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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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ABBREVIATIONS USED IN THE IMPACT ASSESSMENT

ENDS Electronic Nicotine Delivery System

FCTC WHO Framework Convention on Tobacco Control

FMC Factory Manufactured Cigarettes

NCP Nicotine Containing Products

NRT Nicotine Replacement Therapy

PA Policy Area

PO Policy Option

PoS Point of Sale

RYO Roll-Your-Own tobacco

STP Smokeless Tobacco Products

SKU Stock Keeping Unit

TEU Treaty of the European Union

TFEU Treaty on the Functioning of the European Union

TNCO Tar, nicotine and carbon monoxide

TPD Tobacco Products Directive

TVM Tobacco Vending Machine

WHO World Health Organisation

WTO World Trade Organisation

GLOSSARY OF TERMS[1]

Additive – substance contained in a tobacco product, its unit packet or its outside packaging with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants.

Characterising flavour - a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy, menthol or vanilla observable before or upon intended use of the tobacco product;

'Cheap whites / illicit whites' - cigarettes produced (often legitimately) in their country of origin at very low cost, destined to be illicitly sold in other jurisdictions and not respecting the legal requirements in the jurisdiction of destination.

Chewing tobacco - a smokeless tobacco product exclusively designed for the purpose of chewing.

Cigar - a roll of tobacco consumed via a combustion process and further defined in Article 4(1) of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco.

Cigarette – a roll of tobacco consumed via a combustion process and further defined in Article 3(1) of Council Directive 2011/64/EU.

Cigarillo – a small type of cigar with a diameter of up to 8 mm.

Contraband - products which have been diverted into illicit trade, not respecting the legal requirements in the jurisdiction of destination.

Counterfeit –brand protected products which have been falsified without consent of the brand owner and are not respecting the legal requirements in the jurisdiction of destination.

Electronic cigarette (Electronic Nicotine Delivery Systems, ENDS) – electronic device typically consisting of a mouth piece (containing an electronic evaporator) and a cartridge (typically replaceable) and designed to deliver nicotine to the lung through inhalation of a mixture of air & vapours into the respiratory system.

Factory manufactured cigarette (FMC) – a cigarette, produced by a tobacco manufacturer, capable of being smoked as such.

FCTC commitments –political commitments to implement the non-binding guidelines developed under the FCTC to assist Parties in meeting their implementation obligations under the FCTC.

FCTC obligations – obligations to implement the legally binding FCTC and the Illicit Trade Protocol .

Flavouring – an additive that imparts aroma and/or taste.

Herbal products for smoking – a product based on plants or herbs which contains no tobacco and is consumed via a combustion process.

Ingredient – an additive, tobacco (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco), as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives.

Illicit trade – any practice or conduct prohibited by law and which relates to production, shipment, receipt, possession, distribution, sale or purchase, including any practice or conduct intended to facilitate such activity.

Nasal tobacco - a smokeless tobacco product consumed via the nose.

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[1] The purpose of this glossary is to provide the reader with a better understanding of the terms used in the document. It should in no way prejudge the terminology defined in the legal proposal.

Nicotine containing products (NCP) – a product usable for consumption by final consumers via inhalation, ingestion or in other forms and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption.

Nicotine Replacement Therapies (NRT) - remedial administration of nicotine to the body by means other than tobacco, usually authorised under the pharmaceutical legislation as part of smoking cessation. Common forms of nicotine replacement therapy are nicotine patches and nicotine gum.

Novel tobacco product - a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of the Directive.

Pipe tobacco – tobacco consumed via a combustion process and exclusively designed for the purpose of being used in a pipe.

Plain packaging – full standardisation of the packages, including brand- and product names printed in a mandated size, font and colour on a given place of the package; standardised package colour; standardised size and appearance of the package; display of required (textual and pictorial) health warnings and other legally mandated product information, such as tax-paid stamps and marking for traceability and security purposes.

Promotional / Misleading element – any element promoting a tobacco product by a means that is false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, any element suggesting that a tobacco product is less harmful than others or has vitalising, energetic or other positive health effects, any element referring to flavour or taste or the absence thereof, or any elements resembling a food product. Such elements can take the form (but are not limited to) texts, signs, pictures or other graphical elements, references to natural or biological characteristics or to certain flavours or flavourings or other additives, inserts and other additional material, e.g. adhesive labels, stickers, onserts, scratch-offs, sleeves.

Roll-your own tobacco (RYO) – tobacco which can be used for making cigarettes by final consumers or retail outlets.

Smokeless tobacco products (STP) – a tobacco product not involving a combustion process, including tobacco for oral use.

Tobacco for oral use/oral tobacco - all products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets.

Traditional use – Continuous use of a smokeless tobacco product in a Member State or part thereof for at least 30 years.

MAIN REPORTS/STUDIES USED FOR THE IMPACT ASSESSMENT

- First Report on the Application of the Tobacco Products Directive. COM(2005) 339 final (First Application Report 2005)
- Second Report on the Application of the Tobacco Products Directive. COM(2007) 754 final (Second application Report 2007): http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_products_en.pdf
- Report on the public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC, European Commission, Health and Consumer Directorate-General, July 2011 (Public consultation Report 2011): http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm
- Commission Staff Working Document of 23.11.09: Report on the Implementation of the Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (2003/54/EC) (Commission Staff Working Document 2009): http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_report09_en.pdf
- SCENIHR. Health effects of smokeless tobacco products. 6 February 2008 (SCENIHR 2008): http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf
- SCENIHR. Addictiveness and attractiveness of Tobacco Additives. 12 November 2010 (SCENIHR 2010): http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_031.pdf
- Special Eurobarometer 332; 2010 (Eurobarometer 2010): http://ec.europa.eu/health/tobacco/docs/ebs332_en.pdf
- Special Eurobarometer 385, 2012 (Eurobarometer 2012) : http://ec.europa.eu/health/eurobarometers/index_en.htm
- GHK. A study on liability and the health costs of smoking (2008/C6/046) as revised 2012 (GHK 2012): http://ec.europa.eu/health/tobacco/docs/tobacco_liability_en.pdf
- Rand Europe. Assessing the impacts of revising the Tobacco Products Directive. TR-823-EC. September 2010 (RAND 2010): http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf
- Rand Europe. Availability, accessibility, usage & regulatory environment for novel & emerging tobacco, nicotine or related products. Rand Europe. 2012 (RAND 2012)
- Matrix insight. Economic analysis of the EU market of tobacco, nicotine & related products 2012 (Matrix 2012)

1. INTRODUCTION

1.1. CONTEXT

Directive 2001/37/EC 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 products (Tobacco Products Directive, hereafter TPD), was adopted on 5 June 2001.[2]

More than ten years have passed since the adoption of the TPD. In line with market, scientific and international developments it has become necessary to update and complete the TPD. A revision is explicitly foreseen in Article 11 of the current TPD and was repeatedly called for by the Council and the European Parliament[3]. The initiative to revise the TPD is included in the Commission's Work Plan 2012.[4]

The overall objective of the revision is to improve the functioning of the **internal market**. In particular, the proposal aims to:

- Update **already harmonised areas** to overcome Member States' obstacles to bring their national legislations in line with new market, scientific and international developments.[5]

- Address **product related measures not yet covered by the TPD** insofar as heterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market.[6]

- Ensure that certain provisions of the TPD are **not circumvented** by placing on the market of products not compliant with the TPD.[7]

It is also important to ensure a harmonised implementation of FCTC obligations and a consistent approach to non-binding FCTC commitments if there is a risk of diverging national transposition.

In line with Article 114(3) TFEU a high level of **health protection** has been taken as a basis for this impact assessment when choosing between different policy options. In this context, the revision seeks to regulate tobacco products in a way that reflects their specific characteristics (nicotine has addictive properties) and the negative consequences of their

[2] OJ L 194, 18.7.2001, p. 26–35

[3] Council Recommendation of 30 November 2009 on smoke-free environments; Council Conclusions of 1-2 December 2011 on prevention, early diagnosis and treatment of chronic respiratory diseases in children; EP resolution of 15 September 2011 on European Union position and commitment in advance to the UN high-level meeting on the prevention and control of non-communicable diseases; EP Resolution of 24 October 2007 on the Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level; EP Resolution of 26 November 2009 on smoke free environments.

[4] Annex 1 to the Commission work programme 2012 – forthcoming initiatives 2012. COM(2011)777 final. http://ec.europa.eu/atwork/programmes/docs/cwp2012_annex_en.pdf (accessed 28 Nov 2012).

[5] Without an update, Member States cannot, for example, increase the size of the health warnings, change their location of the package or replace the display of tar, nicotine and carbon monoxide levels.

[6] For example, at this stage, eight Member States have adopted pictorial health warnings and the regulations of ingredients differ between Member States.

[7] For example, measures on cross-border distance sales and traceability will facilitate legal activity and thus prevent sale of tobacco products not complying with the TPD (e.g. health warnings and ingredients).

consumption (health risks such as various cancer types, cardiovascular problems, increased risk of blindness, impotence, lower fertility, impact on the unborn child etc.). Their treatment costs more than 25 bEUR per year. Furthermore, tobacco is the most significant cause of premature deaths in the EU, responsible for almost 700,000 deaths every year (see section 2.1.2). The revision focuses on initiation of tobacco consumption, in particular by young people, taking into account that 70% of the smokers start before the age of 18 and 94% before the age of 25 years[8]. This is also reflected in the selection and focus of the policy areas proposed and the products primarily targeted (FMC, RYO and STP).

From a broader perspective, the revision will contribute to the overall aim of the EU to promote the well-being of its people (TEU Article 3) and the Europe 2020 strategy as keeping people healthy and active longer, and helping people to prevent avoidable diseases and premature death, will have a positive impact on productivity and competitiveness. An unintended, but welcome side effect of the measures against trade of products not complying with the requirements of the TPD might be that the tax revenues of Member States are better protected as the products often also circumvent national tax legislations.

The revision of the TPD focuses on five policy areas: (1) STP[9] and extension of the product scope (i.e. NCP and herbal products for smoking), (2) packaging & labelling, (3) ingredients/additives, (4) cross-border distance sales and (5) traceability and security features. When preparing this impact assessment report economic, legal and scientific considerations were taken into account. Particular attention was given to the Fundamental Rights Charter and international obligations (FCTC, WTO-TRIPS, TBT).[10]

This impact assessment report presents the analysis and all relevant results of the impact assessment work. Due to space limitations, citations are limited to key publications and, as appropriate, relevant studies illustrating the current evidence base. More detailed information and supporting materials are also included in the five technical annexes accompanying the main report. The first four annexes provide more detailed information on stakeholders' views, the tobacco market, the regulatory framework and the assessment criteria used when assessing the impacts as well as scoring tables. Annex 5 outlines the socio economic impacts and explains in detail how a reduction in tobacco consumption will impact on stakeholders (indirect impacts).

1.2. APPLICATION, IMPLEMENTATION AND ENFORCEMENT OF THE CURRENT TPD AND NOTIFICATIONS FROM MEMBER STATES

1.1.1. Content of the existing TPD

The existing TPD was adopted to recast two previous internal market Directives.[11] According to its Article 1, the TPD aims at approximating certain national rules regarding tobacco products, e.g. tar, nicotine and carbon monoxide (TNCO), health warnings, ingredients and misleading description of tobacco products. The current TPD is limited to **products** containing tobacco (i.e. NCPs and herbal products for smoking are not subject to the TPD). It applies to all categories of tobacco: FMC, RYO, pipe tobacco, cigars, cigarillos, STP and other forms of tobacco.

[8] Eurobarometer 2012
[9] This includes also novel tobacco products which are primarily expected to fall within the category of STP.
[10] Commission Staff Working Paper. Operational Guidance on taking account of Fundamental Rights in Commission Impact Assessments, SEC(2011)567 final, Brussels, 6.5.2011
[11] Directives 89/622EEC and 90/239/EEC

Article 3 of the TPD sets the maximum levels for **tar, nicotine and carbon monoxide** (TNCO) and Article 4 explains how the TNCO levels should be measured. Regarding **ingredients**, Article 6 foresees reporting obligations for the industry (including available data on toxicology and addictiveness). Article 12 invites the Commission to submit a common list of ingredients authorised for tobacco products. The Commission has not suggested such a list taking into account a shift in regulatory priorities, including in the context of the FCTC and the adoption of partial guidelines on ingredients related to attractiveness.

Article 5 contains **labelling** requirements. It stipulates that all tobacco products except STP must carry a general health warning, (e.g. "Smoking kills"), covering not less than 30% of the front side, and a specific text warning (e.g. "Smoking causes fatal lung cancer"), covering not less than 40% of the back side.[12] The TPD also requires that all STP carry a health warning ("This tobacco product can damage your health and is addictive."). Moreover, the TPD empowers the Commission to adopt rules for the use of additional pictorial warnings that Member States have to comply with if they decide to require those warnings. In addition, the packages should display the levels of tar, nicotine and carbon monoxide (TNCO). Article 7 of the TPD prohibits the use of trademarks and texts suggesting that a particular product is less harmful than others (e.g. "mild" or "light"). To ensure product identification and traceability, the tobacco products should be marked by batch numbering enabling the place and time of manufacture to be determined (Article 5 (9) TPD). The Commission was invited to provide technical details, but has not responded to the invitation in the light of new international developments the Commission concluded that the information on time and location of manufacturing was not sufficient to ensure full traceability and reduce illicit trade effectively.

Article 8 prohibits the placing on the market of **oral tobacco** (snus) outside Sweden.

Articles 9, 10 and 11 of the TPD contain **comitology** provisions and **reporting** obligations. Article 13 sets out the conditions under which Member States can take stricter provisions.

1.1.2. Application of the TPD

Article 11 of the current TPD requires that the Commission reports regularly on the application of the Directive. Two such reports have been issued, a first one in July 2005 and a second one in November 2007.[13] Subsequent reports were not issued in the light of the pending revision/impact assessment process.

The **First Report on the Application of the TPD** concluded that the Commission should consider further the development of labelling, such as the wider use of quit line telephone numbers. As regards reporting of ingredients, it was stressed that Article 6 on the reporting of ingredients needs to be developed, that information transmitted from the industry varies greatly and that there is lack of capacity to analyse the data.

In its **Second Report on the Application of the TPD**, the Commission concluded that it should examine the possibilities with regard to an increased size of the warnings, mandatory pictorial warnings on both sides of the packets and the replacement of TNCO levels by other information. The Commission also stressed that it should explore the possibilities of generic

[12] For Member States having more than one official language, the warnings should be increased to 32-35% and 45-50%. Commission Directive 2012/9/EU, updating text warnings has been adopted on 7 March 2012: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:069:0015:0016:EN:PDF (accessed 28 Nov 2012) A revision of the pictorial warnings is planned for 2013.

[13] First Application Report 2005, Second Application Report 2007

standardised packaging. As regards reporting of ingredients, the report refers to the wish from a number of Member States and the industry to make the formats developed on a voluntary basis compulsory throughout the EU. In terms of oral tobacco, it was concluded that the scientific opinion on the health effects of STP (SCENIHR 2008)[14] should form the scientific basis for any future risk management decision of the Commission. In addition, it was concluded in the report that new tobacco and/or nicotine products should be studied with a view to ensure proper regulation. Both reports have provided input to the current impact assessment. Both reports also covered Article 12 of the TPD on ingredients. For the reasons outlined above, not concrete follow-up was given to this provision.

1.1.3. Implementation of the TPD

Member States have transposed the existing TPD and the Commission has used its powers to adopt rules for the use of colour photographs and other illustrations and to amend the textual health warnings in line with scientific and technical progress.[15] However, the Commission has not made use of its powers to adopt measures for identification and traceability purposes nor has the Commission responded to the invitation from legislators to develop a common list of ingredients.

1.1.4. Enforcement of the TPD and legal challenges

In general, **enforcement** of the TPD has not been seen as a problem and only a limited number of infringement procedures have been launched. However, the current TPD is unclear as regards to the level of harmonisation. While Article 5(5) allows Member States a degree of discretion to adapt the labelling of tobacco products to the requirement of public health protection, Article 13(1) stipulates that they cannot, for considerations relating to health warnings, prohibit or restrict the import of tobacco products complying with the TPD provisions. This Article has been subject to several consultations of the Commission's Legal Service.[16] The current situation implies that Member States are allowed to take certain actions, but only for domestically produced products while they cannot impose the same requirements on imported products.[17] This does not make sense in a globalised market such as the tobacco market and - taking in account the significant cross border trade - can easily result in production moving to countries where less stringent rules are required. Only a revision can address these shortcomings. In addition, the development of the internet as a distribution channel for tobacco products and the definition of "oral tobacco" represent particular challenges in terms of enforcement.[18] Also the current requirement for rotation of the health warnings has been subject to different interpretation and needs to be clarified.

The current TPD has been subject to several **legal challenges** since its entering into force. In 2001 British American Tobacco (BAT) and Imperial Tobacco, initiated legal proceedings in the British Courts on the validity and interpretation of the Directive. The case was referred to

[14] SCENIHR 2008

[15] Commission Decisions 2003/641, C(2005) 1452 final, C(2006) 1502 final, Commission Directive 2012/9/EU

[16] Two judgments concerning the previous tobacco labelling Directive 89/622 also addresses Member States' possibilities of imposing stricter national rules: C-222/91 Ministero delle Finanze and Ministero della Sanità v Philip Morris Belgium SA and others. European Court reports 1993 Page I-03469 and The Queen v Secretary of State for Health, ex parte Gallaher Ltd, Imperial Tobacco Ltd and Rothmans International Tobacco (UK) Ltd, European Court reports 1993 Page I-03545

[17] See, with reference to the previous tobacco labelling Directive 89/622, case C-222/91, Ministero delle Finanze and Ministero della Sanità v Philip Morris Belgium SA and others, [1993] ECR I-03469 and C-11/92, The Queen v Secretary of State for Health, ex parte Gallaher Ltd, Imperial Tobacco Ltd and Rothmans International Tobacco (UK) Ltd, [1993] ECR I-03545.

[18] See for internet: Commission Staff Working Document 2009. STP: see problem identification, section 2.2.1.

the ECJ (Case 491/01).[19] The companies argued that the legal basis for the directive (Article 95 TEC, current article 114 TFEU) was inadequate, because it was a public health measure being introduced as an internal market measure. The companies also argued that the introduction of Article 133 TEC as a second legal basis invalidated the directive. The principles of proportionality and subsidiarity were also claimed to have been infringed. They also argued that the labelling provisions for yields and larger health warnings, and the ban on misleading descriptors breached trade mark and intellectual property rights, as well as being an infringement of the obligation to give reasons. In 2002, the Court upheld the validity of the Directive and confirmed the validity of its provisions.[20]

The directive's ban on the marketing of certain types of oral tobacco (snus) has also been challenged (*Cases C-434/02 and C- 210/03)*.[21] These challenges were brought by Swedish Match, a manufacturer of oral tobacco (snus), against the UK government, and a German wholesaler who brought a case against the German government. They claimed that the directive was in breach of the rules laid down in Articles 95, 133 and 253 TEC. A claim was also made that the ban on oral tobacco was a breach of the principle of subsidiarity. They also alleged the directives' provision to constitute a restriction as referred to in Articles 28 and 29 TEC which prohibits quantitative restrictions in trade between Member States. One of the claimants also alleged that the ban was in breach of the principle of the freedom to pursue an occupation. Also in this case, the Court rejected the arguments and upheld the validity of the directive.

1.1.5. Notifications

A large number of notifications under Directive 98/34/EC[22] have been received from Member States in the area of tobacco including on pictorial health warnings, the maximum number of FMC sticks in the package, display of quit lines on the package, regulations on ingredients and rules for herbal products for smoking. In addition, fourteen RAPEX notifications have been received so far regarding electronic cigarettes (17 December 2012).[23]

1.3. CONSULTATIONS, EXPERTISE AND OTHER INPUT

Stakeholder consultations

A **public consultation** was held between 24 September and 17 December 2010. The Commission received more than 85,000 contributions from a wide range of stakeholders. Citizen contributions accounted for 96% of the survey response, 57% of which are "duplicate"/repeated responses[24] which appear to be the result of several citizen mobilisation

[19] Case C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd. [2002] ECR I-11453.
[20] The Court found, however, that Article 95 TEC was the only appropriate legal base, but that the addition of Article 133 TEC as a legal base was not a reason for declaring the Directive invalid.
[21] Case C-210/03 The Queen, on the application of: Swedish Match AB and Swedish Match UK Ltd v Secretary of State for Health. [2004] ECR I-11893.
[22] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ L 204, 21.7.1998, p. 37–48
[23] RAPEX is the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers with the exception of food, pharmaceutical and medical devices: http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm (accessed 28 Nov 2012).
[24] A response considered "duplicate" in the public consultation was a response fulfilling the following criteria: 1. At least six responses containing the same text. 2. Text box containing more than three words. 3. Text box not containing text directly copied from the consultation document.

campaigns that took place in some Member States.[25] The actions and efforts of these campaigns seem to have affected the overall quantitative data of the public consultation, which indicates that most of the citizens responding to the consultation were against changes to the TPD. This outcome deviates significantly from the latest Eurobarometer survey,[26] published in May 2012. Unlike public consultations, it is important to note that respondents in a Eurobarometer survey are selected randomly. Member States representatives and - even more so - health NGOs favour the introduction of strict tobacco control measures, while tobacco industry and retailers are against some of the stricter measures (for more details, see Annex 1 and separate sections under the assessment of each policy area). A report presenting the outcome of the consultation was published on 27 July 2011 and contributions have been published online.[27]

Targeted discussions with stakeholders took place throughout the revision process. A first exchange of views with health NGOs, tobacco- and pharmaceutical industries took place on 3 and 4 December 2009 and on 19 and 20 October 2010 and discussions with NGOs, growers, FMC producers, other tobacco producers, distributors of tobacco products and upstream suppliers of tobacco products have continued throughout 2011 and 2012.[28]A number of written contributions were also received, which were carefully considered in assessing the impacts of different policy options. In particular, the criticism received in relation to the external study from RAND Europe (see below) was taken into account. Alternative data submitted by stakeholders was also carefully studied. The Commissioner for Health and Consumer Policy met with Health NGOs and economic stakeholders in February-March 2012.[29] The revision of TPD has also been discussed regularly in the **TPD Regulatory Committee** from 2009 to 2012.[30]

The policy area "**traceability and security features**" was added to the revision in response to concerns put forward by some stakeholders that the selling of contraband and counterfeit products not complying with the requirements of TPD is already today a significant problem.[31] For the purpose of this Directive the main concerns associated with illicit products is that these products are non-compliant with the safeguards of the TPD. A more detailed summary of stakeholders' positions in the context of the consultations can be found in Annex 1.

Inter Service Steering Group (ISSG)

An Inter Service Steering Group (ISSG) was established in March 2009 to support the work of DG SANCO. The following services were invited: SG, SJ, AIDCO, AGRI, COMP, DEV, EAC, ECFIN, ECHO, ELARG, EMPL, ENTR, ENV, MARE, INFSO, JLS, JRC, MARKT,

[25] For example, a campaign was organised by a group representing over 75% of Italian Tobacconists (European Voice, 10 February, 2011). This action was followed by over 30,000 submissions, including 99% duplicate responses from Italy

[26] Eurobarometer 2012

[27] Public Consultation Report 2011. In addition to the contributions received on-line, the contributions received through other formats from 20 Member States at the level of Governments or ministries as well as from two EFTA/EEA countries have been published on the same web site.

[28] Minutes for stakeholder meetings can be found at http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4 (accessed 28 Nov 2012).

[29] Idem.

[30] The minutes from the meetings can be found at: http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor0 (accessed 28 Nov 2012).

[31] It is important to underline that the preferred policy options do not – in the assessment of the Commission – lead to increased illicit trade. On the other hand, illicit trade accounts already for 8,25% of the current consumption (Euromonitor data as presented in Matrix 2012).

OLAF, REGIO, RELEX, RTD, TAXUD, TRADE and TREN.[32] The Group held 8 meetings: 5 March 2009, 26 November 2009, 2 July 2010, 18 April 2011, 3 October 2011, 1 March (information meeting and hand-out of draft Impact Assessment Report), 12 March 2012 and 19 July 2012. A meeting with associated services also took place on 30 November to present the legal proposal in the context of the inter-service consultation.

Expertise and input

A number of **external studies** have been commissioned to provide input to this impact assessment. First, a study on liability and the health costs of smoking was presented in December 2009. This study provided valuable input as far as the socioeconomic impacts of tobacco control policies are concerned. An updated version of this study was prepared in 2012.[33] Second, a study assessing the impacts of revising the TPD was presented in September 2010.[34] This report (by RAND Europe) was criticised by many stakeholders for its actual and perceived inaccuracies. In this respect, it is important to stress that this study has provided input to, but has not formed the exclusive basis of this impact assessment. The information was verified on the basis of other sources. Third, a study on novel and emerging tobacco, nicotine or related products was commissioned in 2010.[35] Fourth, a study on the economics of the EU market of tobacco, nicotine and related products was commissioned in September 2011 to fill some remaining data gaps.[36]

The Commission's independent Scientific Committee on Emerging and Newly Identified Health Risks (**SCENIHR**) has presented two opinions relevant to the impact assessment: one on smokeless tobacco in February 2008 and one on additives in tobacco products in November 2010.[37]

Finally, the **Eurobarometer** surveys conducted in October 2009 and February 2012 have been used to provide better insight on tobacco and nicotine use in the EU and on attitudes towards tobacco control policies.[38] In particular the last Eurobarometer showed increased public support for the policy measures envisaged in this impact assessment.

Invitations from European Parliament and the Council

Since October 2007, the European Parliament has repeatedly called on the Commission to present a proposal for an amendment of the TPD and consider measures on ingredients and sales arrangements.[39] A large number of questions on the TPD revision have also been received from the European Parliament during the past years.

The Council has twice invited the Commission to consider strengthening the tobacco control legislation and, in this context, to consider product related measures aimed at reducing the

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[32] Some of the DGs have changed since the launch of the ISSG
[33] GHK 2012
[34] Rand 2010
[35] Rand 2012
[36] Matrix 2012
[37] SCENIHR 2008, SCENIHR 2010
[38] Eurobarometer 2010, Eurobarometer 2012
[39] Resolution of 24 October 2007 on the Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level'. (2007/2105)
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0471+0+DOC+XML+V0//EN (accessed 28 Nov 2012).
Resolution of 26 November 2009 on smoke-free environments. (2009/2751)
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2009-100 (accessed 28 Nov 2012).
Resolution of 15 September 2011 on European Union position and commitment in advance to the UN high-level meeting on the prevention and control of non-communicable diseases. 2011/2802
http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0390&language=EN (accessed 28 Nov 2012).

attractiveness and addictiveness of tobacco products and to analyse the legal issues and the evidence base for the impact of plain packaging, including its effect on the functioning of the internal market.[40]

1.4. IMPACT ASSESSMENT BOARD

A first version of this impact assessment report was submitted to the Impact Assessment Board (IAB) on 21 March 2012. On 18 April 2012 DG SANCO representatives had a meeting with the Board and the written opinion of the Board was received on 20 April 2012. The opinion concluded that the draft report required further work and asked for resubmission. A second version was submitted to the Board in June 2012. The second opinion of the Board, of 12 July 2012, did not request a resubmission but made some further recommendations on how to improve it. The opinion criticised in particular the evidence base for the policy areas "display at PoS" and "STP", which were subsequently dropped/amended. The table below sets out the main comments of the second opinion of the Impact Assessment Board and describes how they have been reflected in this revised version of the report.

Main comments from the IAB	Revision of the draft IA Report
1. Better present the problem: -Present separately problems related to effectiveness, implementation, enforcement and currently non-harmonised areas. -Demonstrate recourse to Article 114 for non-harmonised areas, in particular for limitation of promotion at the PoS. -Clarify compatibility between inequality in health and Member States' competences in defining their health policies.	-Clearer references to effectiveness, implementation, enforcement and non-harmonised issues were introduced in the problem identification (2.2.1-2.2.5). -Internal market justifications were better explained under the problem identification (2.2.1-2.2.5). The policy areas on PoS and TVM were discarded (4.1). The preferred policy option for STP was amended. The section on the legal basis (2.4.1) was reviewed. -The references to equality were replaced by references to the objectives of Article 3 TEU (promote the well-being of its people) where relevant (for ex. 2.2). Health inequalities were, however, maintained as assessment criteria.
2. Develop a robust baseline scenario: -Explain foreseeable national actions in the context of FCTC. -Analyse further the likely take-up of STP, better explain circumvention possibilities of oral tobacco and acknowledge the uncertainty in relation to STP.	-National actions in the context of FCTC have been further explained under the baseline scenario (2.3.2). -The likely take-up of STP is described under the baseline scenario (2.3.3) and assessment of option 1(5.2.1). Circumvention is described in 2.2.1.
3. Better demonstrate the proportionality of policy options -Present measures going beyond current TPD and FCTC. -Discuss a wider range of discarded options. -Justify STP, NCP and cross-border distance sale preferred options and alternative ban-options. -Explain STP derogation, TVM verification and traceability obligations.	-A clarification of the options status in comparison with the current TPD and FCTC has been introduced in a table on TPD and FCTC commitments in Annex 3 (3.2). -A number of discarded options have been added to section 4. -The preferred option on cross-border distance sales have been further justified (5.5.4). New preferred options have been identified for STP (regulation of chewing and nasal tobacco, notification of novel tobacco products and maintaining the ban on oral tobacco, see 5.2.1), NCP (all NCP above a certain nicotine threshold are subject to the medicinal products legislation, see 5.2.2). -The definition of traditional use in the glossary was revised, but no longer part of preferred option (5.2.1). The policy area on TVM was discarded (4.1). Traceability obligations in the context of FCTC were clarified in section 2.1.4 and Annex 3.
4. Improve the assessment of impacts: -Better explain persisting divergences, in particular on ingredients. -Present discounted values. -Assess administrative costs for internet notifications.	-Divergences were better explained, for example under 5.4 on ingredients. -Discounted values are presented in section 5.7.2 and Annex 5. -Administrative costs for internet notifications are better explained under 5.5.1.

[40] Council Recommendation of 30 November 2009 on smoke-free environments. 2009/C 296/02. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:296:0004:0014:EN:PDF (accessed 28 Nov 2012). Council conclusions on Prevention, early diagnosis and treatment of chronic respiratory diseases in children. 16709/11. http://register.consilium.europa.eu/pdf/en/11/st16/st16709.en11.pdf (accessed 28 Nov 2012).

-Breakdown of overall health impacts. -Show where evidence is inconclusive. -Acknowledge trade-offs between internal market and health.	-Breakdown of health impacts are presented in more details under section 5.7 intro. -Evidence was reinforced and the conclusions to be drawn revisited, see for ex. STP baseline (2.3.3), plain packaging (5.3.3) and NCP impacts (5.7 intro) -Trade-offs are further clarified in the table under 6.1

2. PROBLEM DEFINITION

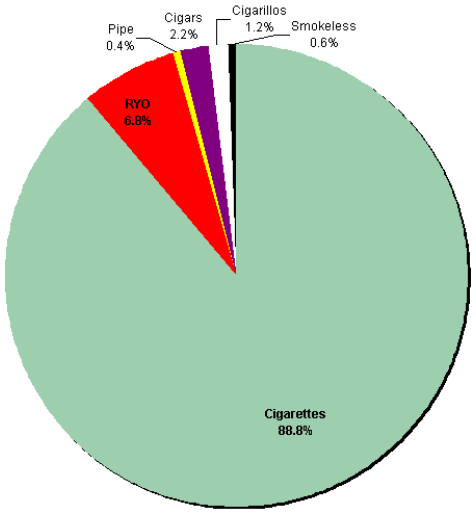
2.1. MARKET DESCRIPTION

1.1.6. Tobacco products market

a) Supply side

The total value of the tobacco market at retail level, including taxes and excise duties, is 136,5 bEUR and the market currently consists of five main categories of products[41]: 1) Factory manufactured cigarettes (FMC), 2) Roll-your own tobacco (RYO), 3) Pipe tobacco, 4) Cigars and cigarillos and 5) Smokeless tobacco products (STP) (oral, chewing and nasal tobacco). The value and volume of sales as well as manufacturing methods and consumption patterns differ significantly between the product categories.

Figure 1 : Comparison of relative market value of tobacco products in 2010



Source: Euromonitor and industry estimates

FMC represent almost 90% (121,3 bEUR) of the total tobacco market value and despite a decline in sales volumes over the last ten years, the overall market value has increased consistently over the same period. This is mainly due to the tax increases and continuous development of premium brands sold at higher prices. FMC manufacturing is increasingly in the hands of four large multinational companies (PMI, BAT, JT and IT) accounting for around 90% of the EU FMC market.

The FMC production is also highly concentrated in geographical terms, with only a few Member States (the United Kingdom, Netherlands and Germany) accounting for more than

[41] This categorisation is in line with the Commission's merger practice. It is important to underline that the notion of a market in this impact assessment is not based on competition law terminology.

50% of the total EU production.[42] American Blend (using a mixture of Burley, Oriental and Virginia leaves) accounts for 76% of the FMC market.[43]

The **RYO** market has increased significantly in recent years and accounts today for about 6,8% (9,3 bEUR) of the total tobacco market. This market is also characterised by strong presence of the four biggest FMC manufacturers (70% of the market), but to a lesser extent than FMC. The markets for **pipe tobacco, cigars, and cigarillos** are considerably smaller. These products as well as chewing and nasal tobacco products are to a large extent manufactured by SMEs.[44] The pipe tobacco and the cigar markets have been continuously declining in the last decade. The increase in cigarillo sales was partly driven by flourishing sales of so called eco-cigarillos which are not typical cigarillos and were recently re-classified as cigarettes.[45] The **STP** market is dominated by oral tobacco (snus) and concentrated to Sweden, the only Member State where the marketing of this product is allowed.[46] Chewing and nasal tobacco account for less than 0.1% of the total tobacco market and sales are concentrated to about 12 companies, mostly SMEs, who also sell other tobacco products.[47] Recent years have seen an increasing interest from bigger cigarette manufacturers to enter the STP market.[48] Novel categories of tobacco products are currently being developed but they are not yet placed on the EU market.[49] Most of these products are expected not to involve a combustion process and therefore would fall in the product category of STP.

Figure 2: **Market value and volume 2000-2010**

Category	**Value 2000** (bEUR)	**Value 2010** (bEUR)	**Change** (%)	**Vol. 2000** (bsticks/ttonnes)	**Vol. 2010** (bsticks/ttonnes)	**Change** (%)
FMC	90.7	121.3	+33.8	793.7 bs	608.8 bs	-23.3
RYO	4.2	9.3	+123	53.1 tt	75.5 tt	+42.2
Pipe	0.576	0.480	-17	6.33 tt	4.03 tt	-36
Cigars/cigarillos[50]	4.62	4.65	+0.6	7.81 bs	9.92 bs	+27
STP[51]	0.48	0.83	+73	5,3	5.9	+10

Source: Euromonitor. Nominal prices

In terms of **market development**, a significant diversification of products has taken place in recent years. For example, the main manufacturer of oral tobacco (snus) increased its portfolio from 22 to 180 brands between 2002 and 2008,[52] distinctive flavoured FMC such as "pina colada" and "chocolate" have been put on the market[53] and FMC with new technology

[42] Eurostat 2008/2009
[43] Euromonitor 2010 (Matrix 2012)
[44] European Smoking Tobacco Industry: Facts & Figures for DG Sanco, ESTA 2011-2012, ECMA, European Cigar Manufacturers Association, Facts and Figures
[45] Directive 2010/12/EC on the structure and rates of excise duty applied on manufactured tobacco. Germany and Hungary have been granted transitional periods until 2014.
[46] Marketing of oral tobacco is banned according to Article 8 of the current TPD and has been banned since 1992. Sweden and Norway were granted a permanent derogation from the ban received in their Accession Treaty; OJ C 241, 29.8.1994 (see article 151 and Annex XV thereof)
[47] European Smoking Tobacco Industry Facts & Figures for DG SANCO, ESTA 2011-2012
[48] In February 2009, Swedish Match entered a joint venture with Philip Morris International. The second largest producer of oral tobacco in Sweden, Fiedler and Lundgren, became part of the British American Tobacco Group in 2008.
[49] DG SANCO's meeting with PMI, 8 March 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120308_mi_en.pdf (accessed 28 Nov 2012).
[50] This covers also "eco-cigarillos" exempted from the definitions for cigars and cigarillos through Directive 2010/12/EC on the structure and rates of excise duty applied on manufactured tobacco.
[51] The data is limited to chewing tobacco in Denmark and Slovenia and oral and nasal tobacco (according to Euromonitor terminology snuff) in Germany, Sweden and Denmark
[52] Swedish Match magazine Inside #2 from May 2008
[53] Matrix 2012

including capsules filled with flavourings embedded in the filter have been introduced in many Member States.[54] New market strategies have also been developed, in particular as a result of the tobacco advertising ban/restrictions in Member States, including innovative packaging and promotion at point of sale.[55]

Illicit trade in FMC currently accounts for 8.25 % of total trade in the EU and is estimated to increase by 1 % per year in the next five years.[56] Three broad categories exist: contraband, counterfeit and cheap whites/illicit whites (see glossary). Typically, these products do not comply with the safeguards of the TPD.

In terms of **employment**, there were 48,500 persons employed in tobacco manufacturing in the EU in 2009.[57] In addition to this, Eurostat data indicates that there are 86,113 farmers.[58] In 2010, there were almost 100 first processors[59] of tobacco in the EU located close to the growers' areas, while the market of second processors[60] is in the hands of two global players[61] with similar market shares. 45,900 persons are employed in wholesale.[62] The retail sector differs widely between Member States, but according to the European retailer association (CEDT), there are almost 990,000 premises selling tobacco in the EU and around 230,000 of these are specialised shops which usually generate 45-50% of their turnover from tobacco.[63]

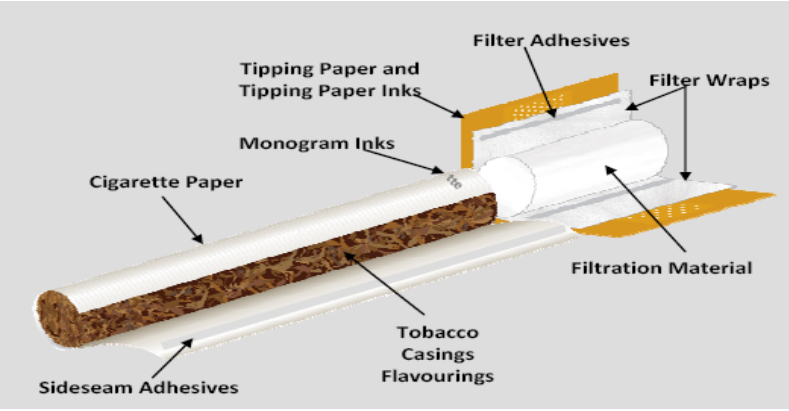
As far as **raw tobacco** is concerned, the EU was a net importer of around 430,000 tonnes (about 2/3 of the quantity needed) in 2010.[64] The EU tobacco production amounted to 294,000 tonnes. The production is often limited to small regions, very specialised and with large family labour requirements. Despite the fact that Virginia is the leading tobacco variety (46% of the EU production), most of the EU tobacco farmers (81%) are involved in labour intensive Burley and Oriental farming which is used in American blend cigarettes.[65] According to tobacco producers, adding certain substances, including sugar, is indispensable for the use of these tobacco varieties. This is because these varieties lose their sugar content during the drying process whereas other varieties (such as Virginia) keep it.

A number of **upstream actors** other than farmers and processors are also involved in the tobacco manufacturing process. These include suppliers of ingredients, cigarette papers, filters

[54] German Cancer Research Center (DKFZ). Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product. Heidelberg: DKFZ; 2012.
[55] Cancer Research UK. The packaging of tobacco products. Stirling: Centre for Tobacco Control Research, University of Stirling; 2012. Harper T. Why the tobacco industry fears point of sale display bans. Tob Control 2006;15(3):270-1.
[56] Euromonitor data presented in Matrix 2012. According to OLAF indications, the ratio between categories of illicit trade is 30 % contraband, 50 % counterfeit and 20 % illicit whites (for definitions, see glossary).
[57] Eurostat. http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Tobacco_processing_statistics_-_NACE_Rev._1.1 (accessed 6 Nov 2012)
[58] Economic stakeholders UNITAB and COPA estimate a number of 400.000 workers involved in growing in total (including family and seasonal working force.)
[59] The first processors collect the raw tobacco cured by farmers and make a first process before selling it to the industry producing FMC, cigars or manufactured tobacco. DG AGRI
[60] The second processors subsequently purchase, process, blend, pack, store and ship tobacco to meet each specifications of manufacturers of FMC and other tobacco products. DG AGRI
[61] Alliance One Int. and Universal Corporation
[62] Eurostat 2010. Bulgarian farmers represent 50% of the EU tobacco farmers, followed by Poland and Greece (both 17%)
[63] Tobacco Retailers Figures. CEDT (Confédération Européenne des Détaillants en Tabac). Sent to DG SANCO in January 2012
[64] Eurostat 2010
[65] Nomisma. The cultivation of tobacco in the European Union and the impact deriving from changes in Directive 2001/37/EC. Analyses of socio-economic impact. October 2010.

and packaging (see also figure 3). Based on industry reported data, the total value of those supplies is around 3 bEUR.

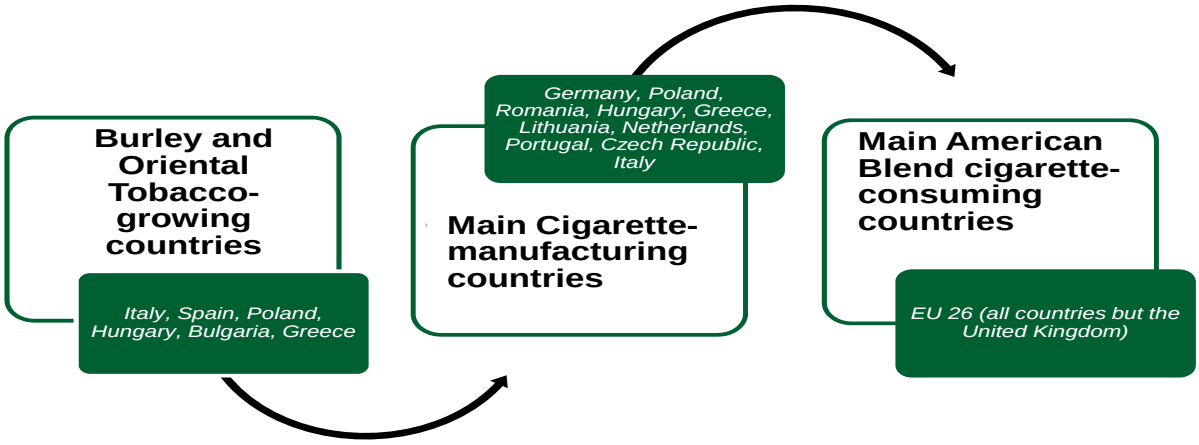
Figure 3: **Composition of a FMC**



Source: Background to Cigarette Manufacturing and Use of Additives.
Prepared by Philip Morris International Management S.A. 8 January 2010

The multinational dimension of the tobacco market combined with the geographic concentration of manufacturers and growers results in significant **cross-border trade**, both within the EU and with third countries. About 268,000 tonnes of raw tobacco were subject to internal trade between Member States in 2010 and the overall value of manufactured tobacco products traded across Member States' borders in 2010 was 9.5 bEUR.[66] Figure 4 illustrates the main intra-EU flows in the production of American blend cigarettes.

Figure 4: Trade flows between tobacco-growing, tobacco-producing and tobacco-consuming countries[67]



More than one third of tobacco products manufactured within the EU are sold across borders.[68] Figure 5 illustrates intra EU trade in tobacco, following the categories used by Eurostat.

[66] Eurostat (Procom) 2008
[67] Matrix 2012 based on information from the industry
[68] As indicated in Annex 5, the total value of the FMC and RYO is 18 bEUR (ex-manufacture price). Almost 8 bEUR (see figure 5) is subject to intra EU trade.

Figure 5: **Intra-EU trade in tobacco 2010**

Category	Value 2010 (bEUR)	Vol. 2010 (100kg)
Cigarettes (containing tobacco)	6.591	3,427,689
Cigars, Cheroots and Cigarillos (containing tobacco)	0.644	68,641
Cigars, Cheroots, Cigarillos and Cigarettes of tobacco substitutes	0.004	1,864
Smoking Tobacco (whether or not containing tobacco substitutes in any proportion)	1.058	970,327
Manufactured Tobacco, Extracts and Essences, N.E.S.	0.279	639,322
Total Manufactured Tobacco (whether or not containing tobacco substitutes)	**8.576**	**5,107,843**

Source: Eurostat intra-EU trade figures

As regards trade between the EU and third countries, the total import to the EU of manufactured tobacco is less than 200mEUR, whilst the export of FMC and other manufactured tobacco products outside the EU accounts for 2.5 bEUR, i.e. a positive trade balance of 2.3 bEUR. On the other hand, import of unmanufactured tobacco (both raw and processed) counts for 2.17 bEUR, while the export accounts for 670 mEUR, what results in a trade deficit of 1.5 bEUR. For more details on the tobacco market and the manufacturing process, see Annex 2.

b) Demand side

According to the latest Eurobarometer **28 % of all EU citizens** and 29 % of young people (aged 15-24 years) smoked in 2012.[69] FMC is the most widely used tobacco product. 70% of the smokers start before the age of 18 and 94% under the age of 25. The overall smoking prevalence differs widely between Member States and ranges from 13% to 40%. Menthol cigarettes account in the EU, for approximately 4% of the EU market, ranging from 25% in Finland to 0.1% in Greece. Cigars and pipes are smoked far less than FMC and tend to be smoked occasionally rather than daily and mostly by older individuals. STP use is most common in Sweden, where around 12% of the population uses STP (mainly oral tobacco/snus) on a regular basis, compared to 2% or less in other EU countries where marketing of oral tobacco is banned, but chewing and nasal tobacco is allowed. The figure is higher if one considers all citizens who have at least tried STP. Chewing tobacco appears to have most users in Denmark and nasal tobacco is mainly used in Germany. Some industry players see a significant growth potential for STP as well as NCP, also in the light of smoke free environments. Figure 6 indicates the trends in smoking prevalence 2006-2012 and STP use 2009-2012.

Figure 6: Smoking Prevalence 2006-2012 and STP use 2009-2012

STP		2009	2012
Regular Users		**Na**	**1%**
Proportion who have tried STP	**EU 27**	**6%**	**7%**
	DK	12%	15%
	FI	20%	13%

[69] Eurobarometer 2012

Smoking tobacco		2006	2009	2012
Smokers		**32%**	**29%**	**28%**
Proportion of smokers who use daily	**FMC**		79%	80%
	RYO		15%	20%
	Cigars		1%	1%
	Pipe		1%	1%

	SE	39%	44%

Source: Eurobarometer

More than six out of ten smokers in the EU have tried to quit, with two out of ten in the previous twelve months.[70] Personal health concerns are the main motivation to quit. While the number of smokers in the EU, and with this also the smoking prevalence, has decreased in the past decades, some Member States have seen an **upwards trend** in young people since 2005. The Health Behaviour in School-aged Children (HBSC) study of WHO Europe from 2012 indicates an increase in smoking prevalence in 14 Member States for 15 year old boys and in nine Member States for 15 year old girls. [71]

According to the 2012 Eurobarometer,[72] smokers and non-smokers commonly **perceive** FMC with lower tar or nicotine levels to be less harmful. The most important factor in choosing a FMC brand is the taste of tobacco (84%), followed by the brand itself (69%) and price (65%), but packaging (23%) and specific tastes (such as menthol, spicy, fruity or sweet) (32%) are also important. Peer group pressure/behaviour is obviously the most important factor for smoking initiation. EU citizens, including smokers, are largely and increasingly in favour of various tobacco control measures. For example, three out of four citizens support putting pictorial health warnings on all tobacco product packages. A third of smokers and ex-smokers also say that health warnings had an impact on their attitudes and behaviours towards smoking.

Most EU citizens who smoke or have smoked **purchase** regularly their cigarettes in a specialised tobacco shop (37%), from a newsagent (26%) a supermarket (22%) or a convenience store (20%). 10% of EU citizens purchase their tobacco from TVM (mounting to 15% in Member States where TVM were accessible). Only 10 EU citizens in 100 report that they have purchased tobacco products in a country other than their country of residence in the past 12 months.[73] Cross border purchases via the internet are also limited (according to self-reporting). However, taking into account the increased use of e-commerce in other sectors, it appears likely that the market segment will grow.

1.1.7. The role of tobacco in the society

Tobacco is a legal product on the EU's internal market, but is **no ordinary commodity** in the sense that it is the largest avoidable health threat in the EU, responsible for almost 700,000 deaths in the EU each year (see Annex 5). Moreover, millions of people in the EU suffer from one or more of the six main disease categories associated with smoking: 1) Bronchitis and other lower respiratory infections, 2) Chronic obstructive pulmonary diseases, 3) Stroke, heart attacks, arterial obstructions (especially in the legs) and other cardiovascular diseases, 4)

[70] Eurobarometer 2012

[71] Currie C, Zanotti C, Morgan A, Currie D, de Looze M, Roberts C, et al., eds. Social determinants of health and well-being among young people. Health Behaviour in School-aged Children (HBSC) study: international report from the 2009/2010 survey. Copenhagen: WHO Regional Office for Europe; 2012. Prevalence increased for boys in: AT, CZ, FR, HE, HU, IT, LV, LT, LU, PT, RO, SK, ES and SE. Prevalence increased for girls in: CZ, HU, IT, LT, RO, SK, SI, ES and SE.

[72] Eurobarometer 2012

[73] Idem.

Asthma, 5) Lung cancers and 6) Other cancers, such as pancreas, oesophagus, and stomach. Studies show that around 50% of smokers die prematurely and if they do so they die on average 14 years earlier. In addition, smokers have more life years that are characterised by serious disease.[74]

In addition to measures at EU and international level, strong **tobacco control policies** are pursued by Member States to address the harmful effects of tobacco and to protect public health. It is commonly agreed among tobacco control regulators that only a comprehensive set of continuously updated and adapted measures (e.g. price/taxation, smoke-free environments, advertising bans, labelling, ingredients regulations, information campaigns) is effective to reduce smoking prevalence over time, including reduced uptake among young people.

Tobacco consumption also has important **economic implications** for society and is associated with important expenditures/costs. Annual EU public healthcare expenditure on treating smoking attributable diseases is estimated around 25.3 bEUR and society loses 8.3 bEUR per annum due to productivity losses (including early retirements/deaths and absenteeism) linked to smoking. In addition, if monetised, the life years lost due to smoking correspond to 517 bEUR every year. Figure 7 summarizes the costs associated with smoking in table format.

Figure 7: Costs associated with smoking in EU27 in mEUR

Monetary value of life years lost	Smoking induced health care costs	Smoking induced early retirements	Smoking-induced absenteeism
516,713	25,300	6,081	2,162

On the other hand, revenue from excise duty on the sale of tobacco product in the EU exceeded 79 bEUR in 2010, contributing to almost 3% of the total Government revenue.[75] For more detailed information on economic impacts on the society, see Annex 5 (A5.2.3).

