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Red Series
Tobacco Prevention and Tobacco Control

Improvement of youth and consumer protection by revision of the EU Tobacco Product Directive 2001/37/EC

Volume 16
German Cancer Research Center, Heidelberg

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Improvement of youth and consumer protection by revision of the EU Tobacco Product Directive 2001/37/EC

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Preface

Every government that assumes office and takes over the responsibility of public health has the duty to create an environment, which encourages smoking cessation among smokers and prevents smoking initiation, especially by young people. To create such an environment, legal regulations have to be established. Every year, more than 650 000 people die as a result of smoking in the European Union.

The German Cancer Research Center has already highlighted the need for legal regulation of tobacco products in several publications, a position it shares with internationally renowned institutions such as the World Health Organization in Geneva and the Harvard School of Public Health in Boston. Also, the European Parliament assessed the current legal situation in Europe as inadequate and requested a revision of the Tobacco Products Directive (Directive 2001/37/EC).

The majority of smokers currently start smoking at around 15 years of age. This early entry into tobacco use has fatal consequences: The tobacco addiction begins already during adolescence. Tobacco associated health effects and the premature invalidity affect people during their active working life. Smokers usually loose on average about 10 years of their life, in some cases even more than 20 years, when they suffer fatal complications.

The consumption of tobacco products also causes significant economic costs not only for individuals but also for society in general. An unemployed person, who smokes 20 cigarettes a day, spends about a quarter of his monthly wage replacement benefits on smoking. The estimated economic burden of smoking exceeds one percent of the European gross domestic product. The great human suffering and high costs are borne by society in general and not by the manufacturers responsible for it. Therefore, effective measures are urgently required to reduce the attractiveness of tobacco products and the risks associated due to their use.

The tobacco industry is deliberately targeting women and youth as new tobacco consumers. The packaging is designed as an advertising vehicle to appeal to young people and encourage them to smoke. Many additives and flavourings are used to soften the harsh tobacco taste, improve the smoking experience and increase its attractiveness, especially for young people. Smokeless tobacco products have the potential to become new starting products for youth. In particular, such products which were already on the market in Sweden, Norway and the United States, are increasingly being consumed by young people.

The German Cancer Research Center therefore calls for a revision of the European Tobacco Products Directive, to ensure that all Member States introduce a standardized tobacco product package which is unattractive for the consumer, ban additives that cause cancer or are suspected to cause cancer as well as all other substances that contribute to the attractiveness of such a dangerous product by further increasing and facilitating consumption by young consumers. In addition, the EU must safeguard that no new, harmful and addictive products are introduced in EU Member States.

Prof. Dr. Otmar D. Wiestler
Chairman and Scientific Director
German Cancer Research Center
Heidelberg, October 2010

1 Europe must take action

The German Cancer Research Center strongly recommends that new mandatory regulations in the revision of the European Directive 2001/37/EC should be set for all member states to ensure improved protection of the health of young people and consumers from the hazards of tobacco smoke. With reference to the revision of the Directive as asked by the European Parliament and the European Commission the three key measures that should be considered to promote the health of the population are detailed in this report. Where appropriate, we illustrated the actual implementation on member state level using Germany as example.

Key points

Tobacco product packaging

- **The design of the tobacco product package is substantial to the advertising effectiveness of the tobacco product. As tobacco industry increasingly designs tobacco products to target young people, this advertising opportunity has to be prohibited to ensure youth protection.**
- **Standardized tobacco product packaging is a cost-effective component in tobacco prevention.**
- **There are no legal barriers to the adoption of standardized packaging.**
- **Large health warnings combining pictures and text on the front and back of the tobacco product packages are another cost-effective element in tobacco prevention and should be introduced in all member states of the European Union.**

Tobacco additives

- **Tobacco additives transform tobacco smoke into an even more complex chemical mixture and thereby further increase the carcinogenic and harmful effects of tobacco smoke.**
- **Additives are used to increase the free nicotine making tobacco products more dangerous, because the nicotine is absorbed more effectively and the potential for dependence increases.**

- **Additives that are used to facilitate smoking contribute to increased addictiveness.**
- **Additives that are used as flavouring agents can increase the attractiveness of tobacco products while concealing their harmful effects.**
- **Certain additives in tobacco products reduce the visibility and the unpleasant odour of tobacco smoke, so that it escapes notice despite its health hazards.**
- **To protect consumers it is obligatory to prohibit additives in tobacco products.**

Smokeless tobacco products

- **Smokeless tobacco products are addictive and cause diseases, which are sometimes lethal. There is no reason to introduce a new, hazardous product on the European market.**
- **Flavoured smokeless tobacco products facilitate the entry into tobacco dependence, primarily for youths.**
- **Smokeless tobacco products are promoted as an alternative to smoking applied to situations where smoking is prohibited. This circumvents measures of tobacco prevention.**
- **Particularly harmful is the dual use of smokeless tobacco products and cigarettes. Thereby, smokeless tobacco products increase the total tobacco consumption.**
- **Smokeless tobacco products are not suitable for cessation. A reduction in the total tobacco consumption succeeds mainly through effective tobacco control measures.**

Recommendations for the revision of the European Directive 2001/37/EC to protect youth and consumers:

- **Implementation of standardized tobacco product packaging with large health warnings combining pictures and text to ensure that fewer young people start smoking and smokers are motivated to stop smoking;**
- **prohibition of harmful and addiction enhancing additives, as they make tobacco products more dangerous than they already are;**
- **continued prohibition of smokeless tobacco products like the Swedish snus, since these are harmful tobacco products.**

2 The EU Directive 2001/37/EC: Contents and opportunities for improvement

In the European Union (EU), tobacco products are regulated by the Directive "on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products" (2001/37/EC)[44]. In Germany, the EU Directive is implemented by the "Tobacco Product Act" (Tabakproduktverordnung, TabProdV)[50], which came into force on 5 December 2002. The Directive 2001/37/EC has two objectives:

- To facilitate the functioning of the internal market by removing trade barriers related to differences in Members State's laws and other provisions on tobacco products.
- To ensure a high level of health protection through uniform regulations having regard to new developments based on scientific facts.

With the introduction of the Directive the previous Directives 89/622/EEC and 92/41/EEC (labelling of tobacco products) as well as 90/239/EEC (maximum tar yield of cigarettes) were repealed and replaced.

The Directive covers, among others, the presentation of health warnings on tobacco product packaging, the prohibition of misleading descriptions such as „mild" or „light", the maximum yields of some emissions of cigarettes (tar, nicotine and carbon monoxide), and the prohibition of some tobacco products for oral use.

2.1 Provisions of Directive 2001/37/EC (Article 3-8)

Article 3: Maximum tar, nicotine and carbon monoxide yields in cigarettes

The Directive regulates the levels of certain emission products of cigarettes released for free circulation, marketed or manufactured in the EU Member States. Since 1 January 2004 the following emissions shall not be greater than:

- Tar: 10 mg per cigarette
- Nicotine: 1.0 mg per cigarette
- Carbon monoxide 10 mg per cigarette

Since 1 January 2007 these values also apply to cigarettes manufactured within the European Community, but exported to third countries.

Article 4: Measurement methods

Accredited laboratories designated by the Member States carry out and verify the compliance with the maximum yields on the basis of internationally approved standards. The results of these tests are presented to the appropriate national authorities on an annual basis and forwarded to the European Commission. Additionally the Member States are required to inform consumers about these results, while taking the protection of potential trade secrets into account.

While the measurements in most countries are performed by governmental or independent laboratories, at least

seven of the eleven accredited laboratories in Germany are owned by the tobacco industry[23]. The currently used machine testing methods according to the standards of the International Organization for Standardization (ISO) are being criticized by international experts, as they do not reflect the true smoking habits and the actual intake of harmful substances by the smoker. The Directive contains the possibility of adapting the methods to scientific and technical progress via the Tobacco Products Regulatory Committee. As the EU plans to keep the applied procedures in accordance with international standards, the guidelines for tobacco product regulation (Art. 9 and 10) of the WHO Framework Convention on Tobacco Control (FCTC), which shall be adopted end of 2010, could provide relevant guidance for a potential revision.

Article 5: Labelling

Information on maximum yields

The data on the maximum yields for cigarettes (tar, nicotine and carbon monoxide) must be printed on the side of the cigarette pack and take at least 10 percent of the outer surface of one side of the cigarette packet. In multilingual EU Member States, the percentage increased to 12 percent in case of two official languages and to 15 percent in case of three official languages. The Directive also specifies where this information is to be placed on the cigarette packet.

Within Member States and the European Parliament the labelling of tar, nicotine and carbon monoxide yields on cigarettes packages has repeatedly been criticized as being misleading to consumers[22].

Warnings

- All tobacco products, except those for oral use and other smokeless tobacco products, must have two mandatory warnings:
  - A general warning („Smoking kills/ Smoking can kill" or „Smoking seriously harms you and others around you"), which must cover at least 30 percent of the outer surface of the most visible broadside of the pack (32 percent and 35 percent for Member States with two or three official languages) and
  - one of 14 additional health warnings with relevant health information, which has to cover at least 40 percent of the outer surface of the other broadside of the package (45 or 50 percent for Member States with two or three official languages).

  The warnings must be surrounded by a three to four millimeters wide, black border, which increases the total area of the warnings to 43 percent on the front and to 53 percent on the back in countries with one national language[17]. The same applies to the maximum yields described above. The implementation is currently inconsistent, because 19 of 27 Member States subtract the border from the area of the warnings. Only Belgium, Estonia, Finland, Latvia, Portugal, Slovenia, Sweden and the United Kingdom are in full conformity with the Directive[17].
- Warnings on packages of tobacco products other than cigarettes:
  For packages with a broadside of more than 75 cm^2 the warnings have to cover at least 22.5 cm^2 on each broadside (24 cm^2 or 26.25 cm^2 for Member States with two or three official languages).
- Warnings on tobacco products for oral use, where their marketing is permitted, and other smokeless tobacco products:
  For these two product types separate provisions are applied. The general warning „This tobacco product can damage your health and is addictive" must cover at least 30 percent of the

outer surface of the corresponding broadside (not including a three to four millimeters wide border) of the pack and outer packaging (32 percent or 35 percent for Member States with two or three official languages).

- Combined visual warnings:
  The European Commission agreed on 5 September 2003 that Member States can decide whether to require health warnings in the form of photographs or other images on the packages of some or all tobacco products, and under which conditions to use them[21]. By decision of 26 May 2005 a library of combined health warnings has been provided to the Member States[21]. Since then, Belgium (2007), Romania (2008), the United Kingdom (2008) and Latvia (2010) have introduced combined health warnings. France and Malta have decided to introduce them in 2011. Additionally, the European Commission facilitated copyright agreements with several countries to allow them the use of the pictorial warning library (e.g. New Zealand, Norway, Switzerland and Turkey).
  A number of Member States called for mandatory combined warnings on all tobacco packages to facilitate their introduction in all EU Member States and to ensure consistent regulation across the Internal Market. Additionally, there were strong voices in the Member States and the European Parliament for making information on cessation services mandatory (helplines and websites), as well as for increasing the size of the warnings and placing pictorials on both package sides[22].
- Identification and traceability:
  All packaging units of tobacco products must have a batch number or similar identification, to assess place and time of manufacture.

Article 6: Further product information

Manufacturers and importers of tobacco products are required to annually submit a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. The list has to be accompanied by an explanation of the reasons for the use by function and category of the ingredients. Member States shall publish this information and annually communicate all data and information received to the European Commission. In Germany this information is published as an electronic database of the Federal Ministry of Food, Agriculture and Consumer Protection[51]. However, the data in the database are very general and sometimes misleading (see chapter 4.1, page 24).
In addition, the tobacco industry has to provide the competent authorities with a list of all available toxicological data regarding the ingredients in burnt and unburned form, in particular to their effects on health and taking into account any addictive effects. This information is not published.

Article 7: Product descriptions

Since 30 September 2003 descriptions (names, terms, figurative or other signs), suggesting that a product is less harmful than others, are not allowed on tobacco packages. Descriptors such as „light“ or „mild“ are therefore not to be used in the context of tobacco products. The tobacco product manufacturers have reacted early on that provision, and renamed their products accordingly („Silver“, „Gold“, etc.) or indicated the supposedly „light“ or „mild“ nature of the products by light colours and other design elements. Although „figurative or other signs“ are covered by the Directive a violation is difficult to prove and such practice unlikely to be challenged in court.

Article 8: Tobacco for oral use

Member States prohibit the marketing of "tobacco for oral use". With the exception of products intended for smoking or chewing, all products for oral use, which partially or completely consist of tobacco, are banned in the European Union since 1992[30]. An exceptional rule (Article 151 of the Act of Accession of Austria, Finland and Sweden), however provides, that in Sweden and Norway (as a member of the European Free Trade Association, EFTA) may continue to place smokeless tobacco products on the market, as long as they do not resemble a food product[20]. Norway and Sweden have also committed to take all measures necessary to ensure that these tobacco products are not placed on the market in other Member States[20]. Contrary to these commitments of the EU accession treaty, Sweden has increasingly called for a lift of the ban in recent years. In the second half of 2009, shortly before the Swedish Presidency started, the Swedish Trade Minister Ewa Bjoerling declared that the Swedish smokeless tobacco product „snus" would be a priority of her mandate[38]. Both, Swedish Match and British American Tobacco, have backed this initiative in the media and tried to influence the public opinion, e.g. through advertisements in party newspapers[75]. A repeal of the so-called snus ban – as intended by the tobacco industry – can only be achieved by political means. The European Court of Justice (ECJ) already dismissed two legal complaints of the tobacco industry in 2004 and confirmed the conformity of the snus ban with EU legislation[40,41].

2.2 Effects of Directive 2001/37/EC on trade issues

The overall economic impact is considered to be positive, as the harmonization and approximation of the rules relevant to the internal market leads to greater clarity and legal certainty for all market participants.

2.3 Implementation and reporting

The Directive provides transition periods or exceptions for the application of certain provisions. The European Commission oversees the implementation of the Directive and submits a biannual report on its application to the European Parliament, the Council and the Economic and Social Committee. Adaptations of the Directive to scientific and technical progress can be taken into account by the European Commission. The Commission will be assisted by a group of tobacco control experts, set up within its Advisory Committee on Cancer Prevention, particularly in connection with the preparation of the reports on the application of the Directive. The European Commission also commissioned an external impact assessment to consider further measures[45].

2.4 Revision of Directive 2001/37/EC

The European Parliament, several States, and various stakeholders expressed the need to revise the Directive 2001/37/EC:

Recommendations of the European Parliament (2007)

On 19 September 2007, the European Parliament called on the European Commission in its resolution on the Green Paper „Towards a Europe free from tobacco smoke: policy options at EU level" (adopted by the European Parliament on 24 October 2007), to present a proposal, by 2008 if possible, for an amendment of Directive 2001/37/EC, containing at least the following:

- "An immediate ban on all addiction-enhancing additives,
- an immediate ban on all additives shown by existing toxicological data to be carcinogenic, mutagenic, or toxic to reproduction as such or upon pyrolysis (burning at a temperature of between 600 and 950 °C),
- the introduction of a detailed registration, evaluation and authorisation procedure for tobacco additives, and complete on-pack labelling of all tobacco additives,
- an automatic ban on all additives for which manufacturers and importers of tobacco products do not have complete data sets by the end of 2008 (including lists of all ingredients by brand name and type, along with their quantities and toxicological data),
- a requirement for manufacturers to make publicly available all existing toxicological data on the additives and ingredients in tobacco smoke, including pyrolysis products (public and in-house data),
- the development of a compendium of tobacco additives and substances in tobacco smoke and the provision of consumer information in this respect,
- introduction of a financing system that makes tobacco product manufacturers liable for all costs of developing and maintaining assessment and supervisory structures (e.g. independent laboratories, staff and scientific investigations),
- application of product liability in respect of manufacturers and introduction of manufacturer liability for the financing of all health costs arising from tobacco consumption"[43].

Recommendations of the European Commission (2007)

On 27 November 2007 the European Commission presented various concrete measures in its „Second Report on the Application of the Tobacco Products Directive"[22]:

- To review the need to adapt the definition of ingredients and ensure consistency with the WHO Framework Convention on Tobacco Control (FCTC).
- To actively follow the scientific and technological developments, particularly with regard to the ISO standards of emission yield measurements to take them into account once there is a more common understanding and agreement on the methods.
- To examine the possible options with regard to an enlargement of the health warnings, the introduction of mandatory pictorial warnings on both sides of the package in accordance with the FCTC guidelines on packaging and labeling of tobacco products (Article 11 of FCTC), adopted in November 2008.
- To consider replacing the maximum limits of tar, nicotine and carbon monoxide on cigarette packets by specifying hotline numbers and/or information about other substances in tobacco products, for example information about the use of genetically modified organisms (GMOs).
- To consider introducing generic standardized packaging for all tobacco products in order to reduce their attractiveness.

With regard to the REACH regulation (1907/2006/EC), adopted in 2006, the Commission committed itself to the implementation of all activities listed in the Commission statement[32]. The report criticizes the inconsistency of reporting, announces possible fines by Member States for non-delivery of information by the industry, and suggests a possible extension of reporting requirements. The ban on all addictive and harmful additives, as requested by the European Parliament, should be studied „positively and thoroughly" and in lights of a possible revision an even

more stringent approach is proposed: to not allow any additives in tobacco products unless manufacturers proved their safety. To improve the effectiveness of the Directive, the European Commission also calls for an extension of its regulatory powers to cover the development of criteria for approving laboratories and other measures to improve laboratory cooperation and mutual recognition. Additionally it proposed the adoption of validated and internationally accepted measurement methods for roll-your-own (RYO) tobacco and the revision of its taxation rules. The Commission also announced a study on the best ways forward to strengthen product liability of tobacco manufacturers and importers in the EU as well as their liability for financing the health costs arising from tobacco consumption[22].

Revision of the Tobacco Product Directive (2010)

On 25 March 2010, the European Commission presented a „roadmap"[24] for a potential revision of the Tobacco Products Directive by December 2011 highlighting current problems in the harmonization of the internal market and the promotion of health protection:

Harmonization of the Internal Market

- Different rules for the labelling of tobacco products, in particular regarding the combined use of pictorial health warnings.
- Complex reporting on the ingredients of tobacco products and difficulties in data analysis without harmonized formats.
- Introduction of different positive or negative lists of ingredients on Member State level.

Promoting health protection

- Insufficient consumer information about the risks of tobacco consumption.
- Misleading effects of labeling tar, nicotine and carbon monoxide levels on cigarette packs.
- Lack of health warnings in local language and possible sale to minors of products distributed over the Internet.
- Lack of coverage of new nicotine and tobacco products, such as electronic cigarettes, nicotine containing drinks, tobacco chewing gum and toothpaste.

These issues shall be discussed in the context of various consultations and reflected in the possible revision of the Directive[24].

With regard to the responsibility towards the protection of health, the German Cancer Research Center considers the implementation of the following items as key priorities:

- **Implementation of standardized tobacco product packaging with large combined health warnings consisting of text and pictures.**
- **Ban of harmful and addiction-enhancing additives as well as of those additives from which harmful combustion products emerge.**
- **Continuation of the ban on smokeless tobacco products including snus.**

3 Standardized tobacco product packages with pictorial health warnings

Directive 2001/37/EC of the European Parliament and the Council requires, amongst others, a general health warning and one out of 14 additional warnings for all tobacco packages released for free circulation, marketed or manufactured in the Member States[44]. Since 2003 Member States are enabled to use additional pictorial health warnings[21]. Currently only 5 countries have introduced pictorial health warnings in Europe and three countries plan to introduce them in 2011. The different regulations concerning the labelling of tobacco product packages and particularly the different use of pictorial health warnings all over Europe cause an inconsistent health protection in the Member States and hinder the trade within the European Community.

Since 2003, according to Directive, misleading terms "suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products"[44].

Regardless of these requirements the tobacco industry is still free to use the tobacco package as a marketing tool. For the revision of Directive 2001/37/EC with regard to the European regulations on the advertising and sponsorship of tobacco products (directive 2003/33/EC), in order to better protect the health of the population, the European Union is considering the introduction of standardized packaging with large pictorial health warnings for tobacco products.

The aim of a standardized package is to deprive the tobacco industry of the possibility to use the pack as an instrument for advertising. Hence the standardized package would be an important tool for tobacco control with regard to the WHO Framework Convention on Tobacco Control (FCTC).

3.1 Legal aspects of introducing standardized packages

Standardized packages for tobacco products have been unanimously recommended by the Parties of the FCTC and they would comply with EU legislation and German legislation.

Guidelines of the FCTC recommend standardized tobacco packages

In their guidelines for the implementation of the FCTC the Parties recommend to consider the introduction of standardized packages to increase the noticeability and effectiveness of health warnings and to prevent the use of the pack as an advertising tool[114,115].

Standardized packages comply with European and German law

Europe: A ruling to introduce generic tobacco packaging would not infringe EU legislation [Art. 1 (2) of Regulation 207/2009 (formerly Reg. 40/94 EC) or Art. 28 EC Treaty (ECT)], particularly if it is introduced on a European level. If generic packaging is introduced universally throughout the entire

European Union, pan-European trademark protection is safeguarded to the same extent throughout Europe. The fundamental right to ownership (Art. 259 ECT) and related rights to intellectual property are not infringed by a European packaging regulation. Exercising an ownership right may also be subject to restrictions, in so far as such restrictions do in fact comply with the Community objectives of common welfare and do not represent a disproportionate, intolerable intervention with regard to the objective pursued, which affects the fundamental content of the rights thus protected. Such rights can likewise be curtailed in the interest of public welfare and safeguarding health [cf. Art. 10 (2) ECHR][42].

Germany: A regulation for standardized packages will violate neither the rights for property (Article 14, German Basic Law) nor the right for freedom of opinion (Article 5, German Basic Law) nor the right for free professionalism (Article 12, par. 1, sentence 2, German Basic Law), because these rights are not absolute and may be constraint by justified interventions[42] (Cf. Decision of the Federal Constitutional Court, 22 January 1997, BVerfGE 95, 173, health warnings for tobacco products).

There are no legal obstacles hindering the introduction of standardized packages for tobacco products.

3.2 The package – a means of advertising for the tobacco industry

The package as a lure

The package attracts the attention of a potential customer and makes the customer feel he should buy the product. This is the case for any sort of product, no matter whether the pack contains cookies, Pizza or cigarettes. The wrapping establishes a connection between the producer and the customer and it is an important means of advertisement[111]. Besides being appealing, its brand name, logo, colours and configuration create a specific brand image which shape consumer expectations about the product in terms of quality and image[33]. The package creates a difference between similar products[111]. It has to be eye catching and attractive both when seen alone, as in use, as well as in close neighbourhood with similar products, as in large retail displays[33].

The brand image is most important

Cigarettes are exceptional products, because smokers carry them – unlike most other products – with them all day long and use them in presence of others several times a day. In doing so the package makes a statement about the smoker, thus making the brand image most important for the tobacco industry. It not only creates a difference between several brands, but it is the definite reason for new customers to opt for a certain brand. It creates such a tight connection between the smoker and his brand that switching between brands is a rare exception[100,109,111]. The brand's identity depends mostly on the design of the pack[33,111].

The pack – last remaining means of advertisement

The more severe advertising bans are adopted, the more the pack becomes important for the tobacco industry. The product innovation group of Philip Morris recognized during a meeting in 1990: "As media restrictions increase, the brand pack should become a media vehicle. The 'book pack' objective is to transform the pack from a 'passive container' into an 'active means of communication', an object that projects an image and a lifestyle by itself"[88].

Addressing specific target groups

In the past decades unique packs appealing to specific target groups like youth and women have been developed again and again. Especially girls and women are being targeted; for them the tobacco industry uses packs with a feminine design. The latest in these series are those resembling perfume and lipstick packs (Fig. 1).

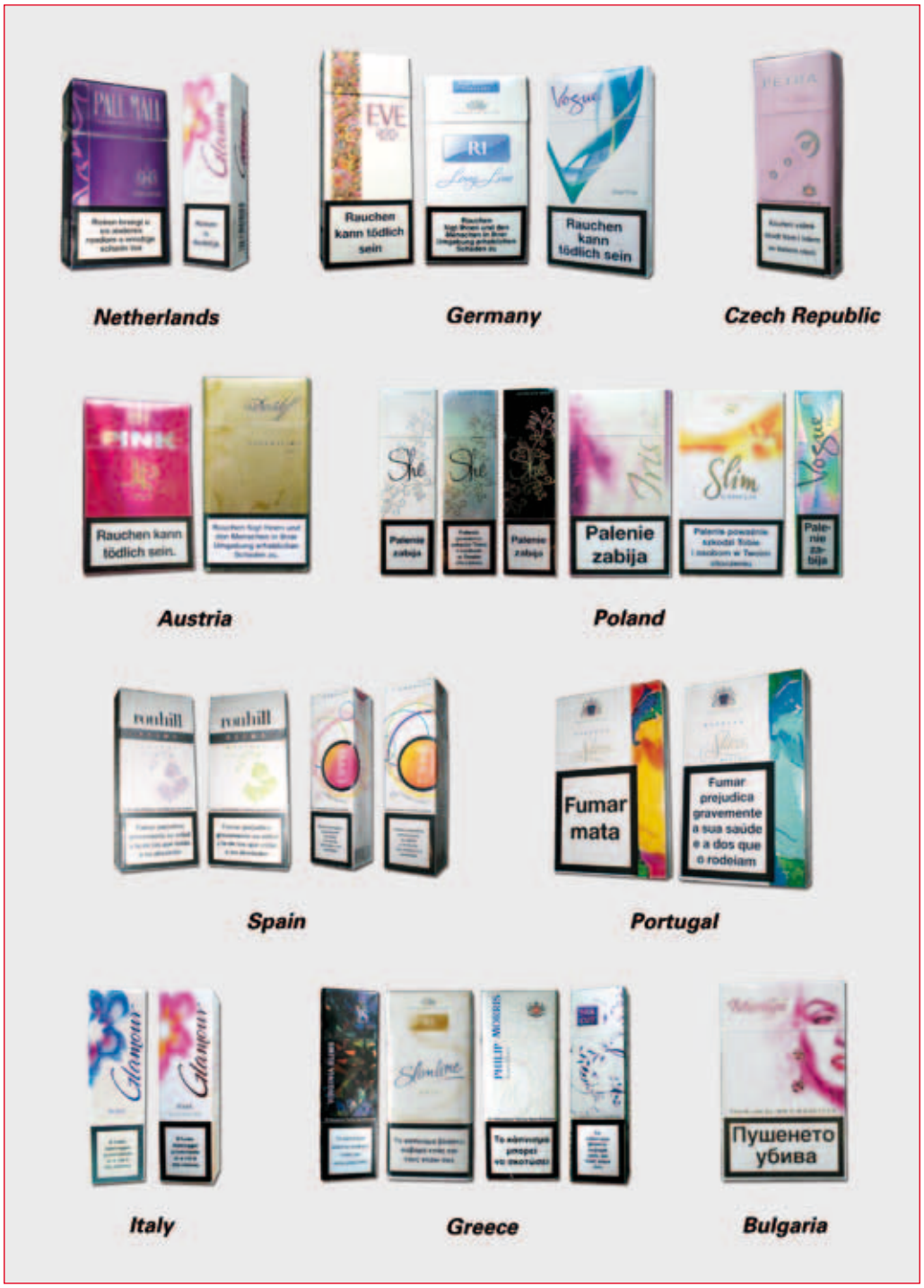

Figure 1:
Cigarette packs designed for women.
Source: German Cancer Research Center, Unit Cancer Prevention, 2010.

Publicity ploy special edition

Special editions are introduced for a limited time with the intention to improve the brand image and to tie the consumer to the brand more

intensely. Such eye-catching limited editions are especially appealing to young people. Sometimes they refer to actual events like the soccer world cup (Fig. 2).

The tobacco industry is targeting young people more intensely by pack design. This means of advertising has to be abolished in order to protect youth.

Figure 2:
Special editions of Lucky Strike (2009 and 2010) and of West (soccer world cup 2010).
Source: German Cancer Research Center, Unit Cancer Prevention, 2010.

3.3 The design makes the difference

All elements of a pack's design are important for its advertising effect:

- **Colour**
  The colour may influence the consumer's perception of taste. Usually red is used for intense and blue for less intense taste, green for menthol cigarettes and white, implying an aspect of clinically clean, is associated with low contents of tar. Gold connotes high quality and pastel colours are used for products with low nicotine contents or mild taste[33,78,89,111]. Accordingly smokers rate cigarettes taken from red packs as strong and cigarettes from packs in blue or light colours as smooth[73]. Even more, smokers believe that cigarettes in light coloured packs have a lower health risk[65] (Fig. 3).

Figure 3:
Suggestive colours of cigarette packages.
Source: German Cancer Research Center, Unit Cancer Prevention, 2010.

Font and graphic elements

The recall effect and the brand image are built up by the font style and characteristic graphic elements. Even barely noticeable changes of the font, the placement or the orientation may influence the impact of the design (Fig. 4)[33].

Figure 4:
Recall effect transported by font and graphic elements using Marlboro as an example: The lettering being unchanged, the typical triangle is subject to multiple variations, but always is easily recognisable as the Marlboro logo.
Source: German Cancer Research Center, Unit Cancer Prevention, 2010.

Structure, material, and shape

The package's structure and material influence how the consumer perceives a product's quality. Embossing for example refines and suggests a high quality. Different shapes of the pack (oval, octagonal, two parts, etc.) had been repeatedly invented to enhance the attention of the consumer[33,62] (Fig. 5, next page).

Figure 5:
Octagonal package (Switzerland) and packages with palpable structures (Germany). The discreet hatching of the Marlboro pack is embossed making it palpable.
Source: German Cancer Research Center, Unit Cancer Prevention, 2010.

- **Listing of machine-measured yields of tar, nicotine and carbon monoxide**
  According to Directive 2001/37/EC the cigarette producers actually indicate information about the contents of tar, nicotine and carbon monoxide per cigarette on the narrow side of the package. These indications are misleading, because they do not reflect the real health risk, but low numbers may be suggesting a lower health risk[89]. About half of the smokers in the European Community believe falsely that the level of tar or nicotine on the side of the pack would indicate that a brand is less or more harmful[107].

The design of the package is very important for the advertising effect of the pack. The introduction of a standardized package would deprive the tobacco industry of this means of advertising.

3.4 The standardized package: A means of tobacco prevention

A standardized package has a neutral design and doesn't allow any space for advertising. It has a consistent design using a standardized font, font size, font colour, and package colour. There will be no logos, individual letterings or other means of advertisement (Fig. 6). Advantages of standardized packages are:

- **Less attractive tobacco products**
  The less brand specific elements are left on a package, the less it is attractive for potential consumers[54,56,96,112]. On the consistent grey or brownish standardized package the only remaining brand specific elements will be the brand name and the number of cigarettes in the pack, but using a unique font.
- **No misleading**
  There will be no suggestive colours, which could transport the misleading information that a certain product would be less harmful than another[65]. For this reason white or light colours must not be used for the package.
- **Information carrier for tobacco control**
  The standardized package will carry large pictorial health warnings, making the package an important means of information in tobacco control. Health warnings are recommended to cover at least 75 percent of the pack's front and 100 percent of the back and should be composed of text and pictures[96]. The less brand specific elements are left on the package, the more the health warnings are recognised and retained[54].
- **The standardized package will support the fight against illicit trade of tobacco products**
  The standardized packages of tobacco products are to be equipped with secure and non-removable identification markings such as codes or stamps to enable effective global tracking and tracing. This tracking and tracing

system has to give all information necessary to monitor and control the movement of tobacco products and their legal status[25,26]. On a standardized package these markings are better visible, marking it easier to detect fraud. A standardized package may be subject to severe criteria (e.g. holograms, invisible ink) hampering illicit trade.

A standardized package would not only deprive the tobacco industry of an important means of advertising, but provides a cost-effective means of information for tobacco control.

3.5 Health warnings are effective

Many studies have proved that health warnings are effective and cost-effective:

- Health warnings are a very direct and cost-effective means of communication. Health warnings reach every smoker and inform him continuously, because every time the smoker sorts a cigarette out of his pack he realises the warning sign. A smoker consuming a pack containing 20 cigarettes a day is exposed to the health warning at least 7 000 times a year[96].
- Health warnings improve the smoker's knowledge about the health risks of smoking[62,63,64,96,99].

advantages of standardized packages:

- tobacco products are more unattractive
- no misleading
- information carrier for tobacco prevention
- improved security against illicit trade
- consistent with European and German law
- meets demands of the FCTC

Figure 6: Prototype of a standardized package. Source: German Cancer Research Center, Unit Cancer Prevention, 2010, adapted from Smokefree Partnership 2010[101].

- Health warnings prevent people from taking up smoking and help ex-smokers staying smoke-free[96,99].
- Health warnings motivate smokers to become smoke-free[63,99].

Combined health warnings using text and large shocking pictures have been proved to be more effective than text warnings alone[96]:

- A pictorial message – in particular, if it is very emotional – is more easy to capture and to understand than a textual information and it is better retained in memory[62].
- Pictorial health warnings are most effective for youth[62], for migrant population and those with a low educational status.
- Health warnings placed on the front of the package are most effective[62,99].

Large pictorial and textual health warnings placed on the front and back of the package of tobacco products are a cost-effective means of tobacco control.

3.6 Strong support in the European Union

Three quarters of EU citizens are in favour of introducing pictorial health warnings on all packages of tobacco products. More than half of the smokers are also in favour of these health warnings[107].

Slightly over half of EU citizens are in favour of a standardized package. Clearly more non-smokers (62 percent) than smokers (34 percent) are in favour of standardized packages[107].

In Germany, 71 percent of the citizens are in favour of pictorial warnings and 52 percent are in favour of a standardized package[107] (Fig. 7).

3.7 Recommendation

For the revision of Directive 2001/37/EC the German Cancer Research Center urgently recommends to adopt mandatory standardized tobacco packages with large pictorial health warnings in all Member States of the European Union.

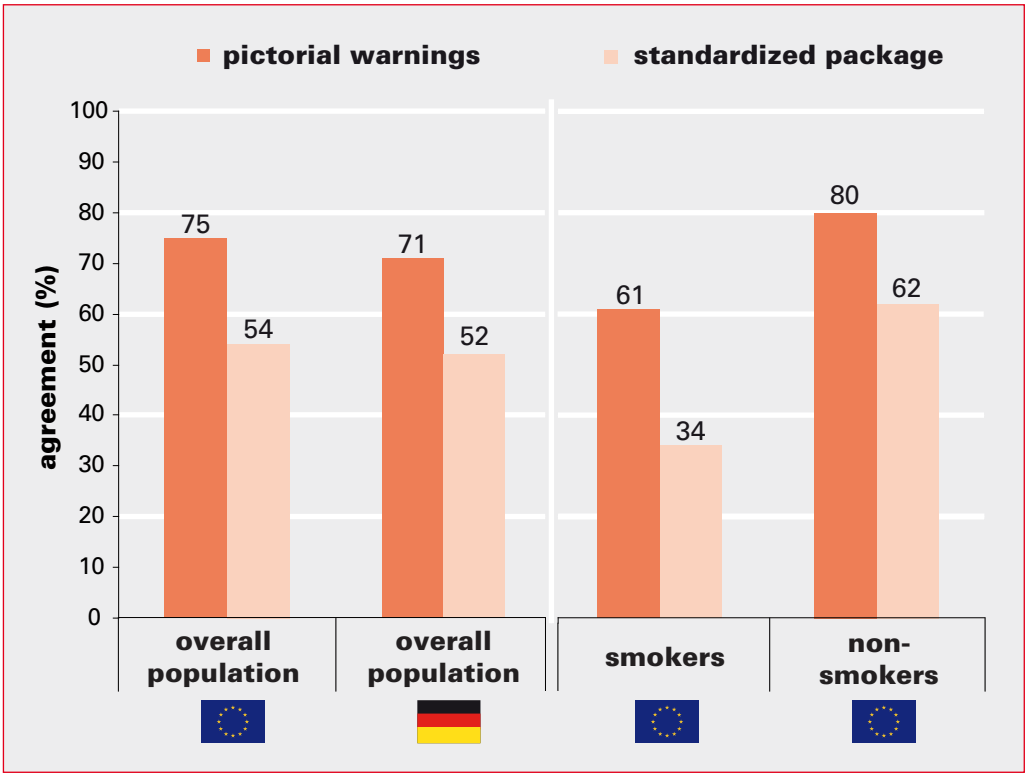

Figure 7:
Support of pictorial health warnings and plain packages for tobacco products in the European Union and Germany.
Source: TNS Opinion & Social, 2010[107].
Illustration: German Cancer Research Center, Unit Cancer Prevention, 2010.

4 Additives

Smoked tobacco products are harmful because tobacco smoke contains numerous toxic and carcinogenic substances. Some of these substances are naturally present in tobacco, but many are added during processing of the tobacco, during manufacturing of tobacco products, or are formed during combustion of the product, for example when used by the consumer. The use of additives in tobacco products increases the number of harmful substances in tobacco smoke considerably, making an already toxic product even more dangerous (Fig. 8). Also, in smokeless tobacco products additives increase the health risk additionally.

Additives in tobacco are added mainly to influence the tobacco taste, but also for moisturizing and improving the burning characteristics. They also include any colouring agents, adhesives, bonding agents and thickeners, plasticizers, binders, etc. that are included in the filter, the filter envelope and the paper of cigarettes and in all other components of tobacco products. More than 600 different

What is an additive?

"Additive" means "any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives"[50].

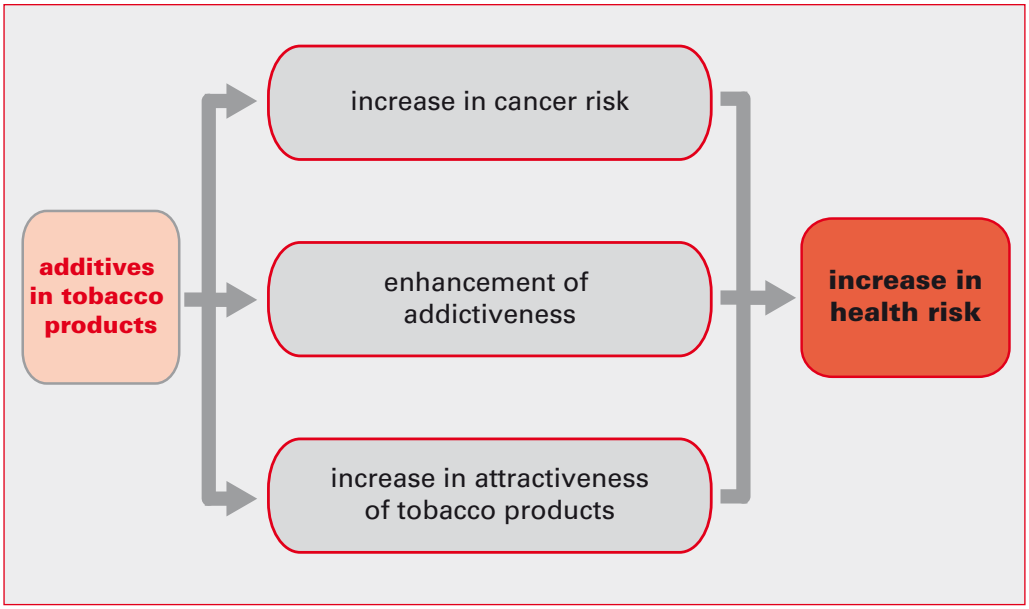

Figure 8: Summary of adverse health effects of additives in tobacco products. Illustration: German Cancer Research Center, Unit Cancer Prevention, 2010.

additives are known that are used by the manufacturers[7,67]. These can account for about 10 percent[7] up to 25 percent[85] of the total weight of a cigarette.

4.1 Legal regulations on additives in tobacco products

In the EU the statutory provisions for the use of additives in tobacco products are inadequate and confusing, every Member State having a legislation of its own. In particular, the German regulation is complicated and confusing:

- Established in 1977, the "Tobacco Act" (Tabakverordnung, TabV)[48] states that substances for a specified purpose may be used in tobacco products, as well as the maximum authorized for some of the substances. By TabV the use of additives was regulated for the first time in Europe. The list of approved substances includes all flavours of the "Flavour Act" (Aromenverordnung)[49] and several hundred other substances.
- The "Tobacco Product Act" (Tabakprodukt-Verordnung, TabProdV)[50], which should meet the demands of the EU Directive 2001/37/EG44, binds in § 5 the manufacturers and importers of tobacco products to inform the authorized government agency about the concentration of all the additives used for production of each brand and product. Additionally, for cigarettes tar, nicotine and carbon monoxide in the smoke should also be reported. Furthermore, the reasons for the use of each additive, its function and product category have to be indicated. In addition, the toxicological data available to the manufacturer or importer regarding these additives, including the combustion products referring in particular to their effects on health and taking into account, *inter alias*, any addictive effects, have to be included. Information on the additives has to be communicated to the public by any appropriate means, while trade secrets are taken into account. Information is presently given on the website of the Federal Ministry of Food, Agriculture and Consumer Protection in the form of a tobacco additive database[51]. However, only additive amounts that exceed one milligram per product unit and the overall category and function of each additive, organized by brand, are stated there. Health-relevant information is withheld.
- The EU Directive 2001/37/EC also aims at establishing a common list of approved additives for all European countries by the European Commission. This list is still missing.

The testing of tobacco products is insufficient and is performed by an inadequate procedure: Tobacco products are tested like food or like commodities by the food monitoring institutions of the German Federal States based on the statutory requirements arising from the TabV and TabProdV. However, the following important aspects that are different in smoked tobacco are not considered:

- Additives in smoking tobacco products are exposed during combustion to temperatures much higher than during food preparation, so that very different chemical changes take place.
- Unlike food, the substances in tobacco smoke are absorbed for the most part through the respiratory tract and not through the gastrointestinal tract.

Both the combustion of the additives in the very high temperatures of the glowing zone and the intake into the body by inhalation may cause toxic effects that do not occur regarding food. Therefore, additives which are safe in food are not necessarily safe in smoked tobacco. They are likely to be turned into harmful substances and should not be equated with food additives.

The investigation of potential health hazards of individual additives and their combustion products, as well as their interactions, are not covered adequately by the existing statutory measures.

4.2 Arguments against the use of additives in tobacco products

The use of additives increases the already unhealthy potential of tobacco products in several respects (Fig. 8, page 23):

4.2.1 Increase in cancer risk

So far, 90 substances that are produced by the combustion of tobacco and tobacco additives are classified as carcinogenic or possibly carcinogenic[58]. Some of the substances, which are added to tobacco products and can pass into tobacco smoke, are already carcinogenic, or suspected to be carcinogenic, by themselves. Examples include[57]:

- **Azo and chromium(VI) compounds** (colours for cigarette paper and cover sheet, tobacco foil and binder of cigars),
- **salts and oxides of cobalt** (materials for printing on cigarette, mouthpiece and filter joining paper),
- **glyoxal** (glue, adhesive, thickener for tobacco foils) and
- **talc** (whitening agent).

Other additives are precursors of carcinogenic compounds formed during combustion (pyrolysis), or they are involved in cancer causation or accelerate cancer development. Carcinogenic substances, which are formed during pyrolysis of tobacco additives, include[57]:

- **Polycyclic aromatic hydrocarbons (PAHs):**
  This group of substances makes a significant contribution to the development of lung cancer in smokers. PAHs can be formed through incomplete combustion of virtually all organic substances[94] – cigarettes, cigars and pipe tobacco also burn incompletely. Some PAHs are predominantly formed from tobacco additives such as cocoa butter, oils, resins, paraffins, waxes, fats, shellac, chocolates, and methyl oleate and methyl palmitate.
- **Tobacco-specific and volatile *N*-nitrosamines:**
  - Examples of tobacco-specific *N*-nitrosamines are: *N*-nitrosonornicotine (NNN) and 4-(methyl-nitrosamino)-1-(3-pyridyl)-1-butanone (NNK). These are *N*-nitrosamines that are formed partly already during tobacco fermentation and pass into the smoke, but they are also formed from tobacco alkaloids (nornicotine, nicotine, anatabine, anabasine) whenever nitrate or ammonium salts are added to the tobacco from which then nitrosating nitrogen oxides are arising.
  - Examples of volatile *N*-nitrosamines are: the highly carcinogenic compounds *N*-nitrosodimethylamine and *N*-nitrosopyrrolidine. They arise, *inter alia*, from added amino acids or flavourings.
- **Carcinogenic aldehydes such as formaldehyde, acetaldehyde, acrolein and others:**
  These arise from the pyrolysis of tobacco additives such as sugars (Fig. 9, next page), polysaccharides, pectins, syrup, caramel, starch, molasses, honey, ethanol, rum and proteins as well as various tobacco humectants such as glycerol and propylene glycol. In addition to their carcinogenic effect, in particular formaldehyde, acrolein and crotonaldehyde also inhibit the self-clearance of the lungs after smoking.
- **Volatile organic substances such as benzene, butadiene and vinyl chloride:**
  Benzene, a common combustion product, is formed by the combustion of many tobacco components. In particular, it isformed during pyrolysis

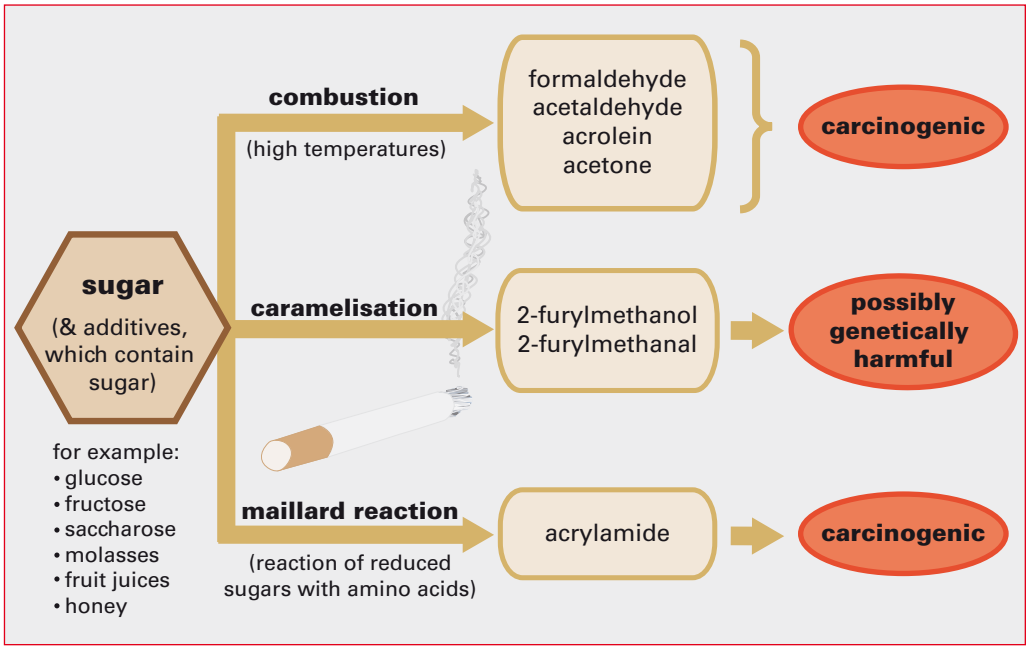

Figure 9:
Examples of harmful substances resulting from the conversion of sugar, while smoking.
Illustration: German Cancer Research Center, 2009[59], edited.

of added flavours such as benzyl alcohol, benzaldehyde, anisaldehyde, vanillin, thymol and heliotropine. Benzene causes leukemia.
Butadiene, another common combustion product, is significantly increased in tobacco smoke when the tobacco humectant 1,2-propanediol is added.
The liver carcinogen vinyl chloride in tobacco smoke is correlated with the chloride content of tobacco. Since ammonium chloride is allowed as a tobacco additive, the amount of vinyl chloride in the smoke increases with the amount of the added chloride salt.

- **Phenol, hydroquinone, catechol and cresols:**
  These substances are formed from tobacco additives such as cocoa, licorice, starch, cellulose, sugar, guar gum, locust bean gum.
- **Nitro compounds such as nitromethane, nitroethane, 2-nitropropane and nitrobenzene:**
  They are generated, among others, in the presence of added nitrate salts.
- **Aromatic amines such as 2-naphthylamine, o-toluidine and 4-aminobiphenyl:**
  These substances are urinary bladder carcinogens. Added nitrates and ammonium compounds contribute to their formation.
- **Styrene:**
  The carcinogenic styrene is preformed, particularly in the tobacco flavouring additives cinnamaldehyde, cinnamyl alcohol and methyl cinnamate, and is produced from these during pyrolysis.
- **Aliphatic epoxides:**
  The humectants 1,2-propanediol, ethylene glycol and others, mostly added to the tobacco in considerable amounts, form the carcinogenic substances ethylene oxide, propylene oxide and other epoxides during pyrolysis. Aliphatic epoxides that are common combustion products, may generally arise from tobacco additives.
- **Coumarins:**
  A commonly used tobacco additive mixture is licorice. This contains several coumarin derivatives, which are very similar to the banned cancer-causing substance coumarin. It is quite likely that some of these hitherto unexamined coumarin derivatives are either carcinogenic themselves or may be converted into the carcinogenic coumarin during pyrolysis. Tobacco smoke contains coumarin.

In addition, numerous other toxins and pollutants such as cyanide, carbon monoxide, quinoline, acetonitrile, mercury, and polonium-210 are present in tobacco smoke[57]. It is also possible that the more than 4 800 substances that have been identified in tobacco smoke[6,69] interact with each other.This allows them to influence their effects mutually.

The additives make tobacco smoke an even more complex chemical mixture, thereby enhancing its already considerable carcinogenic and harmful potential.

4.2.2 Enhancement of addictiveness

The addictive nature of nicotine can be improved by increasing its concentration in the product or by affecting its chemical and physical properties. Both actions lead to an increase in the availability of nicotine. Furthermore, all manipulations that make smoking easier in any regard contribute to an enhancement of addictiveness.

Increasing the availability of nicotine

The addictive nicotine is present in tobacco predominantly in protonated salt form. Only a fraction of nicotine is in its free alkaloid form which can enter the gas phase of tobacco smoke. Only the free form penetrates the cell membranes. By influencing the acid-base chemistry of tobacco, a more basic pH can be achieved, thus increasing the proportion of free nicotine[67,113]. This fact was already known by the tobacco industry in the early 1960s[102] and to increase the pH of the tobacco, the producers applied various methods, such as addition of ammonium compounds[92], basic amino acids such as lysine, calcium carbonate, or by using a variety of tobacco with a naturally higher pH, such as burley tobacco, which is used mainly in American brands[91].
However, whether the pH of tobacco smoke also influences the intake of nicotine in the lung is not clear so far[113]. However, pH is critical for the absorption of nicotine across the oral mucosa for example in smokeless tobacco products like chewing tobacco and snus[15,46,93] (see chapter 5.1, page 32).
Pyrolysis of sugar additives results in the generation of acetaldehyde, a probable carcinogen (see page 25 and fig. 9). In addition, it seems to increase the addictive effect of nicotine[8,104,105].
Another example of increasing addictiveness is the use of levulinic acid which not only increases the nicotine content in smoke but also facilitates the binding of nicotine to receptors in the central nervous system[76,92].

The targeted increase in the proportion of free nicotine by the use of appropriate additives makes tobacco products more dangerous because, thereby, the nicotine is absorbed more effectively and exerts its addictive and harmful effects so that the addictive potential is increased.

Making smoking easier and a more pleasant experience

Some additives exert a pharmacological effect and may facilitate the intake of nicotine. For example glycyrrhizin, an active ingredient of licorice, theobromine, occurring in cocoa, and caffeine expand the bronchial tubes thus allowing more smoke to enter the lungs and causing a higher exposure to nicotine[92]. Glycyrrhizin also inhibits inflammation in the lung and makes inhalation of tobacco smoke easier. Levulinic acid also enables deeper inhaling by desensitization of the upper respiratory tract[76].

Similarly, menthol, added to almost all tobacco products (Fig. 10), has, amongst other things, an analgesic effect and allows a deeper inhalation and thus increases smoke intake[55]. Because it also stimulates cold receptors, it causes a cooling and freshness sensation that makes smoking more pleasant[82]. Besides menthol, other substances are used which act locally as an anesthetic so that they mask the perception of harmful effects[92].

In addition, active agents are used to cover or to suppress the symptoms of damage to health. These are for example antioxidants which trap harmful free radicals. Nevertheless, a health benefit in the use of tobacco products could not be demonstrated so far. The oxidation inhibitor ß-carotene seems to even increase the risk for lung cancer[1,106].

Additives are used to facilitate the process of smoking, which increases the intake of carcinogenic and toxic ingredients of tobacco smoke and nicotine. This can also contribute to the enhancement of addictiveness.

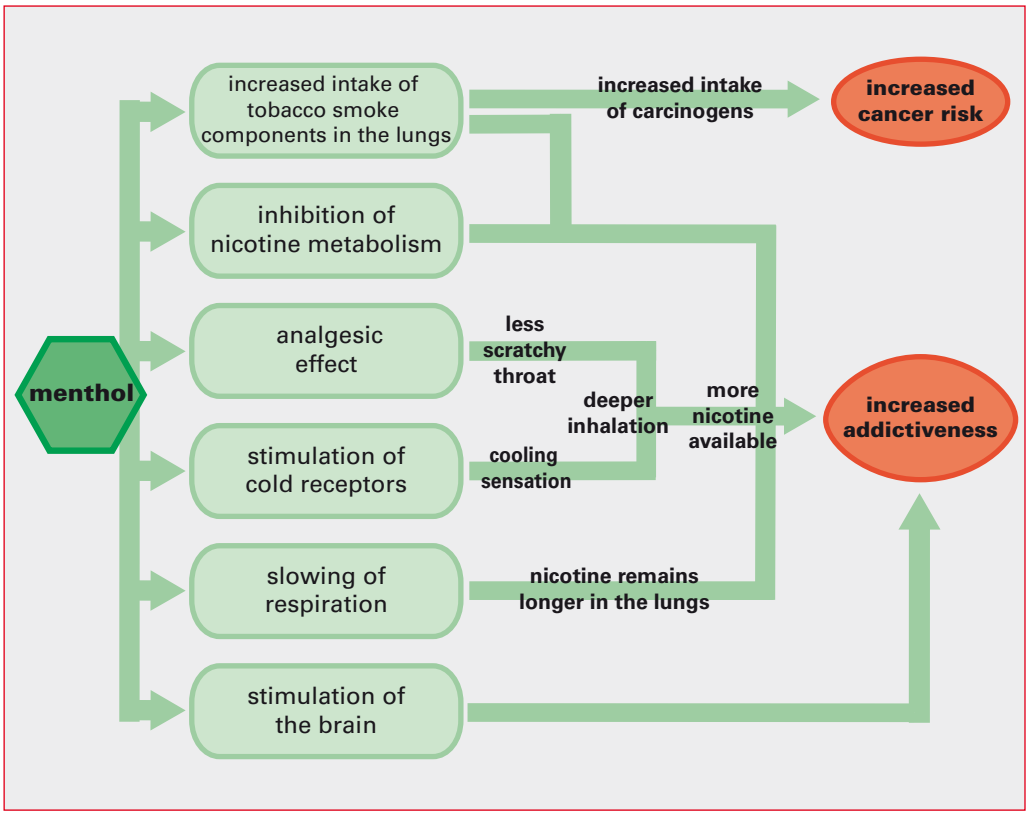

Figure 10:
The effects of menthol during smoking.
Illustration: German Cancer Research Center, 2009[59].

4.2.3 Increasing attractiveness of tobacco products

Menthol, sugar, cocoa, honey, and other flavours mask the harsh tobacco taste and make the tobacco smoke milder. Also humectants are used for this purpose, because dry tobacco has a very strong taste. This is to make smoking easier especially for beginners – mostly young people. Notably tobacco products with a seemingly harmless taste of fruit, beverages or food are most appealing to young people (Fig. 11).

Worldwide, in many countries, including EU countries, tobacco products with special flavours are sold increasingly. This is, because they are marketed

Figure 11:
Examples of cigarettes and cigarillos with different flavours.
Source: German Cancer Research Center, Unit Cancer Prevention, 2010.

with an appropriate design, attractive especially for children and young people, and leads them in an early dependence[19,27,77,79,83]. Some countries, therefore, have responded with restrictions and prohibitions of such additives (see box, next page).

The use of additives or flavours is also aimed at giving a consistent taste to a tobacco product and to offset the seasonal variability of the raw tobacco, an important factor towards maintaining brand loyalty among consumers.

The use of additives as flavouring agents increases the appeal of tobacco products and veils their harmful potential.

4.2.4 Masking the smell and visibility of tobacco smoke

Flavours mask the unpleasant odour of tobacco smoke. In addition, additives are used which affect the appearance of the smoke to make it less visible. The masking of the smell and visibility of tobacco smoke serves the purpose that it is perceived as less annoying by non-smokers[29,92].

Certain additives in tobacco products are used to reduce the visibility and the unpleasant odour of tobacco smoke, so the smoke together with its health hazards is hardly perceived.

Legal bans on tobacco products with distinctive flavours in non-European countries

In response to the increasing sales of tobacco products with distinctive flavours that appeal especially to children and young people, some governments have responded with appropriate legal measures that restrict or even prohibit the use of flavours in tobacco products:

- In **Canada**, since April 2010, the use of characteristic flavourings in the production and, since July 2010, the sale of cigarettes, cigarillos and blunt wraps (These are used as cigarette paper for rolling cigarettes – but in contrast consist of a foil of tobacco.) containing certain additives, are prohibited by the „Act to amend the Tobacco Act" (Bill C-32)[71], which entered into force in October 2009. The new list of approved additives is the most comprehensive to date. Some additives, such as menthol, are still permitted.
- In the **United States**, the national legislation prohibits the use of specific flavours such as fruit, candy, coffee, cloves and spices in cigarettes, fine cut tobacco and certain cigarillos. A possible ban of the widely used menthol should be examined[110].
- In **Australia**, some states have banned cigarettes with the taste of fruits and sweets.

Moreover, the guidelines for implementation of Article 13 of the WHO Framework Convention on Tobacco Control (FCTC), which deal with tobacco advertising bans, point out the importance of limiting the appeal of tobacco products. Paragraph 17 of the Guidelines for implementation of Article 13 states that the use of design features which make tobacco products appear more attractive and appealing to consumers, such as coloured cigarette paper and pleasant odours, should be restricted as far as possible[114]. For the implementation of the Articles 9 and 10, which deal with the use of additives in tobacco products, guidelines are currently being drafted by a working group and will be presented at the fourth session of the Conference of the Parties (COP-4) in November 2010.

4.3 Recommendations

To protect consumers, it is imperative to ban any additives in tobacco products

- which are carcinogenic by themselves or are suspected to cause cancer,
- from which carcinogenic compounds are formed during combustion,
- which are involved in cancer development in any other way,
- those which increase the addictiveness,
- those which make smoking easier, and
- all flavouring agents that increase the attractiveness of the product, especially for young people, leading them into dependency.

All additives which are still used in tobacco products, should be subjected to an rigorous test in which their safety should be established by the manufacturer. This should be done by means of a multistep procedure, based on internationally accepted and validated test methods. Whenever toxicity information is available, this should be used first. All substances that fail in anyone of the test steps should not be approved[60].

5 Smokeless tobacco products

Smokeless tobacco products such as Swedish snus contain nicotine and harmful substances, are addictive and cause damage to health (Fig. 12).

The Member States of the European Union prohibit the placing on the market of tobacco for oral use[44]. "Tobacco for oral use" means "all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product." The rationale behind the ban is as follows[30]:

- New smokeless tobacco products are particularly attractive to young people.
- There is a real risk that the new products for oral use will be used above all by young people, thus leading to nicotine addiction.
- Smokeless tobacco contains particularly large quantities of carcinogenic substances.
- The only appropriate measure to ensure a high level of health is a total ban.

In 1995, Sweden was granted derogation from the ban when it joined the European Union due to a long tradition of snus, a special Swedish smokeless tobacco product. Snus therefore was not a new product in Sweden at the time of accession. But the Act of Accession Sweden engages Sweden to ensure that snus is not marketed in other Member States (Article 151 paragraph 1 of the Act concerning the conditions of accession of the Republic of Austria, Finland and Sweden and the adjustments of the European Union justifying Treaties, OJ 1994 C 241, p. 2120 and OJ 1995 L 1, p. 131).

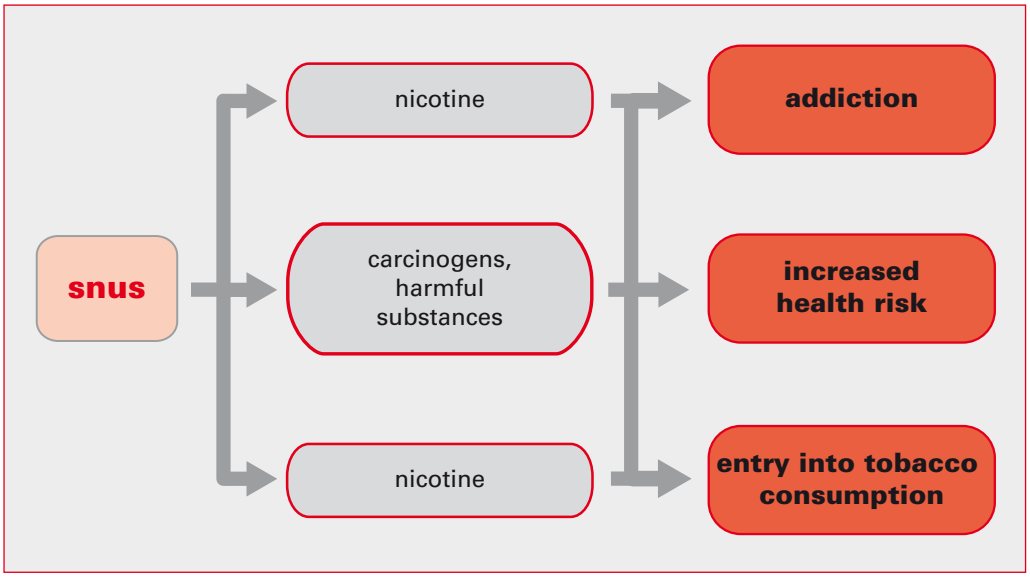

Figure 12: Overview of the adverse effects of smokeless tobacco.
Illustration: German Cancer Research Center, Unit Cancer Prevention, 2010.

Swedish Snus consists of finely ground tobacco, mixed with flavours, salt, water as well as humidifying and chemical buffering agents. It is available loose and portion packed both in different flavour varieties (Fig. 13). It is placed between the lip and gum.

When the Swedish manufacturer Swedish Match wanted to introduce snus on the German market, the European Court of Justice confirmed in 2004 the existing ban of the sale of snus in the EU, pointing out that these products contain nicotine which leads to dependence and whose toxicity is beyond question. In those circumstances, the legislature was entitled to consider that a prohibition of those products, which were new on the market, was necessary and that, in particular, there was no alternative measure which allowed its objective to be achieved as effectively[39]. Since the European Union is committed to take measures to prevent the onset of tobacco consumption, to promote and support tobacco cessation and to reduce the consumption of tobacco products, the ratification of the WHO Framework Convention on Tobacco Control offers an additional international framework for the European Union to maintain the ban of snus in the EU.

5.1 Health risks

Smokeless tobacco products contain nicotine and are addictive

Smokeless tobacco products contain, depending on the type, different amounts of nicotine[66]. Smokeless tobacco products are harmful, cause dependence[5] and deliver similar amounts of nicotine during consumption as cigarettes[10,70]. In contrast to smokers, users of smokeless tobacco usually have a steady concentration of nicotinie in the blood[72]. During the course of a day they absorb on average a similar amount or even higher quantities of nicotine than cigarette smokers[10].

Nicotine is addictive[11] and users of smokeless tobacco are just as dependent as smokers[9]. Young people who consume smokeless tobacco products experience similar, if not greater nicotine dependence and withdrawal symptoms compared to cigarette smokers[90]. For the consumer cessation is difficult[34].

Figure 13:
Swedish Match snus products.
Source: Swedish Match[103].
Illustration: German Cancer Research Center, Unit Cancer Prevention, 2010.

Smokeless tobacco products contain carcinogens and toxic substances

Around 28 carcinogens have been identified in smokeless tobacco products[72].The major and most abundant carcinogens are highly carcinogenic tobacco-specific *N*-nitrosamines, which are present in different concentrations depending on the type of product[72]. In addition, there are volatile *N*-nitrosamines, formaldehyde, benzo[*a*]pyrene, heavy metals, polonium-210, uranium-235 and -238, and other carcinogens[66,72].

Nicotine is a poison and a neurotoxin[53]. The symptoms of poisoning by nicotine include nausea, vomiting, weakness, unresponsiveness and impaired respiration and ultimately may lead to respiratory arrest resulting in death. Nicotine doses of 0.8 to 1.0 mg/kg body weight are considered to be lethal[61].

Infants are susceptible to accidental tobacco ingestion[28]. In children, as little as one milligram of nicotine can produce symptoms of poisoning[61].

Smokeless tobacco products cause serious diseases that may be lethal

The cancer-causing substances in smokeless tobacco products may, with certain variations depending on the product, cause pancreatic cancer[2,12,13,81], oral cancer[95] and oesophageal cancer[13].

Smokeless tobacco products cause serious damage of the oral health[5] including periodontosis, dental caries, tooth loss[35,68,74] and gingival recession[4,16]. Although some changes disappear upon snus cessation, gingival recession is not reversible[34].

Smokeless tobacco products cause premature birth and preeclampsia (pregnancy-related high blood pressure)[36,37].

Some scientific evidence suggests that consumption of smokeless tobacco may be associated with cardiovascular disease[5,14], diabetes and the metabolic syndrome[86] (Fig. 14).

Smokeless tobacco products are addictive and cause severe diseases, some of them being lethal.

