

Common Code of Statutes concerning healthcare, medical care, social services, medicinal products, public health, etc.

ISSN xxx-xxxx, Article number xxxxxxxx

Published by: Head of Legal Department, Pär Ödman, National Board of Health and Welfare

The Public Health Agency of Sweden's regulations on tobacco-free nicotine products;

**HSLF-FS
2023:24**

Published on xx
July 20xx

adopted on 17 May 2023.

By virtue of Section 4 of the Ordinance (2022:1263) on Tobacco-free Nicotine Products, the Public Health Agency hereby lays down¹ the following.

Introductory provisions

Scope

Section 1 These regulations supplement the provisions of the Act (2022:1257) on Tobacco-free Nicotine Products and the Ordinance (2022:1263) on Tobacco-Free Nicotine Products.

Section 2 These regulations shall be applied by manufacturers, importers and distributors of tobacco-free nicotine products that are to be made available to consumers on the market.

The regulations contain provisions on product notification, labelling, reporting obligations and notification obligations.

Definitions

Section 3 Terms and concepts used in the Act (2022:1257) on Tobacco-free Nicotine Products and the Ordinance (2022:1263) on Tobacco-free Nicotine Products have the same meaning in these regulations.

Section 4 The following terms are also used in these regulations:

¹ Notification has been made in accordance with 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.

1. *distributor*: any natural or legal person in the supply chain other than the manufacturer and importer making tobacco-free nicotine products available on the market;
2. *marketing area*: an area intended for commercial advertising in the media as referred to in Section 10, first paragraph, points 1 and 2, of the Act (2022:1257) on Tobacco-free Nicotine Products;
3. *unit packet*: the smallest individual packaging for tobacco-free nicotine products placed on the market;
4. *outer packaging*: any packaging in which tobacco-free nicotine products are placed on the market containing a unit packet or a number of unit packets; transparent wrappings are not considered to be outer packaging.

Product notification

Section 5 Product notification pursuant to Section 5 of the Act (2022:1257) on Tobacco-free Nicotine Products shall be submitted in the format that is used in the technical solution for product notification provided by the Public Health Agency.

Labelling

Declaration of contents

Section 6 A declaration of contents pursuant to Section 11 of the Ordinance (2022:1263) on Tobacco-free Nicotine Products shall be provided on one of the largest surfaces of the unit packet and the outer packaging and cover 20 per cent of this surface. In all other respects, the declaration of contents shall comply with the requirements laid down in Section 9, points c to e and g.

Section 7 The declaration of contents shall be in Swedish.

Section 8 Declarations of contents pursuant to Section 6 may be affixed using stickers, provided that such stickers cannot be removed.

Health warning

Section 9 The health warning referred to in Section 12 of the Ordinance (2022:1263) on Tobacco-free Nicotine Products shall:

- a. be provided on the two largest surfaces of the unit packet and any outer packaging;
- b. cover 30 percent of the surfaces of the unit packet and any outer packaging;
- c. be written in bolded Helvetica font;

- d. be written in black on a white background;
- e. be written in a font size such that the text covers the largest possible percentage of the area reserved for the labelling;
- f. be located at the centre of the reserved area, and on rectangular packaging and any outer packaging, shall be parallel to the side edge of the unit packet or outer packaging; and
- g. be parallel to the main text in the area reserved for these warnings.

Section 10 Health warnings pursuant to Section 9 may be affixed using stickers, provided that such stickers cannot be removed.

Health warning in marketing

Section 11 In marketing in accordance with Section 10, first paragraph, points 1 and 2 of the Act (2022:1257) on Tobacco-free Nicotine Products, a health warning in accordance with Section 12 of the Ordinance (2022:1263) on Tobacco-free Nicotine Products shall be clearly visible every time the product or a trademark for the product is featured. The health warning shall cover 30 percent of the marketing surface area and in all other respects comply with the provisions of Section 9, points c to e and g of these regulations.

In marketing in accordance with Section 10, first paragraph, point 3, of the Act (2022:1257) on Tobacco-free Nicotine Products, a health warning in accordance with Section 12 of the Ordinance (2022:1263) on Tobacco-free Nicotine Products shall be clearly visible every time the product or a trade mark for the product is featured. The health warning shall in all other respects comply with the provisions of Section 9, points c to e, of these regulations.

Reporting obligation

Section 12 Information in accordance with Section 14 of the Act (2022:1257) on Tobacco-free Nicotine Products shall be provided in the same technical solution as is used for product notification pursuant to Section 5 of these regulations.

Notification obligation

Section 13 Notification from a manufacturer, importer and distributor in accordance with Section 16, second paragraph, of the Act (2022:1257) on Tobacco-free Nicotine Products shall be provided in the same technical solution as is used for product notification pursuant to Section 5 of these regulations.

**HSLF-FS
2023:24**

Sections 5 and 12 of these regulations shall enter into force on 1 January 2024; all other sections shall enter into force on 1 July 2023.

Public Health Agency of Sweden

**HSLF-FS
2023:24**

KARIN TEGMARK WISELL

Bitte Bråstad