

No. 641/2002

Decree of the Ministry of Social Affairs and Health on Labelling the Unit Packets of Tobacco Products, on Maximum Yields of and Methods for Measuring Harmful Substances, and on Testing Laboratories

Issued on 31 July 2002

CHAPTER 1

Labelling

Section 1

Each unit packet of tobacco products, except for tobacco for oral use and other smokeless tobacco products, must carry one of the following general warnings:

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

The general warnings shall be rotated in such a way as to guarantee their appearance on an equal number of unit packets to an accuracy of 10 per cent. The warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

The general warning shall cover at least 32 per cent of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

Section 2

Each unit packet of tobacco products, except for tobacco for oral use and other smokeless tobacco products, must carry one of the following additional warnings:

- 1) Smokers die younger.
- 2) Smoking clogs the arteries and causes heart attacks and strokes.
- 3) Smoking causes fatal lung cancer.
- 4) Smoking when pregnant harms your baby.
- 5) Protect children: don't make them breathe your smoke.
- 6) Your doctor or your pharmacist can help you stop smoking.
- 7) Smoking is highly addictive, don't start.
- 8) Stopping smoking reduces the risk of fatal heart and lung diseases.
- 9) Smoking can cause a slow and painful death.
- 10) Get help to stop smoking: tel. 0800 148 484.
- 11) Smoking may reduce the blood flow and causes impotence.
- 12) Smoking causes ageing of the skin.
- 13) Smoking can damage the sperms and decreases fertility.
- 14) Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

The additional warnings shall be rotated in such a way as to guarantee their appearance on an equal number of unit packets to an accuracy of 10 per cent.

The warning shall be printed on the other most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

The additional warning shall cover at least 45 per cent of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

Section 3

The unit packets of tobacco products for oral use, where their marketing is permitted, and of smokeless tobacco products shall carry the following warning: This tobacco product can damage your health and is addictive.

The warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

The warning shall cover at least 32 per cent of the external area of the corresponding surface of the unit packet of tobacco on which the warning is printed.

Section 4

In the case of unit packets intended for tobacco products other than cigarettes, the most visible surface of which exceeds 75 cm², the warnings referred to in sections 1 and 2 shall however cover an area of at least 24 cm² of the outside packaging referred to in said sections.

Section 5

The tar, nicotine and carbon monoxide yields that are produced when a cigarette is smoked shall be printed on the side of the cigarette packet so that at least 12 per cent of the corresponding surface is covered.

Section 6

The text of the warnings and other markings referred to in sections 1 to 5 above shall be:

- 1) printed in 100 per cent black Helvetica bold type on a white background;
- 2) printed in font whose point size occupies 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 of edge of the packet; and
- 5) for tobacco product packets other than those referred to in section 3, surrounded by a 100 per cent black border that is not part of the warning, which is no less than 3 mm and not more than 4 mm in width and which in no way interferes with the legibility of the text of the warning or other marking.

Section 7

To ensure product identification and traceability, the tobacco product shall be marked by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

Section 8

The markings required by this Decree may not be printed on the price tags to be affixed to or on the text to be printed on unit packets according to section 11 of the Act on Excise Duty on Tobacco (1470/1994). Warnings and other texts shall be printed on the packets so that they cannot be detached or otherwise removed. In addition, the texts shall be printed so that they are in no way hidden, interrupted, obscured or otherwise made illegible by other written or pictorial matter or by the opening of the packet. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.

CHAPTER 2

Yields of harmful substances

Section 9

The maximum yields of cigarettes offered for commercial sale or other assignment or cigarettes manufactured commercially shall not be greater than:

- 10 mg per cigarette for tar,
- 1 mg per cigarette for nicotine, and
- 10 mg per cigarette for carbon monoxide.

CHAPTER 3

Measurement methods and testing laboratories

Section 10

The tar, nicotine and carbon monoxide yields that are produced when a cigarette is smoked shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine and 8454 for carbon monoxide. The accuracy of the tar and nicotine indications on packets shall be verified by sampling in accordance with ISO standard 8243.

