

General Code of Regulations Regarding Health and Patient Care, Social Services, Medicines, Public Health etc.

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Public Health Agency of Sweden regulations regarding the design and positioning of health warnings on tobacco product packaging;

**HSLF-FS
2016:46**

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declared this 26th April 2016.

The Public Health Agency of Sweden decrees¹ the following, pursuant to 8 § of the Tobacco Regulation (2016:354).

Chapt. 1 Introductory provisions

Area of application

1 § This Executive Order provides supplementary regulations for the Tobacco Act (1993:581) and Tobacco Regulation (2016:354).

2 § These regulations refer to health warnings on single packets and any outer packaging of tobacco products that are intended for marketing to consumers as per 9 § of the Tobacco Act (1993:581).

Term Definitions

3 § Terms and concepts that are used in the Tobacco Act (1993:581) and Tobacco Regulation (2016:354) have the same meaning in these regulations.

4 § These regulations also use the following term definitions as per Article 2 of European Parliament and Council Directive 2014/40/EU of the 3rd of April 2014 on the harmonisation of member state laws and other Executive Orders regarding the manufacture, presentation and sale of tobacco products and related products, and on the abrogation of Directive 2001/37/EC²:

- Cigarette: a roll of tobacco that can be consumed via combustion and which is defined in more detail in Article 3.1 of the European Parliament and Council Directive

¹ Cf. European Parliament and Council Directive (2014/40/EU) of the 3rd of April 2014 on harmonization of member state laws and executive orders, constitution on the production, and sale of tobacco and related products and the abrogation of Directive 2001/37/EC, in the original formulation (EUT L 127, 29.4.2014, s. 17–21 and 34–35, Celex 32014L0040).

² (EUT L 127, 29.4.2014, s. 10–12, Celex 32014L0040)

2011/64/EU of the 21st of June 2011 on the structure and tax rates for excise duties on tobacco products³.

- Health warnings: a warning as to the negative effects that products have on human health, or other undesirable consequences arising from consumption of same, including warning texts, health warning, combined health warnings, general warnings and information text.
- Importer: The owner of, or a physical or legal person, with disposal rights for tobacco products that have been introduced into the EU area.
- Combined health warning: A health warning that consists of a combination of text warning and an accompanying picture, or an accompanying illustration.
- Pouch: A single packet of rolling tobacco, either in form of, from a rectangular pocket with a flap that covers the opening, or in the form of a flat bottomed pouch.
- Rolling tobacco: tobacco that consumers or retail outlets can use to make cigarettes.
- Smoke free tobacco products: A tobacco product that is not consumed by combustion, amongst other things plug chewing tobacco for nasal ingestion and tobacco taken orally.
- Single packet: the smallest individual packaging for tobacco products, or related products placed on the market.
- Manufacturer: Any physical or legal person that manufactures a product, or arranges their construction or production and offers the product for sale under their name or trade mark.
- Hookah tobacco: A tobacco product that can be consumed via a water pipe. Hookah tobacco is regarded as a tobacco product for smoking. In the event that a product can be used both via a water pipe and as rolling tobacco it is deemed to be rolling tobacco.
- Tobacco products for smoking: Tobacco products other than smoke free tobacco products.
- Outer packaging: Each individual package in which tobacco or related products are placed on the market and that contains a single packet or a number of single packets, whereby transparent covering is not regarded as outer packaging.

5 § These regulations also apply to the definition of a flip-top arrangement for single packets with a foldable lid. Flip-top is used in Article 4 of the Commission's enforcement order (EU) 2015/1842 of the 9th of October 2015 on the technical specifications for the design and form of combined health warnings for tobacco products for smoking⁴.

General provisions

6 § Health warnings on single packets and any outer packaging shall be printed in such a way that they cannot be removed or rubbed off and are fully visible. This means they must not be completely or partially hidden or broken by the tax mark, price mark, security marking, cover, casing, box or other arrangement when said tobacco product is placed on the market

³ (EUT L 176, 5.7.2011, s. 26, Celex 32011L0064)

⁴ (EUT L 267, 14.10.2015, s. 7, Celex 32015D1842)

On single packets of tobacco products other than cigarettes and rolling tobacco, health warnings may be attached using a sticky label, assuming that the label is cannot be removed. **HSLF-FS 2016:46**

7 § Health warnings shall remain intact when the single packet is opened, except for packaging with a foldable lid, flip-top, where the warning may be broken when the packet is opened, but only in way that ensures the graphic integrity and visibility of text, picture and stop smoking info.

