Swedish Code of Statutes

Decree on Tobacco and Similar Products

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The Government prescribes[1] the following.

Chapter 1 Introductory provisions

1 § This decree contains additional provisions to the Act (2018:2088) on Tobacco and Similar Products.

2 §The expressions used in the Act (2018:2088) on Tobacco and Similar Products and in Directive 2014/40/EU of the European Parliament and of the Council of April 3, 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, and repealing Directive 2001/37/EC in its original wording, have the same meaning in this decree.

Chapter 2 Product requirements and mandatory reporting

Tobacco products and herbal products for smoking

1 §The Swedish Public Health Agency must publish such information on

1. emissions and limits for harmful substances having arisen in conjunction with the monitoring of limits according to Chapter 2, §1 of the Act (2018:2088) on Tobacco and Similar Products,
2. ingredients and quantities of these ingredients and analyses of additives reported according to Chapter 2, §2, of the same Act, and
3. ingredients listed on an application for a new tobacco product according to Chapter 2, §3, of the same Act.

Publication must take place on a website. Information constituting proprietary information will not be published.

2 § The Public Health Agency must store such information electronically regarding

1. tobacco products and herbal products for smoking as provided according to Chapter 2, §2, of the Act (2018:2088) on Tobacco and Similar Products,
2. new tobacco products listed on an application for a new tobacco product according to Chapter 2, §3, of the same Act,
3. tobacco products submitted according to Chapter 2, §4, of the same Act, and
4. tobacco products submitted according to Chapter 2, §6, of the same Act.

[1] Cf. Directive 2014/40/EU of the European Parliament and of the Council of April 3, 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, in the original wording.

The Public Health Agency shall keep information according to the first paragraph, items 1 and 4, and the information on ingredients in new tobacco products according to the first paragraph, item 2, available to other Member States and the European Commission. The Public Health Agency shall also keep other information submitted according to the first paragraph, item 2, and information according to the first paragraph, item 3, available to the European Commission.

Electronic cigarettes and refill containers

Product registration

3 §According to Chapter 2, §7, of the Act (2018:2088) on Tobacco and Similar Products, an application must, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

1. name and contact information of the manufacturer, a responsible legal entity or natural person within the European Union and, where applicable, the importer into the EU,
2. a list of all ingredients included in the product and the emissions resulting from use of the product, broken down by brand and type, with information on volumes,
3. toxicological information on the product's ingredients and emissions, including upon heating, particularly in terms of effects on consumer health upon inhalation and with consideration of, among other things, any addictive/habit-forming effects,
4. information on nicotine doses and nicotine uptake upon consumption under conditions that are normal or reasonably foreseeable,
5. a description of the product's components, which, in the current case, include the opening and refill mechanism of the electronic cigarette or refill container,
6. a description of the manufacturing process, including if it includes serial production, and a statement of assurance that the manufacturing process is in conformity with the requirements set on electronic cigarettes and refill containers, and
7. a statement of assurance that the manufacturer and importer take full responsibility for the quality and safety of the product when it is made available to consumers on the market and used under conditions that are normal or reasonably foreseeable.

4 §According to section 3, applications must be submitted electronically through a common web portal in accordance with the annex to Commission Implementing Decision (EU) 2015/2183 of November 24, 2015 establishing a common application format for electronic cigarettes and refill containers.

This information must be submitted through the technical solution provided by the European Commission, known as EU-CEG.

5 §Manufacturers and importers who must submit information according to §3 for the first time must apply for an ID number (Submitter ID) from the administrator of the technical solution provided by the European Commission.

The Submitter ID must be used when submitting information according to §3

6 §Manufacturers or importers must assign each product to be registered according to §3 an e-cigarette ID number (EC-ID) based on the Submitter ID and year of application.

When manufacturers and importers submit information on products with the same composition and design, they must to the greatest extent possible use the same EC-ID, particularly if the information is submitted by various members in a group. This applies regardless of brand, sub-type, and number of markets on which the goods are provided to consumers.

