

Common code of statutes concerning healthcare, medical care, social services, medicinal products, public health, etc.

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Regulations amending the Public Health Agency of Sweden's regulations (HSLF-FS 2019:20) on self-monitoring programmes for the sale of tobacco products, elec- tronic cigarettes and refill containers;

**HSLF-FS
2023:xx**

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adopted on **DDMMYYYY.**

The Public Health Agency of Sweden, by virtue of Chapter 8, Section 14 of the Ordinance (2019:223) on Tobacco and Similar Products and Section 4(7) of Ordinance (2022:1263) on Tobacco-free Nicotine Products hereby lays down¹ as regards the Agency's regulations (HSLF-FS 2019:20) on self-monitoring programmes for the sale of tobacco products, electronic cigarettes and refill containers

that the title of the Agency's regulations should read as follows;

that Sections 1-4, 7-9, 12 and 13 and the heading immediately before Section 3 shall read as follows;

that two new sections shall be introduced, Sections 15 and 16, and, immediately before Sections 15 and 16, a new heading with the following wording.

The statute will therefore be worded as follows from the date this statute enters into force.

The Public Health Agency of Sweden's regulations on self-monitoring programmes for the sale of tobacco

¹ 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.

products, electronic cigarettes and refill containers and tobacco-free nicotine products

Scope

Section 1 This regulation contains rules on the design of a self-monitoring programme pursuant to the Act (2018:2088) on Tobacco and Similar Products and the Act (2022:1257) on Tobacco-free Nicotine Products. (*HSLF-FS 2023:XX*).

Section 2 This statute applies to the:

1. Retail trade of tobacco products, electronic cigarettes and refill containers and tobacco-free nicotine products for traders having their registered office or a permanent establishment in Sweden.
2. Wholesale trade of tobacco products by traders having their registered office or a permanent establishment in Sweden.
3. Cross-border distance sales of tobacco products, electronic cigarettes and refill containers to Sweden.
4. Retail of tobacco-free nicotine products to Sweden in cases where the trader does not have a registered office or permanent establishment for business activities in Sweden. (*HSLF-FS 2023:XX*).

Terms and definitions

Section 3 The words and definitions used in the Act (2018:2088) on Tobacco and Similar Products and the Act (2022:1257) on Tobacco-free Nicotine Products have the same meaning in these regulations. (*HSLF-FS 2023:XX*).

Section 4 A self-monitoring programme documents the procedures needed in the activities to which the self-monitoring programme applies. (*HSLF-FS 2023:XX*).

Updating of self-monitoring programmes

Section 5 A self-monitoring programme shall be regularly reviewed and, if necessary, updated. *HSLF-FS 2019:20*

Language requirements

Section 6 A self-monitoring programme shall be written in Swedish or English. *HSLF-FS 2019:20*

In general, what a self-monitoring programme should contain

Section 7 A self-monitoring programme shall include:

1. Company name;
2. Details of the activities to which the self-monitoring programme applies.

In addition to the provisions of the first subparagraph, a self-monitoring programme shall: contain at the minimum the procedures that ensure compliance with the requirements arising from the Tobacco and Similar Products Act (2018:2088), the Act (2022:1257) on Tobacco-free Nicotine Products and these regulations during sales of tobacco products, electronic cigarettes and refill containers and tobacco-free nicotine products. (*HSLF-FS 2023:XX*).

Retail trade of tobacco products, electronic cigarettes and refill containers

Section 8 For retail trade, the self-monitoring programme shall show how the trader ensures that:

1. the tobacco products sold are reported in accordance with Chapter 2, Section 2 of the Act (2018:2088) on Tobacco and Similar Products;
2. the tobacco products, electronic cigarettes or refill containers sold are notified in accordance with Chapter 2, Section 3 or Chapter 2, Section 7 of said Act;
3. the packages of tobacco products, electronic cigarettes and refill containers sold comply with the requirements for labelling and declaration of contents in accordance with Chapter 3, Sections 1-6 of said Act;
4. there is a clear and visible message at the point of sale with information on the prohibition on selling or dispensing tobacco products, electronic cigarettes and refill containers to those who have not reached the age of 18 under Chapter 5, Section 17, third paragraph, of said Act;
5. age verification of the recipient is carried out both during sales and dispensing in accordance with Chapter 5, Sections 17 and 18 of said Act; and
6. the personnel are informed and receive the support they need in order to be able to comply with the Act on Tobacco and Similar Products and associated regulations. (*HSLF-FS 2023:XX*).

Retail trade of tobacco products

Section 9 For retail trade of tobacco products, in addition to the provisions in Section 8, it shall be clear from the self-monitoring programme how the trader ensures that:

1. the unit packets sold comply with the requirements for identity and security features in accordance with Chapter 3, Section 7 of the Tobacco and Similar Products Act (2018:2088);
2. advertising and other marketing of tobacco products at or in connection with the point of sale complies with the requirements of Chapter 4, Sections 1, 2 and 5 of said Act; and
3. that a unit packet of tobacco products does not contain smaller amounts than that specified in Chapter 5, Section 13 of said Act. (HSLF-FS 2023:XX).