8 § Health warnings must not in any way hide or break tax markings, price markings, tracking or security markings safety on the single packets.

9 § The dimensions of health warnings shall be calculated vis-à-vis the relevant surface when the packet is closed.

10 § health warnings shall be edged with a black rim with a width of 1 mm inside the surface reserved for the warning.

Chapt. 2 Health warnings on packaging for cigarettes, rolling tobacco and hookah tobacco.

1 § The following chapter refers to the following categories of tobacco products for smoking

- cigarettes,
- rolling tobacco, and
- hookah tobacco.

Packaging for these tobacco products shall carry a general a warning and an information text, along with a combined health warning.

General warning and information text

2 § Every single packet, and any outer packaging of tobacco products for smoking as per this chapter shall carry the following general warning:

Smoking Kills

3 § Every single packet, and any outer packaging of tobacco products for smoking as per this chapter shall carry the following information text:

Tobacco smoke contains over 70 carcinogenic substances

Positioning and size

Box shaped packaging

4 § For cigarettes and rolling tobacco with a rectangular box shaped packaging, the general warning must also be shown on the lower part of the single

packet's side surface. These health warnings shall have a width of at least 20 mm.

Carton shaped packaging with a foldable lid

5 § For packets with a flap carton arrangement involving a hinged lid, where the side areas are split when the packet is opened, the general warning and informational text must be placed in their entirety on the biggest of the two split areas. The general warning must also be carried in the inside of the upper area which is visible, when the packet is open.

The side areas on this type of packet must be at least 16 mm in height.

Cylindrical packaging

6 § For rolling tobacco in cylindrical packets, the general warning must be placed on the outer side of the lid's area and the information text on the inside of the lid's area.

Both the general warning and informational text must cover 50 % of the surface on which they are imprinted

Pouches

7 § For rolling tobacco in rectangular packets with a flap that covers the opening, the general warning and information text shall be placed be printed on the two surfaces that become visible when the single packet is fully opened, as per the illustrations in sections 1 and 2 in the appendix of the Commission's Executive Order (EU) 2015/1735 of the 24th of September 2015 on the exact positioning, of the general warning and formation text on rolling tobacco marketed in pouches 5.

8 § The general warning and information text shall be positioned on the upper edge and shall cover 50 % of the surface on which they are imprinted , as per the illustrations in sections 1 and 2 in the appendix of the Commission's Executive Order (EU) 2015/1735⁶.

The general warning shall be printed on the upper the surface.

Standing Pouches

9 § For rolling tobacco in standing pouches, the general warning and information text must be placed at the bottom of the upright pouch, which becomes visible when the pouch is placed on its back, as per the illustration in the Commission's Executive Order (EU) 2015/1735⁷.

10 § The general warning must be printed on the area above the crease in the single packet's base, and the information text on the area beneath the crease. The general warning and information text shall cover 50 % of the respective

⁵ (EUT L 252, 29.9.2015, s. 52–53, Celex 32015D1735)

⁶ (EUT L 252, 29.9.2015, s. 52–53, Celex 32015D1735)

⁷ (EUT L 252, 29.9.2015, s. 55, Celex 32015D1735)

surfaces on which they are printed. These surface areas shall be calculated on the basis of their dimensions when the edges are sealed.

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Other Pouches

11 § With regard to rolling tobacco marketed in pouches not covered by the provisions in §§7–10, the general warning and information text shall be placed exists, is found, is, are situated on those surfaces where the health warning's full visibility can be ensured.

Both the general warning and informational text must cover 50 % of the surface on which they are imprinted

Design

12 § The general warning and information text shall be

- a. be printed in bold type in Helvetica font
- b. printed in black on a white background,
- c. printed with a font size that ensures the biggest possible area of the surface area reserved for the health warning and information text and
- d. be centred in the area reserved for them, and for box shaped packaging and any exterior packaging, the texts shall be parallel with the side edge on the single packet or on the outer packaging.

Combined Health Warnings

13 § Every single packet, and any outer packaging for cigarettes, rolling tobacco and hookah tobacco must carry a combined health warnings. These combined health warnings shall

- a. contain one of the warning texts shown in appendix 1 of these regulations and a corresponding colour photo from the picture collection in appendix II of the European Parliament and Council Directive 2014/40/EU²,
- b. contain stop smoking information as per appendix 2,
- c. cover 65 % of both the outer front side and rear of a single packet and any outer packaging. Cylindrical packaging shall display two equidistant combined health warnings and each health warning shall cover 65 % of the respective rounded surfaces
- d. show the same warning text and corresponding colour photo on both sides of the single packet and any outer packaging,
- e. be reproduced on the upper edge of a single packet and any outer packaging and positioned in the same direction all as the other information on this packaging surface,
- f. be reproduced in accordance with 15–25 §§, and
- g. on single packets of cigarettes, have the following dimensions: height at least 44 mm.; width at least 52 mm.

