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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

(Text with EEA relevance)

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A.3 REGULATORY FRAMEWORK & DEVELOPMENTS IN MEMBER STATES AND AT INTERNATIONAL LEVEL

Part I of this Annex provides an overview of the regulatory situation at EU, national and international level in the five policy areas considered within this impact assessment. Part II presents an overview of the Tobacco Products Directive in relation to the WHO Framework Convention on Tobacco Control obligations and commitments. Part III is based on information collected from the national authorities in the context of the Regulatory Committee established under the Tobacco Products Directive (TPD). It describes in more details the legislation in place in each Member State.¹

A.3.1. PART I: Overview of the regulatory situation at EU, national & international level.1

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¹ It should be noted, however, that the situation evolves over time. Information in the tables in part 3 of this document was collected from the Regulatory Committee in spring 2012.

A.3.1. PART I: OVERVIEW OF THE REGULATORY SITUATION AT EU, NATIONAL AND INTERNATIONAL LEVEL

A.3.1.1. Regulation of STP and possible extension of the scope

A.3.1.1.1. EU Legislation

a) Smokeless Tobacco Products (STP)

The Tobacco Products Directive (hereinafter the TPD) covers tobacco products "for the purpose of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco" (Article 1). Article 8 currently bans one type of smokeless tobacco products (oral tobacco) while others (chewing and nasal tobacco) are freely marketed in the EEA. In their Accession Treaty, Sweden and Norway were granted a permanent derogation from the prohibition to market oral tobacco.¹ According to Article 5(4) of the Tobacco Products Directive where it is allowed, i.e. in Sweden and Norway, oral tobacco shall carry the following warning: "This tobacco product can damage your health and is addictive."

b) Nicotine Containing Products (NCP) and herbal products for smoking

The Commission Orientation note of 22 May 2008 provides some guidance as to which EU legislation applies to electronic cigarettes under the current situation.²

Non-tobacco products, such as NCP and herbal products for smoking, fall outside the TPD.

Whether these products fall under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use³ depends on whether they can be characterised as human medicine by presentation or function. National authorities, acting on a case-by-case basis, decide whether a product falls within the definition of a medicinal product by function. As illustrated below, there is at this stage no convergent view among Member States whether an electronic cigarette should be considered a medicinal product by function or not.

The delivery system (i.e. without the nicotine) of an electronic cigarette may possibly also be qualified as a medical device according to Council the Directive 93/42/EEC if it is intended to administer a medicinal product concerning medical devices.⁴ However, this would imply first that the nicotine cartridge is considered to be a medicinal product under Directive 2001/83/EC. Article 1 (2a) of Directive 93/42/EEC requires that, in order for a product to be qualified as a medical device, it is to have a medical purpose. Products made of nicotine that are ingested are covered by the Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European

¹ OJ L 1, 1. January 1995 (see article 151 and Annex XV thereof)

² http://ec.europa.eu/health/archive/ph_determinants/life_style/tobacco/documents/orientation_0508_en.pdf

³ OJ L 311, 28.11.2001, p. 67–128

⁴ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1–43

Food Safety Authority and laying down procedures in matters of food safety⁵, unless they are regarded as human medicines under Directive 2001/83/EC. The Novel Food Regulation (258/97)⁶ applies to placing on the market of food which has not, by 14 May 1997, been used for human consumption to a significant degree within the EU.

Finally, Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety applies in so far there are no specific provisions with the same objective in other EU law.⁷ The Directive enables a withdrawal from the market if the regulator can show that it is dangerous for the health and safety of consumers.

A.3.1.1.2. The situation in the Member States

a) Smokeless Tobacco Products (STP)

In addition to the EU-wide ban on oral tobacco, five Member States, (Latvia, Lithuania, Ireland, Greece and Poland) have banned the marketing of chewing tobacco and two Member States (Latvia and Lithuania) ban nasal tobacco.

b) Nicotine containing products (NCP)

There is no uniform legislation in place in Member States concerning NCP. As indicated above, the national authorities decide on a case-by case basis whether a product falls within the definition of medicinal product by function. It is therefore difficult to indicate with certainty how the legal landscape looks. However, 14 Member States have reported that they would regard at least some electronic cigarettes as medicinal products by function.⁸ Two Member States ban (Lithuania and Greece) electronic cigarettes under their tobacco legislation and two Member States (Malta and Poland) regulate the products (including ban on advertising). Nine Member States have no specific rules in place for electronic cigarettes.⁹

c) Herbal products for smoking

With regard to herbal products for smoking, the situation in Member States is also fragmented and ranges from banning these products (Lithuania and Greece) to no specific regulation.¹⁰ Other Member States have various provisions in place, including ingredients regulation (Belgium), labelling requirements (Latvia), advertising restrictions (Malta and Finland), smoke-free environment protections (Denmark, Latvia, Malta, Slovakia, and the United Kingdom) or general tobacco provisions (Italy). Austria has reported that it considers herbal products for smoking as a medicinal product by function if it contains a pharmacologically active substance and/or by

⁵ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24

⁶ OJ L 43, 14.2.1997, p. 1–6

⁷ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4–17. For further orientation on electronic cigarettes and EU legislation, see orientation note of 22 May 2008: http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/orientation_0508_en.pdf

⁸ AT, BE, DE (the nicotine containing liquids in the electronic cigarettes), DK, EE, FI (along with advertising ban under the Tobacco Act), FR (depending on the nicotine level as described in the table in part 2), HU, LU (if they contain nicotine without containing tobacco extract, and/or if presented as cessation treatment), NL, PT, RO, SE and SK

⁹ BG, CY, CZ, ES, IE, LV, IT, SI and UK (considering whether all NCPs should be considered medicinal by function)

¹⁰ BG, CY, ES, FR, HU, IE, LU, NL, PL, PT, RO and SI

presentation if the product is promoted for smoking cessation or treatment of nicotine addiction. Some Member States have also reported that they are taxing these products in the same way as tobacco products.¹¹

A.3.1.1.3. *The situation at international level*

The WHO Framework Convention on Tobacco Control (FCTC) covers all tobacco products and contains no specific rules on STP. As regards electronic cigarettes, it can be noted that the WHO Study Group on Tobacco Product Regulation has recommended that these products are regulated as combination drugs and medical devices.¹²

A.3.1.2. Packaging and labelling

A.3.1.2.1. *EU Legislation*

Article 5 of the TPD currently stipulates that all tobacco products must carry one general text warning covering not less than 30% of the most visible side of the package and – except for tobacco for oral use and other smokeless tobacco products - one additional text warning covering not less than 40% of the other most visible side.¹³ Packages of manufactured cigarettes should also display the results of tar, nicotine and carbon monoxide (TNCO) yield measurements. In addition, Article 5 empowers the Commission to take rules on the use of pictorial warnings that Member States must comply with if they decide to require additional warning in that form. If they are required, the pictorial warnings shall, together with the additional text warning, cover 40% of the other most visible side of the package.¹⁴ Moreover, Article 7 of the Directive bans the use of misleading descriptors such as light and mild.

Section 1(f) of Council Recommendation 2003/54/EC recommends prohibiting the sale of single cigarettes and packs of less than nineteen.

A.3.1.2.2. *The situation in the Member States*

Combined health warnings (picture plus text) on cigarette packs are in place in eight Member States¹⁵ (Belgium (2007), Romania (2008), United Kingdom (2008), Latvia (2010), France (2011), Malta (2011), Spain (2011), Denmark (2/2012)). Two Member States have passed legislation introducing pictorial health warnings from 2013 (Hungary, Ireland) and one is planning to pass similar legislations (Poland).

The implementation of their use varies significantly between these Member States. Some of them use pictorial warnings on cigarette packages only and others on all smoked tobacco packages¹⁶. Thirteen Member States have complemented the packages with references to cessation services,

¹¹ CZ, DE, EE, LV and SE

¹² WHO Study Group on Tobacco Product Regulation, Report on the Scientific Basis of the Tobacco Product Regulation: Third Report of a WHO Study Group, WHO 2009.

http://www.who.int/tobacco/global_interaction/tobreg/publications/tsr_955/en/index.html

¹³ These figures are increased to 32% & 45% in MS with 2 official languages and 35% & 50% in MS with 3 official languages.

¹⁴ This figure is increased to 45% in MSs with two official languages and 50% in MS with three official languages.

¹⁵ Starting date of mandatory use in parenthesis

¹⁶ As of June 2012, France, Malta, Latvia (from June 1, 2010), Spain and the UK use pictorial warnings on smoked tobacco products other than cigarettes. Denmark, Ireland and Hungary will start using them in 2012/2013 and Poland is planning to pass legislation which would require their use on all smoked tobacco products.

four of them on a mandatory basis (Belgium, France, the Netherlands and Slovenia)¹⁷. All Member States offer support via cessation services to smokers.

The choice of actual use of pictures also varies from one Member State to another. While Belgium and Hungary are using the whole library of 42 warnings (Belgium: divided into three sets which alternate every year, Hungary: the manufacturer can choose between them, respecting the rules on rotation), the remaining eight Member States have chosen 14 images that they deem most effective for their population.

While no Member State has yet fully standardised tobacco packaging there is at least one Member State, France, where promotional elements on the package are already banned as part of the advertising ban.¹⁸

In addition, the possibility of introducing standardised (plain) tobacco packaging is currently discussed in a number of Member States as well as Norway. In April 2012, the UK launched a public consultation on standardised packaging of tobacco products running until August 2012.¹⁹ A Belgian MP tabled a proposal for plain tobacco packaging in May 2011²⁰ and the Belgian Minister of Health has stated (in the health committee) of the parliament that she will push for the adoption of plain packaging.²¹ In July 2011, France's minister of health asked MP Bur to propose a policy recommendation on tobacco. These were published in March 2012²² and the fifth recommendation was to develop plain packaging. More recently reports in the French media have also confirmed that the French government intends to present a tobacco control plan that includes plain packaging.²³ Finland and Norway are also exploring the possibility of introducing plain packaging. As these discussions are at an early stage, the exact nature of potential national actions, including which features would be standardised, remains uncertain.

Member States have different rules in place as regards the minimum number of cigarettes per package, which affects the size of the package. Fourteen Member States (Austria, Czech Republic, Estonia, Finland, France, Greece, Ireland, Luxembourg, Lithuania, Poland, Portugal, Denmark, Romania and Spain) specify a minimum pack size of twenty cigarettes. In four Member States (Hungary, Germany, the Netherlands and Sweden), the minimum pack size is nineteen cigarettes. Italy specifies that cigarettes must be sold in either packets of ten or twenty. In the UK the minimum pack size is 10 cigarettes. Slovenia expressly bans the sale of single cigarettes or the sale of other tobacco products separately from their original packaging and Lithuania bans the sale of single cigarettes, cigarillos and long cigarettes. Latvia bans the sale of single tobacco products and herbal smoking products, with the exception of cigars and cigarillos. Hungary has also fixed a maximum number of fifty cigarettes.

¹⁷ Quitlines are included in some warnings in Austria, Denmark, Germany, Hungary, Ireland, Latvia, Poland, Sweden, and the United Kingdom.

¹⁸ http://www.inpes.sante.fr/itc/pdf/ITC_rapport_FR.pdf

¹⁹ Article L3511-3 of the French public health code

²⁰ <http://www.lesoir.be/actualite/sciences/2011-05-02/des-paquets-de-tabac-sans-logo-837626.php>

²¹ <http://www.lachambre.be/doc/CCRI/pdf/53/ic096.pdf> Report of the health commission of 19th January 2011, p 29-31

²² http://www.sante.gouv.fr/IMG/pdf/rapport_Y_Bur_nouvelle_politique_de_lutte_contre_le_tabac.pdf

²³ <http://www.leparisien.fr/economie/nouveau-plan-antitabac-ce-que-prepare-le-gouvernement-05-09-2012-2151462.php>

A.3.1.2.3. *The situation at international level*

Article 11 of the FCTC stipulates that warnings should be 50% or more, but no less than 30%, of the principal display areas. The guidelines for implementing Article 11 suggest that the effectiveness of health warnings increases with their size and recommend Parties to consider the use of pictorial health warnings on both principal display areas. Article 11 of the FCTC gives the states three years, running from the time that the convention enters into force for them, in which to adapt and implement effective packaging and labelling measures.

The guidelines for implementing Article 11, (tobacco packaging and labelling) and Article 13, (advertising) recommend to consider the introduction of "plain" (standardised, generic) packaging.

The FCTC guidelines on ingredients (Article 9 and 10) regulation also recommend to ban ingredients that have colouring properties. For cigarettes, Australia is the first jurisdiction in the world to introduce plain packaging, including standardised appearance of individual cigarettes.²⁴ The legislation entered into force as of 1 December 2012.

Moreover, the FCTC guidelines on labelling (Article 11) recommend Parties to consider introducing other innovative measures regarding location of the warnings, including, but not limited to, requiring health warnings and messages to be printed on the filter overwrap portion of cigarettes and/or on other related materials such as filters and papers.

Article 16(3) of the FCTC states that 'each party to the convention shall endeavour to prohibit the sale of cigarettes individually or in small packets, which increase the affordability of such products to minors'.

A.3.1.3. Ingredients

A.3.1.3.1. *EU Legislation*

a) Reporting

Article 6 of the TPD requires that manufacturers communicate all tobacco ingredients information, together with available toxicological data, to the Member States. Member States communicate this information to the Commission.

b) Regulation of ingredients

TPD does not regulate how and by whom the ingredients shall be assessed and invites, in Article 12, the Commission to submit a proposal providing for a common list of ingredients. Such a proposal has not yet been submitted.

²⁴ Tobacco Plain Packaging Act 2011

A.3.1.3.2. *The situation in Member States*

a) Reporting

Despite the development of EU guidelines²⁵ on an electronic model for reporting of ingredients data (EMTOC), different reporting formats (e.g. paper, CDs, electronic) are still used for the submissions of tobacco product information. The use of the electronic model for data submission (EMTOC) is legally binding in Austria and Romania and six other Member States (Belgium, Denmark, Germany, Malta, Netherlands and Poland) use the model on a voluntary basis. Additional Member States are planning to start using the model in the years to come.

b) Regulation of ingredients

Fourteen Member States regulate ingredients in their national law, while 13 Member States have no specific rules in place in addition to the TNCO-levels required in the TPD.²⁶ Poland bans the use of ingredients, which enhance the addictive properties of tobacco.²⁷ Most of the current regulations are based on toxicology considerations and many lists have found inspiration from food legislation. Four Member States (Belgium, France, Romania, and the UK²⁸) have introduced positive lists indicating ingredients which are allowed to be used in tobacco products. Lithuania has introduced a negative list which restricts specific additives (e.g. vanilla root and clove) from being included in tobacco products and the Czech Republic, Germany, Hungary, Bulgaria²⁹ and Slovakia have a combination of positive and negative lists. The positive lists of Germany, the Czech Republic and Hungary are very detailed and include several hundreds of ingredients. Finland and Spain also have lists of permitted substances but these are very broad and cannot be interpreted as a positive list. In 2009, France adopted a legislation focusing more on the attractiveness of certain tobacco products. The French law allows setting up maximum levels for ingredients that impart a sweet or fruity/acid taste to cigarettes (article D3511-16 of the French public health code). In Sweden, there is no positive or negative list but it is possible to regulate ingredients on an ad-hoc basis. Member States are also taking different legal approaches as regards additives integrated in the filter of cigarettes. For example, Germany does not allow cigarettes with flavoured capsules embedded in the filter to be placed on the market. A national court recently confirmed this approach.³⁰ Also in Belgium 3 ingredients ('E418 gomme gellane, E133 « bleu brillant FCF », Medium Chain Triglycerides (MCT)) needed to include the “menthol capsules” in cigarettes were recently banned.

A.3.1.3.3. *The situation at international level*

The Conference of the Parties to the WHO FCTC has adopted partial guidelines for implementation of Articles 9 and 10 of the FCTC (regulation of content and tobacco products disclosure). The guidelines focus mainly on how to reduce the attractiveness of tobacco products in order to reduce the prevalence of tobacco use and dependence among new and confirmed users. More specifically, the guidelines recommend Parties to regulate, by prohibiting or

²⁵ http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/practical_guidance_en.pdf

²⁶ No information received from one Member State

²⁷ Art. 7a of the Health Protection Act against the Consequences of Tobacco Use

²⁸ The United Kingdom has maintained a voluntary agreement between the Department of Health and the manufacturers

²⁹ At this stage the use of the lists is on an informal basis in BU.

