Swedish Code of Statutes

Act on Tobacco and Similar Products

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According to Swedish Parliament's decision[1] the following[2] is prescribed.

Chapter 1 Introductory provisions

Purpose and content of the Act

1 §This Act is intended to limit the health risks and disadvantages associated with the use of tobacco and similar products and exposure to smoke from tobacco and emissions from similar products.

2 §This Act contains provisions for tobacco, electronic cigarettes, and refill containers, herbal products for smoking and on the use of stimulants which in their mode of use are equivalent to smoking, but that do not contain tobacco.

The Act contains provisions on
– product requirements and mandatory reporting (Chapter 2),
– labeling and packaging (Chapter 3),
– marketing (Chapter 4),
– sale (Chapter 5),
– smoke-free environments (Chapter 6),
– oversight (Chapter 7),
– fees (Chapter 8),
– appeals (Chapter 9),
– provisions on penalties and confiscation (Chapter 10), and
– authorization (Chapter 11).

Expressions in the Act

3 §This Act employs terms as defined below:

1. *electronic cigarette*: product that can be used for consumption of nicotine vapor via a mouthpiece, or a component of the product, comprising a cartridge, a tank and a device without cartridge or tank,

2. *refill container*: container thank contains liquid that contains nicotine and that can be used to refill an electronic cigarette,

[1] Prop. 2017/18:156, report 2018/19:SoU3, Parliamentary communication 2018/19:61.
[2] Cf. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 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. See Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

3. *herbal products for smoking*: products based on plants, herbs, or fruits that do not contain tobacco and that can be consumed through combustion,

4. *retail sale*: sales to consumers,

5. *wholesale*: sales other than retail sale,

6. *point of sale*: a given facility or other delimited area for retail sale,

8. *cross-border remote sales*: sales where, at the time the order for the good or product is placed, the consumer is located in Sweden and the point of resale is located in another country, or where the point of resale is located in Sweden and the consumer is located in another Member State, and

9. *Member State:* a state that is a member of the European Union or another state covered by the Agreement on the European Economic Area (EEA) and that has implemented the provisions in Directive 2014/40/EU in national law.

Relationship to other laws

4 §The Act shall not be applied to products classified as narcotics according to the Act on Penal Law on Narcotics (1968:64) or as goods hazardous to health according to the Prohibition of Certain Goods Dangerous to Health Act (1999:42).

With respect to electronic cigarettes and refill containers, the Act shall not be applied to medicines or medical devices covered by the Medicines Act (2015:315) or the Medical Device Act (1993:584).

With respect to electronic cigarettes and refill containers, the Product Safety Act (2004:451) shall also apply.

Chapter 2 Product requirements and mandatory reporting duty

Tobacco products and herbal products for smoking

Flavors, additives and limits

1 § Cigarettes and rolling tobacco with characteristic flavor and tobacco products containing additives banned according to regulations issued on the basis of Chapter 11, §1, may not be provided to consumers on the market. Tobacco products that do not meet the requirements on permitted limits, or the measurement and monitoring of such limits as stated on the basis of Chapter 11, §1, may not be manufactured or provided to consumers on the market.

Goods referred to the second paragraph may not be exported to a country outside the European Union.

Reporting of ingredients

2 §Manufacturers and importers of tobacco products or herbal products for smoking shall provide the Public Health Agency information on ingredients and quantities of these ingredients in tobacco products and in herbal products for smoking.

Manufacturers and importers of tobacco products shall also provide the Public Health Agency information on the effects of the ingredients on health and carry out analyses of additives in cigarettes and rolling tobacco and provide information on the results of these analyses to the Public Health Agency.

Tobacco products and herbal products for smoking may not be provided to consumers on the market if the mandatory reporting duty pursuant to the first paragraph of

and other paragraphs or regulations issued on the basis of Chapter 11, §2, have not been fulfilled.

Registration of new tobacco products

3 §Manufacturers and importers shall register new tobacco products that they intend to provide to consumers on the Swedish market to the Public Health Agency.

A new tobacco product that has not been registered in accordance with the first paragraph, or regulations issued on the basis of Chapter 11, §3, may not be made available to consumers on the Swedish market.

4 §Manufacturers and importers of such new tobacco products registered according to §3 shall submit on an annual basis to the Public Health Agency all new or updated information on the studies, investigations, and other information to be reported in, or in conjunction with, the registration.

Tobacco products may not be provided to consumers on the market if the mandatory reporting duty pursuant to the first paragraph, or regulations issued on the basis of Chapter 11, §3, have not been fulfilled.

Reporting of marketing costs

5 §Manufacturers, wholesalers, and importers of tobacco products shall provide the Public Health Agency information on the costs they have incurred for advertising, other marketing, and sponsorship for such goods.

6 §Manufacturers and importers of tobacco products shall submit to the Public Health Agency on an annual basis studies, reports on sales volumes and, where applicable, such summaries of market surveys as carried out in conjunction with the launch of new tobacco products.

Tobacco products may not be provided to consumers on the market if the mandatory reporting duty pursuant to the first paragraph, or regulations issued on the basis of Chapter 11, §4, second paragraph, have not been fulfilled.