The tar, nicotine and carbon monoxide yields are measured from cigarette samples in two quality control inspections every calendar year. In both inspections one sample of each cigarette brand is inspected.

Section 11

The testing laboratories referred to in section 10 shall have been accredited by the Finnish Accreditation Service (FINAS) of the Centre for Metrology and Accreditation, or by other body meeting the requirements of standard EN 45003 that has joined the Multilateral Recognition Agreement (MLA) of the European Co-operation for Accreditation, in accordance with the requirements of standard SFS EN ISO/IEC 17025. The accredited area of competence of the laboratory shall include the methods complying with the standards referred to in section 10.

An approved testing laboratory shall notify any major changes in its operations to the National Product Control Agency for Welfare and Health.

The National Product Control Agency for Welfare and Health shall submit a list of the approved testing laboratories to the European Commission. The grounds used in approving the laboratories and the methods applied in supervision of their operations must be mentioned in the list. The list shall be submitted for the first time by 30 September 2002 and after that always when any of the information is changed.

CHAPTER 4

Submitting of information

Section 12

The lists referred to in section 6 c of the Act on Measures to Reduce Tobacco Smoking (693/1976) (the Tobacco Act) and well as the reports and other information attached to them shall be submitted to the National Product Control Agency for Welfare and Health by the end of November every year.

Section 13

The list referred to in section 6 c, paragraph 1, of the Tobacco Act concerning tar, nicotine and carbon monoxide yields shall be accompanied by the certificates of the measurements carried out and their results issued by the approved testing laboratory on the basis of its quality control rounds. The results shall be given accredited, and any uncertainties in the measurement results must be reported.

Section 14

The list of ingredients on a brand-by-brand-name basis and type-by-type-basis submitted by manufacturers and importers to the National Product Control Agency for Welfare and Health in accordance with section 6 c, paragraph 1(2), of the Tobacco Act shall include, in addition to what is prescribed in said subparagraph, the following information:

- 1) the grounds for why the ingredients have been included in the tobacco products;
- 2) the purpose and class of the ingredients;
- 3) the toxicological data the manufacturer or importer has access to which concern these ingredients in burnt or unburnt form and which are particularly linked to the health effects of the ingredients when taking into account, among others, their effects causing addiction.

The list shall be established in descending order of the weight of each ingredient included in the product.

When submitting the lists and information referred to in the Tobacco Act to the National Product Control Agency for Welfare and Health the manufacturer or importer shall separately mention which items of the information included in them the manufacturer or importer regards as business secrets and demands to be kept confidential.

Section 15

The National Product Control Agency for Welfare and Health shall communicate the lists and information referred to in the Tobacco Act to the European Commission on an annual basis.

CHAPTER 5

Entry into force

Section 16

This Decision enters into force on 30 September 2002.

This Decree repeals the Decision of the Ministry of Social Affairs and Health on Labelling the Retail Packages of Tobacco Products and on Methods for Assaying Tar and Nicotine Content (1504/1992) of 23 December 1992 with amendments.

Section 5 of the Decree concerning the marking of carbon monoxide yield will be applied as from 30 September 2003.

Section 9 of the Decree will be applied as from 1 January 2004. This section is however applied to cigarettes that are manufactured within and exported from the European Community as from 1 January 2007.

Section 15 of the Decree will be applied for the first time on 31 December 2002 at the latest.

It is further allowed to commercially sell or otherwise assign such cigarettes referred to in the Decree that exist in their finished form at the entry into force of this Decree until 30 September 2003 and tobacco products other than cigarettes until 30 September 2004, although they do not comply with the provisions of Chapter 1 of this Decree, if they comply with the provisions and regulations in force when this Decree enters into force.

Measures necessary for the implementation of this Decree may be undertaken before its entry into force.