

H.1.4.3. Swedish Match Corporate Applicable Procedures

List and Summary of All Applicable SOPs (Kungälv, Sweden)

Swedish Match Europe Division, Quality and Environment Management

Swedish Match Europe Division develops, manufactures, and sells quality products with market-leading brands in the product segments snus, chew bags and nicotine pouches (ZYN). Manufacturing is made in five different production plants in Sweden and Denmark.

Production of nicotine pouches, partly sold to USA, is in the Kungälv plant located 25km north of Gothenburg in Sweden.

Swedish Match also has a plant, organized in the US Division, in Owensboro Kentucky. In this plant the main part of the nicotine pouches for the US market is produced.

The R&D function is located in Gothenburg, Stockholm and Owensboro, where the Development departments are in Gothenburg and Owensboro and the Chemical Analytical departments are in Stockholm and Owensboro.

Marketing, Sales and Logistics of snus and nicotine pouch products are handled by the Swedish Match US Division

Standards and certificates, Swedish operations



R&D and QA

Product development and product formulation



(b) (4)

QA processes

Consumer complaints are handled by Swedish Match US Division. (b) (4)
[REDACTED]
[REDACTED]. For products manufactured in Sweden complaints are communicated to the Customer service department in Gothenburg and (b) (4).

The SOP included in the application are:

- CAPA and Nonconforming Products SOP

Supply Chain Kungälv

Manufacturing Processes

Manufacturing of snus and nicotine pouches in Sweden is regulated as food manufacturing and is monitored by the Swedish Food Agency.

Procurement and material acceptance

Suppliers are approved and evaluated by defined processes in the QEMS.

(b) (4)

The SOP:s included in the application are:

- ID and Monitoring of Suppliers SOP
- Incoming Materials Controls SOP

Production

(b) (4)

The SOP included in the application is:

- Hazard Design Analysis

Other Applicable SOPs in QEMS:

- Customer service process
- Initial start-up inspection Packaging
- Instruction for handling of Non-conforming nicotine salt
- Instruction and checklist Pouch weight (SPC) (b) (4)
- Instruction for granulation solution
- Instruction for manufacturing – main process (b) (4)
- Instruction for preparation of pH-adjuster
- Instruction for weighing dry additives
- Instruction for weighing nicotine salt
- Checklist line mechanics