If manufacturers or importers cannot ensure that the same EC-ID is used for products with the same composition and design, they must at least to the greatest extent possible submit information on the various EC-IDs assigned to these products.

7 §Manufacturers and importers who must submit information according to §3 and who believe that the information comprises company secrets or is otherwise confidential must indicate this when the information is submitted.

8 §The Public Health Agency shall publish the information submitted according to Chapter 2, §7, of the Act (2018:2088) on Tobacco and Similar Products on a website. Information constituting proprietary information will not be published.

Content and design

9 §Liquids containing nicotine can only be provided to consumers on the market in

1. appropriate refill containers not exceeding 10 milliliters, or
2. disposable electronic cigarettes or disposable cartridges where the cartridges or tanks do not exceed 2 milliliters.

10 §Liquid containing nicotine may not include

1. more nicotine than 20 milligrams per milliliter,
2. vitamins or other additives that give the impression that an electronic cigarette or refill container entails a health benefit or reduced health risks,
3. caffeine, taurine, or other additives, or stimulating substances associated with energy and vitality,
4. additives that dye emissions, or
5. additives that are carcinogenic, mutagenic, or that cause reproductive toxicity in non-combusted form.

11 §Only ingredients with high purity can be used in the production of liquids containing nicotine.

Traces of substances other than the ingredients that have been reported according to Chapter 3, §2, in the application may occur up to the detection limit only if it is technically impossible to avoid these traces during manufacturing.

12 §With the exception of nicotine, only such ingredients that do not present a risk to human health in heated or unheated form may be used in the production of liquid containing nicotine.

13 §Electronic cigarettes must deliver nicotine doses at a uniform level under normal conditions of usage.

14 §Electronic cigarettes and refill containers must be child-proof and tamper-proof, must be protected against damage and leakage, and have a mechanism that ensures filling without leakage.

The filling mechanism must

1. include use of a refill container with a securely fixed mouthpiece that is at least 9 millimeters in length and that is narrower than, and easily inserted into, the opening on the tank of the electronic cigarette that it is used together with, and must have a flow control mechanism that delivers up to a maximum of 20 drops of refill liquid per minute in vertical position at an atmospheric pressure of 20 ± 5°C, or

2. that works through use of a docking system that only delivers refill liquids to the tank of the electronic cigarette if the electronic cigarette and refill container are connected.

Reporting of sales volumes

15 §Manufacturers and importers must submit the information referred to in Chapter 2, §9, of the Act (2018:2088) on Tobacco and Similar Products every year by no later than March 31, for the previous year.

16 §The Public Health Agency must keep the information reported according to Chapter 2, §9, of the Act (2018:2088) on Tobacco and Similar Products available to other Member States and the European Commission.

The Public Health Agency must publish when a manufacturer or importer has fulfilled their reporting duties according to Chapter 2, §9, of the same law.

Product control

17 §If a manufacturer, importer, or distributor of electronic cigarettes or refill containers makes a notification according to Chapter 2, §11, second paragraph of the Act (2018:2088) on Tobacco and Similar Products, this party must provide information on risks to human health and safety.

Chapter 3 Labeling and packaging

Tobacco products and herbal products for smoking

Health warnings

1 §Packages for tobacco products and herbal products for smoking intended to be provided to consumers on the Swedish market must bear such health warnings as referred to in Chapter 3, §1, of the Act (2018:2088) on Tobacco and Similar Products. The health warnings must be in Swedish and cover the entire surface area reserved for these on the packages. They may not be commented on, reformulated, or referenced in any form.

Design of unit packs

2 §Unit packs of cigarettes must be of a rectangular cuboid shape and consist of cardboard of a soft material. Such packs may not have an opening that can be reclosed or resealed once they have been opened for the first time, other than by having a folding lid or a hinged lid attached to a box. The lid on the unit pack with a folding or hinged lid may only be attached to the rear of the pack.

