

# **Regulations**

## **on combined image-and-text warnings on tobacco and measurement of maximum yields of harmful tobacco 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 content.

##### 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 oral tobacco.
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 tobacco products, and are still present in the finished product, even if in altered form, including paper, filters, inks and adhesives.

## Section II

### **Combined image-and-text 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, as shown in the Appendix:

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

1. Reykingar drepa. [Smoking kills.]
2. Reykingar eru mjög skaðlegar fyrir þig og þá sem eru nálægt þér. [Smoking seriously harms you and others around you.]

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 any (all) outside packaging, with the exception of transparent wrappers used in the retail sale of the product.

(b) An additional warning in conjunction with each warning picture, as shown in the Appendix:

1. Þeir sem reykja deyja fyrir aldur fram. [Smokers die young]
2. Reykingar stífla slagæðar og valda kransæðastíflu og heilablóðfalli. [Smoking clogs the arteries and causes heart attacks and strokes.]
3. Reykingar valda banvænu krabbameini í lungum. [Smoking causes

fatal lung cancer.]

4. Reykingar á meðgöngu skaða barnið þitt. [Smoking when pregnant harms your baby.]

5. Verndaðu börnin - láttu þau ekki anda að sér tóbaksreyk. [Protect children – don't make them breathe your smoke.]

6. Læknirinn þinn eða lyfjafræðingur geta hjálpað þér að hætta að reykja. [Your doctor or your pharmacist can help you stop smoking.]

7. Reykingar eru mjög ávanabindandi, byrjaðu ekki að reykja. [Smoking is highly addictive, don't start.]

8. Ef þú hættir að reykja dregur það úr líkum á banvænum hjarta- og lungnasjúkdómum. [Stopping smoking reduces the risk of fatal heart and lung diseases.]

9. Reykingar geta valdið hægfara og kvalafullum dauða. [Smoking can cause a slow and painful death.]

10. Fáðu hjálp við að hætta að reykja: sími 800 6030. [Get help to stop smoking: tel. 800 6030.]

11. Reykingar geta dregið úr blóðflæði og valda getuleysi. [Smoking may reduce the blood flow and causes impotence.]

12. Reykingar flýta fyrir öldrun húðarinnar. [Smoking causes ageing of the skin.]

13. Reykingar geta skaðað sæði og draga úr frjósemi. [Smoking can damage the sperm and decreases fertility.]

14. Tóbaksreykur inniheldur bensen, nítrosamín, formaldehyð og blásýru. [Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.]

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, in such a way that the format and proportions of the source document and the graphical integrity of image

and text are preserved. The warning shall also be on all outside packaging, with the exception of transparent wrappers used in the retail sale of the product.

(c) In addition to the above warnings, the following information shall appear regarding assistance available for those who wish to give up smoking.

1. Fáðu hjálp við að hætta að reykja á reyklus.is [Get help to stop smoking on reyklus.is]
2. Fáðu hjálp við að hætta að reykja í síma 800 6030. [Get help to stop smoking on tel. 800 6030.]
3. Fáðu hjálp við að hætta að reykja í síma 800 6030 eða á reyklus.is. [Get help to stop smoking on tel. 800 6030 or on reyklus.is]

#### Art. 4

On smokeless tobacco the following warning shall appear:

"Þessi tóbaksvara getur skaðað heilsuna og er ávanabindandi." [This tobacco product can damage your health and is addictive.]

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 under item a art. 3, and the warning for smokeless tobacco under art. 4, shall cover not less than 30% of the external area of that surface of the unit packet of tobacco on which it is printed.

The combined image-and-text warning under item b art. 3 shall cover not

less than 40% of the external area of that surface of the unit packet of tobacco on which it is printed, excluding the black 3- to 4-millimetre border surrounding the surface.

In the case of unit packets containing products other than cigarettes, the most visible surface of which exceeds 75 cm<sup>2</sup>, the combined image-and-text warnings under art. 3 shall cover at least 22.5 cm<sup>2</sup> 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

Combined image-and-text warnings under arts. 3 and 4 and information on ingredients under art. 6 shall :

- a) be used in rotation so that regular promulgation of all the additional warnings is ensured;
- b) be printed on the most noticeable surface of the pack, in such a way that the format and proportions of the source document and the graphical integrity of image and text are preserved, as provided in arts. 5 and 6, account being taken of the requirements of the language;
- c) occupy the entire area reserved for the additional health warning, be parallel to the top edge of the pack, and be printed in the same direction as other information on the pack;
- d) be published in conformity with EU technical specifications for printing;

e) be 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 or the visual part of the image-and-text warning.

Combined image-and-text warnings under item b. art. 3 shall conform with the following technical specifications for printing provided by the EU. The technical specifications for printing are:

Combined image-and-text warnings shall be placed on packaging without any changes to their composition, i.e. proportions and colour as in the Commission's source document.

Combined image-and-text warnings are conceived as a whole image and must not be amended.

Combined image-and-text warnings shall be printed in four colours /-CMYK-/ screen a minimum of 133 lines per 2.54 cm

#### Art. 8

It is prohibited to print texts under 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 must 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

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

### Section III

#### **Maximum yields of harmful substances and measurements**

##### Art. 11

###### *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. 12

###### *Measurements, tests*

The tar, nicotine and carbon monoxide yields of cigarettes shall be measured, cp. art. 6, under 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 Welfare may require these tests to be carried out or verified by testing laboratories which are recognised 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 Director 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 -by-brand 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 Director of Health, require that such tests be carried out or verified in recognised testing laboratories, cp. para. 2.

The results of tests under para. 3 shall be submitted to the Ministry of Welfare on an annual basis. The Ministry may, however, in consultation with the Director 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 Director of Health and the Tobacco Control Board, 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. 13

Manufacturers and importers of tobacco products shall every year submit to the Director 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 addition of the relevant ingredients to those tobacco products,
2. an explanation of the properties and classification 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*, all addictive effects. The ingredients shall be listed in order of weight.

The Director 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 Director 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 Director of Health shall send to the Ministry of Welfare all data and information submitted under this article.

## Section V

### **Costs, penalties, entry into force etc.**

#### Art. 14

##### *Costs.*

Tobacco manufacturers shall meet 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. 15

##### *Penalties.*

Violations of the provisions of these regulations entail penalties as provided in Section VI of the Tobacco Control Act no. 6/2002.

#### Art. 16

##### *Entry into force etc.*

The provisions of arts. 1 to 13 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 and Commission Decision 2003/641/EC on the use of colour photographs or other illustrations as health warnings on tobacco packages

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. 236/2003 on warning labelling on tobacco and measurement and maximum yields of harmful substances shall be abrogated at the same time.

*Temporary provisions*

Cigarettes which are marked in conformity with Regulations no. 236/2003 on warning labelling on tobacco and measurement and maximum yields of harmful substances may be imported into Iceland until 31 December 2011, and may be offered for sale until 30 June 2012. Other tobacco products marked in conformity with the same regulations may be offered for sale until 30 June 2012.

*Ministry of Welfare, xx xxxxxx 2011*

**Appendix**

Examples of combined image-and-text warnings: