
**Ordinance on Tobacco Products and Products Containing Tobacco
By-products Intended for Smoking
(Ordinance on Tobacco, OTab)****817.06**

of October 27, 2004 (State December 13, 2005)

The Swiss Federal Council

Whereas Article 21, section 2, and Article 37 of the Federal Law of October 9, 1992 on food products¹,

hereby decrees:

Section 1 General Provisions**Article 1² Purpose**

1 This ordinance applies to tobacco products and products containing tobacco by-products intended for smoking, which governs:

- a. Manufacture;
- b. Labeling;
- c. Advertising and feedback to consumers.

2 Chapters 5 through 7 of the Ordinance of November 23, 2005 on food products and usual objects (ODAIOWs)³ and pertinent ordinances of the DFI applicable by analogy to tobacco products and to products containing tobacco by-products.

Article 2 Definitions

In this ordinance, the following definitions apply:

- a. *Tobacco*: The leaves or parts of leaves or sides of plants *Nicotiana tabacum L.* and *Nicotiana rustica L.*;
- b. *Raw tobacco*: Dried, fermented or treated tobacco according to other usual industrial processes;
- c. *Reconstituted tobacco (or homogenized tobacco)*: the leaves, products in the form of leaves or flakes manufactured from finely ground raw tobacco, then agglomerated or from clean manufacture wastes processed in the same way in which the plant parts are no longer identifiable macroscopically; reconstituted tobacco contains at least 70% raw tobacco mass in the dry material.

RO 2004 4533

¹ RS 817.0

² New text according to Chapter II 3 of Attachment 2 in Ordinance of November 23, 2005 on food products and usual objects, in effect since January 1, 2006 (RS 817.02)

³ RS 817.02

- d. *Tobacco products*: The products comprised, in whole or in part, of tobacco and especially intended to be smoked (cigars, cigarettes and similar products, shredded tobacco and rolled tobacco), snuffed, sucked or chewed,
- e. *Tobacco by-products*: Substances other than tobacco, intended to be smoked.

Section 2 Products subject to Authorization and Banned Products

Article 1 Products subject to Authorization

1 The products containing tobacco by-products and intended to be smoked can only be marketed to consumers with authorization from the Federal Office of Public Health (OFSP).

2 Authorization is issued when the product:

- a. Satisfies by analogy the requirements set for tobacco products intended to be smoked.
- b. Is not harmful to human health directly or, in an unexpected manner, and
- c. Does not have any psychotropic effect.

Article 4 Authorization Procedure

1 The request for authorization must be filed with the Federal Office of Public Health (OFSP).

2 The request must be accompanied by the following items:

- a. Composition and anticipated usage of the product;
- b. Content of the product in tar, nicotine and carbon monoxide;
- c. Certificate proving that the product is not harmful to health directly or in an unexpected manner, and it does not have any psychotropic effect.
- d. Anticipated packaging unit.
- e. A sample of the product.

3 By virtue of section 2, item c, the OFSP can, by agreement with the applicant and at the latter's expense, call upon independent experts and require other assessment documents (for example, an analysis report).

4 The authorization is issued only to entities domiciled or that have their principal business office in Switzerland. Other entities must have in Switzerland a representative that will be in charge of filing the request and assume responsibility for the application of the prescription.

5 In the wording of the authorization, the OFSP sets the specific name and the appropriate warnings for the product.

6 The authorization is limited to 10 years maximum. It expires if no request for renewal is filed before its expiration.

7 The OFSP may withdraw authorization when, based on new scientific discoveries, the conditions stated in Art. 3, Section 2 are no longer met.

7 The OFSP publishes the list of authorized products in the official Swiss Commerce paper.

Article 5 Banned Products

1 Tobacco products intended for oral use cannot be imported or sold.

2 Construed as such products are those packaged as a powder, fine particles or any combination of these forms, especially those that come in porous bags or in any other form. Products intended to be smoked or chewed are the exception.

Section 3 Manufacture of Tobacco Products

Article 6 Substances Used for Manufacture of Tobacco Products

1 Only those tobacco products that, apart from raw tobacco, contain only the following substances and within the limit of indicated percentages are admitted without authorization (the proportions are related to the dry material of the finished product, excluding any wrappers made from material other than tobacco):

a. *sapid ingredients*: total quantity does not exceed 15% mass and, if shredded or rolled tobacco is involved, 20% mass; they are defined as:

