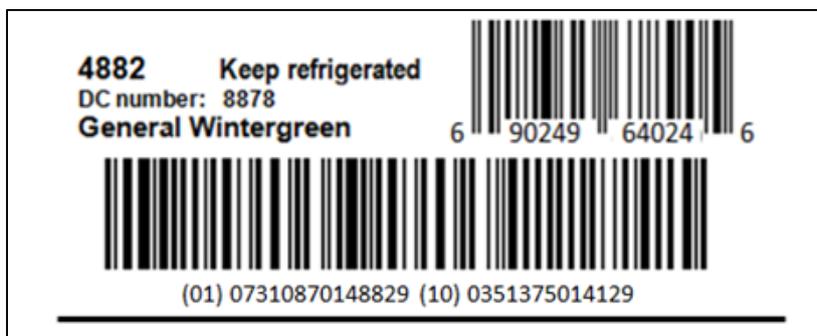
The can label displays key elements including the best before date (01 24 2014), the batch number (14129), and a letter that identifies the manufacturing facility, such as (K) for Kungälv factory. The last number on the label represents the production line (50), the shift (1) and the labeling machine (3) used to produce the can.



**Roll Label** - Cans are packaged into a roll and a white label is affixed to the side of the roll. The key elements of the roll label are product name and the GTIN 128 code combination number which includes the batch number. The code combination number is machine- and human readable.

Below is an example of a roll label with key elements:

Internal Item no: 4882  
Info: Keep refrigerated  
DC No: 8878  
Product Name: General Wintergreen  
UPC- Code: 6 09249 64024 6  
GTIN 128 Code: (01)073 10870148829(10) 0351375014129



**Case label** - Rolls are placed into a case and a white label with yellow frame is placed on top. Case labels enable trading partners to identify the product. The label shows the product identification information including product name, batch number, best before date and the GTIN number (GS1-128) in bar code form and human readable form. The GTIN code allows the case to be identified quickly and throughout the supply chain both manually and electronically, and links to the master item data file at Swedish Match, Sweden.

Quantity  
Place of Issue: 4882  
Production week and day: V36-5  
Current production time: 09:51  
Country: United States  
Product Name: General Wintergreen  
DC Number: 640530  
Item no: 640530  
Batch No: 035137 (production order number) 501 (50 = Line 550, 1=shift 2) 4129 (heat treatment batch no)  
Best before: 01.24.2014 (MMDDYYYY)  
PCS (Number of packages): 18  
UPC Code: 6 09249640536  
GTIN Code 128: (02) 07310870148829 (37) 18 (10) 0351375014129



Visual product audits of the batch number are performed before the tobacco product is packed into a case (b) (4) ). Reference products from the same batch are maintained past the best before date to permit investigational analyses if necessary. These reference samples are kept in the same container- and closure system as a finished tobacco product, and are stored in a secured refrigerator.

The logistic unit is a pallet composed of cases. This logistic unit has a GTIN code that is located on the pallet label, and constitutes the traceable and identifiable unit that can be identified in the event of a recall.

***Traceability of external processes outside of the Gothenburg and Kungälv, Sweden manufacturing facilities***

Swedish Match has established and maintains inventory management controls with external trading partners.

***Receiving supplies/services and evaluating suppliers*** - Suppliers are obligated to satisfy required European Union, (EU) regulations and Swedish Match's internal specifications

(b) (4) [Redacted text block]

***Dynamic AX system*** -The receiving process is managed by trained employees who visually verify and ensure that specifications are consistent with the purchase order. (b) (4)

[Redacted text block]

(b) (4) [Redacted]

**Receiving flavors and evaluating flavor suppliers** – Flavor suppliers are evaluated for conformance with EU and Swedish regulations and Swedish Match’s internal requirements

(b) (4) [Redacted]

**Shipping product to Swedish Match, Owensboro facility** - The logistic units are transported by a third-party logistic carrier on trucks to Landvetter Airport, Gothenburg, Sweden, and an airline, usually (b) (4), is contracted to fly the shipments to the United States.