Unit packs of rolling tobacco must be rectangular cuboid in shape, or cylindrical, or have the form of a pouch.

Traceability

3 §The Public Health Agency is thus the ID issuer as referred to in Commission Implementing Regulation (EU) 2018/574 of December 15, 2017 on technical standards for the establishment and operation of a traceability system for tobacco products.

The Public Health Agency may appoint the role of ID-issuer to an individual. If the Agency decides on such an appointment, it must publish information on the ID issuer's identity and the ID issuer's identification code in accordance with Article 3.7 of the Commission Implementing Regulation.

4 §Article 4.1 second paragraph of Commission Implementing Regulation (EU) 2018/574 of December 15, 2017 on technical standards for the establishment and operation of a traceability system for tobacco products must be applied for tobacco products released on the Swedish market.

5 §Such declarations as referred to in Article 7.2 of Commission Implementing Regulation (EU) 2018/574 of December 15, 2017 on technical standards for the establishment and operation of a traceability system for tobacco products must be submitted to the Public Health Agency.

6 §The Public Health Agency may, under the conditions set out in Articles 15.4, 17.4 and 19.4 of Commission Implementing Regulation (EU) 2018/574 of December 15, 2017 on technical standards for the establishment and operation of a traceability system for tobacco products, decide to deactivate identifier codes.

7 §The Public Health Agency must have full access to the data storage facilities referred to in Chapter 3, §11, of the Act (2018:2088) on Tobacco and Similar Products.

The Public Health Agency is, as such, the national administrator as referred to in Article 25.1 k of Commission Implementing Regulation (EU) 2018/574 of December 15, 2017 on technical standards for the establishment and operation of a traceability system for tobacco products.

The Public Health Agency may, when justified, grant manufacturers and importers access to the stored data.

8 §The report referred to in Chapter 3, §10, second paragraph, of the Act (2018:2088) on Tobacco and Similar Products must be submitted to the Public Health Agency.

Electronic cigarettes and refill containers

Health warnings

9 §A health warning according to Chapter 3, §2, of the Act (2018:2088) on Tobacco and Similar Products must have the following wording: "This product contains nicotine, which is a highly addictive substance."

The health warning must

1. be reproduced on the two largest surfaces on the unit pack and any outer packaging,
2. cover 30% of the surfaces on the unit pack and any outer packaging,
3. be printed in black boldface Helvetica font on a white background,

4. cover the largest possible portion of the area reserved for the warning,

5. be placed in the center of the reserved space, and on cuboid-shaped packs and any outer packaging must be parallel with the side edge of the unit pack or outer packaging, and

6. be parallel with the main text on the area reserved for the warning.

Information leaflet

10 §An information leaflet as referred to in Chapter 3, §5, of the Act (2018:2088) on Tobacco and Similar Products must contain information on

1. instructions for use and storage of the product with mention that the product is not recommended for adolescents and non-smokers,
2. contraindications,
3. warnings addressing specific risk groups,
4. potential harmful effects,
5. addictive properties and toxicity, and
6. contact information for the manufacturer or the importer and a legal entity or natural contact person within the European Union.

11 §Refillable electronic cigarettes and refill containers must include appropriate instructions for filling, including diagrams, as part of the instructions for use referred to in 10, §1.

In the instructions for use for refillable electronic cigarettes and refill containers with a refill mechanism of the type referred to in Chapter 2, §14, second paragraph, item 1, the width of the mouthpiece or tank opening must be indicated so that consumers can determine whether the refill containers and electronic cigarettes are compatible.

In the instructions for use for refillable electronic cigarettes refill containers with a refill mechanism of the type referred to in Chapter 2, §14, second paragraph, item 2, the types of docking systems compatible with such electronic cigarettes and refill containers must be specified.