1.1.8. Non-tobacco products

Nicotine Containing Products (NCP)

In addition to the traditional tobacco market, recent years have seen the emergence of new nicotine containing products (NCP) marketed primarily as consumer/leisure products. Electronic cigarettes appear to be the most commonly available type.

The EU **electronic cigarette** industry is still quite fragmented and the absence of reliable trade statistics makes it difficult to summarise and analyse in terms of market size and value.[76] However, it can be concluded that the market is growing rapidly. An electronic cigarette supplier has estimates that the current value of the German market is around 100 mEUR and that the total value of the EU27 e-cigarette market (including devices and refills) is between 400 and 500 mEUR.[77] The Electronic Cigarette Industry Trade Association (ECITA)

[74] Bronnum-Hansen H, Juel K. Abstention from smoking extends life and compresses morbidity: a population based study of health expectancy among smokers and never-smokers in Denmark. Tobacco Control 2001; 10: 273-8. Nusselder WJ, Looman CW, Marang-van de Mheen PJ, van de Mheen H, Mackenbach JP. Smoking and the compression of morbidity. J Epid Comm Health 2000; 54: 566-74. Klijs B, Mackenbach JP, Kunst AE. Obesity, smoking, alcohol consumption and years lived with disability: a Sullivan life table approach. BMC Public Health 2011; 11:378.

[75] EC, DG Taxud. 2010 For the purpose of this impact assessment, VAT has been excluded from the analysis as money not spent on tobacco will be spent on other goods attracting VAT. In this respect, any measure should be VAT neutral.

[76] See Matrix 2012

[77] Matrix 2012

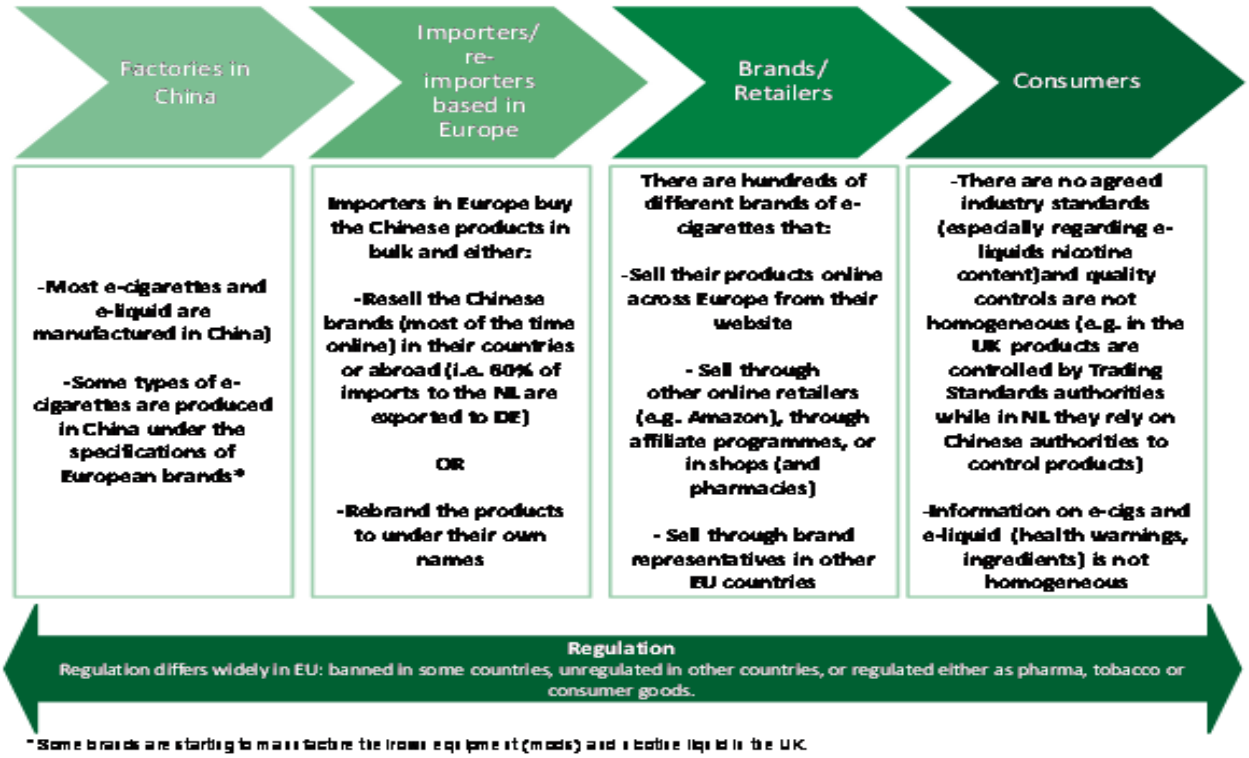
estimates that they represent 60-70% of the volumes sold on the UK market and reports that the market is growing 20-30% monthly.[78]

The EU market is mainly composed of distributors rather than manufacturers and dominated by small enterprises, although there is a growing interest from bigger cigarette manufacturers (including the big four FMC producers) to enter the market.[79]

Most of electronic cigarettes are produced in China. Once imported into the EU, they are subject to significant cross-border trade. For example, in the Netherlands vendors of electronic cigarettes are reported to operate as a hub, reselling most of the electronic cigarettes they import from China to the rest of Europe. Around 20% of their sales are internal to the Dutch market, while around 60% are sold to German vendors and the remaining 20% to vendors in Denmark, Spain, France, Austria and Switzerland.[80]

Figure 8: Value chain of the e-cigarette market in Europe

[78] DG SANCO meeting with ECITA, 20 June 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf (accessed 28 Nov 2012).
[79] Niconovum. Press Room. Helsingborg; Niconovum; 2012. http://www.niconovum.se/Press.aspx (accessed 28 Nov 2012)., Thomas R. Cigarette giant to offer 'safer alternative.' England and Wales: Nicoventures; 2011. http://www.nicoventures.co.uk/Content/Downloads/august-2011/PM_Aug_p2.PDF (accessed 28 Nov 2012).
[80] Matrix 2012. Based on information from the Dutch e-cigarette consumer association.

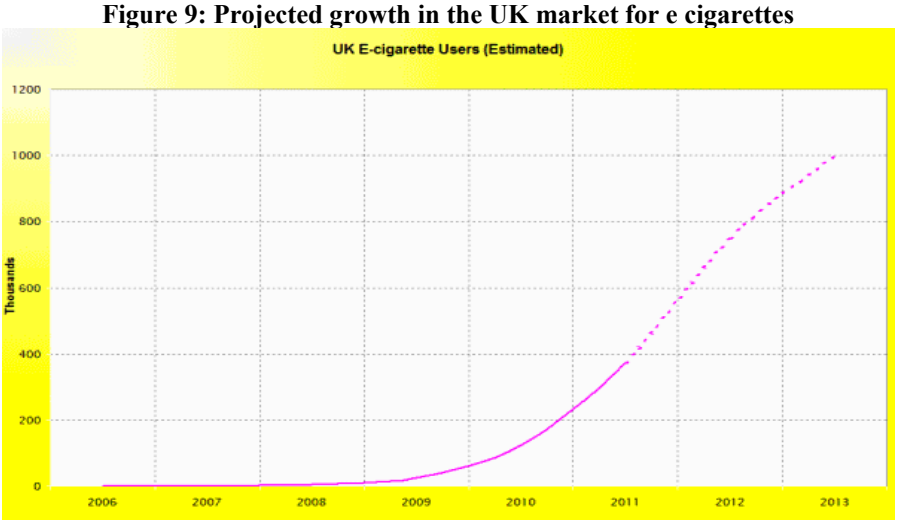


*Some brands are starting to manufacture the frame equipment (mods) and bottle liquid in the UK

Source: Matrix Insight

As for the demand side, the current use of NCP is growing quickly. 7% of EU citizens have reported in the latest Eurobarometer that they have at least tried electronic cigarettes.[81] In the UK an increase in the number of electronic cigarette owners has been estimated from a small number in 2006 to over 1 million by 2013.

Figure 9: Projected growth in the UK market for e cigarettes



Source: Matrix insight 2012

Electronic cigarettes are widely advertised on the internet. A study monitoring Google search queries from January 2008 to September 2012 reported that online interest in electronic cigarettes has surpassed that of oral tobacco (snus) and nicotine replacement therapies.[82]

[81] Eurobarometer 2012

[82] Ayers JW, Ribisl KM, Brownstein JS. Tracking the rise in popularity of electronic nicotine delivery systems (electronic cigarettes) using search query surveillance, Am J Prev Med, 2011; 40(4):448-453.

Electronic cigarettes are most often marketed by their producers as an alternative to FMC rather than a smoking cessation aid.[83] There are limited data available at this stage why people use electronic cigarettes. However, according to a recent survey among electronic cigarette **users** in Poland, most used the product primarily to quit smoking or to reduce harm associated with smoking (both 41%).[84] An online survey of more than 3500 e-cigarette smokers found that the vast majority of respondents were using e-cigarettes to quit smoking or reduce their smoking (92%) and a large proportion felt these products were less toxic than traditional tobacco products (84%).[85] These studies are well in line with information received from the Electronic Cigarette Industry Trade Association (ECITA), namely that the "vast majority of consumers" use e-cigarettes as a harm reduction alternative to smoking/a substitute for FMC/for smoking cessation purposes and that many use them to get around smoke-free environments (including lorry drivers).[86] Due to the high numbers of possible flavours, ECITA has also reported that e-cigarettes would be used as a "fun product" (annual "vape festivals").[87] In terms of age of the users, ECITA has stated that statistics show that the proportion of users under 20 is low but they cannot exclude that young people or minors might use the products, although they believe that the comparatively high start-up costs, together with a lack of peer pressure would make this unlikely.[88] The previously mentioned Polish survey also found that one in five young people had tested electronic cigarettes.[89] As explained in subsequent sections of this report, the regulatory framework for electronic cigarettes and other NCP is complex and varies between Member States and a number of health and safety concerns are associated with the products. **NCP other than electronic cigarettes** appear, at this stage, to be less common on the EU market.

Herbal products for smoking

Euromonitor data indicate that herbal cigarettes were sold in significant amounts in seven Member States over the period 2000-2010. The overall size of the market grew from around 40.6 million units in 2000 to 50 million units in 2010, an increase of around 23%.[90] These products are often marketed as "healthier" and natural products with "no additives", which gives the impression that these products are not harmful.[91]

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[83] Products marketed as smoking cessation aid would fall under the pharmaceutical framework and would need a prior authorization before being put on the market. ECITA explicitly advises its members to refrain from claims such as "quitting smoking" or satisfying cravings" (MOCK Audit Report shared with DG SANCO).

[84] Goniewicz ML, Lingas EO, Hajek P. Patterns of electronic cigarette use and user beliefs about their safety and benefits: An Internet survey. Drug Alcohol Rev 2012.

[85] Etter JF, Bullen, C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. Addiction 2011; 106: 2017–28.

[86] DG SANCO meeting with ECITA, 20 June 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf (accessed 28 Nov 2012).

[87] Idem.

[88] Idem.

[89] Goniewicz ML, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. Pediatrics 2012;130(4):e879-85.

[90] Matrix 2012

[91] Honeyrose. Stop smoking. Ipswich: Honeyrose Products Ltd; 2012. http://www.honeyrose.co.uk/stop.html (accessed 28 Nov 2012). Holland and Barrett. Herbal cigarettes. Nuneaton: Holland and Barrett; 2012. http://www.hollandandbarrett.com/pages/categories.asp?cid=313 (accessed 28 Nov 2012).

1.1.9. Regulatory framework

2.1.1.1. Tobacco control in the EU

Since the 1980s, there have been legislative initiatives in the EU to ensure harmonised product regulation for tobacco whilst also ensuring a high level of health protection. Today, the TPD constitutes, together with the Tobacco Advertising Directive from 2003,[92] the key legislation in the field of tobacco in the EU. The content of the current TPD is described in section 1.2. The Tobacco Advertising Directive bans all forms of cross-border advertising in printed media, information society services, radio and sponsorships of events.

These two main Directives are complemented by two non-binding Council Recommendations: one on the prevention of smoking and on initiatives to improve tobacco control from 2003 and one on smoke-free environments from 2009.[93]

Awareness-raising activities are also important instruments in EU's tobacco control policy. The current campaign (Ex-smokers are Unstoppable) was launched on 16 June 2011 to encourage young adults in the 25 to 34 age group to stop smoking. The previous campaign, "HELP – For a life without tobacco ", which ran from 2005 to 2010, was focused on smoking prevention, cessation, and passive smoking, targeting young Europeans between 15 and 25 years of age.

Measures to regulate and control tobacco are not only initiatives by DG SANCO. Tobacco is a cross-cutting issue which affects numerous policy areas. High taxes on tobacco products are generally seen as a very effective means to reduce tobacco use, with a particularly big impact on young people and people with lower incomes. Council Directive 2011/64/EU amends the structure and rates of excise duty on manufactured tobacco in the EU and in this context more convergence and further increases of tobacco taxes can be expected in the EU. The European Anti-Fraud Office (OLAF) investigates cases of illicit tobacco trade, which deprive Governments of significant tax revenues and undercut the prices charged by legal traders. In the area of advertising, the Audiovisual Media Services Directive [94] complements the EU legislation on tobacco advertising, by providing a ban on all forms of audiovisual commercial communications, including product placement as regards tobacco. Direct tobacco subsidies to growers were once an important but controversial part of the EU's agricultural policy. They have now been phased out, but were partially replaced by other subsidies. The Commission (DG EMPL) is also considering measures addressing the risks of employees arising from exposure to environmental tobacco smoke at the workplace.

The EU also works with international partners to reduce the consumption of tobacco worldwide, including in the context of the WHO Framework Convention on Tobacco Control (FCTC) (see 2.1.4.2).

All the instruments described in this section are mutually reinforcing and play an important role in the comprehensive tobacco control policy.

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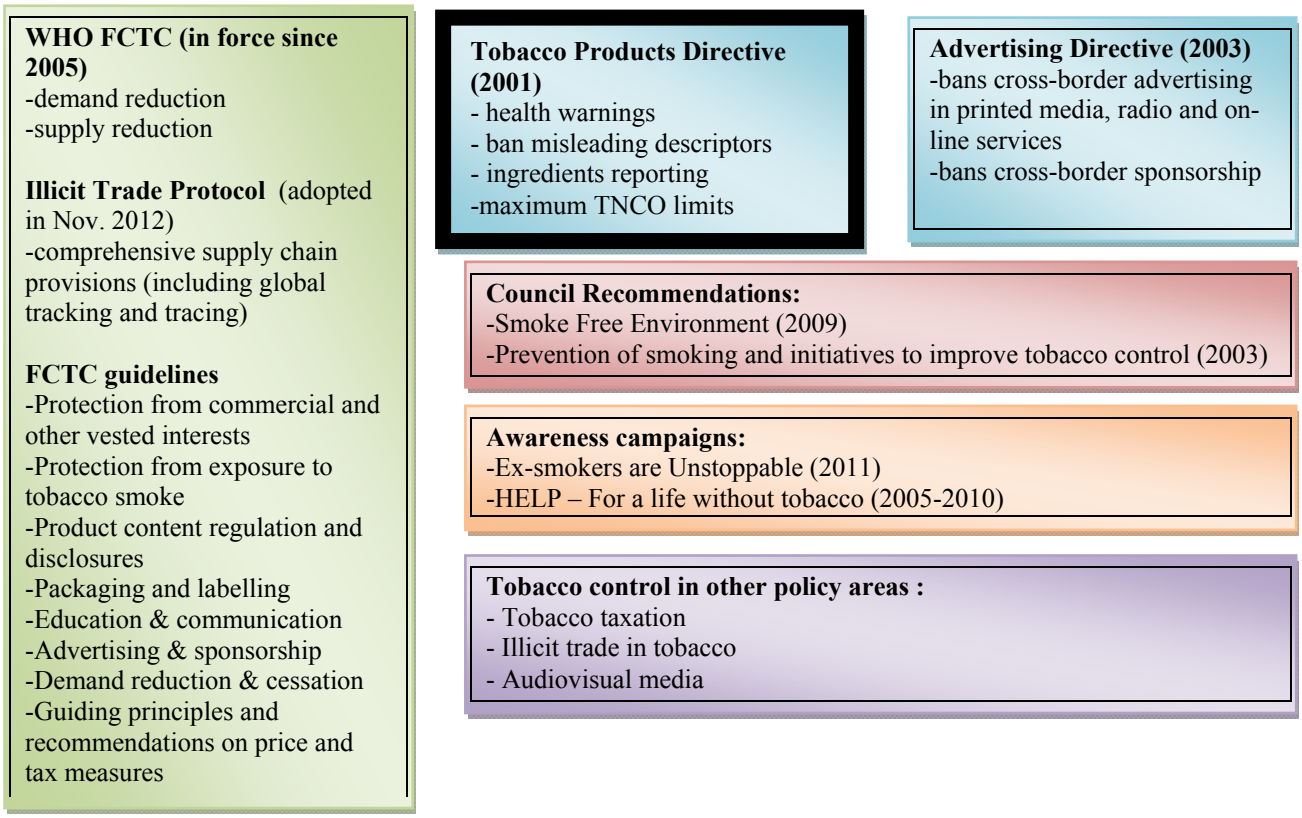
[92] Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products

[93] Council Recommendation 2003/54 of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control and Council Recommendation of 30 November 2009 on smoke-free environments, (2009/C 296/02)

[94] OJ L 95/1 of 15.4.2010

Figure 10: Tobacco control in the EU



2.1.1.2. Obligations in the context of the WHO FCTC

The WHO Framework Convention on Tobacco Control (FCTC) was adopted by the World Health Assembly in May 2003 and is the first ever international treaty on public health developed in response to the globalisation of tobacco consumption. The FCTC includes both demand reduction provisions (such as price and tax measures, protection from exposure to tobacco smoke, content and disclosure of tobacco products, packaging and labelling, education and communication, advertising, promotion and sponsorship) and supply reduction provisions (such as illicit trade, sales to and by minors and support for economically viable alternative activities).

The FCTC is a legally binding instrument which needs to be implemented and enforced by all Parties having ratified the Convention (so far over 170 countries across the world), including the EU and its Member States. At the time of the final approval of the FCTC it was considered that both the EU and Member States have competence in certain areas covered by the Convention (mixed agreement) and need to work together on the uniform application.[95] A legally binding Illicit Trade Protocol based on Article 15 of the FCTC was adopted by the Conference of the Parties to the FCTC in November 2012. The EU and the Member States are expected to become Parties to this new instrument (as is the case for the FCTC). 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

[95] See Council Decision concerning the conclusion of the WHO Framework Convention on Tobacco Control (2004/513/EC), recital 4. See also Annex II thereof referring to Community competence in areas covered by Community legislation, including TPD.

duty free sales, of internet sales and of free zones and a tracking and tracing system. Seven sets of guidelines have also been adopted (by consensus) to assist Parties in meeting their implementation obligations under the FCTC (figure 11). The guidelines, while not legally binding, give an indication of Parties' political commitments under the FCTC. In general, the guidelines are more far reaching than the FCTC and reflect scientific developments in tobacco control. For the purpose of this impact assessment, a distinction has been made between the binding "FCTC obligations" and the political "commitments" contained in the guidelines.

For the purpose of the revision of the TPD, it is relevant to distinguish between the following categories of obligations and commitments stemming from the FCTC:

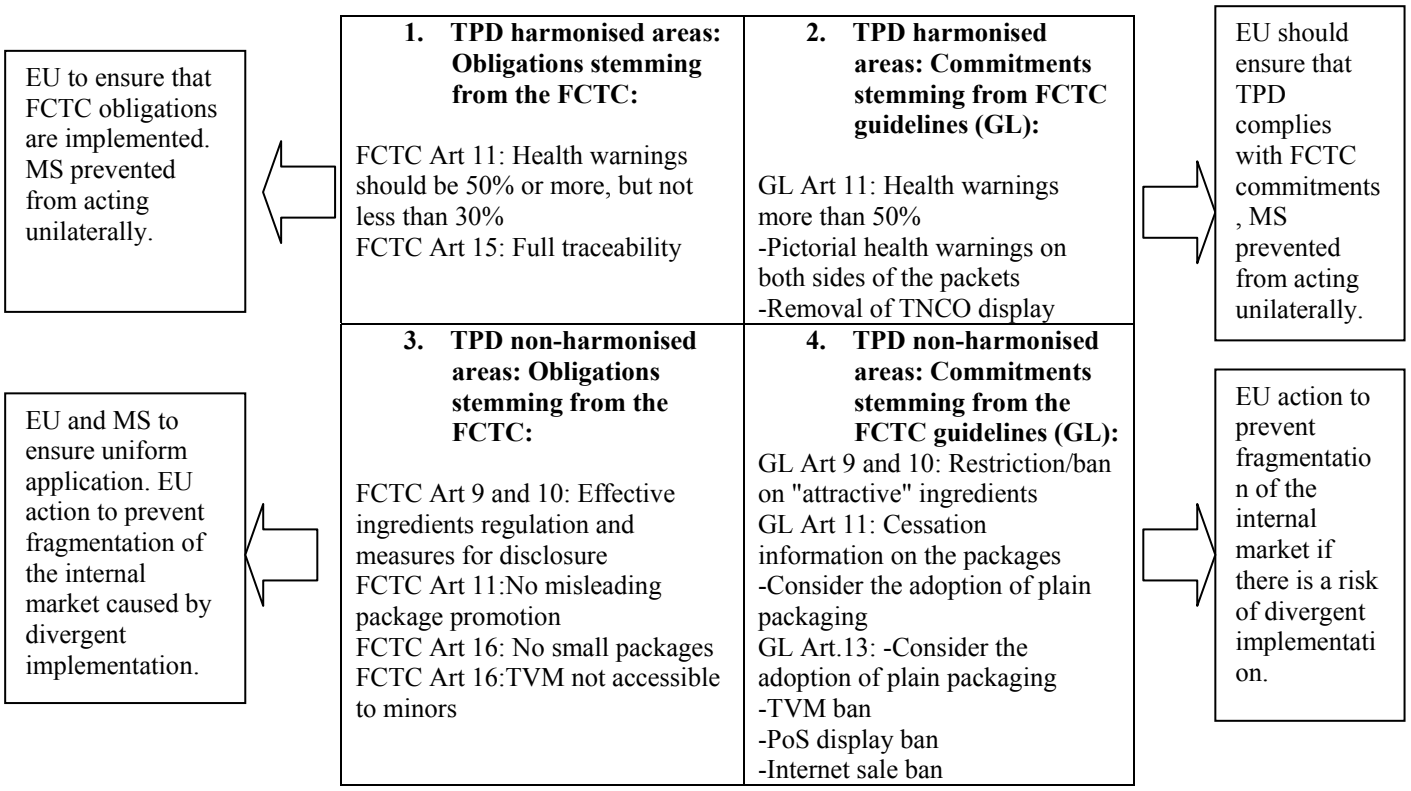
1. **Harmonised areas at EU level: obligations at EU level stemming from the *legally binding FCTC*:**
   The EU (as Party to the FCTC) has an international law obligation to ensure that the TPD provisions comply with the FCTC. Member States are bound by the TPD and cannot take action at national level. The Illicit Trade Protocol will also be a legally binding Treaty once adopted and entered into force. However it is not further considered in the context of this Impact Assessment.

2. **Harmonised areas at EU level: commitments at EU level stemming from the *non-binding FCTC guidelines*:**
   The EU should ensure that TPD reflects new developments based on scientific facts and internationally agreed product standards (TPD Article 11). Member States are bound by the TPD (where it allows no discretion to the Member States) and cannot take action at national level.

3. **Non-harmonised areas at EU level: obligations stemming from the *legally binding FCTC*:**
   The EU and its Member States are legally bound by the FCTC obligations and shall work together to ensure uniform application/avoid fragmentation of the internal market.

4. **Non-harmonised areas at EU level: commitments stemming from the *non-binding FCTC guidelines***
   The EU and the Member States have expressed their (political) support for the FCTC guidelines, but have no legal obligations to implement them. EU action is justified if divergent implementation in Member States leads to (or is likely to lead to) fragmentation of the internal market.

Figure 11: Obligations in the context of FCTC in harmonised and non-harmonised areas



Annex 3 gives a more detailed description of developments and plans in Member States as well as the links between the TPD and FCTC (A.3.2).

2.2. PROBLEM IDENTIFICATION

Market developments, such as the appearance of new products (e.g. electronic cigarettes) and new market strategies (e.g. appealing packages and flavoured tobacco products) have taken place in recent years. The same is true for **scientific development** (e.g. SCENIHR opinions). In terms of **international obligations**, the FCTC was concluded after the adoption of the current TPD, which was later supplemented by guidelines. In particular the guidelines leave Member States with substantial discretion in terms of implementation. This could lead to heterogeneous development in Member States and have a negative effect on the internal market, in general, and, in particular, in Commission legislative proposal in the field of internal market .

The lack of EU action negatively affects EU **citizens** in terms of premature mortality, expensive health care treatment and inadequate consumer information. This is not in line with the overall aim of the EU to promote the wellbeing of its people (TEU Article 3) nor with TFEU Articles 168(1) and 114(3) which foresee a high level of health protection in all EU policies and activities.

Economic stakeholders have referred to some shortcomings with the current TPD (e.g. on the lack of a common ingredients reporting format) and the tobacco industry stressed that they

are not against a revision of the TPD if it improves the functioning of the internal market.[96] The industry has also drawn the attention of the Commission to the risks associated with increased illicit trade. However, in general, the industry does not support further harmonisation, possibly in the fear of stricter regulation ("high level of public health"), although one company interviewed in the context of the revision stated that a single regulation on ingredients across EU might be less expensive than the continuous adaptation to national provisions, as long as the regulation is proportionate and science based.[97] The tobacco industry, in particular Swedish Match, has also asked for the lifting of the ban on oral tobacco. They strongly oppose measures such as plain packaging and display ban at point of sale (PoS). The **health NGOs**, on the other hand called for stricter measures in particular with respect to labelling and ingredients. They requested that the ban on oral tobacco (snus) is not lifted and that stricter measures for chewing and nasal tobacco are introduced. They also called for strict regulation of NCP and supported measures against illicit/non-compliant products. For further details, see Annex 1.

1.1.1. Problem 1: Smokeless tobacco and extension of the product scope

a) Smokeless tobacco products (STP)

Within the category of STP, the placing on the marketing of oral tobacco was banned in the EU in 1992 and this ban was maintained in the TPD in 2001 to stop the expansion of a product considered harmful to health, attractive to young people and new on the markets of all Member States.[98] Before the ban, Member States had started to take individual action, which in 1992 was replaced by action at the Community level. The producers of oral tobacco argue that the ban on oral tobacco is no longer appropriate. The health NGOs and most Member States are of a different view. This section also raises the question whether the current labelling requirements for all STP (Art 5(4) TPD) and ingredients regulation (reporting) are still adequate/sufficient, taking into account the high number of new products which are now marketed/attractive to young people.

- ***Effectiveness of the current TPD***

<u>General problems related to all STP</u>

The current regulation of STP does not effectively address recent and foreseeable market developments. When the current regulation on STP (including the ban on oral tobacco) was introduced in 1992 and confirmed in 2001, chewing and nasal tobacco products were seen as traditional products on a declining market with virtually no market outside certain socio-professional groups (seafarers, miners and sectors of the army) and regions.[99] The situation has somewhat changed since the current TPD was adopted. Recent years have seen an increase in the sale of chewing tobacco as well as a modest increase in sale of nasal tobacco on the main markets concerned.[100] Chewing and nasal tobacco products are subject to

[96] Minutes from the meeting with FMC manufacturers, 2 December 2011: http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4 (accessed 28 Nov 2012).
[97] Matrix 2012
[98] OJ L 158. 11.06.1992. p30-33/ Council Directive 92/41/EEC on 15 May 1992 amending Directive 89/622/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products. See whereas clauses. Sweden has an exemption from the ban granted in its Accession Treaty (see article 151 and Annex XV thereof)), OJ C 241, 29.8.1994.
[99] OJ C 150 E. 30.5.2006. p 43-51. COM (1999) 594 final. 16.11.1999. 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 labelling of tobacco products. See explanatory memorandum.
[100] Euromonitor data indicates an increase in the sale of chewing tobacco from 4 tons to 14.2 tons between 2000 and 2010 in Denmark. Sales of nasal tobacco in Germany saw a small decrease in the beginning of the century,

cross-border trade, including via the internet, meaning that they can reach new user groups and new geographical markets.[101] However, one chewing tobacco manufacturer has reported a greater potential for growth as more restrictions are put in place for smoking tobacco products as STP provides an alternative to be used where smoking is not allowed.[102] The production method (partly done by hand) of traditional chewing tobacco and the relative expensiveness of the products is also an important factor in determining the market potential.

In addition, there has been an important **product development** in STP (both as regards chewing and nasal tobacco and as regards oral tobacco limited to the Swedish market). As indicated in the market description (section 2.1.1), the main manufacturer of oral tobacco (snus) increased its portfolio from 22 to 180 brands between 2002 and 2008.[103] New market strategies target consumers outside the distinctive population groups who traditionally used these products, including young people. For example, there are STP available which are especially developed for modern taste or a younger generation. STP with characterising flavours (including chewing tobacco with tropical or bergamot flavours, nasal tobacco with peanut butter or cheese and bacon flavour and oral tobacco with elderflower and rhubarb taste) are put on the market and nasal tobacco has recently been promoted at youth parties throughout Germany. The packaging and labelling has also become more attractive masking the health risks associated with these products. In this light some Member States have taken action and banned STP all together leading to discrepancy between national markets (see Annex 3). The accession country Iceland is also reflecting about the introduction of a ban on chewing and nasal tobacco.[104]

The current labelling requirements for STP (oral, nasal and chewing tobacco) do not adequately inform consumers about the adverse health effects of STP. In particular, the current warnings lack visibility as they are required on one side of the package only and are often placed on the bottom of the packet.[105] One of the countries (Norway) responding to the public consultation has argued that the current **health warning** on STP (including oral tobacco) is outdated, insufficient and needs to be strengthened. However, Norway cannot take action at national level due to the current TPD requirements (TPD Article 5(4)) which applies to this country through the EEA Agreement.[106]

In terms of health, there are considerable differences between various types of STP, but all STP contain nicotine and are addictive. While according to a relatively recent SCENIHR opinion (2008) STP are less harmful than for example FMC, the report also concluded that STP are not harmless. This is in line with the assessment of IARC, that has classified STP as carcinogenic to humans. These products contain carcinogenic substances, albeit at different levels, and are associated with a number of adverse health effects. The health effects,

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but the trend has reversed in recent years, from 168 tons 2008 to 170 tons in 2011. (Matrix 2012). The trend in chewing tobacco is fully in line with data reported by one manufacturer of chewing tobacco. Other stakeholders involved in chewing and nasal tobacco were not able to provide the Commission with specific data showing the development of the market from 2000 to 2010 despite several reminders.

[101] There are no exact figures on cross-border trade in STP trade available, but indications that such trade exists are available on a number of websites.

[102] SANCO meeting with Oliver Twist, 19 July 2012.

[103] Swedish Match magazine Inside #2 from May 2008

[104] Fontaine P. Ban on snuff a possibility. The Reykavik Grapevine 2012 Jul 17. http://grapevine.is/News/ReadArticle/Ban-On-Snuff-A-Possibility (accessed 28 Nov 2012).

[105] Swedish National Institute of Public Health (FHI). Public Consultation. Possible revision of the Tobacco products directive. Ostersund: FHI; 2010. http://www.fhi.se/Documents/Om-oss/remisser/2010/Remissyttrande-tobacco-products-directiveVERK-2010-546.pdf (accessed 28 Nov 2012).

[106] Comment on the Consultation on the possible Revision of the Tobacco Products Directive 2001/37/EC by the Norwegian ministry of Health and Care Services, December 2010.

including findings from more recent studies, are further developed in section 5.2.1, assessing the impacts of lifting the ban on oral tobacco.

Oral tobacco (snus)

There are divergent views among stakeholders whether the current ban of placing on the market of oral tobacco is justified and whether the ban should be maintained, extended to other STP or lifted. Economic stakeholders, in particular those producing oral tobacco (snus), like Swedish Match, and citizens responding to the public consultation have argued that the ban of oral tobacco is no longer justified considering that oral tobacco is less harmful than FMC and also less harmful than other STP (chewing and nasal tobacco) which are not banned. These stakeholders also claim that oral tobacco can be used for smoking cessation. Other stakeholders, including most Member States and health NGOs, have defended the current ban and/or argued for an extension of the ban to all STP. The main arguments from these stakeholders relate to concerns about the harmful health effects of STP, the risk of STP as a gateway to FMC consumption and the risk of dual use (i.e. consumption of both cigarettes and snus). It was also argued that all STP need to be banned while these products still have relatively limited market shares as the supply of novel forms of STP is likely to increase. Respondents within this category also pointed to the fact that STP cannot be seen as an effective substitute for FMC.

The main producer of oral tobacco in the EU, has also claimed that the **different treatment of oral tobacco and chewing tobacco is discriminatory.** The producer has pointed to the huge marketing potential for oral tobacco (snus) outside Sweden and indicated that the current ban is equal to a hypothetical annual loss in export revenues to at least 3 bEUR and in the most optimistic scenario the market could even reach 9 bEUR per year.[107] The marketing potential for oral tobacco has increased significantly in recent years as STP is a means to consume tobacco/nicotine in public places where smoking is forbidden. Manufacturing of some other STP requires manual labour which significantly limits the growth potential. Also, this type of STP is produced by a very limited number of SMEs who do not have the market power to export into new markets where the products have no traditional use.

The authorities of the autonomous **Finnish island Åland** have argued in their submission to the public consultation on the revision of the Tobacco Products Directive (TPD) that the current ban on oral tobacco distorts competition. Ships under Swedish flag would be allowed to sell oral tobacco (snus), whilst vessels under the flags of Finland or Åland serving the same routes would not be allowed to do so.[108]

Novel tobacco products

The STP market development is not limited to conventional oral, chewing and nasal tobacco products. There are also important developments in **other novel tobacco products**, often claimed to be less harmful than FMC and targeted to consumers who cannot or will not cease

[107] Swedish Match power point, 15 December 2011

[108] Any differential treatment, however, is an effect of the exemption rather than the ban. See the Courts reasoning in Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825, p 41

smoking.[109] The tobacco industry seems to see a very significant potential in this new product development.[110] Like for other the STP, the question is whether these products can act as entry gates into tobacco consumption, in particular among young people, or whether these products prevent established smokers from quitting (dual use). The expected development in consumption of STP in the absence of further EU action is explored under section 2.3 (Baseline scenario).

- **Enforcement of the current TPD**

The current regulation of STP based on the **mode of consumption of different STP categories is sometimes unclear and can facilitate circumvention** of the current legislation. In particular, it may encourage STP manufacturers to market their products as chewing tobacco (allowed) instead of tobacco to be sucked (banned as oral tobacco). For example, the instruction on how to use a product marketed as a chewing tobacco found on an internet store refers to the placing "*under your upper lip and keep in place for 5 minutes to a few hours according to your convenience*", which describes a sucking and not a chewing mode of use.

It has been reported that the current ban of placing on the market of oral tobacco has also led to some enforcement difficulties. A recent study concludes that many internet retailers of Swedish oral tobacco (snus) target non-Swedish customers and that ordering oral tobacco from EU Member States other than Sweden is quick and straight forward despite the current ban. Out of 43 test purchases in 10 Member States, 41 were successfully made.[111] The availability of oral tobacco through internet throughout the EU was also pointed out in the Commission report on Sweden's implementation of measures necessary to ensure that oral tobacco is not placed on the market in other Member States.[112] Further action might be warranted on this issue upon receipt of supplementary information.

b) Nicotine containing products (NCP)

Electronic cigarettes and other NCP for leisure purposes did not exist when the current TPD was adopted in 2001. This raises the question whether there is a need for action and if so how these products should be treated.

- **Implementation of the current legal framework for NCP**

About half of the Member States have reported that they consider electronic cigarettes and other NCP as medicinal products by function, even if they are not presented as smoking cessation aid but rather as alternative to cigarettes (leisure products). One third have said they have no specific regulation in place which means that the General Product Safety Directive[113] applies and a minority of the Member States have chosen to ban these products or apply certain provisions that are used for tobacco products (for further details, see Annex 3, A.3.1.1.2.). So far, no electronic cigarette has been authorised in the EU under the pharmaceutical regulation, but at least one application has been submitted and others are

[109] Minutes from SANCO's meeting with Philip Morris International, 8 March 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120308_mi_en.pdf

[110] See for ex. Thompson C. BAT invests in a smokeless future. Financial Times 2012 Sept 30, where it is reported that the market for tobacco alternatives (including non-combustible cigarettes and nicotine inhalers) could count for as much as 40% of BAT's revenues – which were £15bn in 2011 – in 20 years time.

[111] Peeters S, Gilmore AB. How online sales and promotion of snus contravenes current European Union legislation. Tob Control 2012.

[112] COM (2010) 399 final Report from the Commission to the Council on the implementation of the Kingdom of Sweden of the measures necessary to ensure that oral tobacco is not placed on the market in other Member States. 29.7.2010.

[113] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

foreseen.[114] The increasing market volume (section 2.1.3) and cross-border trade together with the different legislations in Member States **affects negatively the functioning of the internal market.** It contributes to legal uncertainty for manufacturers and distributors and may also negatively affect consumer confidence in the internal market, in particular considering the safety concerns related to NCP (see figure 12). It also prevents NCP from moving freely across borders as manufacturers and distributors are required to comply with many different legal systems. Member States have expressed an urgent need for orientation from the Commission as to which legislation applies to electronic cigarettes.[115]

Nicotine replacement products (NRTs) considered as medicinal products need to undergo strict marketing authorisation procedures and if other NCP can reach the market without such authorisation, it could lead to an **unjustified advantage undermining a level playing field**. The pharmaceutical industry has argued in favour of regulating NCP (some of them in the context of the pharmaceutical legislation and others by including them in the scope of the TPD), while Electronic Cigarettes Industry Trade Association (ECITA) representing primarily vendors of electronic cigarettes in the UK has argued that these products do not need to be further regulated (see Annex 1).

The current fragmented situation is a result of various efforts in Member States to respond to **health concerns** associated with NCP. The Commission has, so far, received fourteen **notifications** concerning (refill) liquids for electronic cigarettes via the RAPEX system, indicating serious health risks for consumers (17 December 2012).[116] The serious health risks were due to the toxicity of nicotine and misleading presentation, for example labelling referring to fruit.

Nicotine is a toxic and addictive substance.[117] Acute nicotine poisoning has occurred in children who accidentally ingest nicotine and the safety of heavy or long terms use are not (yet) known.[118] Cartridges are sometimes sold in containers with minimal protection against tampering, opening by children etc. Ingestion of a single replacement cartridge is very likely to be lethal and users have reported leakage when replacing cartridges, suggesting that the quality of cartridges themselves is highly variable. A study of five different brands of electronic cigarette also found that most brands' cartridges were poorly constructed and leaked.[119]

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[114] Information about one application. It has also been reported in media that at least one of the big FMC manufacturers is preparing for an application: Thomas R. Cigarette giant to offer 'safer alternative.' England and Wales: Nicoventures; 2011. http://www.nicoventures.co.uk/Content/Downloads/august-2011/PM_Aug_p2.PDF (accessed 28 Nov 2012).

[115] See European Commission. Orientation note. Electronic cigarettes and the EC legislation. Brussels: EC; 2008. http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/orientation_0508_en.pdf (accessed 28 Nov 2012).

[116] DG Health and Consumers. Rapid Alert System for non-food products posing a serious risk (RAPEX). Brussels: DG SANCO; 2012. http://ec.europa.eu/consumers/safety/rapex/index_en.htm

[117] Nicotine is classified as a dangerous substance in Directive 67/548/EEC.

[118] Connolly GN, Richter P, Aleguas A Jr, Pechacek TF, Stanfill SB, Alpert HR. Unintentional child poisonings through ingestion of conventional and novel tobacco products. Pediatrics 2010; 125(5):896-9. See: BBC News. Gateshead doctor calls for research into 'e-cigarettes.' England: BBC; 2011. http://www.bbc.co.uk/news/uk-england-12887335 (accessed 28 Nov 2012). A British doctor has called for more research on the risks of electronic cigarettes after a patient died of lung disease following heavy use of these products. The Electronic Cigarette Industry Trade Association claims, however, that 100% of users are former smokers and any lung damage observed in patients will have been the results of traditional cigarette use

[119] Trtchounian A, Talbot P. Electronic nicotine delivery systems: is there a need for regulation? Tobacco Control 2010; 20:47–52.

Studies of the nicotine content of cartridges have shown significant differences between labelled and true levels of nicotine cartridges and refill solutions.[120] Analyses of electronic cigarette samples conducted by the US Food and Drug Administration (FDA) have shown detectable levels of known carcinogens and toxic chemicals; including diethylene glycol, tobacco-specific nitrosamines and tobacco specific impurities.[121] A recent study has found immediate adverse physiologic effects (changes in the lung function) after short terms use which is similar to some of the effects associated with tobacco smoking.[122] Another recent study concludes that 'passive vaping' must be expected from the consumption of e-cigarettes due to prominent components in the gas-phase, including 1,2-propanediol, 1,2,3-propanetriol, diacetin, flavorings, and traces of nicotine.[123]

Some NCP also appear to be subject to **vivid and innovative marketing, which could attract young people in particular**. For example, e-cigarettes are available in a range of flavours, including coffee and cherry and a "smart pack" is being introduced that vibrates and flashes a blue light when a user is within 50 feet of someone with another "smart pack". The popularity of electronic cigarettes was also confirmed in a recent Polish survey which found that one in five young people had tested electronic cigarettes. [124] ECITA on the other hand claims that consumers are mainly established smokers using the product for cessation and reduction purposes.[125]

At this stage the evidence on the **effectiveness** of electronic cigarettes in smoking cessation is inconclusive.[126] As indicated, most users of electronic cigarettes seem to use them for cessation/reduction purposes, but the industry association, ECITA, explicitly advices its members to refrain from such claims as it could trigger application of medicinal products regulation (see section 2.1.3.). There are also some concerns that electronic cigarettes and other NCP can take advantage from national smoke-free environment policies,[127] in particular as the products are often promoted as an alternative to smoking which allows smokers to keep up nicotine addiction in situations where smoking is prohibited. Electronic cigarettes can also become a starter/re-starter product attractive to young people or former smokers.[128] However

[120] Goniewicz ML, Kuma T, Gawron M, Knysak J, Kosmider L. Nicotine Levels in Electronic Cigarettes. Nicotine Tob Res 2012.
[121] US Food and Drug Administration (FDA). Evaluation of e-cigarettes. St Louis, MO: FDA, USDHHS; 2009. US Food and Drug Administration (FDA). Summary of Results: Laboratory Analysis of Electronic Cigarettes. US: FDA; 2009. Knysak J, Gawron M, Goniewicz ML, Kurek J, Kosmider L, Sobczak A. Determination of formaldehyde in aerosol from electronic cigarettes using derivatization and solid phase extraction followed by liquid chromatography, Abstract from 14th young scientists conference on chemistry, 18-21 March 2012, Rostock, Germany. p.95.
[122] Vardavas CI, Anagnostopoulos N, Kougias M, Evangelopoulou V, Connolly GN, Behrakis PK. Short-term pulmonary effects of using an electronic cigarette: impact on respiratory flow resistance, impedance, and exhaled nitric oxide. Chest 2012; 141(6):1400-6.
[123] Schripp T, Markewitz D, Uhde E, Salthammer T. Does e-cigarette consumption cause passive vaping? Indoor Air 2012.
[124] Goniewicz ML, Zielinska-Danch W. Electronic cigarette use among teenagers and young adults in Poland. Pediatrics 2012;130(4):e879-85.
[125] Minutes from SANCO's meeting with ECITA, 20 June 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf (accessed 28 Nov 2012).
[126] Etter JF, Bullen C, Fouris AD, Laugesen M, Eisenberg T. Electronic nicotine delivery systems: a research agenda. Tob Control 2011; 20:243-8.
[127] World Health Organization (WHO) Study Group on Tobacco Product Regulation. Report on the Scientific Basis of Tobacco Product Regulation. WHO Technical Report Series, no. 955. Geneva: WHO; 2010. Yamin CK, Bitton A, Bates DW. E-cigarettes: a rapidly growing Internet phenomenon. Ann Intern Med 2010 Nov 2;153(9): 607-9.
[128] Cobb NK, Abrams DB. E-cigarette or Drug-Delivery Device? Regulating Novel Nicotine Products. N Engl J Med 2011; 365(3):193-5.

there are some studies being published that highlight the electronic cigarettes' potential as a smoking cessation aid. [129]

- **Enforcement of the current legal framework for NCP**

The current uncertainty in relation to the legal classification of NCP makes **enforcement difficult and contributes to circumvention. It also undermines reaching a level playing field** and leads to an unjustified differential treatment of different types of products containing nicotine. Today, there are two categories of products containing nicotine available on the market: NCP placed on the market without any prior control and NRT (Nicotine Replacement Therapies) which have been subject to a strict (and relatively costly) risk/benefit analysis and approved as medicinal products.

As illustrated under the market description (section 2.1.3), most electronic cigarettes are **presented** as alternatives to FMC rather than smoking cessation aids. It appears that the products are presented in this way in order to avoid the relatively burdensome authorisation procedure applicable to medicinal products.[130]

Regardless of the presentation of the NCP, a product which may be used to modify physiological functions falls under the definition of medicinal products by **function** and needs to be authorised under this framework before being put on the market. The pharmacological effects of nicotine in NRTs are well documented. Nicotine attaches itself to receptors in the brain and has a long tradition of use in NRTs to reduce craving and help people stop smoking.[131]

Moreover, electronic cigarettes without prior authorisation appear to be **available** also in Member States which have reported that they consider them as medicinal products or prohibit marketing.[132] According to ECITA, regulatory agencies struggle to provide monitoring and enforcement in regulating the electronic cigarette industry.[133]

c) Herbal products for smoking

- **Fragmentation of the internal market**

Herbal products for smoking, e.g. tobacco- and nicotine-free cigarettes and herbal fillings of water-pipes, fall outside the current scope of the TPD and are currently not subject to harmonised rules in the EU. This raises the question whether these products – considering their similarities with tobacco products – should be regulated in the revised TPD. Herbal products for smoking are subject to many different regulatory regimes in Member States. About half of the Member States have no specific regulation in place, while two Member States do not allow these products, one Member State has labelling requirements in place and

[129] Caponnetto P, Polosa R, Russo C, Leotta C, Campagna D. Successful smoking cessation with electronic cigarettes in smokers with a documented history of recurring relapses: a case series. J Med Case Rep 2011 Dec 20;5(1):585. Etter JF, Bullen C. Saliva cotinine levels in users of electronic cigarettes. Eur Respir J. 2011. Polosa R, Caponnetto P, Morjaria JB, Papale G, Campagna D, Russo C. Effect of an electronic nicotine delivery device (e-Cigarette) on smoking reduction and cessation: a prospective 6-month pilot study. BMC Public Health 2011;11:786.

[130] For example, ECITA recommends to its members to stay out of medical claims as this could render the product illegal (material provided to DG SANCO).

[131] Nicotine patches, sprays, inhalers and chewing gums have already been authorized as medicinal products.

[132] See for example Minutes of SANCO's meeting with ECITA on 20 June 2012 reporting about two members in Greece despite the ban on such products in Greece (see Annex 3: http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf

[133] Electronic Cigarette Industry Trade Association (ECITA). Quarterly Update, June 2012. UK: ECITA; 2012.

the remaining Member States have other rules (see Annex 3, A.3.1.1.1). This **negatively affects the cross border trade** in these products, which appears to be quite significant considering that many products are marketed and sold on-line.[134] Manufacturers and retailers need to be familiar with and keep up to date with many different legal situations in all Member States. The free movement of goods and consumer confidence in the internal market cannot be secured in this case as the health requirements differ significantly from one Member States to another.

The divergent actions taken by Member States are a result of health concerns related to these products. Herbal products for smoking have not been extensively studied from a scientific/health perspective but it is generally acknowledged that inhalation of smoke of any kind can pose a **health** risk. This is also the reason for Member States' actions in this area. Evidence suggests that the combustion of these products produces a level of carbon monoxide similar to tobacco cigarettes as well as other toxic substances such as tar.[135] On the other hand, these products do not contain nicotine and may therefore not be associated with the same risk of addictiveness.[136] It is of particular concern that these products are often perceived as harmless or less harmful by consumers. This perception is reinforced by the current marketing of herbal products for smoking as "healthier" and "natural products without additives".[137]

A particularly worrying trend in this context is the increase in water-pipe (sisha) smoking among young people.[138] The content of the water-pipe filling is often unclear and sometimes herbal filling is used which does not contain tobacco.[139] Water-pipe smoking as such is also often perceived as a less harmful activity than traditional tobacco smoking. As indicated, this is expected to trigger further actions at national level in the years to come.

1.1.2. Problem 2: Packaging and labelling

The type, size and location of health warnings as well as the display of TNCO levels are already subject to harmonised provisions in the current TPD (see figure 12). However, it might be necessary to update these rules to bring them in line with international, market and scientific development.

- **Effectiveness of the current TPD**

The current provisions on packaging and labelling are no longer in line with scientific evidence and commitments in the context of the FCTC. For example, the current obligation to print the TNCO yields on the package have been shown to be potentially misleading, as it makes people believe that some products are less risky to their health.[140]

[134] No exact figures are available, but herbal cigarettes are sold on line

[135] Groman E, Bernhard G, Blauensteiner D, Kunze U. A harmful aid to stopping smoking. Lancet 1999; 353(9151):466-7.

[136] However, addictiveness may also be associated with other factors, including behavioral factors.

[137]Honeyrose. Stop smoking. Ipswich: Honeyrose Products Ltd; 2012. http://www.honeyrose.co.uk/stop.html (accessed 28 Nov 2012). Holland and Barrett. Herbal cigarettes. Nuneaton: Holland and Barrett; 2012. http://www.hollandandbarrett.com/pages/categories.asp?cid=313 (accessed 28 Nov 2012).

[138] Knishkowy B, Amitai Y, Water-pipe (Narghile) smoking: An emerging health risk behaviour, Pediatrics 2005; 116:e 113-19.

[139] Swedish National Institute of Public Health. Waterpipes – smoking without risk? Health effects, habits, attitudes and surveillance. Stockholm: Swedish National Institute for Public Health; 2010.

[140] Eurobarometer 2010. Gallopel-Morvan K, Moodie C, Hammond D, Eker F, Beguinot E, Martinet Y. Consumer understanding of cigarette emission labelling. Eur J Public Health 2010; 21:373-5. National Cancer Institute. Risks associated with smoking cigarettes with low tar machine-measured yields of tar and nicotine.

Scientific evidence also suggests that bigger pictorial pictures on both sides are more effective than text-only warnings on a range of outcomes, including being a deterrent for new smokers[141] and a means to increase cessation among current smokers.[142] In particular, they increase smokers' and potential consumers' awareness of warnings, knowledge and credibility of health risks, depth of processing and also cessation behaviours such as forgoing FMC, quit intentions and actual quitting.[143] Thus, the current TPD provisions in this area are not as effective as they could be.