³⁰ <http://www.echo-online.de/ratgeber/gesundheit/gesundheit/Gesundheit-Urteile-Verbraucher-Tabak:art17704,3258765>

restricting, ingredients that may be used to increase palatability in tobacco products and that have colouring properties.³¹ The guidelines also recommend Parties to prohibit ingredients in tobacco products that may create the impression that they have a health benefit or that are associated with energy and vitality, such as stimulant compounds.

A.3.1.4. Sales arrangements

A.3.1.4.1. EU Legislation

Distribution channels and sales arrangements are not regulated in the current TPD. Council Recommendation 2003/54/EC recommends that Member States remove tobacco from self-service displays in retail outlets, to restrict access to TVM and to restrict tobacco distance sale for general retail such as sales via the internet.³²

It is also recommended to require vendors of tobacco products to establish that tobacco purchasers have reached the age for purchase of tobacco products required in national law, where such an age limit exists.

As regards distance sales, Article 36 of Council Directive 2008/118/EC of 16 December 2008³³ concerning the general arrangements for excise duty, stipulates that tobacco products already released for consumption in one Member State, which are purchased by a consumer in another Member State and which are dispatched or transported to another Member State directly or indirectly by the vendor or on his behalf shall be subject to excise duty in the Member State of destination.

While Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the internal market (Directive on electronic commerce) aims at facilitating electronic commerce, it allows, in Article 3, derogations necessary for the protection of public health.³⁴

A.3.1.4.2. The situation in Member States

All EU Member States have age limits in place as regards purchasing of tobacco. The legal buying age is 18 years in 22 Member States and 16 years in the remaining five.³⁵

a) Tobacco vending machines (TVM)

Thirteen Member States have banned sale of tobacco from TVM completely³⁶ and one Member State (Finland) that currently has restrictions in place has announced that it will introduce a full ban as of 2015.

In the remaining thirteen Member States there are different types of restrictions in place to limit underage consumers' uncontrolled access to tobacco products. Restrictions range from ID control

³¹ http://www.who.int/fctc/protocol/guidelines/adopted/guidel_2011/en/index.html

³² http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_022/l_02220030125en00310034.pdf

³³ OJ L 9, 14.1.2009, p. 12–30

³⁴ OJ L 178, 17.7.2000, p. 1–16

³⁵ AT, BE, IT, LU and NL all stipulate that the legal age to purchase tobacco products is 16.

³⁶ Full ban is in place in Bulgaria, Cyprus, Estonia, France, Greece, Hungary, Lithuania, Latvia, Poland, Romania, Slovakia, Slovenia, and the United Kingdom (as of 1 October 2011, in England only, rest of the UK to follow).

systems to other technical requirements or supervision of the TVM. Germany, Austria and Italy have ID-control systems in place, while other Member States have other restrictions such as locks (Belgium) or electronic or other kind of system (Portugal). More generally worded restrictions are in place in some Member States, where it is simply stated that the TVM needs to be supervised (Finland, Malta, the Netherlands³⁷ and Spain), that the age limits must be respected (Czech Republic and Luxembourg) or that sale by TVM must be regulated in the same way as sale of tobacco from a shop (Sweden).

Some Member States also regulate where the TVM can be installed. Ireland and Denmark permit the use of vending machines only in licensed premises or retail stores. Portugal bans the use of vending machines in certain environments. In cases where tobacco vending machines do not have an age verification system, Germany limits the installation of tobacco vending machines to places that children and adolescents cannot access. However, in practice, most TVM in Germany have an age verification system.

b) Tobacco promotion and display at point of sale (PoS)

Currently, three Member States (Finland, Ireland and the UK³⁸) and two EEA countries (Iceland and Norway) have introduced laws to prohibit the visible display of tobacco products at the PoS. Fourteen Member States (Austria, Denmark, France, Greece, Hungary, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Sweden, and Spain) allowing PoS display have put in place restrictions or bans on promotion at point of sale. Approximately one third of Member States have no regulations in place for Point of Sale display.³⁹

c) Cross-border distance sale of tobacco

Internet sale of tobacco is not allowed in nine Member States.⁴⁰ Among those Member States, some (including France and Lithuania) have introduced outright ban on this type of sale. Others (including Austria, Bulgaria, Hungary, Latvia and Spain) only grant licences or permission to sell tobacco through other sales channels.

Several other Member States have different restrictions in place as far as internet sale of tobacco is concerned. The restrictions range from licensing of the internet retailer (Cyprus, Denmark, Greece and Finland), to age limits (Czech Republic and Sweden) and advertising bans (Germany, Malta, Portugal and the UK).

A.3.1.4.3. The situation at international level

Article 16 (1d) of the FCTC includes measures to ensure that TVM are not accessible to minors in the list of measures that Parties can adopt in order to comply with their obligation to adopt and implement effective measures to prohibit the sale of tobacco products to persons under the age limit.

³⁷ Vending machines must be placed in a spot where they can be supervised to make sure age restrictions are respected. Outdoor vending machines are not allowed.

³⁸ The UK has introduced legislation banning point of sale display in England for large shops from April 2012 and small shops from April 2015 (the rest of the UK to follow).

³⁹ BE, BG, CY, CZ, EE, DE, IT, RO, SI and SK.

⁴⁰ AT, BG, ES, FR, HU, IT, LT, LV and SK.

The guidelines for the implementation of Article 13 of the FCTC call on the Parties to ban display and visibility of tobacco products at point of sale since they constitute a method of advertising and promotion.⁴¹ The same guidelines also recommend Parties ban TVMs.

The guidelines for implementing Article 13 of the Convention also recommend Parties to ban internet sale of tobacco.

A.3.1.5. Traceability and Security Features

A.3.1.5.1. EU Legislation

Only some elements of the current EU regulatory framework address traceability and security of tobacco products.

Article 5(9) of the TPD stipulates that to ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined. Technical measures to apply these provisions should be adopted by comitology, but no such decision has been taken at this stage.

Article 39 of Directive 2008/118/EC states that Member States may require excise goods to carry tax markings or national identification marks used for fiscal purposes.

A.3.1.5.2. The situation in Member States

Thirteen Member States⁴² have indicated they have transposed the requirement enshrined in Art 5 (9) of Directive 2001/37/EC more or less literally. However, they did not provide any information on the concrete implementation. From other responses it can be concluded that such marking is *de facto* done by the tobacco industry (voluntarily or as part of their obligations under the legally binding agreements) (Cyprus, Denmark and Germany), or that further guidance or decisions by the Commission are awaited to implement the provision (Sweden).

A.3.1.5.3. The situation at international level

The FCTC defines illicit trade in Article 1:

For the purpose of this Convention 'illicit trade' means any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct facilitating such activity.

Article 15 FCTC establishes that the elimination of illicit trade in tobacco products is an essential component of tobacco control and outlines the measures that are to be implemented to combat illicit trade in tobacco products. Article 15 FCTC contains various provisions and obligations as regards illicit trade in tobacco products. According to paragraph 2, unit packets have to be marked in order to determine the origin and the point of diversion and to monitor, document and control the movement of tobacco products and their legal status. The development of a tracking

⁴¹ http://www.who.int/fctc/protocol/guidelines/adopted/guidel_2011/en/index.html

⁴² AT, BG, FR, CZ, HU, LV, LT, LU, ES, PT, SI, SE and the UK

and tracing system forms part of Article 15 (2). Article 15 (4) (b) includes the requirement for Parties to "enact or strengthen legislation, with appropriate penalties and remedies, against illicit trade in tobacco products, including counterfeit and contraband cigarettes."

In 2008, it was decided to start negotiations for a Protocol (a stand alone international Treaty) based on Article 15 FCTC to eliminate the illicit trade in tobacco products. These negotiations have resulted in the adoption of the Protocol in November 2012. The Protocol will make a major contribution in the global fight against illicit trade in tobacco products.

The core provisions of the protocol relate to the control of the supply chain for tobacco products through notably licensing (or equivalent approval), due diligence, record keeping, control of duty free sales, of internet sales and of free zones and a tracking and tracing regime.

Apart from legislation, it should be noted that the EU Commission and the Member States have also engaged with legitimate traders in order to address the illicit trade issue. Starting from litigations, the European Union and the participating Member States have signed four legally binding and enforceable multi-year Cooperation Agreements with the four largest tobacco manufacturers⁴³. These Agreements ensure that the manufacturers carry out certain procedures to prevent the diversion of their products into illicit trade channels. These agreements with the tobacco manufacturers have led to positive results, notably in reducing the illicit trade in genuine products, for which case seizure payments have to be paid by the respective manufacturer. In case of counterfeit products, the consequences under the agreements are less severe. The agreements do not address the issue of "illicit white" cigarettes destined for the EU market.

Generally speaking it should be noted, that these agreements are at different stages of implementation, that they solely cover cigarettes and fine cut tobacco for smoking and that only the four largest tobacco manufacturers are covered.

⁴³ Philip Morris International (July 2004), Japan Tobacco International (December 2007), British American Tobacco (July 2010) and Imperial Tobacco Limited (September 2010)

A.3.2. PART II: THE TOBACCO PRODUCTS DIRECTIVE IN RELATION TO THE FCTC OBLIGATIONS AND COMMITMENTS

| Policy Area | TPD | FCTC and Illicit trade protocol (legally binding) | Guidelines or other relevant WHO docs | Preferred options in revised TPD (IA Report, chapter 4) |
|---|--|--|--|--|
| Regulation of STP and possible extension of the scope | <p>Article 2(1) tobacco products</p> <p>STP fall inside the scope of FCTC.</p> <p>NCP and herbal products fall outside the scope of the FCTC.</p> | <p>Article 1c tobacco products</p> <p>STP fall inside the scope of FCTC.</p> <p>NCP and herbal products fall outside the scope of the FCTC, but some provisions could be relevant, for example Article 5(2b) requiring Parties to adopt and implement...effective measures...for preventing and reducing ...nicotine addiction...", Art 13(2) no indirect promotion of a tobacco product, Art 16(1) prohibit the manufacture and sale of any objects in the form of tobacco products which appeal to minors."</p> | <p>WHO Technical Report, 1988</p> <p>-Recommends that countries with no established smokeless tobacco habit should consider a ban on the manufacture, importation, sale and promotion of smokeless tobacco products before they are introduced to market or become established habit.¹</p> <p>WHO Study Group on Tobacco Product Regulation (TobReg) 2009</p> <p>-STP: Recommendations on limits for carcinogenic components for carcinogenic components: Tobacco specific N-nitrosamines (TSNA) and polycyclic aromatic hydrocarbons (PAH).²</p> <p>-Electronic cigarettes: Recommendation to regulate as combination drug and medical devices and not as tobacco products.</p> <p>-Report by the Convention Secretariat to Conference of the Parties (CoP) to the FCTC and CoP5: no conclusive guidance on how to regulate the products.</p> | <p>STP (option 3): Maintain the ban on oral tobacco, subject all novel tobacco products to a notification obligation and all STP placed on the market to stricter labelling and ingredients regulation plus a clearer definition of chewing tobacco.</p> <p>-Stricter than current TPD.</p> <p>-In line with WHO Technical Report 1988</p> <p>-In line with general principle in FCTC Article 4 (4) adopt measures to reduce consumption of all tobacco products.</p> <p>NCP (option 3): Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements</p> <p>-Outside current TPD</p> <p>-In line with WHO TobReg recommendation.</p> <p>-In line with FCTC Article 5(2) to prevent and reduce nicotine addiction, and Article 14 to ensure that the effectiveness of tobacco cessation treatments is scientifically proven.</p> <p>Herbal products for smoking (option 1): Health warning</p> <p>-Outside both TPD and FCTC.</p> |
| Packaging and labelling | <p>TPD Article 5</p> <p>All tobacco products must carry one general text</p> | <p>FCTC Article 11</p> <p>Large, clear, visible and legible health warnings should be 50% or more of the</p> | <p>The FCTC guidelines Article 11</p> <p>-Parties should consider using health warnings covering more than 50% of the display areas.</p> | <p>Option 2: 75% combined warnings on both sides, cessation information, no promotional or misleading elements, Member States allowed to regulate surface not regulated by TPD or other legislation if compatible with</p> |

¹ The scientific basis of tobacco product regulation. Second report of a WHO Study Group. Geneva, World Health Organization, 2008 (WHO Technical Report Series, No. 951). Available from: http://www.who.int/tobacco/publications/prod_regulation/tsr_951/en/index.html

² However, the report does not recommend STP to be put on the market.

| Policy Area | TPD | FCTC and Illicit trade protocol (legally binding) | Guidelines or other relevant WHO docs | Preferred options in revised TPD (IA Report, chapter 4) |
|-------------|--|--|---|--|
| | <p>warning covering not less than 30% of the most visible side of the package and one additional text warning covering not less than 40% of the other most visible side.</p> <p>Packages of manufactured cigarettes should display the results of tar, nicotine and carbon monoxide (TNCO) yield measurements.</p> <p>The Commission has the power to take rules on the use of pictorial warnings that Member States have to comply with if they decide to introduce combined warnings (picture plus text).</p> <p>The pictorial warnings should, together with the additional text warning, cover 40% of the other most visible side of the package.³</p> <p>TPD Article 7 Text, names, trade marks and figurative and other signs suggesting that a tobacco product is less harmful than others should</p> | <p>principal display areas but no less than 30%. They may be in the form of or include pictures or pictograms.</p> <p>-information on relevant constituents and emissions of tobacco products as defined by national authorities.</p> <p>-packaging and labelling should not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra-light”, or “mild”.</p> <p>FCTC Article 16(3) Each party shall endeavour to prohibit the sale of cigarettes individually or in small packets, which increase the affordability of such products to minors’.</p> | <p>-Parties should consider pictorial health warnings on both principal display areas.</p> <p>-Health warnings and messages should in addition to harmful effects address different issues such as advice on cessation.</p> <p>-Parties should prohibit the display of figures for emission yields such as TNCO.</p> <p>-Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.</p> <p>The FCTC guidelines Article 13 Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive.</p> <p>FCTC guidelines Article 9 and 10 –Parties should prohibit or restrict ingredients that have colouring properties in tobacco products.</p> | <p>the Treaty:</p> <p>-Stricter than current TPD</p> <p>-In line with FCTC Article 11.</p> <p>-Less strict than FCTC guidelines for Article 11 and 13 in terms of plain packaging, but Member States are allowed to implement fully the guidelines as not all the elements of the packaging are regulated by the Directive. Other aspects of guidelines are respected (cessation, warning size, both sides of pack, no TNCO display, no promotional elements)</p> |

³ This figure is increased to 45% in MSs with two official languages and 50% in MS with three official languages.