Declaration of contents

12 §A declaration of contents according to Chapter 3, §6, of the Act (2018:2088) on Tobacco and Similar Products must include

1. a list of all ingredients included in the product in descending order of weight,
2. information on content of nicotine in the product and distribution per dose,
3. the batch number, and
4. a recommendation to keep the product out of reach of children.

Chapter 4 Sales

1 §The municipality shall make decisions in any matter regarding sales permits according to Chapter 5, §1, of the Act (2018:2088) on Tobacco and Similar Products within four months from the date of the municipality's receipt of a complete application.

If necessary because of the investigation, the municipality may decide to extend the processing period by a maximum of four months. The applicant must be informed prior to expiration of the original deadline of the reasons for extension of the processing period.

A decision to extend the deadline may not be appealed.

2 §§8 of the Act (2009: 1079) on services on the internal market contains provisions stating that acknowledgment of receipt must be sent to the applicant once a complete application has been received and specifying the content of such an acknowledgment.

Chapter 5 Smoke-free environments

1 §Such areas as referred to in Chapter 6, §6, of the Act (2018:2088) on Tobacco and Similar Products must be designed and ventilated so that smoke is not spread to other parts of the service area.

Chapter 6 Oversight

1 §The Public Health Agency is responsible for regulatory guidance regarding the municipality's oversight over provisions regarding identification and safety labeling in Chapter 3, §7, of the Act (2018:2088) on Tobacco and Similar Products.

The Public Health Agency exercises oversight to ensure that the provisions regarding traceability and safety labeling in Chapter 3, §§7-10, of the Act on Tobacco and Similar Products and in associated regulations are observed in cases other than when the municipality conducts oversight.

Chapter 7 Fees

Tobacco products and herbal products for smoking

1 §Fees shall be paid according to §§2 and 3 for the Public Health Agency's oversight over Chapter 2 §§1, 2, and 6, of the Act (2018:2088) on Tobacco and Similar Products.

2 §Any party that in accordance with Chapter 2, §2, first paragraph, of the Act (2018:2088) on Tobacco and Similar Products pays fees to the Public Health Agency shall, for each brand and type, pay a fee to the Public Health Agency

1. in the amount of SEK 21,200 for cigarettes,
2. SEK 17,200 for rolling tobacco,
3. SEK 13,200 for tobacco for oral use, and
4. SEK 13,600 for tobacco products not covered by 1-3.

3 §Any party that in accordance with Chapter 2, §6, of the Act (2018:2088) on Tobacco and Similar Products pays fees to the Public Health Agency shall, for each brand and type, pay a fee to the Public Health Agency

1. in the amount of SEK 23,000 for cigarettes,
2. SEK 21,500 for rolling tobacco,
3. SEK 900 for tobacco for oral use, and
4. SEK 2,700 for tobacco products not covered by 1-3.

4 §If special reasons prevail, the Public Health Agency may decide to reduce or waive a fee in individual cases.

Electronic cigarettes and refill containers

5 §Any party that in accordance with Chapter 2, §7, of the Act (2018:2088) on Tobacco and Similar Products registers a product intended to be provided to consumers on the Swedish market shall pay a fee to the Public Health Agency in the amount of SEK 3,000 for each brand and type.

6 §Any party that in accordance with Chapter 2, §7, of the Act (2018:2088) on Tobacco and Similar Products reports a significant change to a product must pay a fee of SEK 2,500 to the Public Health Agency for each brand and type.

7 §Fees pursuant to §§5 and 6 shall be paid to the Public Health Agency in the manner specified by the Agency. Processing of the application begins once the payment has been received by the Agency. The application may be rejected if the payment has not been received by the Agency within 30 days from the date of the authority's specification of how payment must be made.

8 §If special reasons prevail, the Public Health Agency may decide to reduce or waive a fee in individual cases.

9 §The Public Health Agency shall on an annual basis, and by no later than September 01, review, and, as needed, make recommendations to the government (Ministry of Health and Social Affairs) on changes to the fees referred to in §§5 and 6.