(b) (4) [Redacted]

**Receiving product at Swedish Match, Owensboro facility** - Upon the arrival of snus from Sweden, the logistic unit is received, segregated in the warehouse and scanned into the Dynamic AX system to verify the shipment contents by batch number and quantity. Quality control staff reviews, approves and releases the logistic unit both electronically and manually.

(b) (4) [Redacted] . (b) (4) [Redacted]

**Labeling the product at Swedish Match, Owensboro facility** - (b) (4) [Redacted]

(b) (4)

**Distribution from Swedish Match, Owensboro facility -** (b) (4)

**Disposition**

**Disposal process for nonconforming components, packaging, labels and final product at Gothenburg and Kungälv manufacturing facilities** - Swedish Match has established, implements, and maintains disposition processes that remove non-conforming, elapsed, unwanted, or unused components, packaging and labels to prevent use in manufacturing.

(b) (4)

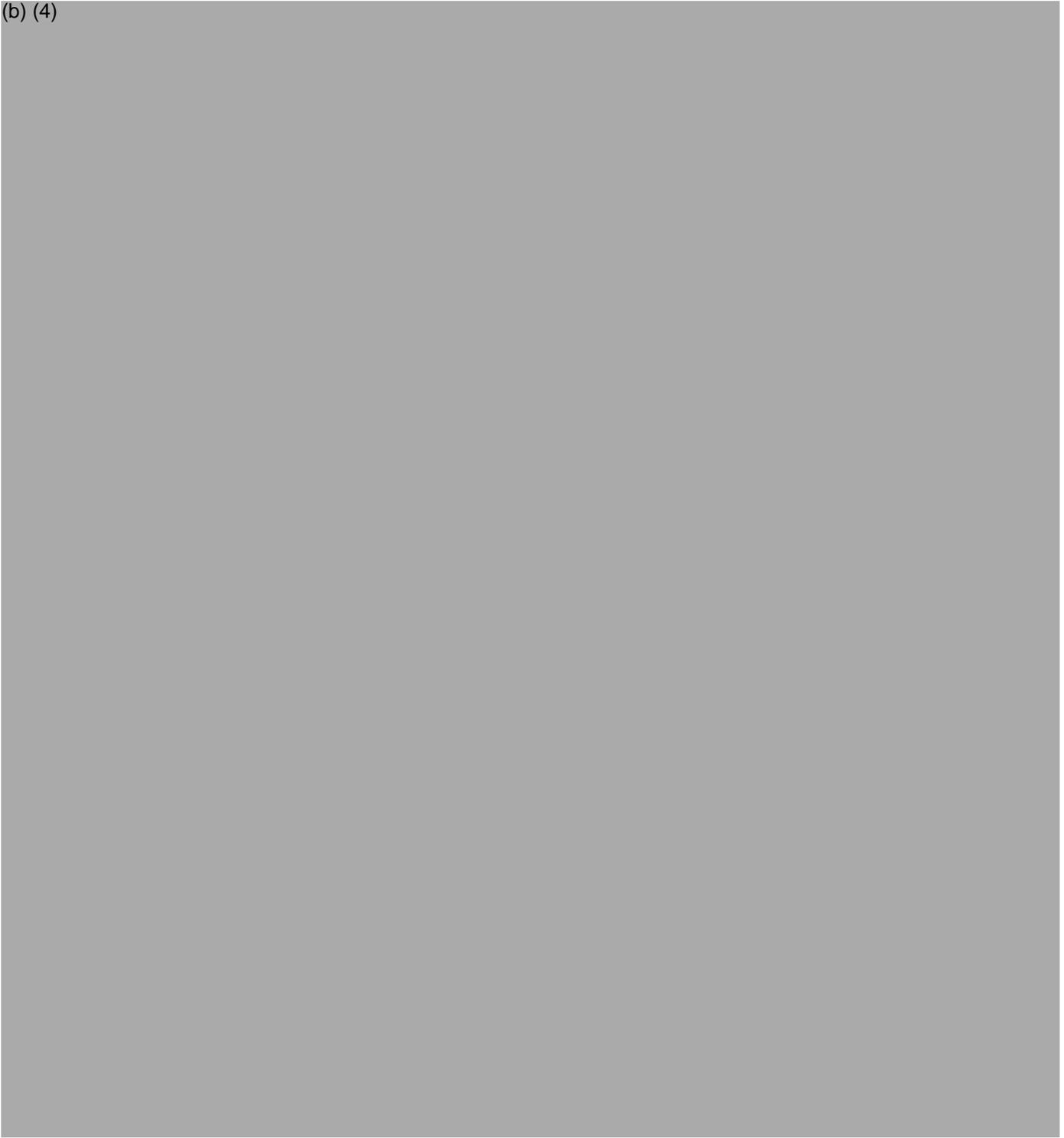
These processes are based Swedish Match's internal requirements of responsibility, certification, safety and security and meet local and Federal regulations and laws. (b) (4)

