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Subsequent changes to Order:

None

Order on threshold limits, health warnings and age checking systems etc. of tobacco products etc.

Pursuant to § 8, clause 1, § 9, clause 1, § 19, clause 2, § 24, clause 2, § 30, clause 2 and § 45, clause 2, in Act 608 of the 7th of June 2016 on tobacco products etc. it is hereby decreed that:

Chapter 1

Term definitions

- §1.1 The following terms in this Order are defined as:
- 1) Tar: nicotine-free anhydride condensate of unfiltered smoke.
- 2) Nicotine: Nicotine alkaloids.
- 3) Emissions: Substances that are released when tobacco or a herbal based product for smoking is used as per its intention, such as substances to be found in smoke, or substances released during the use of smoke free tobacco products. cf. 2014/40/EU.
- 4) Health warnings: A warning relating to a product's harmful effects to health, or other undesirable effects from consuming the relevant product, including text warnings, combined health warnings, general warnings and information bulletins, cf. 2014/40/EU.
- 5) Combined health warnings: A health warning that consists of a combination of text warning and an accompanying picture, or an accompanying illustration, cf. 2014/40/EU.

Chapter 2

Threshold limits for emission levels from tobacco products and measurement methodology for emission content

- § 2. The emission content in cigarettes that are marketed in this country, must not be more than:
- 1) 10 mg tar per cigarette.
- 2) 1 mg nicotine per cigarette.
- 3) 10 mg tar per cigarette.
- *Clause* 2. The emission content of tar, nicotine and carbon monoxide in cigarettes is measured in accordance with ISO-standard 4387 (tar), ISO-standard 10315 (nicotine) and ISO-standard 8454 (carbon monoxide).
- *Clause 3.* The accuracy of the measurements for tar, nicotine and carbon monoxide is determined using ISO standard 8243.

Chapter 3

General regulations for health warnings on tobacco products

- § 3. Every single packet and any outer packaging around a tobacco product shall carry a health warning in Danish.
- § 4. The health warning shall cover the whole area of the relevant single packet, or the exterior packaging used exclusively for it, and it must not carry accompanying comments, be reformulated or carry accompanying references of any kind.
- § 5. The health warning on a single packet, and any outer packaging, shall be imprinted in a such way that it cannot be removed or erased and is completely visible. This also means it must not be completely or partly obscured or broken by a strap, price sticker, safety features, packing material, cover, carton or boxes or other elements, when

the tobacco product is marketed. On single packets of tobacco products other than cigarettes and rolling tobacco in pouches, the health warning can be stuck on using a sticker, as long as this is permanent and cannot be removed. The health warning shall remain intact when the single packet is opened, except for packs with a flip-top-lid, where the health warning may be broken by the opening of the packet, but only in such a way that this ensures the graphic integrity and visibility of the text, pictures, and stop smoking information.

- § 6. The health warning must in no way hide or be placed across straps, price stickers, traceability marks or safety features on the single packets.
- § 7. The dimensions of the health warning are calculated on the basis of the relevant surface when the packet is closed.
- § 8. The health warning shall be edged by a 1 mm wide black rim within the surface area exclusively intended for these warnings, with the exception of health warnings on smoking tobacco other than cigarettes, rolling tobacco and hookah tobacco and also herbal products for smoking.
- § 9. Images of single packets and any outer packaging aimed at consumers, shall adhere to the provisions in this chapter.

Health warnings on cigarettes, rolling tobacco and hookah tobacco

- § 10. Each single packet and any outer packaging surrounding cigarettes, rolling tobacco and hookah tobacco shall carry a general warning, an informational message and a combined health warning.
- *Clause 2.* The general warning shall have the following wording: "Smoking kills".
 - Clause 3. The informational message shall have the following wording:
- "Tobacco smoke contains over 70 carcinogenic substances".
- Clause 4. The combined health warning shall contain one of the text warnings shown in appendix 1 and an accompanying color photograph as specified in the picture collection in appendix 2.

Specific requirements for the general warning and informational message for cigarettes, rolling tobacco and hookah tobacco