Electronic cigarettes and refill containers

Product registration

7 §Manufacturers and importers of electronic cigarettes or refill containers must register all such products that they intend to provide to consumers on the Swedish market, with the Public Health Agency A new registration shall be submitted for each significant change to the product. The registration must be submitted no later than six months before the product is intended to be provided to consumers on the market. The registration must also be made when the product is withdrawn from the market by the manufacturer or the importer.

Electronic cigarettes and refill containers may not be provided to consumers on the Swedish market if registration according to the first paragraph has not been done. The same applies if the registration does not comply with regulations on how registration must be formulated and what it must include, pursuant to Chapter 11, §6, item 1.

Content and design

8 §Manufacturers and importers of electronic cigarettes and refill containers are responsible for ensuring that the products meet the requirements that follow from regulations on the content and design issued on the basis of Chapter 11, §6, item 2.

Electronic cigarettes and refill containers that do not comply with regulations on content and design issued on the basis of Chapter 11, §6, item 2, may not be provided to consumers on the market.

Reporting of sales volumes

9 §Manufacturers and importers of electronic cigarettes and refill containers must submit to the Public Health Agency on an annual basis

1. complete information on sales volume, broken down by brand and product type,
2. information on preferences in various consumer groups, including young people, non-smokers, and the most important types of current consumers,
3. information on the way in which the products are sold, and
4. summaries of, and comments on, any market surveys regarding such information as specified in 1-3 with a translation into English.

Electronic cigarettes and refill containers may not be provided to consumers on the market if the mandatory reporting duty pursuant to the first paragraph has not been fulfilled. The same applies if reporting does not comply with regulations on mandatory reporting issued on the basis of Chapter 11, §6, item 3.

Product control

10 §Manufacturers, importers, and distributors of electronic cigarettes and refill containers must establish and maintain a system to collect information on all suspected harmful effects that these products have on human health.

This information must be submitted to the Public Health Agency upon request.

11 §If a manufacturer, importer, or distributor of electronic cigarettes or refill containers believes, or has reason to assume, that such a product is not safe or of good quality, or that it otherwise is inconsistent with this Act or related regulations, this party must immediately

1. take the corrective measures necessary to ensure that the product in question is brought into conformity with this Act,
2. withdraw the product, or
3. recall the product.

When an action according to the first paragraph is taken, the Public Health Agency must be immediately notified of the defects of the product, what action has been taken, and the results of the action.

Chapter 3 Labeling and packaging

Health warnings

Tobacco products and herbal products for smoking

1 §Packages for tobacco products and herbal products for smoking intended to be provided to consumers on the market must feature texts and illustrations that provide information on the health risks associated with use

of tobacco and herbal products for smoking and on smoking cessation (health warnings).

Manufacturers and importers are responsible for ensuring that packages for tobacco products and herbal products for smoking bear health warnings.

If a packages for a tobacco product or an herbal product for smoking lacks health warnings, the good or product may not be provided to consumers or, in the case of tobacco products, to retailers on the market. The same applies if the health warnings do not meet regulations on the design of the warnings issued on the basis of Chapter 11, §7.

Electronic cigarettes and refill containers

2 § Packages for electronic cigarettes and refill containers must bear health warnings.

Manufacturers and importers of electronic cigarettes and refill containers are responsible for ensuring that packages for such products bear health warnings.

If a packages for an electronic cigarette or a refill container lacks health warnings, the product may not be provided to consumers on the market. The same applies if the health warnings do not meet regulations on the design of the warnings issued on the basis of Chapter 11, §7.

Product presentation and accompanying information

Tobacco products and herbal products for smoking

3 § The labeling on packages for tobacco products and herbal products for smoking, and on the tobacco product itself, may not

1. suggest that a given tobacco product or herbal product for smoking is less harmful than other such goods or products,
2. contain information on the level of nicotine, tar, or carbon monoxide in tobacco products or herbal products for smoking, or
3. resemble a foodstuff or a cosmetic product.

Nor may labeling on packages for tobacco products or, on the tobacco product itself,

1. suggest that a given tobacco product has environmental benefits, or
2. refer to flavor, aroma, or additives.

The prohibition on reference to flavor, aroma, or additives does not, however, apply to snuff.

Electronic cigarettes and refill containers

4 § The labeling on electronic cigarettes and refill containers, or on the packaging of such products, may not

1. suggest that a given electronic cigarette or refill container is less harmful than other such products,
2. contain information on the content of tar or carbon monoxide in the product,
3. resemble a foodstuff or a cosmetic product,
4. suggest that a given product has environmental benefits, or
5. refer to flavor or additives, except when it comes to flavor additives.

Unit packs and any outer packaging for electronic cigarettes and refill containers may not suggest economic benefits by including printed coupons, discount offers, free distribution, two items for the price of one, or similar offers.

5 §Unit packs for electronic cigarettes and refill containers must include an information leaflet.

Manufacturers and importers of electronic cigarettes and refill containers are responsible for ensuring that unit packs for such products include an information leaflet.

If a unit pack for an electronic cigarette or a refill container is lacking an information leaflet, the product may not be provided to consumers on the market. The same applies if the information leaflet does not have the content and the design pursuant to regulations issued on the basis of Chapter 11, §6, item 6.

