

Act on the manufacture, presentation and sale of tobacco products (Tobacco Products Act)¹

Part 1

Application and definitions

§ 1. This Act shall apply to tobacco products, which means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not.

§ 2. In this Act:

- 1) “tar” means the raw anhydrous nicotine-free condensate of smoke;
- 2) “nicotine” means nicotinic alkaloids; and
- 3) “ingredient” means any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives.

Ministry of the Interior and Health, j.nr. 2003-1433-27

¹ This Act contains provisions that implement parts of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (*Official Journal of the European Communities*, 2001(18 July): **L 194**: 26–34.

Part 2

Limit values

§ 3. The Minister for the Interior and Health shall lay down limit values for the maximum yield of tar, nicotine and carbon monoxide in cigarettes manufactured for or released for free circulation on Denmark's market with the aim of implementing European Community legislative acts on this, cf., however, § 22(4).

Subsection 2. The Minister for the Interior and Health may lay down limit values for the maximum yield of tar, nicotine and carbon monoxide in other tobacco products than cigarettes manufactured for or released for free circulation on Denmark's market with the aim of implementing European Community legislative acts on this.

Part 3

Measurement methods

§ 4. The Minister for the Interior and Health shall lay down provisions on measurement methods to measure the yield of tar, nicotine and carbon monoxide in cigarettes, on the verification thereof and on the definitions in relation hereto with the aim of implementing European Community legislative acts on this.

§ 5. The activity governed by § 4 shall be carried out or verified by testing laboratories that are accredited by Danish Accreditation (DANAK) or by a similar accreditation authority.

Subsection 2. Danish Accreditation (DANAK) or a similar accreditation organ shall supervise the accredited testing laboratories in Denmark.

§ 6. The Minister for the Interior and Health may determine that tobacco manufacturers or importers shall carry out any other tests in order to:

- 1) assess the yield of other substances produced by their tobacco products on a brand-name-by-brand-name basis and type-by-type-basis; and
- 2) assess the effects of those other substances on health, taking into account, inter alia, their addictiveness.

Subsection 2. The Minister for the Interior and Health may decide that the tests required pursuant to subsection 1 shall be carried out or verified in

approved testing laboratories, cf. § 5.

Subsection 3. The Minister for the Interior and Health may decide that the results of tests carried out in accordance with subsection 1 shall be submitted to the Minister for the Interior and Health on an annual basis or, in cases where the product specifications have not varied, less frequently.

Subsection 4. The Minister for the Interior and Health shall ensure the dissemination of information submitted in accordance with subsection 1. This shall not apply, however, to any information that may constitute a trade secret.

Part 4

Labelling

§ 7. For cigarettes released for free circulation on Denmark's market, the tar, nicotine and carbon monoxide yields measured in accordance with the provisions laid down pursuant to § 4 of this Act shall be printed on one side of the cigarette packet, so that at least 10% of the corresponding surface is covered.

Subsection 2. The Minister for the Interior and Health may lay down provisions for the implementation of European Community legislative acts stipulating that the rule in subsection 1 shall also apply to:

- 1) other tobacco products than cigarettes; and
- 2) other ingredients than tar, nicotine and carbon monoxide.

§ 8. Each unit packet of tobacco products must carry one of the following general warnings:

- 1) "Smoking can kill"; or
- 2) "Smoking seriously harms you and others around you".

Subsection 2. The provision of subsection 1 shall not apply, however, to smokeless tobacco products, which must carry the following warning: "This tobacco product can damage your health and is addictive."

Subsection 3. Both the general warnings required pursuant to subsection 1 shall be used, and they shall be rotated in such a way as to guarantee that they are changed and appear regularly.

Subsection 4. The general warnings required pursuant to subsection 1 and the warning required pursuant to subsection 2 shall be printed on the most visible surface of the unit packet.

Subsection 5. If the unit packet of tobacco products is covered by outside packaging used in the retail sale of the product, the warnings required pursuant to subsection 1 and the warning required pursuant to subsection 2 shall also be printed on this outside packaging, unless this outside packaging is transparent.

§ 9. The Minister for the Interior and Health shall lay down provisions requiring all unit packets of tobacco products to carry a specific warning and lay down specific rules for the positioning and form of these warnings and how often they shall be changed with the aim of implementing European Community legislative acts on this.

Subsection 2. The Minister for the Interior and Health may lay down provisions governing additional warnings in the form of colour photographs or other illustrations with the aim of implementing European Community legislative acts on this.

§ 10. The general warning required pursuant to § 8(1) and the warning required pursuant to § 8(2) shall cover not less than 30% of the external area of the corresponding surface.

Subsection 2. The specific warning required pursuant to § 9(1) shall cover not less than 40% of the external area of the corresponding surface.

Subsection 3. In the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm², the warnings required pursuant to § 8(1) and to § 9(1) shall cover an area of at least 22.5 cm² on each surface.

§ 11. The text of warnings and yield indications required pursuant to § 7(1) and § 8(1–2) and pursuant to the provisions laid down in accordance with § 9(1) shall be:

- 1) printed in black Helvetica bold type on a white background;
- 2) in a font size such as to occupy the greatest possible proportion of the area set aside for the text required;
- 3) in lower-case type, except for the first letter of the message and where required by grammar usage;

- 4) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;
- 5) surrounded by a black border not less than 3 mm and not more than 4 mm in width that in no way interferes with the text of the warning or information given; and
- 6) in Danish.

