



# Swedish Code of Statutes

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## Act on Tobacco and Similar Products

**SFS 2018:2088**

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According to Swedish Parliament's decision<sup>1</sup> the following<sup>2</sup> 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 on tobacco, electronic cigarettes, and refill containers, herbal products for smoking and on the use of other products that are similar to smoking but do not contain tobacco. The Act also contains provisions on nicotine-free liquids intended for consumption by means of electronic cigarettes.

The Act contains provisions on

- product requirements and mandatory reporting (Chapter 2),
- labeling and packaging (Chapter 3),
- marketing of tobacco products, electronic cigarettes and refill containers (Chapter 4),
- sales (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). [SFS 2022:1262]

#### Expressions in the Act

**3 §** This Act employs terms as defined below:

1. *electronic cigarette*: a product that can be used for the consumption of nicotine vapor via a mouthpiece, or a component of that product, including a cartridge, a tank, and a device without a cartridge or tank,
2. *refill container*: a container that contains liquid containing nicotine and that can be used to refill an electronic cigarette,

<sup>1</sup> Prop. 2017/18:156, report 2018/19:SoU3, Parliamentary communication 2018/19:61.

<sup>2</sup> 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 product for smoking*: a product based on plants, herbs, or fruits not containing tobacco and that can be consumed by combustion,

4. *retail sale*: sales to consumers,

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

6. *point of sale*: a physical point of sale or a retail website,

7. *physical point of sale*: a specific premises or other defined space for retail sales,

8. *sponsorship*: any form of public or private contribution to an event, activity, or person with the aim or the direct or indirect effect of promoting a good or product,

9. *cross-border remote sales*: sales where, at the time of ordering the good or product, the consumer is located in Sweden and the retailer is located in another country, or where the retailer is located in Sweden and the consumer is located in another Member State, and

10. *Member State*: a State that is a member of the European Union or another State that is party to the Agreement on the European Economic Area (EEA) and that has implemented into national law the provisions of 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. [SFS 2022:1262]

## **Relationship to other laws**

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

With regard to electronic cigarettes and refill containers, the Act shall not apply to medicinal products covered by the Medicines Act (2015:315) or to medical devices and other products covered by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

The Product Safety Act (2004:451) also applies with regard to electronic cigarettes and refill containers. [SFS 2021:623]

## **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 of tobacco products, electronic cigarettes, and refill containers**

### **Advertising and other marketing**

#### *Tobacco products*

**1 §** The marketing of tobacco products to consumers is prohibited. However, the prohibition in the first paragraph must not apply to information in:

1. periodicals or other comparable publications covered by the Freedom of the Press Act, except in the case of commercial advertising,
2. other printed matter covered by the Freedom of the Press Act,
3. television broadcasting, on-demand television or radio broadcasting, except in the case of commercial advertising; or
4. other transmissions or technical recordings covered by the Fundamental Law on Freedom of Expression. [SFS 2022:1262]

**2 §** Inside physical points of sale, it is permitted to use such commercial messages for tobacco products that are not intrusive, solicitous, or encouraging the use of tobacco. Such commercial messages must, to the extent possible, be placed so that they are not visible from outside the point of sale. [SFS 2022:1262]

#### *Electronic cigarettes and refill containers*

**3 §** It is prohibited to advertise electronic cigarettes or refill containers to consumers by means of commercial messages in

1. periodicals or other comparable publications covered by the Freedom of the Press Act,
2. information society services; and
3. television broadcasts, on-demand television or audio radio broadcasts.

The first paragraph does not apply to information to which the Freedom of the Press Act or the Fundamental Law on Freedom of Expression applies, except in the case of commercial advertisements. [SFS 2022:1262]

**4 §** Inside physical points of sale, it is permitted to use such commercial messages for electronic cigarettes and refill containers that are not intrusive, soliciting or encouraging the use of such products. [SFS 2022:1262]

### **Use of trademarks**

**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 the 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 §** Sponsorship promoting tobacco products, electronic cigarettes, or refill containers is prohibited if it can be assumed to have cross-border effects. [SFS 2022:1262]

**9 §** Manufacturers, wholesalers, and importers may not sponsor national events or activities to which the public has access if the sponsorship promotes tobacco products, electronic cigarettes, or refill containers. [SFS 2022:1262]

**10 §** Provisions on the prohibition of sponsorship in radio, television, and on video sharing platforms and on product placement in television and on video sharing platforms are found in the Act (2010:696) on Radio and Television. [SFS 2022:1262]

### **Supplementary provisions on marketing**

**11 §** The provisions of the Marketing Act (2008:486) must apply to marketing that contravenes any of §§1-9 in

1. The Swedish Consumer Agency's oversight under Chapter 7, §8 or
2. an action brought by a business or association referred to in Chapter 47, §§2 and 3 of the Marketing Act.