- § 11. The general warning and informational message, cf. § 10, clauses 2 and 3, shall:
- 1) be printed in black, bold type in Helvetica font on a white background. The font size must ensure that the biggest possible area of the surface area reserved for these health warnings is filled with the relevant text,
- 2) be centered in the area reserved for them, and for box shaped packaging and any exterior packaging, they shall be parallel with the side edge on the single packet, or on the outer packaging and
- 3) cover 50 % of the surface on which they are imprinted.
- § 12. On cigarette packets and rolling tobacco in box shaped packets, the general warning is placed on the bottom part of one of the side areas of the single packets. The informational message shall be placed on the bottom part of the other side area. The general health warning and informational message must be at least 20 mm in width.
- Clause 2. 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 message 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.
- *Clause 3.* For rolling tobacco in pouches, the general warning and informational message must be placed on those surfaces that ensure full visibility of them.
- Clause 4. For rolling tobacco in cylindrical packets, the general warning must be placed on the outer side of the lid's area and the information message on the inside of the lid's area. Both the general warning and informational message must cover 50 % of the surface on which they are imprinted.
- Clause 5. For rolling tobacco in rectangular pouches, the general warning and informational message must be printed on the two surfaces that become visible when the single packet is fully opened. The general warning must be printed on the upper area.
- Clause 6. For rolling tobacco in standing pouches, the general warning and informational message must be placed at the bottom of the upright pouch, which becomes visible when the pouch is placed on its back (on the "single packet's base" as described in the following point). The general warning must be printed on the area above the

crease in the single packet's base, and the informational message on the area beneath the crease. The surface area on these type of packets is calculated on the basis of their dimensions when the edges are sealed.

Specific requirements for combined health warnings for cigarettes, rolling tobacco and hookah tobacco

- § 13. The combined health warnings are divided into three sets, cf. appendix 2, and each set shall be used in a given year and replaced by the next set the following year. Replacement of the first set must take place on the 1st of January 2018, so that products produced after 31st December 2017 carry the new set. Display of each individual combined health warning to be used in a given year shall be spread numerically equally across each tobacco brand.
- *Clause* 2. The combined health warnings shall contain the following stop smoking information: "Stop Line: 80 31 31 www.stoplinien.dk.
- § 14. The combined health warnings 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, MIO, Y100 and CO. The combined health warning shall be displayed with a resolution of at least 300 dpi, when printed in actual size.
- Clause 2. The text warning shall printed with white text on a black background. The stop smoking information shall be printed with black text on a warm yellow background, cf. clause 1.
- Clause 3. If a stacked side by side format is used, or an extra wide side by side format, a 1 mm black edge shall be printed between the stop smoking information and the picture in the field with the stop smoking information.

Clause 4. The manufacturer or importer shall ensure that the picture:

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

Clause 5. The manufacturer shall ensure that:

- 1) the text warning and stop smoking information are left-aligned and centered vertically,
- 2) the text warning and stop smoking information are printed in Neue Frutiger Condensed Bold,
- 3) the text warning is printed in a uniform font size,
- 4) the font size in the text warning and stop smoking information is big enough so that the text is as visible as possible,
- 5) Minimum font size in the text warning is 6 pt., and minimum font size for the stop smoking information is 5 pt.,
- 6) 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
- 7) the text warning is displayed as shown in appendix 1 to directive 2014/40/EU, including regarding usage of an initial capital but excluding numbering.
- § 15. The combined health warnings shall display the same text warning, with accompanying color picture, on both sides of the single packet and any outer packaging. The warning shall cover 65% of the outer side of both the front and rear side of the single packet and any outer packaging. Cylindrical packets shall carry two combined health warnings that are equidistant from each other, and each health warning shall cover 65% of their respective halves of the curved surface.
- Clause 2. The warning shall be placed at the top edge of a single packet and any outer packaging and run in the same direction as other information on the surface of the packaging.

Clause 3. For a single packet with cigarettes, the combined health warning shall have the following dimensions:

- 1) Height: not less than 44 mm.
- 2) Width: not less than 52 mm.

Clause 4. If the height of the combined health warning is over 70 % of its width, the manufacturer shall display the combined health warning in a stacked format. 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. If the height of the combined health warning is at least 65% but less than 70% of its width, breadth, 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.

Clause 5. If a stacked format is used, the picture shall be located uppermost in the combined health warning, with the text warning and stop smoking information printed below. 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. If a side by side-format is used, the picture shall be located in the left half of the combined health warning, with the text warning uppermost to the right and the stop smoking information lowest to the right in the warning. 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.

Clause 6. If, due to the shape of the single packet or outer packaging, the height of the combined health warning is less than or equal to 20 % of its width, the combined health warning shall be displayed in an extra-wide side by side-format. 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.

- § **16.** Regardless of the provisions in § 15, the following rules will apply for combined health warnings, that to be placed on the front of single packets with a flip-top-lid:
- 1) If the lid is smaller than the surface area the picture has to cover, cf. § 18, clause 2, and the picture would be broken on opening:
 - a) The text warning shall be located uppermost in the combined health warning, with the stop smoking information and picture below.
 - b) The picture shall cover at least 50% of the combined health warning's surface area, the text warning shall, cover at least 30%, and the stop smoking information at least 10%, but not exceeding 12%, of the combined health warning's surface area within the black edge.
- 2) If the lid is larger than the surface area the picture has to cover, cf. § 18, clause 2, and the text warning or stop smoking information would be broken on opening:
 - a) The picture shall be located uppermost in the combined health warning, with the text warning and stop smoking information below.
 - b) The picture shall cover at least 50% of the combined health warning's surface area, the text warning shall, cover at least 30%, and the stop smoking information at least 10%, but not exceeding 12%, of the combined health warning's surface area within the black edge.
 - c) The manufacturer shall ensure that none of the combined health warning's three elements are broken on the opening of a single packet.