Figure 12: Comparison between harmonised TPD provisions and FCTC guidelines in the area of packaging & labelling

Current TPD Articles 5 and 7	**Article 11 FCTC and Guidelines for implementing Articles 11 and 13 FCTC**
Text warnings not less than 30% + 40% of both sides (Art 5(5)). For Member States having more than one official language, the warnings should be increased to 32-35% and 45-50%.	Health warnings shall be large, clear, visible and legible and should be 50% or more of the principal display areas but not less than 30% (FCTC Art 11b(iii) and (iv)) Health warnings should be more than 50% of the display areas (GL Art 11)
Member States may introduce pictorial warnings on one side of the package (Art 5(3))	Parties should consider pictorial health warnings on both principal display areas. (GL Art 11)
Mandatory display of TNCO levels on the package (Art 5(1))	Parties should prohibit the display of figures for emission yields such as TNCO. (GL Art 11)
Ban on misleading product descriptions (Art 7)	Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive. (GL Art 13)

Some of the current packet shapes make it difficult to effectively display health warnings affecting negatively the visibility and legibility of the warning. This is particularly the case for very narrow (including "lip-stick" shaped) packets which distorts text and picture warnings.[144]

Use of colours and other design features on packages and tobacco products undermines the effectiveness of the ban on misleading descriptors in Article 7 of the current TPD.

Monograph no. 13. Bethesda, MD: National Cancer Institute, 2001. Brown A, McNeill A, Mons U, Guignard R. Do smokers in Europe think all cigarettes are equally harmful? Eur J Public Health 2012;22 (suppl 1):35-40.

[141] Vardavas CI, Connolly G, Karamanolis K, Kafatos A. Adolescents perceived effectiveness of the proposed European graphic tobacco warning labels. Eur J Public Health 2009; 19:212-7. White V, Webster B, Wakefield M. Do graphic health warning labels have an impact on adolescents' smoking related beliefs and behaviours? Addiction 2008; 103:1562-71. Créatec+. Quantitative Study of Canadian Youth Smokers and Vulnerable Non-Smokers: Effects of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packages. Montreal: Créatec+; 2008. (Report for Health Canada). Shanahan P, Elliott D. Evaluation of the Effectiveness of the Graphic Health Warnings on Tobacco Product Packaging 2008. Canberra: Australian Government Department of Health and Ageing; 2009.

[142] Hammond D. Health warning messages on tobacco products: a review. Tob Control 2011; 20:327-3. Thrasher JF, Rousu MC, Hammond D, Navarro A, Corrigan J. Estimating the impact of pictorial health warnings and "plain" cigarette packaging: Evidence from experimental auctions among adult smokers. Health Policy 2011; 102:41– 8.

[143] Hammond D. Health warning messages on tobacco products: a review. Tob Control 2011; 20:327-3. Gallopel-Morvan K, Gabriel P, Le Gall-Ely M, Rieunier S, Urien B. The use of visual warnings in social marketing: The case of tobacco. J Bus Res 2011; 64:7-11. Rey JM, Lacave B, Viedma MI, Gallopel-Morvan K. An image is worth a thousand words: the effects of visual health warnings in the decrease of tobacco consumption: a research from the perspective of social marketing [in Spanish] (Una imagen vale más que mil palabras: efectos de las advertencias sanitarias visuales en el descenso del consumo de tabaco: un estudio desde la perspectiva del marketing social.) Cuadernos de Gestión 2010; 10:149-65.

[144] Tan YL, Foong K. How the Malaysian tobacco industry exploits loopholes in pictorial health warnings. Tob Control 2012;21(1):55-6.

Since the adoption of the current TPD, misleading descriptors such as “light, “mild” and ultra” has been replaced by the use of colours which can be misleading and give the impression that some products are less harmful than others (for example gold and white is used to indicate 'light' FMC).[145] Recent studies have demonstrated that **packages** have the potential to mislead smokers and potential consumers and present them with an erroneous comfort about the risk of smoking.[146] For instance, FMC packets featuring the descriptors 'slim' ot 'extra-slim' were rated significantly more appealing than packets witout those descriptors.[147] In another study of young adults, so-called 'super-slim' 'parfume type' FMC packagets were associated with femininity, elegance, slimness and reduced harm.[148]

Likewise, the shapes (e.g. slim) and colours (e.g. pink, black, denim blue) of **individual FMC** can mislead consumers by creating e.g. the impression of harmlessness.[149] A study found that smokers of 'slim' FMC were more likely to believe that some FMC could be less harmful and that their own brand might be a little less harmful.[150] A recent study in young Australian adults has shown that characteristics of the cigarette stick affect smokers' perceptions of the attributes of cigarettes.[151] Some packages make different types of health claims by conveying the impression that a product has health benefits as it contains fruits, vitamins or is associated with energy. Other packages claim that FMC contain “no additives” or are “natural”, which can lead to misperceptions that certain products are less harmful.

- **Enforcement of the current TPD**

[145] Thrasher J, Hammond D, Arillo-Santillain EA. The alchemy of Marlboro: Transforming “Light” into “Gold” in Mexico. Tob Control 2010; 19:342-3.

[146] Moodie C, Ford A. Young adult smokers’ perceptions of cigarette pack innovation, pack colour and plain packaging. AMJ 2011; 19:174–80. Moodie C, Ford A, Mackintosh AM, Hastings G. Young People's Perceptions of Cigarette Packaging and Plain Packaging: An Online Survey. Nicotine Tob Res 2012; 14:98-105. Hammond D, Parkinson C. The impact of cigarette package design on perceptions of risk. J Public Health. 2009; 31:345-53. Hammond D, Dockrell M, Arnott D, Lee A, McNeill A. Cigarette pack design and perceptions of risk among UK adults and youth. Eur J Public Health 2009; 19: 631-7. Mutti S, Hammond D, Borland R, Cummings MK, O'Connor RJ, Fong GT. Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey. Addiction 2011; 106:1166-75.

[147] Doxey J, Hammond D. Deadly in pink: the impact of cigarette packaging among young women. Tob Control 2011;20(5):353-60.

[148] Moodie C, Ford A. Young adult smokers’ perceptions of cigarette pack innovation, pack colour and plain packaging. AMJ 2011; 19:174–80.[149] Eher F, Gallopel-Morvan K, Béguinot E, Martinet Y. Smokers and non smokers’ perception of current cigarettes vs plain cigarettes. Conference presentation, SRNT Europe, 8.-11.9.2011, Antalya, Turkey http://www.srnteurope.org/assets/SRNT-E-2011-ABSTRACT.pdf , abstract OP30, p. 88. Mutti S, Hammond D, Borland R, Cummings MK, O'Connor RJ, Fong GT. Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey. Addiction 2011; 106:1166-75. Ernster VL, Lloyd G, Norman LA, McCarthy A & Pinto AL, editors. Women and Smoking: A Report of the Surgeon General. Executive Summary. Atlanta, GA: Centers for Disease Control and Prevention; 2001.

[150] Mutti S, Hammond D, Borland R, Cummings MK, O'Connor RJ, Fong GT. Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey. Addiction 2011; 106:1166-75.

[151] Borland R, Savvas S. Effects of stick design features on perceptions of characteristics of cigarettes. Tob Control 2012.

Article 5(5) of the current TPD allows Member States to impose stricter labelling measures for domestically produced products, but Member States can only impose stricter rules on imported products.[152] This can lead to **market distortion and the industry could circumvent strict domestic measures by shifting production to other Member States.**

- **Currently not fully harmonised aspects of packaging and labelling**

Some of the **not fully harmonised** aspects of packaging and labelling are subject to important disparities between national regulations. For example, pictorial health warnings are already in use in eight Member States, two Member States will use them from 2013 onwards while the remaining seventeen Member States for the moment require textual warnings only (see Annex 3). In addition, Member States apply different rules on the package size/minimum number of FMC per package and different rules on display of cessation services on the packages. The choice of pictures used also varies from one Member State to another. At least one Member State (France) bans promotional elements on the package as part of its advertising ban, whilst technical discussions are taking place in a few Member States as regards promotional elements, including FMC and smoke appearance.[153] As described under section 2.3, the disparities are expected to grow in coming years.

The heterogeneous development in Member States is closely linked to the legal obligations and political commitments in the context of the FCTC (see figure 13). The FCTC provides a broad margin of manoeuvre for parties in terms of implementation, both in terms of scope and time.

Figure 13: Political commitments stemming from FCTC guidelines in areas not fully harmonised by the TPD

FCTC and its guidelines (GL)	Situation in Member States
Each Party should endeavour to prohibit the sale of FMC individually or in small packets. (FCTC Article 16)	Fourteen Member States specify a minimum package size of twenty FMC: AT, CZ, DK, EE, FI, FR, EL, IE, LU, LT, PL, PT, RO, ES Four Member States specify a minimum package of nineteen FMC: DE, HU, NL, SE One Member State has a minimum package size of 10: UK One Member States requires FMC to be sold in packages of 10 or 20: IT Two Member States prohibit the sale of single FMC: LV, SI
Parties should consider pictorial health warnings on both principal display areas. (GL Article 11)	Pictorial health warnings (on one side) in use in eight Member States: BE, RO, UK, LT, FR, MT, ES and DK (in IE and HU starting in 2013)
Health warnings and messages should in addition to harmful effects address advice on cessation (GL Article 11)	Four Member States have mandatory references to cessation services displayed on the packages: BE, FR, NL, SI Nine Member States have references to cessation services included in some warnings: AT, DK, DE, HU, IE, LV, PL, SE, UK
Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on, packaging other than	-Public consultation in UK. (16 April -10 August 2012)[154] -Statement of BE Health Minister in the parliament.[155]

[152] Of course, if a measure is outside the scope of the current TPD Member States are entitled to impose stricter rules (even restricting cross-border trade), if the measure can be justified under Art.36 TFEU.
[153] ITC Project. ITC France National Report. Waterloo, CA and Paris: University of Waterloo, Institut national de prévention et d'éducation pour la santé (INPES), Institut national du cancer (INCa), and Observatoire français des drogues et des toxicomanies (OFDT); 2009.

brand names and product names displayed in standard colour and font size (plain packaging) (GL Article 11)	-Proposal by FR MP in report to the FR Health Minister (February 2012).[156] -Informal discussions in FI.
Parties should consider adopting plain packaging requirements to eliminate the effects of advertising and promotion on packaging. (GL Article 13)	
Parties should prohibit or restrict ingredients that have colouring properties in tobacco products. (GL Article 9 and 10)	-At least BE bans an ingredient capable of colouring the smoke blue (see Annex 3).

Discrepancies between national legislations in product related areas are liable in themselves to constitute **obstacles to the free movement of goods**.[157] In this concrete case, the diversity between national legislations obliges the tobacco industry to be familiar with and adapt to multiple national legislations and possibly produce different labels and different packages for different markets.

The fact that the **industry** has not explicitly requested the harmonisation should not be misunderstood to suggest that the problem does not exist. It could rather be a sign that the industry might expect a harmonisation at a higher level ("high level of public health"). SME's could be more open to harmonisation as they have less resources to adapt to diverging legislation and harmonisation would thus facilitate their ambition to expand their activities beyond their home markets.[158] At least one of four big tobacco manufacturers has also indicated that it has no major concerns regarding the introduction of mandatory pictures, TNCO replacement and cessation services displayed on the packages if appropriate space is given for trademarks.[159] Other manufacturers have been less explicit.

For **Member States**, the current lack of harmonisation represents a **lost opportunity** to fully benefit from common solutions across the EU as Member States will have to come up with their own solutions to address scientific, market and international developments.

The divergent labelling schemes in Member States also mean an **unnecessary burden for economic stakeholder** in terms of compliance costs (e.g. familiarisation, multiple adaptations to national measures and different product lines for different countries) (see section 5.1).

1.1.3. Problem 3: Ingredients

The current TPD foresees reporting obligations in a non-harmonised format and invites the Commission to establish a list of ingredients in form of a positive/negative list, which was not accomplished.

a) Reporting

[154] UK Department of Health (UK DoH). Consultation on standardised packaging of tobacco products. London: DoH; 2012.
[155] Commission de la Santé publique, de l'Environnement et du Renouveau de la Société. Report of the health commission of 19th January 2011. Brussels: Chambre des représentants de Belgique; 2011. p 29-31. http://www.lachambre.be/doc/CCRI/pdf/53/ic096.pdf (accessed 28 Nov 2012).
[156] 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. See also: Chantry C. Nouveau plan antitabac: ce que prépare le gouvernement. Paris: Le Parisien; 2012. http://www.leparisien.fr/economie/nouveau-plan-antitabac-ce-que-prepare-le-gouvernement-05-09-2012-2151462.php (accessed 28 Nov 2012).
[157] C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453, p 64
[158] See section 5.1 and the reference to the statement of one company that ingredients legislation across EU might be less expensive than if actions are taken at Member State level, Matrix 2012.
[159] Minutes from the meeting with FMC manufacturers, 2 December 2011: http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4 (accessed 28 Nov 2012).

- **Effectiveness of the current TPD**

Despite its mandatory character, the ingredients reporting set out in Article 6 of the current TPD is not working effectively. This was emphasised by economic (and other) stakeholders in the context of the public consultation of the TPD (see Annex 1) and also highlighted in the Second Application Report. Despite the publication of the EU guide on harmonised reporting format[160] and the development of an electronic tool for data submission (EMTOC[161]), different reporting formats are still used for reporting of ingredients. **This makes it difficult for manufacturers and importers to provide requested information and for Member States to fulfil the reporting obligations** set out in the current TPD. It also makes it difficult for the Commission to analyse the reported data.

Manufacturers also have **concerns about confidential business information** and there is no uniform and reliable basis to inform consumers on the content of tobacco products. Finally, disparities in the current reporting system makes it burdensome for Member States and the Commission to compare, analyse and draw conclusions from the data received.

b) Ingredients regulation

- **Currently non-harmonised aspects of ingredients**

In the absence of a common ingredients regulation, **Member States have adopted different approaches.** Four Member States have introduced positive lists indicating additives allowed to be used in tobacco products, one has introduced a negative list that restricts specific additives from being included in tobacco products and five have a combination. One Member State has maintained a voluntary agreement with the manufacturers (see Annex 3, 3.1.2.2). The EU has no regulatory power within the current TPD to harmonise these national lists and thus prevent obstacles to the internal market.[162] Most of these national regulations appear to be rather old and based on food legislation. However, there is a growing tendency in Member States to regulate ingredients, in particular as regards additives attractive to young people. One key example is the French regulation, fixing maximum levels for additives that impart a sweet or fruity/acid taste to FMC (e.g. vanilla). This has led to the reformulation or removal of certain products on the French market. In the aftermath, the same products were also altered in the other EU markets. Lithuania bans clove, vanilla plant and a number of other additives (see Annex 3.1.3.2). Another example is the different approaches as regards to additives added to the filter of FMC (e.g. menthol burst-capsule which allows a smoker to activate the menthol flavour whenever he/she wishes to do so). These new products are allowed in a number of Member States, while authorisation has been refused in other Member States (Germany, Belgium) (see Annex 3, A.3.1.3). The lack of a harmonised approach on additives affects the functioning of the internal market and prevents free movement of products across the EU. Manufacturers have to produce different products for different markets.

[160] European Commission. Practical guide on reporting on tobacco ingredients. Brussels: European Commission; 2007. http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/practical_guidance_en.pdf (accessed 28 Nov 2012).

[161] EMTOC (Electronic Model Tobacco Control) is a European web application which enables safe submission of the lists of tobacco ingredients to the concerned authorities. It was funded from the Health Programme by the European Executive Agency for Health and Consumers (EAHC) (60%) and a consortium of 13 Member States (40%).

[162] Article 12 of the current TPD invites the Commission to propose a common list taking into account inter alia addictiveness.

As outlined under the baseline scenario (section 2.3), the **heterogeneous development on the internal market is expected to increase further** in coming years in the absence of a common EU approach. The expected development in Member States is not only based on the FCTC guidelines, but also on scientific progress and development of the market.

A significant number of **scientific studies** show that certain tobacco additives make FMC more appealing. The WHO Study Group on Tobacco Product Regulation summarises the international public health knowledge about flavourings added to FMC and other tobacco products and their attractiveness to young and older smokers.[163] The Commission's independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concludes, in its Opinion of 2010, that the use of fruit and candy flavourings in high amounts seems to favour smoking initiation by young people.[164] It is also suggested that some additives decrease the harshness and increase the smoothness of the smoke. This also applies to menthol FMC, which show increased use in some Member States, e.g. Germany where the market share of menthol FMC more than doubled in the past ten years, from 1.3 to 3%.[165]

In terms of market development, additives are added to tobacco products which will make them **more palatable and capable of misleading** consumers to believe that they are less harmful or have some beneficial effects. For example, spices and herbs can also be used to improve the palatability.[166] As mentioned above, another recent development is FMC containing a burst capsule that enhances menthol (or other) flavour when squeezed and turn a FMC from non-menthol to a menthol FMC.[167] Colouring agents are another way of enticing young people. Both pink and black coloured FMC are available on the market and a tobacco company recently wanted to use an additive which would colour the smoke blue.[168] Various additives have been used in tobacco products to help create the misleading impression that such products have health benefits, present reduced health hazards or increase mental alertness and physical performance.[169] For example, an oral tobacco product containing caffeine, taurine and guarana as well as baking soda claimed to help to keep the teeth white are available. 19% of EU citizens (smokers and non-smokers) believe that some FMC, e.g. those with menthol or other taste/flavour (spice, sweet, fruit) or those without additives or labelled as "organic" or "natural" are less harmful than others which is not the case.[170] There is also a trend in several countries to use products labelled "without additives".[171] The tobacco industry has expressed doubts whether a ban on certain fruit and candy flavoured products, such as pina colada and strawberry, would affect smoking behaviour, but showed some understanding for the need of further regulation.[172]

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[163] World Health Organization (WHO) Study Group on Tobacco Product Regulation. Candy flavoured tobacco products: Research needs and regulatory recommendations. The Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series no. 945. Geneva: WHO; 2007. p.25-42.
[164] SCENIHR 2010
[165] German Cancer Research Center (DKFZ). Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product. Heidelberg: DKFZ; 2012.
[166] WHO FCTC guidelines for the implementation of Article 9 and 10.
[167] German Cancer Research Center (DKFZ). Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product. Heidelberg: DKFZ; 2012.
[168] Annex 3 (3.1.3). See also: De Standaard. Belgium. 5 December 2011.
[169] WHO FCTC guidelines for the implementation of Article 9 and 10
[170] Eurobarometer 2012
[171] SCENIHR 2010
[172] Minutes from the meeting with FMC manufacturers, 2 December 2011: http://ec.europa.eu/health/tobacco/docs/ev_20121202_mi_en.pdf (accessed 28 Nov 2012).

Finally, it should be noted that tobacco additives also transform tobacco smoke into an even more complex chemical mixture and thereby may further increase the **carcinogenic and harmful effects of tobacco**. Additives that facilitate deeper inhalation (e.g. menthol) or inhibit the metabolism of nicotine may enhance the **addictiveness** of nicotine indirectly.[173] A review made of nearly 600 additives to FMC suggests that more than 100 are known to "have pharmacological actions that camouflage the odour of environmental tobacco smoke emitted from FMC, enhance or maintain nicotine delivery, could increase the addictiveness of FMC, and mask symptoms and illnesses associated with smoking behaviours."[174] The less aversive, cooler and milder smoke seems to improve the experience of smoking and facilitate smoking initiation. On the basis of an extensive review of all available information, the US FDA Tobacco Products Scientific Advisory Committee confirmed in 2011 that the evidence was sufficient to conclude that it is more likely than not that the availability of menthol cigarettes increases the likelihood of experimentation and regular smoking beyond.[175] However, as mentioned previously (section 1.2) international work on ingredients has, so far, focused on attractiveness and the FCTC guidelines adopted in November 2010 do not address toxicity and addictiveness. However, work has been initiated in the areas of addictiveness and toxicity and it is expected that guidelines will be developed for these issues in coming years.

In the absence of a harmonised approach under the current situation, Member States are faced with **unnecessary administrative burden** in terms of finding their own solutions on how to implement the FCTC guidelines and adapt national legislations to the above mentioned market and scientific developments. They cannot fully benefit from the economy of scale associated with one common solution across the EU and enforcement of national rules is becoming more burdensome. In addition, **economic stakeholders are/would be faced with unnecessary compliance costs** in terms of country specific familiarisation, reformulations of tobacco products and different production lines for different Member States (see section 5.1).[176]

1.1.4. Problem 4: Cross-border distance sales

Cross-border distance sales of tobacco products fall outside the scope of the current TPD. According to Council Recommendation 2003/54, Member States are recommended to restrict tobacco distance sales for general retail. The FCTC guidelines for implementing Article 13 recommend Parties to ban internet sales. The Protocol on Illicit Trade recommends regulating cross-border internet sales.

Cross-border distance sales of tobacco implies a risk of circumvention of the safeguards of the TPD. Typically, tobacco products sold on the internet do not comply with the provisions of TPD, which means that consumers do not benefit from safeguards of the TPD (e.g. health warnings and ingredients). Legal cross-border internet sale of tobacco products also makes very little sense as taxes have to be paid, by the vendor, in the country of the buyer (i.e. no tax savings can be made by the buyer).[177] Given the characteristics of the tobacco market, most tobacco products are also available on the domestic market. If the taxes in the

[173] SCENIHR 2010

[174] Rabinoff MD, Caskey N, Rissling A, Park C. Pharmacological and Chemical Effects of Cigarette Additives. Am J Public Health 2007; 97:1981-91.

[175] Tobacco Products Scientific Advisory Committee (TPSAC). Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Rockville, MD: US Food and Drug Administration; 2011.

[176] Matrix 2012. Summary of industry responses to questionnaire.

[177] Article 36 of Directive 2008/118 on excise duty of tobacco indicates that in the case of cross border sale, the excise duty have to be paid for in the country of destination. However, from a perspective of a consumer, cross-border purchase makes primarily sense when the consumer avoids the higher excise duties in the country of destination.

country of destination are not paid consumers gets access to this product below the price level considered appropriate by the country of destination.

- **Circumvention of the TPD and problems related to enforcement**

The lack of effective common rules on cross-border distance sales of tobacco products increases the volume of **tobacco products circulating on the internal market without complying with the TPD** provisions (e.g. on health warnings, ingredients and ban on the placing on the market of oral tobacco). This is particularly the case under the current situation where internet sale of tobacco products is expected to increase in coming years (see section 2.1.1) and also taking into consideration that legal cross-border internet sales of tobacco products make very little sense as described above.

The **difficulties to enforce the ban of placing on the market of oral tobacco** are further described in section 2.2.1.

In a report from 2009 on the implementation of the Recommendation 2003/54, the Commission also concluded that, despite the overall satisfactory transposition, the area of **distance sale of tobacco represent particular challenges and problems** as far as enforcement is concerned.[178]

In addition to the non-compliance with the TPD provisions, many of the sites offering tobacco products on-line do not have information as regards **sales to minors** and have no system in place to verify the age of the purchaser.[179] In this context, it should be noted that age limits, between 16 and 18 years, for purchasing of tobacco are in place in all Member States (see Annex 3, A.3.1.4).
Access to tobacco on the internet is therefore easier and cheaper than from other sources. Internet sales of tobacco also often imply illegal advertising.[180]

As illustrated in Annex 3 (3.1.4), nine Member States do not allow internet sale of tobacco while some others have no restrictions in place.[181] 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, to age limits and advertising bans. The different regulatory schemes in Member States and the lack of any common rules make it **difficult for Member States to enforce their national legislation.** This is particularly the case given the cross-border dimension of this type of sales and the fact that the economic operators (retailers) compete on the same virtual market and offer their products to consumers regardless of their locations.

- **Impact on the internal market**

[178] Commission Staff Working Document of 23.11.09: Report on the Implementation of the Council Recommendation of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (2003/54/EC);
http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/tobacco_report09_en.pdf
[179] Williams RS, Ribisl KM, Feighery EC. Internet cigarette vendors' lack of compliance with a California state law designed to prevent tobacco sales to minors. Arch Pediatr Adolesc Med 2006; 160(9):988-9.
[180] Peeters S, Gilmore AB. How online sales and promotion of snus contravenes current European Union legislation. Tob Control 2012.
[181] AT, BG, ES, FR, HU, IT, LT, LV and SK do not allow internet sale of tobacco.

As described above, illegal cross-border distance sales of tobacco **undermine the application of the provisions** contained in the TPD, e.g. on health warnings and ingredients.

The steady increase in (illegal) cross-border internet sales also **reduce the legal movement of goods** both within and between Member States and makes it more difficult for legal business (traditional retailers) to compete on the market.

1.1.5. Problem 5: Traceability and security features

- **Implementation of the current TPD**

Illicit trade in FMC currently accounts for 8.25 % of total trade in the EU and is estimated to increase by 1 % per year in the next five years.[182] The negative impact of illicit trade is manifold for the legal supply chain, consumers and Member States. From the perspective of TPD, the main concern is that the safeguards of the TPD are not respected by illicit products (e.g. health warnings in the correct language). For Member States, the loss in tax revenues (10 bEUR per year according to OLAF)[183] is certainly also a major concern. The main beneficiaries are criminals and the organised crime. The main categories of illicit products are contraband (i.e. products which have been diverted into illicit trade, not respecting the legal requirements in the jurisdiction of destination), counterfeit (i.e. brand protected products which have been falsified without consent of the brand owner and are not respecting the legal requirements in the jurisdiction of destination) and illicit/"cheap" whites (i.e. products produced (often legitimately) in their country of origin at very low cost, destined to be smuggled into other jurisdictions and not respecting requirements in the jurisdiction of the destination). According to According to OLAF indications, the ratio between these categories is 30 % contraband, 50 % counterfeit and 20 % illicit whites.

The current TPD contains, as part of its Article 5(9) the possibility to introduce provisions on traceability and product identification, but so far **no effective implementation has taken place**. In particular, the Commission has not used the power in Article 5(9) to adopt technical measures related to traceability and identification. A major reason for this delay was that since 2000 the concepts of traceability have been discussed internationally in the development of Article 15 FCTC and later on in the negotiations of the Illicit Trade Protocol based on Article 15 FCTC. It would therefore not appear useful if the Commission made use of the powers under Article 5(9) TPD at this stage, as the current provision does not provide for a fully-fledged traceability concept and is thus no longer state of the art. The currently foreseen batch marking is only one element for achieving traceability and control of the supply chain. Already the FCTC goes further and stipulates that each unit package has 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. As regards Article 5 (9) TPD, in the absence of the adoption of an implementing measure, Member States are, in principle, unable to take actions unilaterally, while being obliged by the FCTC. Taking into account that a very significant part of FMC and RYO are traded across EU borders (2.1.1), an EU wide system would clearly provide added value.

[182] Euromonitor data presented in Matrix 2012. According to OLAF indications, the ratio between categories of illicit trade is 30 % contraband, 50 % counterfeit and 20 % illicit whites (for definitions, see glossary).
[183] OLAF. Huge Illegal Cigarette Factory in Poland Raided. Brussels: OLAF; 2011. http://ec.europa.eu/anti_fraud/media-corner/press-releases/press-releases/2011/20110315_01_en.htm (accessed 28 Nov 2012).

- **Enforcement of the TPD**

Typically, illicit trade products (both contraband and counterfeit) do not comply with the TPD. **This undermines the enforcement of the Directive and thus the effectiveness of the internal market** in legal tobacco products. Sales of products not complying with TPD mean that the consumers do not benefit from the safeguards in form of the appropriate labelling (e.g. text warnings in a different language), or ingredients control.

In terms of traceability, there is currently no level playing field for economic operators on the internal market. The four largest tobacco manufacturers have concluded legally binding agreements with the EU and the participating Member States ('the agreements'),[184] including provisions on tracking and tracing, but other manufacturers and importers do not have similar legal obligations to control the supply chain through tracking and tracing.

It is highly likely that Member States will also consider additional measures in terms of **security features** to act against counterfeit and empower consumers to verify the authenticity of the product concerned. Article 15 FCTC contains obligations in this regard, but without a common EU approach Member States are expected to take different approaches. **Such heterogeneous development will have a negative impact on the internal market and prevent free movement of products**.

2.3. BASELINE SCENARIO

This section describes how the tobacco market is expected to evolve in the coming years if no changes are made to the TPD. In this respect it is first important to underline that the current difficulties in terms of implementation, application and enforcement of the current TPD (see section 1.2) would persist under the baseline scenario.

1.1.6. Development of the market

As mentioned in the market description (section 2.1) significant development and diversification have taken place on the tobacco market in recent years. This development towards further fragmentation of the internal market is expected to continue under the baseline scenario.

The rapid development of the traditional **STP (oral, chewing and nasal) market** is likely to continue under the baseline scenario (new brands, new flavours, new attractive packaging). The development of novel tobacco products is also a priority for FMC manufacturers and this market is expected to increase significantly.[185] In addition, the development of tobacco-free products, such as **NCP (notably electronic cigarettes)** described in the market description section, 2.1.3) is expected to continue and even intensify.[186] One of the main drivers for this trend is the implementation of smoke-free environments and tobacco control measures in the Member States.

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[184] Anti-Contraband and Anti-Counterfeit Agreement and General Release with Philip Morris (2004), Cooperation Agreement with Japan Tobacco (2007), Cooperation Agreement with British American Tobacco (2010) and Mutual Cessation Agreement with Imperial Tobacco (2010). The agreements start to expire as of 2016.

[185] Minutes from SANCO's meeting with Philip Morris International, 8 March 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120308_mi_en.pdf (accessed 28 Nov 2012).
See also: BAT. Harm reduction. London: BAT; 2012. http://www.bat.com/harmreduction (accessed 28 Nov 2012).

[186] SANCO discussion with an e-cigarette manufacturer, July 2012. SANCO meeting with ECITA, 20 June 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf (accessed 28 Nov 2012).

Also the new marketing strategies for tobacco for smoking are expected to continue. This applies in particular to innovative and appealing **tobacco packaging** (e.g. new "lip stick" packets with slim FMC). The development is even expected to aggravate under the baseline scenario, especially following stricter advertising regimes in Member States and taking into consideration that packaging constitutes an important factor in choosing a FMC brand (23%).[187]

Moreover, further market development as regards **ingredients for combusted tobacco** is expected to continue in coming years, in particular in light of the recent development of distinctive flavoured tobacco products (see section 2.1.1). The various patents required by tobacco industry to embed flavourings in the filter are also an indication of further development in this regard.[188] Increased sale of menthol FMC can also be expected under the baseline scenario and these products are likely to be most popular among young people. The market share of menthol FMC has more than doubled in Germany in the past ten years, from 1.3 to 3%.[189] In the United States, menthol FMC sales have remained stable as cigarette sales have decreased and the share of menthol brands is higher in new adolescent smokers, who have been smoking for less than one year, than for those who have smoked for more.[190]

1.1.7. Development in Member States

2.3.1.1. Already harmonised areas

In areas already covered by harmonisation, **Member States would be prevented under the baseline scenario from taking actions** to maintain or strengthen a high level of health protection.

2.3.1.2. Non-harmonised areas

In reaction to the market developments outlined above, some Member States have already taken actions and more are likely to follow (see sub-sections under 2.2 and Annex 3). Member States will also adapt to **scientific progress and international development, e.g. implement the FCTC and its guidelines.**

Although the FCTC provides good orientations, it leaves significant discretion to Member States on how to implement the Convention and guidelines in terms of content and time. For example, the Convention refers to health warnings of a certain size (50% or more but not less than 30%) and effective ingredients regulation. However, the Convention itself does not specify how and where to place the warnings on the packets, nor which ingredients should be addressed by the regulation. The guidelines are a bit more specific and more far reaching, but also they give some discretion to Member States and they are not legally binding. Whilst some Member States are expected to take actions to implement fully also the non-binding guidelines, others are likely to be less ambitious in this respect. The legal obligations stemming from FCTC are also different from obligations based on an EU Directive in the sense that the enforcement mechanisms are different. Whilst a failure to implement an EU

[187] Eurobarometer 2012

[188] German Cancer Research Center (DKFZ). Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product. Heidelberg: DKFZ; 2012.

[189] Giovino GA, Sidney S, Gfroerer JC, O'Malley PM, Allen JA, Richter PA et al. Epidemiology of menthol cigarette use. Nicotine Tob Res 2004;Suppl 1:S67-81 German Cancer Research Center (DKFZ). Menthol Capsules in Cigarette Filters – Increasing the Attractiveness of a Harmful Product. Heidelberg: DKFZ; 2012.

[190] Kreslake JM, Wayne GF, Connolly GN. The menthol smoker: tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior. Nicotine Tob Res 2008; 10:705-15.

Directive may lead to infringements procedures, settlement of the disputes in the context of FCTC leaves more flexibility to Parties (FCTC Article 27 refers to negotiations or any other peaceful means of their choice). Also this can affect the implementation of the FCTC. In light of this, further discrepancies can be expected under the baseline scenario.

More specifically, in the areas of **STP, NCP and herbal products for smoking**, it can be expected that Member States continue to take unilateral actions to address the market development described above. For example, some Member States can be expected to react to the development of flavoured STP and implement the FCTC guidelines on Articles 9 and 10 which recommend banning additives capable of making these products more attractive or of misleading consumers to believe they are less harmful or have health benefits. Some Member States are also likely act to ensure maximum effect of their smoke-free environment policies. Although it is difficult to predict the exact shape and timing of these actions, it appears certain that they will consist of divergent approaches reinforcing the already existing discrepancies.

Also in the area of **packaging and labelling**, the disparities are expected to grow in coming years as Member States continue to take further measures, e.g. to adopt pictorial health warnings, introduce cessation information and/or further standardise tobacco packaging in line with the guidelines for implementing Articles 11 and 13 of the FCTC. In the context of the public consultation on the TPD, five Member States who have not yet adopted pictorial health warnings nevertheless supported such a proposal at the EU level.[191] It is likely that at least some of them will go forward at national level in the absence of a common EU approach. The UK Government launched a public consultation on plain packaging on 16 April 2012 and appears to be the most advanced in terms of considering the full standardisation of the package,[192] but reflections on plain packaging are also on-going at various levels in some other Member States, including Belgium, Finland and France (see Annex 3, A.3.1.2.2). Member States' interest in plain packaging is also reflected in a Council Recommendation from 2009 inviting the Commission to analyse the legal issues and the evidence base for the impact of plain packaging, including its effect on the functioning of the internal market.[193]

In order to comply with their obligations under FCTC (see Annex 3, A.3.1.3.1), Member States have already different measures in place and are likely to adopt rules on **ingredients** unilaterally in the years to come, in particular to address the attractiveness of tobacco products and considering the market development in recent years with more flavoured tobacco products being placed on the market. At least one Member State has declared that it will discuss a national ban on "candy-cigarettes" if no action is taken at EU level.[194] A majority of Member States also supports some kind of regulation in the context of the public consultation (see Annex 1, section A1.2.2). It is also likely that Member States will seek inspiration from other jurisdictions. A number countries around the world have taken measures (e.g. Canada and Brazil banning in principle all additives and US banning characterising flavours).[195]

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[191] AT, FI, LV, PL and SI.

[192] UK Department of Health (UK DoH). Consultation on standardised packaging of tobacco products. London: DoH; 2012.

[193] Council Recommendation of 30 November 2009 on smoke-free environments. 2009/C 296/02. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:296:0004:0014:EN:PDF (accessed 28 Nov 2012).

[194] DK political agreement between the Government and the Alliance of 21 April 2012

[195] Canada has an exemption for menthol and Brazil accepts sugar up to a certain level. US bans cigarettes with characterising flavours other than tobacco or menthol, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry or coffee

Finally, Member States are expected to further develop their legislation in order to address easy access to and visibility of tobacco, including through the **internet**. In this case the FCTC plays an important role as well as the enforcement difficulties faced by Member States under the current situation (e.g. age limits for purchasing of tobacco).

1.1.8. The demand side

The overall smoking prevalence has decreased significantly in the EU in recent decades.[196] Whilst Euromonitor predicts also some moderate decline in consumption (decrease in volume sales) in the years to come **it cannot be assumed that this predicted decrease will in reality continue** in the absence of new adjusted tobacco control measures.[197] Firstly, the decline was the effect of a concerted and comprehensive tobacco control policy consisting of a broad range of measures used in a complementary manner and where new elements have been constantly introduced. This includes the adoption of the FCTC, increases in tobacco taxation, bans on tobacco advertising, restrictions on sales to minors, comprehensive laws on smoke-free environments, health warnings on tobacco packages, awareness raising campaigns as well as measures adopted in other policy areas (see section 2.1.4). In the absence of further tobacco control measures at EU level, it is likely that the trend in prevalence would revert, at least in those Member States not taking actions under the baseline scenario. In any case, even if some Member States take stronger actions on their own initiative, this would create a patchwork of legislations interfering with the internal market.

Secondly, market developments in terms of packaging, ingredients, new products and sales strategies have the potential of misleading consumers, undermining **awareness** of health risks and encouraging (in particular) young people to take up smoking. This has been demonstrated in the problem identification above (section 2.2.1-2.2.5) for each of the relevant policy areas, including references to scientific evidence. Over time, this could encourage young people to take up smoking and prevent current smokers from quitting. Whilst the latest Eurobarometer showed a welcome decline in smoking prevalence amongst young people, studies from the WHO showed that several Member States have seen an increase in smoking prevalence among youth since 2005.[198]

Based on this it is assumed that the overall smoking prevalence will remain at the current level if no EU action is taken. The **precise prediction of the baseline is, however, of limited relevance** for this impact assessment as the impact of all measures is expressed in relative terms, i.e. if the consumption/prevalence were to decrease as predicted by Euromonitor, the proposed measures would accelerate the decrease. If, on the other hand, the consumption were to remain stable, it could decrease thanks to the envisaged measures.

Consumption of STP is expected to increase under the baseline scenario in light of new product developments and the introduction of smoke-free environments in more and more Member States.[199] This prediction is also shared by one of the chewing tobacco manufacturers who sent information to the Commission in the context of the revision of the TPD. The same

[196] According to 2012 Eurobarometer survey, smoking prevalence was 28% in the EU-25 (excluding RO and BU) and 27% in EU-15. This is considerably less than 32% in 2006 (EU-25), respectively 39% in 2002 (EU-15). The volume of the EU-27 cigarettes market in 2010 was 608.8 bn sticks, what represents a decline of 23.3% in comparison to 2000, when 793.7 bn sticks were sold across the EU.
[197] Matrix 2012.
[198] Currie C, Zanotti C, Morgan A, Currie D, de Looze M, Roberts C, et al., eds. Social determinants of health and well-being among young people. Health Behaviour in School-aged Children (HBSC) study: international report from the 2009/2010 survey. Copenhagen: WHO Regional Office for Europe; 2012. Eurobarometer 2012
[199] Despite repeated efforts to gather reliable statistics from the industry (European Associations and larger producers such as Pöchl) no information could be obtained.

manufacturer also confirmed that multinational tobacco companies' engagement in the STP segment is likely to lead to greater awareness of STP in general. Moreover, reports from other jurisdictions also suggest an upwards trend in STP worldwide. Use of nasal tobacco in Iceland has increased significantly from 11.7 tons in 2003 to 30.2 tons in 2011.[200] New STP products have also been introduced on the US market, including dissolvable STP resembling candies.

There is not conclusive evidence as regards the substitution between STP (including novel non-combusted tobacco products) and smoking products and it is therefore not possible to draw any firm conclusion whether the expected increase in STP use will have an impact on the smoking prevalence. STP can, indeed, be used by current smokers, e.g. to reduce consumption or in any effort to quit, but at the same time and as illustrated above, STP can attract young people who do not yet smoke and who do not intend to take up smoking (entry gate). STP can also prevent people from effectively quitting (dual use). The issue of substitution will be further explored in section 5.1.1.

The lack of visible health warnings on STP under the current TPD (see 2.2.1) could also undermine consumers' and potential consumers' awareness of the adverse health effects of STP and thus lead to higher uptake of these products.

2.4. EU BASIS TO ACT

This section includes a general assessment of the relevant legal basis, subsidiarity and proportionality. The proportionality is further examined as part of the assessment and comparison of policy options (section 5).

Compliance with fundamental right has also been ensured throughout the document. The proposal affects the freedom of economic operators to conduct business (Article 16) as well as their freedom of expression and information (Article 11) and right to property (Article 17) but the obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the internal market while ensuring a high level of health protection.

1.1.9. Legal basis

The current TPD is based on Article 95 TEC (now Article 114 TFEU).[201] The choice of the legal base has been confirmed by the Court of Justice of the European Union (hereinafter: "the Court").[202] The same legal basis is appropriate for revising the TPD. Article 114(1) TFEU empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. According to Article 114(3) TFEU, the Commission should aim at ensuring a high level of health protection in its proposal envisaged in paragraph 1 of Article 114.

It follows from the case law that measures adopted on the basis of Article 114 TFEU must genuinely have as their object the improvement of the conditions for the establishment and functioning of the internal market. A mere finding of disparities between national rules is not

[200] Information received from the Icelandic Ministry of Welfare, July 2012.
[201] In addition to Article 95 TEC the TPD was also adopted on the basis of Article 133 TEC. Case: C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd. [2001] ECR I-11453, the Court found, however, that Article 95 TEC was the only appropriate legal base, but that the addition of Article 133 TEC as a legal base was not a reason for declaring the Directive invalid.
[202] C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453

sufficient to justify having recourse to Article 114 TFEU.[203] At the same time it is settled case-law that recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from divergent development of national laws. The emergence of such obstacles must be likely and the measures in question must be designed to prevent the discrepancies.[204] The (existing or likely) disparity must have (actually or probably) the effect of creating an obstacle to trade, by preventing a product or service from moving freely within the Union,[205] or by appreciably distorting competition on the internal market.

The Court has held that, provided that the conditions for recourse to Article 114 TFEU are fulfilled, the legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.[206] On the contrary, priority must be given to measures ensuring a high level of health protection.

In line with the jurisprudence of the Court, the following situations of relevance for this impact assessment can be distinguished, under which harmonisation based on Article 114 is justified:

1. There is an **existing level of harmonisation** which needs an update in light of scientific and international developments.[207] This is the case for display of TNCO levels, the size of the warnings and certain aspects of traceability features. The current legislation needs to be updated to take into account new evidence.

2. For **product specific measures** the decisive question is whether there are discrepancies between national legislations impacting on the marketing of products across borders or whether there is a sufficient likelihood that such discrepancies will appear in the future. Measures related to scope, labelling and ingredients typically fall within this category. It follows from jurisprudence that these types of product requirements are in themselves liable, in the absence of harmonisation at EU level, to constitute obstacles to the free movement of goods. [208]

3. Even a measure not directly aimed at improving the conditions for the functioning of the internal market can be adopted under Article 114 if its purpose is to **ensure that certain provisions concerning the internal market** are not circumvented.[209] This is

[203] C-376/98 Federal Republic of Germany v European Parliament and Council of the European Union. [2000] ECR I-08419, p 84 and C-380/03 Federal Republic of Germany v European Parliament and Council of the European Union [2006] ECR I-11573, p 37

[204] C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453, p 61, C-380/03 Federal Republic of Germany v European Parliament and Council of the European Union [2006] ECR I-11573, p 38 and C-58/08 The Queen, on the application of Vodafone Ltd and Others v Secretary of State for Business, Enterprise and Regulatory Reform. [2010] ECR I-04999, p 33

[205] Cases, C-371/98, The Queen v Secretary of State for the Environment, Transport and the Regions, ex parte First Corporate Shipping Ltd, interveners: World Wide Fund for Nature UK (WWF) and Avon Wildlife Trust. [2000], p I-09235, para 84. C-380/03, Federal Republic of Germany v European Parliament and Council of the European Union.[2006], p I-11573, para 37.

[206] C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453, para 62

[207] Idem, para 77-79

[208] Idem, para 64

[209] Case C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453, p 82-83

particularly relevant for the areas on cross-border distance sales and tracking, tracing and security features in this impact assessment.

4. A **ban of a product** can also, under specific circumstances, be adopted on the basis of Article 114.[210] In the case of oral tobacco, the Court confirmed the validity of the ban taking into consideration that national legislations were divergent and were therefore such as to constitute obstacles to the free movement of goods, the product (oral tobacco) was new on the market and could be attractive to young people. The Court also found the ban on oral tobacco proportionate due to the harmful effects, the uncertainty of oral tobacco as a substitute for cigarettes, the addictive and toxic characters of nicotine, oral tobacco's danger to young people and the novelty of the product. [211]

1.1.10. Subsidiarity

In accordance with the principle of subsidiarity, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional or local level, but can rather be better achieved at Union level (Article 5(3) TEU).

As indicated above, some of the areas included in this impact assessment are already **covered by the current TPD**, but need to be updated in accordance with market, scientific and international developments. Due to the harmonisation which already exists, Member States are prevented / limited from acting unilaterally. For example, Member States are not allowed to remove the display of tar, nicotine and carbon monoxide (TNCO) levels or choose to put the pictorial health warning on the most visible side of the package and they have limited competence in terms of traceability. Only a common approach is possible to update these provisions.

Other areas relevant for this impact assessment are subject to **different approaches** in Member States which have led to obstacles to the functioning of the internal market. For example, in policy areas labelling and ingredients, the heterogeneous situations in Member States have resulted in a situation where the industry has to produce different product lines for different markets. Even more disparity is expected in coming years when Member States implement the FCTC obligations and commitments. Only a harmonised approach at EU-level can remove obstacles to cross-border trade. Only a harmonised approach would ensure that industry is not obliged to adapt at different times to 27 national regimes.

Finally, in some areas it would be very **difficult for a Member State to act unilaterally** due to the difficulties to enforce such an action when other Member States have different rules. For example, it appears almost impossible for a Member State to enforce restrictions on tobacco internet sales if such sales are unregulated in other Member States. The current Council Recommendation 2003/54/EC does not indicate how tobacco distance sale should be regulated and the challenge related to enforcement was outlined in the Commission's Staff Working Document from 2009 on the implementation of the Recommendation. A legally binding and EU wide measure in the framework of the revision of the TPD would therefore produce clear benefits. The same holds true for the EU system for tracking and tracing, when tobacco products regularly move across borders.

[210] For example Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825

[211] Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825

EU action would also contribute to greater consistency, both between and within Member States, and a higher level of legal certainty, for example in the area of NCP where the legal situation is complex and unclear, which undermines the level playing field.

1.1.11. Proportionality

Under the principle of proportionality, the content and form of the Union action shall not exceed what is necessary to achieve the objectives of the Treaty (Article 5(4) TEU). In the area of health, the Court has held that the EU legislature must be allowed **broad discretion** and the legality of a measure can be affected only if the measure is **manifestly inappropriate** having regard to the objective which the competent institution is seeking to pursue.[212] The revision shall aim at providing an appropriate level of margin for implementation by the Member States and it must fully respects responsibilities of the Member States to organise, finance and deliver health services and medical care.

3. POLICY OBJECTIVES

Overall objectives

The overall objective of the revision is to improve the functioning of the internal market, while ensuring a high level of health protection. In terms of **internal market**, the proposal aims to:

1. Update **already harmonised areas** to overcome Member States' obstacles to bring their national legislations in line with new market, scientific and international developments.[213]

2. Address **product related measures not yet covered by the TPD** insofar as heterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market.[214]

3. Ensure that certain provisions of the TPD are **not circumvented** by placing on the market of products not compliant with the TPD.[215]

It is also important to ensure a **harmonised implementation of international obligations** following from the WHO Framework Convention on Tobacco Control (FCTC), which is binding for the EU and all Member States, and a consistent approach to non-binding FCTC commitments, if there is a risk of diverging national transposition.

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[212] See C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453, p 123

[213] Without an update, Member States cannot, for example, increase the size of the health warnings, change their location of the package or replace the display of tar, nicotine and carbon monoxide levels. For example, at this stage, eight Member States have adopted pictorial health warnings and the regulations of ingredients differ between Member States.

[214] For example, at this stage, eight Member States have adopted pictorial health warnings and the regulations of ingredients differ between Member States. For example, measures on cross-border distance sales and traceability will facilitate legal activity and thus prevent sale of tobacco products not complying with the TPD (e.g. health warnings and ingredients).

[215] For example, measures on cross-border distance sales and traceability will facilitate legal activity and thus prevent sale of tobacco products not complying with the TPD (e.g. health warnings and ingredients).

The revision will contribute to the overall aim of the EU to promote the well-being of its people (TEU Article 3). The proposal should contribute to the Europe 2020 strategy in so far as keeping people healthy and active longer will have a positive impact on productivity and competitiveness. The revision should also fully respect the EU Charter on Fundamental Rights.

Specific and operational objectives

Specific objectives	**Operational objectives** (PA=Policy Area)
A To remove obstacles to cross-border trade and ensure a level playing field for manufacturers and other economic operators	1. remove unjustified differential treatment between products (PA1a, b, 3) 2. facilitate a level playing field for economic actors in the field of STP, NCP and herbal products for smoking (PA1), for retailers involved in cross-border distance sale (PA4) and traceability and security features (PA5) 3. remove national disparities and ensure a harmonised approach in packaging & labelling and ingredients (PA1, 2,3) and traceability and security features (PA5)
B To reduce the administrative burden for economic actors and public authorities due to the complexity of the current TPD and remaining disparities in legislations	1. unify the rules on labelling and ingredients and establish one single format for ingredients reporting (PA1, PA2, PA3) 2. facilitate market surveillance of Member States and improve the overall enforceability, including by reducing the number of products on the market which do not comply with TPD specifications (PA 1a, 3, 4, 5)

Choosing between options

A high level of **health protection** has been considered when choosing between different policy options. In this context, the revision seeks to regulate tobacco products in a way that reflects their characteristics and negative impact on health, e.g. by ensuring that the ingredients and packaging of the products do not encourage or facilitate initiation by young people. [216] The focus on young people is also reflected in the selection of the policy options and the products primarily targeted (FMC, RYO and STP). In addition, the revision should create conditions which allow all citizens across the EU to take informed decisions about the products, based on accurate information on the health consequences of consuming tobacco products. Finally, all smokers should benefit from measures contained in the TPD (e.g. health warnings and ingredients regulation). [217]

Specific considerations	**Operational considerations** (PA=Policy Area)
C To provide a high level of protection to citizens throughout the EU	1. regulate the placing on the market of hazardous and potentially hazardous products (PA1, 3) 2. remove from the market products which are particularly attractive, in particular to young people, because of their appearance or taste/smell (PA1, 2, 3) 3. assist consumers to verify the authenticity of tobacco products and protect them against non-complying supply (PA5) 4. inform the consumer, through the labelling, about the harmful effects of tobacco and related products and remove misleading information (PA1, 2) 5. reduce easy availability and access of tobacco and related products in the interest of protecting vulnerable groups, in particularly young people (PA1a, c, 4, 5) 6. ensure that consumers across the EU benefit from a minimum level of protection when purchasing tobacco products (e.g. health warnings and ingredients control) and reduce the appeal of cheaply available illicit tobacco products to protect vulnerable groups. (PA4, 5)

[216] Riordan M. The path to smoking addiction starts at very young ages. Washington, DC: Campaign for Tobacco-Free Kids; 2009. http://www.tobaccofreekids.org/research/factsheets/pdf/0127.pdf (accessed 28 Nov 2012).

[217] An unintended, but welcome side effect of the measures against illicit trade is that it protects tax revenues of Member States

4. POLICY OPTIONS

A number of **factors have been taken into consideration when identifying the policy options**, most prominently the benefits for the internal market and its main stakeholders (industry, suppliers, distributors, consumers, NGOs and Governments), international obligations and commitments (notably FCTC and its guidelines), and the EU Charter on Fundamental Rights. The views put forward by stakeholders have been carefully considered. Reference is also made to the criteria contained in Annex 4. Some general comments are necessary upfront.