| Policy Area | TPD | FCTC and Illicit trade protocol (legally binding) | Guidelines or other relevant WHO docs | Preferred options in revised TPD (IA Report, chapter 4) |
|----------------------------|--|--|---|---|
| | not be used. | | | |
| Ingredients | <p>TPD Article 6 Manufacturers are required to communicate all tobacco ingredients information, together with available toxicological data, to the Member States. Member States communicate this information to the Commission.</p> <p>TPD Article 12 The Commission is invited to submit a proposal providing for a common list of ingredients. (Such a proposal has not yet been submitted.)</p> | <p>FCTC Article 9 Guidelines shall be proposed for the regulation of ingredients. Parties shall adopt and implement effective measures for such regulation.</p> <p>FCTC Article 10 Each Party shall adopt and implement effective measures to disclose to governmental authorities information about content and emissions. Each Party shall adopt effective measures for public disclosure of information on toxic constituents and emissions.</p> | <p>FCTC guidelines Article 9 and 10</p> <p>-Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products and that have colouring properties.</p> <p>-Parties should prohibit ingredients in tobacco products that may create the impression that they have a health benefit or that are associated with energy and vitality, such as stimulant compounds.</p> <p>-Parties should consider making information about the toxic constituents and emissions disclosed to governments publicly available.</p> | <p>Option 2: Ban products with characterising flavours, common reporting and information publicly available.</p> <p>-Stricter than current TPD. -In line with FCTC Article 9 and 10 -In line with FCTC guidelines for Article 9 and 10</p> |
| Cross-border distance sale | <p>TPD No provisions</p> <p>Council Recommendation 2003/54/EC recommends that Member States restrict tobacco distance sale for general retail such as sales via the internet.</p> | <p>FCTC Article 16 (1d)</p> <p>Parties shall adopt measures to prohibit the sale of tobacco to under-aged persons. The future Protocol on illicit trade foresees in Article 11 (1) that Parties shall require that all legal and natural persons engaged in any transaction with regard to tobacco products through Internet-, telecommunication- or any other evolving technology-based modes of sale comply with all relevant obligations, including licensing. Article 11 (2) provides that Parties shall consider banning retail sales of tobacco products through Internet, telecommunication or any other evolving technology.</p> | <p>FCTC guidelines Article 13FCTC</p> <p>-Internet sales of tobacco should be banned as they inherently involve tobacco advertising and promotion.</p> | <p>Cross-border distance sale (option 1): Notification of retailers:</p> <p>-Outside current TPD. -In line with Illicit Trade Protocol. -Less strict than FCTC guidelines for Article 13. -</p> |

| Policy Area | TPD | FCTC and Illicit trade protocol (legally binding) | Guidelines or other relevant WHO docs | Preferred options in revised TPD (IA Report, chapter 4) |
|------------------------------------|---|---|---------------------------------------|---|
| Traceability and Security Features | <p>TPD Article 5(9)</p> <p>Tobacco products shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of the manufacture to be determined.</p> <p>Technical measures shall be adopted by "comitology". (This has not been done).</p> | <p>FCTC Article 1</p> <p>For the purpose of this Convention 'illicit trade' means any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase including any practice or conduct facilitating such activity.</p> <p>FCTC Article 15</p> <p>The elimination of illicit trade in tobacco products is an essential component of tobacco control. Article 15 FCTC contains various provisions and obligations as regards illicit trade in tobacco products. According to paragraph 2, unit packets have to be marked in order to determine the origin and the point of diversion and to monitor, document and control the movement of tobacco products and their legal status. The development of a tracking and tracing system forms part of Article 15 (2). Article 15 (4) (b) includes the requirement for Parties to "enact or strengthen legislation, with appropriate penalties and remedies, against illicit trade in tobacco products, including counterfeit and contraband cigarettes."</p> <p>Protocol on illicit trade</p> <p>The provisions relevant for the TPD revision relate to a tracking and tracing regime. (Part III of the Protocol on Supply Chain Control)</p> | | <p>Preferred option 2: Tracking and tracing system plus security feature</p> <ul style="list-style-type: none"> -Stricter than current TPD. -Compatible with FCTC Article 15 and Illicit Trade Protocol. |

A.3.3. PART III: LEGISLATION IN MEMBER STATES

A.3.3.1. Regulation of STP and possible extension of the scope

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|----------|--|---|--|
| Austria | Allowed, only snus forbidden (see § 2 Abs. 1 lit. 2 Tabakgesetz) | Regarded as medicinal products by function if the product contains nicotine or other pharmacologically active substances and/or by presentation if the product is promoted for smoking cessation or treatment of nicotine addiction (see § 1 Arzneimittelgesetz). In this case the apparatus is also regulated as a medical device (see § 5(1) Medizinproduktegesetz). | Regarded as medicinal products by function if the product contains a pharmacologically active substance and/or by presentation if the product is promoted for smoking cessation or treatment of nicotine addiction (see § 1 Arzneimittelgesetz). If an apparatus is used, it will be regarded as a medical device if it is intended to be used with a medicinal product (see § 5(1) Medizinproduktegesetz). |
| Belgium | | With nicotine regarded as pharmaceuticals by function and/or presentation. - Considered as tobacco products if it contains tobacco extract - considered as pharmaceuticals by function if it contains nicotine without containing tobacco extract. - considered to be pharmaceutical by presentation if, even without nicotine, there are claims that it helps to quit smoking | Royal decree of 13 August 1993 regulating tobacco products refers to “product that replace tobacco” (art. 1, 5°). Herbal cigarettes are considered to be part of this category. Subject to the same positive ingredients list as tobacco products. No authorisation needed. http://www.health.belgium.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/15760531_fr.pdf |
| Bulgaria | The chewing and nasal tobacco products are not banned and they are available at the market in Bulgaria. Only the oral tobacco products are banned for selling in accordance with the Tobacco Product Directives (TPD) 2001/37/EU and the Law for Tobacco and Tobacco Products. | Not regulated as a pharmaceutical or medicine device by legislation. The regulation is only under the Consumer Protection Act. The position of MoH is that the scope of the TPD have to be widened and could be called Directive for Tobacco and Tobacco Imitative products (with an external or internal imitative characteristics of tobacco products by shape, contents, name etc.). According to (3) and (4) paragraphs of the Preamble of TPD 2001/37/EU we have to protect the individual and public health by the TPD. The future Directive have to forbid each novel tobacco or tobacco imitative product and should list the old and already approved tobacco products. The main arguments are: 1) that tobacco industry will become as more creative as more the public invented instruments will press industry and restrict its industry | Not regulated. There is not an information to be sold in Bulgaria. They fall under the text which is written for the electronic cigarettes |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|----------------|--|--|--|
| Cyprus | Chewing tobacco non-banned by Dir 2001/37 is permitted to be marketed in Cyprus. Although such product are only popular among ethnic groups. | <p>activities; 2) there is not a safty level of consumption of tobacco or tobacco imitative products; 3) we have to put combined health warning pictures on each product which stimulate, support, associated etc. the tobacco consumption.</p> <p>Regarded as medicinal products by presentation provided they are sold as a product to quit smoking. In the market there are also nicotine containing products which are not regarded as medicinal products but rather "nicotine consumer or leisure products. Such products are not regulated.</p> | Such products are not regulated. There use is not popular among consumers. |
| Czech Republic | These kinds of products are not banned and they are available on the market in CZ (only tobacco for oral use is banned). | <p>Electronic cigarettes are not regulated explicitly as regards status of product : If presented as a product for tobacco cessation treatment - considered as pharmaceuticals in combination with medical device (however, no registrated electronic cigarette in this regard so far). If this function not presented - general product safety law applies.</p> <p>There is a definition in Act no. 379/2005 Coll. on measures for protection against the harmful effects of tobacco products, alcohol and other addictive substances and on the amendment of related laws, as subsequently amended. According to this act sale of electronic cigarettes to minors (less than 18 yrs old) is prohibited. (since July 2010).</p> | Herbal products are not regulated as regards status of the product etc. However, they are taxed as other tobacco products (Act No. 353/2003 Coll., on Excise Duties, as subsequently amended) |
| Denmark | <p>Covered by Law on Tobacco Products.</p> <p>https://www.retsinformation.dk/Forms/R0710.aspx?id=121336 and</p> <p>https://www.retsinformation.dk/Forms/R0710.aspx?id=135884</p> | With nicotine regulated as pharmaceuticals due to the pharmacological function of the nicotine. | <p>Not regulated by Law on Tobacco Products but herbal cigarettes are like tobacco cigarettes covered by Law on smoke-free environment.</p> <p>https://www.retsinformation.dk/Forms/R0710.aspx?id=11388</p> |
| Estonia | | Electronic cigarettes are regarded as pharmaceuticals if with nicotine. | Herbal cigarettes are not classified as pharmaceuticals. They are taxed like other tobacco products. |
| Finland | Chewing and nasal tobacco are regulated as the other tobacco products by Tobacco Act. | <p>Treated as pharmaceutical products but with problems. Nicotine cartridges are classified as medicinal products by function.</p> <p>Possible ban coming on all nicotine products other than medicine and pesticides.</p> <p>The Finnish Medicines Agency (Fimea) is the national competent authority for regulating pharmaceuticals. Fimea considers nicotine cartridges as medicine. Furthermore, it has been equated with a prescription drug (Fimea's statement given to the Customs laboratory on 27 September 2010). The plastic device or transformer or the nicotine-free cartridge are not considered medicine.</p> | Not regulated in Tobacco Act. However, advertising of tobacco imitations is banned. |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|---------|--|--|---|
| | | <p>The product cannot be sold in Finland without license.</p> <p>Fimea has specified its opinion for the classification on 23 November 2010. It still classifies the nicotine cartridge and nicotine solutions as a medicine irrespective of the concentration. However if the amount of the nicotine exceeds 0,42 grams in the whole product or 10 mg in one portion (cartridge) it must be considered as a prescription drug. If the nicotine content is lower than this, prescription is not needed.</p> <p>There has been at least one case in Vantaa district court (16.2.2011), where a man was freed from medicine offence charges because the court thought that the portions were small and therefore did not need a prescription. Tobacco Act bans advertising of tobacco, tobacco products, substitute tobacco, tobacco imitations (like e-cigarettes) and smoking accessories.</p> | |
| France | <p>The manufacturing, the sale and the distribution of tobacco products for oral use are forbidden with the exception of those which are intended to be smoked or chewed.</p> <p>Nasal tobacco products are authorized</p> | <p>If presented as cessation treatment, whatever the nicotine dosage, the product is regarded as a medicinal product.</p> <p>If not presented as cessation treatment, regarded as a medicinal product by function if the quantity of nicotine within the vial is equal or above 10 mg nicotine or if the refill solution has a nicotine concentration equal or above 20 mg/ml.</p> <p>If not medicinal products according to the description above, the General Product Safety Directive applies.</p> <p>French consumer code provides rules of security.</p> | <p>Some plants are regulated upon pharmaceutical monopoly and as such are medicinal products by presentation.</p> <p>Herbal cigarettes presented as tobacco cessation treatment are also medicinal products.</p> <p>Other herbal products are considered as products of general consumption and must answer to the general rules of security defined by the French consumer code.</p> |
| Germany | | <p>Nicotine containing liquids in electronic cigarettes have been qualified as medicinal products (a few special products). Therefore, a marketing authorization according to the German Medicinal Products Act is required prior to any marketing of these products. No marketing authorizations for electronic cigarettes have been granted yet. Without this authorization a marketing would be unlawful. The execution of the German Medicinal Products Act falls within the competencies of the German Federal States. Accordingly, if the Federal States authorities notice an unlawful sale or offering of electronic cigarettes (containing nicotine) they ought to prohibit it.</p> <p>There are currently court proceedings pending regarding the classification of electronic cigarettes as medicinal products.</p> | <p>Taxed as tobacco products. Exception: products containing no tobacco and used exclusively for medical purposes under German drug law are exempt from taxation.</p> |
| Greece | <p>Common Minister Decision 266/2001, art.8.</p> <p>According this decision chewing tobacco is</p> | <p>Prohibited under the new tobacco legislation unless approval by the Ministry of Health.</p> | <p>Prohibited under law 3730/23.12.08, art.2, par.1&2 unless a) they have received approval by the Ministry of Health that they present a reduced health risk compared to conventional tobacco products, or, b) they have</p> |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|---------|---|---|--|
| | banned | <p>Law 3730/23.12.08, art. 2, par. 1 & 2. Art. 2 Regulations for tobacco products 1. From the date of publication of this law, it is forbidden: c) The manufacture, promotion, trading and sale of objects that have the external shape of tobacco products, as well as the electronic cigarette, with the reservation of paragraph 2 of this Article. 2. "From the date of publication of this law, it is forbidden, without previous approval by the MoH: ... i) any accompanying indication on the packaging of tobacco products or any other form of communication, according to which the use of tobacco products presents a reduced health risk and ii) the circulation of products that are intended for the cessation of smoking. The conditions for the granting of such an approval, as well as the relevant procedure, will be determined by a Common Decision by the Minister of Health and the Minister of Development."</p> | <p>received approval by the National Medicines Organization that they can be used as a tool for smoking cessation</p> <p>Law 3730/23.12.08, art. 2, par. 2. Art. 2 Regulations for tobacco products 1. From the date of publication of this law, it is forbidden: c) The manufacture, promotion, trading and sale of objects that have the external shape of tobacco products, as well as the electronic cigarette, with the reservation of paragraph 2 of this Article. 2. "From the date of publication of this law, it is forbidden, without previous approval by the MoH: i) any accompanying indication on the packaging of tobacco products or any other form of communication, according to which the use of tobacco products presents a reduced health risk and ... ii) the circulation of products that are intended for the cessation of smoking. The conditions for the granting of such an approval, as well as the relevant procedure, will be determined by a Common Decision by the Minister of Health and the Minister of Development."</p> |
| Hungary | <p>Authorised Additives regulated in Annex 2 and 4 to Decree 102/2005 (X. 31.) FVM which applies to tobacco products in general, involves chewing tobacco as well (the reference will change with the adoption of the new tobacco products decree, but content remains the same)</p> | <p>Not regulated explicitly, but regarded as medicinal products by function. Interested parties (prospective manufacturers, distributors, their legal representatives, consumer protection organs) receive the following information: nicotine is contained as an active pharmacological ingredient in the European Pharmacopoeia. It has pharmacological action undoubtedly. Some authorized pharmaceutical products contain 1,5 mg nicotine per unit and the pharmacological efficacy has been recognized by the competent authority. Consequently, nicotine containing electronic cigarettes are considered as medicinal products by function.</p> | <p>Not regulated explicitly, they are considered as consumer products as long as they do not fall under the definition of pharmaceutical products by function.</p> <p>Interested parties have been asked to provide the national competent authority with the exact composition to decide whether pharmacological action plays a role in the claimed use. If not, it would not be a medicinal product. Some of these questions remained unanswered. Some products contained medicinal herbs, the prospective applicant could not exclude pharmaceutical action.</p> |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|---------|---|--|--|
| Ireland | The Tobacco (Health Promotion and Protection) Act, 1988 prohibits the importation, manufacture, sale, disposal, offer for sale or other disposal, or advertisement of oral smokeless tobacco (defined as product or substance, made wholly or partly from tobacco, which is intended for use, unlit, by being placed in the mouth and kept there for a period, or by being placed in the mouth and sucked or chewed). | Not regulated. Electronic cigarettes currently on the Irish market are not presented as medicinal products for smoking cessation or as medical devices with therapeutic purpose. If presented as medicine, containing medicinal claims etc. the product would be regulated as medicinal product. However, Ireland has had difficulties in classifying nicotine as a medicinal product (i.e. by function) because there are other products on the market containing nicotine which produce pharmaceutical effect but which are clearly not medicines, eg tobacco products. In addition, nicotine has other uses, such as pesticide. | Not regulated. |
| Italy | | Electronic cigarettes are not regarded as medicinal products in Italy. Decreto legislativo 14 marzo 2003, 65 regulates the labelling of dangerous substances. A decree forbidding the sale of electronic cigarettes to persons aged less than 16 years has been issued. | The herbal cigarettes are under the same legislation as tobacco products except if they are registered as medicinal products. |
| Latvia | All chewing and nasal tobacco products are banned. Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products Section 5. Restrictions on the Manufacture, Sale and Release for Free Circulation of Tobacco Products and Herbal Smoking Products It is prohibited: 1) to sell snuff and chewing tobacco; 7) to sell tobacco products for oral use. | Electronic cigarettes and nicogel - Not specially regulated. Electronic cigarettes follow the rules as for all consumers' products (Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety). Electronic cigarettes follow the Unfair Commercial Practice Prohibition Law. The purpose of this Law is to ensure the protection of the rights and economic interests of the consumers by prohibiting the performers of commercial practices from utilizing unfair business-to-consumer commercial practices. (Consumer Rights Protection Centre has made some administrative decisions about misleading advertising, for instance, electronic cigarettes were advertised as healthier and cheaper products than conventional cigarettes.) Electronic cigarettes are sold in shops and on Internet. Nicogel is sold on Internet or using distance selling possibility (through catalogues), for example, http://www.hansapost.lv/pl/nicogel_sma_aizvietotjs/220303017 Electronic cigarettes are mostly sold as alternative to traditional (conventional) cigarettes. Nicogel is sold as smoking replacement. Latvia does not consider these products as pharmaceuticals. When electronic cigarettes appeared on the market, there was an interest from merchants to sell them as cessation product. | Herbal cigarettes fall under the Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products (amended from 4 March 2010). Herbal smoking products are defined as plants or plant ingredients (for example, industrially produced herbal cigarettes, industrially produced mixtures of plants for rolling up), which are intended for smoking and do not contain tobacco. Each packaging unit of herbal smoking products to be sold in Latvia shall display the following: 1) an indication in the official language of the tar and carbon monoxide yields in milligrams per cigarette; and 2) an attached excise duty stamp. It is prohibited to place on the packaging of herbal smoking products texts, names, trade marks or other signs indicating that the particular product is less harmful than tobacco products. Herbal cigarettes have requirements for smoke-free environments. It is prohibited to sell them to persons who are under 18 years of age. Herbal cigarettes are taxed as tobacco products (law On Excise Duties). No regulations on ingredient rules in place, no need to submit to the Health Inspectorate of Latvia a list of all ingredients. Latvia does not consider herbal cigarettes as pharmaceuticals. |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|-------------|---|--|--|
| Lithuania | Marketing of all forms of tobacco intended for oral use and snuff is prohibited by the Law on Tobacco Control. | No specific legislation, but all imitation products are banned by the Law on Tobacco Control. The ban also covers non-nicotine products: Law on Tobacco Control: Article 18. Other Prohibitions related to Tobacco Products 1. It shall be prohibited in the Republic of Lithuania: 8) to manufacture and/or sell toys, food products and other goods <u>whose design imitates tobacco products or packaging</u> | No specific legislation, but all imitation products are banned by the Law on Tobacco Control. The ban also covers non-nicotine products, including Herbal cigarettes. Law on Tobacco Control: Article 18. Other Prohibitions related to Tobacco Products 1. It shall be prohibited in the Republic of Lithuania: 8) to manufacture and/or sell toys, food products and other goods <u>whose design imitates tobacco products or packaging</u> |
| Luxembourg | | - Considered as tobacco products if they contain tobacco extracts. - Considered as pharmaceuticals by function and/or presentation, if they contain nicotine without containing tobacco extract, and/or if presented as cessation treatment. - Electronic cigarettes not yet regulated specifically (probably they will be considered as pharmaceuticals if they contain nicotine and are used in smoking cessation treatment) | Not regulated. |
| Malta | | With nicotine, regulated under tobacco act – requirements for labelling, no advertising, no cessation claims and smoke-free environments requirements apply | Any product labelled as tobacco or intended to substitute a tobacco product is legally considered as a tobacco product and therefore legislation on advertisements and smoking-free environments apply. Please refer to http://www.doi.gov.mt/EN/legalnotices/2010/01/LN%2022.pdf |
| Netherlands | We have implemented the definition of tobacco products as mentioned in the current directive. Any other products which do not fall under the scope of the Directive are not specifically regulated. | Considered pharmaceutical by function or presentation if it contains nicotine. | Herbal cigarettes without tobacco are not regulated. |
| Poland | All smokless tobacco, with exception of nasal tobacco powder are banned (<i>Art. 7 of the Health Protection Act against the Consequences of Tobacco Use of 9 November 1995</i>) | Electronic cigarettes are not regarded as medicinal products. Advertising of these products is banned. | Not regulated |
| Portugal | Chewing tobacco non-banned by Dir 2001/37 is permitted to be marketed. Although such product are not very popular among the Portuguese population. | According to a Informative Provision by the portuguese National Authority on Medicines and Health Products (INFARMED) electronic cigarettes containing nicotine should be regarded as medicinal products by presentation and/or function. | Not regulated |
| Romania | | Regarded as medicinal products by function. | Not regulated |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|-----------|---|--|--|
| Slovakia | | Regarded as medicinal products by function. Act no. 377/2004 in protecting of non-smokers – total ban on selling and smoking electronic cigarettes in public places such as schools, bus stations, hospitals and cinemas. Smoke-free environments. | Act no. 377/2004 in protecting of non-smokers Restriction on sale and smoke-free environments (applies to all products where the method is smoking). |
| Slovenia | | If presented as cessation treatment, regulated as pharmaceuticals; if not covered by the General Product Safety Directive. | If containing even a small amount of tobacco regulated under Restriction of the use of tobacco products act, otherwise not regulated. Available but not popular |
| Spain | Not banned but there are no products marketed. Regulated under same legislation that tobacco products as smokeless tobacco products. | No specific regulation. Electronic cigarettes have not been considered medicinal products, unless the intended use falls under the definition of medicinal product. The products have been considered recreational consumer products without therapeutic indications. Protection of consumers' interests Directive (1) and General Product Safety Directive applies (2) | No specific regulation, unless the intended use falls under the definition of medicinal product. Protection of consumers' interests Directive and General Product Safety Directive applies. |
| Sweden | <p>The Swedish National Institute of Public Health is the regulatory agency regarding the parts in the Tobacco Act (1993:581) concerning Dir. 2001/37/EG.</p> <p>Chewing, sucking (snus) and sniffing (nasal) tobacco are regulated, as any other tobacco product, by the Tobacco Act (1993:581), according to the definition in article 2 of Dir. 2001/37/EC.</p> <p>The Swedish Food Agency regulates additional requirements as stipulated by the food regulations in e.g. LIVSFS 2012:6 for chewing and sucking tobacco (i.e. snus), but not sniffing (nasal) tobacco, regarding e.g. permitted food additives, flavours, new ingredients, labelling, hygiene, hazard analysis and critical control points, traceability, contaminants, and materials and products in contact with chewing and sucking (i.e. snus) tobacco.</p> <p>The production of chewing and sucking tobacco (i.e. snus) has further to comply with</p> | <p>Products containing purely nicotine are not regulated by the Tobacco Act (1993:581) but are generally classified as medical products since nicotine has a well-known pharmacological effect on the body according to section 1 point 2 of the Medicinal Products Act (1992:859).</p> <p>The Medical Products Agency regulates and classifies nicotine containing products, which do not contain tobacco. The Medical Products Agency classifies the ampoules/filters of “electronic cigarettes”, but not the “cigarette” itself. The classification applies irrespective of the intended use, as stated by the seller. The products need approval as medicinal products and can only be sold at certain premises.</p> | <p>Herbal products are not regulated according to the Tobacco Act (1993:581) but may be taxed as tobacco product according to section 1 e of the Act (1994:1563) on Excise Duties on Tobacco. For example herbal cigarettes (if not solely used for medical purposes), but not herbal non-tobacco “snus”, are taxed as tobacco products. Taxes are regulated and collected by the Swedish Tax Agency.</p> <p>Herbal non-tobacco “snus” for sucking, but not herbal cigarettes for smoking, are regulated according to the Food Act (2006:804), the Food Decree (2006:813) and other food regulations.</p> <p>The general issue of how electronic cigarettes e.g. without nicotine should be interpreted and regulated is currently being investigated by the Government, regarding for example market surveillance responsibility for ensuring safety and other compliance issues.</p> |