1. ⁴the aromas in terms of Attachment 3, Chapter 24, of the DFI Ordinance of November 23, 2005 on labeling and advertising of food products (OEDA)⁵,
2. the *Folia liatris*; the total content in coumarin does not exceed 0.1% mass,
3. the varieties of sugar, honey and spices, as well as any other inoffensive part of plants and their extracts,
4. ⁶the sweeteners in terms of Attachment 1, Section C, Chapter 1, of DFI Ordinance of November 23, 2005, on additives (OADdd)⁷, with the exception of sucralose E955 and aspartame acesulfame salt E962;

b. *Moistening agents*: In total quantity not exceeding 10% mass; authorized moistening agents are: glycerol, sorbitol, 1,2-propylene glycol, 1,3-butylene glycol, triethylene glycol, orthophosphoric acid and alpha glycerophosphoric acid and their sodium, potassium, calcium and magnesium salts.

c. *Ash bleaching products and combustion accelerators* are authorized: aluminum hydroxide, aluminum oxide, aluminum silicate, aluminum sulfate, alum, silicic acid,

⁴ New text according to Chapter II.3 of Attachment 2 in the Ordinance of November 23, 2005 on food products and usual objects, in effect since January 1, 2006 (RS 817.02).

⁵ RS 817.022.21

⁶ New text according to Chapter II.3 of Attachment 2 in the Ordinance of November 23, 2005 on food products and usual objects, in effect since January 1, 2006 (RS 817.02).

⁷ RS 817.022.31

talcum, magnesium oxide, titanium dioxide, carbonic, acetic, malic, citric, tartaric, lactic and formic acids and their sodium, potassium, calcium and magnesium salts, ammonium, sodium, potassium, calcium and magnesium phosphates, ammonium chloride and ammonium sulfate, for cigars and shredded tobacco, potassium nitrate.

- d. *Preservation agents* for which, in case of combined usage, the sum of all quotients obtained by dividing, for each agent used, the amount added by the maximum authorized content must not exceed 1 (one):
1. For cigarettes:
 - Benzoic acid as well as its sodium, potassium and calcium salt and sorbic acid, as well as its potassium and calcium salts, up to 3 g (grams) per kilogram for each cigarette;
 - Ethyl or propyl ether of parahydroxybenzoic acid, as well as its sodium salts, up to 1 g per kilogram for each cigarette.
 2. For cigars, shredded tobacco, rolled tobacco and reconstituted tobacco:
 - Benzoic acid, as well as its sodium, potassium and calcium salts, sorbic acid and its potassium and calcium salts and ethyl or propyl ether parahydroxybenzoic acid, as well as its sodium salts, up to 5 g per kilogram for each cigarette.
 - 2 (thiazolyl-4-)-2-benzimidazole and formic acid, up to 1.5 g per kilogram for each cigarette.
- e. *Adhesive and bonding agents*: Gelling and thickening agents, in accordance with Attachment 3 OAdd, as well as gelatine, lack gum, collodion, ethyl cellulose, acetyl cellulose, hydroxyethyl cellulose, hydroxytethyl methyl cellulose, hydroxypropylguar and glyoxal; in addition, for wrapper glues, aqueous dispersions of polyvinyl acetate and copolymers of polyvinyl acetate.

2 The proportion of substances listed in Section 1, subsections "a" through "e", related to the dry material of the finished product, must not exceed 25% mass in cigarettes, cigar and similar items for smokers, and 30% mass in the other tobacco products; wrappers made from materials other than tobacco are not taken into account.

3 Upon a founded request, the OFSP may authorize other substances. The authorization is limited in time and published in the official Swiss Commerce paper.

Article 7 Cigar Preparation

1 The dry or wet powder of cigars and similar products intended to equalize or to accentuate color is allowed if you use tobacco powder and small quantities of extract from logwood, yellow wood, buckthorn berry, liquorice juice, sodium humate or walnut extract.

2 In addition, dyes allowed in food products pursuant to Attachment 1, Section "A", of the Ordinance of March 27, 2002 on additives (OAdd)⁸ may be used to equalize coloring.

Article 8 Cigarettes: Maximum tar, nicotine and carbon monoxide content

Cigarette smoke distributed in Switzerland must not have, per cigarette, content higher than:

⁸ (RO) 2002 1201, 2004 1843 3039 2005 1065 RO 2005 – **Article 7**). See presently the Ordinance of Nov. 23, 2005 on additives (RS 817.022.31).

- a. 10 mg for tar;
- b. 1.0 mg for nicotine;
- c. 10 mg for carbon monoxide.

Article 9 Test Laboratory and Measurement Methods

1 The tar, nicotine and carbon monoxide content measurements must be taken by a test laboratory:

- a. Accredited in Switzerland according to the provisions of Ordinance of June 17, 1996 on Accreditation and Designation⁹.
- b. Recognized by Switzerland under an international agreement, or
- c. Otherwise qualified or recognized in accordance with Swiss law.