The role of public health

While all options identified seek to **improve the functioning of the internal market**, the **protection of public health has played a key role in designing/shaping the policy options**. This follows from the Commission's duty to ensure a high level of health protection in its proposals and is logical considering that the national legislations, which the revised TPD seeks to harmonise, have been adopted in order to protect public health.

The relation to FCTC

The table in section 3.2 of Annex 3 sets out the relation between the current TPD obligations, obligations stemming from FCTC, commitments in the context of FCTC guidelines as well as the preferred policy options.

The products primarily targeted

The policy options identified in this impact assessment cover in principle all tobacco products. However, in the policy areas on packaging & labelling (PA2), ingredients (PA3), and traceability & security features (PA5), stricter rules will - in a first stage - apply only to **FMC, RYO and STP** and other products will be exempted. The products initially exempted will continue to be subject to current TPD requirements. This means that the identified options primarily target large manufacturers of FMC and RYO and exempt the SMEs and micro-enterprises involved in the manufacturing of pipe tobacco and cigars.[218] This reasoning is based on a proportionality assessment, taking into account the interest of these economic stakeholders, their marketing mainly towards adult consumers and the focus of this report on regulating tobacco products in such a way that they do not appeal to underage citizens. However, for policy area 5 (traceability and security features) the exemption is only of a temporary nature (longer transitional period) and for the other concerned policy areas the exemption will be removed if the consumption trend changes and consumption in young people increases significantly.

The level of harmonisation

In general, the policy options foresee full harmonisation, but obviously Member States are allowed to maintain or introduce stricter national measures in areas not covered by the harmonisation provided that national rules are compatible with the Treaty, in particular with the principle of free movement of goods. The Directive also foresees the possibility for Member States to maintain or introduce stricter measures in areas falling within the scope of

[218] It should be noted, however, that also in the FMC, RYO and STP segment, some smaller manufacturers will be affected by the proposal.

the Directive provided that the measures are notified to and approved by the Commission which will assess if they are necessary, proportionate and non-discriminatory taking into account the high level of harmonisation achieved by the Directive.

Delegated and implementing powers

Delegated and implementing powers are foreseen to allow for an appropriate reaction to market, scientific and international developments, to amend or supplement the basic act and to give effect or shape the rules laid down in the basic act. The exact scope of these two categories of acts is further defined in the legislative proposal and the nature of the power is clearly defined in each case and linked to strict conditions in order to ensure legal certainty and respect the institutional division of tasks. Delegated/implemented powers are foreseen in the following situations:

- Establish rules for the use **of health warnings, unique identifiers and security features** and adapt **health warnings** to technical and scientific developments.
- Establish further rules for the **shape and size of unit packets**.
- Setting/adapting **maximum yields** for emissions and their measurement methods.
- Establish the **format of ingredients** reporting.
- Remove from the market of **tobacco products with characterising flavours and products with increased toxicity or addictiveness levels.**
- To **remove the exemption for products other than FMC and RYO** as regards the labelling and other than FMC, RYO and STP as regards ingredients.

Subsequent impact assessments for implementing measures and delegated acts will be carried out as appropriate and in line with the Impact Assessment guidelines.[219]

4.1. DISCARDED POLICY AREAS

A number of additional policy areas were considered at an earlier stage of the impact assessment, but these were subsequently rejected.

Firstly, regulation of **toys and sweets resembling tobacco** was considered at one stage. This suggestion has not been retained in the impact assessment as it was concluded in an early stage that the TPD is not the most adequate instrument to deal with these products.

Secondly, the introduction of **manufacturer liability for the financing of all health costs arising from tobacco consumption** was proposed by the European Parliament in its resolution from 2007. Full implementation of the "polluter pays principle" was assessed in the external study produced by RAND Europe in September 2010.[220] An external study on liability and the health costs of smoking was also commissioned to examine this proposal in more detail.[221] However, the proposal has not been assessed further in the context of this impact assessment in the light of subsidiarity and legal considerations.

Thirdly, a **total ban of all tobacco products** was discarded without further analysis. Despite the harmful effects of tobacco consumption, this option was not considered feasible. A total ban on tobacco products would lead to unreasonable compliance costs and not have the

[219] European Commission. Impact Assessment guidelines. Brussels: European Commission; 2009. http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf (accessed 28 Nov 2012).
[220] Rand 2010
[221] GHK 2012

desired effect of stopping the use of tobacco in the EU. An illegal market would most likely appear, in particular considering that 28% of EU citizens currently smoke.

Fourthly, the approximation of Member States' legislations on **Tobacco Vending Machines** (TVM) was considered in the impact assessment process and public consultation. This policy area was discarded given subsidiarity concerns and taking into account the already good progress in this area following the Council Recommendation 2003/54 and the FCTC provisions and guidelines. Thirteen Member States have banned TVM, while all remaining Member States have put in place some kind of restrictions to limit access to young people under the legal age for purchasing.[222] For more information about FCTC obligations and commitments as well as national legislations see Annex 3 (A.3.1.4.2).

Fifthly, the approximation of Member States' legislations in the area of **tobacco display at point of sale** (PoS) was considered in the impact assessment process and the public consultation. Also this policy area was discarded due to subsidiarity concerns as well as the limited support from Member States at this point in time. For further information on international commitments and regulations in Member States, see Annex 3 (A.3.1.4.2).

4.2. PROBLEM 1A – SMOKELESS TOBACCO PRODUCTS (STP)

For STP, the main issues are how to effectively regulate the products (including oral tobacco, chewing and nasal tobacco as well as novel non-combustible tobacco products), which develop rapidly (labelling and ingredients) and which are addictive products with adverse health effects (although less harmful than FMC), taking into account the growth potential (smoke-free environments)) and the current differential treatment between oral tobacco (snus) and other STP. The following options were considered:

- ***Option 0: No change***

Status quo means:
a) Oral tobacco is banned (except for Sweden which has an exemption but needs to respect labelling requirements, i.e. health warnings, and ingredients reporting).
b) Placing on the market of chewing and nasal tobacco is allowed subject to labelling requirements (health warning) and ingredients reporting.
c) Placing on the market of novel forms of STP is allowed subject to labelling requirements (health warnings) and ingredients reporting.

- ***Option 1: Lift the ban on oral tobacco and subject all STP to stricter labelling and ingredients regulation***

a) The current ban on oral tobacco is lifted and these products can be placed on the market subject to stricter labelling and ingredients requirements (e.g. health warnings on both sides of the package and a ban of products with characterising flavour (glossary) and increased toxicity or addictiveness).[223]
b) The placing on the market of chewing and nasal tobacco continues to be allowed, but subject to the same rules on labelling and ingredients as set out under a.
c) Placing on the market of novel tobacco products (glossary) continues to be allowed subject to the same rules on labelling and ingredients as set out under a.

[222] Some of the national systems might be confronted with enforcement challenges.
[223] The product regulation developed under this option could be inspired by the voluntary industry standards already used for snus, the Gothia Tek standards. Rutqvist LE, Curvall M, Hassler T, Ringberger T, Wahlberg I. Swedish snus and the GothiaTek standard. Harm Reduct J 2011; 8:11.

Delegated/implementing power to adapt health warnings, act on products with characterising flavours on products with increased toxicity or addictiveness and to regulate additives that cause a characterising flavour.

- ***Option 2: Maintain the ban on oral tobacco, subject all novel tobacco products to a notification obligation and all STP to stricter labelling and ingredients regulation***

a) The current ban on oral tobacco is maintained (except for Sweden which has an exemption), but oral tobacco needs to comply with stricter labelling and ingredients regulation (e.g. health warnings on both sides of the package and a ban of products with characterising flavours and increased toxicity or addictiveness).

b) The placing on the market of chewing and nasal tobacco continues to be allowed, subject to the same rules as set out under a. A clearer definition of chewing tobacco is inserted in the TPD.

c) A notification obligation is introduced for novel tobacco products (glossary) and a report on the market development in these products will be issued by the Commission five years after the transposition of the TPD. Novel tobacco products placed on the market must respect the rules on labelling (health warnings on both sides) and ingredients regulation (ban on products with characterising flavours).

Delegated/implementing power as in option 1.

- ***Option 3: Maintain the ban on oral tobacco, restrict the sale of other STP to areas of traditional use only and subject all STP to stricter labelling and ingredients rules***

a) The current ban on oral tobacco is maintained (except for Sweden which has an exemption), but oral tobacco needs to comply with stricter labelling and ingredients regulation (e.g. health warnings on both sides of the package and a ban on products with characterising flavours and increased toxicity or addictiveness).

b) The placing on the market of chewing and nasal tobacco is banned unless traditionally used (glossary) in Member States. The placing on the market of traditionally used STP is limited to the relevant territory/Member State and must comply with the same labelling and ingredients requirements as set out under a. Member States will have to prove traditional use and notify to the Commission.

c) The placing on the market of novel tobacco products is banned.

Delegated/implementing power as in option 1.

- ***Option 4: Ban all STP with the exception of oral tobacco in Sweden which would be subject to stricter labelling and ingredients rules***

  a) The current ban on oral tobacco is maintained (except for Sweden which has an exemption)

  b) The placing on the market of chewing and nasal tobacco is banned given their circumvention potential, in particular as regards chewing tobacco.

  c) The placing on the market of novel tobacco products is banned.

- ***Discarded options:***

An alternative option would have been to lift the ban of placing on the market of oral tobacco without suggesting any regulation. However, this option was not considered viable as it would

mean lifting a ban for a product with adverse health properties without adequate control/limits. This option was not suggested by any of the stakeholders.

Another option which was discarded was to introduce a new authorisation regime for novel tobacco products. Apart from the very significant burden for the evaluating and authorising bodies (either at national or EU level) and possibly new structures to be set up, more information is needed about these products as well as expected overall health effects, including on non-smokers, young people and people who would otherwise had quit tobacco consumption altogether.

4.3. PROBLEM 1B – NICOTINE CONTAINING PRODUCTS (NCP)

The main issue is how to effectively regulate NCP considering the heterogeneous development in Member States. Also, the addictive nature of NCP, health and safety concerns and uncertainty, growth potential (smoke-free environments) and market development (labelling and ingredients) need to be considered.

- ***Option 0: No change***

Status quo means: The TPD remains limited to tobacco products. NCP remain subject to the General Product Safety Directive,[224] or other more specific legislations.

- ***Option 1: Subject NCP to labelling and ingredients requirement under TPD***

NCP placed on the market are subject to adapted health warnings, ingredients reporting and a prohibition to place on the market NCP with characterising flavours (glossary). Delegated/implementing power to adapt health warnings and act on products with characterising flavours, on products with increased toxicity or addictiveness and to regulate additives that cause characterising flavours.

- ***Option 2: Establish a new authorisation scheme for NCP***

Only NCP that have been authorised under a new authorisation procedure (risk/benefit analysis) set up under TPD are allowed to be placed on the market. Otherwise, placing on the market of NCP is prohibited. The authorisation procedure would also cover labelling and additives control.

- ***Option 3: Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements***

NCP with a nicotine level over a certain threshold may only be placed on the market if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance under the medicinal products legislation.[225] NCP with nicotine levels below this threshold will be subject to an adapted health warning. The nicotine threshold identified under this policy option should be established by considering the nicotine content of medicinal products (NRTs) for smoking cessation which have already received a market authorisation under the medicinal products' legislation.

Delegated/implementing power to adapt the health warning and the identified nicotine threshold taking into account scientific and technical developments.

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[224] 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

[225] 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 use. OJ L 311, 28.11.2001, p. 67, as last amended by Directive 2011/62/EU, OJ L 174, 1.7.2011, p. 74

- ***Option 4: Subject all NCP to the medicinal products' legislation***

Only NCP that are authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance are allowed to be placed on the market. Otherwise, the placing on the market of NCP is prohibited. The authorisation procedure is described under option 3.

- ***Discarded option***

Development of minimum safety standards for NCP under the General Product Safety Directive[226] was not considered to address the health problems identified. Safety standards developed under this Directive and referenced in the Official Journal provide that products complying with the standards are presumed to be safe. However, since nicotine is toxic and addictive, it is impossible to set safety standards for products releasing nicotine. A safety standard under the General Product Safety Directive could therefore not fulfil its objective.

Another option would have been to update the orientation note on electronic cigarettes from 2008,[227] but considering the non-binding character of such a document and the need for a clear legal framework, this option has been discarded.

4.4. PROBLEM 1C – HERBAL PRODUCTS FOR SMOKING

The main concern related to herbal products for smoking is the different regulatory approaches in Member States. Also, the misperception of adverse health effects needs to be taken into account.

- ***Option 0: No change***

Status quo means: TPD remains limited to tobacco products. Herbal products for smoking remain unregulated or subject to different national regulations.

- ***Option 1: Subject all herbal products for smoking to labelling requirements under TPD***

Adapted health warnings are required for herbal products for smoking. Delegated/implementing power to adapt the warnings.

- ***Option 2: Phase out the placing on the market of herbal products for smoking***

Placing on the market of herbal products for smoking is phased out.

- ***Discarded option***

An alternative option would have been to regulate the content of these products. However, this option was discarded as not relevant for the main problem identified.

[226] 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

[227] European Commission. Orientation note. Electronic cigarettes and the EC legislation. Brussels: EC; 2008. http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/orientation_0508_en.pdf (accessed 28 Nov 2012).

4.5. PROBLEM 2 – PACKAGING AND LABELLING[228]

The main issues are that some of the current provisions are outdated (e.g. size of the warnings, display of quantitative TNCO-values) and that there is heterogeneous development in Member States (e.g. pictorial warnings). There is also a need to implement FCTC obligations and commitments, to address the potential of packaging and labelling to mislead consumers and encourage people to start or maintain smoking.

- ***Option 0: No change***

Status quo means: Current labelling rules are maintained, i.e. a general text warning of not less than 30% and an additional text warning of not less than 40%.[229] Member States can choose to use a combined warning (picture and additional text warning) instead of the additional text warning (40%). Delegated/implementing power to adapt the additional health warnings.[230]

- ***Option 1: Mandatory enlarged picture warnings***

Combined warnings (picture plus text) of 75%[231] displayed on both sides of the packages of tobacco products, presented in rotation. TNCO levels on the packages are replaced with descriptive information on content, emissions and risks. Display of cessation information (e.g. quit-lines, websites) is added to the packages.

Tobacco products other than FMC and RYO are exempted (current TPD rules apply). Delegated/implementing power to remove/extend the exemption for these products if there is a change of circumstances and to adapt the health warnings.

- ***Option 2: Option 1 plus harmonise certain aspects of packets and prohibit promotional and misleading elements[232]***

Option 1 plus:
1) The tobacco labelling and packaging and the tobacco product itself shall not include any promotional and misleading elements (e.g. misleading colours, symbols, slim FMC),
2) setting certain requirements for packages (e.g. cuboid shape, minimum number of and FMC per package) as well as for the size of the warnings

Member States are allowed to regulate the area not regulated by the TPD or other Union legislation, including adopting provisions providing full standardisation of packaging of tobacco products (i.e. plain packaging) as far as these provisions are compatible with the Treaty. The Commission will report on experiences gained with respect to surfaces not governed by the TPD five years after the transposition of the TPD.

For Point 2) Tobacco products other than FMC and RYO are exempted (current TPD rules apply). Delegated/implementing power to remove the exemption for these products if there is a change in circumstances.

- ***Option 3: Option 2 plus full plain packaging***

Option 2 plus: standardised colour, font, size and position of brand name and brand variant on packages (plain packaging) and a readable health warning on each FMC stick.

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[228] For STP, NCP and herbal products for smoking, see problem 1a, 1b, and 1c
[229] Required increase of the size if more than one official language (32-35% and 45-50%)
[230] Procedures foreseen in current TPD
[231] The size of the health warning proposed is based on scientific evidence and international developments.
[232] For definition, see glossary

Other tobacco products than FMC and RYO will be exempted from the requirements (current TPD rules apply). Delegated/implementing power to remove the exemption if there is a change in circumstances.

- ***Discarded policy option***

An additional option which was considered in an earlier stage of the impact assessment was to introduce health warnings on pipes and water-pipes as such. This option was not considered appropriate within this revision.

4.6. PROBLEM 3 – INGREDIENTS[233]

The main problems are the lack of a harmonised reporting format resulting in additional burden for all stakeholders involved, the heterogeneous development in Member States in terms of ingredients regulation (toxicity, addictiveness, attractiveness) and the need to implement FCTC obligations and commitments. Also, the potential of certain tobacco products to mislead consumers and encourage people to take up or maintain smoking should be considered.

- ***Option 0: No change***

Status quo means: Current mandatory reporting without common format. No common ingredients regulation beyond toxicity and addictiveness reporting.

- ***Option 1: Common reporting format on a voluntary basis. Prohibit toxic, addictive and attractive additives in tobacco products.***

Member States are free to decide whether they oblige manufacturers to report additives in tobacco products. If Member States decide to make the reporting obligatory, the common reporting format must be used. Member States shall prohibit additives based on the general criteria toxicity, addictiveness and attractiveness.

- ***Option 2: Mandatory reporting in harmonised format. Prohibit tobacco products with characterising flavours and products with increased toxicity or addictiveness.***

Manufacturers are obliged to electronically report ingredients (glossary) of tobacco products in accordance with a common format and provide supporting data (e.g. marketing reports). Fees charged by Member States for handling the information submitted to them shall not exceed the cost attributable to those activities. Placing on the market of new or modified tobacco products must not take place before the submission of ingredients data. Reported data, excluding confidential information, is published. Delegated/implementing power to specify the reporting format.

Tobacco products with characterising flavours (glossary) are prohibited (this is similar to the US model). Test panels assist in the decision making process. Additives associated with energy and vitality (e.g. caffeine and taurine) or creating the impression that products have health benefits (e.g. vitamins) are prohibited. No flavourings are allowed in filters, papers or packages. Tobacco products with increased toxicity or addictiveness shall not be placed on the market. Member States shall remove from the market tobacco products that include ingredients not complying with REACH. Delegated/implementing power to set limits for additives imparting a characterising flavour, toxicity and addictiveness.

[233] For STP, NCP and herbal products for smoking, see problem 1a, 1b and 1c.

Tobacco products other than FMC, RYO and STP (i.e. cigars, cigarillos and pipes) are exempted from the prohibition of products with characterising flavour and the prohibition of additives associated with energy and vitality or health benefits. Delegated/implementing powers to remove the exemption for these products are foreseen if there is a substantial change of circumstances.

This approach is similar to the US approach.

- ***Option 3: Mandatory reporting in harmonised format. Prohibit all additives not essential for manufacturing.***

Ingredients reporting as in option 2. In terms of ingredients regulation, all additives in tobacco products, except those essential for manufacturing are prohibited. Maximum limits are set for sugar and sweeteners.
Other tobacco products than FMC, RYO and STP are exempted from the ingredients regulation. Delegated/implementing power to remove the exemption for these products if there is a change of circumstances.

This option is similar to legislations in Canada and Brazil.

- ***Discarded options***

An alternative approach would have been to develop a common list of ingredients based on addictiveness and toxicity as foreseen in the current TPD (Articles 6 and 12). This would have responded to the concerns expressed by the European Parliament in its Resolution from October 2007.[234] However, as explained in previous sections, at this stage scientific and international progress has primarily been achieved in terms of attractiveness rather than addictiveness and toxicity. Therefore, this approach was not considered, but should rather be seen as a measure to be taken at a later stage/over time.

4.7. PROBLEM 4 – CROSS-BORDER DISTANCE SALES OF TOBACCO PRODUCTS

Cross-border distance sales of tobacco products undermine the safeguards/full effect of the TPD provisions (labelling, ingredients, ban on oral tobacco) and encourages illicit cross-border trade (legal purchasing via the internet makes little sense).[235] There is also a need to implement FCTC obligations and commitments. Finally, it facilitates access for young people.

- ***Option 0: No change***

Status quo means: Regulation is left to Member States. Council Recommendation 2003/54 applies, i.e. recommendation to restrict tobacco distance sales for general retail.

- ***Option 1: Notification and age verification system***

Retailers of tobacco products intending to engage in cross-border distance sales shall notify their cross-border activities to the Member States where the company has its seat and where it intends to sell. Member States may require the retailer to appoint a natural person, who ensures compliance with the TPD of products delivered to customers in Member States concerned. Mandatory age verification mechanism is foreseen.

- ***Option 2: Prohibit cross-border distance sales of tobacco products***

[234] Resolution of 24 October 2007 on the Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level'. (2007/2105)
[235] Council Directive 2008/118/EC of 16.12.2008, OJ 9/12 of 14.1.2009

Cross-border distance sales of tobacco products are prohibited in the EU.

4.8. PROBLEM 5 – TRACEABILITY AND SECURITY FEATURES

The main problem in this area is that illicit products (estimated 8.25 % of the market with increasing tendency[236]) undermine the safeguards/full effect of the TPD provisions (labelling, ingredients). The current TPD provisions are incomplete, do not provide for a fully-fledged traceability system, and consumers have difficulties to verify the authenticity of tobacco products. There are also obligations as regards the fight against illicit products stemming from the FCTC (Article 15).

- ***Option 0: No change***

The legally binding Agreements between the four biggest FMC manufacturers and the EU and Member States would continue to apply (until potential expiry as of 2016).[237] Equivalent measures would not be in place for tobacco manufacturers without Agreement. The EU could adopt measures only on batch numbering (TPD Article 5(9)).

- ***Option 1: EU tracking and tracing system***

An EU tracking and tracing system at packet level for tobacco products throughout the supply chain (excluding retail) is introduced. Tobacco manufacturers shall conclude contracts with independent third parties that provide data storage capacities for such system ensuring full transparency and accessibility by Member States at all times. Tobacco products other than FMC and RYO are granted a transitional period of five years.

Delegated/implementing power to adopt technical specification to ensure compatibility between the systems used.

- ***Option 2: Tracking and tracing system, complemented by security features***

Option 1 plus: security features against counterfeiting and against illicit/cheap whites (glossary) on all tobacco products (e.g. holograms). Tobacco products other than FMC and RYO are granted a transitional period for five years. Delegated/implementing power to adopt technical specifications for the security features.

5. ANALYSIS OF IMPACTS

In accordance with the Commission's impact assessment guidelines,[238] this impact assessment analyses the likely impacts of identified policy options. As the overall objective of revising the TPD is to ensure a good functioning of the internal market while ensuring a high level of health protection, the **focus of the analysis is on economic-, social and health impacts**. Environmental impacts have been considered to be less significant and are therefore not specifically referred to in this section. The assessment criteria (listed in Annex 4) have been identified based on the specific objectives and health considerations set in chapter 3. Some additional comments are warranted upfront.

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[236] Euromonitor as presented by Matrix 2012.

[237] The European Union and all Member States have signed legally binding and enforceable agreements with PMI (2004) and JTI (2007) and the European Union and 26 Member States have signed agreements with BAT and ITL (2010)

[238] European Commission. Impact Assessment guidelines. Brussels: European Commission; 2009. http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf (accessed 28 Nov 2012).

Effectiveness, efficiency and coherence

The comparison of policy options and the identification of preferred options are based on the general evaluation criteria **effectiveness** (the extent to which options achieve the objectives of the proposal), **efficiency** (the extent to which objectives can be achieved for a given level of resources/at least cost) and **coherence** (the extent to which options are coherent with the overarching objectives of EU policy).

Data collection

Collecting data and presenting it in a coherent form was a challenge when preparing this report. Data has been collected/received a.o. from NGOs, industry, external consultants, scientific studies, Member States, other Commission services and publicly accessible information. When, despite these efforts, information was considered inadequate, information from other comparable sectors were used.[239] The analysis was complemented by qualitative assessments. Some stakeholders did not provide the information as requested or not in the format requested. Sometimes it was also difficult to reconcile publicly available data (e.g. Eurostat) with information received from the economic stakeholders. The data sets received from industry were also not always fully coherent (here an effort was made to reconcile the data to the extent possible). In order to ensure overall quality some of the key data was verified with the associated services (e.g. on tax revenues) and the industry (e.g. on turnover generated with tobacco products and the value chain by various stakeholders (farmers, upstream suppliers, tobacco industry, downstream distributors). Finally, information on the illicit part of the market is by definition difficult to establish in a robust form taking into account the nature of these activities.

Direct impacts

This impact assessment distinguish between direct impacts associated with the implantation of the options for the stakeholders' one-off and on-going costs and indirect impacts associated, in particular, with their effect on revenues. As for the **direct costs** for the economic stakeholders, five main cost categories have been identified and considered throughout the impact assessment: 1) familiarisation with the requirement of the new regulation, 2) redesign/reformulation of the package/product, 3) acquisition of new equipment (e.g. printing equipment), 4) costs for disposal of old stocks and equipment (e.g. printing equipment) and 5) variable/on-going costs (e.g. changes in types and quantities of material to be used). The estimation of the direct cost factor 1-4 has also been used as an indicator for the functioning of the internal market, i.e. the preferred option should normally lead to reduced compliance costs compared to the status quo, as economic stakeholders can adapt to EU provisions (as nationally implemented) in one go compared to consecutive changes at national level leading to diverging set of rules. For Governments, direct impacts are also estimated, e.g. in terms of administrative burden associated with the options.

Indirect impacts

The **indirect impacts** affect both the economic stakeholders (industry concerned, upstream/downstream actors, others) and Governments. Economic stakeholders are impacted in terms of revenue/profit and in terms of employment. In particular as regards employment, an input/output model was used which describes that money not spent on tobacco would be spent on other sectors. The expected main gain for **Governments/society** is the improvement of public health (gained life years). This impact has been monetised in line with the

[239] For ex., see: Matrix 2012: "Industry has been able to provide limited data to demonstrate how particular regulatory change has impacted across the value chain in terms of costs or sales. The majority of evidence provided was indicative or too general."

Commission's impact assessment guidelines.[240] In addition, the impacts on health care costs, reduced absenteeism and tax revenues are addressed. The calculations are based on an expected consumption drop of 2% within five years after the transposition.[241] The indirect impacts are further described in section 5.7 and Annex 5.

SMEs

When analysing the impacts, specific considerations have been given to **SMEs and micro-enterprises** both in identifying the policy options and assessing their impacts. A summary of the impact on SMEs is set out in section 6.2.2.

Stakeholders' comments and concerns have also been carefully considered throughout the document, as illustrated by separate sections under each policy area describing the views expressed by key stakeholders, integration of key comments or essential points, and a detailed description in Annex 1.

The text is divided in five subsections following the five identified policy areas (STP and extension of the product scope, packaging & labelling, ingredients, cross-border distance sales and traceability & security features). Assessment of impacts, comparison of policy options and presentation of a preferred option will thereafter be undertaken separately for each of the policy areas. Scoring tables for the different policy areas can be found in Annex 4. A general conclusion presenting the overall combined preferred options can be found in section 6.1.

5.1. ASSESSMENT OF POLICY OPTION 0: NO CHANGE

5.1.1. Economic impacts

Internal market

The increasing divergence between Member States' legislations under the baseline scenario leads to further fragmentation of the **internal market**. Given the significant amount of cross-border trade in tobacco and related products (section 2.1), this will negatively affect cross-border trade and undermine the level playing field for the economic actors involved.[242]

Direct impacts

More fragmentation of the internal market leads to higher **costs for economic stakeholders to comply** with different national measures. In general, a qualitative description of the various cost categories suggests that the compliance costs under option 0 (consecutive national changes) are expected to be higher than if a harmonised approach across the EU was taken.

Following the cost categories identified above, the direct economic impact (compliance costs) can be described according to the table below. Categories 1-4 refer to one-off costs, while category 5 is a variable/on-going cost.

[240] For each life year, a value of 52,000 EUR is assumed.
[241] For further information on how this drop was estimated, see Annex 5.
[242] In certain areas Member States cannot adapt their legislation due to existing level of harmonisation. Also, there is a risk that the safeguards of the Directive are undermined by non-compliant products.

Cost category (compliance cost)	Description
1. Familiarisation with the requirements of the new regulation.	Economic stakeholders need to monitor 27 different legal systems and get familiar with all unilateral changes adopted by Member States.[243] This can also include seeking legal advice.
2. Redesign/reformulation of the package/product	Economic stakeholders need to adapt to unilateral changes adopted by Member States. This also includes testing and legal/marketing/scientific advice. Stakeholders also have to adapt production lines to comply with different national legislations.
3. Acquisition of new equipment	Economic stakeholders may need to buy new equipment (e.g. printing equipment) to comply with national measures.
4. Costs for disposal of old stocks and equipment	Cost for the disposal of stocks can normally be disregarded provided sufficient transposition periods are granted.
5. Variable/on-going costs	Economic stakeholders might have to change the types and quantities of material to be used in the manufacturing process. This could be either a cost (e.g. more expensive ink) or a saving (e.g. less ingredients to be used) and is proportionate to the volume of sale.

The approach can be exemplified for the area of **labelling, ingredients and traceability and security features**. For estimations of costs, see impact assessment sections 5.2-5.6.

Indirect impacts

As far as **indirect impacts** (linked to consumption) are concerned, the impact on companies' revenues under the baseline scenario is expected to be neutral. This is based on the estimated stagnation of smoking consumption/prevalence (see above under baseline scenario, 2.3.3).

Also **Governments'** monetised value of public health, the tax revenues, health care costs and productivity losses are linked to the consumption/prevalence forecast. As mentioned in section 2.1.2, approximately 25 bEUR are currently spent every year to treat smoking related diseases and 8.3 bEUR are lost annually on productivity losses. From an economic point of view, the baseline scenario constitutes a **missed opportunity for Governments to further reduce costs**. From a macro-economic point of view, taxes are not a cost (taxes just reallocate revenues from economic stakeholders to the Government), but obviously reduced taxes have an impact on Government revenues.

Consumers

Under option 0, industry would have an incentive to present **consumers** with a larger choice of products.[244] Consumers would also be subject to new innovative marketing, likely to target young consumers in particular and there would be a lack of protective measures.[245] No particular impact is foreseen as far as the price is concerned. Consumers would also be exposed to serious health risks due to a lack of harmonised standards for some of the products, including STP, NCP and herbal products for smoking. The supply of illicit tobacco products would continue to be of (increasing) safety concern and to undermine tobacco control measures intended to protect consumers. In addition, as indicated in the problem identification, certain aspects of packaging & labelling, as well as certain ingredients may have the capacity to mislead consumers.

[243] It could be noted that a UK administrative burden exercise estimated the costs attributed to familiarisation and understanding of the food labelling regulation as 13% of all administrative costs across food legislation, see FSA (2006), "Food Standards Agency: Administrative Burdens Measurements Exercise: Final Report", June 2006

[244] In the light of existing entry barriers it might not be easy, in particular for SMEs to enter the market in a sustainable manner with new brands.

[245] See for ex. Cancer Research UK. The packaging of tobacco products. Stirling: Centre for Tobacco Control Research, University of Stirling; 2012.

International

In terms of **international** impact, under option 0, the EU does not fully comply with its international obligations/non-binding commitments (FCTC)[246] and lags behind other jurisdictions (including Canada, Australia and the US) in many of the areas covered by this impact assessment, including labelling and ingredients.

5.1.2. Social impacts

The specific impact on **employment** is estimated under option 0 following the consumption forecast foreseen under the baseline scenario (section 2.3.3) (including redistribution effects). This is without prejudice to further consolidation and automatisation of production methods which can be expected and that would potentially entail employment cuts. In terms of **equality**, option 0 has negative consequences on young people in particular. As illustrated in the problem definition, many of the products on the market currently target young people. This is true both for STP, NCP and herbal products for smoking, but also for FMC marketed in appealing packages or with flavours particularly attractive to young people. Due to the price structure RYO are also attractive for young people. The targeting of young people is expected to continue in coming years.

5.1.3. Health impacts

As outlined above, under the baseline scenario (section 2.3.2), Member States would be prevented from taking unilateral actions in **areas already harmonised in the TPD**, notably as regards the size and placement of the health warnings, the removal of misleading TNCO levels and in the area of traceability. This is unsatisfactory from a public health point of view and is not in line with the obligation to ensure a high level of health protection in all policies and activities (TFEU Articles 168 and 114). The high level of premature mortality and morbidity would prevail (see section 2.1.2).

5.2. SMOKELESS TOBACCO PRODUCTS AND EXTENSION OF THE PRODUCT SCOPE

1.1.12. Smokeless tobacco products (STP)

5.2.1.1. PO1: Lift the ban on oral tobacco and subject all STP to stricter labelling and ingredients regulation

a) The current ban on oral tobacco is lifted and these products can be placed on the market subject to stricter labelling and ingredients requirements (e.g. health warnings on both sides of the package and a ban of products with characterising flavour (glossary) and increased toxicity or addictiveness). b) The placing on the market of chewing and nasal tobacco continues to be allowed, but subject to the same rules on labelling and ingredients as set out under a. c) Placing on the market of novel tobacco products (glossary) continues to be allowed subject to the same rules on labelling and ingredients as for oral tobacco. Delegated/implementing power to adapt health warnings, act on products with characterising flavours on products with increased toxicity or addictiveness and to regulate additives that cause a characterising flavour.

[246] For ex. FCTC refers to effective legislation regulating the content of tobacco products, marking of all tobacco packages in order to determine the origin and health warnings of 50% or more (but no less than 30%).

Economic impacts

Option 1 would allow the placing on the market of oral tobacco (snus) in the EU and remove the current differential treatment between different types of STP. However, when the ban on oral tobacco was introduced in 1992, three Member States had already adopted national bans. It is likely that, at the very least, these Member States will wish to maintain their approach, in particular when considering that most of the Member States responding to the public consultation explicitly supported keeping the ban on oral tobacco (Annex 1). This could negatively affect the functioning of the internal market if it reintroduces the fragmentation of the market that existed before 1992. Moreover, it is difficult to draw any firm conclusion on the effectiveness on STP in smoking cessation (see below under health impacts). In **regional** terms, option 1 would have a positive impact on the Finnish island Åland which claims being subject to unequal treatment under the current situation (section 2.2.1).

The most important impact for the **economic stakeholders** is that of increased sales of oral tobacco following the lifting of the ban, in particular as this product is new to the EU market (except for Sweden) and is potentially attractive to new customers, including young people.[247] Smoke-free environments are a key driver for this expected growth. It is not possible to quantify the expected increase in sales as it is very difficult to foresee how new and unexplored markets would react to this product. The oral tobacco producer, Swedish Match, has indicated that the sale of oral tobacco in the EU could potentially generate gross profits to the retail sector in the amount of 3-9 bEUR.[248] Chewing and nasal tobacco producers are likely to be confronted with decreased or stagnating sales in the light of increased competition from oral tobacco and a reduced product portfolio (no STP with characterising flavours, additional health warning).[249] The same could be true for producers of NRT, FMC and RYO if oral tobacco is – as claimed by Swedish Match - used for smoking cessation purposes. However, the evidence to that end is not compelling (see also below on health impacts). Also, products claiming to assist smokers to quit smoking would require authorisation as medicinal products.

All STP producers would be faced with limited additional **compliance costs** in terms of the required additional health warnings and the restrictions in terms of ingredients (ban on STP with characterising flavours).[250] On the other hand, an EU based approach is still cheaper than consecutive changes at national level. Additional compliance costs would consist of familiarisation and understanding of the new requirements, redesign of the packages and reformulation of the products.[251] The industry has estimated the medium range cost for changing the labelling to 6,000 EUR per SKU, although this can vary from company to company.[252] As regards reformulation, an important market development has taken place in STP (including oral tobacco) in recent years. Many products are presented with characterising

[247] This presupposes that potentially reduced sales in Sweden due to labelling and ingredients regulation are compensated through increased sales outside Sweden.
[248] Swedish Match, power point from 15 December 2011. See also Swedish Retail Institute (HUI). Snus in the EU The potential economic impact of snus on retail taxes and employment in the EU. Stockholm: HUI; 2010. The lower estimate is based on the assumption that only former smokers would use snus while the higher estimate ("normal consumption scenario") is based on additional recruitment of new users. The calculation does not take into account a corresponding drop in FMC sale.
[249] Currently there is a growth potential for STP in the light of smoke-free environments, see option 1.
[250] As previously explained a common EU approach is expected to be beneficial compared to consecutive amendments of national legislations.
[251] Additional costs for changing in printing, packaging and production equipment as well as disposal of existing stocks could be removed if sufficient transposition periods are given.
[252] European Smoking Tobacco Industry, facts and figures for DG SANCO, ESTA 2011-2012

flavours, including raspberry/pepper and rhubarb/ginger.[253] These products would have to be reformulated or withdrawn from the market. While chewing and nasal tobacco producers are often SMEs, they typically also sell other tobacco products,[254] making them less vulnerable.

Overall, it is expected that the costs linked to compliance with the suggested product standards would be significantly surpassed by the overall increased sales following the lifting of the ban on oral tobacco and thus result in positive economic impact for the oral tobacco industry. Significant product development in novel STP products claimed to imply a lower risk than FMC is also expected under option 1 (see 2.2.1).[255]

As there are no harmonised excise duties on STP in the EU, the impacts on **governments** in terms of tax incomes would vary among Member States. Governments would be confronted with some additional health risks/costs (see below under health impacts). Overall a broader range of products would be available to EU **consumers** (including oral tobacco also outside Sweden). However, the option would impact negatively on consumer protection due to the health risks referred to below under health impacts. Prohibiting STP with characterising flavours would be in line with the **FCTC** guidelines on ingredients. Lifting the ban on oral tobacco would not be in line with the WHO recommendation from 1988 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".[256]

Social impacts

Option 1 would result in increased **employment** in STP overall, mainly benefitting the oral tobacco industry (Swedish Match as leading actor) which would have the possibility to explore new markets. It is also expected that the big FMC manufacturers will use this opportunity to enter the STP market on a large scale (further reinforcing this on-going trend). On the other hand, some negative impacts are expected as far as chewing and nasal tobacco employment is concerned following increased competition from oral tobacco. In terms of **equality**, the already on-going targeting of young people would continue under option 1, but the attractiveness of the products would be reduced under option 1 due to stricter measures on labelling and ingredients.

Health impacts

Studies show that STP are less hazardous to health than FMC[257] and even option 1 would prevent STP with increased toxicity or addictiveness to enter the market.

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[253] Swedish Match magazine Inside #2 from May 2008 reports that Swedish Match portfolio has grown from 22 products in 2002 to 180 varieties in 2008 and that 14 new products are launched every year. New tastes flavours have been marketed in recent years, including raspberry/pepper (2011), mint/vanilla (2011), rhubarb/ginger (2010).

[254] European Smoking Tobacco Industry: Facts & Figures for DG Sanco, ESTA 2011-2012

[255] For example, the US market has seen a diversification of STP in recent years, including marketing of "dissolvable" tobacco products often sold in brightly coloured packaging an in an appearance similar to candy: Krisberg K. New types of smokeless tobacco present growing risks for youth: Survey: Products mistaken for candy. The Nation's Health 2010; 40:1-14. http://thenationshealth.aphapublications.org/content/40/6/1.2.full (accessed 28 Nov 2012).

[256] World Health Organization (WHO). Smokeless tobacco control. Report of a WHO Study Group. Geneva: WHO; 1998.

[257] Levy DT, Mumford EA, Cummings KM, Gilpin EA, Giovino G, Hyland A, et al. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes: estimates of a panel of experts. Cancer Epidemiol Biomarkers Prev 2004;13(12):2035-42.

Therefore, for individuals who replace FMC entirely with STP the overall benefits would outweigh the risks although full abstention from tobacco use would be the most beneficial. The overall health impacts on the population at EU level under option 1 would, however, largely depend on how the EU market reacts on the introduction of oral tobacco and in particular if this measure would contribute to reducing the number of smokers in the EU (substitution) or if it would rather increase the overall tobacco use contribute to initiation and undermine tobacco cessation efforts.

Health effects of STP

In terms of **health**, all STP tobacco products contain nicotine and are addictive. They also contain carcinogenic substances, including tobacco specific N-nitrosamines (TSNA) and polycyclic aromatic hydrocarbons (PAH). The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded, in its opinion on 6 February 2008, that STP in all its forms can cause cancer (with the pancreas as a main target organ) and are addictive.[258] The International Agency for Research on Cancer (IARC) has also classified smokeless tobacco as "carcinogenic to humans".[259] A study on smokeless tobacco and cancer from 2008 concludes that the cancer risk of smokeless tobacco users is probably lower than that of smokers but higher than that of non-tobacco users.[260]

There are many forms of smokeless tobacco products, which **differ considerably** in their composition and toxic potential. Some chewing tobacco products, in particular some products used by the South Asian community in the UK, according to a recent study, contain a wide range of toxic substances, such as tobacco-specific nitrosamines (TNSA) chromium, nickel and lead.[261] During the last two decades, the level of tobacco-specific nitrosamines (TNSA), the major group of carcinogens in smokeless tobacco, has been considerably lowered in some STP, including Swedish oral tobacco (snus).[262] This means that the adverse health effects of snus might differ from other non-combustible tobacco products. However, it does not mean that snus or any other oral tobacco product is safe or harmless. Products with lower levels of carcinogenic tobacco-specific nitramines (TNSA) have also been on the market for too short time for any convincing support in favour of the presence or absence of a lower cancer risk. The WHO Study Group on Tobacco Product Regulation concludes in its report from 2009 that existing evidence has not established that lowering TSNA or PAH levels in smokeless tobacco will lower cancer risks.[263]

The link between STPs and **pancreatic cancer** has been discussed by the research community in recent years. Based on a number of case-control and cohort studies, the two authoritative international research groups SCENIHR and IARC have concluded that there is sufficient

[258] SCENIHR, 2008
[259] International Agency for Research on Cancer (IARC). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 89: Smokeless Tobacco and some Tobacco-specific N-nitrosamines. Lyon: IARC Press; 2007. International Agency for Research on Cancer (IARC). A Review of Human Carcinogens: Personal Habits and Indoor Combustions. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100E. Lyon: IARC Press; 2012.
[260] Boffetta P, Hecht S, Gray N, Gupta P, Straif K. Smokeless tobacco and cancer. Lancet Oncol 2008; 9(7):667-75.
[261] Longman JM, Pritchard C, McNeill A, Csikar J, Croucher RE. Accessibility of chewing tobacco products in England. J Public Health (Oxf) 2010;32(3):372-8.
[262] Rutqvist LE, Curvall M, Hassler T, Ringberger T, Wahlberg I. Swedish snus and the GothiaTek standard. Harm Reduct J 2011; 8:11.
[263] World Health Organization (WHO) Study Group on Tobacco Product Regulation. Report on the Scientific Basis of Tobacco Product Regulation. WHO Technical Report Series, no. 955. Geneva: WHO; 2010.

evidence that STPs cause pancreatic cancer in humans.[264] A recent case-control study suggests, however, that there is no significant association between pancreatic cancer and smokeless tobacco.[265] The discrepant results of this study with other case-control studies have been questioned by a number of researchers calling for a cautious interpretation in view of existing strong cohort data supporting an association between STP and risk of pancreatic cancer.[266]

Risk of **oral cancer** have been found for various smokeless tobacco products, including some of the chewing tobacco products (e.g. areca nut and betel quid) used by ethnic minorities in the UK.[267] There are also suggestions that nasal tobacco increases the risk of certain cancers, e.g. oral cancers.[268] The risk for oral cancer is less clear as regards Swedish oral tobacco (snus).[269]

SCENIHR concluded in 2008 that published studies support a causal role of STP in the etiology of **oesophageal cancer**.[270] According to IARC, there is now sufficient evidence that there is a causal association between smokeless tobacco and oesophageal cancer.[271]

In addition, there is evidence for an increased risk of **fatal myocardial infarction** among STP users.[272] Hansson concluded in a study from February 2012 that current snus users had a higher probability of dying from acute myocardial infarction (AMI) as compared to non-users, and that this increase may be explained in confounding factors, although a small increased risk of sudden death from AMI among snus users cannot be ruled out.[273]

Some data also indicate that STP use is associated with several **pregnancy complications**, including pre-term birth, intrauterine growth restriction, placenta abruption and still birth.[274]

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[264] Alguacil, J and Silverman, DT. Smokeless and other non cigarette tobacco use and pancreatic cancer: A case-control study based on direct interviews. Cancer Epidemiol Biomarkers Prev 2004; 13:55–8. Boffetta P, Aagnes B, Weiderpass E, Andersen A. Smokeless tobacco use and the risk of cancer of the pancreas and other organs. Int J Cancer 2005; 114(6):992-5. Cogliano V, Straif K, Baan R, Grosse Y, Secretan B, El Ghissassi F. Smokeless tobacco and tobacco-related nitrosamines. Lancet Oncol 2004; 5(12):708. Luo J, Ye W, Zendehdel K, Adami J, Adami HO, Boffetta P, et al. Oral use of Swedish moist snuff (snus) and risk for cancer of the mouth, lung, and pancreas in male construction workers: a retrospective cohort study. Lancet 2007;369(9578):2015-20. Secretan B, Straif K, Baan R, Grosse Y, El Ghissassi F, Bouvard V, et al. A review of human carcinogens--Part E: tobacco, areca nut, alcohol, coal smoke, and salted fish. Lancet Oncol 2009; 10(11):1033-4.

[265] Bertuccio P, La Vecchia C, Silverman DT, Petersen GM, Bracci PM, Negri E, et al. Cigar and pipe-smoking smokeless tobacco use and pancreatic cancer: an analysis from the International pancreatic Cancer Case-Control Consortium (PanC4). Ann Oncol 2011; 22(6):1420-6.

[266] Nyrén O, Lambe M, Ye W, Adami HO. Are cohort data on smokeless tobacco use and pancreatic cancer confounded by alcohol use? Ann Oncol 2011; 22(8):1930-1; author reply 1931-2.

[267] Action on Smoking and Health (ASH). ASH Fact sheet: Tobacco and ethnic minorities. London: ASH; 2011.

[268] SCENIHR 2008

[269] Idem

[270] Idem

[271] International Agency for Research on Cancer (IARC). A Review of Human Carcinogens: Personal Habits and Indoor Combustions. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100E. Lyon: IARC Press; 2012. Secretan B, Straif K, Baan R, Grosse Y, El Ghissassi F, Bouvard V, et al. A review of human carcinogens--Part E: tobacco, areca nut, alcohol, coal smoke, and salted fish. Lancet Oncol 2009; 10(11):1033-4.

[272] SCENIHR 2008. Boffetta P, Straif K. Use of smokeless tobacco and risk of myocardial infarction and stroke: systematic review with meta-analysis. BMJ 2009 ; 339:b3060.

[273] Hansson J, Galanti MR, Hergens MP, Fredlund P, Ahlbom A, Alfredsson L, et al. Use of snus and acute myocardial infarction: pooled analysis of eight prospective observational studies. Eur J Epidemiol 2012.

[274] England LJ, Levine RJ, Mills JL, Klebanoff MA, Yu KF, Cnattingius S. Adverse pregnancy outcomes in snuff users. Am J Obstet Gynecol 2003; 189: 939-43. McNeill A, Pritchard C, Longman J, Leonardi-Bee J, Myles P, Aveyard P. Smokeless tobacco in the UK – products, populations and policy. Summary of final report.

In conclusion, despite differences in composition and carcinogenic potential, there is scientific evidence that all STPs are addictive and harmful to health. As shown above, some of the epidemiological data are questioned by studies (partly sponsored by the industry) inconsistent but this does not put into question the overall conclusion. In any event it justifies the application of the precautionary principle, i.e. it justifies not allowing market entry of products, which are addictive and harmful.[275]

Cessation, initiation, dual-use

In terms of substitution, some studies suggest that oral tobacco (snus) can play a role in smoking cessation[276] or that oral tobacco users are more likely to quit smoking than users of medicinal smoking cessation products.[277] Most of the studies are based on observational data, which makes it difficult to draw reliable conclusions as to the relative effectiveness of smokeless tobacco in smoking cessation.[278] On the other hand, a randomised controlled trial showed that use of STP in cessation did not have any long-terms efficacy.[279] Swedish Match recently sponsored two clinical trials comparing the effectiveness between oral tobacco (snus) and placebo products in smoking cessation in Serbia and the US.[280] The studies suggest that smokers using Swedish snus were 2-3 times more likely to quit smoking than those using placebo-products. However, the studies took place over a relatively short time (24 and 28 weeks) and it is impossible to say whether the relatively few people quitting smoking in these studies would have done so also without oral tobacco or also, or even more, with the

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Stirling: UK Centre for Tobacco Control Studies (UKCTCS); 2010. Wikström AK, Stephansson O, Kieler H, Cnattingius S. Snuff during pregnancy no risk-free alternative to smoking. [in Swedish] (Snus under graviditet ar inget riskfritt alternativ till rokning.) Lakartidningen 2011;108(29-31):1430-3.

[275] Swedish National Institute of Public Health (FHI). Public Consultation. Possible revision of the Tobacco products directive. Ostersund: FHI; 2010. http://www.fhi.se/Documents/Om-oss/remisser/2010/Remissyttrande-tobacco-products-directiveVERK-2010-546.pdf (accessed 28 Nov 2012).

[276] Royal College of Physicians (RCP). Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007. Scheffels J, Lund KE, McNeill A. Contrasting snus and NRT as methods to quit smoking. an observational study. Harm Reduct J 2012; 9:10.

[277] Lund KE, McNeill A, Scheffels J. The use of snus for quitting smoking compared with medicinal products. Nicotine Tob Res. 2010 Aug;12(8):817-22. Lund KE, Scheffels J, McNeill A. The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies. Addiction 2011;106(1):162-7. Ramstrom LM, Foulds J. Role of snus in initiation and cessation of tobacco smoking in Sweden. Tob control 2006; 15(3): 210-214. Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. Lancet 2007; 369(9578):2010-4.

These findings are challenged by Barrett SP, Campbell ML, Temporale K, Good KBP. The acute effect of Swedish-style snus on cigarette craving and self-administration in male and female smokers. Human psychopharmacology 2011; 26(1):58-62. The study suggests that Swedish snus is effective in acutely suppressing craving and smoking in at least some smokers, but that its acceptability may be limited. Also, Kotlyar M, Hertsgaard LA, Lindgren BR, Jensen JA, Carmella SG, Stepanov I et al. Effect of oral snus and medicinal nicotine in smokers on toxicant exposure and withdrawal symptoms: a feasibility study. Cancer Epidemiol Biomarkers Prev 2011; 20(1):91-100 found that Camel Snus and Taboka use was not superior to medicinal nicotine in reducing withdrawal symptoms.

[278] SCENIHR 2008, p 110

[279] Tonnesen P, Mikkelsen K, Bremann L. Smoking cessation with smokeless tobacco and group therapy: An open, randomized, controlled trial. Nicotine Tob Res 2008; 10(8):1365-72.