Retail sale of electronic cigarettes and refill containers

Section 10 For retail sale of electronic cigarettes and refill containers, in addition to what is stated in Section 8, it shall be clear from the self-monitoring programme how the trader ensures that the electronic cigarettes and refill containers sold comply with the requirements on content and design in accordance with Chapter 2, Section 8 of the Tobacco and Similar Products Act (2018:2088). HSLF-FS 2019:20

Wholesale trade of tobacco products

Section 11 For wholesale trade of tobacco products, the self-monitoring programme shall show how the trader ensures that:

1. the packaging sold meets the requirements for labelling and declaration of contents in accordance with Chapter 3, Sections 1 and 3 of the Tobacco and Similar Products Act (2018:2088);
2. The unit packets sold comply with the requirements for identity and security features in accordance with Chapter 3, Section 7 of said Act;
3. the person to whom the sale is made has a permit in accordance with Chapter 5, Section 10 of said Act; and
4. the personnel are informed and receive the support they need in order to be able to comply with the Tobacco and Similar Products Act and related regulations in accordance with Chapter 5, Section 12 of said Act. HSLF-FS 2019:20

Cross-border distance sales to Sweden

Section 12 In cross-border distance sales to Sweden, the self-monitoring programme shall show how the trader ensures that:

1. the tobacco products sold are reported in accordance with Chapter 2, Section 2 of the Act (2018:2088) on Tobacco and Similar Products;
2. the tobacco products, electronic cigarettes or refill containers sold are notified in accordance with Chapter 2, Section 3 or Chapter 2, Section 7 of said Act;
3. the packaging sold complies with the labelling and content declaration requirements in accordance with Chapter 3, Sections 1-6 of the Tobacco and Similar Products Act;
4. age verification of the recipient is carried out both during sales and dispensing in accordance with Chapter 5, Sections 17 and 18 of said Act; and
5. the personnel are informed and receive the support they need in order to be able to comply with the Act on Tobacco and Similar Products and associated regulations. (HSLF-FS 2023:XX).

Cross-border distance sales of tobacco products

Section 13 In cross-border distance sales of tobacco products to Sweden, in addition to what is stated in Section 12, a self-monitoring programme shall show how the trader ensures that:

1. the unit packets of tobacco products sold comply with the requirements for identity and security features in accordance with Chapter 3, Section 7 of the Tobacco and Similar Products Act (2018:2088); and
2. that a unit packet of tobacco products does not contain smaller amounts than that specified in Chapter 5, Section 13 of said Act. (HSLF-FS 2023:XX).

Cross-border distance sales of electronic cigarettes and refill containers

Section 14 In cross-border distance sales of electronic cigarettes and refill containers to Sweden, in addition to what is stated in Section 12, it shall be clear from the self-monitoring programme how the trader ensures that the electronic cigarettes and refill containers sold comply with the requirements on content and design in accor-

Retail trade of tobacco-free nicotine products

Section 15 For retail trade of tobacco-free nicotine products, the self-monitoring programme shall show how the trader ensures that:

1. the tobacco-free nicotine products sold are notified in accordance with Section 5 of the Act (2022:1257) on Tobacco-free Nicotine Products;
2. the packaging of tobacco-free nicotine products sold complies with the requirements for labelling and declaration of contents in accordance with Sections 7-8 of said Act;
3. there is a clear and visible message at the point of sale with information on the prohibition on selling or dispensing tobacco-free nicotine products to those who have not reached the age of 18 in accordance with Section 19(3) of said Act;
4. age verification of the recipient is carried out both during sales and dispensing in accordance with Sections 19-20 of said Act; and
5. advertising and other marketing of tobacco-free nicotine products at or in connection with the point of sale complies with the requirements of Sections 9-10 of said Act. (*HSLF-FS 2023:xx*).

Retail trade to Sweden

Section 16 For retail trade of tobacco-free nicotine products to Sweden, where the trader does not have a registered office or a permanent establishment for business activities in Sweden, the self-monitoring programme shall show how the trader ensures that:

1. the tobacco-free nicotine products sold are notified in accordance with Section 5 of the Act (2022:1257) on Tobacco-free Nicotine Products;
2. the packaging of tobacco-free nicotine products sold complies with the requirements for labelling and declaration of contents in accordance with Sections 7-8 of said Act; and
3. age verification of the recipient is carried out both during sales and dispensing in accordance with Sections 19-20 of said Act; and (*HSLF-FS 2023:XX*).

Public Health Agency of Sweden

HSLF-FS
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KARIN TEGMARK WISELL

Bitte Bråstad

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