

**Tobacco Product Ordinance\*)**

**of 20 November 2002**

Pursuant to § 21 para. 1 no. 2 (c) to (f) and (h) to (j) and no. 2 in conjunction with § 19 para. 1 no. 2 (b) and para. 1 no. 4 (c) and § 22 para. 3 of the Food and Consumer Products Act as amended in the publication of 9 September 1997 (FGL. I p. 2296) from which § 19 para. 1 and § 22 para. 3 by Article 42 no. 4 of the Ordinance of 29 October 200 (FGL. I p. 2785) and § 21 para. 1 last amended by Article 2 of the law of 8 August 2002 (FGL. I p. 3116), in conjunction with § 1 of the Jurisdiction Adjustment Act [Zustaendigungsanpassungsgesetz] of 16 August 2002 (FGL. I p. 3165) and the organization decree of 22 October 2002 (FGL. I p. 4206), the German Ministry for Consumer Protection, Food and Agriculture with the German Ministry for Economics and Labour hereby order:

§ 1

**Definitions**

For the purposes of this Ordinance,

1. Tobacco products are :

Tobacco products within the meaning of § 3 para. 1 of the Food and Consumer Goods Act;

2. Packages are:

Finished packages within the meaning of § 6 para. 1 of the Weights and Measures Act [Eichgesetz], which are intended for consumers within the meaning of § 6 para. 1 of the Food and Consumer Goods Act;

3. Tar is:

The nicotine-free, dry smoke condensate;

4. Nicotine is:

The nicotine alkaloids

5. Additives are:

Any substance or component used in the manufacture or preparation of a tobacco product and in the end product, also in modified form, including paper, filters, printing ink, and adhesives but with the exception of the tobacco leaf and other natural or unprocessed parts of the tobacco plant.

§ 2

**Tar, nicotine and carbon monoxide content in cigarettes**

Cigarettes may only be manufactured commercially such that tar, nicotine and carbon monoxide content in the smoke of cigarettes do not exceed the following maximum limits:

1. Tar content: 10 milligrams per cigarette,
2. Nicotine content: 1.0 milligram per cigarette,
3. Carbon monoxide content: 10 milligrams per cigarette.

§ 3

**Measurement methods**

For the measurements of tar, nicotine and carbon monoxide content in cigarette smoke, the following requirements apply:

1. The analytical methods published in the Official Collection of Analytical Methods pursuant to § 35 of the Food and Consumer Goods Act (Official Collection)<sup>1)</sup> under the classification numbers

T 60.05-3 (DIN ISO 4387)      Version of April 2001

T 60.05-4 (DIN ISO 10315)      Version of April 2001

T 60.05-7 (DIN ISO 8454)      Version of August 1997

2. The analyses of the labeling on tar and nicotine content on the packages are conducted in accordance with the method published in the Official Collection under the classification number

T 60.05-1 (DIN ISO 8243)      Version of July 1993

§ 4

**Accreditation of test laboratories**

- (1) Test laboratories that take the measurements in accordance with §3 must be approved by the responsible authorities.
- (2) Test laboratories are only approved if the following requirements are met:
  1. Accreditation according to DIN EN ISO/IEC 17025 (2001)<sup>1)</sup> by an accreditation body in the German Accreditation Council,
  2. Successful participation in proficiency tests, which must take place at least once a year.
- (3) The responsible authority checks at least once a year whether the requirements mentioned in paragraph 9 are met. If the requirements are not met, the accreditation must be revoked without prejudice to the provisions of federal state law corresponding to § 49 of the Administrative Procedure Act.
- (4) Accreditation according to paragraph 1 is equivalent to accreditation granted by the responsible authority of another member state of the European Union or another signatory to the European Economic Agreement.

§ 5

**Reporting obligations**

- (1) Manufacturers and importers of tobacco products inform the responsible authority, in accordance with the guidelines of paragraph 3 clause 1 in a list arranged by brand name and type, all of the additives used in the manufacture of the individual tobacco products, including the quantities in decreasing order of their percentage by weight. For cigarettes, the tar, nicotine and carbon monoxide content in the smoke must also be reported.