[280] Joksić G, Spasojević-Tišma V, Antić R, Nilsson R, Rutqvist LE. Randomized, placebo-controlled, double-blind trial of Swedish snus for smoking reduction and cessation. Harm Reduct J 2011; 8(1):25. Fagerstrom K, Rutqvist LE, Hughes JR. Snus as a smoking cessation aid: a randomized placebo-controlled trial. Nicotine Tob Res 2012;14(3):306-12.

assistance of NRT.[281] In this context it should also be considered that 2/3-3/4 of smokers quit un-aided.[282]

Sweden's low smoking prevalence in combination with the availability of oral tobacco (snus) is sometimes referred to as an indication of snus as an effective cessation method and there are some data indicating that snus has been used by Swedish smokers as an alternative to smoking.[283] On the other hand, SCENIHR concluded in 2008 that the overall smoking prevalence in Norway, as well as in young Norwegians, had decreased at the same rates in men and women during the last decade, whereas a marked increase in oral tobacco (snus) use during this time period has only occurred in young men.[284] In California, both the prevalence of smoking and smokeless tobacco use have decreased concurrently.[285] Some countries which have invested heavily in preventive measures have also managed to reduce smoking rates without the availability of STP.[286] These data imply that the association between patterns of STP tobacco use and smoking cessation differs between populations and is likely to be affected by **cultural, societal and other factors**. In this context, SCENIHR has concluded that it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco from countries where oral tobacco is available to EU-countries where oral tobacco is not currently available.[287] This is highly relevant, as the sale of the product cannot be limited to people who wish to stop smoking, unless the product is a medicinal product available only on prescription.

Option 1 is also expected to result in **uptake of STP** use among individuals (including among young people) who would otherwise not have used tobacco. A survey undertaken by the Swedish National Institute of Public Health reveals that four out of ten oral tobacco (snus) users started using tobacco with oral tobacco.[288] In Norway, recruitment of oral tobacco (snus) users among young people, including recruitment of those with no previous experience of smoking, is increasing.[289] Results from cross-sectional studies from Norway show that over 40% of young people (16-20 years old) of daily snus users had no previous smoking

[281] The Fagerstrom study (2011) reported that only 4% (5 persons) abstained from week 6-28.
[282] Chapman S, MacKenzie R. The Global Research Neglect of Unassisted Smoking Cessation: Causes and Consequences. PLoS Med 2010;7(2):e1000216.
[283] Stenbeck M, Hagquist C, Rosén M. The association of snus and smoking behaviour: a cohort analysis of Swedish males in the 1990s. Addiction 2009;104(9):1579-85. See also SCENIHR 2008 although SCENIHR also concludes that it is not clear whether or by how much the availability of snus has influenced smoking prevalence.
[284] This conclusion by SCENIHR is based on Norwegian data up until 2006. Data after 2006, however, indicates a significant increase of oral tobacco (snus) uptake also among women: http://www.helsedirektoratet.no/folkehelse/tobakk/tall-og-undersokelser/snus/Sider/unge-snuser.aspx (accessed 28 Nov 2012). Scheffels (2012) also concludes that Norwegian men frequently use snus as a method for quitting smoking whereas women are more likely to use NRT.
[285] SCENIHR 2008
[286] Holm LE, Fisker J, Larsen BI, Puska P, Halldórsson M. Snus does not save lives: quitting smoking does! Tob Control 2009;18(4):250-1.
[287] SCENIHR 2008
[288] Holm LE, Fisker J, Larsen BI, Puska P, Halldórsson M. Snus does not save lives: quitting smoking does! Tob Control 2009;18(4):250-1. See also Swedish Retail Institute (HUI). Potential savings on social costs by the use of Swedish snus as a harm reduction device in the EU: HUI; 2010. In this study, 5 million new snus users are estimated if snus was allowed in the EU.
[289] According to SSB Statistics Norway responsible for coordinating all official statistics in Norway, use of oral tobacco (snus) has increased from 9% to 25% among men 16-24 years old from 2001-2011 and from almost not measureable figures to 11% for women in the same age group.: http://www.ssb.no/english/subjects/03/01/royk_en/ and http://www.helsedirektoratet.no/folkehelse/tobakk/tall-og-undersokelser/snus/Sider/unge-snuser.aspx (accessed 28 Nov 2012). Lund KE. A tobacco-free society or tobacco harm reduction? Which objective for the remaining smokers in Scandinavia? SIRUS Report 6/2009. Oslo: Norwegian Institute for Alcohol and Drug Research (SIRUS); 2009.

experience.[290] Considering the current marketing strategies described under the problem identification (e.g. STP with distinctive tastes) and the obvious interest of the industry to recruit new users, a non-negligible uptake rate is expected under option 1. Smoke-free environment also play an important role in this respect.

Although there is currently limited evidence regarding novel STP, which are yet to be marketed to consumers, there may also be a risk of uptake of these products among new users and smokers who would otherwise have quit smoking altogether. Despite the claim that these products are reduced risk products, they are addictive and harmful to health. As BAT states on their web site: "Cigarette smoking is a cause of serious and fatal diseases and the only way to avoid the health risks associated with tobacco products is to not use them."[291]

There is also uncertainty as regards STPs' potential as a "**gateway**" to future smoking. Evidence from the US indicates that oral tobacco use may lead to subsequent FMC smoking, while some Swedish data do not support this hypothesis.[292] The SCENIHR opinion of February 2008 suggests caution in translating these data.[293]

Moreover, there is a risk of "**dual use**". One study of snus as a cessation method found that 20% of unsuccessful quitters continued to use snus on a daily basis (**dual use**).[294] A recent Norwegian study has also found that around 30% of daily snus users were smoking at least occasionally.[295] Oral tobacco (snus) use in early adolescence has also been associated with increased risk of taking up occasional smoking in addition to snus in late adolescence.[296] There is also a risk that consumers taking up STP will become chronic users.[297]

Finally, there is a risk under option 1 that lifting the ban on oral tobacco could have a negative **impact on overall tobacco control policies**. Norway has in its response to the public consultation on the TPD pointed to difficulties from a communication point of view of advocating non-use of oral tobacco (snus) among young people and at the same time advocating the use of the same product as a smoking cessation tool for another group.[298] The same is true for other types of STP, including novel non-combustible products. In addition, the introduction of oral tobacco could potentially weaken cessation policies, in particular as it would allow people to keep up their nicotine addiction in situations where smoking is not allowed (e.g. smoke-free environments) and subsequently resume smoking.

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[290] Lund KE, Scheffels J, McNeill A. The association between use of snus and quit rates for smoking: results from seven Norwegian cross-sectional studies. Addiction 2011; 106(1):162-7.
[291] http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO52AMGZ?opendocument&SKN=1
[292] SCENIHR 2008. See also Timberlake DS, Huh J, Lakon CM. Use of propensity score matching in evaluating smokeless tobacco as a gateway to smoking. Nicotine Tob Res 2009; 11(4):455-62. O'Connor RJ, Kozlowski LT, Flaherty BP, Edwards BQ. Most smokeless tobacco use does not cause cigarette smoking: results from the 2000 National Household Survey on Drug Abuse. Addict Behav 2005; 30(2):325-36.
[293] SCENIHR 2008
[294] Scheffels J, Lund KE, McNeill A. Contrasting snus and NRT as methods to quit smoking. an observational study. Harm Reduct J 2012; 9:10.
[295] Lund KE, McNeill A. Patterns of Dual Use of Snus and Cigarettes in a Mature Snus Market.
[296] Grøtvedt L, Forsén L, Stavem K, Graff-Iversen S. Patterns of snus and cigarette use: a study of Norwegian men followed from age 16 to 19. Tob Control 2012.
[297] Lund KE, McNeill A, Scheffels J. The use of snus for quitting smoking compared with medicinal products. Nicotine Tob Res. 2010 Aug;12(8):817-22. Also, almost 60% of successful quitters in the Scheffels study (2012) continued using snus.
[298]Norwegian Ministry of Health & Care Services. Comment on the Consultation on the possible Revision of the Tobacco Products Directive 2001/37/EC. Oslo: Norwegian Ministry of Health & Care Services; 2010. http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm (accessed 28 Nov 2012).

Summarising the findings on oral tobacco, it is not possible at this stage to draw the conclusions oral tobacco is an effective smoking cessation aid in the long term. Any impacts therefore on smoking-related diseases remain uncertain under option 1. On the other hand, it is likely that new oral tobacco users would be recruited under option 1 who would otherwise not have used tobacco (entry gate) and current smokers who would otherwise have quit using tobacco altogether might switch to oral tobacco or use both products (dual use). This would lead to increased adverse health effects (see section 2.2.1). In this light, it appears difficult to reconcile lifting the ban with the precautionary principle.

5.2.1.2. PO2: Maintain the ban on oral tobacco, subject all novel tobacco products to a notification obligation and all STP to stricter labelling and ingredients regulation

a) The current ban on oral tobacco is maintained (except for Sweden which has an exemption), but oral tobacco needs to comply with stricter labelling and ingredients regulation (e.g. health warnings on both sides of the package and a ban of products with characterising flavours and increased toxicity or addictiveness).

b) The placing on the market of chewing and nasal tobacco continues to be allowed, subject to the same rules as set out under a. A clearer definition of chewing tobacco is inserted.

c) A notification obligation is introduced for novel tobacco products (glossary) and a report on the market development in these products will be issued by the Commission five years after the transposition of the TPD. Novel tobacco products placed on the market must respect the rules on labelling (health warnings on both sides) and ingredients regulation (ban on products with characterising flavours).

Delegated/implementing power as in option 1.

Economic impacts

This option would contribute to a more homogenous development in terms of labelling and ingredients regulation of all STP. The insertion of a clearer definition of chewing tobacco (compared to tobacco products for oral used) would increase legal certainty and prevent circumvention of the TPD provisions. Compared to the baseline scenario, option 2 is considered to have a positive impact on the internal market. The differential treatment in terms of regional impact on Åland would remain neutral under option 2, i.e. ships under Swedish flag would be allowed to sell tobacco whilst vessels under the flags of Finland and Åland serving the same routes would not be allowed to do so. However, this differential treatment is an effect of the Swedish exemption on oral tobacco rather than the ban itself.[299] The differential treatment of oral tobacco and other forms of STP would also persist, as oral tobacco producers would not have the option to expand sales outside Sweden, but as the Court ruled, the differential treatment was justified in 2001. The underlying analysis has not changed.

The impact in terms of compliance costs for the **economic stakeholders** involved in STP manufacturing would be similar to the once described under option 1, i.e. costs linked to the change of labelling and possible reformulation of additives. Option 2 also implies an obligation for manufacturers to report novel tobacco products prior to their placing on the market. The notification would also be accompanied by available scientific and market studies

[299] This is also in line with the Courts reasoning in Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825, p 41

as well as other available and relevant information, including risk/benefit analyses of the products. This obligation would imply an additional burden for manufacturers intending to place novel tobacco products on the market. However, the burden is considered limited as it focus on already available information and information already required under the ingredients reporting requirements (policy area 3). In terms of indirect costs linked to consumption, the sale of oral tobacco would remain limited to Sweden and the sales potential to other Member States allowed for under option 1 cannot be explored under this option. The prohibition of STP with characterising flavours would also affect negatively sales of STP as well as the increased labelling requirements providing consumers with more visible information about the health risks associated with the products.

The administrative burden for Member States of introducing a notification obligation for novel tobacco products under option 2 would be limited, if any. Option 2 would also result in reduction of the tax income for **Governments** following the drop in STP consumption, but they are expected to benefit from better health outcomes.[300] EU **consumers** would have a more limited choice of STP than today due to the ban on STP with characterising flavours, but in particular young potential consumers could be better protected against initiation and better informed. The ban on STP with characterising flavours would be in line with **FCTC** guidelines on ingredients (also covering STP). Overall the option would lead to a consistent approach for all tobacco products that are likely to be used by young people (tobacco consumption initiation).

Social impacts

Option 2 would have some limited negative impact on **employment** due to the forecasted reduction in use and also because no new STP with characterising flavours attractive to young people could be developed. For the chewing and nasal tobacco industry, this would particularly affect certain regions where chewing and nasal tobacco products currently are produced (mainly in Germany, Denmark, Belgium and Poland). This negative impact, however, is more limited than the impact under option 4 as the products could still remain on the market. Overall, it is expected that some redistribution will take place as money not spent on STP is spent on other economic activities (see reasoning in Annex 5).

Option 2 would remove the current targeting of young people and thus contribute to increased **equality**. It is not expected to impact on specific population groups using STP.

Health impacts

Under option 2, chewing and nasal tobacco would lose part of their current appeal and the future development of STP with distinctive tastes or aroma would be prohibited. Option 2 would result in decreased **use** of STP. Also the additional health warning would reduce the appeal of these products and better inform consumers. As in option 1, option 2 would also prevent STP with increased toxicity or addictiveness to be placed on the market. Under option 2, Member States would be placed in a better position to monitor market developments with regard to novel STP.

[300] Member States would also have to ensure that sales are limited to territory, i.e. they would have to prohibit cross-border distance sales. Taking into account that the number of traditional STP is limited, the administrative burden for enforcement is limited.

5.2.1.3. PO3: Maintain the ban on oral tobacco, restrict the sale of other STP to areas of traditional use only and subject all STP to stricter labelling and ingredients rules

a) The current ban on oral tobacco is maintained (except for Sweden which has an exemption), but oral tobacco needs to comply with stricter labelling and ingredients regulation (e.g. health warnings on both sides of the package and a ban on products with characterising flavours and increased toxicity or addictiveness). b) The placing on the market of chewing and nasal tobacco is banned unless traditionally used (glossary) in Member States. The placing on the market of traditionally used STP is limited to the relevant territory/Member State and must comply with the same labelling and ingredients rules as set out under a. Member States will have to prove traditional use and notify to the Commission. c) The placing on the market of novel tobacco products is banned. Delegated/implementing power as in option 1.

Economic impacts

Option 3 would impact positively on the **internal market** by removing current regulatory disparities for chewing & nasal tobacco and by ensuring equal treatment between different STP. It would reduce the growth potential (e.g. smoke-free environments) of STP with adverse health effects and prevent the launch of novel tobacco products with adverse health effects.

The impact for the **economic stakeholders** would be that the sale of oral tobacco would remain limited to Sweden (having an exemption from the ban) and the sale of other STP would be limited to Member States with traditional use. All STP industries would have to comply with stricter rules on labelling (an additional health warning to be added to the packages) and on ingredients (prohibit STP with characterising flavours). The compliance costs would be linked to the change of labelling and possible reformulation of additives. Again, an EU approach is more cost effective than consecutive changes at national level. The companies affected are mainly SMEs although they are also involved in other tobacco products,[301] which means that most of them would not have to exit the market altogether. The negative impact would be further reduced by allowing Member States exemptions for traditionally used STP.

Option 3 would result in reduction of the tax income for **Governments** following the drop in STP consumption, but they would benefit from better health outcomes.[302] EU **consumers** would have a more limited choice of STP than today due to the ban on STP with characterising flavours but in particular young (potential) consumers would be protected and/or at least better informed . In terms of **international** impacts, option 3 could have some negative impact on international trade due to the current import of certain STP from third countries (e.g. import for ethnic minorities). However, considering that chewing and nasal tobacco products count for less than 0,1% of the total tobacco market, this impact is considered limited. Also, the exemption of traditional use could apply. The ban on STP with characterising flavours would be in line with FCTC guidelines on ingredients (also covering STP). Overall the option would lead to a consistent approach for all products that are likely to be used by young people (tobacco consumption initiation).

[301] European Smoking Tobacco Industry, facts and figures for DG SANCO, ESTA 2011-2012

[302] Member States would also have to ensure that sales are limited to territory, i.e. they would have to prohibit cross-border distance sales. Taking into account that the number of traditional STP is limited, the administrative burden for enforcement is limited.

Social impacts

Option 3 would have some negative impacts on **employment** due to the forecasted reduction in use and also because no new STP with characterising flavours attractive to young people could be developed. For the chewing and nasal tobacco industry, this would particularly affect certain regions where chewing and nasal tobacco products currently are produced (mainly in Germany, Denmark, Belgium and Poland). This negative impact is mitigated by the fact that most of these manufacturers are also involved in the production of other tobacco products as well and that Member States can ask for derogations for traditionally used STP for their own territory. In macroeconomic terms the potentially negative impact will be linked to the size of the operators concerned and the expected derogations. Overall, it is expected that some redistribution will take place as money not spent on STP is spent on other economic activities (see reasoning in Annex 5).

Option 3 would remove the current targeting of young people and thus contribute to increased **equality**. The option could impact on certain ethnic minority groups using specific chewing tobacco products (gutkha, zarda, khaini) if Member States do not ask for an exemption of these products.

Health impacts

Under option 3, chewing and nasal tobacco would lose part of their current appeal and the significant market potential of novel STP would be supressed. Option 3 would result in decreased **use** of STP and remove the circumvention potential that certain STP have following the ban of oral tobacco. The option also has the potential of impacting positively on smoking cessation by motivating current smokers to free themselves from nicotine addiction altogether rather than using STP in environments where smoking is not allowed. Also Member States exempting STP for traditional use, the ban on products with characterising flavour and the additional health warning would reduce the appeal of these products and better inform consumers. In terms of toxicity and addictiveness, reference is made to options 1 and 2.

5.2.1.4. PO4: Ban all STP with the exception of oral tobacco in Sweden which would be subject to stricter labelling and ingredients rules

a) The current ban on oral tobacco is maintained (except for Sweden which has an exemption)
b) The placing on the market of chewing and nasal tobacco is banned given their circumvention potential, in particular as regards chewing tobacco.
c) The placing on the market of novel tobacco products is banned.

Economic impacts

Similarly to option 2, option 4 would remove the legal uncertainty as to the classification of STP, which is currently based on the mode of use ("sucking" vs "chewing"). Option 4 would thus prevent circumvention of the ban by products which are comparable (see section 2.2.1). This would improve the effectiveness of the TPD and thus impact positively on the **internal market.** It would also remove the growth potential (e.g. smoke-free environments) of products with adverse health effects and prevent innovation and launch of novel STP, including non-combustible tobacco products claimed to be less harmful than traditional FMC. The impact on Åland would be similar to options 2 and 3.

The compliance costs for **economic stakeholders** involved in oral tobacco would mean some costs for complying with labelling and ingredients regulation while the actual sales of oral

tobacco in Sweden could continue. For chewing and nasal tobacco, it is expected to result in negative impact as all STP are prohibited under this option. This negative impact would exceed the impact outlined under options 2 and 3. For novel tobacco products, the effects of options 3 and 4 are identical.

Option 4 would result in reduction of the tax income for **Governments** following the estimated drop of chewing and nasal tobacco use. The administrative burden would be limited. EU **consumers** outside Sweden would have no access to STP (except for private import, but excluding purchases via internet). In terms of international impacts, option 4 could have some negative impact on international trade due to the current import of certain STP from third countries. However, considering that chewing and nasal tobacco products count for less than 0,1% of the total tobacco market, this impact would be limited.

Social impacts

Employment in oral tobacco would somewhat decrease compared to the baseline scenario, while a negative impact is expected for the chewing and nasal tobacco following the ban of these products. This would particularly affect certain regions where chewing and nasal tobacco products currently are produced (mainly in Germany, Denmark, Belgium and Poland). This negative impact is mitigated by the fact that most of these manufacturers are involved in the production of other tobacco products as well.[303] In macroeconomic terms the potentially negative impact will be linked to the size of the operators concerned. As option 4 (opposite to option 3) does not allow derogations for traditionally used STP, the impact on economic stakeholders would be more important under option 3. The option would also have a negative impact in terms of innovation of novel STP products. Overall, it is expected that some redistribution will take place as money not spent on STP is spent on other economic activities (see reasoning in Annex 5).

In terms of equality, option 4 would remove the current targeting of young people. It would also impact negatively on certain ethnic minority groups using specific chewing tobacco products (gutkha, zarda, khaini).

Health impacts

A ban of all STP would remove access to STP (except for oral tobacco in Sweden) and thus result in less adverse health effect linked to STP use.

5.2.1.5. The views of stakeholders

The tobacco industry (including the STP industry) has expressed support for lifting the current ban on oral tobacco and subject all STP to product standards which already apply to oral tobacco (snus). In this context it has been argued that the current ban on oral tobacco is discriminatory, that oral tobacco is less harmful than FMC and other STP and could help current smokers quitting. Sweden (and the Finnish island Åland) is also in favour of lifting the current ban on oral tobacco (snus), while most of the other Member States have expressed support for keeping the current ban or extend it to all STP (see Annex 1).[304] On the other hand, the Swedish National Institute of Public Health supports keeping the ban on oral tobacco with the argument that the introduction of every new tobacco product on the EU

[303] European Smoking Tobacco Industry, facts and figures for DG SANCO, ESTA 2011-2012

[304] Member States (including Sweden's) positions can be found on the public consultation web site: http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm (accessed 28 Nov 2012). The Swedish position has also been reiterated in a letter from the Minister of Trade on 14 December 2010. The Swedish Ministers for Children and the Elderly and for Trade also asks for a uniform and responsible regulation covering all tobacco products in a letter of 24 October 2012.

market increases the dependency and all forms of tobacco is damaging to health.[305] Also health NGOs have argued in favour of keeping/extending the current ban on oral tobacco. One FMC manufacturer has also suggested a new legal framework for regulating potentially reduced harm products.[306]

5.2.1.6. Comparing the options and preferred option

In terms of **effectiveness**,[307] options 1, 3, and 4 would formally ensure equal treatment of all STP categories (chewing, nasal, oral) in terms of placing the products on the market, but these options do not take into account the significant differences between the products, e.g. in terms of consumption patterns and growth potential.[308] Accordingly, options 1, 3 and 4 do result in the achievement of policy objectives A1 and A2. The ban on STP with characterising flavours under option 2 would contribute to a consistent approach for all tobacco products capable of encouraging young people to take up smoking because of their distinct taste or flavour. This would partly contribute to objectives A1 and A2 (equal treatment and level playing field). Options 1-3 would all contribute to the achievement of objective B1 as they would set common requirements for labelling and ingredients. This objective is less relevant for option 4, implying a ban of STP. Option 1 would facilitate market surveillance (objective B2) as it implies a lifting of the ban on oral tobacco and thus removes the circumvention potential for such products. Also options 3 and 4 would contribute to objective B2 as they would result in a ban of all STP (except in Member States of traditional use in option 3). Also option 2 would contribute to this objective as it would include a clearer definition of chewing tobacco and thus prevent circumvention and facilitate surveillance. Policy consideration C1, regulating hazardous products, would be fully fulfilled under policy options 3 and 4 as these options allow no new STP on the market This policy consideration (C1) is partly fulfilled by option 2 as this option prevents oral tobacco to be placed on new markets and limits the development of novel STP in the sense that it prevents products with characterising flavours to be developed. Options 1, 2 and 3 are well in line with policy considerations C2 and C4 as they prohibit STP with characterising flavours and strengthen the labelling provisions, i.e. increase the visibility of the information to consumers. Option 3 and in particular 4 would also contribute to policy consideration C5 as they would reduce/remove access to STP. Option 2 would partly fulfil this consideration, but only as regards oral tobacco and STP with characterising flavours.

Lifting the ban on oral tobacco in option 1 provides market opportunities and thereby advantages for certain **economic** operators (others are likely to suffer). Options 2, 3 and 4 would mean that STP producers have to comply with the requirements in terms of labelling and ingredients and the growth potential for oral tobacco would remain unexplored but an EU solution is preferable to consecutive changes at national level. Option 3 and 4 would also limit novel tobacco products from being placed on the market and require some chewing and nasal tobacco manufacturers to exit the markets, but the effect on existing chewing and nasal tobacco producers would be mitigated under option 3 by exemptions for traditionally used STP.

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[305] Swedish National Institute of Public Health (FHI). Public Consultation. Possible revision of the Tobacco products directive. Ostersund: FHI; 2010. http://www.fhi.se/Documents/Om-oss/remisser/2010/Remissyttrande-tobacco-products-directiveVERK-2010-546.pdf (accessed 28 Nov 2012).

[306] Minutes from SANCO's meeting with PMI, 8 March 2012: http://ec.europa.eu/health/tobacco/docs/ev_20121202_mi_en.pdf (accessed 28 Nov 2012).

[307] Only the objectives/considerations relevant for this policy area are discussed in this section.

[308] See the Courts reasoning in Case C--434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825, p 41.

Lifting the ban on oral tobacco (option 1) would have adverse **health** effects. It could also attract new tobacco users who would otherwise not have taken up tobacco consumption. Moreover, it would have a negative health impact on smokers who would otherwise have quit smoking, but who continue to use both FMC/RYO and STP (dual use) and for smokers taking up STP use who would otherwise have quit using tobacco altogether. For individuals replacing FMC/RYO with STP completely, the health effects would be positive. Considering the uncertainty in relation to substitution, an overall negative outcome under option 1 cannot be excluded. Therefore, this option raises doubts in terms of coherence with the **precautionary** principle.

Preferred policy option 2: 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

The **preferred option** would provide a common framework for STP in terms of ingredients and labelling while keeping the current ban on placing of the market of oral tobacco untouched. The proposed ban of placing on the market of STP with characterising flavour would address recent market development and discourage young people from taking up STP use. Putting health warnings on both sides of the package will increase the visibility and thus better inform consumers about the health risks associated with STP use. The preferred option is well in line with FCTC guidelines on ingredients (ban on STP with characterising flavours) and labelling (warnings on both sides). The preferred option would also contribute to increasing the knowledge base as regards novel tobacco products following Member States' notifications of these products.

It is not considered justified to lift the current ban of placing on the market of **oral tobacco** which was introduced already in 1992 and which was justified from an internal market point of view since three Member States had already banned or announced bans of the product due to its harmful and addictive effects. At that point in time oral tobacco had also started to be distributed on the market of certain Member States in such a way as to attract young people. Given the introduction of smoke-free environments and the continuous development of oral tobacco, although limited to the Swedish market, the risk of uptake in new population groups (including young people) remains. The industry has also confirmed that oral tobacco has huge market potential, referring to gross revenues to the retail sector in the amount of 3-9 bEUR per year, if the ban was lifted (see section 2.2.1). Although industry emphasises that oral tobacco is less harmful than FMC, they do not claim that it is harmless.[309] Adverse health effects were indeed confirmed by several risk assessment bodies, including one of the Commission's advisory Committees (SCENIHR).[310]

Maintaining the ban of placing on the market of oral tobacco is considered to be the **only effective measure** to contain the use of this product and avoid uptake in new population groups, among non-smokers and by young people. Reinforcing the health warnings and ban oral tobacco with characterising flavours would not be a sufficient measure in this regard. Although it could have some effect on discouraging young people from taking up use of oral tobacco, the product would still be promoted for use in smoke-free environments and as described under option 1, in particular given the significant growth potential referred to by manufacturers. The establishment of general product regulation (option 1) could reduce, to a

[309] See the minutes from SANCO meeting with ESTOC, Swedish Match and other stakeholders on 19 December 2011: http://ec.europa.eu/health/tobacco/docs/ev_20111219_mi_en.pdf (accessed 28 Nov 2012). See also the potential ranking of the overall risk of different products by BAT:
BAT. Harm reduction. London: BAT; 2012. http://www.bat.com/harmreduction (accessed 28 Nov 2012).
[310] SCENIHR 2008

certain extent, the hazardous effect of STP, but as illustrated in the assessment section (option 1), the product remains addictive and has adverse health effects. The current ban was also seen as **proportionate** by the Court in 2003 due to the harmful effects of oral tobacco, the uncertainty of oral tobacco as a substitute for FMC, the addictive and toxic properties of nicotine, oral tobacco's risk potential for young people and the novelty of the product.[311] This reasoning is still valid today. The current ban was moreover deemed **non-discriminatory** by the Court in view of the fact that oral tobacco was new to the markets of the Member States, authorising a difference in treatment with regard to other STP.[312] This reasoning is also still valid today.

The addictive properties and the adverse health effects are also an issue as far as **other STP** are concerned (see option 1), but despite some market increase (see section 2.3.1) these product have still very small markets in the EU although a certain diversification in terms of flavours used and promotion of these products could be observed in recent years (see section 2.3.1). Moreover, the cost-intensive production method (partly done by hand) and the very limited number of SMEs who do not have the financial strength to enter new markets where STP has no traditional use reduce the export potential of other STP (e.g. chewing and nasal tobacco) and preserves a small scale manufacturing.[313]

For these products, it is therefore considered that further development and recruitment of new users can be contained without a general EU ban of placing these STP on the market. However, the preferred option would also ban STP other than oral tobacco with characterising flavour and make the health warnings more visible. These considerations provide another reason why maintaining the ban of oral tobacco with its significantly greater market potential (see above in this section) is considered compatible with the principle of proportionality.

There are **no less stringent** alternative measures that would guarantee the same level of health protection as those suggested under option 2. Subjecting STP to general product standards would not discourage young people from using these products although it could somehow reduce the hazardous effects of STP. The option is also a proportionate limitation of STP companies' freedom to conduct business (Article 16 of the Charter of Fundamental Rights of the European Union) justified in order to protecting public health.

The preferred option would provide an **EU added value** as it would ensure a harmonised approach throughout the EU and create a level playing field for operators involved in STP while ensuring a high level of health protection. By definition, only an initiative at EU level is capable of ensuring a harmonised approach. Unilateral actions by Member States can contribute to a certain extent to the protection of health, but would certainly result in divergences and unequal health protection.

1.1.13. Nicotine containing products (NCP)

5.2.1.7. PO1: Subject NCP to labelling and ingredients requirement under TPD

NCP placed on the market are subject to adapted health warnings, ingredients reporting and a prohibition to place on the market NCP with characterising flavours (glossary). Delegated/implementing power to adapt health warnings and act on products with

[311] Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825 paras 44-56.
[312] Idem, paras 68-70.
[313] SANCO discussions with stakeholders involved in STP.

characterising flavours, on products with increased toxicity or addictiveness and to regulate additives that cause characterising flavours.

Economic impacts

Option 1 would contribute to a more homogenous development, but some Member States are expected to continue to consider NCP as medicinal products by function, which would maintain legal uncertainty and two parallel legal systems.[314] Overall, it is therefore expected that the functioning of the **internal market** is not improved in a satisfactory manner. The use of NCP for smoking cessation purposes (see section 2.1.3) can be expected to continue to a certain extent under option 1. This would result in maintained negative impact on the internal market of smoking cessation products authorised under the medicinal products' legislation.

In terms of compliance costs for the **NCP industry**, option 1 implies a saving compared to the baseline scenario. This is mainly due to the reduced one-off costs related to familiarisation, redesign of the package/labelling and possible reformulation of the products following from an EU-wide measure rather than several consecutive measures at national levels. The costs for adding a textual health warning is estimated to around 7,000-9,000 EUR per.[315] Additional costs for new equipment and disposal of stocks costs are disregarded as these costs could be addressed by granting sufficiently transitional periods. Variable costs for changes in printing, packaging and production are estimated to be marginal and in any case passed on to the subsequent levels of trade. The same reasoning is applicable as far as ingredients regulations (ban on NCP with characterising flavours) are concerned. Continuous increase in the sale of NCP is expected under this option although at a lower pace due to increased information and stricter ingredients regulation.

Option 1 could influence some **Governments** to adapt taxes on NCP similar to tobacco products and thus contribute to increased tax income. Current increase in health care risks/costs associated with NCP is expected to slow down due to stricter ingredients regulation and increased awareness. Enforcement would remain an issue in light of many small companies active in the business and internet sales. Option 1 would allow EU **consumers** to maintain a wide choice, with some limitations due to the ban on products with characterising flavours.

Social impact

The current increase in **employment** opportunities in NCP is likely to continue at a pace in line with the expected consumption. Option 1 would contribute to more **equal** protection, but targeting of young people cannot be excluded, although the marketing of products with characterising flavours would be removed and health warnings would be added. The prohibition of advertising for tobacco products pursuant to Directive 2003/33/EC does not apply to these products.

[314] Following the EU case-law, for the purposes of determining whether a product falls within the definition of a medicinal product by function, the national authorities, acting under the supervision of the courts, must decide on a case-by- case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (Case C-319/05, Commission of the European Communities v Federal Republic of Germany, ECR [2007] p I-09811, para 55)

[315] Impact Assessment Report from the European Commission on General Food Labelling Issues, 30 January 2008. As for tobacco products, RAND Europe has estimated an annual cost of 2000-9720 EUR per SKU related to administrative burden of labelling (i.e. not only costs related to redesign). As these products are currently not subject to labelling requirements it has been estimated more appropriate to apply these food related figures than figures available for tobacco products.

Health impacts

A health warning would provide more accurate information and increase **awareness.** The current increase in the **use** of NCP is expected to continue, but at a slower pace due to improved information and less attractive products.

The uncertainty in terms of adverse health effects associated with NCP use outlined in the problem identification (section 2.2.1) would persist under option 1. In terms of substitution, there is no conclusive evidence at this stage that NCP can be effectively used in smoking cessation (see section 2.2.1) and, as described in section 2.1.3, manufacturers and distributors of these products normally make no such claims because they know it would oblige them to ask for authorisation as medicinal products. On the other hand, option 1 would allow people to keep up their nicotine dependence also in situations where they cannot smoke and then resume smoking when this is allowed.

If, on the basis of the reporting obligation, data is collected on the content of NCP, this option would allow for further content regulation over time based on toxicity and addictiveness consideration through delegated/implementing act. Such a measure could remove some of the **health** hazards associated with NCP.

5.2.1.8. PO2: Establish a new authorisation scheme for NCP

Only NCP that have been authorised under a new authorisation procedure (risk/benefit analysis) set up under TPD are allowed to be placed on the market. Otherwise, placing on the market of NCP is prohibited. The authorisation procedure would also cover labelling and additives control.

Economic impacts

Option 2 would result in two parallel authorisation schemes for NCP: one scheme which would apply if the product falls under the medicinal products' legislation by presentation or by function and another one for consumer products. Competition between these two categories cannot be excluded. Some of the current **legal uncertainty** would persist under this policy option due to this dual approach which means that similar (or even identical) products could be subject to different schemes. Such uncertainty does not favour the functioning of the **internal market**. It raises also the question of equal treatment with existing nicotine replacement therapies (NRT), which are subject to medicinal products' authorisations.

In terms of impact on **economic stakeholders**, option 2 would imply fees linked to the authorisation scheme established under this option. The level of the fees would depend on the nature of the scheme and the authorisation procedure foreseen, including the criteria used in the assessment. The estimations used under the medicinal products' framework can give an indication, but it is likely that the costs would be lower under this policy option as no efficacy in terms of smoking cessation would have to be proven.

As far as **Governments** are concerned, option 2 is expected to result in significant costs in terms of establishing and hosting the new authorisation system. The new structure would require important human resources to assess the products, ensure follow up and provide secretariat and support functions. This would only be partly compensated by the fees paid by industry for the actual assessment. The identification of assessment criteria (risk/benefit

analysis) is somehow difficult. The pharmaceutical framework provides a safety/efficacy assessment where the efficacy is seen in terms of benefit from smoking cessation. As NCPs falling under this scheme do not claim to assist in smoking cessation, the efficacy assessment is therefore different in particularly as the safety consideration needs to take into account that nicotine is a toxic and addictive substance and therefore, per se, not safe. Another open question is whether the assessment can be limited to a current smoker using NCP or whether also uptake/use among other population groups, including non-smokers and risk for dual use should be taken into account. Another approach would be to assess the "attractiveness" in order to avoid that, for example, NCP with distinctive flavours are put on the market. Such an approach however, would not target the safety or quality of the product as such.

The impact on **Governments'** tax revenues is expected to be similar to the impact described under option 1. A certain reduction of adverse health effects associated with NCP use is expected due to the authorisation requirement, but no impact is foreseen in terms of health costs linked to smoking attributable diseases. **Consumers** would enjoy a higher degree of health protection due to the prior authorisation requirement removing the most hazardous products from the market. However, nicotine as such is a toxic and addictive substance.

Social impacts

In terms of **employment**, a shift from SMEs to larger companies is expected under option 2, mainly as a result of the additional requirements and the fees to be paid for assessment/authorisation. However, this is already part of an on-going trend. It is likely that the targeting of **young people** could develop under option 2 as the products would be distinguished from pharmaceuticals through the establishment of a parallel authorisation scheme.

Health impacts

Option 2 would reinforce the character of NCP as "leisure products" rather than a product used in smoking cessation. This is inherent in the very nature of establishing a separate authorisation scheme. Option 2 is therefore expected to lead to increased consumption among young people, and people wishing to experiment with new products or to use alternatives to FMC where smoking is not allowed. Products authorised under the scheme suggested under option 2 are expected to be less interesting for people wishing to quit. On the other hand, a reduced **health risk** is expected following the requirement for prior authorisation as well as better control and knowledge of the NCP put on the market. No impact is foreseen in terms of tobacco related diseases as, to the contrary, NCP might develop into an entry gate to smoking initiation and dual use might prevent smokers intending to quit from quitting.

5.2.1.9. PO3: Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements

NCP with a nicotine level over a certain threshold may only be placed on the market if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance under the medicinal products legislation. NCP with nicotine levels below this threshold will be subject to an adapted health warning. The nicotine threshold identified under this policy option should be established by considering the nicotine content of medicinal products (NRTs) for smoking cessation which have already received a market authorisation under the medicinal products' legislation.

Delegated/implementing power to adapt the health warning and the identified nicotine threshold taking into account scientific and technical developments.

Economic impacts

Option 3 would consolidate current developments in Member States and ensure a harmonised approach for NCP with nicotine levels above a certain threshold, to be based on nicotine content in medicinal products authorised for smoking cessation. This would increase legal certainty and respond to Member States' requests for clarification. It is difficult to estimate with precision how many of the currently marketed NCP would have a nicotine level above the identified threshold and how many of those products would pass a prior authorisation, but considering that many consumers are reported to use the products for cessation/limitation purpose and presuppose a pharmacological reaction it is believed that the majority of products currently on the market would be affected. However, if a product is authorised under the medicinal products' framework, this would enable application of the mutual recognition procedure (MRP) and thus facilitate sale of the authorised products throughout the **internal market.** The approach also ensures equal treatment with NRT which are authorised smoking cessation aids with a positive risk/benefit analysis. Option 3 would also approximate the labelling requirements as regards NCP with nicotine levels below the identified threshold.
Option 3 would imply costs for **economic players** related to the authorisation scheme under the medicinal products' legislation. The costs will vary between Member States (e.g. 10,400 EUR-47,230 EUR per application in the UK, Netherlands, Germany and Denmark plus additional costs for each Member States where the applicant wants to enter thereafter under Mutual Recognition Procedure).[316] However, this would be no change to the current situation. As set out in Annex 2, a significant number of Member States see NCP as medicinal products by function. The already on-going development towards bigger companies is expected to continue and at a higher speed due to innovation opportunities and a clear legal framework. Also, bigger companies are more likely to have resources for obtaining market authorisations. In addition, some adaptations in terms of composition and/or design might be needed to ensure compatibility with the medicinal products framework.

Products below the identified threshold would be subject to national legislation and could be placed on the market without prior authorisation. This would imply less cost for economic stakeholders, but on the other hand these “low-nicotine” NCP would not respond to users cravings for nicotine and could thus be less interesting from a marketing point of view. The potential of NCP in smoking cessation under this policy option (see below under health impacts) is expected to reduce, to some extent, indirect costs linked to tobacco consumption.

The impact on **Governments** is expected to be positive as NCP could develop their potential as smoking cessation aid and thus lead to improved health outcomes (less premature mortality, health care costs, productivity). Governments' tax revenues are expected to be neutral but they could no longer charge excise duties for NCP (for indirect impacts, see section 5.7 and Annex 5). The administrative burden is limited due to making use of an established authorisation regime with adequate fees. **Consumers** would have a more limited choice, but a higher degree of health protection. Some unauthorised low-nicotine NCP are likely to remain on the market, but these are expected to be of less interest for smokers trying to quit or smokers using NCP as an alternative where smoking is not allowed. In addition, consumers would be informed, through the labelling, that these products contain nicotine and can have adverse health effects. In terms of **international** impacts, it should be recalled that many of NCP are imported from third countries (notably China). However, given the estimated market value (section 2.1.3) this impact is considered limited overall. The option would be in line with the recommendations of the WHO Study Group on Tobacco Product

[316] Matrix 2012

Regulation that has recommended that these products are regulated as combination drugs and medical devices.[317]

Social impacts

In terms of **employment**, a shift from SMEs to larger companies is expected. However, this is already part of an on-going trend. Option 3 would lead to improved **equality** within and between Member States, in particular as it would remove NCPs' appeal for young people. In particular NCP with characterising flavours are unlikely to be authorised under the medicinal products' legislation. NCP with nicotine contents below the identified nicotine content are not limited in terms of flavours.

Health impacts

Option 3 is expected to reinforce the character of NCP as smoking cessation rather than "leisure" product, in particular as the nicotine threshold would be set based on nicotine levels already authorised under the medicinal products' legislation. A significant drop in **consumption** of NCP among young people and people wishing to experiment with new products or to use alternatives to FMC where smoking is not allowed is expected. It would also provide the consumer with more appropriate information, including through the patient leaflet and better controlled marketing activities. Improved information about the **adverse health effects** associated with NCP is expected following the requirement for prior authorisation.

Under option 3, NCP would primarily target people wishing to quit smoking. Further research on the efficacy of NCP (notably electronic cigarettes) in smoking cessation would be encouraged and products put on the market would be safer and more adapted for smoking cessation. It is estimated that option 3 would lead to some reduction of tobacco related diseases and mortality due to the potential of NCP in smoking cessation under this option. Post-authorisation obligations, including pharmacovigilance, would provide further protection. It would put NRTs and NCPs on a level playing field.

5.2.1.10. PO4: Subject all NCP to the medicinal products' legislation

Only NCP that are authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance are allowed to be placed on the market. Otherwise, the placing on the market of NCP is prohibited. The authorisation procedure is described under option 3.

Economic impacts

Option 4 would go one step further than option 3 and provide a fully harmonised approach in the sense that all NCP placed on the **internal market** (regardless of the nicotine content) would need a prior authorisation as a medicinal product. However, as it is not certain whether all NCP would fall under the medicinal products definition under Directive 2001/83 it is possible that some products would be excluded from the market.

[317] World Health Organization (WHO) Study Group on Tobacco Product Regulation. Report on the Scientific Basis of Tobacco Product Regulation. WHO Technical Report Series, no. 955. Geneva: WHO; 2010. If the nicotine containing part of the NCP/the nicotine cartridge/refill bottle would be (was?) considered a medicinal product, the device designated to administer the nicotine would most likely be considered a medical device under Directive 93/42.

The **costs** related to authorisation and the market developments are expected to be the same as under option 3. However, it is possible that some NCP would have to be taken off the market as they do not fit under the regulatory framework for medicinal products (no efficacy).

The impact on **Governments** and the international impact are very close to the impact under option 3. The consumer would have a more limited choice than under option 2, but a somehow higher degree of protection considering that only authorised NCP (regardless of nicotine level) would be put on the market.

Social impacts

The social impact is expected to be similar to the impact under option 3.

Health impacts

Similarly to option 3, option 4 is expected to reinforce the character of NCP as smoking cessation rather than "leisure" product. This is expected to lead to a drop in **consumption** similar to the impact under option 3.

5.2.1.11. The views of stakeholders

The tobacco industry and consumer focused advocacy groups have argued that NCP are different from tobacco products and therefore require a separate regulation. The argument of consumers' choice was reiterated. Part of the pharmaceutical industry also supported this approach, while another part argued that NCP should be regulated as medicinal products. The European Respiratory Society (ERS) is opposed to the use of all (tobacco and) unapproved nicotine delivery products, including electronic cigarettes.[318] The approach of subjecting NCP to the pharmaceutical legislation was also supported by health NGOs expressing concerns about the health risks of NCP. Among Member States responding to the public consultation, the views were divided. Some presented arguments for regulating NCP as medicinal products (which is already the situation in about half of the Member States) and others for the inclusion of electronic cigarettes in the TPD. Electronic cigarettes industry trade (ECITA) referred to self-regulation and claimed that no further regulation is needed.

5.2.1.12. Comparing the options and preferred option

In terms of **effectiveness**, regulating NCP under the medicinal products' legislation (partly policy option 3 helps to remove differential treatment between NCP and NRT (policy objective A1) and facilitate a level playing field (policy objective A2) as it would subject all economic stakeholders involved in NCP and NRT to the same rules. Regulating NCP under the TPD (options 1 and 2) would lead to the creation of different legal systems, associated with legal uncertainty. Policy option 1 would contribute to the achievement of objective B1 as it would result in harmonised labelling and the same is true to a certain extent for NCP under the identified nicotine threshold. Options 2, 3 and 4 would facilitate market surveillance (objective B2) as it would set up requirements for prior authorisation. Options 3 and 4 are well in line with policy consideration C1 as it would require prior authorisation and thus regulate NCP in the sense that only products which have passed a risk benefit balance would be allowed on the market. Option 2 would partly contribute to this consideration as also this option would require an authorisation scheme although the benefit criteria is less clear under this option. Adding health warnings and banning NCPs with characterising flavour (option 1) or authorising these products under pharmaceutical legislation (options 3 and 4) would help to

[318] European Respiratory Society (ERS). European Respiratory Society statement on E-cigarettes and emerging products. Lausanne: ERS; 2012. http://www.ersnet.org/news/item/4494-european-respiratory-society-statement-on-e-cigarettes-and-emerging-products-.html (accessed 28 Nov 2012).

remove NCP that could be attractive to young people (policy consideration C2). Regulating NCP under the TPD (policy options 1 and 2) or under the medicinal products' legislation (policy options 3 and 4) would also contribute to improved consumer information (policy consideration C4) due to labelling and/or the patient leaflet. In any event, for all products covered by the TPD, the pharmaceutical legislation is lex specialis.

Regulating NCP under the TPD (policy option 1) is a cost effective solution given that no prior authorisation is required and the products could thus make use of the already existing tobacco legislation. Requiring authorisation of NCP (policy options 2, 3 and 4) would imply additional **costs**, but these assessment costs would primarily be paid through fees from industry. Setting up of a new structure for authorisation under option 2 entails however important costs for public administrations, while options 3 and 4 take advantage of already existing structures under the pharmaceutical legislation.

Authorising NCP under the medicinal products' legislation (policy options 3 and 4) would be **coherent** with the medicinal products' framework, but option 4 would fully exclude some NCPs from the market as they might not fit under the legal framework.

Preferred policy option 3: Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements.

The **preferred option** would remove current legislative divergence between Member States and the differential treatment between NRTs and NCP, increase legal certainty and consolidate the on-going development in Member States based on the function of these products. It would encourage research and innovation in smoking cessation with the aim of maximising health gains.

It appears appropriate to focus, at this stage, on NCP above a certain nicotine threshold, in particular considering these products' similarities with already existing medicinal products for smoking cessation. In addition, most consumers use these products for cessation/limitation purpose, which presupposes a pharmacological reaction, i.e. a certain level of nicotine.

For NCP below the identified nicotine threshold, a less stringent measure appears more proportionate, in particular as there are not sufficient evidence that these products would fit under the medicinal products' legislation. The economic burden on industry is also taken into consideration in the proportionality assessment concluding that the suggested labelling requirement is sufficient for NCP below the identified nicotine threshold.

There are no less strict measures available to obtain the objectives. Subjecting all NCP to labelling requirements and ingredients regulation only (option 1) would have a positive impact on health, but to a lesser extent than the preferred option. A separate authorisation scheme (option 2) could address some safety concerns, but this option would not have the same potential in smoking cessation.

In terms of economic costs and burden weighed against the benefits, it is likely that some of the current NCP would be removed from the market or would have to change composition or design under the preferred option, but this burden is considered appropriate due to the health concerns associated with NCP. In any case, the economic impacts on industry under the preferred option are lower than the additional burden of a separate authorisation mechanism (option 2) or the option of subjecting all NCP to the medicinal products' regime (option 4).

The preferred option provides a clear **added value** as it contributes to a level playing field for operators involved in NCP and NRT. Only an initiative at EU level is capable of preventing further diversity and legal uncertainty.

1.1.14. Herbal products for smoking

5.2.1.13. PO1: Subject all herbal products for smoking to labelling requirements under TPD

Adapted health warnings are required for herbal products for smoking. Delegated/implementing power to adapt health warnings.

Economic impacts

Option 1 would ensure increased convergence of national rules and removal of some of the existing discrepancies on the **internal market**.

The **benefit for economic players** (cost savings compared to baseline scenario) would be similar to that described above for NCP because taking action at EU level in one go is less costly than consecutive changes at national level. In terms of sales, the current increase is expected to slow down due to stricter requirements and less demand due to more accurate health information. The expected slowdown in sales, would affect **Governments'** tax income, but taking into account the market size the decrease would be moderate if any. In return, the Governments would benefit from improved public health as herbal products for smoking are associated with some health concerns as indicated in the problem identification (section 2.2.1). Option 1 would have a positive impact on **consumers** as it would provide adequate protection in terms of health warnings while maintaining a wide choice of products.

Social impacts

Current increase in herbal products for smoking (see section 2.1.3) is likely to slow down, having a limited negative impact on **employment**. Option 1 would lead to improved and more **equal** protection of citizens throughout the EU, in particular by reducing some of the products potential of attracting/misleading consumers, including young people.

Health impacts

The labelling requirements under option 1 would contribute to increased **awareness**. It would also contribute to removing some misleading features, including wording such as natural, no additives etc. and better inform consumers of the health risks associated with herbal products for smoking e.g. herbal cigarettes and tobacco-free filling to water-pipes (sisha). This is expected to lead to reduced **consumption** which will, over time, result in less health problems related to herbal products for smoking.

5.2.1.14. PO2: Phase out the placing on the market of herbal products for smoking

Placing on the market of herbal products for smoking is phased out.

Economic impacts

Option 2 provides full harmonisation of national rules, but removes the current cross-border trade of herbal products for smoking on the **internal market.** Under the assumption that the product could not be regarded as medicinal products, option 2 would result in reduced sale and possible closure of businesses involved in herbal products for smoking, mainly affecting SMEs involved in this sector. This limits the freedom to conduct business need to be balanced against health cosiderations. A reduction of **Governments'** tax income as well as health care

costs/concerns is expected under option 2, but due to the modest market size, this impact would be limited. **Consumers** would enjoy a higher level of health protection, but less choice.

Social impacts

Option 2 would have a negative impact on **employment** in herbal products for smoking, including possible regional impact, but redistribution is expected to take place. Option 2 would provide full and **equal** protection of EU consumers.

Health impacts

A ban would remove the current **appeal** of herbal products for smoking and reduce significantly the **consumption**, resulting in reduced health risks from herbal products for smoking. No impact on tobacco consumption is foreseen as it has not been demonstrated that the two categories are interchangeable.

5.2.1.15. The views of stakeholders

Health NGOs argued for the inclusion of herbal cigarettes into the TPD framework, referring to the harmful aspects following the combustion of these products. Most Member States which submitted contributions to the public consultation were either in favour of extending the scope of the TPD or did not refer to the question in a detailed manner. Other key stakeholders have not addressed specifically this area.

5.2.1.16. Comparing the options and preferred option

In terms of effectiveness, both regulating herbal products for smoking under the TPD or phasing them out (policy options 1 and 2) would create a level playing field and remove current national disparities (policy objectives A2 and A3). Option 1 would also partly fulfil objective B1 as it would unify the labelling rules, while this objective is not relevant as far as a full phasing out (option 2) is concerned. Phasing out herbal products for smoking (policy option 2) would provide regulation of products harmful to health and thus be fully in line with policy consideration C1, while option 2 (labelling rules) only partly would achieve this consideration. The labelling requirements suggested under option 2 would be well in line with policy consideration C4 as it would contribute to better information to consumers, while phasing out these products (option 2) would reduce the availability of herbal products for smoking and thus fulfil policy consideration C5.

Regulating herbal products for smoking under the TPD (policy option 1) would provide a **cost-effective** measure to better inform consumers about the health risks of these products, while phasing them out (policy option 2) would have more important consequences for economic stakeholders having to exit the market altogether (except export possibilities).

