

# Statutes of the National Institute of Public Health

Publisher: Gunnar Ågren  
ISSN 1650-6928

---

## **The Regulations of the National Institute of Public Health on health warnings on tobacco products and on content declaration for and limitations on the levels of certain constituents of cigarette smoke**

**FHIFS 2001:2**

Printed on  
January 25, 2002

Adopted on 21 December 2001.

The Tobacco Act (1993:581) states that tobacco packaging that is intended to be provided through a business operation to consumers in the country must have health warnings and content declarations to the extent required (see Articles 9–11 of the Tobacco Act).

The Tobacco Act allows for the prescription of limits for the toxic chemicals that the tobacco product may contain or give rise to. A product that fails to comply with these prescriptions may not be manufactured in or brought into Sweden for sale to consumers (see Article 18 of the Tobacco Act).

In Directive 2001/37/EC of 5 June 2001, the European Parliament and the Council of the European Communities have established provisions on the convergence of the member states' laws and regulations concerning the manufacture, presentation and sale of tobacco products <sup>1</sup>.

Under Article 2 Tobacco Ordinance (2001:312), the National Institute of Public Health provides the following.

### **Warnings on tobacco products that are intended to be smoked**

**Article 1** Warnings must appear on any package of a tobacco product that is intended to be smoked, and that is made available through a business operation to consumers in the country. The same applies to any external packaging that may be found in the retail sale of the product, with the exception of transparent wrappers.

**Article 2** All packages and outer wrappers as referred to in Article 1 shall have, on the most visible surface of the package and its outer cover, one of the following warnings:

Smoking kills.

Smoking seriously harms you and others around you.

The warning shall cover at least 30 per cent of the exterior of the surface on which it is printed. Regarding the packages of products other than cigarettes, the most visible area of which is greater than 75 cm<sup>2</sup>, the surface designated for the warning must not be not less than 22.5 cm<sup>2</sup>.

---

<sup>1</sup> Act reprinted 1996:941.  
EGT L 194, 18.7.2001, p. 26 (Celex32001L0037). ([http://www.fhi.se/pdf/dir2001-37\\_eg.pdf](http://www.fhi.se/pdf/dir2001-37_eg.pdf))

The texts shall be rotated so that each of them occurs regularly.  
The texts must conform to the provisions of Articles 7 and 8.

## **FHIFS 2001:2**

**Article 3** In addition to the text set out in Article 2, every package and its outer wrapper as referred to in Article 1 shall have, on its second most visible surface, and additional warnings from List 1, below.

That warning must cover at least 40 per cent of the exterior of the surface on which it is printed. Regarding the packages of products other than cigarettes, the most visible area of which is greater than 75 cm<sup>2</sup>, the surface designated for the warning must not be not less than 22.5 cm<sup>2</sup>. The texts shall be rotated so that each of them occurs regularly. The text must conform to the provisions of Articles 7 and 8.

### **Warnings on tobacco products that are not intended to be smoked**

**Article 4** Warnings must be provided on all packages of tobacco products that, while not intended to be smoked, are intended to be made available through a business operation to consumers in the country. The same applies to any external packaging that may be found in the retail sale of the product, with the exception of transparent wrappers.

All packages and outer wrappers shall have, on the most visible surface of the package and its outer cover, the following warning:

This tobacco product may damage your health and is addictive.

The warning shall cover at least 30 per cent of the exterior of the surface on which it is printed.

Regarding packages the most visible area of which is greater than 75 cm<sup>2</sup>, the surface designated for the warning must not be not less than 22.5 cm<sup>2</sup>.

The text must be formulated in accordance with the provisions of Articles 7 and 8.

### **Information on levels of certain constituents in cigarette smoke (content declaration)**

**Article 5** Content information on tar (non-aqueous, nicotine-free smoke condensate), nicotine (nicotinic alkaloids) and carbon monoxide in cigarette smoke must be printed on the sides of all cigarette packages. The content declaration must cover at least 10 per cent of the surface on which it is printed and conform to the provisions of Articles 7 and 8. The levels shall be measured in accordance with Article 9.

### **Maximum levels of certain constituents of cigarette smoke**

**Article 6** The smoke from cigarettes manufactured in or imported to the country for sale to consumers must not contain more than

- 10 mg of tar per cigarette,
- 1 mg of nicotine per cigarette and

- 10 mg carbon monoxide per cigarette.

The levels shall be measured in accordance with Article 9.

### **Label design**

**Article 7** The warnings and the content declaration referred to in Articles 2–5 shall be

- clear, legible, and written in Swedish,
- printed in Helvetica bold,
- printed in a font size that ensures that the text covers the largest possible proportion of the space provided for it,
- printed in lower-case type, except for the first letter of each sentence,
- printed in black on a white background
- centred in the space where the text is printed,
- positioned parallel to the upper edge of the package, and
- surrounded by a black border that is not less than 3 mm and not more than 4 mm wide and does not interfere with the space reserved for warnings or the content declaration.

The positional and text-border requirements do not apply to the warning text referred to in Article 4.

**Article 8** The warnings and the content declaration referred to Articles 2–5 must not be

- printed on the highest price mark, tax mark or the equivalent mark on the package, or on a transparent wrapper,
- removed or obliterated,
- hidden, obscured or interrupted by other text or pictorial elements or by the opening of the package.

With regard to products other than cigarettes, the texts may be affixed to packages in the form of stickers, provided that they cannot be removed.

### **Methods of measurement and reporting**

**Article 9** The content of tar, nicotine and carbon monoxide shall be measured in accordance with ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

The accuracy of the values for tar and nicotine to be verified in accordance with ISO standard 8243.

**Article 10** By 15 December each year, manufacturers and importers of cigarettes shall report to the National Institute of Public Health the applicable values for tar, nicotine, and carbon monoxide for all cigarette brands they deal with, and the names of the persons responsible for the measurements.

### **List 1**

Additional warnings under Article 3:

Smokers die younger.

Smoking clogs the arteries and causes heart attacks and strokes.

Smoking causes fatal lung cancer.

Smoking when pregnant harms your baby.

Protect your children. Do not let them breathe your smoke.

Smoking is highly addictive. Do not start smoking.

If you stop smoking reduces the risk of fatal heart and lung diseases.

Smoking can cause a slow and painful death. Smoking may reduce blood flow and causes impotence. Smoking causes ageing of the skin.

Smoking can damage sperm and decreases fertility. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

### **Transitional provisions**

1. These regulations come into force on the date they are received from the printer.
2. The provisions of Article 6 shall apply as of 1 January 2004. Until then, the provisions of older regulations limiting the tar content of cigarettes apply.
3. These regulations will replace Article 2 of the Regulations and General Guidelines of the National Institute of Public Health of 1 July 2001 (FHIFS 2001:1).
4. Cigarette packages with labelling under the old rules may be made available through business operations to consumers in the country until 30 September 2003. Other tobacco packages with labelling under older provisions may be made available through business operations to consumers in the country until 30 September 2004.

Gunnar Ågren

Ola Assarsson