6 §Packages for electronic cigarettes and refill containers must come with a declaration of contents.

Manufacturers and importers are responsible for ensuring that packages for electronic cigarettes and refill containers bear a declaration of contents.

If a package lacks a declaration of contents, the product may not be made available to consumers on the market. The same applies if the declaration of contents does not comply with regulations on content and design issued on the basis of Chapter 11, §6, item 7.

Traceability and safety labeling of tobacco products

7 §Unit packs for tobacco products must bear a unique identifier label and a safety label.

Manufacturers and importers are responsible for ensuring that unit packs for tobacco products bear such a label.

Tobacco products may not be provided to consumers or retailers on the market if such labeling is missing.

8 §A business engaged in the trade of tobacco products without conducting retail trade, must make sure that all unit packages are registered when they come into and leave its possession. Actions relating to unit packs taken during their time in the possession of the business must also be recorded. Registered information may not be changed or deleted.

Manufacturers of tobacco products must provide businesses engaged in trade of tobacco products the equipment necessary to register tobacco products purchased, sold, stored, transported, or otherwise handled.

9 §A business engaged in the supply chain for tobacco products must establish a record of all relevant transactions.

10 §Manufacturers and importers of tobacco products must conclude agreements for data storage with an independent third party that will serve as the host for the data storage facility for all relevant information. The data storage facility must be physically located on the territory of the European Union. The agreement and the third party's suitability are subject to approval by the European Commission.

The third party's activities must be monitored by an external auditor, whom shall be recommended and paid by the manufacturer of tobacco products and approved by the European Commission. The external auditor must on an annual basis submit a report to the European Commission and the authority designated by the government.

11 §The European Commission, the authority designated by the government, relevant agencies in other Member States and the external auditor must have full access to the data storage facilities.

The authority designated by the government may, when justified, grant manufacturers and importers access to the stored information. The European Commission can also make such a decision.

Chapter 4 Marketing

Advertising and other marketing

Tobacco products

1 §A business activity that markets tobacco products to consumers may not use commercial advertisements in

1. periodical publications or other comparable publications to which the Freedom of the Press Act applies,
2. audio radio or television programs or television broadcasts by satellite covered by the Radio and Television Act (2010:696), or
3. other transfers or technical recordings to which the Freedom of the Press Act applies.

2 §Marketing of tobacco products to consumers other than referred to §1 is also prohibited. This does not, however, apply

1. to printed publications to which the Freedom of the Press Act applies or in transfers or technical recordings to which the Fundamental Law on Freedom of Expression applies,
2. marketing that consists only of providing tobacco products for sale, or
3. commercial messages within points of sale that are not coercive, solicitous, or encouraging the use of tobacco.

Commercial messages according to the first paragraph, item 3, must be positioned so they are not visible from outside the point of sale, to the greatest extent possible.

Electronic cigarettes and refill containers

3 §A business marketing electronic cigarettes or refill containers to consumers may not use commercial advertisements in periodical publications or other comparable publications to which the Freedom of the Press applies.

4 §A business may not market electronic cigarettes or refill containers to consumers

1. within the information society's services, or
2. in audio radio broadcasts, television broadcasts, or subscription TV covered by the Radio and Television Act (2010:696).

The prohibition in the first paragraph does not, however, apply to

1. marketing that consists only of providing electronic cigarettes or refill containers for sale, or
2. marketing in transfers or technical recordings to which the Fundamental Law on Freedom of Expression applies, with the exception of marketing through commercial advertisements.

Use of trademarks **SFS 2018:2088**

5 §A business that markets either a product other than a tobacco product or a service to consumers may not use a trademark that is wholly or partly used for a tobacco product or according to applicable provisions if the trademark is registered or established for such a good, if the marketing takes place in commercial advertisements in

1. periodical publications or in other comparable publications to which the Freedom of the Press Act applies,
2. audio radio or television programs or television broadcasts by satellite covered by the Radio and Television Act (2010:696), or
3. other transfers or technical recordings to which the Freedom of the Press Act applies.

6 §If a business uses such a trademark referred to in §5 in marketing to consumers in a manner other than described therein, the trader must observe the restraint required by he fact that the trademark can also be associated with the tobacco product.

7 §The provisions in §§ 5 and 6 do not apply

1. in questions regarding a trademark that only occurs in the marketing of tobacco products to a limited extent,
2. in questions regarding a trademark that appears in a form that is clearly distinct from the appearance on the trademark of the tobacco product, or
3. in other cases, if this is unreasonable.

Sponsorship and product placement

8 §Manufacturers, wholesalers, and importers of tobacco products, electronic cigarettes, or refill containers may not sponsor an event or activity accessible by the general public or that can be assumed to have a cross-border effect if such sponsorship can be assumed to promote the sale of tobacco products, electronic cigarettes, or refill containers.

Provisions on the prohibition of sponsorship of programs on radio and television and on product placement in TV are found in the Radio and Television Act (2010:696).

Chapter 5 Trade

Sale of tobacco products

Permits

1 §Only parties holding a permit may conduct retail sale or wholesaling of tobacco products.