Preferred policy option 1: Subject all herbal products for smoking to labelling requirements under TPD

The preferred option would ensure a more homogenous development in the EU and create a safety net for consumers. The preferred option would also provide consumers and potential consumers with more appropriate information about the adverse health effects of herbal products for smoking and thus allow them to make informed choices.

A stricter measure (option 2) would further harmonise Member States' legislations, and fully remove the adverse health effects associated with herbal products for smoking. However, considering that the main health concern is the frequent misperception about the health risks and that herbal products for smoking entail more limited risks of developing an addiction

compared to tobacco products, a full ban (option 2) is not considered **proportionate**. In addition, such a measure would be unnecessarily burdensome for economic stakeholders.

The objective of harmonising the labelling of herbal products for smoking is to ensure a harmonised approach throughout the EU and to create a level playing field for operators involved in these products while ensuring a high level of health protection. By definition, only an initiative at EU level is capable of ensuring a harmonised approach and thus **added value**. Unilateral actions by Member States can contribute to the protection of health, but would certainly result in divergences.

5.3. PACKAGING AND LABELLING

1.1.15. PO1: Mandatory enlarged picture warnings

Combined warnings (picture plus text) of 75% displayed on both sides of the packages of tobacco products, presented in rotation. TNCO levels on the packages are replaced with descriptive information on content, emissions and risks. Display of cessation information (e.g. quit-lines, websites) is added to the packages. Tobacco products other than FMC and RYO are exempted (current TPD rules apply). Delegated/implementing power to remove/extend the exemption for these products if there is a change of circumstances and to adapt the health warnings.

Economic impacts

Increased convergence of national rules on labelling and packaging, including mandatory pictorial warnings, would facilitate the functioning of the **internal market** in terms of cross border trade and improve the level playing field for economic stakeholders.

The actual **one-off cost** for introducing pictorial warnings for **economic players** (manufacturers) changing the labelling on FMC is estimated to range between 14,500 and 50,000 EUR per SKU and for RYO between 2,500 and 9,000 EUR per SKU (see section 5.1).[319] However, considering the economies of scale referred to in section 5.1, it should substantially reduce the burden for manufacturers if changes are done in one go across the EU instead of individual adaptation to different national legislations. In particular SMEs could benefit from a harmonised approach in one go as they might have less resources to adapt to many different legal systems in case they would like to expand their activities to other Member States.

In addition, the package producers have reported that they have already made the investments necessary to comply with the expected regulation on pictorial health warnings.[320] Therefore, there would be no additional costs for buying new equipment (e.g. printing equipment). Costs for disposal of old stocks are also disregarded as a transitional period would allow manufacturers to adapt the production process and retailers to manage their inventory accordingly.

In terms of **running costs** (e.g. use of more expensive ink to produce combined instead of text-only warnings), the packaging industry has reported that the on-going costs related to

[319] Matrix 2012. ESTA estimations for RYO (fine cut tobacco), Facts and figures for DG SANCO 2011-2012. In addition to the one-off cost, FMC industry has reported an increase of 1,3-1,5% in variable costs.
[320] Minutes from SANCO's meeting with tobacco suppliers on 6 February 2012: http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4 (accessed 28 Nov 2012).

pictorial warnings would be "slightly above" the costs for packages with text-only warnings.[321] It has been estimated that costs could increase by 1.3-1.5% following the introduction of EU-wide pictorial warnings.[322] Assuming this reported increase can be extrapolated across the four biggest tobacco companies, this would imply an annual cost increase for them of between 59 mEUR and 68 mEUR. Comparing these estimates to data from impact assessments in other jurisdictions (e.g. the UK, the US, Canada and Australia)[323] compliance costs, in particular recurrent costs as presented here, appear to be relatively high. Taking into account that the printing is generally outsourced, the costs would not occur in the first place with tobacco manufacturers, but rather with the packaging and paper industry. If the packaging industry manages to charge higher prices from the tobacco manufacturers as has been suggested it is likely that the costs would be passed on by the tobacco industry to the subsequent levels of trade.[324] In terms of **innovation**, the option maintains the possibilities of the tobacco industry to redesign packages and labels, albeit with limited space.

Under the provisions considered under option 1, **manufacturers** would be confronted neither with commoditisation of the market nor with a prohibition of the use of trademarks on the package. The measures proposed would continue to allow brand recognition albeit the space of the trademarks would be somewhat limited. However, this is considered to be a proportionate limitation of the right of property (trade marks).[325]

Overall, the option would have a neutral or even positive direct effect on economic players (manufacturers) as possible minor increases in variable costs would be counterbalanced by savings in familiarisation costs due to implementation in one go. The same applies to the packaging industry. The indirect impact in terms of reduced profit following the estimated drop in consumption is further described in section 5.7 (and Annex 5).

As all Member States already have cessation services in place, only a limited additional burden is expected for **Governments** as a result of the introduction of references to such cessation services (quit-lines or other services) on the packages, e.g. in form of an increase in call volume.[326] Outsourcing this role to NGOs with an expertise in providing such services could be an effective and efficient approach to reduce costs. Other administrative burdens

[321] Idem. This is in line with the estimates given in the context of industry interviews carried out, Matrix 2012.
[322] Matrix 2012
[323] UK Department of Health (UK DoH). The Introduction of Picture Warnings on Tobacco Packs – Final Regulatory Impact Assessment. London: UK DoH; 2007. US Dept. of Health and Human Services. Required Warnings for Cigarette Packages and Advertisements. 2011 Federal Register Vol. 76, 22 June 2011/Rules and Regulations, pp.36628-36777. Industrial Economics Incorporated (IEc). Economic evaluation of Health Canada's proposal to amend the tobacco product information regulations: Final report. Cambridge, MA: IEc; 2009. (Report for Health Canada). Applied Economics. Cost-benefit analysis of proposed new health warnings on tobacco products. Canberra: Applied Economics; 2003. (Report prepared for the Commonwealth Department of Health and Ageing, Australia)
[324] Industrial Economics Incorporated (IEc). Economic evaluation of Health Canada's proposal to amend the tobacco product information regulations: Final report. Cambridge, MA: IEc; 2009. (Report for Health Canada).
[325] There is no absolute right to use a trademark and the Court has confirmed the validity of Articles 5 (health warnings) and 7 (ban on misleading descriptors) of the current TPD which constitutes a limitation to use the trademarks. BAT case: C-491/01 The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd.[2001] ECR I-11453, para 131-132. Although not precedent for the Union, , the High Court of Australia ruled, on 15 August 2012 the Government's tobacco plain packaging legislation to be constitutionally valid.
[326] Such an increase has been shown in the past. See e.g.: Willemsen MC, Simons C, Zeeman G. Impact of the new EU health warnings on the Dutch quit line. Tob Control 2002; 11:381–2. Miller CL, Hill DJ, Quester PG, Hiller JE. Impact on the Australian Quitline of new graphic cigarette pack warnings including the Quitline number. Tob Control 2009; 18:235-7. Wilson N, Weerasekera D, Hoek J, Li J, Edwards R. Increased smoker recognition of a national quitline number following introduction of improved pack warnings: ITC Project New Zealand. Nicotine Tob Res 2010;12 Suppl:S72-7.

associated with this policy option are rather limited. For indirect impacts (e.g. improved public health and reduced tax revenues), see section 5.7 and Annex 5. Furthermore, the adoption of uniform rules across Member States could reduce the burden of developing individual solutions. The proposed measure would improve **consumer** protection across the EU, including providing assistance to smokers wishing to quit (e.g. quit lines, web sites), protecting consumers from misleading information on the health impact of smoking (replacement of TNCO levels) and providing appropriate information (strengthened labelling). At the same time, it is expected that the measures would affect neither the range of products available on the EU-market nor their quality. It can be expected that the tobacco industry will try to pass on the additional compliance costs to consumers, but these are expected to be very small if any (see above). In terms of **international** impact, the labelling requirements under option 1 would bring the EU more in line with international developments and the FCTC commitments.

Social impacts

The impact on **employment** would follow the expected drop in prevalence. This is further described in section 5.7 and Annex 5, but in the light of the input/output model, money not spent on tobacco is spent on other goods and services. No major impact is expected on package manufacturers, as these generate only 10% of their turnover with tobacco industry. Positive impact is expected in terms of **equality**. Pictorial warnings appear to be more effective than texts among persons with lower levels of literacy and particularly in young people.[327] References to cessation services would have a positive impact on vulnerable groups.[328]

Health impacts

Overall, it is expected that option 1 would make a substantial contribution to the expected decrease in **consumption** and prevalence over five years (see section 5.7 and Annex 5).

Evidence suggests that the effectiveness of **health warnings** depends on their size, location and design. In general, prominent pictorial warnings placed on the front of the packages are seen to be the most effective in increasing perceptions of risk and promoting behavioural change.[329] Enlarged picture warnings on both sides of the package are expected to result in greater noticeability and salience for consumers, stronger beliefs about the health risks of smoking, as well as increased motivation to quit smoking.[330] There is evidence that the

[327] Malouff J, Gabrilowitz D, Schutte N. Readability of health warnings on alcohol and tobacco products. Am J Public Health 1992; 82:464. Créatec+. Effectiveness of Health Warning Messages on Cigarette Packages In Informing Less-literate Smokers, Final Report. Montreal: CREATEC+; 2003. (Prepared for Communication Canada). Warner KE, Tam J. The impact of tobacco control research on policy: 20 years of progress. Tob Control 2012; 21:103-9Hammond D. Health warning messages on tobacco products: a review. Tob Control 2011; 20:327-3. Gagné L. Econometric Evaluation of Tobacco Control Initiatives in Canada, 1999-2009, Final Report. Victoria: University of Victoria; 2010.

[328] Wilson N, Weerasekera D, Hoek J, Li J, Edwards R. Increased smoker recognition of a national quitline number following introduction of improved pack warnings: ITC Project New Zealand. Nicotine Tob Res 2010;12 Suppl:S72-7.

[329] As reviewed in Hammond D. Health warning messages on tobacco products: a review. Tob Control 2011; 20:327-3. Sambrook Research International. A Review of the Science Base to Support the Development of Health Warnings for Tobacco Packages. Newport: Sambrook Research International; 2009. (Report prepared for the European Commission). Borland R, Wilson N, Fong GT, Hammond D, Cummings KM, Yong H-H, et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. Tob Control 2009;18:358–364

[330] Wardle H, Pickup D, Lee L, Hall J, Pickering K, Grieg K, Moodie C, Mackintosh AM. Evaluating the impact of picture health warnings on cigarette packets. London: Public Health Research Consortium; 2010.

warnings are more visible if placed on the front panel in the upper part of the package.[331] Furthermore, messages and images which elicit strong emotional reactions are considered particularly effective.[332] Finally, evidence suggests that the impact of health warnings tends to decrease over time (wear-out effect) whereas regular rotations and updates of the health warnings and messages, already prescribed in the current TPD, are associated with increased effectiveness.[333]

Research comparing pictorial warnings with text-only warnings from several countries (e.g. Australia, France, Spain, the UK and US) also demonstrates that pictorial warnings increase consumers' awareness of warnings, knowledge and credibility of health risks, depth of processing and also cessation behaviours such as forgoing FMC, quit intentions and quitting.[334] They also contribute to reduced consumption as indicated above.[335] Research conducted for the Canadian Government also found that larger warnings are more effective at eliciting negative reactions, conveying information about the health risks of smoking and reducing consumption.[336] Consumers living in countries that have introduced graphic tobacco health warnings have a greater knowledge on the health effects of smoking[337,] and may have

[331] Moodie C, MacKintosh AM, Hammond D. Adolescents' response to text-only tobacco health warnings: results from the 2008 UK Youth Tobacco Policy Survey. Eur J Public Health 2009: 20; 463-9.

[332] Gallopel-Morvan K, Gabriel P, Le Gall-Ely M, Rieunier S, Urien B. The use of visual warnings in social marketing: The case of tobacco. J Bus Res 2011; 64:7-11. Hammond D, Fong GT, McDonald PW, Brown KS, Cameron R. Graphic Canadian cigarette warning labels and adverse outcomes: evidence from Canadian smokers. American Journal of Public Health 2004; 94(8):1442–5. Crespo A, Barrio A, Cabestrero R, Hernandez O. Cognitive processing and assessment of anti-smoking combined warning labels set by the European Commission: an empirical study with a Spanish sample. [in Spanish] (Procesamiento cognitivo y valoración de las nuevas advertencias combinadas antitabaco propuestas por la Comisión Europea: estudio empírico en una muestra española) Clinica y Salud 2007;18(2):163–80Hammond D, Thrasher J, Reid JL, Driezen P, Boudreau C, Santillán EA. Perceived effectiveness of pictorial health warnings among Mexican youth and adults: a population-level intervention with potential to reduce tobacco-related inequities. Canc Causes Contr 2012; 23:57-67. Goodall C, Appiah O. Adolescents' perception of Canadian cigarette package warning labels: investigating the effects of message framing. Health Communication 2008;23 (2): 117–27.

[333] Source: UK Department of Health (UK DoH). The Introduction of Picture Warnings on Tobacco Packs – Final Regulatory Impact Assessment. London: UK DoH; 2007. Gallopel-Morvan K, Gabriel P, Le Gall-Ely M, Rieunier S, Urien B. The use of visual warnings in social marketing: The case of tobacco. J Bus Res 2011; 64:7-11. Strahan EJ, White K, Fong GT, Fabrigar LR, Zanna MP, Cameron R. Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective. Tob Control 2002; 11:183-90.

[334] Gallopel-Morvan K, Gabriel P, Le Gall-Ely M, Rieunier S, Urien B. The use of visual warnings in social marketing: The case of tobacco. J Bus Res 2011; 64:7-11. Hammond D, Fong GT, Borland R, Cummings KM, McNeill A, Driezen P. Text and graphic warnings on cigarette packages: findings from the international tobacco control four country study. Am J Prev Med. 2007; 32:202-9. Rey JM, Lacave B, Viedma MI, Gallopel-Morvan K. An image is worth a thousand words: the effects of visual health warnings in the decrease of tobacco consumption: a research from the perspective of social marketing [in Spanish] (Una imagen vale más que mil palabras: efectos de las advertencias sanitarias visuales en el descenso del consumo de tabaco: un estudio desde la perspectiva del marketing social.) Cuadernos de Gestión 2010; 10:149-65.

[335] Sambrook Research International, "A Review of the Science Base to Support the Development of Health Warnings for Tobacco Packages," Report prepared for the European Commission, Directorate General for Health and Consumers, 2009: http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf

[336] Créatec+. Quantitative Study of Canadian Adult Smokers: Effects of Modified Packaging Through Increasing the Size of Warnings on Cigarette Packages. Montreal: Créatec+; 2008. (Report for Health Canada). Environics. Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Adult Smokers. Toronto: Environics; 2008. (Report for Health Canada).

[337] Thrasher JF, Hammond D, Fong GT, Arillo-Santillan E. Smokers' reaction to cigarette warnings with graphic imagery and with only text: a comparison between Mexico and Canada. E.Salud Publica Mex 2007; 49 suppl 2: S233-40. Hammond D, Fong GT, Borland R, Cummings KM, McNeill A, Driezen P. Text and graphic warnings on cigarette packages: findings from the international tobacco control four country study. Am J Prev Med. 2007; 32:202-9. Hammond D, Fong GT, Borland R, McNeill A, Cummings KM, Hastings G. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. Tobacco Control 2006; 15 (Suppl III):iii19–iii25. Environics.

fewer disparities in health knowledge across educational levels.[338] In countries with picture warnings on one side of the package the products are typically displayed in such a way that the side of the text warnings is visible to consumers.

The **replacement of TNCO levels** with descriptive information on contents/emissions under option 1 would help to better address a possible confusion among consumers regarding possible effects of the product (see problem identification 2.2.2). The inclusion of concrete **quitting information** is strongly supported by smokers and has been shown to increase the use of these services dramatically. [339]

1.1.16. PO2: PO1 plus harmonise certain aspects of packets and prohibit promotional and misleading elements

Option 1 plus:
1) The tobacco labelling and packaging and the tobacco product itself shall not include any promotional and misleading elements (e.g. misleading colours, symbols, slim FMC),
2) setting certain requirements for packages (e.g. cuboid shape, minimum number of and FMC per package) as well as for the size of the warnings

Member States are allowed to regulate the area not regulated by the TPD or other Union legislation, including adopting provisions providing full standardisation of packaging of tobacco products (i.e. plain packaging) as far as these provisions are compatible with the Treaty. The Commission will report on experiences gained with respect to surfaces not governed by the TPD five years after the transposition of the TPD.

For Point 2) Tobacco products other than FMC and RYO are exempted (current TPD rules apply). Delegated/implementing power to remove the exemption for these products if there is a change in circumstances.

Economic impacts

Option 2 would further advance the functioning of the **internal market** following e.g. harmonisation of additional elements including the removal of promotional/misleading elements where some Member States already have taken actions (2.2.2). The standardisation of the size of the health warnings as well as the shape of the package would contribute to effective display of the warnings and thus maximise the effect of the TPD.

Option 2 would further reduce **compliance costs for tobacco manufacturers** and it would result in even larger economies of scale, including standardised package size. The harmonisation of legislation in one go under option 2 rather than consecutive changes at national level would be cost efficient for the industry. The prohibition of promotional and

Consumer Research on the Size of Health Warning Messages – Quantitative Study of Canadian Youth. Toronto: Environics; 2008. (Report for Health Canada).

[338] Siahpush M, McNeill A, Hammond D, Fong GT. Socioeconomic and country variations in knowledge of health risks of tobacco smoking and toxic constituents of smoke: results from the 2002 International Tobacco Control (ITC) Four Country Survey. Tob Control 2006;15 Suppl 3:iii65-70.

[339] Such an increase has been shown in the past. See e.g.: Willemsen MC, Simons C, Zeeman G. Impact of the new EU health warnings on the Dutch quit line. Tob Control 2002;11:381–2. Miller CL, Hill DJ, Quester PG, Hiller JE. Impact on the Australian Quitline of new graphic cigarette pack warnings including the Quitline number. Tob Control 2009; 18:235-7. Wilson N, Weerasekera D, Hoek J, Li J, Edwards R. Increased smoker recognition of a national quitline number following introduction of improved pack warnings: ITC Project New Zealand. Nicotine Tob Res 2010;12 Suppl:S72-7.

misleading elements, including inserts prepared by several manufacturers for marketing reasons[340] would lead to some cost savings. For indirect impacts linked to consumption, see below references to section 5.7 and Annex 5. According to industry reports, the total ongoing administrative burden for producing inserts from reduced factory efficiency (i.e. higher production cost per unit of output) and the costs of the insert itself (i.e. paper and printing ink) would be likely to be between 42.2 and 75.5 mEUR a year in the EU-27.[341] Regulating the appearance of FMC should not place a major burden on manufacturers as most FMC currently on the market comply with a standard format, but products with a misleading size ("slim") would be affected. No impact beyond option 1 is expected on package producers and retailers. For tobacco products other than FMC and RYO the rules of the existing TPD could continue to apply (e.g. size and location), but with some minor modifications of the health warnings.

The further harmonization of packages and labelling requirements will support and save costs for **Governments** who would not have to invest in developing their own legislation. The measures reduce the administrative burden as the measures are self-executing and mutually reinforcing (package shape/sized pictures). For the indirect impact on Governments following the estimated additional drop in consumption reference is made to section 5.7 and Annex 5. The protection of **consumers** would be reinforced by regulating promotional and misleading aspects of the packaging (see glossary). Option 2 would complement those measures foreseen under policy area 3 (ingredients), which aim at banning characterising flavours (see glossary), as these provide tobacco products with a misleading taste and smell. As in option 1, it is expected that the measures would affect neither the range of products available on the EU-market nor their price and quality. Option 2 provides a further step towards implementing the **FCTC** guidelines. It does not prevent Member States from regulating surfaces not regulated by TPD or other legislation and thus implement full standardisation (plain packaging).

Social impacts

The impact on **employment** following the estimated drop in prevalence is further described in section 5.7 and Annex 5, including redistribution effects. No additional impact is foreseen for package manufacturers. Option 2 is expected to strengthen the effects of option 1 on **equality,** in particular as it would further limit the possibility of developing packages and FMCs particularly appealing to young people.

Health impacts

The envisaged measures under option 2 are expected to significantly contribute to the projected decrease of **consumption** and **prevalence**. Reducing the packages' potential to mislead consumers would have a positive impact on **awareness**.

As illustrated in the problem identification (section 2.2.2), many studies indicate that package design influences the perception of risks and has the potential of misleading consumers.

The measures proposed under this option are expected to reduce these problems. A ban on promotional/misleading elements would reduce the packages' potential to mislead consumers and increase the noticeability of health warnings. Setting certain requirements for package appearance and regulate the size of health warnings would reduce the promotional and misleading potential of the package, ensure that labelling requirements are not undermined

[340] Moodie C, Hastings G. Tobacco packaging as promotion. Tob Contr 2010; 19:168-170. International Union Against Tuberculosis and Lung Disease (The Union). Tobacco Packaging and Labelling.
Technical guide. Edinburgh: The Union; 2009. http://www.tobaccofreeunion.org/files/186.pdf (accessed 28 Nov 2012).
[341] RAND 2010

and that the enlarged picture warnings can be appropriately and fully displayed on the package in order to ensure their full effectiveness. A minimum number of FMC in each package and a minimum weight of tobacco in RYO packages would ensure that the size of the package allows a sufficient space for health warnings.

1.1.17. PO3: PO2 plus full plain packaging

Option 2 plus: standardised colour, font, size and position of brand name and brand variant on packages (plain packaging) and a readable health warning on each FMC stick. Other tobacco products than FMC and RYO will be exempted from the requirements (current TPD rules apply). Delegated/implementing power to remove the exemption if there is a change in circumstances.

Economic impacts

The precise economic effects of plain packaging in real life are difficult to quantify at present due to lack of empirical data and experience with plain packaging in Member States or other countries.

Option 3 would maximise the effects on the **internal market**. Product would have a homogenous appearance throughout the EU and all discrepancies between national legislations would be removed. Again, the direct (compliance) costs for **economic stakeholders** would be further reduced under option 3. The industry claims that the initial burden of introducing mandatory plain packaging would be the same as the burden of mandatory pictorial warnings, i.e. 32.5-125.4 mEUR.[342] However, this does not appear to be realistic. It is rather expected that companies would spend far less resources on the development of packages, considering that their possibility to develop individual packages are excluded under this option. Therefore, it is estimated that this option would result in overall cost savings as packages would remain the same and regular changes would become obsolete.[343] Also, the production of a plain package is expected to be cheaper as e.g. fewer, simpler and less expensive colours are used on the package itself.[344] Finally, the harmonisation of legislation in one go would be cost efficient for the industry. In terms of on-going costs, the full standardisation package appearance would also lead to economies of scale in the production of packages and FMC. Printing a health warning on a cigarette stick would result in some on-going costs for the printing process (colours, maintaining equipment), but no quantitative figures are available.

On the other hand, it is expected that plain packaging would result in reduced possibilities of brand differentiation, affecting in particular high margin/premium brands which could, over time, result in price competition and commoditisation of the market. Whilst it would be very difficult to establish new premium brands, entry barriers for non-branded products would be

[342] According to self-reported data of one major cigarette producer in Europe that provided quantitative estimates to RAND Europe (RAND 2010). The company disclosed that the initial administrative burden would be approximately 40 to 45 million EUR for the company if considerable time were not allowed for compliance. This translates into 18,100–20,400 EUR per SKU (no data available on costs for printing a warning on a cigarette stick).

[343] According to information from one tobacco product manufacturer, the cost of a general brand re-design which tends to happen about every two to three years is more than 20,000 EUR per SKU (Matrix 2012), which would be saved by manufacturers under this option.

[344] Minutes from the meeting with suppliers to the tobacco industry, 6 February 2012. http://ec.europa.eu/health/tobacco/docs/ev_20120206_mi_en.pdf (accessed 28 Nov 2012). Information provided by ECMA to DG SANCO.

lowered.[345] Considering the high degree of market concentration observed at present there is an increased risk of collusion between producers of premium brands. The industry has argued that plain packaging will increase illicit trade. However, no convincing evidence has been submitted and the argument appears counter-intuitive taking into account that counterfeiters try to benefit from the brand recognition associated with premium brands (currently recognisable from their trade marks which is not possible with plain packaging). Anyway, the actual and alleged additional risk of illicit trade is addressed in policy area 5 (traceability and security features). Regarding FMC papers/sticks, representatives from the fine paper industry confirmed that tipping paper is subject to very frequent changes[346] and it is therefore not expected that this would have any significant negative impact.

As regards other economic stakeholders, **package producers** could be slightly affected by the provisions under this option, as the production of the packages would become cheaper and could result in a drop in price per package, and possibly also in profit margins. However, this impact would be limited, in particular as package producers supply various sectors.[347] **Retailers** have claimed that plain packaging would make it more difficult for sales persons to identify packages. Therefore, management of stock and identification of products would become more cumbersome, increase transaction time and slow down the selling process, resulting in complaints from customers and higher business costs, affecting SMEs and small family enterprises disproportionally.[348] However, this problem is expected to be solved after an initial period of familiarisation, while staff is getting used to the new system, and by an appropriate reorganisation of the display.

For the indirect impact on economic players and **Governments** following the estimated additional drop in consumption, reference is made to section 5.7 and Annex 5. It is very likely that any shift from premium to low cost brands. However, Member States are likely to counter this with tax increases given the fact they can, in the context of the mixed structure of the EU excise duty system, make use of both the specific and the ad valorem component as needed.

Consumer protection would be further reinforced by regulating additional promotional and misleading aspects of the packaging and highlighting the health warnings, including also a warning on the stick. Consumer choice may be limited in the long run as new premium brands would have more difficulties to enter the market and second tier brands might exit the market. On the other hand, entry barriers of non-branded products would be lowered. No relevant impact on quality and price are expected as potential price drops could be compensated by tax increases. Option 3 is fully in line with the **FCTC** guidelines. Legal proceedings have been initiated following Australia's adoption of a similar measure as of 1 December 2012. While the High Court of Australia ruled the Government's tobacco plain packaging legislation to be constitutionally valid on 15 August 2012,[349] discussions are still on-going in the WTO

[345] Glossary of statistical terms – Barriers to entry from: Khemani RS, Shapiro DM (compilers). Glossary of Industrial Organisation Economics and Competition Law. Paris: Directorate for Financial, Fiscal and Enterprise Affairs, OECD; 1993.
[346] Minutes from the meeting with suppliers to the tobacco industry, 6 February 2012. http://ec.europa.eu/health/tobacco/docs/ev_20120206_mi_en.pdf (accessed 28 Nov 2012).
[347] Related figures were not delivered by the industry despite repeated requests.
[348] Information provided by EU retailer association, CEDT, to DG SANCO
[349] High Court of Australia. Judgement Summary: Cases S389/2011 and S409/2011.Canberra: High Court of Australia; 2012. http://www.hcourt.gov.au/assets/publications/judgment-summaries/2012/projt-2012-08-15.pdf (accessed 29 Nov 2012).

following requests for consultations by Ukraine, Honduras and the Dominican Republic.[350] Legal proceedings are also on-going under the Australia-Hong Kong Bilateral Investment Treaty.[351]

Social impacts

The impact on employment due to further reduction in consumption is described in section 5.7, including the input / output model. No major impact on package manufacturers is foreseen as they are also serving multiple other industries. Option 3 would, overall, improve **equality,** in particular as it would further limit the possibility of developing packages appealing to young people. However, standardising the font and size of brand and product name could to a certain degree make products less easily identifiable to people with lower levels of literacy.

Health impacts

Option 3 is expected to strengthen further the effects of option 2. Although, no studies based on real life experiences are available at this stage, many recent studies indicate that plain packaging not only increases the noticeability and effectiveness of health warnings, but also reduces substantially the attractiveness and appeal of tobacco packaging, the product, particular brands, the user and smoking (both to smokers and potential smokers) as well as false beliefs about the risks associated with different brand variants.[352]

These **effects are expected to be particularly strong in young people and for initiation.** For example, a recent eye tracking study showed that plain packaging increased the salience of health warnings among non-smokers and light (i.e. non-established) smokers.[353] These results have recently been replicated in adolescents.[354] As a consequence, plain packaging may help to reduce tobacco **consumption** and smoking prevalence, in particular by discouraging young people from taking up smoking, by reducing tobacco consumption among young adult smokers, by keeping the "in-between-category" of occasional smokers from

[350] World Trade Organization (WTO). Dispute Settlement: Dispute DS434. Geneva: WTO; 2012. http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds434_e.htm (accessed 29 Nov 2012). World Trade Organization (WTO). Dispute Settlement: Dispute DS435. Geneva: WTO; 2012. http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds435_e.htm (accessed 29 Nov 2012). World Trade Organization (WTO). Dispute Settlement: Dispute DS441. Geneva: WTO; 2012. http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds441_e.htm (accessed 29 Nov 2012).

[351] Australian Attorney-General's Department. Investor-State Arbitration - Tobacco Plain Packaging. Canberra: Attorney-General's Department; 2012. http://www.ag.gov.au/tobaccoplainpackaging (accessed 29 Nov 2012).

[352] See various papers reviewed in: Moodie C, Stead M, Bauld L, McNeill A, Angus K, Hinds K, et al. Plain Tobacco Packaging: A Systematic Review. PHRC Report. Stirling: University of Stirling; 2012. Hammond D. Tobacco packaging and labelling: A review of evidence. Waterloo: Department of Health studies: University of Waterloo; 2007. Bansal-Travers M, O'Connor R, Fix BV, Cummings KM. What do cigarette pack colors communicate to smokers in the U.S.? Am J Prev Med 2011: 40:683-9. Hoek J, Wong C, Gendall P, Louviere J, Cong K. Effects of dissuasive packaging on young adult smokers. Tob control 2011; 20:183-8. Hoek J, Gendall P, Gifford H, Pirikahu G, McCool J, Pene G, et al. Tobacco branding, plain packaging, pictorial warnings, and symbolic consumption. Qual Health Res 2012;22(5):630-9. Moodie C, Hastings G, Joossens L. Young adult smokers' perceptions of illicit tobacco and the possible impact of plain packaging on purchase behaviour. Eur J Public Health 2012; 22(2):251-3. Wakefield M, Germain D, Durkin S, Hammond D, Goldberg M, Borland R. Do larger pictorial health warnings diminish the need for plain packaging of cigarettes? Addiction 2012; 107(6):1159-67. Freeman B, Chapman S, Rimmer M. The case for the plain packaging of tobacco products. Addiction. 2008; 103:580-90. McCool J, Webb L, Cameron LD, Hoek J. Graphic warning labels on plain cigarette packs: Will they make a difference to adolescents? Social Science & Medicine. 2012; 74:1269-73.

[353] Munafò MR, Roberts N, Bauld L, Leonards U. Plain packaging increases visual attention to health warnings on cigarette packs in non-smokers and weekly smokers but not daily smokers. Addiction 2011; 106:1505-10.

[354] Maynard OM, Munafò MR, Leonards U. Visual attention to health warnings on plain tobacco packaging in adolescent smokers and non-smokers. Addiction 2012.

becoming regular smokers and by encouraging - in particular young and occasional – smokers to give up their habit.[355]

1.1.18. The views of stakeholders

The tobacco industry has argued that bigger pictorial health warnings or plain packaging have no effect on smoking prevalence, that plain packaging increases illicit trade and that it undermines their intellectual property rights (trademarks). On the other hand, at least one of the four big FMC manufacturers expressed no major concerns with the introduction of mandatory picture warnings, replacement of TNCO-levels display and mandatory printing of cessation services, although the importance for keeping appropriate space for trademarks was underlined.[356] Concerns about increased illicit trade following a plain packaging regime were also expressed by suppliers to the tobacco industry (packaging, fine paper, ingredients industries), but again they were not able to fully substantiate their arguments. Cigar manufacturers have referred to the specificity of cigars as an argument against strengthened labelling requirements and highlighted that SMEs would be affected disproportionately by stricter regulation/plain packaging. Health NGOs have argued that large mandatory pictorial warnings and plain packaging reduce the attractiveness and do not facilitate illicit trade. Most of the Member States responding to the public consultation were in favour of enlarged mandatory pictorial warnings, while the positions on plain packaging were more diverse.

1.1.19. Comparing the options and preferred option

Full plain packaging (policy option 3) would be most **effective** in terms of removing national disparities (policy objective A3), but requiring mandatory pictorial warnings and/or harmonising package shape and prohibiting promotional elements (options 1 and 2) would also help to achieve this aim, albeit to a lesser extent. Additionally, full plain packaging (policy option 3) would help to reduce administrative burdens by fully unifying labelling rules (policy objective B1), whereas requiring mandatory pictorial warnings and/or harmonising certain aspects of the package shape and prohibiting promotional and misleading elements (options 1 and 2) would contribute to a lesser extent to this objective. Harmonising certain aspects of the package shape and banning promotional elements or introducing full plain packaging (policy options 2 and 3) would remove the misleading potential of packages from the market (policy consideration C2). Introducing bigger mandatory pictorial warnings (policy options 1-3) would help improve consumer information (policy consideration C4).

The assessment above has illustrated that all options 1-3 would lead to **cost** savings compared to status quo in terms of compliance costs and because action is taken at one go at EU level rather than many consecutive changes by Member States. Overall, however, it is expected that plain packaging (option 3) would also reduce the possibilities for brand differentiation, in particular affecting high margin/premium brands and impact more negatively on revenues/profits due to the drop in consumption (see section 5.7 and Annex 5), which is expected to be more important than under options 1 and 2.

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[355] Moodie C, Hastings G, Ford A. A brief Review of Plain Packaging Research for Tobacco Products, report prepared for the UK Department of Health. Stirling: Centre for Tobacco Control Research; 2009. Germain D, Wakefield MA, Durkin SJ. Adolescents' perceptions of cigarette brand image: Does plain packaging make a difference. J Adol Health 2010; 46:385-92. Thrasher JF, Rousu MC, Hammond D, Navarro A, Corrigan J. Estimating the impact of pictorial health warnings and "plain" cigarette packaging: Evidence from experimental auctions among adult smokers. Health Policy 2011; 102:41– 8.

[356] Minutes from the meeting with FMC manufacturers, 2 December 2011: http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4 (accessed 28 Nov 2012).

Preferred policy option 2: Mandatory enlarged picture warnings plus harmonise certain aspects of packets and FMC appearance and prohibit promotional and misleading elements.

The preferred option addresses the current heterogeneous development in Member States, in particular as regards pictorial warnings and cessation information where different regimes affect the internal market negatively. The suggested standardisation of the package appearance will ensure effective display of the health warnings. The option provides an ambitious and balanced approach taking into consideration the concerns of some stakeholders. It addresses in particular the concerns of the tobacco industry as it leaves a certain space on the package for manufacturers to display their trademark. The limitation of the product scope to FMC and RYO in a first stage would also take into consideration the concerns expressed by cigar manufacturers (often SME's). This is justified also because cigars (and pipe tobacco) are primarily used by adult smokers (see section 2.2.1). The option is based on new evidence showing that bigger and pictorial warnings are more effective and current indications of TNCO level and other aspects of packaging and labelling are misleading. The exact size of the warning (75%) has been suggested after thorough analysis of scientific evidence and international experience[357] and developments as well as the impact on economic stakeholders.

There is **no less stringent measure** available to reach the objective of improving the internal market while protecting public health. All elements included in option 2 would contribute to the objective, but none of them can, on their own, be expected to achieve the objective as effectively as the package of measures proposed in the preferred option. It is assumed that the measures proposed in the preferred option reinforce each other. Finally, some of the measures proposed need to be regulated jointly to avoid circumvention of legislation (e.g. picture warnings and package shape). Also, the costs associated with the preferred options are considered proportionate compared to the overall benefits. On the other hand, a stricter measure (option 3, full plain packaging), is expected to achieve the policy objectives even more effectively, but, given the current lack of real life experience,[358] pending legal disputes regarding the plain packaging and serious concerns expressed by some stakeholders it appears most appropriate at this stage to choose option 2, while providing an opportunity to evaluate the situation after 5 years with a view to considering further standardisation (plain packaging). The option would not prevent Member States to regulate surfaces of the packages not covered by TPD or other legislation and thus implement full standardisation (plain packaging) provided it is compatible with the Treaty.

As illustrated above, only an **EU action** can bring some of the current provisions in line with international and scientific development as Member States are prevented from taking actions on their own (e.g. TNCO levels display). Other aspects of labelling (e.g. pictorial warnings) are associated with a lot of diversity and only an EU action can ensure a homogenous development facilitating the functioning of the internal market.

[357] 75% on both sides in Canada, 30% and 90% in Australia and New Zealand, 80% of both sides in Uruguay, 60% and 70% in Mauritius, 30% and 100% in Mexico.
[358] Plain packaging entered into force in Australia as of 1 December 2012.

5.4. REPORTING AND REGULATION OF INGREDIENTS[359]

1.1.20. PO1: Common reporting format on a voluntary basis. Prohibit toxic, addictive and attractive additives in tobacco products.

Member States are free to decide whether they oblige manufacturers to report additives in tobacco products. If Member States decide to make the reporting obligatory, the common reporting format must be used. Member States shall prohibit additives based on the general criteria toxicity, addictiveness and attractiveness.

Economic impacts

A harmonised reporting format would remove current disparities and facilitate the monitoring and analysis of ingredients data across the EU, but a voluntary reporting regime would provide an incomplete picture of ingredients used across the EU, which is not beneficial for the functioning of the **internal market**. Regarding ingredients regulation, Member States would have to ban additives which increase toxicity, addictiveness and attractiveness. This is expected to have a positive impact on the internal market, especially as a result of increased convergence as regards additives with toxic and addictive properties. Following the obligation to ban toxic and addictive additives, Member States are also expected to re-evaluate their current ingredients lists (where such lists exists) and update those according to scientific developments. Also this, would remove some of the current divergence. In terms of "attractive" additives, the effect is expected to be more limited as this concept is more subjective and no further guidance would be given in the legislation. Member States could be expected to take the FCTC guidelines for implementing Article 9 and 10 as guidance, but they give significant discretion to Parties and are expected to be interpreted in different ways.

The optional and harmonised reporting system would lead to cost savings for **economic stakeholders, Governments** (in particularly those opting for no reporting) and the Commission as it would reduce the compliance costs compared to the baseline scenario. Also the harmonised ingredients regulation under option 1 is expected to lead to some cost savings compared to the baseline scenario due to the increased convergence in terms of additives allowed or banned in tobacco products. However, as indicated above, some discrepancies can still be expected under option 1, in particular in terms of "attractive" additives where Member States are expected to interpret the concept differently. For the indirect impact on economic players and Governments following the estimated marginal drop in consumption, reference is made to section 5.7 and Annex 5.

Under option 1, **consumers** would benefit from a somewhat increased protection due to the ban on toxic, addictive and attractive additives. The consumer choice is expected to be remain stable. Even if some of the tobacco products currently on the market would have to be reformulated, it is likely that alternative additives or mixture of additives would be used in order to maintain the product or a similar one on the market.

Social impacts

The indirect impact on **employment** is expected to follow the limited drop in consumption. As indicated above, it is likely under option 1 that the rather general criteria, and in particular on attractiveness could be interpreted differently in Member States. This could have a negative impact on **equality** between Member States, i.e. lead to different level of protection.

[359] For definition, see glossary

As the criteria suggested under option 1 are related to the additives as such and not the tobacco products, it is likely that the producers would find alternative additives (instead of those banned because of their attractiveness) to create a similar product. Therefore, it is expected under option 1 that attractive tobacco products, including fruit and candy-flavoured FMC would continue to be marketed, at least in some Member States. This would particularly affect **young people** who are more vulnerable in relation to these products.

Health impacts

Option 1 is expected to remove some of the most hazardous additives from tobacco products. However, as explained previously in this impact assessment, tobacco consumption as such is linked to a number of health risks which would remain despite the regulation foreseen under this policy option. It is also likely that an additives-based approach only in terms of attractiveness is less effective than a product-based approach (see option 2), in particular considering the risk that alternative additives could be used to produce a similar (distinctive) flavour.

1.1.21. PO2: Mandatory reporting in harmonised format. Prohibit tobacco products with characterising flavours and products with increased toxicity or addictiveness

Manufacturers are obliged to electronically report ingredients (glossary) of tobacco products in accordance with a common format and provide supporting data (e.g. marketing reports). Fees charged by Member States for handling the information submitted to them shall not exceed the cost attributable to those activities. Placing on the market of new or modified tobacco products must not take place before the submission of ingredients data. Reported data, excluding confidential information, is published. Delegated/implementing power to specify the reporting format.
Tobacco products with characterising flavours (glossary) are prohibited (this is similar to the US model). Test panels assist in the decision making process. Additives associated with energy and vitality (e.g. caffeine and taurine) or creating the impression that products have health benefits (e.g. vitamins) are prohibited. No flavourings are allowed in filters, papers or packages. Tobacco products with increased toxicity or addictiveness shall not be placed on the market. Member States shall remove from the market tobacco products that include ingredients not complying with REACH. Delegated/implementing power to set limits for additives imparting a characterising flavour, toxicity and addictiveness.
Tobacco products other than FMC, RYO and STP (i.e. cigars, cigarillos and pipes) are exempted from the prohibition of products with characterising flavour and the prohibition of additives associated with energy and vitality or health benefits. Delegated/implementing powers to remove the exemption for these products are foreseen if there is a substantial change of circumstances.

Economic impacts

Mandatory reporting of additives in combination with a harmonised format would ensure a level playing field and facilitate analysing and monitoring of data. Also the ingredients regulation suggested under option 2 would further harmonise national legislations, prevent a patchwork of national regulations, facilitate cross-border trade and thus improve the functioning of the **internal market**. The approach in terms of attractiveness, addictiveness and toxicity would rather focus on the tobacco product itself than the additives used in option 1. In addition, some easily determined additives, such as vitamins and caffeine would be banned throughout the EU. This would result in less discrepancy for Member States. Also, implementing/delegated powers are foreseen to ensure a consistent approach. Test panels would assist in determining products with characterising flavour, which would further

increase convergence. Overall, option 2 would increase further the positive impact on the internal market compared to option 1.

The EU guide on harmonised reporting format and the already developed tool for data submission (EMTOC) would provide a basis for a mandatory harmonised reporting system. The **costs** for introducing such a system on a mandatory basis would therefore be marginal and largely off-set by the savings generated by the use of one single format across the EU. A robust electronic system as the one suggested would also address the concern expressed by tobacco manufacturers as regards trade secrets as publication for general public could take into account legitimate confidentiality requests. If Member States charge a fee for the reporting, the economic players have indicated in the context of the public consultation that they would be ready to participate to the financing of an electronic reporting system.[360] Available market studies and scientific studies (e.g. on toxicity) would need to be submitted.

In terms of ingredients regulation, the **economic actors** (the tobacco industry) would benefit from cost savings under option 2.[361] For products sold across various Member States the decision is adopted once across the EU rather than several times consecutively, which reduces the compliance costs, including understanding of the new requirements and possible reformulation of products. In order to quantify these costs, a question was submitted to four major FMC manufacturers to know the average cost per brand of changing the composition of cigarettes. The replies provided were incomplete which made it difficult to quantify the extra costs for changes of ingredients regulation in a given Member State. One company stated, however, that a major product redesign would cost in excess of 1 mEUR per brand. Costs included in this figure are development work, specification maintenance, pre-trials, pilot plant trials, analytical work, as well as the cost impact on stock holdings and factory efficiency. It is estimated, under option 2, that a limited part of the market would be affected by the change (including the menthol FMC counting for 4% of the market). Also the ban of flavourings added to the filters, paper and packages would affect the (limited) segment of products currently including such flavourings. Moreover, the regulation of products with increased toxicity or addictiveness is harmonised under this policy option, which could result in limited additional costs savings for economic stakeholders. The possibility for the Commission to adopt harmonised rules (delegated/implementing acts) should further reduce compliance costs compared to option 1. The production costs would also decrease under option 2 as less ingredients are expected to be used. Ultimately, option 2 would allow manufacturers to produce one product which could be sold across borders in all Member States. The measure would primarily affect a specific segment of the market, namely products with characterising flavours or additives giving the misleading impression of energy or vitality (such as caffeine and taurine) or associated with health benefits (such as vitamins).[362]

Menthol-flavoured FMC are more common than other FMC with characterising flavours. They account for 4% of all FMC sales over the past ten years ranging from 25% in Finland

[360] CECCM submission to the public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC.

[361] Matrix 2012. One company stated, in the context of an interview carried out by Matrix, that a single regulation across Europe might be less expensive than Member State level changes with different limits across each of the EU Member States, as long as ingredient regulation is proportionate and evidence based.

[362] Certain flavourings are used in relatively high quantities, such as cocoa and liquorice, without necessarily resulting in a product with a characterising flavour, whilst other products includes flavourings in lower quantities giving the product a characterising flavour (distinguishable taste or aroma). Often, the characterising flavour is indicated on the package. Tobacco products overtly marketed as containing additives (e.g. menthol cigarettes) command a relatively small market share in EU (SCENIHR 2010)

and 0,1% in Greece.[363] As indicated under health impacts below, it is estimated that flavours have an effect on smoking initiation.[364] It is impossible to predict with certainty the response of already established smokers of menthol FMC if these products were not allowed. However, it appears likely, in particular taking into account addictiveness that a significant part of these smokers would switch to traditional FMC without characterising flavours. Sales lost from menthol cigarettes would therefore be partially off-set by sales of other FMC or by efforts to acquire the products outside the EU or illicitly. However, some current menthol smokers are also expected to quit others are expected not to start. The impact on growers is limited to the drop in consumption and there is no risk of distortion between growers of different tobacco types. The impact on flavouring suppliers is expected to be limited as they normally supply multiple actors and multiple flavourings. The indirect impacts on the economic stakeholders following the expected drop in consumption are further described in section 5.7 and Annex 5.

Regarding the reporting obligations, the main impact expected for **Governments** is that enforcing and verifying the reporting obligations is facilitated. National authorities would also be able to charge a fee for the ingredients reporting. Regarding ingredients reformulation, however, there may be some additional administrative burden for Governments and the Commission when analysing the market studies submitted by industry or when taking decisions on characterising flavours. From an **international** perspective, option 2 is well in line with the FCTC guidelines on ingredients and similar to the US approach. All products with characterising flavours (e.g. menthol and clove) are treated the same way to avoid un justified differences of treatment.[365] The indirect impacts directly linked to consumption/prevalence are further developed in section 5.7 and Annex 5.

Social impacts

In terms of **employment**, the impacts of option 2 are in line with trends outlined above for the economic stakeholders, i.e. they would broadly correspond to the foreseen reduction in consumption (see section 5.7 and Annex 5). This applies to upstream suppliers (e.g. growers and producers of additives), tobacco industry and distributors. Reference is also made to the redistribution effect which is based on the input/output model (see Annex 5). The option would not affect additives essential for the manufacturing of tobacco products (other than those imparting a characterising flavour). It would not discriminate between different tobacco varieties. Option 2 would provide improved and more **equal** protection due to the removal of certain appealing products. This is expected to have a particular impact on young people.

Health impacts

As described in the problem identification, scientific studies have demonstrated an influence of flavourings on smoking initiation.[366] Tobacco products may also be designed in such a way that they are easier to start smoking with. This may be attained by making it easier to inhale the smoke in the lungs and by creating a sweeter, milder or "colder" smoke. By reducing and changing the harshness of the smoke, special target groups may be reached.[367] In a number of

[363] Matrix 2012. Based on Euromonitor (volume) data for 24 Member States (no data available for Cyprus, Malta and Luxembourg)
[364] SCENIHR 2010
[365] See WTO Appellate Body, AB-2012-1, United States – Measures Affecting the Production and Sale of Clove Cigarettes (DS406)
[366] SCENIHR 2010
[367] Carpenter C, Wayne GF, Connolly GN. Designing cigarettes for women: new findings from the tobacco industry documents. Addiction 2005; 100: 837-51.Carpenter CM, Wayne GF, Pauly JL, Koh HK, Connolly GN.

countries, sweet and tasteful tobacco products are the most preferred tobacco products among children and adolescents as well as experimenting smokers.[368] A study by Hersey et al., using data from the National Youth Tobacco Survey in the US, found that menthol FMC use was significantly more common among newer, younger smokers.[369] A recent study analysing data of more than 47,000 US-pupils US found a greater risk of progression to regular smoking and nicotine dependence for those who start smoking menthol cigarettes compared to those starting with non-menthol cigarettes.[370] The US FDA Tobacco Products Scientific Advisory Committee has also confirmed, on the basis of the extensive review of all available information, that the evidence was sufficient to conclude that it is more likely than not that the availability of menthol FMC increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such FMC were not available.[371] Overall, it is expected that option 2 would result in lower appeal and increased **awareness**. Additives that give the impression that FMC are less harmful, contain healthy properties or are associated with energy and vitality (including fruits, vitamins and caffeine) would no longer be allowed and if new attractive products appeared on the market, the Member States and the Commission would be able to react, if necessary, through a delegated/implementing act. This would contribute to the projected decrease in **consumption**. The option is likely to reduce smoking uptake rather than affecting habits of established smokers although a certain impact is also expected for established smokers. Option 2 would be further reinforced by stricter requirements in the area of packaging and labelling (see policy area 2), namely by the removal of misleading and promotional elements under that policy area. Over time, it will result in reduced morbidity/mortality from smoking and a higher level of well-being.

1.1.22. PO3: Mandatory reporting in harmonised format. Prohibit all additives not essential for manufacturing (similar to Canada model)

Ingredients reporting as in option 2. In terms of ingredients regulation, all additives in tobacco products, except those essential for manufacturing are prohibited. Maximum limits are set for sugar and sweeteners.

Other tobacco products than FMC, RYO and STP are exempted from the ingredients regulation. Delegated/implementing power to remove the exemption for these products if there is a change of circumstances.

New cigarette brands with flavors that appeal to youth: Tobacco marketing strategies. Health Aff (Millwood) 2005; 24:1601-10. Cummings KM, Morley CP, Horan JK, Steger C, Leawell NR. Marketing to America's youth: evidence from corporate document. Tob Control 2002; 11:15-7. Wayne G, Connolly G. How cigarette design can affect youth initiation into smoking: Camel cigarettes 1983-93. Tob Control 2002; 11(Suppl 1):i32-39.

[368] Ashare RL, Hawk LW Jr, Cummings KM, O'Connor RJ, Fix BV, Schmidt WC. Smoking expectancies for flavored and non-flavored cigarettes among college students. Addict Behav 2007; 32:1252-61. Giovino GA, Yang J, Tworek, Cummings KM, O'Connor J, Donohue K, et al. Use of flavored cigarettes among older adolescent and adult smokers: US 2004. Presentation at the National Conference on Tobacco or Health. Chicago, Illinios; May 6, 2005. Klein SM, Giovino GA, Barker DC, Tworek C, Cummings KM, O'Connor RJ. Use of flavored cigarettes among adolescent and adult smokers. United States 2004-2005. Nicotine Tob Res 2008; 10: 1209-14.

[369] Hersey JC, Ng SW, Nonnemaker JM, Mowery P, Thomas KY, Vilsaint MC, et al. Are Menthol Cigarettes a Starter Product for Youth? Nicotine Tob Res 2006; 8:403-13.