Subsection 2. The provision of subsection 1, no. 5 shall not apply to smokeless tobacco products.

Subsection 3. The Minister for the Interior and Health may lay down specific rules relating to the provision in subsection 1, no. 5.

§ 12. The printing of the warning texts on the tax stamps of unit packets shall be prohibited, cf. § 7(1), § 8(1–2) and § 9(1).

Subsection 2. The texts required pursuant to § 7(1) and § 8(1–2) and pursuant to the provisions laid down in accordance with § 9(1) shall be irremovably printed and indelible.

Subsection 3. The texts required pursuant to § 7(1) and § 8(1–2) and pursuant to the provisions laid down in accordance with § 9(1) shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet.

Subsection 4. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.

§ 13. The warnings required pursuant to § 8(1–2) and § 9(1–2) may be accompanied by a reference, outside the box for warnings, that the warning was issued by “the European Parliament and the European Council”.

§ 14. The Minister for the Interior and Health shall lay down provisions stipulating that tobacco products must be marked in any appropriate manner on the unit packet enabling the place and time of manufacture to be determined and lay down specific provisions on the technical measures to apply this provision with the aim of implementing European Community legislative acts on this.

Part 5

Further information

§ 15. Manufacturers and importers of tobacco products shall submit to the Minister for the Interior and Health a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type.

Subsection 2. The list required pursuant to subsection 1 may include fragrances as a combined group by brand name. Manufacturers or importers of tobacco products shall simultaneously indicate which fragrance ingredients are included in their tobacco products.

Subsection 3. The list required pursuant to subsection 1 shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. It shall indicate their function and category.

Subsection 4. The list required pursuant to subsections 1 and 2 shall be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate.

Subsection 5. The ingredients included in the applicable tobacco product shall be listed in the list required pursuant to subsection 1 in descending order of the weight.

Subsection 6. The information required pursuant to subsections 1–5 shall be submitted to the Minister for the Interior and Health on a yearly basis and for the first time by 31 December 2002 at the latest.

§ 16. The Minister for the Interior and Health may decide which ingredients are authorized to be used in tobacco products with the aim of implementing European Community legislative acts on this.

Subsection 2. The Minister for the Interior and Health may temporarily lay down rules that prohibit the use of ingredients that have the effect of increasing the addictive properties of tobacco products.

§ 17. The Minister for the Interior and Health shall ensure that the information provided in accordance with § 15, including a list of ingredients for each product indicating tar, nicotine and carbon monoxide yields, is made public. This shall not apply, however, to information on specific product formulae that constitutes a trade secret.

Part 6

Product descriptions

§ 18. The Minister for the Interior and Health shall lay down specific rules stipulating that specific texts, names, trademarks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products, with the aim of implementing European Community legislative acts on this.

Subsection 2. The rules required pursuant to subsection 1 shall not hinder the printing of information on content on the packaging of tobacco products, cf. § 7.

Part 7

Tobacco for oral use

§ 19. The sale of pulverized tobacco in the form of snuff packaged in porous sachet portions or the like for placement in the oral cavity shall be prohibited.

Part 8

Provisions on authorization and penalties

§ 20. The Minister for the Interior and Health may authorize an institution under the Ministry of the Interior and Health to exercise the authority conferred on the Minister by this Act.

Subsection 2. The Minister for the Interior and Health may lay down specific rules about the right to appeal rulings made based on the authority conferred in accordance with subsection 1, including regulations stipulating that such rulings may not be appealed to any other administrative authority.

§ 21. A fine shall be imposed on anyone who:

- 1) infringes § 5(1), § 7(1), § 8(1–5), § 10(1–3), § 11(1), § 12(1–4), § 15(1–6) or § 19; or
- 2) infringes provisions laid down in accordance with § 3(1–2), § 4, § 6(1–3), § 7(2), § 9(1–2), § 11(3), § 14, § 16 or § 18(1).

Subsection 2. Companies and the like (legal persons) may be penalized in accordance with the rules of Part 5 of the Criminal Justice Act.

Part 9

Entry into force etc.

§ 22. This Act shall enter into force on 30 September 2002.

Subsection 2. Products that do not comply with the provisions of this Act may continue to be released for free circulation on Denmark's market until 30 September 2003. There will, however, be a requirement that such cigarettes would be able to be released for free circulation on Denmark's market in accordance with the previously applicable legislation, cf. subsection 5.

Subsection 3. Products other than cigarettes that do not comply with the provisions of this Act may continue to be released for free circulation on Denmark's market until 30 September 2004. There will, however, be a requirement that such tobacco products would be able to be released for free circulation on Denmark's market in accordance with the previously applicable legislation, cf. subsection 5.

Subsection 4. The rules that are laid down in accordance with § 3(1) shall enter into force on 1 January 2007 as regards cigarettes manufactured within Denmark but exported to countries outside the European Community.

Subsection 5. Simultaneous to the entry into force of this Act, Act No. 426 of 13 June 1990 on the labelling of tobacco products, on the tar yield of cigarettes and on the prohibition of the sales of certain snuff tobacco products shall be repealed.

§ 23. This Act shall not apply to the Faroe Islands and Greenland.