⁸ As per the Commission's delegated Directive 2014/109/EU of the 10th of October 2014 on amendments to appendix II of European Parliament and Council Directive 2014/40/EU for the establishment of a catalogue with warning pictures to be used on tobacco products (EUT L 360, 17.12.2014, s. 24–27, Celex 32014L0109).

14 § The combined health warnings are divided into three sets as per the manner shown appendix II of European Parliament and Council Directive 2014/40/EU⁹. Each set shall be used in a given year and alternate on a yearly basis. Each combined health warning that is used during a given year shall, to the greatest extent possible, be spread numerically equally across each tobacco brand.

Layout

15 § If the height of the combined health warning is over 20 % but less than 65% of its width, the manufacturer shall display the combined health warnings in a side by side format as per the illustration in point 2 of the appendix in the Commission's Executive Order (EU) 2015/1842 of the 9th of October 2015 regarding the technical specifications for the layout, design and form of the combined health warnings for tobacco products for smoking¹⁰.

16 § If the height of the combined health warning is at least 65% but less than 70% of its width, the manufacturer can choose either a stacked or side by side format, as long as all the elements in the combined health warning remain fully visible and nothing is distorted.

17 § If the height of the combined health warning is greater than 70% of its width the manufacturer shall place the component parts of the combined health warnings below each other as per the illustration in point 1 of the appendix in the Commission's Executive Order (EU) 2015/1842¹¹.

Formats

18 § If a format is used whereby the component parts are placed below each other the picture shall be placed uppermost in the combined health warning, with the warning text and stop smoking information below it as per the illustration in point 1 of the appendix in the Commission's Executive Order (EU) 2015/1842¹². The picture shall cover 50%, the text warning 38% and the stop smoking information 12% of the combined health warning's surface area within the outer black edge.

19 § If format used whereby the component parts are placed side by side the picture shall be positioned on the left half of the combined health warning, with the warning text above and to the right and the stop smoking information below to the right of the health warning as per the illustration in point 2 of the appendix in the Commission's Executive Order (EU) 2015/1842¹³. The picture shall cover 50%, the text warning 40% and the stop smoking information 10% of the combined health warning's surface area within the outer black edge.

⁹ As per the Commission's delegated Directive 2014/109/EU (EUT L 360, 17.12.2014, s. 22–27, Celex 32014L0109).

¹⁰ (EUT L 267, 14.10.2015, s. 9, Celex 32015D1842)

¹¹ (EUT L 267, 14.10.2015, s. 9, Celex 32015D1842)

¹² (EUT L 267, 14.10.2015, s. 9, Celex 32015D1842)

¹³ (EUT L 267, 14.10.2015, s. 9, Celex 32015D1842)

20 § If the height of the combined health warnings is no more than 20% of its width due to the shape of the single packet or outer packaging, an extra wide format shall be used whereby the component parts of the combined health warning are positioned side by side as per the illustration in point 3 of the appendix in the Commission's Executive Order (EU) 2015/1842¹⁴. The picture shall cover 35%, the text warning 50% and the stop smoking information 15% of the combined health warning's surface area within the outer black edge.

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Design

21 § The combined health warning shall be printed with the four color printing process CMYK (cyan, magenta, yellow and black). For all black elements CO, M0, Y0 and K100 are used, and for warm yellow elements CO, M10, Y100 and CO. The combined health warning shall be displayed with a resolution of at least 300 dpi, when printed in actual size.

22 § The text warning shall be printed with white text on a black background. The stop smoking information shall be printed with black text on a warm yellow background as per the illustration in the appendix of the Commission's Executive Order (EU) 2015/1842¹⁵.

23 § If a format is used whereby the component parts are placed side by side on both sides of the packaging, or if an extra wide format is used when the component parts are positioned next to each other, a 1 mm black edge shall be printed between the stop smoking information and the picture within the surface intended for the stop smoking information.

24 § Manufacturers or importers shall ensure that the picture

- is displayed without the use of effects, adjustment of colors, retouching, or expansion of the background,
- is not set too close to, or too far away from, the picture's focus point and
- is scaled proportionately, without being stretched or compressed.