| MS | Chewing and nasal tobacco (i.e. non-combustible products not banned by Dir 2001/37) | Nicotine containing products (electronic cigarettes and poss. other products) | Herbal products (herbal cigarettes and other non-tobacco and non-nicotine products) |
|----------------|---|--|--|
| | food regulations section 3 point 2 of the Food Act (2006:804) and the local authority may exercise control and can issue e.g. injunctions according to section 22-23 of the Food Act (2006:804). | | |
| United Kingdom | | Not regulated at present (other than by General Product Safety Directive). Consideration is being given to regulation of all nicotine containing products as medicinal products by function. | Products not regulated but smokefree legislation prohibits smoking of anything in enclosed work and public places (including specified vehicles) |
| Iceland | | Regarded as medicinal products both by presentation and function. | Under tobacco act |
| Norway | Labelling requirements are the same as regulation of oral tobacco products .In other areas chewing and nasal tobacco is regulated as other tobacco products under the Tobacco Control Act (i.e advertising ban, reporting requirements, display ban etc). The Norwegian Directorate of Health is the supervisory authority. | <p>New products with tobacco or nicotine are prohibited Regulations no. 1044 of 13 October 1989 concerning the prohibition against new tobacco and nicotine products</p> <p>Section 2. Prohibition It is prohibited to produce, bring to Norway, sell or hand over to others new types of tobacco and nicotine-containing products. The same applies to tobacco and nicotine-containing products which are intended to be used in other ways than those normally practised in Norway.</p> <p>Section 3. Definitions In these regulations, the term "new types" of tobacco and nicotine-containing products means all products containing tobacco or nicotine, with the exception of the products which, by tradition, are or have been sold in Norway (cigarettes, cigars, cigarillos, smoking tobacco, chewing tobacco and snuff).</p> <p>In these regulations, the expression "intended to be used in other ways" means intake of tobacco and nicotine-containing products to the human body in ways other than the form of smoking, taking snuff and chewing used today.</p> <p>Electronic cigarettes and waterpipe/shisha tobacco are banned under this regulation.</p> <p>There is a limited derogation for private import of electronic cigarettes under medicinal products legislation.</p> | <p>If herbal products contain nicotine and/or tobacco, they are covered by Regulations no. 1044 of 13 October 1989 concerning the prohibition against new tobacco and nicotine products.</p> <p>If they do not, herbal products are not directly covered by the Tobacco Control Act as they do not contain tobacco. However, herbal cigarettes and herbal snus may, in some cases, be covered by the display ban (section 5) as the display ban also covers "imitations of tobacco products". They may also be covered by the ban on indirect advertising.</p> |
| Turkey | | | |

A.3.3.2. Packaging and labelling

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks <i>(including implementation of Article 5.9 of Dir 2001/37/EC)</i> |
|--------------|---|---|--|--|---|--|---|
| Austria | No legislation yet. | No | No | -None | Yes, included in one of the periodically changing warnings – not included in every warning. [The " Rauchertelefon ", a cooperation project of the Austrian Social Security Insurance, the Austrian Provinces and the Austrian Federal Health Ministry, runs a cessation service including quitline, website and fax- and email-service.] Error! Bookmark not defined. | Minimum 20 cigarettes in a pack. The marketing of single cigarettes or unpacked cigarettes is also forbidden. | Art. 5.9 of Dir 2001/37/EC implemented literally ⁴ |
| Belgium | Legislation adopted, pictures already in place | Yes (from April 2007) | No | 42 pictures divided into three sets alternating each year | Yes (mandatory on all packs since 1 January 2011) http://www.sante.belgique.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/17860636_fr.pdf | Belgian MP tabled a proposal for plain tobacco packaging in May 2011 and the Belgian Minister of Health has stated (in the health commission of the parliament) that she will push for the adoption of plain packaging. ⁵ | |

⁴ see § 7 Abs. 1 Tabakgesetz

⁵ <http://www.lachambre.be/kvvcr/showpage.cfm?section=flwb&language=fr&rightmenu=right&cfm=flwbn.cfm?lang=F&legislat=53&dossierID=1424>

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|---|---|--|---|--|---|--|
| Bulgaria (02/07/12) | <p>Work on the introduction of pictorial health warnings is ongoing.</p> <p>Since the end of 2011, as a result of dialog between two deputy ministers and experts – from MoH and Ministry of Economics, Energy and Tourism (MEET), a working group has been set up to amend and supplement the old Ordinance for labeling and packaging of the tobacco products.</p> <p>The draft for the amendment of the Ordinance for requirements for labeling, marking and external appearance of tobacco products is developed and it is in a procedure to be presented to the political cabinet of the</p> | The size of the pictures is 50%. It's difficult to predict the starting date of actual use of the pictorial warnings because the ordinance is not yet adopted and there will be a transitional period after the adoption. | The size is 50%. It's difficult to predict the starting date of actual use of the pictorial warnings because the ordinance is not yet adopted and there will be a transitional period after the adoption | Generally all the 42 pictures are used but they are divided on three groups and if they will be adopted, they will be rotated every 8 months. The period when two groups may meet each other is 4 months. | <p>If adopted, one of the combined health warnings will contain reference to a National tobacco smoking telephone quit line 0700 10 323. In addition, on all the packages will be printed the National tobacco smoking telephone quit line 0700 10 323 and the web page www.aznepusha.bg of the National Tobacco Control Program printed on one side.</p> <p>[The website www.aznepusha.bg provides lists of free-of- charge and paying cessation services.</p> <p>Free of charge services have been run by the MoH since 2005 in the regional Health Inspections of the 28 administrative districts in Bulgaria.</p> <p>The costs of the services (private, in hospitals etc.) where the clients pay depend</p> | <p>If the warnings are changed, we will require that each packet of cigarettes has written: "The Ministry of Health warns that in 1 cigarette there is (information on tar, nicotine and CO yields).</p> <p>The internal labelling of the packages would also be banned.</p> | <p>Article 5.9 of Directive 2001/37/EC has been transposed by:</p> <p>1) the Law of Tobacco and Tobacco Products, art. 30, paragraphs 2, points 7 & 8: Art. 30 (2) The selling of tobacco products shall be prohibited: (...) 7. (amend. SG 110/96) without pointed out on the packing obligatory elements for informing of the consumers in Bulgarian language and the coding of the tobacco products of the Bulgarian and the foreign producer; 8 (new – SG 110/96) without stuck excise band;</p> <p>2). the Ordinance for requirements for labeling, marking and external appearance of tobacco products and on defining standards for evaluation of the compliance with the yield of harmful ingredients in cigarettes, art. 8, paragraph 1: Article 8</p> |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|--------------|---|---|--|--|--|--|--|
| | <p>MoH for approval.</p> <p>The approved draft will be presented at the Council of Ministers for adoption. After the adoption of the Ordinance the combined health warnings on the packages of tobacco products will be used after a transitional period, mentioned in the ordinance.</p> <p>See the draft for amendments in the Law for Tobacco and Tobacco products in a favour of the draft of the Ordinance: http://www.parliament.bg/bg/bills/ID/13838/.</p> | | | | <p>on the methods of the services and are between 10-20 levs to 300-400 levs.]</p> | | <p>1. The unit packet of the tobacco product shall be marked in any appropriate manner (by batch numbering or equivalent) to ensure the identification of the place and time of manufacture of the product and its traceability.</p> |
| Cyprus | No | No | No | No | No | Warnings according to Directive 2001/37/EC. No plans of plain package. | Use of coding by tobacco industries. Such coding is available to the competent authority on demand |
| Czech | No legislation | No | No | | No. | Minimum of 20 cigarettes per | Article 5 (9) of the Directive |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products <i>e.g. RYO, cigar, cigarillos, pipe, water pipe (please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|---|--|---|--|---|---|---|
| Republic | | | | | [Quit line is run by Czech Coalition against Tobacco since 2005, e.g. websites of the Society for tobacco dependence treatment (Společnost pro léčbu závislosti na tabáku) where to find among others addresses of centers for tobacco dependence treatment (www.slzt.cz) | pack. | 2001/37/EC is transposed into art. 7 (5) of the Decree No 344/2003 Coll., on requirements on tobacco products. ⁶ |
| Denmark | Legislation adopted https://www.retsinformat ion.dk/Forms/R0710.aspx?id=135884 and https://www.retsinformat ion.dk/Forms/R0710.aspx?id=137083 | Yes (from February 2012) | Yes (from August 2012) | 14 warnings | Yes- the helpline appears on one of the 14 rotating health warnings for cigarette packages. However, no mandatory display of quitline details on cigarette packaging or packaging for other tobacco products. | Cigarette packages with less than 20 cigarettes are prohibited. | Currently no regulation regarding tracking and tracing. According to agreements between Denmark and leading producers of tobacco such regulations will be adopted if production of relevant products should occur in Denmark. |
| Estonia | | | | | It is not mandatory for a quitline number to be displayed on packaging or labelling. | Minimum 20 cigarettes in a pack. | |

⁶ The Czech wording of the decree in this regard is: „U tabákových výrobků se na obalech určených spotřebiteli uvede vhodným způsobem číslo šarže nebo rovnocenný údaj, který umožní určit místo a dobu výroby tak, aby byla umožněna jasná identifikace a sledovatelnost tabákového výrobku“.