A marketing action that contravenes any of §§1-9 or Chapter 3, §3 or 4 must, in application of §§5, 23, and 26 of the Marketing Act, be considered inappropriate for consumers. A marketing action that contravenes §1, first paragraph, and that is carried out in a medium referred to in the second paragraph, 3 or 4, or that contravenes §3, first paragraph, 1 or 3, or §5, 2, or 3, may result in a market disruption fine in accordance with the provisions of §§29-36 of the Marketing Act. [SFS 2022:1262]

## **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 fixed period or until further notice. If a permit applicant intends to engage in retail trade from a physical point of sale, the permit must relate to that specific location. [SFS 2022:1262]

**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.

A permit for retail trade is granted by the municipality where the point of sale is located. If there is no physical point of sale, the permit is granted by the municipality where the company wishing to engage in 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 operation.

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. [SFS 2022:1262]

**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*

**13 §** 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. [SFS 2022:1262]

### **Sales of electronic cigarettes and refill containers**

#### *Registration*

**14 §** A business with a registered office or permanent operation for business activities in Sweden may not conduct retail trade in electronic cigarettes or refill containers without first having registered such sales.

The registration must be made to the municipality where the physical point of sale is located. If there is no physical point of sale, the registration must be made to the municipality where the company has its registered office or, if the company has no registered office in the country, to the municipality where the company has a permanent operation. [SFS 2022:1262]

#### *Cross-border remote sales*

**15 §** 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. [SFS 2022:1262]

#### *Internal audits and the submission of information*

**16 §** Any party conducting sales under §14 or 15 must exercise self-monitoring of the sale and other handling of electronic cigarettes and refill containers and ensure that there is a self-monitoring program suitable for the business.

The self-monitoring program and the other information required for oversight by the municipality and the Public Health Agency of Sweden must be attached to the registration of sale under §14 or registration under §15. Changed information must be announced without delay to the municipality or the Public Health Agency of Sweden. [SFS 2022:1262]

### **Age restrictions**

**17 §** Tobacco products, electronic cigarettes, and refill containers may not be sold or otherwise supplied in business activities to any person who has not reached 18 years of age. Any party who provides such a good or product must take measures to ensure that the recipient has reached that age.

If there is particular reason to believe that the goods or products are intended to be dispensed to someone under the age of 18, they may not be dispensed.

Points of sale must display a clear and prominent notice presenting information on the prohibition on selling or supplying goods or products referred to in the first subparagraph to any person under the age of 18. [SFS 2022:1262]

**18 §** Tobacco products, electronic cigarettes, and refill containers sold to consumers must be provided in such a way that the recipient's age can be checked. This also applies when sales are made through vending machines, distance selling, or by similar means. [SFS 2022:1262]

**19** §Tobacco goods, electronic cigarettes, and refill containers may only be imported into the country by individuals 18 years of age or older. [SFS 2022:1262]

### **Personal information in cross-border remote sales**

**20** §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. [SFS 2022:1262]

**21** §[Has been designated Ch. 5, §120 by law (SFS 2022:1262).]

## **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. the use of other products that in terms of their manner of use are equivalent to smoking but do not contain tobacco. [SFS 2022:1262]

### **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, in fenced outdoors areas intended primarily for athletic activities,
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. the prohibition on providing flavored liquids under Chapter 2, §6a in physical points of sale,
2. health warnings, product presentation, and identity- and safety marking in accordance with Chapter 3, §§1, 3, 4, and 7 at physical points of sale,
3. provision of electronic cigarettes and refill containers in accordance with Chapter 2, §§7-9 and Chapter 3, §§2, 5, and 6 at physical points of sale