[370] Nonnemaker J, Hersey J, Homsi G, Busey A, Allen J, Vallone D. Initiation with menthol cigarettes and youth smoking uptake. Addiction 2012 Aug 3.

[371] Tobacco Products Scientific Advisory Committee (TPSAC). Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Rockville, MD: US Food and Drug Administration; 2011.

Economic impacts

As regards ingredients **reporting**, the impacts would be similar to option 2, although the volume of reporting could be reduced following the restriction of ingredients allowed.

Regarding ingredients regulation, option 3 would further improve the functioning of the **internal market** due to the removal of the remaining discretion for Member States. Products could then circulate freely across borders without additional health concerns. Compared to the previously described options, **manufacturers** would be faced with significantly higher costs associated with reformulation and removal of products from the market. Using the same cost estimated as under option 2 means that a major product redesign would cost in excess of 1 mEUR per brand, but compared to option 2, most brands across the EU are expected to be affected by option 3. The costs associated with a change at EU level would however still be lower than consecutive changes at national level.[372]

Option 3 would also impact negatively on product differentiation opportunities for the industry and is therefore likely to reduce turnover and profits, see section 5.7 and Annex 5. Option 3 would have a particular impact on economic players involved in Burley and Oriental tobacco (growers, manufacturers of American blend FMC) compared to Virginia as more additives, including sugar, are used in the manufacturing of FMC based on these tobacco types. Some additional impacts on flavouring suppliers can be expected compared to option 2, although they normally supply multiple sectors.

On balance, the option is not expected to have any additional direct impacts on **Governments.** Compared to option 2, the costs of option 3 associated with ingredients regulation are on the one hand lower (less administrative burden), but on the other hand result in significantly reduced choice for **consumers** although they would benefit from a more comprehensive protection. In terms of **international impacts**, option 3 is well in line with the FCTC guidelines and similar to the Canadian and Brazilian approaches which have been discussed in the framework of the WTO. It could have some impact on EU trade, considering that it would affect primarily Burley and Oriental producers (mainly in the EU), while Virginia producers (including non-EU) would be less affected.

Social impacts

The indirect impact on **employment** linked to the drop in consumption is described in section 5.7 and Annex 5. In terms of distributional effects, option 3 is expected to have a greater impact on employment related to Burley and Oriental tobacco (American blend FMC) as explained above. In this context, it should be recalled that more than 80% (69,000) of the EU farmers are involved in these tobacco types. These are often small family businesses concentrated in specific regions, including rural areas in Bulgaria, Poland, Greece, Spain and Italy. In terms of **equality**, option 3 would provide similar (or marginally improved) protection of young people compared to option 2 as it would remove additional products from the market that could be attractive for young people.

Health impacts

Option 3 would further reinforce the effect on **awareness** and prevalence outlined under option 2, although only to a limited extent as most of the particularly appealing products are already banned under option 2. The indirect impacts are further developed in section 5.7 and Annex 5.

[372] This is certainly true if one Member State opts for a full ban on additives (Canadian/Brazilian model).

1.1.23. The views of stakeholders

All stakeholders have expressed support for mandatory **reporting on ingredients** in a common format.[373] The tobacco industry has referred to commercially sensitive data and the importance of keeping this data confidential. In addition, FMC manufacturers have indicated that they agree to participate to the financing of a reporting system with regard to running costs.[374]

In relation to **ingredients regulation**, the tobacco industry as well as the flavouring industry have emphasised that there is no scientific basis to regulate attractiveness arguing it would be a "subjective concept". Growers have expressed particular concern that a ban on all additives would discriminate against certain types of tobacco (Burley and Oriental) and have very negative impact on employment. Cigar manufacturers have argued against further requirements on ingredients, in particular stressing that cigars are mainly used by adult users and not by young people taking up smoking. The four big FMC manufacturers indicated, however, that prohibiting certain characterising fruit and candy-like flavours for products such as pina colada and strawberry can be further explored[375]. Growers indicated that a ban on dominant flavour could be acceptable.[375] Health NGOs have expressed support for an approach addressing the attractiveness of tobacco products. A majority of the Member States that responded to the public consultation supported some kind of ingredients regulation (Annex 1).

1.1.24. Comparing the options and preferred option

In terms of **effectiveness**, prohibiting products with characterising flavours (policy option 2) or (even more so) prohibiting all additives not essential for manufacturing (policy option 3) would remove national disparities and unify national rules (policy objectives A3 and B1). Option 1 would partly contribute to the achievement of these objectives. The mandatory and electronic reporting system under options 2 and 3 would also be well in line with objective B2 as it would facilitate enforcement and verification by Governments as regards reporting obligations. All options 1-3 would contribute to policy consideration C1 as they would regulate the most hazardous products on the market. Options 2 and 3 would fulfil consideration C2 as they would remove products which are particularly attractive, including to young people.

Prohibiting products with characterising flavours (policy option 2) appears to be a manageable and **efficient** measure to regulate tobacco products appealing and attractive to young people, therefore taking into account the concept of “attractiveness”. The measure would affect a limited number of products, while prohibiting all additives not essential for manufacturing (policy option 3) would affect most of the products on the market and thus have more significant economic impact. A ban of all products with characterising flavours, rather than just a limited number of identified flavours would ensure **coherence** and equal treatment and avoid unjustified differences of treatment (e.g. menthol vs clove).

Preferred policy option 2: Mandatory reporting in harmonised format. Prohibit tobacco products with characterising flavours and products with increased toxicity or addictiveness.

[373] Based on the existing system, EMTOC.

[374] The European Association for Cigarette Manufacturers (CECCM) considers the introduction of fees for operating costs acceptable in its contribution to the public consultation on a possible revision of the Tobacco Products Directive

[375] Minutes from the meetings are available at : http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4 (accessed 28 Nov 2012).

A harmonised reporting format and mandatory reporting will create a level playing field and facilitate collection, analysing and monitoring of data. It will also reduce the administrative burden of the industry, Member States and the Commission and provide a more robust system to handle sensitive data. All stakeholders support this approach and the European Association for Cigarette Manufacturers (CECCM) considers the introduction of fees for operating costs acceptable (see above).

The preferred option also addresses the heterogeneous development in Member States in relation to ingredients regulation and takes into account international developments (FCTC). It allows industry to adapt the production lines in one go whilst allowing industry some margin to differentiate products. It focuses on products particularly attractive to young people and is estimated to reduce smoking initiation. It addresses recent market developments, including the new technology of inserting additives (e.g. menthol) in the filters of the cigarettes, and allows for further guidance and developments through implementing/delegated acts. A general ban on characterising flavours (instead of regulating individual additives) makes it more difficult to circumvent the ban by developing alternative chemical combinations with the similar properties (taste/aroma). The option provides a balanced approach, taking into consideration the concern of some stakeholders, in particular regarding demand for certain tobacco types (Burley and Oriental) and EU growers have indicated that they could accept the suggested approach.[376]

The preferred option would contribute to the achievement of the policy objective, i.e. improve the functioning of the internal market through further alignment of Member States' regulations. In terms of health, it would in particular target smoking initiation among young people. A stricter approach (option 3) would go beyond the focus on young people and affect a substantial number of products which could be seen as less proportionate to the expected additional impact on smoking initiation. A less stringent measure (option 1) would not improve the functioning of the internal market. Also, when balancing the benefits with the costs for the economic operators, option 2 appears to be a **proportionate** solution given the number of products affected compared to option 3.

Only an **initiative at EU level** is capable of removing the current and expected diversity in terms of regulation and provide a standardised format for reporting of additives.

5.5. CROSS-BORDER DISTANCE SALES OF TOBACCO

1.1.25. PO1: Notification and age verification system

Retailers of tobacco products intending to engage in cross-border distance sales shall notify their cross-border activities to the Member States where the company has its seat and where it intends to sell. Member States may require the retailer to appoint a natural person, who ensures compliance with the TPD of products delivered to customers in Member States concerned. Mandatory age verification mechanism is foreseen.

Economic impacts

Option 1 would provide more equal market conditions for internet retailers operating on the EU market. The requirement to notify internet retail under option 1 is expected to ensure/improve compliance with the law (including TPD) and is expected to reduce the amount of illegal sales of tobacco products in favour of legal business (traditional retailers

[376] Minutes from SANCO's meeting with tobacco growers, September 2012: http://ec.europa.eu/health/tobacco/docs/ev_20110914_mi_en.pdf (accessed 28 Nov 2012).

and legal internet retailers) operating in compliance with the TPD (e.g. labelling and ingredients regulation). This would maximise the effect of TPD and have positive impact on the **internal market**.

The notification requirement and the age control mechanism are expected to impose some **compliance costs** on tobacco internet retailers. The cost of notification is expected to be minor as the actual requirement will be limited to sending an e-mail/letter to the competent authorities of the host Member State as well as Member States of destination. This must be seen in the context of the specificities of tobacco products responsible for almost 700,000 deaths in the EU each year. The designation of a natural person to ensure compliance with the TPD is optional for Member States and it is expected that the retailer can make use of resources already required by other legal frameworks (tax legislation). The age control verification is also expected to result in minor costs. Option 1 is expected to result in a reduced number of internet retailers as many of the current retailers would close their business rather than notify their (illegal) activity.[377] This reduction would partially reduce consumption, partially lead to a return of consumption to the legal supply chain. Overall, the impact on economic stakeholders is expected to be positive following the estimated shift from illegal to legal sale, despite the somehow reduced consumption.

The shift towards legal sale would also have the unintended but welcome side effect of increased tax revenues for **Governments** and would facilitate criminal investigations, as internet sales by non-notified businesses would be automatically illegal. On the other hand, option 1 would imply additional, but limited costs for national authorities in terms of setting up the notification system. It is expected that 0.5 full time equivalent (FTE) would be more than adequate whilst law enforcement would be simplified compensating largely for the additional costs. **Consumers** would continue to have access to several sales channels, including cross-border distance sale and have access to products not available on their domestic markets. They could verify before purchase whether the internet seller is a legal entity competent to engage in such activity. The protection against illicit supply and protection of young people would be improved and more consumers would obtain products complying with the TPD, including with warnings in their own language. Consumer prices are expected to increase as a result of the shift from illegal to legal supply. Option 1 provides a step towards, but is not fully in line with the **FCTC** guidelines recommending a full ban.

Social impacts

As most of the consumers currently purchasing from illegal internet sources are expected to divert to other legal distribution channels, option 1 is likely to have a positive overall impact on **employment** in the legal supply chain. Option 1 would lead to improved protection of **young people** as internet retailers would be obliged to control the age of the purchaser.

Health impacts

Option 1 is expected to further reduce availability and access to tobacco, in particular for under-aged people. The option would improve **awareness** as the safeguards of the TPD would be better respected and would contribute, to some extent, to a drop in **consumption**/prevalence, particularly in the illicit segment of the market. Most of the consumers currently using the internet as a source for tobacco products are expected to turn to alternative, legal sources, but some are also expected not to start, quit or reduce their consumption. It would also limit young people's access to promotional aspects often visible

[377] Some retailers are also expected to continue illegal, non-notified activities.

on the internet and could discourage uptake of tobacco use, in particular among young people. Overall this is beneficial for public health.

1.1.26. PO2: Prohibit cross border distance sales of tobacco products

Cross-border distance sales of tobacco products are prohibited in the EU.

Economic impacts

A ban on cross-border distance sales of tobacco would remove current divergences on the internal market and ensure that certain provisions concerning protection of the internal market (e.g. labelling and ingredients rules set out in the TPD) are fully respected/not circumvented.[378] The measure would also facilitate enforcement.[379] The current disadvantage of traditional retailers having to compete with lower prices applied by (mainly) illegal internet retailers would be removed. This would have the positive impact on the **internal market.** However, option 2 would also remove legal cross-border distance sale.

Option 2 could imply a one-off compliance cost of lost stocks and of equipment used for the tobacco **internet retail** activity, although these costs would be very limited considering the transposition period. The products can also still be sold domestically and there is no legitimate expectation for illicit activities to continue. Option 2 would interfere with the freedom to conduct business which would need to be balanced against the principle of health protection.[380] The shift towards sales in the legal supply chain is also expected, as an unintended side effect, to improve **Governments'** ability to collect taxes resulting in increased tax revenues. Indirect impacts directly linked to consumption are further described in Section 5.7 and Annex 5. Option 2 would limit the number of sales channels for **consumers**, but provide a higher level of protection as it would reduce the availability of illicit tobacco products not necessarily complying with the TPD. The measure is fully in line with the **FCTC** guidelines, but needs to be justified under WTO rules.

Social impacts

Option 2 would further reinforce the positive impact on legal **employment** in tobacco outlined under option 1. It would also remove the current negative impact on **young people** and apply in an equal manner to all EU citizens.

Health impacts

Many of the current internet sites include promotional aspects and the products are unlikely to comply with required labelling or content rules. This has a negative impact on availability and **awareness**. Option 2 is expected to further reduce access, both to under-aged people who might be tempted to purchase on the internet due to less strict age controls and cheaper prices and adults who wish to avoid paying the applicable taxes. This would lead to a drop in **consumption** exceeding the one described in option 1.

1.1.27. The views of stakeholders

The FMC manufacturers expressed support for distance selling of tobacco products to adults provided that such sale is regulated and proper tax payments are ensured (see Annex 1). Retailers have indicated that internet sale of tobacco is associated with problems in relation to

[378] Compare the reasoning in Case C-491/01, The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, ECR [2002], p I-11453, para 81-91.
[379] Whilst it is true that distance purchases can also take place from countries outside the EU, remaining customs control offer better chances of detection.
[380] Article 16 v. Article 35 of the Charter of Fundamental Rights of the European Union

under age control and collection of taxes. They argue that stricter measures, if any, should be introduced at national levels. Health NGOs have asked for a ban of internet sales of tobacco as a logic extension of the advertising ban.

1.1.28. Comparing the options and preferred option

In terms of **effectiveness**, both a notification system combined with age verification (option 1) and prohibiting cross-border distance sale (option 2) would facilitate the creation of a level playing field (policy objective A2). Both options would also facilitate market surveillance (policy objective B2). Moreover, both options (and even more so, option 2) would contribute to reduced access for young people (policy consideration C5) and minimum level of health protection (policy consideration C6).

In terms of costs, the establishment of a notification system under option 1 would imply additional, however limited, **costs** for national authorities whilst facilitating law enforcement. Prohibiting cross-border internet sales (policy option 2) would fully remove one sales channel and thereby limit market opportunities. It would deprive consumers of the possibility to buy tobacco products not available in the Member States of location. Both options are also expected to lead to reduced illicit trade and thereby benefit economic players involved in the legal supply chain.

Preferred policy option 1: Notification and age verification system

The **preferred option** will facilitate legal activity without removing any sales channel, while allowing consumers legitimate access to tobacco products not available on their domestic market. The option reinforces the effect of the TPD by preventing purchasing of products not complying with the Directive, including health warnings in the right language and ingredients regulation. An unintended side-effect is that the preferred option also will reduce the availability of cheaper products not respecting national price policies, address underage purchasing and allows Governments to better collect applicable taxes.

The preferred option complies with the principle of **proportionality**. It contributes to the achievement of the internal market objective by ensuring TPD safeguards and facilitating trade in products complying with TPD. The additional burden for retailers involved in cross-border distance sale of tobacco products is considered justified taking into consideration the specific characteristics of tobacco products (responsible for almost 700,000 death in the EU each year) not comparable with any other product on the internal market. The preferred option will also contribute to a drop in consumption/prevalence. Given that option 1 will contribute to better compliance with TPD, a full prohibition of cross-border distance sale (option 2) would go beyond what is necessary to obtain the objective. There is no less strict measure available to attain the objective. The costs associated with the preferred option both for economic operators and Governments are considered limited (if any) compared to the benefits following from reduced consumption, reduced illicit trade in tobacco and facilitated enforcement.

Cross-border distance sales can only be addressed effectively at EU level as the sales, by definition take place between Member States. Therefore, an EU action in these areas is of **added value.**

5.6. TRACEABILITY AND SECURITY FEATURES

1.1.29. PO1: EU tracking and tracing system

An EU tracking and tracing system at packet level for tobacco products throughout the supply chain (excluding retail) is introduced. Tobacco manufacturers shall conclude contracts with independent third parties that provide data storage capacities for such system ensuring full transparency and accessibility by Member States at all times. Tobacco products other than FMC and RYO are granted a transitional period of five years. Delegated/implementing power to adopt technical specification to ensure compatibility between the systems used.

Economic impacts

Ensuring full traceability and a strong control of the supply chain by a tracking and tracing system will contribute to the functioning of the internal market by reducing the volume of illicit supply, which is undermining the safeguards of the TPD. The system would create a level playing field for all operators on the **internal market** and remove the current situation where only the four biggest tobacco companies are bound by obligations as regards tracking and tracing via the Agreements with the EU and the Member States (see section 2.2.5). Currently, there is no harmonisation of national legislations on tracking and tracing in the EU although, in practice, there is increasing convergence in terms of technical standards used by tobacco manufacturers.[381] Option 1 would thus ensure a harmonised approach in Member States.

Tracking and tracing systems are generally seen as an effective means to address the risk of diversion of genuine products into the illicit market and such systems have already been developed and used in recent years. Based on industry data an effective tracking and tracing system reduces illicit contraband by 30% in five years. The main part of these additional revenues will go to the legal supply chain (FMC/RYO manufacturers and distribution chain), but some smokers are also expected to stop smoking/not to start smoking.

Due to the existing Agreements between the four largest tobacco manufacturers and the EU and participating Member States (see section 2.2.5), the largest **tobacco manufacturers** are already implementing some of the requirements foreseen under option 1 and additional costs (e.g. associated with the outsourcing of the data storage are considered proportionate when compared with the existing contractual obligations (tracking and tracing at packet level). It should also be noted, that the Agreements will start expiring as of 2016 (unless they are extended). The proposed measure will be more burdensome for smaller operators who will possibly have to build up a tracking and tracing system from scratch. However, there are possibilities to benefit from existing experience[382] and in any case it will be easier if such a system is introduced at EU level rather than in 27 Member States individually. Operators involved in tobacco products other than FMC and RYO products (e.g. cigars and pipe tobacco) will benefit from longer transitional periods.

It is not easy to fully estimate the costs associated with the introduction of a tracking and tracing system. However, the following cost estimates, which were provided in the context of

[381] Divergence might still exist regarding the package level and the level of trade.

[382] For example, PMI declared its readiness to grant royalty free licenses to third parties that want to use PMI's tracking and tracing software. Presupposing that the PMI system is compatible with the international obligations this would reduce the costs for introducing such a system substantially.

the international negotiations for an Illicit Trade Protocol (based on information from PMI) [383] are a good indication:

For the currently used carton level tracking and tracing, the industry's indications are that the actual one-off costs include machines for printing the label for master cases (5,000–20,000 EUR per machine) and for cartons (10,000–35,000 EUR) as well as for carton coding system (10,000-35,000 EUR) and carton tracking system (30,000-50,000 EUR). To this should be added hardware (10,000-30,000 EUR), IT infrastructure for the retention of tracking and tracing data (10,000-150,000 EUR) and hosting and maintenance of data (50,000-150,000 EUR). All costs for the equipment etc. would be covered by the manufacturers (including equipment used in the distribution chain). The only additional costs at distributor level are handling costs, but it is believed that the system would be highly automated.

Taking into account the significant cross-border trade, only an EU system can be effectively enforced. On the positive side, it also needs to be noted that the expected decrease of illicit trade would have the effect of increasing the sales in the legal supply chain. The total illicit market at retail level (excluding taxes) is estimated to amount to 3 billion EUR, of which 30% are attributed to contraband products. Based on industry data an effective tracking and tracing system reduces illicit contraband by 30% in five years. Part of these additional revenues will go to the FMC/RYO manufacturers (other parts to the distribution chain, and some smokers are also expected to stop smoking/not to start smoking).

For **Governments**, option 1 would have positive impacts in that it strengthens the legal supply chain and ensures that consumers benefit from the safeguards of the TPD. A tracking and tracing system which gives the authorities access to the data storage of the independent third party, will help the authorities (including the Commission) to monitor systematically the movement of tobacco products from the place of their manufacture, through the distribution chain to the intended market of retail sale **("tracking").** It will also enable the authorities, at the time of an audit or seizure of a product, to recreate the route taken by the product from the place of its manufacture, through the distribution chain to the point at which the product was diverted into illegal trade channels **("tracing").** On the other hand, some administrative costs are expected from the monitoring of the system. The measure would thus facilitate market surveillance. An unintended but welcome side effect would be that the measure would increase Governments' tax revenues by decreasing tax evasion. For **consumers**, option 1 would mean a higher level of protection. It would also mean that the availability of cheap illicit FMC and RYO that do not comply with the TPD is reduced. Option 1 improves compliance with the **FCTC**.

Social impacts

The shift from illegal to legal trade would result in increased **employment** opportunities in the legal tobacco sector despite the predicted overall prevalence drop (which would essentially come from the illicit segment). There would also be increased employment opportunities in the setting up and operating tracking and tracing systems (including data storage). In terms of **equality**, the measure would contribute to removing illicit tobacco products' potential to target young and deprived people.[384]

Health impacts

[383] FCTC/COP/4/INF.DOC./1 of 15 September 2010.

[384] On the question of price elasticity of demand cf. International Agency for Research on Cancer (IARC). IARC Handbooks of Cancer Prevention: Tobacco Control. Volume 14. Effectiveness of Tax and Price Policies for Tobacco Control. Lyon, France: IARC; 2011.

The proposed measure would ensure that the intended increase in awareness is not circumvented by illegal **products which do not comply with the relevant requirements** (such as labelling and ingredients regulation). Part of the demand previously met by illicit products would shift to the legal supply chain, whereas another part is expected not to be substituted, i.e. would result in reduced consumption, which would in turn lead to reduced health risks and increased well-being in the long term. For the indirect impacts, see section 5.7 and Annex 5 which apply, however, primarily to the legal supply chain (as the illegal part of the supply chain has no legitimate expectations).

1.1.30. PO2: Tracking and tracing system, complemented by security features

Option 1 plus: security features against counterfeiting and against illicit/cheap whites (glossary) on all tobacco products (e.g. holograms). Tobacco products other than FMC and RYO are granted a transitional period for five years. Delegated/implementing power to adopt technical specifications for the security features.

The subsequent assessment only covers the additional elements beyond option 1.

Economic impacts

Adding special security features to limit sales of counterfeits and illicit whites (glossary) at EU level would help limiting sales of these products and further facilitate the functioning of the **internal market** of legal tobacco products. It avoids disparities and differences as regards security features and prevents further heterogeneous development in coming years following national measures to address illicit trade. It would also improve compliance of tobacco products with the safeguards of the TPD. Adding a security feature would imply additional costs for the **industry** to comply with the requirements. These costs depend largely on the technology chosen and might reach 0.005 EUR per package, for example for a hologram.[385] According to Euromonitor, 608 billion sticks of FMC were sold in the EU in 2010. This corresponds to approximately 30.4 billion packages of FMC (assuming a package size of 20 sticks per package). The costs for applying holograms on all cigarette packages would thus amount to **approximately 150 mEUR**[386]. It is assumed that these costs would be passed on to subsequent distribution level and ultimately to the consumer.

On the other hand, the industry would benefit from reduced illicit trade. In addition to the reduction of illicit trade (contraband) estimated under option 1, it is assumed that counterfeit and illicit white products would be reduced by 10% under option 2. Again, the larger part of these additional revenues is expected to go to the legal supply chain (FMC/RYO manufacturers, distribution chain), but some smokers are also expected to stop smoking/not to start smoking. In addition, the economic operators would benefit from a harmonised approach as they do not have to adapt to different regimes in different Member States. The calculations of the indirect impacts linked to a change of consumption patterns are set out in Section 5.7 and Annex 5.

Governments would benefit from a common system for security features. Whilst only seen as an unintended side effect for the purpose of the TPD revision, option 2 would also contribute to the collection of taxes. As the costs for the security features will be borne by industry, no

[385] This is based on costs for a self-adhesive frangible (tamper evident) polyester hologram closure seal to be machine-applied at the packing or filling station, which is considered one of the more sophisticated security measures. (indication by the International Hologram Association)

[386] The calculation presupposes that the actual application of the security features on the package is included in the price.

additional costs beyond option 1 are foreseen. Increased tax income and facilitated market surveillance as well as effective implementation of the **FCTC** are further benefits for Governments. Moreover the security feature would assist **consumers** in determining whether the product is authentic and ensure a higher level of protection against products not complying with the TPD.

Social impacts

The positive impacts on **employment** outlined in option 1 would apply and be reinforced under this option. In addition, some employment would also be created in the production and application of security features. The option would also further strengthen **equality** due to the reduction of counterfeit and illicit white products (or at least by slowing down their growth). Availability of cheap (illegal) products would be reduced, which are through their lower price particularly appealing to young or deprived persons.

Health impacts

Security features will increase the awareness of the problems around illicit tobacco products and thus indirectly lead to increased **awareness** of the risks associated with tobacco consumption in general. Option 2 would further reinforce the positive health impacts outlined in option 1 and is expected to contribute to a significant reduction in **consumption.**

1.1.31. The views of stakeholders

Policy area 5 was introduced in reaction to concerns expressed by the industry (in particular FMC and RYO manufacturers, upstream suppliers and downstream distributors) in the context of the public and targeted stakeholder consultations. They argued that illicit trade already accounts for a large part of the market and is expected to increase. They pointed in particular to the risks associated with some of the policy options on plain packaging and display ban at PoS (which was subsequently disregarded in this impact assessment, see section 4.1) (*nota bene*: the evidence submitted by the economic stakeholders to support this argument is not considered compelling/convincing). No concrete proposals on how to effectively address illicit trade were made, but tracking and tracing is believed to provide the appropriate response and is already standard practice for the big four tobacco manufacturers. Providers of security systems (e.g. holograms) said that such a measure would reduce counterfeit to a certain degree (up to 30%) but would not eliminate it all together (*nota bene*: for the purpose of this impact assessment reduction of 10% was assumed). Member States are generally supportive, in particular in view of their tax revenues. Health NGOs contested that other planned TPD measures, e.g. on packaging would increase illicit trade, but nevertheless expressed support for additional measures to fight illicit trade.

5.6.1.1. Comparing the options and preferred option

In terms of **effectiveness**, an EU tracking and tracing system complemented by security features (policy option 2) would contribute the most to facilitating a level playing field (policy objective A2), although a tracking and tracing system on its own (policy option 1) would also go into this direction. Both options would contribute to better market surveillance (policy objective B2). A tracking and tracing system complemented by security features (policy option 2) would assist consumers in verifying the authenticity and ensure a minimum level of health protection (policy considerations C3 and C6). Both options would contribute to reducing accessibility to young people (policy consideration C5).

An EU tracking and tracing system without security features (policy option 1) would provide a less **costly** solution to set up, in particular as a large part of the market already has a tracking and tracing system in place, at least at carton level. However, it would not specifically address

the issue of counterfeiting which is important in terms of ensuring a high level of health protection in line with the TPD. The costs associated with these two measures are expected to be outweighed by the significant benefits in terms of reduced illicit trade, resulting in increased sales for economic stakeholders (for more details, see Annex 5).

Preferred policy option 2: Tracking and tracing system, complemented by security features

The preferred option maximises the effect of the TPD and ensures that consumers throughout the EU benefit from a minimum level of protection when purchasing tobacco products (e.g. health warnings and ingredients regulation). The option creates a level playing field between different operators (currently only the biggest four tobacco manufacturers are bound to develop and use tracking and tracing systems) and would be beneficial for them (unless they are themselves involved in illicit trade). The option ensures compliance with Article 15 FCTC and ensures a common EU approach. It also facilitates market surveillance and empowers consumers in verifying the authenticity of tobacco products. The option addresses concerns of some stakeholders claiming that revision of the TPD would result in increased illicit trade (however without substantiation). The option also foresees a longer transitional period for manufacturers of tobacco products other than FMC and RYO (e.g. STP, cigars and pipe tobacco). This will allow small business to adapt and learn from bigger companies.

There is **no less restrictive measure** available, because only if the market is effectively protected against illegal supply can the measures foreseen in the TPD achieve their objective. The two elements included in the preferred option are mutually reinforcing and address two separate aspects of illicit trade. A tracking and tracing system addresses contraband products non-complying with the TPD, while the security features deal with counterfeit and illicit whites.

The costs associated with these two measures are expected to be outweighed by the benefits in terms of reduced illicit trade which partially benefit the legal supply chain and leads to reduced consumption.

By definition, only an initiative at EU level is capable of ensuring a harmonised approach. Unilateral actions by Member States can contribute to the protection of health, but result in many legal and factual divergences and reduced effectiveness taking into account the significant cross-border nature of the market. The preferred option would provide an **EU added value** and an EU wide measure also facilitates enforcement in Member States. The preferred option is a necessary addition to all other measures in this proposed TPD, as only strong measures can provide for a protection of the legal market with all the necessary safeguards for consumers, manufacturers and retailers.

In designing the legislation, due attention will be paid to the freedom to conduct business and to the protection of personal data in line with existing legal requirements.

5.7. INDIRECT EFFECTS / HEALTH IMPACTS

As explained the various policy options are expected to impact the economic stakeholders and Governments not only in a direct manner (e.g. costs/benefits associated with the implementation of the measure), but also in an indirect manner. Over time the proposed measures are expected to impact on peoples' awareness on the risks associated with tobacco products, which in turn will lead to a change in behaviour. Less young people will start smoking and some adults will successfully quit smoking. This is expected to lead to a reduction of smoking consumption/prevalence.

When comparing with international experiences, it is assumed for the purpose of this impact assessment that the combination of the preferred policy options will lead to a **reduction of consumption of around 2 %** (1.7-2.6% see figure 14 below) within a five year period after transposition beyond the baseline for FMCs and RYO. This corresponds to a reduction of 2.4 million smokers in the EU. It has to be stressed that this figure is a best effort estimation.

The assumption of 2% is mainly based on experiences and estimations from other jurisdictions. All policy areas are expected to make a contribution to the overall consumption drop, albeit not to the same degree. The main contributions are expected from the policy areas on packaging and ingredients which are mutually reinforcing.

Several independent studies have assessed and attempted to quantify the impacts of **packaging and labelling measures**. Practically all reached the conclusion that such measures impact on the awareness of consumers, which over time changes also smoking behaviour but there was some divergence as to the exact level. The prevalence of adult smoking in Canada has declined approximately 6% since the implementation of large pictorial warnings in 2001, which is at least partially attributable to the picture warnings.[387] Another study prepared for Health Canada assessing a set of policy measures on labelling similar to the ones proposed in option 1 under packaging and labelling estimated a rather small reduction of 0.3 percent to 0.8 percent in the number of smokers within ten years.[388] Assuming uniform quit rates across smokers with different consumption levels this corresponds to a comparable drop in consumption of about 0.3-0.8% resulting from those quitting.[389] It should be emphasized that at the time of the Canadian assessment picture-based warnings were already in use which could limit the additional impact to be expected. A cost-benefit analysis prepared for the Australian Government estimated that introducing pictorial warnings covering 50% of the front and back of the packets would result in a 1.3% decline in smoking prevalence rate per annum (12.3% decrease in 10 years) and a 3% decrease in tobacco consumption per capita per annum (26.3% decrease in 10 years).[390] The UK Department of Health's impact assessment (2007) estimated that the introduction of pictorial warnings would result in a 0.5% decrease in smoking prevalence in the long term compared to 0.05 percent decrease in consumption if the status quo (text warnings only) were maintained.[391] Finally, a more recent US impact assessment estimated the reduction in smoking prevalence as a result of introducing nine pictorial warnings, occupying 50% of both display areas, including a mandatory reference to a toll-free quitline.[392] The reduction in the US smoking population in 2013 was estimated at 213,000 persons (corresponding to a prevalence reduction of 0.45%), with small subsequent effects.

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[387] Health Canada. Canadian Tobacco Use Monitoring Survey (CTUMS). Ottowa: Health Canada; 2008. www.hc-sc.gc.ca/hc-ps/tobac-tabac/research-recherche/stat/ctums-esutc_2008-eng.php (accessed 06 Nov 2012) as referenced in Hammond D. Health warning messages on tobacco products: a review. Tob Control 2011; 20:327-3.

[388] Industrial Economics Incorporated (IEc). Economic evaluation of Health Canada's proposal to amend the tobacco product information regulations: Final report. Cambridge, MA: IEc; 2009. (Report for Health Canada).

[389] As a result of the measures proposed, an additional reduction in consumption levels can also be expected for those who keep smoking

[390] Applied Economics. Cost-benefit analysis of proposed new health warnings on tobacco products. Canberra: Applied Economics; 2003. (Report prepared for the Commonwealth Department of Health and Ageing, Australia)

[391] UK Department of Health (UK DoH). The Introduction of Picture Warnings on Tobacco Packs – Final Regulatory Impact Assessment. London: UK DoH; 2007.

[392] US Dept. of Health and Human Services. Required Warnings for Cigarette Packages and Advertisements. 2011 Federal Register Vol. 76, 22 June 2011/Rules and Regulations, pp.36628-36777.

In its opinion from 2010, SCENIHR concluded that the use of fruit and candy flavours seems to favour smoking initiation in young people and that some additives decrease the harshness and increase the smoothness of the smoke.[393] The US FDA Tobacco Products Scientific Advisory Committee confirmed, on the basis of the extensive review of all available information, that the evidence was sufficient to conclude that it is more likely than not that the availability of menthol FMC increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such FMC were not available.[394]

The contribution to the reduced smoking prevalence from policy area "**STP and extension of the product scope**" is primarily expected to result from the possibility that e-cigarettes can develop a potential as a smoking cessation aid under the preferred option.

Also the measures in the policy areas dealing with **cross-border distance sales**[395] **and traceability & security features** are expected to contribute to a drop in consumption, in particular in the illicit segment of the market. Part of this demand will return to the legal supply chain, which is however more expensive and therefore it is expected to encourage some consumers not to start smoking/stop smoking or smoke less, in particular in parts of society with lower revenues such as young people. Also, consumers are better informed by the health risks of tobacco products fully compatible with the TPD.

Figure 14 provides a tentative break-down of the contributions of individual policy areas. More information is provided in Annex 5. While 2% is estimated reasonable, it needs to be underlined that even a lower drop in consumption remains beneficial from a macro-economic and Governmental/societal perspective (see section 6.2.4 and Annex 5). It needs also to be stressed that conclusive empirical data is lacking for some of the measures, including NCP (where no electronic cigarettes have been authorised, at this stage, under the medicinal products' legislation).

Figure 14: Tentative contributions of individual policy areas to the projected decrease of cigarette/RYO consumption

Policy area		Foreseen contribution to the decrease in %
Scope	(STP)	0.2-0.3
	NCP	
	(Herbal)	
Packaging & Labelling		1-1.5
Ingredients		0.5-0.8

[393] SCENIHR 2010.

[394] Tobacco Products Scientific Advisory Committee (TPSAC). Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Rockville, MD: US Food and Drug Administration; 2011.

[395] In an experimental Californian study from 2004 96.7% of participating minors were successful in finding and ordering tobacco on the internet. Jensen JA, Hickman NJ 3rd, Landrine H, Klonoff EA. Availability of tobacco to youth via the Internet. JAMA 2004; 291(15):1837.

TOTAL		1.7-2.6%
Cross-border distance sales + Illicit trade		Additional decrease of consumption, however not in the legal supply chain. (Decreases in illicit consumption could mitigate the decrease in the legal chain).

In addition to the predicted drop in smoking prevalence, the preferred options are also likely to result in reduced uptake of **STP and herbal products for smoking**. In particularly, it is expected that STP use will remain limited to specific population groups already using these products and that recruitment of new users will become more difficult. However, it is difficult to quantify this effect, also in the light of increased use of smoke-free environments.

1.1.32. Economic Stakeholders

For the **tobacco industry** (the manufacturers of FMC and RYO) a reduction of consumption in the range of 2% within five years would mean that their revenues would decrease by 376 mEUR per annum. This figure is a "**worst case scenario**" for the industry, as it does not take into account the effects of the policy options developed in policy areas 4 and 5, which have the effect that certain sales in the illicit supply channel return to the legal supply chain. In terms of employment, the reduction of consumption is also expected to reduce the work force of the tobacco industry. Based on the input output model explained in Annex 5 the reduction is expected to amount to 1500 employees. On the other hand it should be noted that money not spent on tobacco products will be spent on other goods and services. In this respect the "input-output model" used for the purpose of the impact assessment indicates **net gains in employment of around 2,200.**[396] Industries that are most likely to benefit are food/beverage, textiles manufacture and the service sector.

Annex 5 also presents what a reduction of tobacco consumption would mean for the **upstream suppliers** (e.g. growers, ingredients suppliers, paper industry) and **downstream distributors** (wholesale, retail). Overall the impacts associated with the reduction in consumption do not seem to be of a significant nature, as the economic stakeholders typically sell other products (e.g. package industry makes only around 10% of its turnover with the tobacco industry) or generate a significant part of their turnover with export sales outside the EU which would not be affected. Even the impact on specialised retailers does not seem to be significant as – according to the EU association of the retailers (CEDT) – these specialised shops nowadays generate about half of their turnover with non-tobacco products. The impact on the revenues for tobacco growers would mean an annual reduction in income of 158 EUR per farmer, which would however, not affect all farmers alike. Rather it is expected in line with previous trends (discontinuation of direct subsidies) that certain farmers will discontinue their activities irrespective of the TPD revision.

1.1.33. Governments/society

The main socioeconomic impact for Governments/society – associated with a reduction of tobacco consumption - is the improvement of public health. Non-smokers live longer and benefit from more **healthy life years**. It has been estimated that smokers who die as a result of their tobacco consumption pass away 14 years earlier than people who never-smoked (see Annex 5, 5.2.3.1.1). A reduction of consumption of 2% corresponds to 2,4 million smokers

[396] Yurekli A, de Beyer J (eds). Understand and Evaluate the Impact of Tobacco Control Policies on Employment. Washington, DC: World Bank; 1999.

stopping the behaviour and 16.8 million life-years (not quality adjusted) gained.[397] The gain of (healthy) lifeyears is a value in its own right and of greatest importance for the persons concerned as well as their families. On the basis of the impact guidelines it is possible to monetise the gain in public health.[398] In this light, a reduction of the tobacco consumption by 2 % would correspond to a benefit for society of 10.3 bEUR annually.

In addition, a reduction of tobacco consumption will reduce **health care expenditure** by 506 mEUR annually. Also society would benefit from a reduction of productivity losses (less absenteeism and premature retirements) in the region of 165 mEUR annually (see Annex 5). As explained these are conservative estimates as other studies report about significantly larger cost savings for health care and gains in productivity.

Another impact for Governments would be that they are confronted with a risk of reduced tax revenues by 1.6 bEUR annually because of reduced consumption. It is important to note from a macro-economic perspective the reduction of taxes is not a cost, but only a question of allocations within society (State/companies). It also needs to be taken into account that the reduction of taxes is an unlikely "worst case scenario". The figures do not yet take into consideration the positive effects of the policy options developed in policy areas 4 and 5 which would increase Governments' tax revenues. Additionally, a reduction of tobacco consumption does not necessarily lead to lower tax incomes as tax rates can be increased (like in the past). As a matter of fact despite decrease of tobacco consumption since 2000 tax revenues for Member States increased very significantly in the same period. In addition, money not spent on tobacco would be spent on other sectors also benefitting the Governments in terms of taxes.

In summary it can thus be concluded that the impact of reduced tobacco consumption would lead to **overall benefits of 9.4 bEUR per annum**. The calculation is based on present values and thus in principle expressed in current prices.

Social discounting[399] allows comparison of benefits and costs that occur at different times based on the rate at which society is willing to make such trade-offs. This is also relevant in the case of tobacco control as some of the expected benefits will only develop over time whilst certain impacts (e.g. on tax revenues) would materialise earlier. Different scenarios for social discounting have been developed in Annex 5 (5.2.3.4). Under the most likely scenario (i.e. when decrease in tax revenues and health care/absenteeism savings materialise in the period of 5 years, while on average the benefits from reduced premature mortality accrue only in 25 years), the annual net benefit of a reduction in tobacco consumption by 2 % would be 4 bEUR.

Figure 15 provides a breakdown of the overall net costs and benefits (including discounted values).

Figure 15: Overall net costs and benefits (mEUR)

	Different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%

[397] Population over 15 is covered by EB - according to Eurostat this is 431 million adult citizens. 28% percent of them, thus 120.8 million are smokers. 2% of those correspond to 2.426 million smokers. Assuming than 7 years are gained per smoker (14 years /2 prematurely dying), this result in 16.8 million lifeyears (not quality adjusted).
[398] European Commission. Impact Assessment guidelines. Brussels: European Commission; 2009. http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf (accessed 28 Nov 2012).
[399] Social discounting renders benefits and costs that occur in different time periods comparable by expressing their values in present terms based on the rate at which society is willing to make such trade-offs.

Decrease in excise tax revenues[400]	794	1588	2382	3176	3970
Decrease in health care expenditures	253	506	759	1012	1265
Decrease of productivity loss	83	165	248	331	413
- due to early retirement / deaths	61	122	183	244	305
- due to absenteeism	22	43	65	87	108
Decrease in premature mortality costs	5,167	10,334	15,501	20,669	25,836
Overall net benefit	**4,709**	**9,417**	**14,126**	**18,836**	**23,544**
Discounted values	2,016	4,032	6,048	8,064	10,080

The preferred options would have a significant positive impact on public **health**. For example, the current targeting of young people with specifically developed products like candy-flavoured FMC and attractive packages would be removed, young people's access to tobacco would be further restricted and improved health warnings would improve all citizens' possibilities to make informed decisions. In addition, due to the foreseen reduction in illicit trade smokers would benefit more from the protective rules set up by TPD (e.g. health warnings and ingredients control).

6. OVERALL CONCLUSION OF THE IMPACT ASSESSMENT

6.1. COMPARING THE OPTIONS AND THE PREFERRED OPTIONS

Following the conclusions in the previous sections, the table below gives an overview of the policy options as well as justifications for choosing the preferred options (which are marked in grey).

PA / Options	1	2	3	4	Justification
1a. STP	Lift the ban on oral tobacco and subject all STP to stricter labelling and ingredients regulation	**Maintain the ban on oral tobacco, subject all novel tobacco products to notification obligation and all STP to stricter labelling and ingredients regulation**	Maintain the ban on oral tobacco, restrict the sale of other STP to areas of traditional use only and subject all STP to stricter labelling and ingredients regulation.	Ban all STP with the exception of oral tobacco in Sweden. Subject oral tobacco in Sweden to stricter labelling and ingredients regulation.	-achievement of policy objectives/considerations: B1, C2, C4 and partly A1, A2 and C1. -harmonised labelling and ingredients regulation for all STP. -facilitated level playing field. -proportionate to prevent the introduction / expansion of new addictive, harmful products in the internal market -health concerns with all STP -no evidence that STP leads to smoking cessation, risk of entry gate and dual use -risk for market development (ingredients and smoke-free environments) -Trade-off/ impact on SME justified due to health risks associated with product development, marketing and expansion to new user groups. Option 3 and 4 would have more positive impact on health, but option 2 was considered more proportionate after a cost/benefit balance.

[400] Disregarding measures taken against illicit trade and possibility to increase tax levels.

1b. NCP	Subject NCP to labelling and ingredients requirements under TPD	Establish a new authorisation scheme for NCP	**Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements**	Subject all NCP to the medicinal products' legislation	-achievement of policy objectives/considerations: A1, A2, B2, C1, C2, C4 -clear and well established legal framework for risk/benefit analysis facilitating the free circulation of duly authorised products, in conformity with their nature -possibility of mutual recognition within the internal market. -same treatment of NCP and NRT. -harmonised approach, consolidating trend in MS -minimum safety standard -potential in smoking cessation -Trade-off: additional burden for application justified by the setting up of a harmonised safety net with potential to reduce smoking.

PA / Options	**1**	**2**	**Justification**
1c. Herbal products for smoking	**Subject all herbal products for smoking to labelling requirements under TPD**	Phase out marketing of herbal products for smoking	-achievement of policy objectives/considerations: A2, A3, C4 and partly B1, C1 -facilitates the free circulation of products -remove current misperception on health Trade-off: Removes misperceptions while minimising compliance costs.

PA / Options	**1**	**2**	**4**	**Justification**
2. Packaging and labelling	Mandatory enlarged picture warnings	**Option 1 plus harmonise certain aspects of packets and FMC appearance and prohibit promotional and misleading elements**	Option 2 plus full plain packaging	-achievement of policy objectives/considerations A3, B1, C2, C4 -removes disparities on internal market and facilitates free circulation -improves awareness and removes misleading elements -in line with FCTC commitments -proportionate: focus on smoking initiation, products attractive for young people -takes into account economic stakeholders' concerns (e.g. no plain packaging/interference with trademarks) -allows awaiting international and scientific developments -allows Member States to adopt plain packaging to comply with FCTC guidelines as far as it is compatible with the Treaty -Trade-off: Option 3 more effective from health point of view, but appropriate to wait for real life experience.
3. Ingredients	Common reporting format on a voluntary basis. Prohibit toxic, addictiveness and attractive additives in tobacco products.	**Mandatory reporting in harmonised format. Prohibit products with characterising flavours and products with increased toxicity**	Mandatory reporting in harmonised format. Prohibit all additives not essential for manufacturing.	-achievement of policy objectives/considerations: A3, B1, B2, C1, C2 -removes disparities on the internal market and facilitates free circulation -reduces administrative burden (reporting)

		and addictiveness.		-in line with FCTC obligations/commitments -proportionate: focus on smoking initiation, products attractive for young -takes into account stakeholders concerns, including growers (no discrimination of Burley/Oriental) -Trade-off: Focus on smoking initiation while minimising costs for economic stakeholders. Option 3 would have been more effective from a health point of view.
PA / Options	**1**		**2**	**Justification**
4. Cross-border distance sale	**Notification and age verification system**		Prohibit cross-border distance sale of tobacco products	-achievement of policy objectives/considerations: A2, B2, C5, C6 -ensures that safeguards of the TPD are respected -facilitates legal activities (retail) -limited economic impact on legal activity -Trade-off: Option 2 would have been more effective from a health point of view, but more costly for industry.
5. Traceability and security features	EU tracking and tracing system		**Tracking and tracing system, complemented by security features**	-achievement of policy objectives/considerations: A2, B2, C3, C5, C6 -ensures that safeguards of the TPD are respected -level playing field (small-big industry) -costs compensated by savings following shift from illegal to legal trade -addresses economic stakeholders' concerns regarding illicit trade Trade-off: Costs for industry are outweighed by benefits from reduced illicit trade.

In terms of **effectiveness**, the combined preferred options contribute to the overall objective of the revision of the TPD to guarantee a proper functioning of the internal market while ensuring a high level of public health. As illustrated below, the preferred options are also well in line with the objectives and considerations identified in section 3.

As far as the main objective **(internal market)** is concerned, the options:

- facilitate the free movement of goods in the internal market by removing existing or expected discrepancies between national legislations and/or,
- adapt the level of harmonisation in the current TPD to a new level warranted by scientific development or international obligations/commitments and /or,
- ensure that the safeguards of the TPD are not undermined by illicit products or by cross-border sales not respecting these safeguards.

As far as **health** considerations are concerned, the envisaged revision focuses on discouraging young people from taking up tobacco consumption and allowing adult consumers to take informed decisions. The revision also allows smokers to benefit from the protective measures

set by the TPD. In instances where new products aim at exploiting smoke-free policies, this is also tackled.

The combined preferred options would allow/facilitate Member States/EU to fulfil their commitments/obligations in the context of **FCTC**. In many policy areas (herbal products for smoking, packaging & labelling, ingredients, and cross-border distance sales) **a stricter option** than the one identified as preferred option would have been more beneficial for health. However, the overall assessment of all applicable assessment criteria, including impact on economic stakeholders, has led to the conclusion that a less strict measure was more appropriate (see table above).

There are also important **synergies between individual options** increasing the overall effectiveness of the "preferred options package". For example, prohibiting tobacco products with characterising flavours is reinforced by the removal of misleading and promotional elements on the labelling and the obligation to notify cross-border distance sale will reinforce the reduction of illicit trade expected from the measure on traceability and security features.

The combined preferred options are **cost-efficient** in the sense that they are expected to result in overall socio economic benefits for society. For economic stakeholders the preferred options are foreseen to lead to reduced direct (compliance) costs which, however, can be outweighed by lost revenues due to a decrease in consumption. The overall impacts of the preferred options are further described in the next section, 6.2.

The identified options constitute a **coherent** approach consistent with international commitments and fundamental rights and values as well as the overall aim of the EU to promote well-being of its people (Article 3 TEU). The combined options contribute to the Europe 2020 strategy in the sense that keeping people healthy longer will have positive impact on productivity and competitiveness.

A proper **stakeholder** consultation has been carried out throughout the impact assessment process (section 1.3) and the comments from various stakeholders have been considered carefully. The next section (section 6.2) describes further the overall impact on key stakeholders.

6.2. OVERALL IMPACTS OF THE PREFERRED OPTIONS

1.1.34. Internal market

As explained, it is expected that the combined preferred options would improve the functioning of the **internal market** by removing current disparities in national legislation, ensure homogenous development and facilitate the creation of a level playing field among economic actors. In contrast to the baseline scenario, the preferred options would also contribute to a consistent approach in the implementation of international commitments (FCTC).

1.1.35. Economic stakeholders

6.2.1.1. FMC and RYO manufacturers

The impacts on FMC and RYO manufacturers consists of the direct impact from complying with the preferred options (direct effects) and indirect impacts following an expected decrease in consumption.

The **direct impact on FMC and RYO manufacturers is expected, to be positive compared to the baseline scenario**. The benefits stem in particular from reduced one-off costs associated with familiarisation (all product related areas) and redesign/reformulation (labelling and ingredients) as well as acquisition of new equipment (tracking and tracing). With respect to the variable costs it is assumed that no noteworthy additional costs are expected. To the contrary in certain areas such as traceability and security features, cost savings are expected. In any event additional costs are likely to be passed on to consumers taking into account the significant market power of the tobacco manufacturers.[401] Higher revenues are also expected for FMC/RYO manufacturers as a result of the measures against illicit trade. While a precise quantification is not possible, the table below describes the situation in general terms and refers to figures to the extent possible.

Cost category (compliance cost)	Preferred option	Baseline scenario
One-off costs	-Economic stakeholders only have to get familiar with one legal system, implemented within a limited time frame. -Economic stakeholders have to undertake one redesign/reformulation only adapted to the markets of all Member States. -Some economy of scale is/can be achieved when acquiring of new equipment due to harmonisation. -Disposal of old stocks. This cost can normally be disregarded taking into account transposition and transitional periods. **Packaging and labelling:** FMC: 14,500-50,000 EUR per SKU RYO: 2,500-9,000 EUR per SKU **Ingredients**: Product redesign: 1mEUR per brand **Tracking and tracing:** Indicative costs for carton level tracking and tracing: Printing machine master case: 5,000-20,000 EUR per machine Printing machine carton: 10,000-35,000 EUR per machine Carton coding system: 10,000-35,000 EUR Carton tracking system: 30,000-50,000 EUR Hardware: 10,000-30,000 EUR IT infrastructure: 10,000-150,000 EUR Hosting and maintenance: 50,000-150,000 EUR	-Economic stakeholders need to monitor 27 different legal systems and get familiar with all unilateral changes adopted by Member States. This can also include seeking legal advice. -Economic stakeholders need to adapt to subsequent unilateral changes adopted by Member States. This also includes testing and legal/marketing/scientific advice. Stakeholders also have to adapt production lines to comply with different national legislations. -Economic stakeholders might have to buy new equipment to comply with national measures. -Disposal of old stocks. This cost can normally be disregarded provided sufficient transitional periods are granted. The cost estimates provided for the preferred option would be higher under the baseline scenario due to multiple and consecutive adaptations to national systems under the baseline scenario.