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products <i>e.g. RYO, cigar, cigarillos, pipe, water pipe (please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|----------------------|--|--|---|--|---|--|---|
| Finland | Plans but no concrete date yet | No | No | No | It is not mandatory for quitline numbers to appear on packaging or labelling. However, there is web address, through which quitline number can be found. | Is exploring the possibility to introduce plain packaging. Cigarettes may only be sold in packets with a minimum of 20 cigarettes. ⁷ | Tobacco Act requires that manufacturers or importers of tobacco products must label the unit packets and there must be information necessary to identify and trace the product. |
| France (13 Jun 2012) | Legislation adopted the 15th of April of 2010. | Yes (from 20 April 2011) | Yes (from 20 April 2012) | 14 pictures selected on the basis of focus group testing | Yes, the quitline is indicated on each warning. This is mandatory for cigarette packages but not for packages of other tobacco products. [Quitline "Tabac info service" run by Inpes (Institut national de prevention et education pour la santé) : Phoneline (0.15 €/min, from 8 am-20 pm, 6 days/7) + website : http://www.tabac-info-service.fr] | Promotional elements on the packaging have been regarded as part of the advertising ban and thus not permissible. In France, a legislative proposal on plain packaging was presented to the National Assembly in December 2010 but failed in the Assembly. ⁸ A new proposal was been submitted in February 2012. ⁹ The list of ingredients (tobacco %, paper %, flavour, texture and conserving agents %) are also indicated on the packaging. | The following shall be indicated in an apparent manner on each unit of packaging of manufactured tobacco for detailed trade. The lot number or an equivalent permitting the identification of the place and date of manufacturing. |

⁷ Section 7.1; Tobacco Act.

⁸ <http://www.assemblee-nationale.fr/13/propositions/pion3005.asp>

⁹ Yves Bur. Propositions pour une nouvelle politique de lutte contre le tabac. Rapport au Ministre du Travail, de l'Emploi et de la Sante. Paris: 2012.

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products <i>e.g. RYO, cigar, cigarillos, pipe, water pipe (please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|--|--|---|--|---|---|--|
| | | | | | | Minimum 20 cigarettes in a pack. If more than 20 must be divisible by 5. Fine cut tobacco for smoking: at least 30g by pack. | |
| Germany | | | | | Yes the quitline is one of the rotating health warnings. [The federal center of health promotion is running a quitline and an internet-based cessation programm for adults www.rauchfrei-info.de/ and a special one for young people www.rauch-frei.info . There are also cessation services on the local level which can be found under www.anbieter-raucherberatung.de] | Minimum 19 cigarettes in a packet. Minimum 30 gram fine-cut tobacco in a packet. There is a ban on selling single cigarettes. | Concerning Tracking and Tracing reference to Article 7 of the draft protocol to eliminate illicit trade in tobacco products (FCTC/COP/4/5) and the agreements between the EU, the member states and Philip Morris, British-American Tobacco, Imperial Tobacco and Japan International Tobacco. |
| Greece | No | No | No | No | | Law: forbids packs with less than 20 cigarettes. ¹⁰ | |
| Hungary | The newly amended Act XLII of 1999 on the | Yes, from 1 st January 2013. ¹¹ | Yes, cigar, cigarillo, pipe | 42 pictures of the Commission | Yes Two of the warnings (6 | Not yet | The following should be marked in this regard on the |

¹⁰. There is a ban on selling single or unwrapped cigarettes There are no plans for standardised packaging. The Greek Government is against standardised packaging as this lead towards a “Commoditisation” of tobacco products to an increase in counterfeit and will violate international treaties (such as the TRIP’s agreement, Paris Convention for the protection of Industrial Property).

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|--------------|--|---|--|--|--|--|---|
| | Protection of Non-smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products introduces pictorial health warnings, referring to a future Government Decree establishing the detailed rules of their application and containing the pictorials themselves. The referred Government Decree is in course of preparation. | | tobacco, and tobacco in other processed form, any other tobacco-based products intended for smoking | library. The manufacturer can choose between them, but should respect the rules on rotation regular appearance on every main side should be guaranteed | pictorials) contain information on cessation, giving the phone number and website address of the quitline. [A quitline has been run by the National Health Promotion Institute since 2005.] | For cigarettes; packages containing minimum 19 cigarettes and maximum 50 cigarettes. For cigars and cigarillos, they may be sold by the piece or in packs of minimum 5 pieces. | packaging of tobacco products: Date of production (year, month, day) and the place of production or a batch numbering or coded identification enabling the place and time of manufacture to be determined. |
| Ireland | Legislation adopted 16 December 2011. ¹² | Yes | Yes | 14 pics selected on the basis of focus group testing | Quitline included in 1 pictorial warning. [Operated by the Health Service Executive (HSE) throughout the country.] | Minimum 20 cigarettes in a pack. | |
| Italy | Evaluation after the revision of the Tobacco | | | | It is not mandatory to display quitlines on packaging or | Cigarettes may only be sold in packs of 10 or 20 pieces. | The Italian law, to fight against smuggling provides that |

¹¹ Cigarette products that do not meet the new requirements of the Modifying Act shall a) from the first day of the 8th month following the entry into force of the detailed legislation on pictorials, not be manufactured and they shall not be put into free circulation and b) from the first day of the twelfth month after the same date they shall not be put into circulation or handed over to end consumers.

¹² The regulations shall apply to all tobacco packages placed on the market on or after 1 Feb 2013. To allow for the “wash through” of older stock or slow moving stock, tobacco packages placed on the market before 1 Feb 2013 have an additional year on the market i.e. 1st February 2014.

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|--------------|---|---|--|--|--|--|--|
| | Products Directive 2001/37/EC | | | | labelling. [According to a survey conducted by National Institute of Health (ISS) December 2011, there are 396 Anti-smoking Centres in Italy, of which 303 are affiliated with the Italian national health service and 93 with the Italian anti-cancer league (LILT). The ISS provides consultancies, support, and information on problems related to smoking through the anti-smoking toll-free number 800 554088 (http://www.iss.it/tele/cont.php?id=49&lang=1&tipo=35) affiliated with the national observatory on smoking, alcohol, and drugs of the national Institute of Health. The LILT operates the toll-free number 800 998877 (http://www.legatumori.it/sos_lil_t.php?area=995) a Quit-Line service provided by | Fine cut tobacco for the rolling of cigarettes cannot be sold in less than 10g. packages. “No plans on standardized or plain packaging because of possible negative effects on the contrast of smuggling and counterfeiting. On this theme we consider more effective the possibility to introduce limitations on the use of wording and graphical elements on packages that can be increase tobacco products consumption” | cigarettes manufacturers shall adopt a system of identification on pack to identify the date, place and machinery of production and the first buyer. |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks <i>(including implementation of Article 5.9 of Dir 2001/37/EC)</i> |
|--------------|--|---|--|---|---|---|--|
| | | | | | professional physicians and psychologists affiliated with the LILT, and which aims to help smokers who are unable to physically attend one of the quit-smoking support programmes offered by local health districts.] | | |
| Latvia | Legislation adopted, pictures already in place Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products Section 6. Design of the Packaging of Tobacco Products <u>Cabinet Regulation No. 868 (Adopted 21 October 2008) Regarding Addition of Colour Photographs or Illustrations to Tobacco Packaging Units</u> | Yes (from 1 June 2010) | Yes (from 1 June 2010) | 14 pictures (same as those in the UK) | Quitline included in 1 pictorial warning | No plans or legislation concerning plain packaging yet. Discussions were only in the Ministry of Health. Taking into account that pictorial warning appeared in Latvia only in June 2010, the Ministry of Health supports bigger pictorial warning on both sides of the package as the next step in order to reduce the consumption of tobacco products. ¹³ The sale of single tobacco products and herbal smoking products, with the exception of cigars and cigarillos, is banned. | Article 5.9 of Directive 2001/37/EC is implemented in the Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products stating that - In order to ensure tobacco product identification and traceability, the tobacco products shall be marked with a batch number or equivalent marking on each packaging unit, so that the place and time of manufacture may be determined. ¹⁴ |

¹³Health sector NGOs support the plain packaging, but representatives from tobacco industry and Latvian Traders Association do not support the idea of implementation of the plain packaging.

¹⁴In reality it is a number printed using deep print machine. The number is located on the bottom of vertically oriented package.

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|--|--|---|---|--|---|---|
| Lithuania | No concrete plans yet | | | | It is not mandatory to display a quitline on packaging or labelling. | In March 2010, a Draft Law Amending the Law on Tobacco Control was considered in the <i>Seimas</i> of the Republic of Lithuania ¹⁵ However, this proposal was not approved by the <i>Seimas</i> since provisions like this appear to be contradictory to the Constitution of the Republic of Lithuania. It is prohibited to sell cigarettes in packs of less than 20. Lithuania bans the sale of single cigarettes, cigarillos and long cigarettes | Provisions of Article 5.9 of Directive 2001/37/EC have been transposed to Article 8 of the Law on Tobacco Control ¹⁶ |
| Luxembourg | No (but 16 health warnings) | No pictures. Size of health warnings regulated. | No. | | Not included in health warnings. [Programme de sevrage du Ministère de la Santé, fonctionnant avec un réseau de | Sale limited to packs of minimum 20 pieces. | Yes (RGD du 10 septembre 2003: Article 4, paragraphe (7): "Afin d'assurer l'identification et la traçabilité des produits, le numéro du lot ou un équivalent est indiqué sur l'unité de |

¹⁵ the Draft Law proposed to establish that tobacco products for sale in the Republic of Lithuania must be packed in a standard white packaging and all the information must appear on the packaging in a single font, except the information relating to the harm caused by smoking.

¹⁶ „Article 8. Labelling Requirements of Tobacco Products Intended for Marketing in Republic of Lithuania

To ensure product identification and traceability, the tobacco product shall be marked by batch numbering or equivalent on the unit packet (packaging) enabling the place and time of manufacture to be determined. Where the batch number or equivalent are encoded, which makes it impossible to determine the place and/or time of manufacture of tobacco products, the undertakings manufacturing, importing or bringing in tobacco products to Lithuania must provide controlling institutions with a code key for subsequent decryption.“

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|--|--|---|---|--|---|---|
| | | | | | médecins offrant des consultations en tabacologie : cure de 8 mois, 1 ^{ière} et dernière consultation gratuites, produits de substitution nicotinique remboursés à concurrence 100€. Tabac-Stop : ligne téléphonique, d'information, d'aide et de soutien de la Fondation Cancer. Projet e-Coach : Website d'aide au sevrage par internet, organisé par la CE.] | | conditionnement sous toute forme appropriée permettant d'identifier le lieu et le moment de la fabrication".) (Directive 2001/37/EC) |
| Malta | Legislation has been adopted; this is the Use of Colour Photographs or Other Illustrations as Health Warnings on Tobacco Packages Regulations, | Yes (from 27 April 2011) | Yes (from 27 October 2011) | 14 warnings | No | | |
| Netherlands | No plans. | | | | It is mandatory to display a quitline on packaging. | Minimum of 19 cigarettes per pack. | |
| Poland | The project of the regulation introducing the pictorials is waiting for the signature. According to the project | The sizes of the warnings reflect Art. 5.5 of Directive | The pictorial warnings will be applied to all smoked tobacco | 14 combined additional warnings selected from the library approved by the | Only one warning contains the tel. number of quit line of the Cancer Institute in Warsaw. [Different units on central, | Minimum 20 cigarettes per pack; Plain packaging is not planned at present. | On tobacco product packet there are placed: name and address of manufacturer, date of produce and/or serial |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|--|--|---|---|--|---|---|
| | pictorials will appear on the packages 1 March 2013 | 2001/37/EC | | EC according to Commission Decision on 5 Sept. 2003 and 12 Apr. 2006. | regional and rural level exist. Therapeutic units are led by the public and non-public institutions, clinics, NGOs etc.] | | number. |
| Portugal | Not adopted | Not adopted | Not adopted | Not adopted | <p>It is not mandatory to display a quitline on packaging or labelling.</p> <p>[The National Health Service offers a few Smoking cessation consultations at hospitals – specialty in Respiratory diseases services.</p> <p>In December 2007 the General Directorate of Health approved a National Programme to normalize the smoking cessation services offered by the Portuguese NHS.</p> <p>The new Tobacco Act (Lei 37/2007 of 14th August – article 31.º - established the obligation of creating specially consultations dedicated to the intensive support of smokers, in all primary care health canters and some hospitals.</p> | Minimum 20 cigarettes in a pack. | <p>Provisions of Article 5.9 of Directive 2001/37/EC have been literally transposed to Article 11, nº 11 of the Law on Tobacco Control Lei 37/2007 of 14th August.</p> <p>All the tobacco products sold in Portugal must have an official fiscal stamp, annually approved by law by the Ministry of Finance. There is also an obligation for the electronic reporting of importers and manufacturers use of these stamps in each fiscal year. This process is under the control of the national Authority for Customs and Excise Duties.</p> |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products <i>e.g. RYO, cigar, cigarillos, pipe, water pipe (please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] <i>*All MS have cessation services in some form (e.g. website, quitline).</i> | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|--|--|---|--|--|---|--|
| | | | | | Nowadays there are available about 200 of these consultations throughout the country. Additionally Family Physicians (GPs) can help smokers using brief interventions in the context of family practice.] | | |
| Romania | Legislation adopted, pictures already in place | Yes (from 1 July 2008) | Yes (from 1 July 2009) | 14 warnings selected on the basis of public consultation | No | Minimum 20 cigarettes in a pack. | |
| Slovakia | | | | | It is not mandatory to display a quitline on the packaging or labelling. | | |
| Slovenia | Plans but no concrete date yet | | | | Yes (mandatory on all cigarette packs since 5. August 2007) Not mandatory on packaging for other tobacco products. | Under Restriction of the use of tobacco products Act it shall be prohibited to sell single cigarettes and other tobacco products outside the manufacturer's original packaging | The batch numbering or equivalent must be indicated on the packaging of a tobacco product to allow the place and date of manufacture to be determined. |
| Spain | Legislation adopted on 14 May 2010. | Yes (from 26 May) 2011 | Yes (from 26 May) 2012) | 14 warnings | No | Under the Spanish legislation, 2 other labelling requirements are mandatory: 1) "Las autoridades sanitarias | The article 5.9 has been literally transposed. Under the regulation of the market control the products must be identified by specific documents along |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|--------------|---|---|--|---|---|---|---|
| | | | | | | <p>advertieren.”, placed in both sides over the main warnings with specific requirements</p> <p>2)“PROHIBIDA LA VENTA A MENORES DE 18 AÑOS”, 13% on one side with specific requirements.</p> <p>Plain packaging is under consultation.</p> <p>Minimum pack size of 20 cig.</p> | <p>the distribution chain. An annual report should be submitted by manufacturers, importers, distributors and retail shops to the competent authorities, including identification of the products and quantity of each one.</p> |
| Sweden | Sweden does not require the additional warnings in the form of colour photographs or other illustrations, as described in article 5.3 of Dir. 2001/37/EG. | No | No | No | <p>The quit-line’s name and telephone number is included in accordance with Dir. 2001/37/EC in one of the additional health warnings (Annex I – health warning number 10). Get help to stop smoking: (telephone/postal address/internet address/consult your doctor/pharmacist)</p> <p>This is regulated by the Swedish National Institute of Public Health regulation; FHIFS 2002:4</p> <p>Sök hjälp för att sluta röka: fråga din läkare, på apotek eller</p> | <p>Legal requirement does exist in section 12 b of the Tobacco Act (1993:581) with regards to pack size i.e. at least 19 cigarettes in each pack and cigarettes are not allowed to be sold loose.</p> <p>Other tobacco products than cigarettes are not regulated with regard to pack size.</p> <p>Legal requirements exists with regards to pack shape according to article 5.7 of Dir. 2001/37/EG and the Swedish National Institute of Public Health regulation FHIFS 2001:2</p> | <p>The possibility to require all tobacco products to be provided with information to secure the identification of the place and time of production is adopted in section 9.3 of the Tobacco Act.</p> <p>Nevertheless, the implementation of article 5.9 in Dir.2001/37/EG awaits further regulation from the Regulatory Committee and the European Commission.</p> <p>However, tracking and tracing, with regards to sucking and chewing tobacco, is regulated according to LIVSFS 2012:6.</p> |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|----------------|---|---|--|--|---|---|---|
| | | | | | <p>Sluta röka-linjen 020-840000.</p> <p>[The quit-line "SLUTA-RÖKA-LINJEN" on 020- 84 00 00 and www.slutarokalinjen.org is a national, cost free helpline, which started initially as a voluntary project in 1998. From 2002 onwards the quit-line receives a 5 million SEK governmental grant (subsidy) for the activity. The quit-line is run by the County Council of Stockholm and receive yearly about 10 000 calls, mainly from smokers and users of sucking tobacco (i.e. snus).]</p> | <p>The Swedish National Institute of Public Health is regulatory agency regarding pack size and shape.</p> <p>Legal requirements exist with regards to marketing in section 14 of the Tobacco Act. The law only gives a few exceptions to the general ban on advertising.</p> <p>According to practice, it is not possible to have advertising on the package, in an onsert, insert etc.</p> <p>The Swedish Consumer agency is regulatory agency regarding marketing etc.</p> <p>Sweden does, nevertheless, take a negative view of the concept of "plain packaging" due to the interest of trademark protection; of property protection pursuant to the European Convention on Human Rights; of observance of other international obligations such as those of the TRIPS agreement; of combating traffic on counterfeit and contraband products etc.</p> | |
| United Kingdom | Legislation adopted, pictures already in place. Regulations made on 23 August | Yes, came into force on 1 October 2008. | Yes, came into force on 1 October 2008 | 14 warnings selected on the basis of public | Not all of them but one warning does include quitline number | In the Tobacco Control Plan for England (March 2011), the Government undertook to consult on options to reduce | The Schedule to the Tobacco Products Regulations 2001 requires manufacturers to be able to provide information on |