## Unofficial Translation

- (2) A statement is to be included with the list pursuant to paragraph 1 in which the reasons for adding the additives to the tobacco products are explained. The function and category of the additives are to be indicated in it. The toxicological data that the manufacturer or importer has on these additives, including the combustion products, are also to be included in the list, particularly with regard to their effects on health and addictive properties.
- (3) The list must be sent to the responsible authority every year by 30 November, by 30 November 2002 the first time. The Federal Office for Consumer Protection, Food and Agriculture gives the content of the list in a suitable form to educate the consumer. With the disclosure, sufficient consideration must be given to protecting the information on certain product formulations, which represent a business secret.

## §6

### Identification of the content of smoke constituents and lot number

- (1) Packages of cigarettes may only be marketed commercially if the tar, nicotine and carbon monoxide content in cigarette smoke measured according to § 3 no. 1 are printed on the narrow side of the cigarette package in accordance with clause 2. These labels must cover at least 10% of the area concerned.
- (2) Tobacco products may only be marketed commercially if the lot number or a corresponding identifier is included on the package, which allows the place and time of manufacture to be identified.

## §7

### Warnings

- (1) Packages of tobacco products, with the exception of tobacco products not intended for smoking, may only be marketed commercially if one of the following general warnings is included on the label, in accordance with clauses 2 and 3:

1. "Smoking kills" or "Smoking can kill" or
2. "Smoking seriously harms you and others around you".

These general warnings are to be used on a rotating basis so that they regularly appear on the packages; either of the warnings under number 1 is to be used. These warnings must be printed on the most visible broadside of the package and on any outside packaging used in the retail sale of the product, with the exception of additional transparent packaging.

- (2) Products pursuant to paragraph 1 may only be marketed commercially if they bear an additional warning in accordance with the annex and according to the requirements of clauses 2 and 3. These warnings are to be used on a rotating basis so that they regularly appear on the packages. They are on the other broadside of the package and on any outside packaging used in the retail sale of the product, with the exception of additional transparent packaging.
- (3) Tobacco products not intended for smoking may only be marketed commercially if they bear the following warning pursuant to clause 2:

This tobacco product can harm your health and be addictive."

## Unofficial Translation

The warning is on the most visible broadside of the package and on any outside packaging used in the retail sale of the product, with the exception of additional transparent packaging.

- (4) Tobacco products may only be marketed commercially if the words “The EU Health Minister:” precede the warnings pursuant to paragraphs 1 to 3 and this information appears outside a specified edge pursuant to § 8 para. 1 no. 4.

## § 8

### Labeling

- (1) The labels pursuant to § 6 para. 1 and § 7 are to be printed as follows:
1. In black Helvetica bold type on a white background;
  2. In lower case type except for the first letter of the message, as long as not otherwise necessary due to German spelling;
  3. Centered in the area in which the text is required to be printed, parallel to the top edge of the package;
  4. For products other than those listed in § 7 para. 3 surrounded by a black border not less than three mm in width and not more than 4 mm in width, which does not in any way interfere with the legibility of the warnings or the other information;
  5. In German.
- (2) The warnings required pursuant to § 7 para. 1 and 3 must cover at least 30% of the outer surface of the broadside of the package on which it is printed. The warning required pursuant to § 7 para. 2 must cover at least 40% of the outer surface of the broadside of the package on which it is printed. For packages of tobacco products other than cigarettes, on which the most visible side is larger than 75 cm<sup>2</sup>, the warnings specified in § 7 para. 1 and 2 must cover an area of at least 22.5 cm<sup>2</sup> on each broadside.
- (3) The information pursuant to §§ 6 and 7 may not be printed on the tax stamp of the package. They must be irremovably fixed, indelible and shall not be hidden, obscured or interrupted by other written or pictorial matter, nor by the opening of the package. For tobacco products other than cigarettes, the warnings may be applied using adhesives as long as they cannot be removed.
- (4) Packages of tobacco products may only be marketed commercially if the information and warnings pursuant to § 6 para. 1 and § 7 comply with the requirements of paragraphs 1 to 3.