25 § Manufacturers or importers shall ensure that

- the warning text and stop smoking information are left-aligned and centred vertically,
- the warning text and stop smoking information are printed in Neue Frutiger Condensed Bold
- the warning text is printed in a uniform font size,
- the font size in the warning text and stop smoking information is big enough so that the text is as visible as possible,
- minimum font size in the warning text is 6 pt., and minimum font size for the stop smoking information is 5 pt.,
- spacing is 2 pt. larger than the font size in the text warning and 1-2 pt. larger than the font size in the stop smoking information and
- the warning text is displayed as per appendix 1 in these regulations.

¹⁴ (EUT L 267, 14.10.2015, s. 9, Celex 32015D1842)

¹⁵ (EUT L 267, 14.10.2015, s. 9–10, Celex 32015D1842)

**HSLF-FS Chapt. 3 Health warnings on packaging for other tobacco products
2016:46 for smoking**

1 § This chapter refers tobacco products for smoking other than
– cigarettes,
– rolling tobacco, and
– hookah tobacco.

Health warnings

2 § Every single packet, and any outer packaging of tobacco products for smoking as per this chapter shall carry the following general warning:
Smoking Kills

3 § In the general warning referred to in 2 § a reference to stop smoking information as per appendix 2 shall be included.

4 § Apart from the general warning in 2 §, every single packet and any outer packaging of other relevant tobacco products for smoking shall carry one of the warning texts shown in appendix 1 of these regulations.

5 § Each health warning shall, to the greatest extent possible, be shown in the same number on every brand of these products.

Positioning

6 § The general warning shall be displayed on the most visible surface of the single packet and any outer packaging.

7 § The text warnings shall be displayed on the second most visible surface on the single packet and any outer packaging.

8 § For single packets with a hinged lid, the second most visible surface is that which becomes visible when the packet is opened.

Size

9 § The general warning shall cover 30% of the relevant surface of the single packet and any outer packaging.

10 § The text warnings shall cover 40 % of the relevant the surface of the single packet and any outer packaging.

11 § If the health warning is to appear on a surface larger than 150 cm², the warning shall cover a surface of 45 cm².

Design

12 § The health warnings referred to in this chapter shall be
- printed in bold type in Helvetica font

- printed in black on a white background,
- printed with a font size that ensures the biggest possible area of the surface area reserved for the health warning,
- be centred in the area reserved for them, and for box shaped packaging and any exterior packaging, the texts shall be parallel with the side edge on the single packet or on the outer packaging, and
- parallel with the main text on the surface reserved for these warnings.

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Chapt. 4 Health warnings on packaging for smoke free tobacco products

1 § This chapter refers to smoke free tobacco products.

Health warnings

2 § Every single packet and any outer packaging for smoke free tobacco products shall carry the following health warning:

This tobacco product is harmful to your health and is addictive

Positioning

3 § The health warning shall be placed on the two biggest surfaces of the single packet and any outer packaging.

Size

4 § The health warning in 3 § shall cover 30 % of the respective surfaces.

Design

5 § The health warning shall be

- a. printed in bold type in Helvetica font
- b. printed in black on a white background,
- c. printed with a font size that ensures the text covers the biggest possible area of the surface area reserved for the health warning,
- d. centred in the area reserved for them, and for box shaped packaging and any exterior packaging, the texts shall be parallel with the side edge on the single packet or on the outer packaging, and
- e. parallel with the main text on the surface reserved for these warnings.

Chapt. 5 Exceptions

Edging around health warnings

1 § An exception applies to Chapt. 1, 10 § for tobacco products for smoking other than cigarettes, rolling tobacco and hookah tobacco. Instead, the relevant health warnings shall be edged by a black frame of at least 3 mm width and no more than 4 mm height. This edge shall be displayed around the surface reserved for health warnings.

Rectangular Pouches

2 § An exception applies to Chapt. 2, 7–8 §§ as and from the 20th of May 2018 for rolling tobacco in rectangular pouches with a surrounding folding cover made of polythene, polypropylene or laminate material, as per the illustration in section 3 of the appendix in the Commission's Executive Order (EU) 2015/1735¹⁶. Instead, the following regulations shall apply to these packages

- a. the information text is placed on the surface that becomes visible when the single packet is partially opened,
- b. The general warning is placed on the lower surface that becomes visible when the single packet is completely opened.
- c. the internal part of the flap that becomes visible when the single packet is opened completely must not carry any other text or be used in any other way, and
- d. the general warning and information text is placed on the uppermost edge of the respective surfaces on which they imprinted.