| Member State | Pictorial warnings: state of implementation <i>(please include info (e.g. name, date) and weblinks to relevant legislation)</i> | Pictures on cigarettes + required size of the warning <i>(please specify, e.g. starting date of actual use of pictures)</i> | Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe <i>(please indicate which products and specify, including starting date of actual use)</i> | Pictures used <i>(how many? rotation, please specify)</i> | Are cessation services* included in warnings? <i>(please specify)</i> [Further details on cessation services.] *All MS have cessation services in some form (e.g. website, quitline). | Other packaging or labelling requirements <i>(including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.)</i> Legislation/Plan <i>(please specify)</i> | Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC) |
|---------------------|--|--|---|---|--|--|---|
| | 2007. | | | consultation | | the promotional impact of tobacco packaging, including plain packaging. The consultation. was published on 16 April 2012. ¹⁷ Minimum pack size of 10 cigarettes. | seized products, incl the date & place of manufacture, destination, customer and invoice details. Packets manufactured in UK bear batch codes which enable place & time of manufacture to be established. |
| Norway | Legislation adopted Regulations no. 141 of 6 February 2003 on the contents and labelling of tobacco products | Yes (from June 2011) Text warning covers 30 % of front Pictorial warning covers 40% of back | Yes (from January 2012) | 14 warnings | Yes. It is mandatory for all tobacco products. [National quitline since 1996 and website since 2010. Run by the Norwegian Directorate of Health. Personell:4.5] | Norway is exploring the possibility to introduce plain packaging. ¹⁸ | Packets manufactured in Norway bear batch codes which enable place & time of manufacture to be established, see Regulations no. 141 of 6 February 2003 on the contents and labelling of tobacco products, section 16. |

¹⁷ http://consultations.dh.gov.uk/tobacco/standardised-packaging-of-tobacco-products/consult_view

¹⁸ Report through the Regulatory Committee in June 2011

A.3.3.3. Ingredients

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|--------------|---|-------------------|---|--|
| Austria | Yes | Electronic | Yes, mandatory since 2010 | No To protect consumers from preventable damage caused to their health If necessary, the Federal Minister of Health has to release a regulation on ingredients including positive and/or negative lists. (Art. 3 Tobacco Act) |
| Belgium | Yes, mandatory by decree http://www.sante.belgique.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/19071574_fr.pdf | both | Yes, on voluntary basis | Positive list. The list is valid for all ingredients used for the product including the filter or other parts. Arrêté royal du 13 août 1990 relatif à la fabrication et à la mise dans le commerce de produits à base de tabac et de produits similaires, Annex 1 over five pages detailed list http://www.sante.belgique.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/19071570_fr.pdf Also in Belgium 3 ingredients ('E418 gomme gellane, E133 « bleu brillant FCF », Medium Chain Triglycerides (MCT)) needed to include the “menthol capsules” in cigarettes were recently banned. Basically, it was proposed not to accept them because of the increase of the attractiveness of the product. The intern debate was more on the capsule. But the public debate was also on the fact that one of the three product could change the colour of the smoke (that could increase attractiveness). |
| Bulgaria | No | Both | We plan to use EMTOC obligatory by project of Law for amendment and supplementing the Law for Tobacco and Tobacco Products which is in the Parliament now. We are expecting to be adopted. See: http://www.parliam | The legislation regulates the kind of ingredients, their toxicity and the addictiveness by the Law for Tobacco and Tobacco Products. At this time we use informally both a positive and a negative list for ingredients. There is an opportunity to find a consensus to be preferred the positive list. The main argument is: the scientists has enough knowledge and experience to know which components/ingredients are obligatory for one tobacco product, including the filter, the liquid for printing on the tobacco products and so on. That's enough to elaborate a positive list. It will be one time effort. If we will choose a negative list then we have to have a working group which uninterruptedly has to change it because of the creativeness of the tobacco industry. |

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|----------------|---|-------------------|--|---|
| | | | ent.bg/bg/bills/ID/13838/ . | |
| Czech Republic | No Nevertheless there is some recommended structure of it. It was proposed a 3 list format for reporting ingredient information. This 3 list format comprises: List 1 – Composite list of ingredients added to tobacco, List 2 – Composite list of non-tobacco ingredients and List 3 – Brand lists of ingredients added to tobacco in each brand. | Both | Not planned | Positive and negative list Decree No 344/2003 Coll., on requirements on tobacco products http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=344/2003&typeLaw=zakon&what=Cislo_zakona_smlouvy 17 pages positive list, 1,5 page negative list The usage of ingredients and flavours being put in the filter and other paraphernalia of tobacco products is regulated in CZ. The positive list of ingredients in the annex of the Decree No 344/2003 Coll., on requirements on tobacco products, is divided into sections. One section contains ingredients which are allowed when manufacturing tobacco products directly for the filters and also other sections concern other parts of tobacco products (not only the tobacco mixture). |
| Cyprus | Yes Common reporting formats according to the practical Guide of Reporting on Tobacco Product Ingredients of 31/5/2007 SANCO C6 TPE/ub D(2007) 360206 | Both | No | No positive or negative list flavours are also not regulated |
| Denmark | No, but EMTOC recommended as of 2012. | Both | Start voluntary use of EMTOC as of Jan 2012 | No |
| Estonia | Voluntary | Both | No, but discussions ongoing | No |
| Finland | No | Both | No, but follow the process | List of ingredients that tobacco can contain, but it is very broad and has not been interpreted as a positive list http://www.finlex.fi/en/laki/kaannokset/2002/en20020641?search%5Btype%5D=pika&search%5Bpika%5D=tobacco Decree on Measures to Reduce Tobacco Smoking 225/1977 CHAPTER 2 Composition Section 2 The following may be used in tobacco products and in their manufacture: |

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|-------------------|---|--------------------------------|---|--|
| | | | | <p>1) tobacco; 2) tobacco substitutes originating from other plants not dangerous or harmful to health; 3) sugars, honey and cocoa; 4) tobacco leaves for wrapping, ground tobacco and paper or man-made films manufactured from other plant fibres; and 5) spices and odorants, other additives and glues and colours which are not dangerous or harmful to health.</p> |
| France (13/06/12) | <p>Yes (ministerial order (arrêté) of the first of December 2011 : http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025596638)</p> | Electronic | Not yet, but intend to make it compulsory | <p>Positive list of ingredients classified by categories ministerial order (Arrêté) of the 12th of September 1995</p> <p>Code de la Santé Publique : Article L3511-2 Modifié par <u>LOI n°2009-879 du 21 juillet 2009 - art. 98 (V)</u></p> <p>The sale, the distribution or the offer for free of flavoured cigarettes which content in ingredients giving a sweet or acidulated flavour exceeds thresholds fixed by decree are forbidden</p> <p>Article D3511-16 Créé par <u>Décret n°2009-1764 du 30 décembre 2009 - art. 1</u> The maximal content of ingredients giving a flavour sweet or acidulated to flavoured cigarettes, mentioned at <u>article L. 3511-2</u>, is defined as follow : 1° Vanilline : 0, 05 % of tobacco mass ; 2° Ethylvanilline : 0, 05 % of tobacco mass ; 3° Sweetener applied to the cuff of the cigarette: threshold of analytical detection.</p> <p>http://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006688201&dateTexte=&categorieLien=cid</p> |
| Germany | Not mandatory, but 95% uses | Both, but 95 % uses electronic | Voluntary since 2010. 30% uses EMTOC, others use free electronic data submission via national network or mail | <p>Positive and negative list</p> <p>Positive list: http://bundesrecht.juris.de/tabv_1977/anlage_1_14.html Negative list: http://bundesrecht.juris.de/tabv_1977/anlage_2_15.html http://bundesrecht.juris.de/tabv_1977/index.html</p> <p>Over 10 pages positive list and 1 page negative list Ingredients in filter and other paraphernalia like paper are regulated.</p> |

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|--------------|---|------------------------------------|-------------------------------|--|
| Greece | Voluntary | Both | No | No |
| Hungary | No | Both | Plan to start using | Positive and negative list of additives for tobacco products, including filters and other paraphernalia. Tobacco leaf is not part of the definition of "ingredient". |
| Ireland | No | Both | No | No |
| Italy | Yes | Both | No | No |
| Latvia | Yes Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products Section 7. | Both, but majority uses electronic | No, but discussions ongoing | No |
| Lithuania | Yes Republic Of Lithuania Law On Tobacco Control Article 9. Reports of Tobacco Product Manufacturers and/or Importers on the Ingredients of Tobacco Products Manufactured for Marketing in the Republic of Lithuania http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=389583 | Both | No, but intend to start using | Negative list of ingredients. Republic Of Lithuania Law On Tobacco Control Article 4. General Ingredient and Quality Requirements for Tobacco Products 4. The Government of the Republic of Lithuania or an institution authorised by it, acting in conformity with research-based evidence, shall have the right to prohibit the use of ingredients which have the effect of increasing the addictive properties of tobacco products. Order of the Minister of Health Care of the Republic of Lithuania On the Approval of the Lithuanian Hygiene Norm HN38:2009 "Maximum amounts of noxious substances permitted in tobacco products", 11 September 2009, no. V-736 lists maximum levels of substances in tobacco products and substances prohibited for use during the manufacturing tobacco products or mixtures with tobacco.(23 restricted and 27 prohibited substances listed) The following additives are forbidden: Agaric Acid, Birch Tar Oil, Tansy Herb, Yellow Melilot, Juniper Tar Oil, Camphor, Camphor Oil, Camphorwood, Bitter Almond Oil, Woody Nightshade Stems, Areca Nut Palm, Coumarin, Vanilla plant, Sweet Woodruff, Cloves, Soap Bark, Quassia Wood, Rue Herb, Indian Tobacco, Safrole, Oil of Sassafras, Sassafras Leaves, Sassafras Wood, Sassafras Root Bark, Polypody Rootstock, Pennyroyal herb, Tonka Beans and Thujone. |
| Luxembourg | No but reporting is compulsory (Article 4 de la loi du 11 août 2006; Article 5 du RGD du 16 septembre 2003) | Not specified. | No | Depending on implementing regulation. |

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|--------------|---|---|--|--|
| Malta | No, but recommended | Both | Start voluntary use of EMTOC as of January 2012 | No |
| Netherlands | Yes Regeling aanmelding en publicatie tabaksingrediënten 2007 | Only electronic | Voluntary, may become compulsory later | No |
| Poland | No. There is some recommended structure of report: list of ingredients by brands which needs name of the substance, the aim of use, quantity (dose), toxicological dates. | Mostly electronic (paper reports are accepted as well) | In 2011 we introduced EMTOC as voluntary, recommended system | No. Only ingredients which may increase the addictive properties of tobacco products are prohibited. (Art. 7a of the Health Protection Act against the Consequences of Tobacco Use) |
| Portugal | No, but its use is promoted. Almost 100% of tobacco companies or importers use the harmonised formats. | Both | No | No |
| Romania | Yes, since 2009 | No | No, but start using in 2012 (compulsory) | Positive list – a list with the ingredients allowed for all tobacco products, classified by categories |
| Slovakia | No | Both | No, but plan to start using it | Positive and negative list By Regulation of Ministry of Agriculture of the Slovak Republic and Ministry of Health of the Slovak Republic on 21th of October 2004 no. 2606/2004 on tobacco products. Almost 50 pages listed ingredients |
| Slovenia | Not obligatory, recommended | Both | No | No |
| Spain | Obligatory | Both, but very few use it by paper. | No | Spanish Food Code, where some general indications on ingredients that are or are not permitted in tobacco products are given. Spanish Food Code, Chapter XXV Section 8 Ingredients: 3.25.79. Manipulaciones. |

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|--------------|---|----------------------|--------------|--|
| | | | | <p>En la elaboración de tabaco, cigarros y cigarrillos se permite utilizar o adicionar:</p> <p>a) Agua, amoníaco, ácido acético, láctico, cítrico y tartárico.</p> <p>b) Azúcar de caña, de higos, de arce o invertida, glucosa, melaza, miel, regaliz, sustancias aromáticas autorizadas y agua de rosas.</p> <p>c) Mentol, vainillina, cumarina, cacao, goma, cloruro sódico, nitratos, carbonatos, cloruros alcalinos y hasta 1 por 100 de cal en forma de agua de cal.</p> <p>d) Jugos concentrados de frutas y extractos o partes de haba Tonka («Dipterix odorata», Willd), meliloto («Mellilotus officinalis», Ders.), asperilla («Asperula odorata», L.), vainilla de carolina («Liatrix odoratissima», Mich.) y otras especies que contengan cumarina.</p> <p>f) Glicerina, etilenglicol o propilenglicol.</p> <p>g) Los edulcorantes artificiales y productos conservadores autorizados para estas elaboraciones en las listas positivas complementarias de los Capítulos XXXI y XXXIII de este Código.</p> <p>h) En la elaboración de cigarros y cigarrillos, el empleo de adhesivos a base de agua con caseína, almidón, dextrina, goma tragacanto o arábica y otros productos inofensivos.</p> <p>Papers 3.25.80. Papeles para cigarrillos. Reunirán fundamentalmente las siguientes condiciones:</p> <p>a) Serán elaborados con fibra de lino, cáñamo, cereales, algodón, «cargas» autorizadas, y los edulcorantes artificiales incluidos en las listas positivas de este Código.</p> <p>b) Estarán exentos de sustancias nocivas.</p> <p>c) No producirán en la combustión olor o gusto desagradable.</p> <p>d) Contendrán solamente indicios de acidez, cloruros y nitratos.</p> <p>Filters: 3.25.81. Filtros. Los filtros para cigarros y cigarrillos, así como aquellos para utilizarse en pipas y boquillas, estarán formados por una base inerte filtrante, impregnada o no por sustancias absorbentes fijas. C:\Documents and Settings\ampelan\Local Settings\Temporary Internet Files\OLK7E7\Codigo alimentario español- Documento BOE-A-1967-16485 última actualización.mht</p> |
| Sweden | Not mandatory but recommended using EU's practical guide. | Both. | No. | <p>Article 3.1 Dir. 2001/37/EC (i.e. TNCO levels for cigarette smoke) is implemented by section 18 of the Tobacco Act (1993:581), 2 § 2 of the Tobacco Regulation (2001:312) and further regulated by section 6 of the Swedish National Institute of Public Health regulation; FHIFS 2001:2.</p> <p>For tobacco products, other than chewing and sucking tobacco (i.e. snus), there is no positive or negative lists in place but according to section 17-18 and 20 of the Tobacco Act (1993:581) and section 2 of the Tobacco Decree (2001:312) it is possible to regulate tobacco ingredients on an ad hoc basis, in justified cases.</p> <p>The tobacco leaf is not regulated as a tobacco ingredient according to Dir. 2001/37/EG. However according to the food regulations it may be seen as part of the tracking and tracing process of the new</p> |

| Member State | Use of harmonised reporting formats | Paper/ electronic | Use of EMTOC | Regulation of ingredients (Positive and/or negative lists or other type of regulation? are ingredients in filter and other paraphernalia regulated Is the tobacco leaf regulated and if yes, how?) |
|----------------|-------------------------------------|-------------------|--|---|
| | | | | regulation LIVSFS 2012:6 regarding chewing and sucking (i.e. snus) tobacco (see above). |
| United Kingdom | Not mandatory but recommended. | Both | Not mandatory but we are currently considering starting to use it in the UK through a voluntary arrangement. | Have a positive list based on a voluntary agreement between the Department of Health and manufacturers and importers on permitted additives to tobacco products which includes a comprehensive list of ingredients allowed with maximum quantities. The agreement mentions that other compounds not included in the list, but approved by another MS are allowed. http://www.dh.gov.uk/ab/scoth/dh_095371#_4 25 pages of listed substances |
| Norway | Voluntary | Both | No, but intend to make it obligatory | No regulation of ingredients, but the Regulations no. 141 of 6 February 2003 on the contents and labelling of tobacco products mandate the Directorate of Health to ban addictive enhancing ingredients. This has not been done. The tobacco leaf is not regulated. |