Permits are not required for retailers or wholesalers who have neither a registered office or permanent business premises for economic activity in Sweden.

A permit may be valid for a given period of time or indefinitely. If the party applying for a permit intends to conduct retail trade from a point of sale, the permit must indicate the point of sale.

2 §A permit may be granted only to a party demonstrating that he or she, with respect to his or her personal and economic conditions and other circumstances, is eligible to conduct the activity and that the activity will be conducted in accordance with the requirements established in this act.

3 §A permit application must be submitted in writing.

Permits for retail sale are issued by the municipality where the point of sale is located. In the absence of a point of sale, the permit is issued by the municipality where the company wishing to conduct such trade has its registered office or, if the company has no registered office in the country, by the municipality where the company has a permanent business premises.

Permits for wholesale trade are issued by the municipality where the company wishing to conduct such trade has its registered office, or if the company has no registered office in the country, by the municipality where the company has a permanent business premises.

4 §In reviewing an application for a permit for retail sales, the municipality may obtain an opinion from the Police Authority. An application for a wholesale permit may not be granted without obtaining opinions from the Police Authority and Swedish Customs.

The authorities must deliver an opinion on the applicant's general suitability for the activity and in their statement must present the circumstances serving as the basis for their assessment in the individual case.

Cross-border remote sales to Sweden

5 §A business not covered by the permit requirements in §1 may not conduct cross-border remote sales of tobacco products to Sweden without first having registered these sales with the Public Health Agency and receiving confirmation of this registration. The confirmation must be provided promptly.

Internal audits and the submission of information

6 §Any party conducting sales of tobacco products or cross-border remote sales subject to permit requirements must exercise special audit (internal audit) over the sales and will be responsible for ensuring that there is an appropriate internal audit procedure in place.

7 §The internal auditing procedure and the other information necessary for the municipality's review and oversight, or oversight by the Public Health Agency, must be attached to the permit application pursuant to §3, or registration pursuant to §5.

Revised information must be immediately reported to the municipality and the Public Health Agency.

Permit upon changes to the activity

8 §If a party holding a sales permit according to this Act has died or been appointed a trustee according to Chapter 11, §7, of the Parental code with assignments including the business operation and if the estate of the deceased or trustee wishes to continue this operation, an application must be submitted to the municipality. The application must be received by no later than two months after the death or decision on trustee. If the application has not been received by this deadline, the permit shall cease to apply.

If a party holding a permit for retail trade transfers the operation, the stock of tobacco products may also be included in the transfer if the transferee has a permit for retail sale.

9 §A sales permit ceases to apply if the permit holder has entered into bankruptcy. If the bankruptcy estate wishes to continue the business, a new application must be submitted to the municipality. The municipality must process such an application with priority.

A bankruptcy estate or estate of the deceased, or, in questions of distrained property, the Swedish Enforcement Authority, may despite this Act sell tobacco products to the party holding a sales permit for trade in such goods. The same applies when an operation must be closed down as a result of revocation of the permit.

Wholesaler's duty to conduct checks

10 §A party conducting wholesale trade of tobacco products may only sell such goods to a party holding a sales permit. The seller must make sure that the buyer has such a permit.

Information

11 §The municipality must provide information on what applies according to this Act and related regulations.

12 §A business that provides tobacco products for sales must provide the staff the information and the support necessary for the staff to be able to comply with this Act and related regulations.

Unit sales of cigarettes, rolling tobacco, and snuff

14 §A unit pack of

1. cigarettes must contain at least 20 cigarettes,
2. rolling tobacco must contain tobacco weighing at least 30 grams, and
3. individual portion packs of snuff must contain at least 20 portions.

Cigarettes, rolling tobacco, and individual portion packs of snuff may not be provided to consumers on the market in volumes smaller than what is specified in the first paragraph.

Sales of electronic cigarettes and refill containers

Registration

15 §A business with a registered office or permanent place of business for operations in Sweden may not conduct retail trade in electronic cigarettes or refill containers without first registering the sales to the municipality where the sales shall take place.

Cross-border remote sales

16 §A business may not conduct cross-border remote sales of electronic cigarettes or refill containers without having first registered the sales with the Public Health Agency and received confirmation of registration. The confirmation must be provided promptly.

Internal audits and the submission of information

17 §Any party conducting sales according to §15 or 16, must conduct internal controls over the sale sand other handling of electronic cigarettes and refill containers and make sure that there is an appropriate internal audit procedure in place.

The internal audit procedure and the other information necessary for the oversight by the municipality and the Public Health Agency must be attached to the notification of sales according to §15, or registration according to §16. Revised information must be immediately notified to the municipality and the Public Health Agency.

Age restrictions

18 §Tobacco products, electronic cigarettes, and refill containers may not be sold or otherwise distributed as part of business activities to anyone under 18 years of age. The party releasing such a good or product must make sure that the recipient has reached the said age.

If there is special reason to believe that the good or product is intended to be transferred to someone who is below 18 years of age, it may not be released.

At the point of sale there must be an unambiguous and clearly visible sign with information on the prohibition on selling or issuing such goods or products referred to in the first paragraph to anyone who is under 18 years of age.