Health warnings on smoking tobacco other than cigarettes, rolling tobacco and hookah tobacco

- § 17. Each single packet and any outer packaging of smoking tobacco other than cigarettes, rolling tobacco and hookah tobacco shall carry one of the text warnings shown in appendix 1.
- Clause 2. If the health warning is to appear on a surface larger than 150 cm2, the warning shall cover a surface of 45 cm 2.
- *Clause 3.* The health warning shall fulfil the requirements in § 12, nos. 1 and 2. The health warning's text shall run parallel with the main text on the surface reserved for these warnings.
- Clause 4. The health warning shall be edged by a black rim with a width of at least 3 mm and at most 4 mm. This rim shall be placed outside the area reserved for the health warnings.
- § 18. Furthermore, each single packet and any outer packaging of smoking tobacco other than cigarettes rolling tobacco and hookah tobacco shall carry a general warning, cf. § 10, clause 2. The general warning shall be displayed on the most visible surface on the single packet and any outer packaging.
 - Clause 2. The general warning shall cover 30% of the surface of the single packet and any outer packaging.
- *Clause 3.* The general warning shall include the following stop smoking information: "Stop Line: 80 31 31 31 www.stoplinien.dk.
- § 19. The text warning shall be displayed on the second most visible surface on the single packet and any outer packaging. For single packets with a hinged lid, the second most visible surface is that which becomes visible when the packet is opened.
 - Clause 2. The text warning shall cover 40% of the surface of the single packet and any outer packaging.

Health warnings on smoke free tobacco products

§ 20. Each single packet and outer packaging for smoke free tobacco products shall carry the following health warning that shall fulfil requirements in § 11, nos. 1 and 2.

"This tobacco product is harmful to your health and is addictive".

Clause 2. The health warning's text shall run parallel with the main text on the surface reserved for these warnings. Furthermore, the health warning shall be placed on the two largest surfaces of the single packet and any outer packaging and shall cover 30% of the surface on the single packet and any outer packaging.

Chapter 4

Age checking system

§ 21. Those who wish to market tobacco products to consumers in this country, or in another EU/EEA country by cross border distance selling, shall provide the Danish Safety Technology Authority with more detailed information as to the age checking system that has been put in place as per the Act's § 24. This information shall cover the system's content and application.

Chapter 5

Herbal products for smoking

- § 22. Each single packet and any outer packaging for herbal products for smoking shall carry the following health warnings:
- "Smoking this product is harmful to health".
- § 23. The health warning shall be printed on the outer front surface on the front and back of the single packet (the exterior surface) and on any outer packaging.
- § 24 The health warning shall fulfil the requirements in § 11, nos. 1 and 2. It shall cover 30% of the area of the relevant single packet and any outer packaging.

Chapter 6

Penalties

§ 25. Unless a more serious penalty, as per another Act, is warranted, persons concerned incur fines if they contravene §§ 3-20 and §§ 22-24.

Clause 2. Companies etc. (legal persons) can face criminal liability charges as per the stipulations in Chapter 5 of the Criminal Law Act.

Chapter 7

Coming into force and transitional orders

- § 26. This order comes into force on the 10th of June 2016.
- § 27. Rolling tobacco in pouches, produced or released for sale before the 20th of May 2018 that carry a general warning and an informational message as per § 11 and § 12, clauses 3-6, can be marketed until 20th of May 2019.
- Clause 2. Regardless of § 12, clause 5, the following rules apply until the 20th of May 2018 for rolling tobacco in rectangular folding pouches made of polyethylene, polypropylene or a laminate material:
- 1) The informational message can be placed on the surface that becomes visible when the single packet is partially opened.
- 2) The general warning can be placed on the surface of the underside that becomes visible when the single packet is opened completely.
- 3) The internal part of the flap that becomes visible when the single packet is opened completely must not carry any printed content or be used in any other way.
- 4) The general warning and informational message shall be placed uppermost on the surfaces on which they each are imprinted.
- § 28. § 15, clause 2, and § 16 first come into effect from the 20th of May 2019, if the strap or national identification label used as a duties mark is placed on the upper edge of the single packet carton package.
- Clause 2. In the transition period, the combined health warning can be placed just under the strap or national identification label.