Chapter 8 Authorization

Tobacco products and herbal products for smoking

Product requirements and mandatory reporting

1 §The Public Health Agency may issue regulations on

1. which cigarettes and which rolling tobacco shall be considered to have a characteristic taste,
2. what additives in tobacco products shall be prohibited,
3. the limits for harmful substances that tobacco products may contain or give rise to, and
4. measurement and monitoring of such limits.

2 §The Public Health Agency may issue regulations on the duty to provide information as specified in Chapter 2, §2, of the Act (2018:2088) on Tobacco and Similar Products.

Requirements on the registration of new tobacco products

3 §The Public Health Agency may issue regulations on

1. how applications for new tobacco products must be submitted according to Chapter 2, §3, first paragraph, of the Act (2018:2088) on Tobacco and Similar Products,
2. what such an application must include, and
3. the mandatory reporting specified in Chapter 2, §4, first paragraph, of the same Act.

Reporting of marketing costs for tobacco products

4 §The Public Health Agency may issue regulations on the mandatory reporting specified in Chapter 2, §6, of the Act (2018:2088) on Tobacco and Similar Products.

Electronic cigarettes and refill containers

Product registration

5 §The Public Health Agency may issue additional regulations on the design and content of an application according to Chapter 2, §7, of the Act (2018:2088) on Tobacco and Similar Products.

Information leaflet

6 §The Public Health Agency may issue additional regulations on the design and content of the information sheet according to Chapter 3, §5, of the Act (2018:2088) on Tobacco and Similar Products.

Declaration of contents

7 §The Public Health Agency may issue additional regulations on the content and design of the declaration of content according to Chapter 3, §6, of the Act (2018:2088) on Tobacco and Similar Products.

Reporting of sales volumes

8 §The Public Health Agency may issue additional regulations on fulfillment of mandatory reporting duties specified in Chapter 2, §9, of the Act (2018:2088) on Tobacco and Similar Products.

Product control

9 §The Public Health Agency may issue regulations on the system for information collection specified in Chapter 2, §10, first paragraph, of Act (2018:2088) on Tobacco and Similar Products.

10 §The Public Health Agency may issue additional regulations on the duty to notify according to Chapter 2, §11, second paragraph, of the Act (2018:2088) on Tobacco and Similar Products.

Health warnings

11 §The Public Health Agency may issue additional regulations on how health warnings according to Chapter 3, §§1 and 2, of the Act (2018:2088) on Tobacco and Similar Products must be designed.

Traceability and safety labeling

12 §The Public Health Agency may issue regulations on the design of the unique identification labeling and safety labeling according to Chapter 3, §7, of the Act (2018:2088) on Tobacco and Similar Products.

The Public Health Agency shall provide information on safety labeling in the manner indicated in Article 3.3 and 3.4 in the Commission Implementing Decision (EU) 2018/576 of December 15, 2017 on technical standards for security features applied to tobacco products.

13 §The Public Health Agency may issue regulations on

1. mandatory registration and the duty to keep records according to Chapter 3, §§8 and 9, of the Act (2018:2088) on Tobacco and Similar Products and
2. technical standards for establishment and operation of a system for tracing.

Internal auditing programs

14 §The Public Health Agency may issue regulations on the design of the internal auditing programs specified in Chapter 5, §§6 and 7, of the Act (2018:2088) on Tobacco and Similar Products.

Controlled purchase **SFS 2019:223**

15 §The Public Health Agency may issue regulations on the implementation of controlled purchases according to Chapter 7, §22, of the Act (2018:2088) on Tobacco and Similar Products.

Provisions for enforcement

16 §The Public Health Agency may issue regulations on the enforcement of the Act (2018:2088) on Tobacco and Similar Products and of this decree.

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1. This decree enters into force on July 1, 2019.
2. This decree repeals

a) the Decree on Tobacco (2016:354),

b) the Decree (2017:429) on Electronic Cigarettes and Refill Containers.

On behalf of the Government

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