19 §Tobacco products, electronic cigarettes, and refill containers sold to consumers must be provided in such a way that it is possible to verify the recipient's age. This also applies when sales take place through a vending machine, by mail order, remote sale, or in a similar manner.

20 §Tobacco goods, electronic cigarettes, and refill containers may only be imported into the country by individuals 18 years of age or older.

Personal information in cross-border remote sales

21 §A business that conducts cross-border remote sales with tobacco products, electronic cigarettes, or refill containers may not release personal data about the consumer to the manufacturer of such goods and products or to companies belonging to the same group or to other third parties. Nor may personal data be used or transferred for purposes other than the actual purchase.

Chapter 6 Smoke-free environments

Scope of application

1 §In the context of application of the provisions in this chapter, the term "smoking" refers to

1. smoking of tobacco,
2. inhalation after vaporization or other heating of tobacco,
3. use of electronic cigarettes,
4. smoking of herbal products for smoking, and
5. use of stimulants which in their method of use correspond to smoking but that do not contain tobacco.

Smoking ban

2 §Smoking is prohibited

1. in facilities intended for childcare, school activities or other activities for children or youths and in schoolyards and in equivalent areas outdoors in preschools and daycare centers,
2. in facilities intended for health and medical care,
3. in facilities intended for common use in residential buildings and establishments for special service or care,
4. in modes of transport in domestic public transport, or in facilities and other spaces intended to be used by persons traveling by such means of transport, and in equivalent areas outdoors,
5. in restaurants and at other points of service,
6. in facilities other than those referred to in 1-5 when a public gathering or a public event referred to in Chapter 2, §§1-3, of the Act (1993:1617) on public order is arranged and in facilities intended to be used by persons participating in the gathering or event,
7. in facilities other than those referred to in 1-6 if the public has access to the premises,

8. in fenced outdoors areas intended primarily for athletic activities,
9. on playgrounds to which the public has access, and
10. at the entrance points to such facilities and other spaces referred to in 1-7 to which the public has access.

3 §In hotels and other establishments where temporary accommodations are commercially rented, smoking must be prohibited in a certain number of the rooms or equivalent being made available. With respect to sleeper cars and other spaces made available for temporary accommodation in means of transport in domestic public transport, §2, item 4, shall instead apply.

Exemptions from smoking prohibitions

4 §The provisions in §2 do not apply with respect to housing and other facilities for accommodation that are not temporary.

5 §Despite §2, items 2-4, 6 and 7, smoking is permitted in parts of the facilities or other areas referred to therein if these parts are specifically designated for smoking. The same applies to facilities referred to in §2, item 1, that are made available only for personnel.

6 §Despite §2, item 5, smoking may be permitted in restaurants and in other service locations in separate rooms specifically reserved for smoking. Spaces where smoking is permitted may only constitute a minor section of the area of the point of service. These areas must be situated so that visitors do not have to pass through them. Employees must not need to be more than temporarily present in areas where smoking takes place. Service or other similar activity may not be carried out in spaces where smoking takes place. This does not, however, apply to activities directly connected to the function of the space. Food or drink may not be brought into these areas.

7 §Deviation from §2, items 1-3, 6 and 7, and §3, may be made if there are special reasons for this because of the nature or means of use of the space or area or other circumstances. The same applies for such means of transport, facilities, and other spaces referred to in §2, item 4.

Responsibility to uphold the smoking ban

8 § Any party who, in their capacity as owner or who otherwise has disposal of a facility, another space or an area outdoors covered by any of the provisions in §2, items 1-9, or §3, is responsible for ensuring compliance with the provisions. For areas covered by §2, item 10, it is instead the party who in their capacity as owner or who otherwise has disposal of the premises or space in question inside the entrance that is responsible.

9 §Any party who is responsible according to §8 shall by means of signage clearly communicate the smoking prohibition and when necessary intervene with information and corrective warnings. If any party despite corrective notice smokes where smoking is not permitted, this party may be removed from the premises.

Smoke-free working environment

10 §In cases other than referred to in §§2 and 3, the employer is responsible for ensuring that an employee is not unwillingly exposed to tobacco smoke or emissions from products referred to in §2-5 in the working premises or similar area where the worker is engaged. The term "employee" here refers to any persons referred to in Chapter 1 §2 first paragraph and §3 of the Working Environment Act (1977:1160).

Chapter 7 Oversight

Regulatory responsibility

1 §The Public Health Agency is responsible for regulatory guidance regarding the municipality's oversight according to §3, items 1, 2 and 4, and the oversight of the municipality and the Police Authority according to §4.

The authority designated by the government is, however, responsible for regulatory guidance regarding the municipality's oversight according to §3, item 1, of the provisions on identification and safety labeling in Chapter 3, §7.

The Swedish Consumer Agency is responsible for regulatory guidance regarding municipal oversight according to §3, item 3.

2 §The County Council conducts oversight within the county according to §§3 and 4. Oversight includes

1. monitoring municipal activity and assisting the municipalities with information and advice, and
2. promoting cooperation between various regulatory agencies and between regulatory agencies and others.