- Clause 3. Brand names or logos must not be placed over combined health warnings.
- § 29. § 15, clause 2, and § 16 first have effect from the 20th of May 2019, if a single packet had been produced with a soft material.
- Clause 2. In the transitional period, a rectangular surface with a height of at most 13 mm can be placed between the upper edge of the packet and the combined health warning's upper edge to the strap or the national identification label for duties purposes.
 - Clause 3. Brand names or logos must not be placed over combined health warnings.
- § 30. Regardless of the stipulation in § 10, clause 2 on the general health warning, manufacturers and importers can, until 20th of May 2017, market cigarettes, rolling tobacco and hookah tobacco with the following general health warnings:
- "Smoking kills Stop today".
- § 31. Regardless of the stipulation in § 13, clause 2 and § 18, clause 3 on stop smoking information, manufacturers and importers can, until 20th of May 2017, market tobacco products with the following stop smoking information: "Stop smoking line: 80 31 31 31".

Ministry of Health, 30th of May 2016

SOPHIE LØHDE

/ Erich Erichsen

The Order implements parts of the European Parliament's and Council's directive 2014/40/EU of 3rd of April 2014 on mutual harmonization of member state laws and administrative orders on the production, presentation and sale of tobacco and related products and about the abrogation of directive 2001/37/EU, Official Journal of the European Union 2014, no. L 127, p. 1 and the Commission's delegated directive 2014/109/EU of 10th of October 2014 on changes to appendix II of the European Parliament and Council directive 2014/40/EU by the establishing of a collection of pictorial warnings that shall be used on tobacco products, Official Journal Of The European Union 2014 no. L 360, p. 22 and the Commission's implementation ruling (EU) 2015/1735 of 24th of September 2015 on the exact positioning of the general warning and informational message on rolling tobacco in pouches, Official Journal Of The European Union 2015 no. L 252, p. 49 and the Commission's implementation ruling (EU) 2015/1842 of 9th of October 2015 on technical specifications for the layout. Design and shape of combined health warnings relating to smoking tobacco, Official Journal Of The European Union 2015 no. L 267, p. 5

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Appendix 1

- 1) Smoking is the cause of 9 out of 10 instances of lung cancer
- 2) Smoking can cause throat and mouth cancer
- 3) Smoking damages your lungs
- 4) Smoking can cause heart attacks
- 5) Smoking can cause strokes and disabilities
- 6) Smoking can cause of clogging of the arteries
- 7) Smoking increases the risk of blindness
- 8) Smoking damages your teeth and gums
- 9) Smoking can kill your unborn child
- 10) Your smoke harms your children, your family and friends
- 11) Children of smokers are more likely to smoke
- 12) Stop today live longer for the sake of your family and friends
- 13) Smoking reduces reproductive ability
- 14) Smoke increasers the risk of impotence















- Smoking is the cause of 9 out of 10 instances of lung cancer
- 2 Smoking can cause throat and mouth cancer
- 3. Smoking damages your lungs
- 4. Smoking can cause heart attacks
 - 1 Smoking can cause strokes and disabilities
 - 2 Smoking can cause clogging of the arteries
 - 3. Smoking increases the risk of blindness
 - 4. Smoking damages your teeth and gums

















1 Smoking can kill your unborn child 2 Your smoke harms your children, your family and friends 3. Children of smokers are more likely to smoke 4. Stop today — live longer for the sake of your family and friends 1. Smoking lowers your reproductive ability 2. Smoking increases the risk of impotence 3. Smoking is the cause of 9 out of 10 instances of lung cancer





1) Smoking damages your lungs 2) Smoking can cause heart attacks 3) Smoking can cause strokes and disabilities 4) Smoking can cause clogging of the arteries 1. Smoking increases the risk of blindness 2. Smoking damages your teeth and gums 3. Smoking can kill your unborn child 4. Your smoke harms your children, your family and friends

















- 1) Children of smokers are more likely to smoke
- Stop today live longer for the sake of your family and friends
- 3) Smoking reduces your reproductive abilities
- 4) Smoking increases the risk of impotence
- Smoking is the cause of 9 out of 10 instances of lung cancer
- 2) Smoking can cause throat and mouth cancer
- 3) Smoking damages your lungs
- 4) Smoking can cause heart attacks

















- 1) Smoking can cause strokes and disabilities
- 2) Smoking can cause clogging of the arteries
- 3) Smoking increases the risk of blindness
- 4) Smoking damages your teeth and gums
- 1) Smoking can kill your unborn child
- 2) Your smoke harms your children, your family and friends
- 3) Children of smokers are more likely to smoke
- 4) Stop today live longer for the sake of your family and friends 33





- 1) Smoking reduces your reproductive abilities
- 2) Smoking increases the risk of impotence