## § 9

### Misleading information

Terms, names, brands and pictorial or other signs that give the impression that a certain tobacco product is less harmful than another may not be used on the packaging of tobacco products.

§ 10

**Criminal Offences and Administrative Offences**

- (1) Pursuant to § 52 para. 2 no. 1 of the Food and Consumer Goods Act, whoever who intentionally commercially manufactures cigarettes without complying with the maximum content of tar, nicotine or carbon monoxide stipulated in § 2 shall be penalized. Whoever commits any of the acts described in clause 1 through negligence, commits an administrative offence according to § 53 para. 1 of the Food and Consumer Goods Act.
- (2) Whoever intentionally or through negligence puts on the market packages of cigarettes, packages, packages of tobacco products or tobacco products against § 6 para. 1 clause 1, § 7 para. 1 clause 1, para. 2 clause 1, para. 3 clause 1 or para. 4 or § 8 para. 4, commits an administrative offence within the meaning of § 53 para. 2 no. 1(c) of the Food and Consumer Goods Act.
- (3) Whoever intentionally or through negligence, contrary to § 5 para. 1, does not make a disclosure or does not make a disclosure accurately, completely, not in the prescribed manner or not in a timely manner, commits an administrative offence within the meaning of § 54 para. 2 no. 1 of the Food and Consumer Goods Act.

§ 11

**Transitional regulations**

- (1) Cigarettes that comply with the provisions of the Ordinance concerning the labeling of tobacco products and concerning the maximum amounts of tar in cigarette smoke of 29 October 1991 (FGL. I p. 2053), last amended by Article 2 of the Ordinance of 8 March 1996 (FGL. I p. 460), may still be marketed until 30 September 2003. In deviation from clause 1, cigarettes that comply with the regulations of the Ordinance mentioned in clause 1 may still be offered for sale, displayed, kept in stock for the purposes of the sale or other transfer to the consumer and delivered to the consumer until 30 June 2004.
- (2) Products other than cigarettes, which comply with the regulations of the Ordinance mentioned in clause 1, may still be marketed commercially. In deviation from clause 1, products other than cigarettes that comply with the regulations of the Ordinance mentioned in clause 1 may still be offered for sale and displayed, kept in stock for the purposes of the sale or other transfer to the consumer and delivered to the consumer until 30 September 2004.
- (3) Cigarettes with tar, nicotine and carbon monoxide content that exceed the maximum quantities mentioned in § 2 may still be manufactured and marketed until 31 December 2003. Cigarettes that are intended for export of the European Community, may still be manufactured and exported until 31 December 2006.
- (4) Tobacco products, for which information is used contrary to the provisions in § 9, may be marketed until 30 September 2003 subject to clause 2. In deviation from clause 1, in clause 1, they may be offered for sale and displayed, kept in stock for the purposes of the sale or other transfer to the consumer and delivered to the consumer:
  1. Cigarettes, for which information is used contrary to the provisions in § 9, until 30 June 2004,

2. Tobacco products other than cigarettes, for which information is used contrary to the provisions in § 9, until 30 September 2006.

§ 12

**Entry into force, termination**

This Ordinance shall enter into force on the day after its promulgation. At the same time, the Ordinance on the labeling of tobacco products and maximum limits of tar in cigarette smoke of 29 October 1991 (FGL. I p. 2053), last amended by Article 2 of the Ordinance of 8 March 1996 (FGL. I p. 460), shall be terminated.

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The Bundesrat has given its approval.

Bonn, 20 November 2002

The Federal Minister for Consumer Protection, Food and Agriculture

Renate Künast

**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 pharmacist can help you to 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: (telephone/postal address/internet address/consult your doctor/pharmacist).
11. Smoking may reduce blood flow and cause impotence.
12. Smoking causes aging of the skin.
13. Smoking can damage sperm and decreases fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.