3 §The municipality conducts oversight to ensure that this Act and related regulations are observed with respect to

1. health warnings, product presentation, and identification and safety labeling according to Chapter 3, §§1, 3, 4, and 7, at the point of sale,
2. provision of electronic cigarettes and refill containers according to Chapter 2 §§7-9 and Chapter 3, §§2, 5, and 6, at the point of sale,
3. marketing according to Chapter 4, §§1, 2 and §§5-7, with respect to marketing actions at or in connection with the point of sale, and
4. smoke-free environments referred to in Chapter 6, §2, and that are not made available only for personnel and facilities referred to in Chapter 6, §3.

4 §The municipality and the Police Authority conduct oversight to ensure that this Act and related regulations are observed with respect to

1. providing new tobacco products according to Chapter §2, item 3, on points of sale,
2. the sale of tobacco products, in cases other than where cross-border remote sales are concerned, according to Chapter 5, §§1, 6-10, 12 and 14,
3. the reporting of sales of electronic cigarettes and refill containers and internal audits, in cases other than where cross-border remote sales are concerned, according to Chapter 5, §§15 and 17, and
4. age restrictions according to Chapter 5, §§18 and 19.

5 §The Public Health Agency conducts oversight to ensure that this Act and related regulations are observed with respect to

1. product requirements and mandatory reporting duties, in cases other than referred to in §4, according to Chapter 2, §1, first and second paragraphs, and Chapter 2, §§2-11,
2. health warnings, product presentation, and accompanying information, in cases other than referred to in §3, according to Chapter 3, §§1-6,
3. registration according to Chapter 5, §§5 and 16, in cross-border remote sales and internal audits per chapter 5, §§6, 7, and 17, in such remote sales, and
4. prohibition on such manufacturing or import referred to according to regulations issued on the basis of Chapter 11,

6 §The authority designated by the government conducts oversight to ensure that this Act and related regulations are observed with respect to traceability and safety labeling, in cases other than referred to in §3, according to Chapter 3, §§7-11.

7 §The Working Environment Authority conducts oversight to ensure that this Act and related regulations are observed with respect to facilities and other spaces referred to in Chapter 6, §2 and that are made available only for personnel and facilities and other spaces referred to in Chapter 6, §10.

8 §The Swedish Consumer Agency conducts oversight to ensure that this act and related regulations are followed with respect to marketing in cases other than specified in §3, according to Chapter 4, §§1-8.

The provisions of the Marketing Act (2008:486) are applied in connection to oversight by the Swedish Consumer Agency.

A marketing action in conflict with Chapter 3, §3 or 4, or Chapter 4, §§1-8, shall, upon application of §§5, 23, and 26, of the Marketing Act shall be considered unfair to consumers. A marketing action in conflict with Chapter 4, §1, item 2, or §3, item 3, or §4, first paragraph, item 2 or §5, item 2 or 3, may result in market disruption fees in accordance with the provisions of §§29-36 of the Marketing Act. Act (2020:344).

Authority

Tobacco products and herbal products for smoking

9 §A regulatory agency specified in §§2-7, may impose the injunctions or bans necessary to ensure compliance with this Act and related regulations, as part of its regulatory activities.

In a decision on an injunction or a ban, the regulatory agency may impose a fine.

Fines may not be converted into imprisonment.

10 §A municipality may revoke a sales permit if

1. the permit is no longer being used,
2. the permit holder does not meet the requirements applicable for issuance of the permit,
3. illegal activity has been carried out with the permit holder's knowledge at the point of sale or in connection to the point of sale or otherwise within the operation subject to the permit and the permit holder failed to intervene, or
4. the permit holder has been issued a warning without correcting the conditions for which the warning was issued.

11 §In place of revocation according to §10, the municipality may issue a warning to the permit holder if a warning can be considered a sufficient intervention.

A warning may also be issued to permit holders in the event of serious or repeat violations of what applies according to this Act or related regulations.

Electronic cigarettes and refill containers

12 §A regulatory agency specified in §§3-7, may impose the injunctions or bans necessary to ensure compliance with this Act and related regulations, as part of its regulatory activities.

13 §In the event of serious or repeated violations of this Act, the municipality may prohibit any party conducting retail sales of electronic cigarettes

or refill containers from continuing these sales or may issue a warning in cases where a ban may be seen as an excessive intervention. Decisions of the municipality apply immediately, unless otherwise specified in the decision.

A ban may be imposed for a period of up to six months.

14 §If the Public Health Agency observes or has reasonable grounds to assume that a type of or specific electronic cigarettes or refill containers may constitute a serious risk to human health, despite the fact that the product meets the requirements in this Act, the authority may prohibit the products from being made available to consumers on the market. If such products have already been made available to consumers on the market, the Public Health Agency may order the manufacturer, importer, or distributor of the products to withdraw or recall them.

The Public Health Agency must immediately notify the European Commission and the competent authorities of other Member States of measures taken according to the first paragraph and provide other relevant information.

Once the European Commission has announced whether it considers a measure according to the first paragraph to be justified, the Public Health Agency must decide whether the measure shall proceed.

15 §Decisions on injunctions or prohibition according to §§12 and 14 may be associated with fines. Fines may not be converted into imprisonment.