Combined Health Warnings

3 § An exception applies to Chapt. 2, 13 § e, as and from the 20th of May 2019 for each single packet and any outer packaging for cigarettes, rolling tobacco and hookah tobacco. This applies in those instances where the tax mark or ID mark for taxation is fixed on the upper edge of a single packet made of carton material: the combined health warning shown on the rear surface may be placed directly below the tax or ID mark.

If a single packet is made of a soft material, a rectangular surface may be reserved for the tax or ID mark for taxation with a height of 13mm between the packet's upper edge and surface and the upper part of the combined health warnings.

Brand names and logos must be placed over the health warnings.

Combined health warnings on flip-top packages

4 § An exception applies to Chapt. 2, 18 § for combined health warnings that shall be placed on the front of single packets with foldable covers, flip-top lids. On these packets the combined health warnings are designed as per the regulations in 5–7 §§.

5 § If the lid is smaller than the surface intended for the picture in Chapt. 2, 18 § and if the picture is split in two when the packet is opened

- the text warnings shall be placed uppermost in the combined health warning, with the stop smoking info and the picture below, as per the illustration in point 4 of the appendix in the Commission's Executive Order (EU) 2015/1842¹⁷, and
- the picture must cover at least 50% of the combined health warning's surface, the warning text at least 30% and the stop smoking information at least 10%, but at most 12%, of the combined health warning's surface within the black edge.

¹⁶ (EUT L 252, 29.9.2015, s. 54, Celex 32015D1735)

¹⁷ (EUT L 267, 14.10.2015, s. 10, Celex 32015D1842)

6 § If the lid is larger than the surface intended for the picture in Chapt. 2, 18 § and if the warning text and health warning is split in two when the packet is opened **HSLF-FS 2016:46**

- picture shall be placed uppermost in the combined health warning, with the warning text and stop smoking info below, as per the illustration in point 1 of the appendix in the Commission's Executive Order (EU) 2015/1842¹⁸, and
- the picture must cover at least 50% of the combined health warning's surface, the text warning at least 30% and the stop smoking information at least 10%, but at most 12%, of the combined health warning's surface within the black edge.

7 § Manufacturers shall ensure that the picture, the text warnings or stop smoking information are not split in two when the single packet with foldable cover/flip-top lid is opened.

This Executive Order comes into force on the 20th of May 2016 when the statutory regulations (FoHMFS 2014:9) for text warnings on tobacco products and content declarations for, and restrictions on, certain component parts in cigarette smoke cease to apply.

Transitional Regulations

- Tobacco products manufactured or offered for open sale before the 20th of May 2016 and which are labelled in accordance with 1–5 and 7–8 §§ in (FoHMFS 2014:9) may remain on the market for consumers after the 20th of May 2016, though only until the 20th of May 2017.
- Tobacco products for oral use, apart from those intended for inhalation or chewing, that have been manufactured or offered for open sale before the 31st of August 2016 and which are labelled in accordance with 1–5 and 7–8 §§ in (FoHMFS 2014:9) may remain on the market for consumers after the 20th of May 2016, though only until the 20th of May 2017.
- Rolling tobacco in pouches, as per Chapt. 5, 2 § that have been manufactured for open sale up to and including the 20th of May 2018, as per this transitional regulation, may be placed on the market up to and including the 20th of May 2019.

The Public Health Agency of Sweden

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¹⁸ (EUT L 267, 14.10.2015, s. 9, Celex 32015D1842)

**Catalogue for text warnings as per appendix I in
European Parliament and Council Directive
2014/40/EU¹⁹**

Smoking is the cause of 9 out of 10 instances of lung cancer
Smoking can cause throat and mouth cancer
Smoking damages your lungs
Smoking can cause heart attacks
Smoking can cause strokes and disabilities
Smoking can cause clogging of the arteries
Smoking increases the risk of blindness
Smoking damages your teeth and gums
Smoking can kill your unborn child
Your smoke harms your children, your family and friends
Children of smokers are more likely to smoke
Stop today — live longer for the sake of your family and friends
Smoking lowers your reproductive ability
Smoking increases the risk of impotence

Stop Smoking Information

The Stop Smoking Line: 020-84 00 00 www.slutarokalinjen.se

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Agency of Sweden. Web:
www.folkhalsomyndigheten.se

This Executive Order can be
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