2 The conformance certification or test report established by a foreign organization that is not recognized by virtue of Section 1 is valid as proof only if it is plausible that:

- a. The conformance test or evaluation procedures that were applied meet Swiss requirements, and
- b. The foreign organization has qualification procedures equivalent to those required in Switzerland.

3 The measurements are taken in conformity with recognized scientific and technical rules.

4 The OFSP publishes in the official Federal paper and in the handbook of food products a list of technical standards that can meet the requirements relative to the measurement methods, with their titles and the reference or the address where it is possible to obtain them.

Article 10 Requirement to File Declaration

1 The manufacturer or importer of tobacco products must communicate to the OFSP the following indications concerning the tobacco products that such entity distributes in Switzerland:

- a. List 1: Specific substances added to raw tobacco in a brand: listing, by type, by brand and by quantity used (in decreasing order) of substances that contain a percentage, by weight, of more than 0.1% of raw tobacco used; the substances present in a weaker proportion can be grouped in a single category (for example, aromas);
- b. List 2: Functions and maximum quantities of all the substances added to raw tobacco: listing, by type and by alphabetical order, of all the additives added to the tobacco products; for every substance, the function and maximum quantity used in a tobacco product must be indicated;
- c. List 3: Added substances in tobacco-free component parts: listing, by type and by alphabetical order, of all the substances added to the tobacco-free component parts (for

⁹ RS 946.512.

example, paper, glues, filter); for every substance, the maximum quantity used in a tobacco product must be indicated;

- d. List 4: Harmful substances in cigarettes: listing, by brand, of tar, nicotine and carbon monoxide content in each cigarette.

2 The toxicological data of additives used, with and without combustion, must be indicated to the extent that these facts may be known to the person who submits the declaration.

3 The indications must be addressed to the OFSP in all the official languages and in electronic format for publication, once a year, no later than September 30.

4 The OFSP does publish the data.

Section 4 Labeling of Tobacco Products

Article 11 Mandatory Indications

When marketed to the consumer, each packaging unit of tobacco products must bear the following indications:

- a. ¹⁰ The specific designation set forth in Article 2, section 1, subsection “a”, OEDAI¹¹
- b. The name of the manufacturer under the terms of Article 16, section 1, subsection “b” of the federal law of March 21, 1969 on tobacco taxation¹² or the back number assigned by the General Customs Directorate;
- c. The producer country, as long as it is not derived from the indication according to subsection “b”;
- d. For products in which coloring has been equalized: the mention of “color-equalized”;

¹⁰ New content according to Chapter II.3 of Attachment 2 in the Ordinance of Nov. 23, 2005 on food items and usual objects, in effect since January 1, 2006 (RS **817.02**).

¹¹ RS **817.022.21**

¹² RS **641.31**

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- e. For cigarettes: the tar, nicotine and carbon monoxide contents;
 - f. The general and supplementary warnings.

Article 12 Warnings

1 Each packaging unit of tobacco products intended to be smoked must display a general warning and a supplementary warning.

2 The general warnings are the following:

- a. "Smoking kills";
- b. "Smoking is seriously harmful to your health and to the health of those around you."

3 The supplementary warnings are the following:

- a. "Smoking shortens your life";
- b. "Smoking clogs arteries and causes heart attack and stroke";
- c. "Smoking can cause fatal lung cancer";
- d. "Smoking during pregnancy is harmful to the health of your baby";
- e. "Protect children, do not smoke in their presence";
- f. "Specialists in the medical field will help you quit smoking";
- g. "Smoking creates a strong dependence";
- h. "Quitting smoking reduces the risk of fatal heart and lung disease;"
- i. "Smoking causes cancer of the oral cavity";
- j. "Help yourself quit smoking: 0848 000 181 / www.fumercafaitdumal.ch";
- k. "Smoking can reduce blood flow and causes impotence";
- l. "Smoking ages your skin";
- m. "Smoking can alter sperm and decrease fertility";
- n. "Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide."

4 Warnings must be issued alternately, so that each warning will appear regularly on packaging units.

5 Supplementary warnings must be combined with color photographs or other illustrations showing and explaining consequences of tobacco addiction on health. In an ordinance, the Federal Department of the Interior (DFI) sets the illustration and their combination with the supplementary warnings. It can decide the requirement of incorporating other visual indications (for example, logos, telephone numbers, Internet sites) relative to the prevention of tobacco addiction.

6 Every packaging unit of tobacco products not intended for smoking bears the following indication: "This tobacco product can be harmful to your health and creates a dependency".