**Disposition of nonconforming, elapsed, unwanted or unused final product at Owensboro, Kentucky manufacturing facility** – Swedish Match has established, implements, and maintains disposition processes that remove nonconforming, elapsed, unwanted or unused product. These processes are based on Swedish Match's internal requirements of responsibility, safety and security and meet local, State, and Federal regulations (b) (4)

(b) (4) [Redacted text block]

**Traceability chain**

(b) (4)



**Recall -** (b) (4)



**Recall process for Swedish products sent to the Owensboro, Kentucky manufacturing facility** – The contact information on the cans include the relevant U.S. phone number so all U.S. consumer contacts are initiated at the U.S. Consumer Contact Center (Product Recall, QP 8.3.3). (b) (4)

The Consumer Contact Center is staffed by quality control employees who are trained in the consumer/customer complaint handling process. Defective products are defined as:

- Does not match the specification
- Has wrong smell or taste
- Has microbiological activity above upper limit value
- Has incorrect date of production on the product
- Is adulterated in a way that might increase toxicity
- Any other reasonable cause

The information is compiled and sent to Swedish Match North Europe AB. (b) (4)

If the quality deficiency is considered to be potentially harmful to an individual consumer's health, or if the consumer for any other reason should be contacted, the decision and related information will be communicated internally by the recall team to all departments and units concerned.

## References

[Regulation \(EC\) No 178/2002 of the European Parliament and of the Council of 28 January 2002, Chapter II General Food Law, Section 4; General Requirements of Food Law, Article 18; Traceability and Article 19, Responsibilities for food: Food producers.](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:sv)

([http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:sv)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:sv](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:sv)).

[Swedish Food agency directives on snus and chewing tobacco LIVSFS 2012:6, §12 Traceability](http://www.slv.se/upload/dokument/lagstiftning/2012/2012_6_snus_kons.pdf)

([http://www.slv.se/upload/dokument/lagstiftning/2012/2012\\_6\\_snus\\_kons.pdf](http://www.slv.se/upload/dokument/lagstiftning/2012/2012_6_snus_kons.pdf)).

Directive 2000/12/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling presentation and advertising of foodstuffs  
(<http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2000/L/02000L0013-20070112-en.pdf>).

WHO/FAO standards Codex Alimentarius, General Principles of Food Hygiene CAC/RCP 1-1969, Section V Control of Operation; 5.7 Documentation and Records, 5.8 Recall Procedures  
([http://www.codexalimentarius.org/standards/list-of-standards/en/?no\\_cache=1](http://www.codexalimentarius.org/standards/list-of-standards/en/?no_cache=1)).

## Appendices

1. (b) (4) [Redacted]
2. (b) (4) [Redacted]
3. (b) (4) [Redacted]
4. (b) (4) [Redacted]
5. (b) (4) [Redacted]
6. (b) (4) [Redacted]
7. (b) (4) [Redacted]
8. (b) (4) [Redacted]
9. (b) (4) [Redacted]
10. (b) (4) [Redacted]
11. (b) (4) [Redacted]
12. (b) (4) [Redacted]
13. (b) (4) [Redacted]
14. (b) (4) [Redacted]
15. (b) (4) [Redacted]
16. (b) (4) [Redacted]
17. (b) (4) [Redacted]