4. marketing in accordance with Chapter 4, §§1, 2 and 4-7 when it comes to marketing actions at or in connection with physical points of sale, and

5. smoke-free environments as referred to in Chapter 6, §2, which are not exclusively for staff and premises as referred to in Chapter 6, §3. [SFS 2022:1262]

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

1. provision of new tobacco products under Chapter 2, §3 at physical points of sale,
2. sales of tobacco products, in cases other than cross-border distance sales, in accordance with Chapter 5, §§1, 6-10, 12, and 13,
3. registration of the sale of electronic cigarettes and refill containers and self-monitoring, other than in the case of cross-border distance sales, in accordance with Chapter 5, §§14 and 16, and
4. age limit according to chapter 5, §§17 and 18. [SFS 2022:1262]

**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, in cases other than those referred to in §4, in accordance with Chapter 2, §1, first and second paragraphs and Chapter 2, §§2-11,
2. prohibition on flavoring, in cases other than those referred to in §3, under Chapter 2, §6a,
3. health warnings, product presentation, and accompanying information, in cases other than those referred to in §3, in accordance with Chapter 3, §§1-6
4. registration according to Chapter 5, §§5 and 15 for cross-border distance sales and self-monitoring according to Chapter 5, §§6, 7, and 16 for such distance sales, and
5. prohibition of such manufacture or importation as referred to in regulations issued pursuant to Chapter 11, §5. [SFS 2022:1262]

**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 compliance with this Act and associated regulations with regard to marketing, in cases other than those referred to in §3, in accordance with Chapter 4, §§1-9. [SFS 2022:1262]

## **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. with the knowledge of the permitholder, criminal activity has taken place in, or in connection to, the physical point of sale, or otherwise within the permitted activity without the intervention of the permitholder, or
4. a warning has been issued to the permitholder and the conditions that gave rise to the warning have gone unrectified. [SFS 2022:1262]

**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.

**16 §**[Has been designated Ch. 7, §19a by law (SFS 2022:1145).]

#### **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.

#### **Market surveillance**

**19a §**The Public Health Agency of Sweden is the market surveillance authority under Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and

compliance of products and amending Directive 2004/42/EC and Regulations (EC) No. 765/2008 and (EU) No. 305/2011 as regards the products covered by Directive 2014/40/EU. [SFS 2022:1145]

**19b** §For market surveillance under Regulation (EU) 2019/1020, the Public Health Agency has the authority to

1. require, under Article 14(4)(a) to (c), economic operators to provide documents, specifications, data, or information
2. carry out, under Article 14(4)(d), unannounced on-site inspections and physical checks of products
3. gain access, under Article 14(4)(e), to premises, land, or means of transport
4. conduct, under Article 14(4)(f), investigations on its own initiative
5. require, under Article 14(4)(g), economic operators to take appropriate measures to remedy non-compliance or eliminate a risk
6. undertake, under Article 14(4)(h), actions on its own
7. obtain, inspect, and dismantle, under Article 14(4)(j), samples of goods, and
8. order, under Article 14(4)(k), the removal of content on an online interface, the display of a warning, or the restriction of access.

The Public Health Agency may acquire a sample under disguised identity under Article 14(4)(j) of Regulation (EU) 2019/1020 only where this is necessary to achieve the purpose of the control. The agency must inform the economic operator that the acquisition was made under disguised identity as soon as possible without compromising the purpose of such action.

The authority referred to in the first paragraph no. 8 does not apply to databases covered by the Freedom of the Press Act or the Fundamental Law on Freedom of Expression.

When warranted by a change in circumstances, the Public Health Agency must decide that an obligation referred to in the first paragraph of no. 8 will no longer apply. [SFS 2022:1145]

**19c** §The Public Health Agency may issue the orders or injunctions necessary to ensure compliance with Regulation (EU) 2019/1020. [SFS 2022:1145]

**19d** §A decision on an order or injunction under § 19b or 19c may be combined with a fine. [SFS 2022:1145]

**19e** §The Public Health Agency may determine that the decision will apply immediately, when making a decision pursuant to § 19b or 19c. [SFS 2022:1145]

**19f** §The Swedish Police Authority will, at the request of the Public Health Agency, provide the assistance necessary for the Public Health Agency to undertake measures in accordance with § 19b.