Market surveillance

16 §In questions of such requirements on content and design pursuant to Chapter 2, §8, the Public Health Agency shall conduct market surveillance of electronic cigarettes and refill containers covered by this Act..

Provisions concerning market surveillance are set forth in articles 15.3 and 16-29 in Regulation (EC) no. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

Right to information and access

17 §Upon request, a regulatory agency has the right to receive the information, documents, product samples and similar that are necessary for the agency's oversight according to this Act.

18 §In order to fulfill its duties according to this Act, a regulatory agency has the right to access to areas, facilities, and other spaces concerned by this Act or related regulations and may there conduct investigations and take samples. No compensation is paid for samples collected.

19 §The Police Authority shall, upon request by another regulatory agency, provide the assistance necessary for the application of §18.

A request according to the first paragraph may only be made if

1. on the basis of special circumstances it may be feared that the measure cannot be carried out without resorting to the special powers of police officers according to §10 of the Police Act (1984:387), or

2. if other exceptional reasons exist.

Notification

20 §The municipality and the Police Authority must notify each other of conditions of significance to their oversight.

A municipality that has made a decision in matters according to this Act must send a copy of the decision to the Public Health Agency, the Police Authority, and the county council concerned by the decision.

21 §The municipalities must inform the Public Health Agency if by means of their activities they become aware of anything that may have significance for the oversight of the Public Health Agency.

Controlled purchase

22 §For the purpose of providing documentation of a dialog between the municipality and a party distributing tobacco products, electronic cigarettes, or refill containers of the obligation to make sure that the recipient is at least 18 years of age, the municipality may carry out controlled purchases. The municipality may only employ a person of at least 18 years of age for such purchases.

A controlled purchase may be carried out without notifying the business, in advance of the controlled purchase. The municipality must notify the business of the controlled purchase immediately after its execution.

23 §The outcome of a controlled purchase may not constitute the basis for the municipality to issue an injunction, prohibition, recall, or warning according to §§9-13.

Non-disclosure

24 §Any party who has taken a position in a matter according to this Act may not without authorization disclose or otherwise exploit what he or she has come to know about professional secrets or business conditions.

In general practice, the provisions of the Public Access to Information and Secrecy Act (2009:400) are applied.

Chapter 8 Fees

Sales permit application fee

1 §The municipality may charge a fee for review of the application for sales permit according to Chapter 5, §1, on the grounds determined by the municipal commissioner.

Fees for oversight

2 §A municipality may charge fees for their oversight of any party conducting sales subject to permit according to Chapter 5, §1, and of any party conducting sales subject to mandatory sales reporting according to Chapter 5, §15.

3 §The Public Health Agency may charge fees for its oversight to ensure that manufacturers and importers of tobacco products follow Chapter 2, §§1, 2 and 6.

Product registration fee

4 §The Public Health Agency may charge fees to manufacturers and importers of electronic cigarettes or refill containers for receipt, storage, processing, and analysis of the information submitted to the agency according to Chapter 2, §7.

Chapter 9 Appeals

1 §Decisions according to this Act, or related regulations, may be appealed to the general administrative court.

Leave to appeal is required for appeals to the court of appeal.

Chapter 10 Provisions on penalties and confiscation

1 §Any party that deliberately or through negligence sells tobacco products without a permit shall, if the sale is not permitted according to Chapter 5, §8 or 9, be sentenced for *unlawful sale of tobacco* to fines or up to two years in prison.

A crime as specified in the first paragraph, if serious in nature and committed deliberately, is punishable by a prison term ranging from a minimum of six months to a maximum of six years. When assessing whether the crime is serious, special consideration shall be paid as to whether the violation constituted part of a commercial operation or to a greater extent or has been directed to minors.

2 §Any party who deliberately in violation of the prohibition in Chapter 3, §1, third paragraph, provides tobacco products lacking the prescribed health warnings shall be sentenced for *unlawful tobacco handling* to fines or up to six months in prison.

The same applies for any party who deliberately or through negligence sells or distributes tobacco products in violation of Chapter 5, §18, first or second paragraphs.

If the violation is considered a minor offense, it will not result in liability.

3 §Any party who deliberately or through negligence fails to comply with mandatory registration duty in Chapter 5, §5, first paragraph, shall be sentenced to fines or up to six months in prison.

If the violation is considered a minor offense, it will not result in liability.

4 §Any party who deliberately violates Chapter 3, §2, third paragraph, or §6, third paragraph, or sells electronic cigarettes or refill containers in violation of a prohibition issued in accordance with Chapter 7, §13, shall be sentenced to fines or up to six months in prison.

The same applies for any party who deliberately or through negligence violates Chapter 5, §15 or 16, or sells or distributes electronic cigarettes or refill containers in violation of Chapter 5, §18, first or second paragraph.

If the violation is considered a minor offense, it will not result in liability.

5 §Any party who disregards a penalty order or punitive ban shall not be sentenced to liability according to this Act for the offense or offenses covered by the injunction or prohibition.

6 §Provisions on liability for unlawful import and unlawful export of tobacco products, electronic cigarettes, and refill containers are found in the Act (2000:1225) on penalties for smuggling.

