

Regulations

No. 236, 24 March 2003

on warning labelling on tobacco and measurement
and maximum yields of harmful substances.

Section I

General provisions.

Art. 1

Tobacco may only be kept for sale or distribution in Iceland if warnings of the harmfulness of the product appear on its packaging, as provided in these regulations. Packets of cigarettes shall in accord with art. 6 be especially marked with information on tar, nicotine and carbon monoxide yields.

Art. 2

Definitions.

In these regulations the following words shall have these meanings:

1. *Tobacco/tobacco product*: Product made wholly or partly from tobacco plants, such as cigarettes, cigars, pipe tobacco, snuff and tobacco for oral use.
2. *Smokeless tobacco*: Tobacco products not intended for smoking.
3. *Tar*: Raw anhydrous nicotine-free condensate of smoke.
4. *Nicotine*: Nicotinic alkaloids.
5. *Carbon monoxide*: CO.
6. *Ingredients*: All substances or constituents, except for tobacco leaf and other natural or unprocessed tobacco plant parts, which are used in the manufacture or preparation of a tobacco product, and are still present in the finished product, even if in altered form, including paper, filters, inks and adhesives.

Section II

Warnings of the harmfulness of tobacco and information on harmful tobacco substances.

Art. 3

On all packages containing tobacco products, with the exception of smokeless tobacco, the following warnings shall appear:

(a) a general warning, one of the following:

1. Reykingar drepa.
2. Reykingar eru mjög skaðlegar fyrir þig og þá sem eru nálægt þér.

These warnings shall be rotated in such a way as to guarantee their regular appearance. The warning shall be printed on the most visible surface of the unit packet, and on all outside packaging, with the exception of transparent wrappers used in the retail sale of the product.

(b) an additional warning, one of the following:

1. Þeir sem reykja deyja fyrir aldur fram.
2. Reykingar stífla slagæðar og valda kransæðastíflu og heilablóðfalli.
3. Reykingar valda banvænu krabbameini í lungum.
4. Reykingar á meðgöngu skaða barnið þitt.
5. Verndaðu börnin - láttu þau ekki anda að sér tóbaksreyk.
6. Læknirinn þinn eða lyfjafræðingur geta hjálpað þér að hætta að reykja.
7. Reykingar eru mjög ávanabindandi, byrjaðu ekki að reykja.
8. Ef þú hættir að reykja dregur það úr líkum á banvænum hjarta- og lungnasjúkdómum.
9. Reykingar geta valdið hægfara og kvalafullum dauða.
10. Fáðu hjálp við að hætta að reykja: sími 800 6030.
11. Reykingar geta dregið úr blóðflæði og valda getuleysi.
12. Reykingar flýta fyrir öldrun húðarinnar.

13. Reykingar geta skaðað sæði og draga úr frjósemi.
14. Tóbaksreykur inniheldur bensen, nítrosamín, formaldehýð og blásýru.

These warnings shall be rotated in such a way as to guarantee their regular appearance. The warning shall be printed on the other most visible surface of the unit packet, and on all outside packaging, with the exception of transparent wrappers used in the retail sale of the product.

Art. 4

On smokeless tobacco the following warning shall appear:

"Þessi tóbaksvara getur skaðað heilsuna og er ávanabindandi."

This warning shall be printed on the most visible surface of the unit packet, for instance on the lids of boxes, and all outside packaging, with the exception of transparent wrappers used in retail sale of the product.

Art. 5

The general warning required pursuant to item a art. 3, and the warning for smokeless tobacco required pursuant to art. 4, shall cover not less than 30% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

The additional warning required pursuant to item b art. 3 shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

In the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm², the warnings as referred to in arts. 3 shall cover an area of at least 22.5 cm² of each surface.

Art. 6

Information on how many mg of tar, nicotine and carbon monoxide are yielded by each cigarette shall be printed in Icelandic on one side of the cigarette packet, and cover at least 10% of the side surface.

Art. 7

Warnings required under arts. 3 and 4 and yield indications required under art. 6 shall be:

- a) printed in black Helvetica Condensed Bold type on a white background. The point size of the font shall be chosen for each text so that the text occupies the greatest possible proportion of the area set aside for it as required under arts. 5 and 6, account being taken of the requirements of the language;
- b) in lower-case type, except for the first letter of the message, and where required by grammar usage;
- c) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;
- d) for products other than those referred to in art. 4, surrounded by a black border not less than 3 mm and not more than 4 mm in width, which in no way interferes with the text of the warning or information given. The border is not counted as part of the minimum space to be covered with warnings and yield information as required under arts. 5 and 6.

Art. 8

It is prohibited to print texts required by arts. 3, 4 and 6 on the tax stamp of the unit packets.

The texts shall be printed in such a way that they cannot be removed or erased, and they shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet.