Article 13 Location, Form and Language of Indications

1 Indications according to Article 11

2 Indications according to Article 11, sections "a" through "d", appear in, at least, one official language and indications according to Article 11, sections "e" and "f", appear in all the official languages and according to this order: German, French and Italian.

Article 14 Location and Size of Indications Relating to Harmful Substances

1 The tar, nicotine and carbon monoxide contents of cigarettes are indicated on one of the side faces of the cigarette pack.

2 These indications cover at least 15% of such surface.

Article 15 Location and Size of Warnings

1 The general warning and the warning according to Article 12, section 6, are indicated:

- a. On the most visible face of the packaging unit, and
- b. On every external packaging used for retail sale of the product, except for transparent packages.

2 The supplementary warning is indicated on the opposite face.

3 The general warning covers at least 35% and the supplementary warning covers at least 50% of the corresponding area of the packaging unit on which the warnings are printed.

4 The warnings must not be covered up or destroyed by opening of the pack.

5 For the packaging units intended for products other than cigarettes in which the most visible surface area exceeds 75 square centimeters, the area for warnings is at least 26.25 square centimeters for each face.

Article 16 Presentation of Indications on Harmful Substances and Warnings

1 The text of indications of tar, nicotine and carbon monoxide contents and warnings appears as follows:

- a. In black and bold Helvetica characters on white background, in small letters, except for the first letter of the message and whenever required by the spelling;
- b. Centered on the surface on which the text must be printed, parallel to the upper edge of the pack;
- c. Separated visually from the other official languages;
- d. Surrounded by a black frame, with a minimum thickness of 3 mm and a maximum thickness of 4 mm, not interfering in any way with the text of the warning or the information given.

2 For the combination of supplementary warnings and illustrations, the DFI may waive presentation requirements at the color of the writing and text alignment if this measurement allows for obtaining an optimum text and image presentation.

Section 5 Protection from Deceit, Advertising, Marketing**Article 17** Protection from Deceit

1 The names, indications and illustrations that appear on the package or used in the advertisements or advertising for tobacco products must correspond to the facts. They must not be misleading with regard to the nature, origin, manufacture, composition, production method or effects.

2 Any words in the advertisement that suggests any beneficial effect of the tobacco products on health is prohibited.

3 It is forbidden to use, on the packaging of tobacco products, texts, designations, marks and figurative signs or others, such as "light", "ultra light" or "mild", leading the public to believe that a particular tobacco product is less harmful than the others.

Article 18 Advertisements Addressing Young People

For tobacco products, it is prohibited and for products containing tobacco by-products and intended for smoking, any advertising that addresses especially young people under the age of 18 (teenagers), especially:

- a. In the places frequented mainly by teenagers;
- b. In newspapers, magazines and other publications intended mainly for teenagers;
- c. On school material (binders, school kits, ball-point pens, etc.);

- d. On advertising supports provided to young people free of charge, such as T-shirts, caps, pennants, beach balloons;
- e. On toys;
- f. Free-of-charge distribution to young people of tobacco products and products containing tobacco by-products and intended for smoking;
- g. During cultural, sporting or other events, attended mainly by young people.

Article 19 Cigarette Marketing

Cigarettes are pre-packaged and marketed to consumers in packages of at least 20 cigarettes.

Section 6 Final Provisions

Article 20 Repeal and Amendment of the Current Law

1 The Ordinance of March 1, 1995 on tobacco¹³ is now repealed.

2 The Ordinance of March 1, 1995, concerning fees received for control of food products¹⁴ is amended as follows:

Attachment, section B, Chapter 4

Article 21 Transitional Provisions

1 Cigarettes may be marketed to consumers in accordance with former provisions until April 30, 2006.

2 Tobacco products other than cigarettes may be marketed to consumers in accordance with former provisions until April 30, 2007.

3 The supplementary warnings must only be combined with color photographs or other illustrations according to Article 12, section 5, on the date defined in the related DFI ordinance.

4 The lists of substances according to Article 10 must be turned over to the OFSP for the first time from now until September 30, 2005,

5 Authorizations obtained pursuant to the current law to date for products intended for smoking and containing tobacco by-products must be subject to a request for renewal to be filed from now until October 31, 2005. until the decision is made with regard to such authorization, those products may be marketed to consumers pursuant to the current law to date.

¹³ [RO 1995 1659, 1998 148]

¹⁴ [RO 1995 1759, 2002 679, Chapters I and II 2004 1115 RO 2005 545] Attachment 2, Chapter I.8]

Article 22 Effective Date

This Ordinance becomes effective on November 1, 2004.