7 §Tobacco goods, electronic cigarettes, and refill containers subject to violations of this act or their value and the proceeds of such offenses shall be declared forfeited, if this is not evidently unreasonable.

Chapter 11 Authorization

Tobacco products and herbal products for smoking

Product requirements and mandatory reporting duty

1 §The government or the authority designated by the government 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 limit values for harmful substances that tobacco products may contain or give rise to, and
4. measurement and monitoring of such limits.

2 §The government or the authority designated by the government may issue additional regulations on the duty to provide information as specified in Chapter 2, §2.

Requirements on the registration of new tobacco products

3 §The government or the authority designated by the government may issue regulations on

1. how the registration of new tobacco products shall be done according to Chapter 2, §3, first paragraph, and what it must include, and
2. the mandatory reporting duty specified in Chapter 2, §4, first paragraph.

Reporting of marketing costs for tobacco products

4 §The government may issue regulations on the scope of the mandatory reporting duty specified in Chapter 2, §5.

The government or the authority designated by the government may issue regulations on the mandatory reporting duty specified in Chapter 2, §6.

Prohibition on certain manufacturing and importation

5 §The government may, if there are special health reasons, issue regulations that certain types of tobacco products may not be manufactured in or imported into Sweden for sales to consumers.

Electronic cigarettes and refill containers

6 §The government or the authority designated by the government may issue regulations on

1. how an application according to Chapter 2, §7, must be formulated and what it must include,
2. product content and design of electronic cigarettes and refill containers according to Chapter 2, §8,
3. fulfillment of the mandatory reporting duty specified in Chapter 2, §9,
4. the system for information collection specified in Chapter 2, §10, first paragraph,
5. the notification duty according to Chapter 2, §11, second paragraph,
6. what information the information leaflet according to Chapter 3, §5, must include and how it must be designed, and
7. the content in and design of the declaration of contents according to Chapter 3, §6,

Health warnings

7 §The government or the authority designated by the government may issue regulations on how health warnings according to Chapter 3, §§1 and 2, must be configured.

Traceability and safety labeling

8 §The government or the authority designated by the government may issue regulations on the design of the unique identification and safety labeling according to Chapter 3, §7.

9 §The government or the authority designated by the government may issue regulations on

1. mandatory registration and the duty to keep records according to Chapter 3, §§8 and 9, and
2. technical standards for establishment and operation of a system for tracing.

Deadlines for decisions on sales permits

11 §The government may issue regulations on the time by which the municipality must make a decision on the sales permit according to Chapter 5, §1.

Internal auditing programs

12 §The government or the authority designated by the government may issue regulations on the design of the internal auditing programs specified in Chapter 5, §§6 and 17.

The design of unit packs for cigarettes and rolling tobacco

13 §The government may, in addition to the requirements that follow from Chapter 5, §14, issue additional regulations on unit packs for cigarettes and rolling tobacco.

Requirements regarding the ventilation of rooms specifically reserved for smoking

14 §The government or the authority designated by the government may issue regulations on the design and ventilation of such rooms that according to Chapter, §6, item 6, are specifically reserved for smoking.

Controlled purchase

15 §The government or the authority designated by the government may issue regulations on the implementation of controlled purchases according to Chapter 7, §22.

Fees

16 §The government or the authority designated by the government may issue regulations on the obligation to reimburse the supervisory authority's costs for sampling and investigation of samples according to Chapter 7, §18.

17 §The government or the authority designated by the government may issue additional regulations on fees according to Chapter 8, §3.

18 §The government or the authority designated by the government may issue regulations on the size of the fees specified in Chapter 8, §4.

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1. This Act enters into force on May 20, 2019 with respect to Chapter 3, §§7-11, Chapter 7, §6, and Chapter 11, §§8 and 9, and otherwise on July 1, 2019.

2. This Act repeals

a. the Tobacco Act (1993:581),

b. the Act (2017:425) on Electronic Cigarettes and Refill Containers.

3. With respect to tobacco products other than cigarettes and rolling tobacco, the provisions in Chapter 3, §§ 7-11, and Chapter 11, §9, first apply for the period beginning 20 May 2024.

4. A retailer, who prior to the Act's entry into force, has applied for the sale of tobacco products according to §12c of the Tobacco Act may continue to conduct such sales if the retailer applies by no later than November 1, 2019 for a sales permit according to the new Act. Sales may continue after such an application pending the decision by the permit authority. For sales taking place before the permit authority has issued a decision regarding the permit, the provisions of the Tobacco Act shall apply.

5. Wholesale of tobacco products may be carried out without a permit until November 1, 2019. If an application for a retail sales permit has been received by the permit authority before this date, the operation may continue until a decision on the permit issue has been announced.

6. Unit packs containing packs of individual portions of snuff manufactured prior to July 1, 2019 and that do not contain at least 20 portions can continue to be provided to consumers on the market after entry into force, though through December 31, 2019 at the latest.

7. Cigarettes and rolling tobacco with characteristic flavor that upon entry into effect have a market share of at least 3% in the European Union in a certain product category may continue to be provided to consumers on the market after entry into force, though through May 20, 2020 at the latest.

On behalf of the Government

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