Assistance in accordance with the first paragraph may be requested only if

1. it may be feared, due to particular circumstances, that the measure cannot be carried out without recourse to the special powers of a police officer under § 10 of the Police Act (1984:387), or
2. exceptional reasons otherwise prevail. [SFS 2022:1145]

**19g** §The government may issue regulations on the tasks that municipalities must execute with regard to market surveillance under Regulation (EU) 2019/1020. [SFS 2022:1145]

## 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** §A municipality must inform the Public Health Agency if, in the execution of its activities, it becomes aware of any circumstances that may be of significance to the Public Health Agency's oversight or to the agency's market surveillance under Regulation (EU) 2019/1020. [SFS 2022:1145]

## **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 its oversight of operators conducting sales requiring a permit under Chapter 5, §1, operators conducting sales subject to mandatory reporting under Chapter 5, §14, and operators conducting sales of nicotine-free liquids intended for consumption by means of electronic cigarettes. [SFS 2022:1262]

**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.

**4** §The act (2014:140) authorizing the issue of certain regulations on market surveillance of goods and other related oversight states that regulations on fees for market surveillance under Regulation (EU) 2019/1020 may be issued. [SFS 2022:1145]

### **Product registration fee**

**5** §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. [SFS 2022:1145]

**6** §The Public Health Agency may charge fees to manufacturers and importers of tobacco products for receiving, storing, handling, analyzing, and publishing the information submitted to the Agency in accordance with Chapter 2, §§2 and 6. [SFS 2022:1262]

## **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 to any party who intentionally or negligently sells or distributes tobacco products in violation of Chapter 5, §17, first or second paragraph.

Minor infractions must not give rise to liability. [SFS 2022:1262]

**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 to any party who intentionally or negligently violates Chapter 5, §14 or 15, or sells or distributes electronic cigarettes or refill containers in violation of Chapter 5, §17, first or second paragraph.

Minor infractions must not give rise to liability. [SFS 2022:1262]

**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. additives according to Chapter 2, §6a,
2. how a registration under Chapter 2, §7 must be formulated and what it must contain,
3. product content and design of electronic cigarettes and refill containers in accordance with Chapter 2, §8,
4. the fulfillment of the mandatory reporting set out in Chapter 2, §9,
5. the information collection system referred to in Chapter 2, §10, first paragraph,
6. the obligation to notify under Chapter 2, §11, second paragraph,
7. what details information sheets pursuant to Chapter 3, §5 must contain and how they must be formulated, and
8. the content and format of the declaration of contents in accordance with Chapter 3, §6. [SFS 2022:1262]

### **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 prescribe regulations on the design of self-monitoring programs specified in Chapter 5, §§6 and 16. [SFS 2022:1262]

### **The design of unit packs for cigarettes and rolling tobacco**

**13 §** The Government may, in addition to the requirements pursuant to Chapter 5, §13, prescribe further regulations on unit packaging for cigarettes and loose tobacco. [SFS 2022:1262]

### **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.

**19 §**The government may issue regulations on such fees for unique identifiers as referred to in Article 3.9 of Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products. [SFS 2019:124]

### **Delegation of certain administrative tasks**

**20 §**The authority determined by the government may entrust an individual party with the task of being the ID issuer referred to in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products. [SFS 2019:124]

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2018:2088

1. This act enters into force on April 01, 2019 with regard to Chapter 11, §§ 19 and 20, on May 20, 2019 with regard to Chapter 3, §§ 7-11, Chapter 7, § 6 and Chapter 11, §§ 8 and 9, and otherwise on July 01, 2019. [SFS 2019:124]

This Act repeals

- a. the Tobacco Act (1993:581),
- b. the Act (2017:425) on Electronic Cigarettes and Refill Containers.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

2022:1262

1. This law enters into force on August 1, 2022.

2. Liquids intended to be consumed by means of electronic cigarettes, where these liquids were manufactured or released for free circulation before the entry into force, may continue to be made available to consumers on the Swedish market despite the fact that they contain additives that result in a clearly perceptible smell or taste other than tobacco, but no later than through January 1, 2023.

On behalf of the Government

STEFAN LÖFVEN

ANNIKA STRANDHÄLL  
(Ministry of Health and Social Affairs)