A.3.3.4. Sales arrangements

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|--------------------|-----------------|---|---|---|
| Austria (18/07/12) | 16 | Restriction Minors (< 16) are not allowed to buy tobacco from vending machines and there is an electronic age control by bank card or mobile phone. No advertising allowed (general ban on advertising and sponsoring, Art. 11 Tobacco Act) with the exception of a TVM that is part of the outer face or the interior of the tobacconist's shop as advertising is allowed on these surfaces. | Ban. Only licensed merchants are allowed to sell tobacco products. (see § 5 Tabakmonopolgesetz) | Restricted. ¹⁹ Allowed: <ul style="list-style-type: none"> ➤ presentation of tobacco products meant for sale including prices at points of sale; ➤ distribution of single pieces of newly introduced trademarks free of charge for a period of 6 months in the interior of points of sale to grown up smokers; ➤ further advertising allowed at the exterior and interior of points of sale if health warning covers 10% of surface. Not allowed: <ul style="list-style-type: none"> ➤ promotion of cigarettes without filter; ➤ promotion that leads to false impression that smoking is not unhealthy; ➤ promotion concerning minors; ➤ promotion towards smokers aged under 30, |

¹⁹ see § 11 Abs. 4 and 5 Tabakgesetz together with § 39 Abs. 1 Tabakmonopolgesetz

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|--------------------|-----------------|--|--|--|
| | | | | <p>athletes, prominents including their comments on smoking;</p> <ul style="list-style-type: none"> ➤ comics; ➤ distribution of promotional items to minors or intended for minors; ➤ discounts, distribution free of charge (exception: see above) and direct mail. |
| Belgium (18/07/12) | 16 | <p>Restriction: Royal decree http://www.health.belgium.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/15748533_fr.pdf -vending machines can only be installed where tobacco products are sold traditionally. -vending machines have to be locked -the responsibility to unlock the vending machines for the persons over 16 is the seller selling tobacco traditionally.</p> <p>Advertising banned except for the display of trademarks in tobacco shops and newsagents.</p> | None | <p>Display of the trademark permitted at point of sale</p> <p>Art 7 § 2bis. Of following law http://www.sante.belgique.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/15748531_fr.pdf</p> |
| Bulgaria | 18 | <p>Ban</p> <p>Art. 30. (1) (amend. SG 110/96; amend. SG 57/04; amend. - SG 70/06; suppl. - SG 110/08, in force from 01.01.2009; amend. – SG 12/09, in force from 13.02.2009; amend. – SG 95/09, in force from 01.12.2009) The tobacco products shall be sold by traders, who have permission for selling tobacco products, issued under the conditions and by order of the Law on the Excise and Tax Warehouses. (2) The selling of tobacco products shall be prohibited: (...) 11. (new – SG 110/01, in force from January 1, 2002; amend., SG 70/04; suppl. - SG 70/06) from automatic machines for sale of tobacco products and from self-service stands;</p> | <p>Ban</p> <p>Internet sale is not mentioned as a permitted way of selling in the Law for the Tobacco and Tobacco Products and Law on excises and tax warehouses and Trade law putting together a retail system for tobacco products.</p> <p>But this fact open the doors: which is not banned it is allowed. That's why we have a project of Law for amendment and supplementing the Law for Tobacco and Tobacco Products which is in the Parliament now and we are expecting to be adopted. By this amendments and supplementation we forbid the selling</p> | <p>Permitted.</p> <p>The MEET is absolutely against such kind of amendment of law. That's why we need so much such kind of ban in the new TPD.</p> <p>There is a Canadian research – 60% from smokers by cigarettes when they see them at point of sale inspite of that they have cigarettes in their pocket.</p> <p>The scientific results of Ireland are very positive and inspiring after ban at point of sale.</p> |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|---------------------------|-----------------|--|--|---|
| | | | of tobacco products by the services of the information society, including internet. | |
| Cyprus | 18 | <p>Ban</p> <p>Article 9 of the Law providing for the taking of measures to restrict smoking states that:</p> <p>A person who-</p> <p>(a) Has under his control or in his possession any automatic vending machine for sale of tobacco, or allows the installation of such a machine or its use in any of the premises under his control or possession, or</p> <p>(b) Uses or puts in operation any tobacco vending machine, or</p> <p>(c) Imports or manufactures for local use any automatic vending machine for the sale of tobacco,</p> <p>Shall be guilty of an offence and shall be liable on conviction to a fine not exceeding one thousand pounds (1,700 euros) or imprisonment not exceeding six months or both imprisonment and fine and the court adjudicating the case may order the confiscation of the vending machine in connection with which the offence was committed.</p> | No specific restriction, but the sale of tobacco products requires a license granted by the public authorities. Custom services are also posted at the Post Office. | Not Regulated |
| Czech Republic (16/07/12) | 18 | <p>Restriction.</p> <p>TVM must display a clearly visible text in Czech that states that the sale of tobacco products to persons less than 18 years of age is prohibited. If there is an advertisement on the TVM it must be accompanied by the health warning "Ministry of Health warns: Smoking causes cancer."</p> <p>Act no. 379/2005 Coll. on measures for protection against the harmful</p> | <p>Restriction</p> <p>Act no. 379/2005 Coll. on measures for protection against the harmful effects of tobacco products, alcohol and other addictive substances and on the amendment of related laws stipulates it in Division 1 – Section 4 : (§ 4)</p> | No restriction |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|---------------|-----------------|--|--|---|
| | | <p>effects of tobacco products, alcohol and other addictive substances and on the amendment of related laws stipulates it in Division 1 – Section 4 :</p> <p>(§ 4)</p> <p>The sale of tobacco products, tobacco accessories and electronic cigarettes in vending machines, where the sale to persons less than 18 years of age cannot be precluded, is prohibited. Act No. 379/2005 Coll., as subsequently amended, is available on-line here:</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=379/2005&typeLaw=zakon&what=Cislo_zakon_a_smlouvy</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=225/2006&typeLaw=zakon&what=Cislo_zakon_a_smlouvy</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=274/2008&typeLaw=zakon&what=Cislo_zakon_a_smlouvy</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=305/2009&typeLaw=zakon&what=Cislo_zakon_a_smlouvy</p> | <p>.... The mail-order sale and all other forms of sale of the products listed in the first sentence, during which it is not possible to verify the buyer's age, are prohibited. Act No. 379/2005 Coll., as subsequently amended, is available on-line here:</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=379/2005&typeLaw=zakon&what=Cislo_zakona_smlouvy</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=225/2006&typeLaw=zakon&what=Cislo_zakona_smlouvy</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=274/2008&typeLaw=zakon&what=Cislo_zakona_smlouvy</p> <p>http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=305/2009&typeLaw=zakon&what=Cislo_zakona_smlouvy</p> | |
| Denmark | 18 | <p>Restriction at point of sales: In special automatic dispensers which are operated by a card that can only be obtained or bought from the cashier.</p> <p>https://www.retsinformation.dk/Forms/R0710.aspx?id=121329</p> <p>Advertising, besides that on the cigarette package, is prohibited.</p> | <p>Businesses from other EU-member states which carry out distance selling to Danish consumers are liable to pay excise duties and VAT in DK. The businesses have an obligation to apply for a license with the Danish customs and excise authorities. Also sellers have an obligation to produce a guarantee before shipping the goods.</p> <p>https://www.retsinformation.dk/Forms/R0710.aspx?id=13234</p> | <p>Ban on all Tobacco Product Advertisements and sponsoring.</p> <p>The ban does not cover neutral display at point of sale that does not give rise to a promotional effect.</p> <p>https://www.retsinformation.dk/Forms/R0710.aspx?id=121329</p> |
| Estonia | 18 | <p>Ban</p> <p>Tobacco Act Passed 4 May 2005 (RT² I 2005, 29, 210), entered into force on 5 June 2005:</p> <p>§ 22. Prohibitions upon retail trade in tobacco products</p> <p>(2) Retail trade in tobacco products is prohibited...</p> <p>2) from automatic vending machines;</p> <p>...</p> | None | None |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|----------------------|-----------------|---|---|---|
| Finland (16/07/2012) | 18 | <p>Restriction. Advertising on TVM is banned. Ban of TVM to be introduced from 2015.</p> <p>The wording currently in force: Tobacco Act 693/1976 Section 11 (14.6.2002/498) Tobacco products and smoking accessories may be sold from automatic vending machines only where such sales are under supervision. An automatic vending machine shall be placed so that its use can be monitored continuously. The placing and supervision of the use of an automatic vending machine is the responsibility of the owner, proprietor or responsible manager of the premises where the vending machine is placed or by an employee designated to perform this task. New wording : Tobacco Act 693/1976 Section 10 a (Tobacco Act 20.8.2010/698) It is forbidden to sell tobacco products from automatic vending machines.</p> | <p>No specific restriction, but</p> <ul style="list-style-type: none"> - sale of tobacco products requires a retail license - it must be possible for the seller to supervise the purchase situations - advertising ban covers also Internet sale - tobacco products must be labeled by warnings and some information | <p>Banned from 2012 onwards</p> <p>Act amending the Tobacco Act Section 8a of the Tobacco Act (693/1976), as it appears in Act 698/2010:</p> <p>"Display of tobacco products and their trademarks in retail sale facilities for tobacco, tobacco products, tobacco substitutes, tobacco imitations and smoking materials is forbidden. Paragraph 1 shall not apply to points of sale that have a separate entrance and mainly sell tobacco products and smoking materials where the tobacco products sold, or their trademarks, are not visible outside the point of sale. Paragraph 1 shall not apply to the sale of tobacco products on board vessels engaged in international maritime traffic. Retailers of tobacco products may present a purchaser of tobacco products, upon request, with the printed collection of pictures showing the packaging of tobacco products available for retail sale at the point of sale. Retailers may also supply the purchaser, upon request, with a printed catalogue of tobacco products and their prices. The content and outward appearance of the collection of pictures and the catalogue shall be regulated in greater detail by Decree of the Ministry of Social Affairs and Health. Paragraph 4 concerning the collection of pictures and catalogue of tobacco products shall also apply to tobacco, tobacco substitutes, tobacco imitations and smoking material."</p> |
| France (13/06/12) | 18 | <p>Ban Code de la Santé Publique : Article L3511-2 Modifié par <u>LOI n°2009-879 du 21 juillet 2009 - art. 98 (V)</u> ... Sales of tobacco products by vending machines is forbidden</p> | <p>Ban http://www.douane.gouv.fr/page.asp?id=34 Code général des impôts</p> | <p>According to Public Health Code, Article L3511-3 : Propaganda or advertising, direct or indirect, in favour of tobacco, tobacco products or the ingredients, as defined in the second paragraph of the L. 3511-1 article, as well as any free distribution or sale of a tobacco product at a</p> |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|----------------------|-----------------|--|---|---|
| | | | <p><u>Article 568 ter</u></p> <p>The remote sale of tobacco products is forbidden in metropolitan France and in French overseas departments.</p> | <p>price lower than that mentioned in the article 572 of the general taxes code are forbidden.</p> <p>These measures do not apply to the signs of tobacco retail outlets, nor to the posters situated inside these establishments, not visible from the outside. These signs or posters must respect the characteristics defined by interministerial order.</p> |
| Germany (16/07/2012) | 18 | <p>Restriction (ID verification card)</p> <p>The selling machine has to be installed at a location not accessible for <i>Children</i> and for <i>Adolescents</i></p> <p><u>or</u></p> <p>The selling machine has to be furnished with mechanical devices or has to be permanently guarded to ensure that <i>Children</i> and <i>Adolescents</i> cannot take tobacco products out of them.</p> <p>Protection of Young Persons Act, §10:</p> <p>http://www.gesetze-im-internet.de/juschg/</p> <p>There are no advertising restrictions at the federal level. Several tobacco firms have, however, voluntarily removed advertising from TVM, although brands are still displayed under this commitment.</p> | <p>Restriction.</p> <p>Advertising: Restrictions apply to internet sales VTabakG §21a (3&4) " It is forbidden to do advertising for tobacco products in the press..." "(3) equally applies to advertising for tobacco products in services of the information-society."</p> <p>http://www.gesetze-im-internet.de/img_1974/_21a.html</p> <p>Sales: The long distance sale of tobacco products from other member states to consumers in Germany is according to provisions of the tobacco tax law strictly regulated. The long distance sale of tobacco from the German fiscal territory has to be notified to the competent main customs office.</p> <p>Tobacco tax law, Art. 22 (1) / (2) and Art. 23 (1) / (3): http://www.gesetze-im-internet.de/tabstg_2009/BJNR187010009.html</p> | National legislation permits tobacco display and promotion at the point of sale. |
| Greece | 18 | Ban | No specific restriction, but the sale of tobacco products requires a license | Restrictions (Law 3730/23.12.08, art. 2 par1 & Law 3868/03.08.10, art.17 par. 3): |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|--------------------|-----------------|---|---|---|
| | | <p>Law 3730/23.12.08, art. 2, par. 2.</p> <p>Art. 2</p> <p>.....</p> <p>3. One year after the publication of the law, the sale of tobacco products through vending machines and the sale of single cigarettes or in packs with less than 20 cigarettes will be forbidden.</p> | granted by the public authorities. | Advertising/promotion is only allowed inside points of sale of tobacco products. Product placement is prohibited at the front windows of shops with the exception of kiosks, duty free shops and tobacconists. |
| Hungary | 18 | <p>Ban</p> <p>According to para (6) of Section 6 of Act XLII of 1999 on the Protection of Non-Smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products, tobacco products shall not be sold by vending machines</p> | <p>Ban</p> <p>Annex 3. of Government Decree 210/2009. (IX. 29.) on the conditions of pursuing commercial activities enlists tobacco products as a product that can only be sold in shops.</p> | <p>Tobacco display is permitted.</p> <p>Restriction applies to point of sale promotion: According to point c) of para (4) of Art. 19 of Act XLVIII of 2008 on the Basic Requirements and Certain Restrictions of Commercial Advertising Activities, the prohibition on the advertisement of tobacco products shall not apply to an advertisement installed inside a store, in a section designated solely for the sale of tobacco products in accordance with specific other legislation on the marketing of tobacco products, that contains only the name and price of tobacco product, provided that it does not exceed size A/5 (148x210 mm) for any tobacco product brand name, or twenty per cent of the entire surface of the entrance of the store section designated for tobacco products only through which tobacco products may be accessed, or maximum size A/1 (594x841 mm) in any store. Therefore the display not complying with these conditions are prohibited.</p> |
| Ireland (18/07/12) | 18 | <p>Restriction</p> <p>Section 43 (3) of the <u>Public Health (Tobacco) Act</u> as amended, states that "It shall be lawful for tobacco products to be sold by retail, in accordance with regulations made by the Minister, by means of a vending machine on licensed premises or the premises of a registered club by such persons, or by persons belonging to such classes of persons, as are specified in the regulations (being persons who are registered under section 37 in respect of the licensed premises concerned or the premises of the registered club</p> | None | <p>Ban</p> <p>Section 33 of the Public Health (Tobacco) Act as amended prohibits the advertisement of tobacco products in premises in which the business of selling tobacco products by retail is carried on in whole or in part.</p> <p>A display or other publication of a trademark, emblem, marketing image or logo, by reference to which the product is marketed or sold is included in "advertisement".</p> |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|------------------|-----------------|--|---|---|
| | | <p>concerned).”</p> <p>The Public Health (Tobacco) (Self Service Vending Machines) Regulations 2009 outline the procedures for selling tobacco products by means of a vending machine.</p> <p>Self-service vending machines must be free of all tobacco related advertising. Selection decals/buttons for self-service vending machines must not display tobacco product trademarks, emblems, marketing images or logos. The registration number(s) issued by the National Office of Tobacco Control, must be affixed to the self-service vending machine(s) following registration.</p> | | |
| Italy (18/07/12) | 16 | <p>Restriction</p> <p>All vending machines should be equipped with electronic devices to control the age of the purchaser.</p> <p>Advertising is forbidden but cigarette packs may be displayed on the TVM. The packages displayed have health warnings.</p> | Ban | National legislation permits tobacco display at the point of sale. |
| Latvia | 18 | <p>Ban</p> <p>Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products</p> <p>Section 7. Procedures for Trade in Tobacco Products and Herbal Smoking Products</p> <p><u>It is prohibited to sell tobacco products:</u> 5) <u>Utilising vending machines.</u></p> | <p>Ban</p> <p>No specific restriction, but the sale of tobacco products requires a license granted by the State Revenue Service (taxation legislation). The Licensing Commission (under the State Revenue Service), issuing the licence, indicates the address of the sales premises. This address of the sales premises is always only a physical address (where a person can go and buy products), but not a virtual or electronic address.</p> | <p>Restriction</p> <p>Tobacco advertising is banned. Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products states that tobacco products advertisement is information disseminated in any form, including commercial notices (for example, printed matter, posters, adhesive labels, advertising images on walls, radio and television broadcasts, clips, cinema films and videos), the purpose of which is the direct or indirect promotion of the purchase and consumption of tobacco products.</p> <p>Displays (without any promotional cigarettes' brand names or slogans) itself are allowed.</p> |
| Lithuania | 18 | Ban | <p>Ban</p> <p>Law On Tobacco Control</p> | <p>Display of tobacco products at point of sale is allowed. Advertising of tobacco products at points of sale, except</p> |