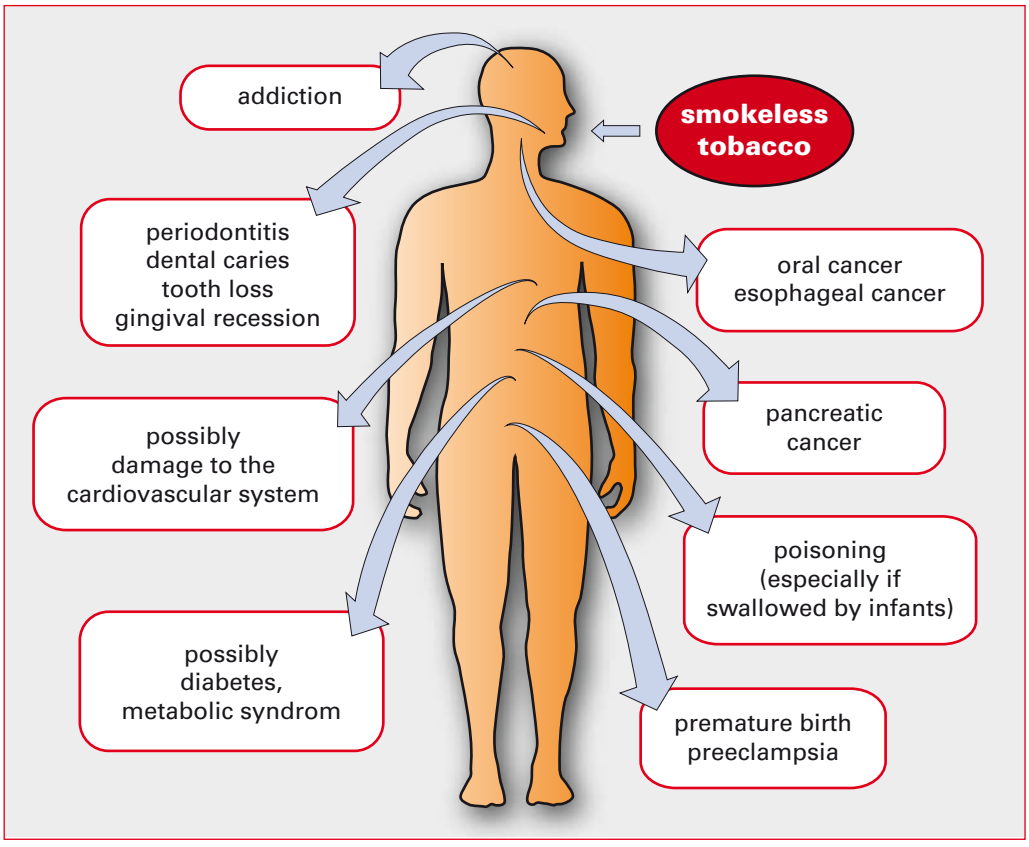

Figure 14:
Health damage caused by the consumption of smokeless tobacco.
Source: Ashley 2008[5].
Illustration: German Cancer Research Center, Unit Cancer Prevention, 2010.

5.2 There is no reason to introduce smokeless tobacco products on the European market

WHO and the Scientific Committee on Emerging and Newly Identified Health Risks of the European Union consistently categorized smokeless tobacco products as harmful and classified them as addictive[97,98].

Smokeless tobacco products do not provide any health benefit for the European population. However, in the long term they would increase the total tobacco consumption.

Smokeless tobacco products are attractive to young people

In the United States and Sweden, consumption of smokeless tobacco products increased significantly in recent years, particularly among young men[3,87]. The dual use of smokeless tobacco and cigarettes is common among young males[87,108]. The manufacturers introduce more and more products, many of which are suitable as initiation products for young people due to their low nicotine content and intense flavours[3,5,84].

On the long term smokeless tobacco products will increase the total tobacco consumption

Manufacturers promote their products as a substitute for smoking in situations where smoking is not allowed[5]. This may result in additional smokeless tobacco consumption by smokers. Thus, more tobacco is consumed and political efforts to reduce tobacco use are undermined[18,84].

There is no reason to introduce a harmful product such as snus or any other smokeless tobacco products on the European market, even though manufacturers have a financial interest in opening up a new market.

5.3 Smokeless tobacco products are not effective for smoking cessation

Currently, there is no scientific evidence that smokeless tobacco products could be helpful in smoking cessation[5,97,98].

To recommend smokeless tobacco products as an aid in smoking cessation may promote a false perception of safety. A lower health risk is achieved by reducing smoking and not by substituting another form of tobacco use[97].

Experience from Sweden shows that smokeless tobacco products are sometimes used to switch from smoking to smokeless tobacco products, but not for tobacco cessation: In Sweden, the proportion of smokers decreased significantly in the population, and the proportion of snus users increased significantly. But most smokers (66 percent) succeed cessation without snus[80]. Approximately one in four former smokers switches to snus[87]. The decline in the proportion of smokers is primarily due to the sharp rise in proportion of never smokers thanks to strong tobacco control measures (Fig. 15).

The number of smokers declines even in countries without smokeless tobacco products

Thanks to increasingly implemented tobacco control measures in recent years in many countries where the sale of smokeless tobacco products is prohibited, smoking prevalence decreased. In the UK, the Netherlands, Italy and Finland, in the period of 2006 to 2009, the proportion of smokers declined by five percent[107]. In Germany, the proportion of smokers also decreased over the last ten years, since stronger tobacco control measures have been implemented. Among young smokers, the proportion was significantly reduced from 28 percent in 2001 to 15 percent in 2008 (Fig. 16).

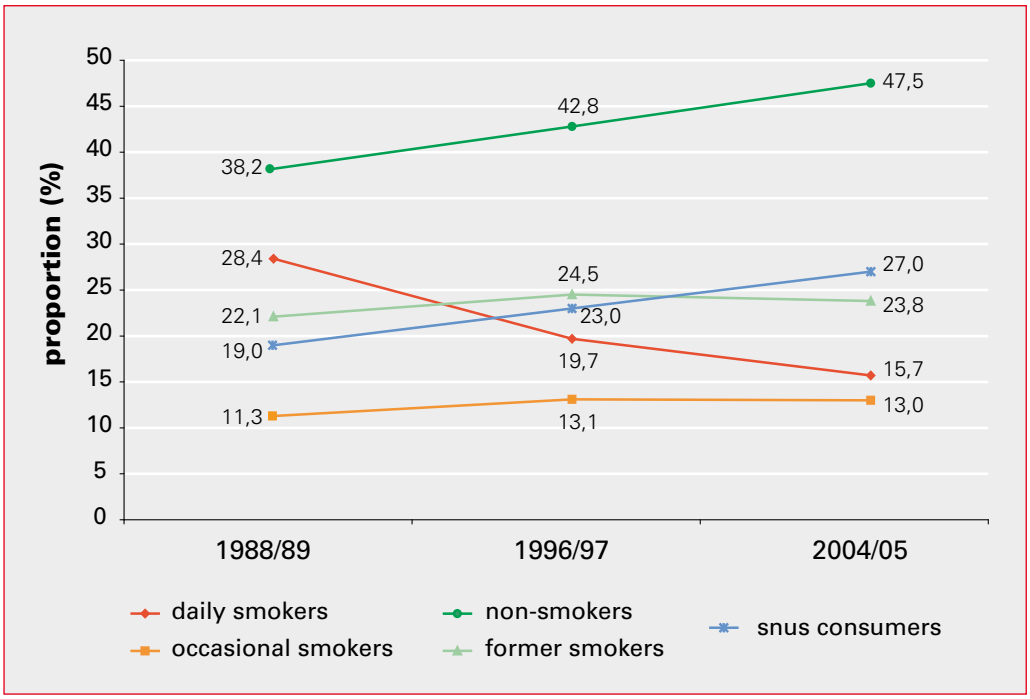

Figure 15:
Smoking behaviour of men in Sweden.
Source: Patja 2009[87].
Illustration: German Cancer Research Center, Unit Cancer Prevention, 2010.

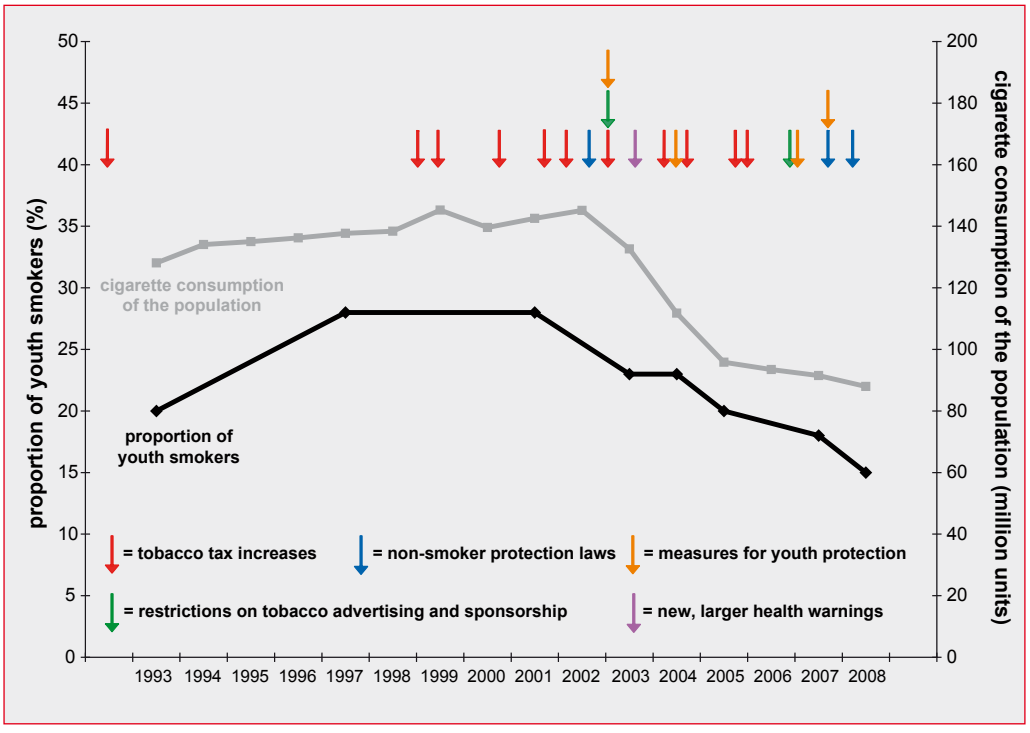

Figure 16:
Cigarette consumption of the population and the proportion of young smokers (15 – 17 years) in Germany.
Sources: Federal Statistical Office 2009[52], Federal Centre for Health Education 2008[47].
Illustration: German Cancer Research Center, Unit Cancer Prevention, 2009[59].

Smokeless tobacco products increase the overall tobacco consumption. A reduction in the total tobacco consumption succeeds mainly through effective tobacco control measures.

5.4 Recommendation

For the revision of Directive 2001/37/EC the German Cancer Research Center recommends that the placing on the market of smokeless tobacco products continue to be prohibited in the Member States in order to protect the health of the European population.

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