Order on labelling and health warnings on tobacco substitutes[1]

Pursuant to Section 19a(2), Section c and Section 45(2) of the Act on tobacco products, etc., cf. Consolidation Act No 1161 of 4 November 2024, as amended by, the following is laid down:

Chapter 1

Definitions

Section 1. In this Order, tobacco substitute means: Product containing nicotine that is not a tobacco product, cf. No 2, or an electronic cigarette, cf. Section 2(1) of the Act on electronic cigarettes etc. and which is not approved by marketing permission in accordance with the Act on medicinal products or EU law laying down common procedures for approval of medicinal products for human use and equipment intended to be used in conjunction with this product.

Chapter 2

Labelling

Section 2. Each single packet and any outer packaging of tobacco substitutes must contain a list of:
1) All the ingredients included in the product in descending order by weight.
2) Nicotine content per unit. For nicotine bags, it is per bag.
3) Batch number.
4) A recommendation to keep the product out of the reach of children.

Section 3. Each unit packet and any outer packaging of tobacco substitutes shall bear the following nicotine cessation information: Stoplinien: 80 31 31 31 www.stoplinien.dk.

Section 4. The person who markets a tobacco surrogate in this country must ensure that each single packet and any outer packaging does not contain elements or features that
1) encourage use or give a false impression of the characteristics, effects, risks or emissions of the products;
2) give the impression that a particular tobacco substitute is less harmful than other products;
3) give the impression that a particular tobacco substitute has revitalising, energising, healing, rejuvenating, natural, ecological properties or other positive purposes or other positive health or lifestyle effects;
4) refer to taste, smell, flavourings or other additives or states that the product does not contain them, with the exception of the words "With tobacco taste" or "With menthol taste";
5) make the product resemble a foodstuff or a cosmetic product; or
6) give the impression that a particular tobacco ubstitute has an improved biodegradability or other environmental benefits.
(2) The elements and features prohibited under Section 4, Nos 1–6, include, but are not limited to, text, symbols, names, trade marks, figures or other signs.

[1] The draft order was notified in compliance with European Parliament and Council Directive 2015/1535 (EU) concerning an information procedure with respect to technical regulations, as well as regulations for information society services (codification).

Section 5. The person who markets tobacco substitutes in this country must ensure that each single packet and any outer packaging do not contain or are otherwise associated with coupons offering discounts, free distribution, two-for-one offers or other promotional measures.

Chapter 3

Health warning

Section 6. Each single packet and any outer packaging of tobacco substitutes must be provided with the following health warning in Danish: “This product contains nicotine, which is a highly addictive substance.”

Section 7. The health warning on each single packet and any outer packaging of tobacco substitutes must:
1) be placed on the three largest surfaces on the single packet and any outer packaging, respectively;
2) cover 30 % of the surface of the unit packet and any outer packaging;
3) be printed in black Helvetica bold type on a white background;
4) designed with a font size that ensures that the largest possible proportion of the area reserved for the health warning is filled with the relevant text;
5) be placed in the centre of the area reserved for the warning;
6) be in a straight line and in the same reading direction as the main text of the surface reserved for the warning; and
7) on packages with a cuboid shape and any outer packaging be placed parallel to the side edge of the single packet or the outer packaging or on all surfaces, provied that the single packet and any outer packaging has fewer than three surfaces;
(2) The dimensions of the health warning shall be calculated in relation to the surface concerned when the packet is closed.

Section 8. Each health warning on a single packet and any outer packaging must be printed or affixed in such a way that it cannot be removed or erased and is fully visible, including it must not be completely or partially obscured or broken by price tags, packaging material, covers, boxes or cases or other items when the tobacco substitute is marketed.

Section 9. The health warning may not be commented on, reformulated or covered by references of any kind on the single packet or any outer packaging.

Section 10. Each health warning must remain intact after opening the single pack.
(2) For at least one of the other health warnings, the legibility and visibility of the text must remain intact if broken by opening the unit packet.

Section 11. Images of unit packets and any outer packaging targeting consumers shall comply with the provisions of this Chapter.

Section 12. Unless a higher penalty is justified under another law, the person who violates Sections 2-11 is fined.
(2) Companies etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code.

Chapter 4

Entry into force

Section 13. *(1)* This Order shall enter into force on 1 July 2025.
(2) Order No 251 of 4 March 2025 on labelling and health warnings on tobacco substitutes is hereby repealed.
Section. 3. For tobacco substitutes produced prior to 1 July 2025, Sections 2(1), no. 2, Section 3, Section 4(1), no. 4 and Section 7(1), no. 1, take effect on 1 April 2026.

The Ministry for the Interior and Health, on x

P.M.V.

/ Anna D. Madsen

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