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

Art. 9

Unit packets of tobacco products shall be marked with a batch number or in other comparable manner, in order that the place and time of production may be traced.

Art. 10

A person who manufactures, imports or sells tobacco may not, without the consent of the Minister of Health and Social Security, place his own information regarding the health effects of consuming the product on the product's packaging, in words or symbols.

Art. 11

It is entirely prohibited to use, on the packaging of tobacco products, texts, names, trademarks, images and figurative or other signs suggesting that a particular tobacco product is less harmful than others.

Section III

Maximum yields of harmful substances and measurements

Art. 12

Maximum yields of harmful substances

Cigarettes marketed in Iceland shall have a maximum yield, per cigarette, of 10 mg of tar, 1 mg of nicotine, and 10 mg of carbon monoxide.

Art. 13

Measurements, tests

The tar, nicotine and carbon monoxide yields of cigarettes shall be measured, cp. art. 6, 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 is verified in accordance with ISO standard 8243.

The Ministry of Health and Social Security may require these tests to be carried out or verified by testing laboratories which are approved and monitored by the Directorate of Health in consultation with the State Wine, Spirit and Tobacco Authority.

The Ministry may also in consultation with the Directorate of Health require tobacco manufacturers or importers to carry out various other tests in order to 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 in order to assess the effects of those other substances on health, taking into account, *inter alia*, their addictiveness. The Ministry may, in consultation with the Directorate of Health, require that such tests be carried out or verified in approved testing laboratories, cp. para. 2.

The results of tests carried out in accordance with para. 3 shall be submitted to the Ministry of Health and Social Security on an annual basis. The Ministry may, however, in consultation with the Directorate of Health, provide for less frequent disclosure of test results in cases where the product specifications have not varied. The Ministry shall be notified of changes in product specifications.

The Ministry shall, in consultation with the Directorate of Health and the Committee for Tobacco Use Prevention, ensure the dissemination of information submitted in accordance with para. 4 by appropriate means with a view to informing consumers. Where relevant, account shall be taken of information which constitutes a trade secret.

Section IV

List of ingredients

Art. 14

Manufacturers and importers of tobacco products shall each year, on the first occasion no later than 30 September 2003, submit to the Directorate of Health a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type.

This list shall be accompanied by:

1. a statement setting out the reasons for the inclusion of such ingredients in those tobacco products,
2. an explanation of the function and category of the ingredients,
3. toxicological data available to the manufacturer or importer regarding these ingredients, in burnt or unburnt form as appropriate, referring in particular to their effects on

health and taking into account, *inter alia*, any addictive effects. The ingredients on the list shall be established in order of weight.

The Directorate of Health shall ensure in an appropriate manner the dissemination of the information provided in accordance with this article, with a view to informing consumers. Due account shall nevertheless be taken of protection of any information on specific production methods which constitutes a trade secret.

The Directorate of Health shall ensure that the public have access to the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields.

Each year the Directorate of Health shall send to the Ministry of Health and Social Security all data and information submitted pursuant to this article.

Section V

Costs, penalties, entry into force etc.

Art. 15

Costs.

Tobacco manufacturers shall pay the costs of labelling as provided in arts. 3 to 9, measurements and tests as provided in art. 13 and the list of ingredients as provided in art. 14.

Art. 16

Penalties.

A violation of the provisions of these regulations shall entail a fine or, in the case of a serious or repeated offence, imprisonment for up to two years.

Art. 17

Entry into force etc.

The provisions of arts. 1 to 9 and arts. 11 to 14 of these regulations are consistent with Directive no. 2001/37/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

The regulations are issued on the authority of arts. 6 and 8 of the Tobacco Control Act no. 6/2002, with subsequent amendments, and take force immediately. Regulations no. 719/2002 on warning labelling on tobacco shall be abrogated at the same time.

Temporary provision

Cigarettes which are marked in conformity with Regulations no. 433/1995 on warning labelling on tobacco may be imported into Iceland until 31 August 2003, and may be kept for sale until 31 December 2003.

Other tobacco products marked in conformity with the same regulations may be kept for sale until 30 September 2004.

The provisions of art. 11 take force on 30 September 2003.

The provisions of art. 12 take force on 1 January 2004. Until that time, the provisions on maximum tar yield under item 9 art. 4 of Rules no. 642/2000 on purchase and sale of tobacco and conditions on dealings with suppliers, shall apply.

Ministry of Health and Social Security, 24 March 2003

Jón Kristjánsson

Davíð Á. Gunnarsson

Appendix

Samples of warning labels as provided in arts. 3 to 8:

Letter type: Helvetica Condensed Bold

The labels illustrated are of the correct size for unit packages whose front and rear surfaces are 54 x 88 mm. Side surface is 21 x 88 mm.