| Member States | Age restriction | Vending machines (Ban or restriction. If restriction specify type, i.e. age control such as identification control, remote control, ID coins, supervision or other + other types of restrictions such as rules on location of the machines and advertising rules) | Cross border distance sale, including Internet (Ban or restriction. Specify how it is regulated, i.e. through licensing, advertising, taxation) | Tobacco promotion and display at point of sale (Ban or restriction. If restriction specify type, i.e. advertising ban, limited display and other) |
|---------------|-----------------|--|--|---|
| | | <p>Law On Tobacco Control Article 15. Restrictions on the Marketing of Tobacco Products and Tobacco Sales Outlets It shall be prohibited to sell tobacco products in the Republic of Lithuania in the following manner: 1) through automatic vending machines; http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=389583</p> | <p>Article 15. Restrictions on the Marketing of Tobacco Products and Tobacco Sales Outlets It shall be prohibited to sell tobacco products in the Republic of Lithuania in the following manner: 2) through communication tools; http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=389583</p> | <p><u>an information specified in paragraph 3 of Article 17 of the Law on Tobacco Control is prohibited</u>, i.e. only the following information may be presented on showcases used to display tobacco products at tobacco sales outlets:</p> <ol style="list-style-type: none"> 1) the name of the manufacturer, marketing undertaking and address of the headquarters 2) the brand names of the tobacco products sold; 3) the words "We trade in" "We sell"; 4) the tar, nicotine and carbon monoxide yields of cigarettes; 5) the indication of prices of tobacco products. <p>It shall be permitted to present the information outlined in paragraph 3 of this Article only along with the displayed tobacco products. It may not be displayed in folders, flyers, or other means of advertising, intended for the consumers to take with them; additionally, it shall be prohibited in tobacco product sales outlets to display imitations and pictures of tobacco products or packaging thereof.</p> <p>Information (warnings) must also be displayed regarding the harmful effect of the use of tobacco products to health and concerning the prohibiting of the sale of tobacco products to persons under 18 years of age.</p> <p>No other visual or graphic information concerning tobacco products not specified in the Law of Tobacco Control may be displayed in tobacco product sales outlets.</p> <p>It is prohibited also:</p> <ol style="list-style-type: none"> 1) to apply fixed discounts for owners of disseminated coupons, which have been printed in the mass media or by other means, or to consider these coupons as an alternate means of payment; 2) to supply (disseminate) tobacco products and (or) new samples thereof, free; 3) to grant the buyer an immediate right or over a certain term of time following the conclusion of a buy-sell contract, to receive gifts or a supplement to the tobacco products; 4) to influence buyers through persistently offering tobacco products by indicating supposed price reductions on price lists, price labels, indoor store windows and other means and measures contrary to good morals and public order; 5) to sell tobacco products included in an assortment with other goods; 6) to supply tobacco products as prizes in lotteries, contests, sports competitions, game prizes or along with them; |

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| | | | | <p>7) organise games or competitions and lotteries, which would promote acquisition and (or) consumption of tobacco products;</p> <p>8) to manufacture and (or) sell toys, food products and other goods, whose design imitates tobacco products or packs;</p> <p>9) to sell other (non tobacco) products, marked with tobacco goods trademarks and etc.</p> |
| Luxemburg | 16 | <p>Restriction</p> <p><u>Article 9 de la Loi du 11 août 2006 relative à la lutte anti-tabac, article 9(2) :</u> «Tout exploitant d'appareils automatiques de distribution délivrant du tabac et des produits du tabac est tenu de prendre des mesures empêchant les mineurs âgés de moins de seize ans accomplis d'avoir accès auxdits appareils.»</p> <p>(Régulation: Utilisation de jetons ; Apposition d'un autocollant portant l'interdiction de la vente aux mineurs de moins de 16 ans; L'exploitant peut refuser l'octroi du jeton aux personnes refusant de prouver l'âge requis; Pas d'appareils automatiques sur les voies publiques; Pas de design spécifique, ni d'avertissements sanitaires spécifiques, hormis ceux figurant sur les unités de conditionnement)</p> | No regulation | <p>Display limited to the name and the price of the tobacco product as well as the logo of the brand.</p> <p>(Article 3 paragraphe 4 de la loi du 11 Août 2006 : « Toute publicité en faveur du tabac et de ses produits est interdit, sauf dans les surfaces réservées à la vente des produits du tabac, et/ou à proximité immédiate des étalages exposant des produits du tabac à la vente. La publicité autorisée ne peut être effectuée alors qu'au moyen d'affiches et de panneaux-réclames, mentionnant le nom de la marque, le logo et le prix du produit de tabac. Elle ne peut s'adresser aux mineurs, ni utiliser des arguments axés sur la santé, ni faire croire qu'un produit particulier est moins nocif qu'un autre, ni montrer une personne connue du public. »)</p> |
| Malta (18/07/12) | 18 | <p>Restriction</p> <p>TVM need to be supervised at all times.</p> <p>TVMs are only allowed to sell cigarettes and tobacco products.</p> <p>Decoys should include the health warning.</p> | <p>Restriction regulated through the Advertising and Promotion of Tobacco Products Regulations, 2010 (LN344/10) available on http://www.doi.gov.mt/EN/legalnotices/2010/07/LN%20344.pdf</p> | Advertising ban |
| Netherlands (16/07/2012) | 16 | <p>Restriction.</p> <p>Besluit van 26 januari 2004 houdende uitvoering van artikel 9, vierde lid, van de Tabakswet (Besluit tabaksautomaten)</p> <p>Vending machines have to be placed in a spot where personnel of the</p> | None | Restricted |

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| | | <p>location where they are situated in can supervise them to make sure age restrictions are respected. Outdoor vending machines are not allowed.</p> <p>Tobacco advertisement is regulated by the national Tobacco Act. Tobacco advertising is prohibited in general except for a few small exceptions. One of our exceptions is that an image of the brand can be shown on de push buttons of the machine, as long as the image is not larger than the original package itself. Large advertisement posters on the machine are not allowed. On this part of the machine only non-tobacco advertisement is allowed.</p> | | |
| Poland | 18 | Banned since 1996 | None | Tobacco promotion and advertising is banned. Display at point of sale is allowed. |
| Portugal (16/07/12) | 18 | <p>Restriction</p> <p>According the new Tobacco Law (Law 37/2007 of 14 th of August) it is forbidden to sell tobacco (trough vending machines or direct vending) in public administration services; health services; schools, kindergartens, holiday camps, or other educative or leisure places for persons under 18 years old; ageing homes; canteens, in public or private enterprises or institutions, for exclusive use of its employees.</p> <p>Vending machines should have an electronic system or other kind of system in order to prevent the access of minors (under 18 years old).</p> <p>These machines should be placed inside the establishments, under the visual control of the vendor, and they cannot be placed in corridors, stairs or other spaces out of shops in commercial malls.</p> <p>Advertising on TVM is prohibited.</p> | Advertising is prohibited. | Advertising is prohibited, including advertising in the points of sale; display of tobacco products on the points of sale is allowed. |
| Romania | 18 | Ban | None | allowed |
| Slovakia | 18 | <p>Ban</p> <p>By § 6 art. 5 law no. 377/2004 on protecting of non-smokers in amendment the sale of tobacco products by vending machines is prohibited.</p> | Ban | |
| Slovenia | 18 | Ban | Restriction | Allowed. |

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| Spain (18/07/12) | 18 | <p>Restriction</p> <p>Art 3.1 & 4.b of the Ley 28/2005 amended by Ley 42/2010 and Real Decreto-Ley 14/2011</p> <p>Vending machines can only be placed inside stationery, bars, restaurants and convenience shops of petrol stations, under the direct surveillance of the owners or their employees and under registration procedure, inspection and control carried out by the Comisionado para el Mercado de Tabacos.</p> <p>The machines must include a technical device to block the access to minors.</p> <p>All types of advertising are forbidden under the Spanish regulation included on the vending machines. (Article 9.1 of the Ley 28/2005, amended by the Ley 42/2010).</p> <p>Health warnings about the risk of smoking in Spanish and co-official language of the autonomic region should be displayed on a visible part of the machine.</p> | <p>Ban</p> <p>Art.3.1 of the Ley 28/2005</p> <p>The sale of tobacco products is only allowed in tobacco shops or vending machines placed in specific places and having a state authorisation. Any other sort of selling is forbidden.</p> <p>Art. 3.6 of Ley 28/2005</p> <p>It is forbidden the sale and the supply of tobacco product for any other method other than direct personal sale. In particular, the sale and the supply of tobacco products by means of mail-order selling or similar procedures is forbidden.</p> | <p>Art. 10.Tres of the Real Decreto 1199/1999</p> <p>Only indoor. Views from outside is forbidden.</p> |
| Sweden (16/07/12) | 18 | <p>Restrictions apply.</p> <p>The sale has to comply with the same rules as if made in a shop. 12 § of the Tobacco Act (1993:581) stipulates that “The sale of tobacco products has to be made in such a way that makes it possible to control the ‘recipients’ age. This includes sales by vending machines, postal order and by similar ways”.</p> <p>The Swedish National Institute of Public Health is regulatory agency regarding sales.</p> <p>The same rules apply as for point of sale display – marketing in general is banned and the display cannot be invasive, outreaching or encourage anyone to use tobacco.</p> | <p>Restrictions apply.</p> <p>The sale has to comply with the same rules as if made in a shop. 12 § of the Tobacco Act (1993:581) stipulates that “The sale of tobacco products has to be made in such a way that makes it possible to control the recipients’ age.</p> <p>This includes sales in vending machines, postal order and similar ways”.</p> <p>The Swedish National Institute of Public Health is regulatory agency</p> | <p>Marketing etc. are as a general rule banned.</p> <p>The display at point of sale is, however, according to 14 § second part 3 of the Tobacco Act (1993:581) allowed, but cannot be invasive, outreaching or encourage anyone to use tobacco.</p> <p>This is regulated by the Swedish Consumer Agency regulation KOVFS 2009:7.</p> <p>The Swedish Consumer Agency is regulatory agency for marketing etc.</p> |

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| | | | regarding sales. | |
| United Kingdom | 18 | <p>Prohibition of the sale of tobacco from vending machines</p> <p>England - the sale of tobacco products directly from an automatic vending machine was prohibited from 1 October 2011</p> <p>The legislation is set out in:-Children and Young Persons (Protection from Tobacco Act 1991 section 3A (as inserted by Health Act 2009 section 22). Statutory Instrument 2010 No. 864 The Protection from Tobacco (Sales from Vending Machines) (England) Regulations 2010 The above legislation can be found at:- http://www.legislation.gov.uk</p> <p>Wales – prohibited sales of tobacco products from vending machines on 1 February 2012. See The Protection from Tobacco (Sales from Vending Machines) (Wales) Regulations 2011 on this link - http://www.legislation.gov.uk/wsi/2011/2498/contents/made?text=Tobacco%20vending%20machine#match-1</p> <p>Northern Ireland – prohibited sales of tobacco products from vending machines on 1 March 2012. See The Protection from Tobacco (Sales from Vending Machines) Regulations (Northern Ireland) 2012 (http://www.legislation.gov.uk/2012?text=Tobacco%20vending%20machine)</p> <p>Scotland – commencement of legislation prohibiting tobacco sales from vending machines has been delayed pending the outcome of legal challenges brought by Sinclair Collis and Imperial Tobacco. See the Tobacco and Primary Medical Services (Scotland) Act 2010 section 9 (http://www.legislation.gov.uk/asp/2010/3/contents)</p> | Restriction based on transposition of Advertising Directive | <p>Displays of tobacco products prohibited in England starting from 6 April 2012 (with other parts of UK to follow) The legislation is set out in:-</p> <ul style="list-style-type: none"> (a) Sections 6(A1),7A, 7B and 7C of the Tobacco Advertising and Promotion Act, as inserted by sections 20 and 21 Health Act 2009 (b) The Tobacco Advertising and Promotion (Display)(England) Regulations 2010 (S.I.2010/445) (c) The Tobacco Advertising and Promotion (Display of Prices)(England) Regulations 2010 (S.I.2010/863) (d) The Tobacco Advertising and Promotion (Specialist Tobacconists) Regulations 2010 (S.I.2010/446) (e) The Tobacco Advertising and Promotion (Display and Specialist Tobacconists) (England) (Amendment) Regulations 2011 (S.I.2011/1256). (f) The Tobacco Advertising and Promotion (Display and Specialist Tobacconists)(England)(Amendment) Regulations 2012 (S.I.2012/677). <p>The above legislation can be found at:- http://www.legislation.gov.uk Permanent open displays of tobacco products to the public in England will end on 6 April 2012 in large shops and on 6 April 2015 in all other businesses. Displays will be limited to 1.5 square metres when actively carrying out specified activities such as serving customers and restocking and must last only as long as necessary to complete the activity. This will help reduce take up by young people and support adult quitters.</p> |
| Norway | 18 | <p>Ban</p> <p>Act No. 14 of 9 March 1973 relating to Prevention of the Harmful</p> | None | <p>Ban</p> <p>Act No. 14 of 9 March 1973 relating to Prevention of the</p> |

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| | | <p>Effects of Tobacco (the Tobacco Control Act) Section 8. Prohibition against the sale of tobacco products from self-service vending machines The sale of tobacco products from self-service vending machines is prohibited. This prohibition does not encompass systems where customers get tobacco products from vending machines using a prepaid vending machine card.</p> <p>Cards for use in vending machines may not be labelled with trademarks or company logos or other identifying marks for tobacco products. Vending machine cards may be labelled only with a neutral indication of the trademark name of the relevant tobacco product.</p> <p>Vending machines may not be labelled with trademarks or company logos or other identifying marks for tobacco products. They may only have a neutral written indication that the device is a vending machine for tobacco products.</p> <p>The Ministry may lay down further rules to implement and supplement these provisions.</p> | | <p>Harmful Effects of Tobacco (the Tobacco Control Act) Section 5. Prohibition against the visible display of tobacco products and smoking accessories The visual display of tobacco products and smoking accessories at points of sale is prohibited. The same applies to imitations of such products and cards for use in vending machines that allow customers to obtain tobacco products or smoking accessories from vending machines. The prohibition in the first paragraph does not apply to tobacconist shops.</p> <p>At points of sale neutral information may be given regarding prices and the tobacco products sold there. The same also applies to smoking accessories.</p> <p>The Ministry may issue regulations regarding implementation and supplementation of these provisions and may allow exemption from them.</p> |