[401] In the latest Eurobarometer 2012 consumers stated that they are ready to accept price increases to fight against illicit trade.

Variable/on-going costs	Proportionate to the volume of products affected, which means that costs can be slightly higher or lower than in the baseline scenario. However, it is likely that these on-going costs would be passed on to subsequent level of trade. **Packaging and labelling[402]:** 59-68 mEU per year for combined warnings **Ingredients**: Depends on ingredients used after reformulation. **Security Feature:** e.g.Hologram: 150 mEUR per year	Economic stakeholders might have to change the types and quantities of material to be used in the manufacturing process. This could be either a cost (e.g. more expensive ink) or a saving (e.g. less ingredients to be used) and is proportionate to the volume of sale.

On the other hand, the **indirect impacts following from an expected decrease in consumption will over time lead to a loss of revenue** for the FMC and RYO manufacturers of 376 mEUR ("worst case scenario" as the benefits from reduced illicit trade are not considered in this figure). This negative impact on FMC and RYO manufacturer might outweigh the benefits from the cost savings referred to above. However, money not spent on tobacco is expected to be spent on other sectors which would then benefit.

6.2.1.2. Upstream suppliers

Growers would only be affected indirectly by the reduction of smoking and the annual reduction in the farmers' income has been estimated to amount to 158 EUR per farmer. However, as explained under section 5.7.1, it is expected in line with previous trends (discontinuation of direct subsidies) that certain farmers will discontinue their activities irrespective of the TPD revision. The preferred options would not discriminate between growers of different tobacco types (Oriental, Burley, Virginia).

Similarly to the FMC and RYO manufacturers, the **packaging and labelling** industry is expected to benefit from the "one go" solution at EU level compared to multiple adaptations under the baseline scenario. The industry reported to have carried out the main investments already. On the other hand, a negative impact on revenues of around 18.2 mEUR is estimated following the reduced tobacco consumption. This represents 0.2% of the total sector turnover taking into account that the packaging and labelling industry only generates 10% of its turnover with the tobacco industry. A similar reasoning applies to **producers of additives and flavours**.

6.2.1.3. Downstream sectors and other industries

Wholesalers are primarily affected indirectly by the reduction in tobacco consumption resulting in reduced revenues of around 465 mEUR[403] and by compliance with the tracking and tracing system (no cost estimate available). This needs to be counterbalanced, however, with the increased revenues stemming from reduced illicit trade benefitting wholesalers. The introduction of EU **tracking and tracing systems** will call for some technical adjustments in warehouses, but the costs for the equipment should normally be limited as they should be borne by the tobacco industry, which is under the obligation to introduce the tracking and tracing system. The introduction of a common EU wide system is beneficial for the wholesalers, as one system takes less space and is easier to handle for its staff.

[402] As pointed out in sections 5.3.1, the cost increases reported by industry seem exaggerated.
[403] Obviously, the wholesalers would have reduced purchasing costs in the region of 376 mEUR.

Retailers are in a similar situation as wholesalers regarding the indirect impacts. The measures on tracking and tracing and security features are not expected to lead to additional costs for retailers as retailers are not part of the tracking and tracing system. As even specialised tobacco retailers generate only up to 50% of their revenues from tobacco products (dependence of other retailers on tobacco products, e.g. supermarkets, is even lower), the impact is not expected to be disproportionate.

A variety of **other industries** are expected to benefit from certain of the preferred policy options, e.g. companies developing tracking and tracing systems or security features.

6.2.1.4. Small and medium sized enterprises (SMEs)

The particular situation of micro-enterprises and SMEs has been taken into account when identifying the preferred option. The preferred policy options are primarily targeting FMC, RYO and STP. Pipe tobacco and cigars which are often manufactured by SMEs are not affected, in the first stage, in most policy areas. As referred to above, the impact on growers is limited. The impact on retailers is also expected to be limited as referred to above, in particular since the policy area/option of restricting display of tobacco at point of sale was discarded (see section 4.1). Products other than FMC and RYO which will be included in the tracking, tracing and security regime will be granted an additional transitional period which will benefit primarily SMEs.

1.1.36. Employment

In terms of **employment** it is estimated that jobs lost in tobacco will be off-set by jobs gained in other sectors (input/output model), as money not spent on tobacco is spent on other goods/services. This will be a gradual process as tobacco consumption is expected to decrease over time (2% in five years). The input/output model suggests that a 2% reduction of tobacco consumption would lead to a net gain in employment of 2,235 employees in the EU taking into account that tobacco is not a labour intensive industry whilst a number of the sectors benefitting from the redistribution are (e.g. hospitality sector). Possible regional employment impacts, as well as the specific situations of SMEs and micro-enterprises, have been carefully considered when formulating the preferred options. Obviously it cannot be excluded that some tobacco manufacturers will use the TPD revision as a welcome excuse to further automate production/concentration and would therefore lead to factory closure. On the other hand, keeping people healthy and active for longer has a positive impact on the productivity and competitiveness in general and is an integral part of Europe 2020 strategy. In the light of an ageing population in the EU it also appears important to assist young people staying healthy.

1.1.37. Governments/Society

The main benefit for Governments is the improvement of health which is a value in its own right. The preferred options are expected to result in a 2% drop in consumption within a five year period, corresponding to 2.4 million smokers. The expected socio-economic benefits (reduction of health care costs, productivity losses and monetised life years saved) represents an annual amount to the EU of 9.4 bEUR (see section 5.7) even if one deducts reduced tax revenues. A somewhat lower figure would be achieved if discounting is applied.

The preferred options are also associated with a number of **administrative costs** for national authorities. With respect to the measures envisaged in the scope section (STP, NCP and herbal products for smoking), a limited additional burden is expected when assessing NCP under the medicinal products' framework, however in a well-established legal framework and against fees. For labelling, no major impact is expected for Governments, possibly with one exception, namely that additional resources might be needed for cessation services. Regarding

ingredients reporting, costs savings associated with the improved reporting system and additional revenues in terms of fees from the industry are expected. Regarding ingredients regulation some investment might be needed to develop further – in conjunction with the Commission – the concept of attractiveness. Regarding cross-border distance sales the notification system would lead to very limited additional costs, but will also facilitate law enforcement. Also regarding traceability and security features, the main direct impact is on law enforcement, but overall it is assumed that law enforcement is facilitated/simplified by the proposed measures, i.e. the costs for Governments should be reduced.

7. MONITORING AND EVALUATION

The successful implementation of the revised TPD will depend on several factors:

Transposition of the Directive

Member States need to transpose the revised TPD correctly and in time. The European Commission should assist Member States in this exercise through meetings where Member States report about transposition progress and can discuss problems and seek clarifications. Member States should also be encouraged to communicate their draft transposition measures to the Commission.

An implementation plan will be developed to ensure effective implementation of the Directive.

Indicators

A key indicator for achievement of the objectives outlined in this impact assessment is the implementation by Member States, infringement cases launched and the number of complaints.

In addition, the following indicators will be monitored on a regular basis
- the smoking consumption and prevalence in the EU, including smoking uptake in young people
- the awareness of the harmful effects of tobacco
- the number of novel tobacco, nicotine and niche products as reported by Member States
- the frequency of use of quit lines/cessation services
- the number of electronic cigarettes authorised as medicinal products
- the consumption of herbal products for smoking
- the number of seizures of illegal tobacco products reported by Member States
- the level of additives used in marketed products and their variations between Member States
- the number of cross-border distance sale notifications.

Consultation and reporting

A network of Member States will provide a regular platform to discuss issues related to the implementation of the Directive.

The Commission should report to the European Parliament and the Council about the implementation of the revised TPD five years after transposition. The report should address the impact of the new rules in respect of the internal market, public health and international developments. In particular, the Commission should report on international, legal and scientific developments in terms of labelling and packaging as well as on novel tobacco products and, if appropriate, provide suggestions for further EU action in this area.

Brussels, 19.12.2012
SWD(2012) 452 final

Part 2

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)

{COM(2012) 788 final}
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A.1 OUTCOME OF CONSULTATIONS AND STAKEHOLDERS' OPINIONS

This annex summarises the comments and opinions expressed by stakeholders in the context of the revision of the Tobacco Products Directive. The first part of the annex refers to comments and opinions expressed by stakeholders in targeted discussions throughout the process. The second part contains a summary of the public consultation organised between September and December 2010. The third part of the annex presents a more detailed picture of citizens' attitudes towards tobacco control measures, as published in the latest Eurobarometer survey on "Attitudes of Europeans towards Tobacco."[1]

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[1] Special Eurobarometer 385, May 2012.

A.1.1. SUMMARY OF STAKEHOLDERS' POSITIONS IN THE CONTEXT OF TARGETED STAKEHOLDER CONSULTATIONS ON THE REVISION OF THE TOBACCO PRODUCTS DIRECTIVE

A.1.1.1. Health NGOs

General

- Concerns were expressed regarding some of the data and estimates presented by the external contractor RAND Europe in its study assessing the impacts of revising the Tobacco Products Directive. Health NGOs claimed that the health impacts and health costs of various policy options were underestimated and that industry costs were overestimated. The assumption made by the contractor that smoking prevalence would decline without further intervention was questioned. It was also expressed that tobacco companies are already reducing employment through efficiency savings. The "transferable" nature of tobacco tax revenue and employment should also have been recognised. Money not spent on tobacco would be spent on something else.

Smokeless tobacco products (STP), Nicotine Containing Products (NCP) and herbal products for smoking

- Health NGOs expressed support for keeping or even extending the current ban on oral tobacco and argued that oral tobacco cannot be seen as a rational substitute to cigarettes.
- Health NGOs expressed concerns that many of the NCP, in particular electronic cigarettes, are not subject to any specific safety rules and argued that they should be regulated similarly to pharmaceuticals.
- Health NGOs were in favour of including herbal products for smoking in the scope of the TPD.
- The European Respiratory Society (ERS) is opposed to the use of all (tobacco and) unapproved nicotine delivery products, including electronic cigarettes.[1]

Labelling

- It was concluded that plain packaging and pictorial warnings reduce the attractiveness of tobacco.
- It was argued that plain packaging would not increase illicit trade.
- It was suggested that the costs for plain packaging estimated by the external evaluator (RAND Europe) were overestimated.
- The importance of a quit-line number placed on the cigarette packages was emphasised.
- It was mentioned that there is a difference in the extent of knowledge between Member States regarding the harmful effects of tobacco consumption and that information should be equally provided within the EU.
- Health NGOs expressed support for mandatory pictorial health warnings of 80% on both sides of the packs.

[1] European Respiratory Society statement on E-cigarettes and emerging products, February 2012: http://www.ersnet.org/news/item/4494-european-respiratory-society-statement-on-e-cigarettes-and-emerging-products-.html

Ingredients

- Additives in cigarettes often transform tobacco smoke into an even more complex chemical mixture and thereby increase the carcinogenic and harmful effects of tobacco.
- Too little is mentioned on how additives increase the attractiveness of tobacco products, in particular among young people.
- Support was expressed for banning flavours and sweeteners which increase the palatability and make tobacco uptake more attractive among young people.

Access to tobacco

- It was pointed out that Internet-sales lead indirectly to advertising on the Internet.
- It was concluded that the discussions regarding Internet sales raise questions of identification and enforcement as well as proportionality.
- It was concluded that different rules apply among the Member States in this area.
- Health NGOs argued that stricter regulations on tobacco vending machines, promotion and display of tobacco at point of sale and cross-border distance sale of tobacco were effective means for reducing tobacco consumption among young people. They emphasised, however, the importance of not losing what has already been achieved at national levels.

A.1.1.2. Tobacco industry

General

- The study assessing the impact of revising the Tobacco Products Directive prepared by the external contractor RAND Europe was heavily criticised. The respondents claimed that the study does not sufficiently analyse the impacts on the functioning of the internal market, EU competence, subsidiarity, proportionality and legal basis. They also stressed that other vital elements such as illicit trade, intellectual property rights and competition aspects were missing. The effects on SMEs and growers should have been analysed further and the study does not provide enough scientific data. Respondents in this group also argued that the methodology of the study was weak, and the analysis poor.

Oral tobacco

- It was argued by some of the stakeholders in this group that the health statistics showing that Swedish men consume fewer cigarettes (even though they have the highest consumption of oral tobacco) and have a lower incidence of lung cancer compared to the overall EU population supports lifting the ban on oral tobacco.
- Oral tobacco was presented as a substitute to cigarettes which could help smokers quit and it was argued that Swedish oral tobacco is less harmful than other smokeless tobacco products currently allowed on the EU market.
- The current ban on oral tobacco was seen as discriminatory compared to other STP.
- Some stakeholders within this group also referred to the negative economic consequences of the current ban on oral tobacco as well as the current unequal treatment of similar products. They also referred to the unfavourable position of the Aland Island.

Labelling

- It was suggested, by respondents in this group, that the introduction of plain packaging would increase the amount of counterfeit goods. It would also reduce the possibilities to protect IP-rights and make it harder for consumers to make informed purchases.
- It was stressed that there is no evidence that plain packaging would reduce the smoking prevalence.
- It was also argued that bigger pictorial warnings would have no effect on smoking prevalence.

Ingredients

- Support was expressed for **mandatory reporting on ingredients** in a common format and the tobacco industry referred to commercially sensitive data and the importance of keeping this confidential.
- It was argued that there is no scientific basis to regulate attractiveness of cigarettes as this was considered inherently subjective.

Access to tobacco

- In particular wholesalers and tobacco vending machine operators questioned the legal competence of the EU for regulating or banning tobacco vending machines. The same stakeholders also argued that an ID age verification system provided a good protection from underage purchasing.
- Stakeholders from the tobacco industry also claimed that there is no evidence to justify a ban on tobacco display at point of sale.

Cigars and pipe tobacco

- Cigar manufacturers argued that cigars are mainly used by adult users and not by young people taking up smoking.
- It was explained that most of the economic stakeholders involved in this business are SMEs.
- Cigar manufacturers argued against stricter rules on labelling, ingredients and on display at points of sale.
- Pipe tobacco manufacturers also stressed the need for a different treatment compared to cigarettes due to different production methods and consumer profiles. It was emphasised that pipes are not used by young people.

A.1.1.3. Retailers

- Tobacco retailers argued against a tobacco display ban at points of sale and stressed that such a ban would be very burdensome for retailers and have no effect on smoking prevalence. In particular it was indicated that many SMEs would be affected by such a regulation and that is would increase illicit trade.
- Tobacco retailers also argued against plain packaging.
- Concerning the issue of internet-sale, CEDT (European retailer association) has recognised that this activity should be regulated at the national level by each Member State, considering the negative impact on the sale network and its possibility of public health control.[2] CEDT has also underlined that internet-sale would increase the risks for public health, since it is easier to bring non-genuine products onto the market

[2] Correspondence of 12 March 2012.

while tobacco retailers ensure both a control on minors purchase and the actual collection and precise transfer of state revenues.

A.1.1.4. Tobacco growers

- The main concern of tobacco growers expressed throughout the revision process was in relation to ingredients, where they argued against a full ban. It was said that sugar and some other flavours are necessary for the manufacturing of certain varieties of tobacco (e.g. Burley and Oriental tobacco).
- The tobacco growers also emphasised that a ban on ingredients would have important negative impacts on employment, in particular as a vast majority of growers have tobacco growing as their principal source of income and many live in poor and rural areas.

A.1.1.5. Tobacco suppliers

- The tobacco cartons manufacturers, fine paper industry and cellulose acetate industry expressed some concerns in relation to plain packaging and the risk for increased illicit trade.
- The flavouring industry emphasised the need for basing the revision on science based criteria, rather than subjective concepts such as attractiveness.

A.1.1.6. Electronic cigarettes Industry Trade (ECITA)[3]

- ECITA argued that electronic cigarettes are neither pharmaceuticals nor tobacco products and that these products do not require further regulation. A self-regulation document has been established by ECITA to regulate electronic cigarettes.
- ECITA stated that although they view existing regulations as sufficient, they are not always properly enforced. ECITA urged the European Commission to encourage stricter enforcement in Member States.

A.1.1.7. Pharmaceutical industry

General

- It was stressed that it is very hard to assess the impact of switching from tobacco to nicotine products.
- Production can drop quite a lot before there is an effect on employment. There are other factors which affect employment.

Scope

- Smoking addiction should be seen as a disease which should be treated with medicine (for example nicotine products).
- It was suggested, by some respondents within this group, that non-tobacco nicotine products should be put more firmly into the medicinal area and consequently fall into the scope of pharmaceutical regulation.
- Other respondents argued that all nicotine containing products, which are not otherwise regulated by EU food or pharmaceutical legislation, should be included in the scope of the EU Tobacco Products Directive.

[3] Representing vendors of electronic cigarettes in the UK

Labelling

- Health warnings are a good way to decrease smoking prevalence.
- The regulatory procedures are very different for pharmaceuticals, this means it might be hard to compare. Control of packages is more rigorous in the pharmaceutical area.

A.1.1.8. Tobacco vending machine manufacturers[4]

- Stricter national regulations on tobacco vending machines (TVM) have affected different companies in different ways. Some companies were negatively affected by national TVM bans and their sales dropped, while others had anticipated the development and benefitted from new areas of activities, e.g. "ban-compliant" dispensers of tobacco.

A.1.2. SUMMARY ON THE OUTCOME OF THE PUBLIC CONSULTATION ON A POSSIBLE REVISION ON THE TOBACCO PRODUCTS DIRECTIVE

A.1.2.1. General

The public consultation generated over 85 000 contributions. Citizen contributions accounted for 96% of the survey response. While it is encouraging to see such a large number of responses, it should be noted that this volume appears to be a result, to a large extent, of several citizen mobilisation campaigns that took place in some Member States. For example, a campaign was organised by a group representing over 75% of Italian Tobacconists. This action was followed by submissions of personal signatures by over 30,000 tobacconists across Italy.[5]

The actions and efforts of these campaigns seem to have affected the overall results of the public consultation. This is illustrated by the significant number of pre-programmed "duplicate" responses which counted for 57% of all citizens' responses.[6]

The full report, including arguments used by respondents can be found on:
http://ec.europa.eu/health/tobacco/docs/consultation_report_en.pdf

A.1.2.2. Government representatives

Scope

A significant majority of Member States who submitted contributions to the public consultation were either in favour of extending the scope of the Directive or did not refer to the question in a detailed manner. Two EFTA States were also in favour of extending the scope of the Directive. A small number of respondents were in favour of either maintaining the status quo or extending the directive to all tobacco products, but not to tobacco-free nicotine products, ENDS (Electronic Nicotine Delivery Systems), or herbal cigarettes.

[4] Interviews with four main manufacturers of tobacco vending machines in Europe carried out by the external contractor, Matrix insight. See Matrix Report 2012.
[5] European Voice, 10 February, 2011
[6] A response considered "duplicate" in the public consultation was a response fulfilling the following criteria: 1. At least six duplicate responses containing the same text. 2. Text box containing more than three words. 3. Text box not containing text directly copied from the consultation document.

As regards the future regulation of 'electronic cigarettes' in tobacco legislation, Member States responding to the consultation seemed to be divided, with some presenting arguments for regulating the product as a pharmaceutical or medical device, and others arguing for the inclusion of electronic cigarettes in the Tobacco Products Directive.

Reactions from MEPs, National Parliamentarians, and local/regional authority respondents were mixed.

Smokeless tobacco

The majority of Member States were in favour of banning all types of smokeless tobacco products, which was also the position of the two EFTA countries responding to the consultation. A very small number Member States proposed that the EU considers lifting the ban on snus. One Member State expressed a particularly strong interest in this. The main arguments for this solution came from the concerns about the harmful health effects of STP, STP as a gateway to FMC consumption and dual use. It was also argued that all STP need to be banned while these products still have relatively limited market shares as the supply of novel forms of STP is likely to increase.

Very few MEPs provided a response to this question, and of those who did, the majority was in favour of keeping the existing ban on oral tobacco products. Most responses from National Parliamentarians, and local/regional authorities favoured lifting the current ban on snus products, while a small group of respondents were interested in extending the current ban to all smokeless tobacco products.

Consumer information

Almost half of the respondents among Member States supported the introduction of plain packaging alongside the other suggested recommended changes including mandatory pictorial warnings, but several indicated that plain packaging should be more carefully analysed. A small number of Member States were in favour of maintaining the existing regulations, noting a strong reservation against plain packaging.

Overall, almost all Member States were in support of removing the tar, nicotine and carbon monoxide levels.

MEPs, National Parliamentarians, and local/regional authority representatives responding to the consultation were split over this issue.

Reporting on ingredients

Member States were in favour of establishing a common compulsory reporting format for communicating ingredients information. A majority of them referred to the Electronic Model Tobacco Control (EMTOC), an application already used for this purpose in some Member States, as the basis on which such a system should be established. There were also proposals encouraging the Commission to consider a reporting system where tobacco industry would report directly to the Commission in order to enable the further development of European legislation in this field.

Almost all responses from MEPs, National Parliamentarians and local/regional authorities were in favour of establishing a common compulsory reporting format.

Regulation of ingredients

As a whole, a majority of Member States supported some sort of ingredients regulation, though when asked to select a specific policy option, Member States were less likely to provide a response. Some supported a positive common list of ingredients, while others supported the use of a negative common list of ingredients. Two EFTA countries supported the use of a negative common list of ingredients, insofar as it is not an exhaustive list.

A few Member States expressed concerns about the EU's ability to quantify the term 'attractiveness'. Others were against any change to the status quo.

Most responses from MEPs, National Parliamentarians, and local/regional authority representatives were not in favour of introducing EU-level ingredients regulation.

Access to tobacco

Almost all Member States supported some form of increased tobacco control across the range of options, though the specific breakdown of options was quite varied. Most Member States supported a ban on internet sales or a ban on vending machines. About one fourth of Member States, and the two EFTA States were in favour of a wide ban in all three cases. Finally, a small number of Member States were in support of leaving these areas to Member State competence.

Very few responses from MEPs, National Parliamentarians, and local/regional authority representatives were in favour of an outright ban on all three options i.e. internet sales, vending machines and retail displays.

A.1.2.3. Non-governmental organisations

Scope

Public health organisations universally supported regulating tobacco and nicotine products. They also argued for the inclusion of herbal cigarettes into this framework.

Smokeless tobacco

Public health organisations emphatically maintained the 'high priority' status of the current ban on snus within the EU. It was also argued by some NGOs that other forms of smokeless tobacco products should be regulated but not necessarily banned, because many are only popular within specific ethnic groups.

Smokers' rights groups pushed for lifting the ban on snus.

Consumer information

Public health organisations supported increasing the size of pictorial warnings to 80% of the pack, to regularly rotate warning messages to maintain the 'freshness' of each statement, and to include information on the packaging about a 'quit line' to help stop smoking.

Additionally, public health organisations opted for plain packaging.

Smokers' rights groups, argued against plain packaging and pictorial warnings.

Reporting on ingredients

For many stakeholder organisations, the solution was clear cut: the current situation which allows for different formats and reporting mechanisms is unsatisfactory. They argued that

tobacco companies should be required to use a standardised reporting format and pay a registration fee to cover the costs of administering the data collection.

Smokers' rights groups argued that information on ingredients is already appropriately mandated by the Directive on an annual basis.

Regulation on ingredients

In general, public health organisations were in favour of establishing common ingredients lists. As an example they often referred to the Guidelines on Article 9 and 10 of the WHO FCTC, adopted by consensus at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

While respondents were split over what type of list should be included, they almost universally supported that the main purpose of such a list should be to regulate flavours and ingredients that mainly enhance attractiveness, encourage youth initiation and discourage cessation.

Access to tobacco

Public health organisations were universally in favour of banning sales of tobacco via the internet, tobacco vending machines and display of tobacco at point of sales.

Smokers' rights group were against changes in this area.

A.1.2.4. Industry and tobacco growers

Scope

The tobacco industry representatives argued almost universally that a fundamental difference exists between products which use tobacco to deliver nicotine and those that do not. They claim that the Directive is aimed at regulating tobacco products, and no further regulation is needed for other products.

The Pharmaceutical industry favoured regulation of nicotine products, some of them in the context of the pharmaceutical legislation and others by including them in the scope of the Tobacco Products Directive.

Smokeless tobacco

The great majority of respondents from the tobacco industry and EU tobacco growers were in favour of lifting the ban on smokeless tobacco (snus) across the EU.

Consumer information

According to tobacco industry representatives and EU tobacco growers, packaging and labelling does not affect or help predict the rates of youth uptake, and thus without a direct link, the basis for change is inaccurate.

Representatives from the cigar industry cited additional challenges with the changes proposed, as many of these changes would impose an excessive financial burden on a relatively small industry.

The pharmaceutical industry argued in favour of improving consumer information about smoking, especially smoking cessation services. They cited evidence suggesting that advertising quit lines and cessation services on tobacco packaging results in increased usage of these services in the short- and medium-term. Representatives also argued for mandatory

pictorial warnings and expressed support for the replacement of the tar, nicotine and carbon monoxide information on packaging.

Reporting on ingredients

The tobacco industry representatives and the flavouring industry seemed to be in favour of synthesising reporting standards.

Other stakeholders, such as smokeless tobacco manufacturers, retailers and growers questioned the validity of this issue, as several organisations stated they were completely unaware of difficulties within the compliance processes.

Several organisations raised concerns that common reporting standards could release information about trade secrets.

The pharmaceutical sector advocated a common compulsory reporting format.

Regulation of ingredients

Across the tobacco industry, a significant amount of representatives did not support the establishment of a common list of ingredients. EU tobacco growers were particularly concerned that a general ban on ingredients would put EU blends at a disadvantage and have a devastating effect on employment. Burley organisations were particularly concerned over a possible ban on sugars. The flavouring industry and retailers also raised concerns about establishing a positive or negative ingredients list.

On the contrary, the pharmaceutical industry pushed for regulation of ingredients through a positive common list of tobacco ingredients.

Access to tobacco

The tobacco industry, retailers and growers were against regulating or restricting tobacco vending machines, tobacco display at point of sales and internet sale of tobacco. Smokeless tobacco manufacturers raised particular concerns over restricting internet sales of tobacco.

The pharmaceutical industry pushed for a ban on all three distribution channels.

A.1.2.5. Citizens

Scope

A significant majority of respondents were against extending the scope of the Directive.

Smokeless tobacco

A vast majority, but not all, of respondents were in favour of lifting the ban on snus.

Consumer information

Most respondents were largely in favour of maintaining the status quo.

Reporting on ingredients

Respondents were generally in favour of establishing a common compulsory reporting format.

Regulation of ingredients

A significant majority of respondents disagreed with the regulation of ingredients at the EU level.

Access to tobacco

A significant majority of respondents opposed limiting access to tobacco products and opted rather for more effective controls, such as age verification, in these channels of tobacco products.

A.1.3. SUMMARY OF CITIZENS' ATTITUDES TOWARDS TOBACCO CONTROL POLICY MEASURES

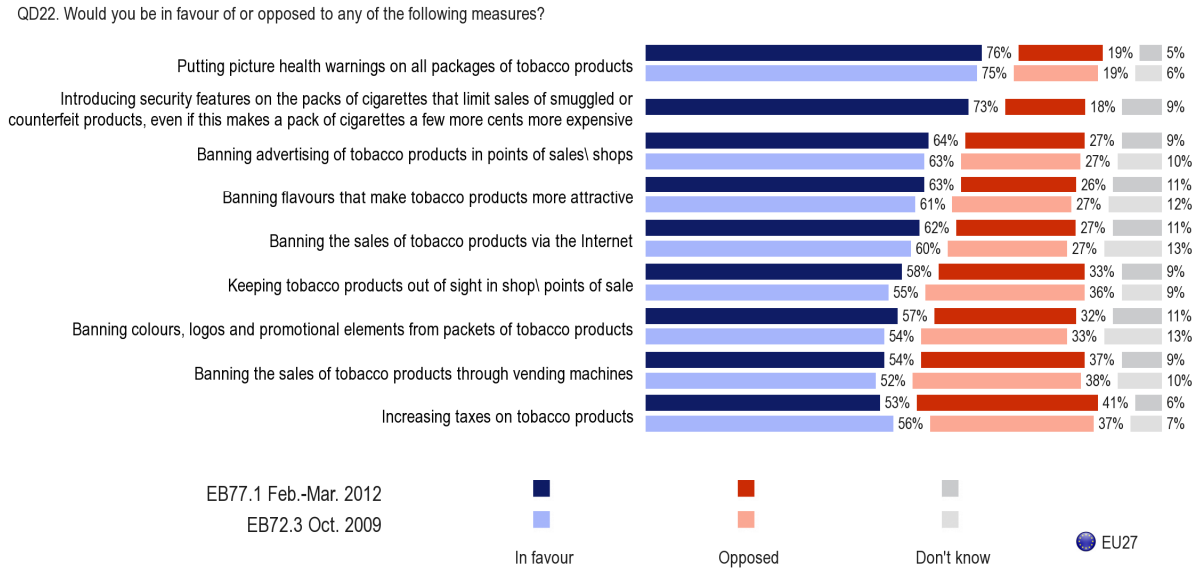
A.1.3.1. General

The Eurobarometer survey was carried out in all 27 Member States of the European Union in early 2012. [7] Face-to-face interviews were conducted with 26,751 respondents aged 15 and older. Citizens' were asked a number of questions related to tobacco consumption, including their support for various policy options considered in the revision of the Tobacco Products Directive. These figures were also compared to citizens' attitudes towards tobacco control measures three years ago in the 2009 Eurobarometer survey.[8]

A.1.3.2. Results

EU citizens, including smokers, were largely and increasingly in favour of tobacco control measures. As shown in the figure below, the absolute majority of EU citizens were in favour of the policy options polled.

Figure 1: European citizens' attitudes towards tobacco control policy measures[9]



Source: Special Eurobarometer 385, May 2012

[7] Special Eurobarometer 385, May 2012.
[8] Special Eurobarometer 332, May 2010.
[9] Eurobarometer 385, May 2012.

Three out of four citizens supported putting pictorial health warnings on all tobacco product packages (76% favourable). Over six in ten supported banning advertising at points of sale (64%) and almost six in ten supported keeping tobacco products out of sight in shops (58%). Roughly the same number believed that flavours that make tobacco products more attractive should be banned (63%). Slightly more than half of respondents were in favour of increasing taxes on tobacco products (53%), which made this the least popular policy option amongst citizens. In comparison to 2009, support for all policy measures, except increasing taxation, went up.

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Part 3

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)

{COM(2012) 788 final}
{SWD(2012) 453 final}

A.2 DESCRIPTION OF THE TOBACCO MARKET, MANUFACTURING OF CIGARETTES AND THE MARKET OF RELATED NON-TOBACCO PRODUCTS

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A.2.1. THE TOBACCO MARKET

This annex provides an overview of the EU tobacco market including the main product categories. It sets out the value and volume of sales as well as manufacturing methods and consumption patterns.

The second part of this annex describes in detail the production process and main tobacco production-related economic activities in Europe including farming, product manufacturing, distribution and sales.

A.2.1.1. Tobacco products

The total value of the **EU Tobacco Market** at retail level **including taxes** was **136.5 bEUR in 2010.** The market consists of the five main tobacco products categories:[1]

1. Factory manufactured cigarettes (FMC);
2. Roll-your own tobacco (RYO)
3. Pipe tobacco;
4. Cigars and cigarillos
5. Smokeless tobacco products (STP): oral, chewing and nasal tobacco.

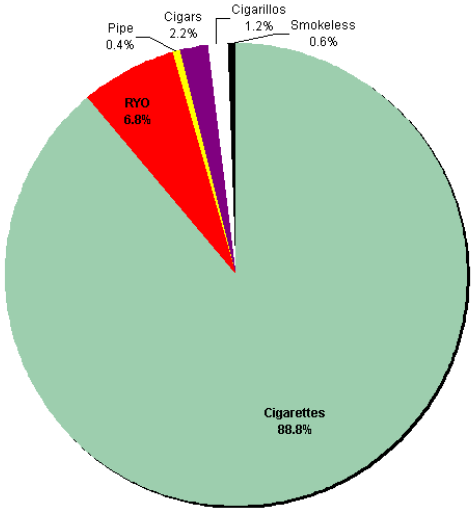


Figure 1: Comparison of relative market value of tobacco products in 2010

Source: Euromonitor, and industry estimates

The figure shows that FMC are by far the largest part of the market (almost 90%), followed by RYO (almost 7%). Nicotine containing products such as e-cigarettes are not part of the market tobacco markets. It is expected that in coming years a number of new tobacco products might be launched, which are allegedly less harmful.

The sales trends from 2000 to 2010 for the five main product categories are set out in the table 1. It can be observed that although volume has decreased in the ten year period between 2000 and 2010 by 19%, there has been an increase in the revenues (including taxes) by 37%. This increase can be attributed primarily to tax increases.

[1] This categorisation is in line with the Commission's merger practice. It is important to underline that the notion of a market in this impact assessment is not based on competition law terminology. Value includes excise tax and VAT. Merger cases: M4424, M4581, M5086.

Table 1: Market trends 2000-2010

Category	Value 2000 (bEUR)	Value 2010 (bEUR)	Change (%)	Vol. 2000 (bsticks/ ttonnes)	Vol. 2010 (bsticks/ ttonnes)	Change (%)
Cigarettes	90.7	121.3	**+33.8**	793.7 bs	608.8 bs	**-23.3**
Roll-your-own	4.2	9.3	**+123**	53.1 tt	75.5 tt	**42.2**
Pipe tobacco	0.576	0.48	**-17**	6.33 tt	4.03 tt	**-36**
Cigars/cigarillos[2]	4.62	4.65	**+0.6**	7.81 bs	9.92 bs	**27**
Smokeless tobacco[3]	0.48	0.83	**+73**	5.3	5.9	**10**
Total[4]	100.6	136.6	**+36**			

Source: Matrix,[5] based on Euromonitor data

A.2.1.1.1. Factory Manufactured Cigarettes

For the year 2010, was the value of the market for FMCs, by far the most significant sector of the tobacco market in the EU, 121.3 billion EUR.[6] As illustrated in figure 1, FMCs represent almost 90% of the market value and the last ten years have seen an increase of 34% in the overall market value of FMCs despite a decline of 23% in volume sales over the same period. Taxes accounted for most of the turnover, net value of the cigarette market at retail level was calculated at 28.3 bEUR (23% of the total retail value) as shown below. Government taxes on tobacco products serve two aims; they act as a source of revenue for governments and increasingly as a public health measure against smoking, as by definition they render tobacco products more expensive and thus less affordable.

It is estimated that the margin of retailers and wholesalers accounts for approximately 40% of this amount, which means that the ex-factory revenues of the cigarette manufacturers amounted to 17 bEUR. These amounts do not capture illicit sales of cigarettes which according to Euromonitor represent more than 8% of the market.

Table 2: FMC revenue breakdown

Pre-tax value	28.345 billion EUR
Excise-tax	72.519 billion EUR
VAT	20.400 billion EUR
Total	**121.264** billion EUR

Source: Euromonitor, DG TAXUD, Matrix 2012

Cigarettes containing the American blend, based on the combination of Virginia, Burley and Oriental tobacco varieties, continue to have the biggest share of the market compared to

[2] This covers also the so-called "eco-cigarillos" exempted from the definitions for cigars and cigarillos through Directive 2010/12/EC on the structure and rates of excise duty applied on manufactured tobacco.
[3] The Euromonitor data on STP covers only a small number of countries: Sweden, Denmark, Slovenia and Germany. Sweden accounts for the most significant share of the STP market.
[4] Total does not include cigars and cigarillos taking into account that average tobacco content of cigars and cigarillos vary and nowadays more cigarillos are sold. For FMC is was assumed that each FMC contains 1 gr of tobacco.
[5] Economic analysis of the EU market of tobacco, nicotine and related products. Further referred to as Matrix report, 2012.
[6] Euromonitor data processed by Matrix, and industry estimates.

Virginia and other blends. In 2010, American blend cigarettes accounted for 462.6 billion sticks (76% of the market), Virginia for 72 billion sticks (12%, in particular in the UK, Ireland, Cyprus and Malta), and other blends for 71.6 billion sticks (12%).

Despite the general decline in FMC sales, sales of slim cigarettes, particularly popular among female and younger smokers, grew, according to the Euromonitor data, by 50% from 23,855 million sticks in 2000 to 35,673 million sticks in 2010. A small increase has also been observed in the segment of menthol cigarettes (+2.4%), a product which is particularly suitable for smoking initiation.[7] In addition a range of cigarettes with fruit, candy and alcohol flavours have been recently introduced to the market as well as some unusual ones such as black tea, cassis, lemongrass and natural rose oil.[8] Flavourings are often used to enhance the taste and reduce the harshness of tobacco smoke and thus to make the product more attractive and palatable to consumers.

A.2.1.1.2. Roll Your Own

RYO cigarettes are usually made of fine cut tobacco, the oldest form of smoking tobacco. The RYO market in the EU was reported to be worth 9.3 billion EUR (incl. taxes) in 2010.[9] Part of these sales can be attributed to the segment of MYO ("make your own" using a specialised equipment), which has grown and contributed significantly to the expansion of the market in recent years, most likely as a result of higher FMC prices and more favourable tax regimes for fine-cut tobacco. The net value of the RYO market was estimated at 3.0 bEUR in retail prices (33% of the total revenue) as shown in Table 3.

Table 3: RYO revenue breakdown

Pre-tax value	3.019 billion EUR
Excise-tax	4.734 billion EUR
VAT	1.534 billion EUR
Total	**9.287** billion EUR **€**

Source: Euromonitor, DG TAXUD, Matrix

In the context of the Commission's merger control practice[10] the conclusion was reached that FMC and RYO are not part of the same "product market". At the same time, tobacco manufacturers acknowledged there could be a degree of switching between FMC and RYO tobacco in view of differing excise treatment and consumer preferences. This discussion is of limited relevance for the purpose of this impact assessment.

Between 2000 and 2010, the size of the RYO market in the EU grew by 42.2% and Euromonitor estimates that this market segment will continue to grow up to the year 2015.[11] The Member States in which RYO has a significant share of tobacco sales are Germany, Belgium/Luxembourg, the Netherlands, France, Spain, the UK and Poland.

[7] Addictiveness and Attractiveness of Tobacco Additives, SCENIHR Opinion of 12 November 2010.
[8] Euromonitor. Trend Watch – Flavoured cigarettes controversy rages on, 23 April 2008.
[9] Euromonitor data processed by Matrix and industry estimates
[10] M.4424 / Gallaher; M.4581 Imperial Tobacco / Altadis; M.5086 BAT/ Skandinavisk Tobakskompagni
[11] Matrix report, 2012.

A.2.1.1.3. Pipe Tobacco

Compared to other tobacco products, the segment for pipe tobacco is quite small, reported to be worth 0.48 bnEUR in the EU in 2010 at retail level including taxes.[12] The primary markets are Germany, France, Denmark and the United Kingdom.[13] Pipe tobacco is considered to be a niche product, generally sold in small quantities by specialist shops. According to European Smoking Tobacco Association (ESTA), the typical pipe tobacco consumer is male, 80% over the age of 60 years. The industry association recognises that its market is decreasing, as the current consumer is getting older and younger consumers are not choosing pipe tobacco.13 Most varieties of pipe tobacco are flavoured and these flavours are added to pipe tobacco at higher quantities than is the case for other tobacco products.[14] The cut and flavour differentiate pipe tobacco from RYO. The legal definition of pipe tobacco has been recently amended to avoid substitution between pipe tobacco and fine-cut tobacco[15].

A.2.1.1.4. Cigars and Cigarillos

Cigars are rolls of tobacco with an outer wrapper of natural tobacco or of reconstituted tobacco. They are produced and sold in a significant variety of models, sizes, brands, types of packaging and prices. Cigarillos are in principle following the same definition (outer wrapper), but they can contain a filter and until recently the outer wrapper normally consisting of tobacco could made of other material (so called eco-cigarillos). In 2010, according to Euromonitor, **1.98 billion cigars** and **7.94 billion cigarillos** were sold across the EU. The largest market for cigars during the ten year period was the United Kingdom, where 20% of all cigar purchases in the EU took place.[16] The cigarillos market is largely made up of sales from three countries: 47% of the cigarillos market in 2010 consisted of German sales, whilst French and Spanish sales made up 16% and 14% of total sales, respectively.

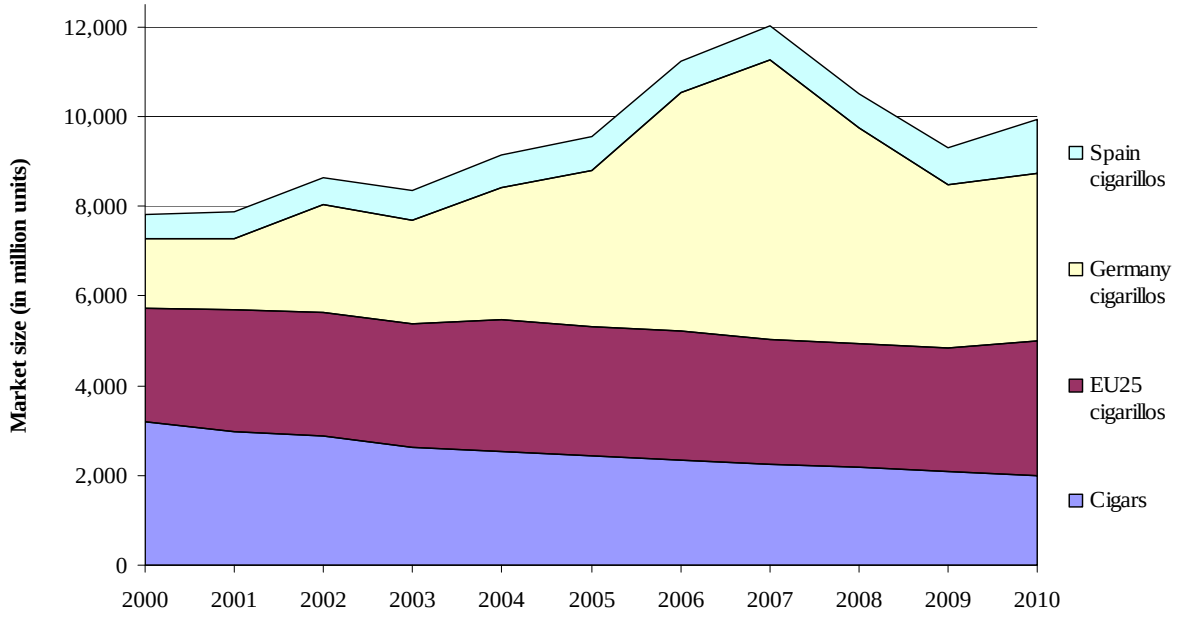
Producers of **cigars** argue that their product, similarly to the pipe tobacco, is not targeted at younger consumers. Absolute cigar sales decreased over by 1.2 billion units (a 38% fall) between 2000 and 2010. Approximately 15-20% of their products contain added flavourings, of which 80% are coffee, vanilla and caramel-like flavours.[17] Estimates from European Cigar Manufacturing Association suggest that the demand for cigars and cigarillos (in line with their definition in the taxation legislation) in the EU between 2002 and 2010 experienced a more modest decrease i.e. a fall from 6,712 million units in 2002 to 6,252 million units in 2010.[18]

This statement seems not in line with the information provided by Euromonitor (see figure 2). However the difference can be explained by the reclassification of so-called **eco-cigarillos** as cigarettes in the amended EU tax legislation.[19] These products are presented as cigars/cigarillos in order to benefit from the reduced tax rate, despite being similar in function, taste, filter and presentation to a cigarette.[20] However, these products are classified

[12] Euromonitor, and industry estimates
[13] ESTA European Smoking Tobacco Industry: Facts and Figures for DG Sanco (ESTA 2011-2012)
[14] ECMA Data: Annex III: Estimated Size of the EU Cigar Market 2002 and 2010
[15] Council Directive 2011/64/EU
[16] Matrix report, 2012.
[17] ECMA Data: Annex III: Estimated Size of the EU Cigar Market 2002 and 2010
[18] Meeting with Industry Stakeholders and DG SANCO, 19th December 2012
[19] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1149&format=HTML&aged=0&language=EN&guiLanguage=en
[20] See for example: http://www.tabak-brucker.de/themes/kategorie/index.php?kategorieid=591

as cigarettes (exceptions apply for Germany and Hungary until 2014). In **2007**, **cigarillos consumption peaked in Germany** at 6.2 billion sticks, the bulk of which consisted of eco-cigarillos.

Figure 2: Cigars and cigarillos market size, EU27, in million units, 2000-2010



Source: Euromonitor. EU25 exlcude sales in Spain and Germany which are shown separately

Despite the amendment of the EU definition the sales of filter cigarillos soared in a number of countries in 2010. These products are sold in packs of twenty units similar to those of cigarettes. Unlike traditional cigarettes, the paper wrapping of a stick is not white but brown, and its flavour is more intense. Given this formula, consumers have turned to these products as substitutes for the classic cigarettes. **In Spain** a price of a pack of "**minicigarritos**" marketed under the brands Coburn, Braniff, Rex, Friends or Salsa starts from 1.20 EUR, 2.75 EUR less than a pack of cigarettes. Their sales **grew by more than 300%** in the first eight months of 2010.[21] Introduction of economy Partner cigarillos by Philip Morris **in Latvia** and **Lituania** in early 2010 caused cigarillo sales to skyrocket **from 4 million sticks to more than 100 million sticks** in both countries **within one year period**, as many smokers switched from cigarettes to twice cheaper Partner cigarillos.[22]

Since the cigar/cigarillos market ranges from hand-made premium cigars to machine-made mass market products and the so-called little cigars or cigarillos, overall market trends needs to be analysed also **in value terms**. The overall market value of cigars and cigarillos sold across the EU in 2010 was €4.65 billion, with **cigars constituting 64%** of the total market value (€2.98 billion) and **cigarillos 36%** of the total market value (€1.67 billion). In 2000, the value of the total market was €4.62 billion, i.e. market value increased by 0.6% over the ten years. The relatively constant market value over the time period is to be attributed to the fact

[21] http://www.expansion.com/2010/10/11/empresas/1286821650.html?a=385a9cdddfda0b345033eaf5a569dc47&t=1331819951

[22] http://www.euromonitor.com/tobacco-in-latvia/report

that cigars are, on average, more expensive than cigarillos and their reduction in sales has offset the increase in value from more cigarillos being sold.

A.2.1.1.5. Smokeless Tobacco Products

Smokeless Tobacco Products (STP) can be defined in a broad sense as non-combustible tobacco products, including chewing tobacco, nasal tobacco and oral tobacco (snus, snuff et alia).[23] Marketing of oral tobacco is banned in the EU according to the current Directive, except for Sweden having an exemption in its Accession Treaty[24]. In general, Eurobarometer statistics indicate that daily use of tobacco products other than FMC and RYO is low, at just 1% per category.[25] The market for nasal and oral tobacco is small, comprising just **0.6% of the EU tobacco products** market.

Sweden is the largest market for STP market, consisting mainly of oral tobacco (snus). Other significant markets are Denmark (chewing and nasal tobacco consumption), Slovenia (chewing tobacco) and Germany (chewing and nasal tobacco) and the UK (use of chewing tobacco is largely restricted to members of the Indian, Pakistani and especially Bangladeshi communities). The sales of chewing tobacco increased by 255% between 2000 and 2010 in Denmark (from 4 tonnes to 14.2 tonnes) and sales are expected to increase further by 4 tonnes up to the year 2015.[26] For Slovenia and Germany a decline was observed, but German sales of nasal tobacco grew again in recent years, possibly in reaction to the smokefree environment policy.

A.2.1.2. Tobacco manufacturing

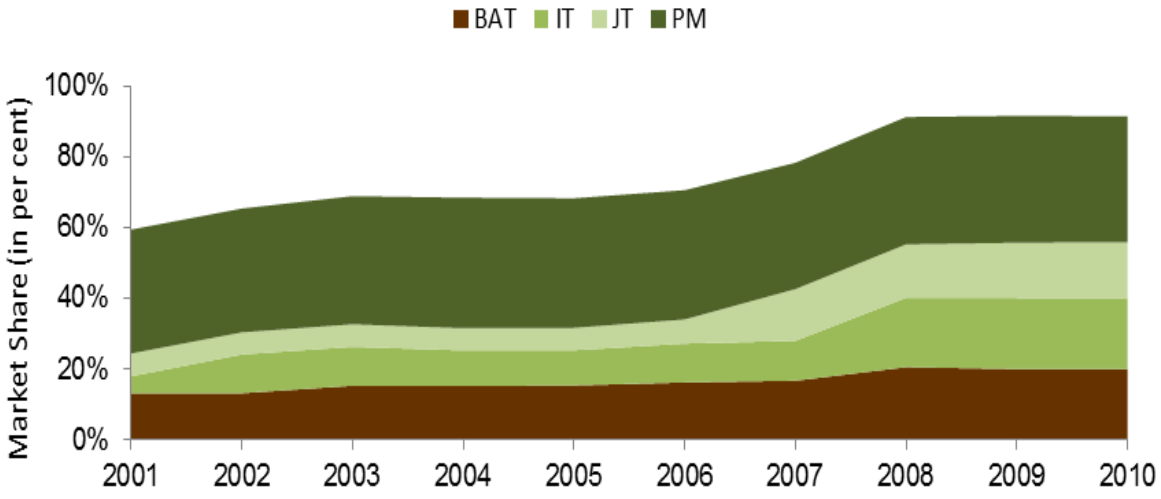
EU **FMC** manufacturing is increasingly concentrated and dominated by four large multinational companies. In 2010, British American Tobacco (BAT), Imperial Tobacco (IT), Japan Tobacco (JT), and Phillip Morris International (PM) – collectively often referred as Big Four - together shared 91.41% of the European Union cigarettes market, up from 59.4% in 2000. This increasing consolidation is attributed to both organic growth and acquisitions.26 The only other companies with a market share above 0.5% are Bulgartabac Holding Group and Karelia Tobacco Co Inc.

Case study 1

In 1990's, the German company Reemtsma acquired and upgraded a number of production facilities in Central Europe which had benefited from considerable tax benefits from the national governments. In 2002 Reemtsma was acquired by Imperial Tobacco. Shortly after EU enlargement in 2004, Imperial Tobacco closed the facilities in Hungary, Slovenia and Slovakia in order to remove over capacities. Imperial claimed to save around £20m a year as a result of the restructuring exercise cutting 940 jobs.

[23] Commission Staff Working Document accompanying the 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 Products.
[24] Treaty concerning the accession of Norway, Austria, Finland and Sweden to the European Union, 24th June 1994
[25] Attitudes of Europeans towards Tobacco, Special Eurobarometer 385, May 2012.
http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco_2012_en.pdf
[26] Matrix report, 2012

Figure 3: EU24 market (size, in million sticks) share of 'Big Four' (in per cent), 2000-2010



Source: Euromonitor. No data on Cyprus, Luxembourg or Malta. Refers to the global brand owner.

Case study 2

Japan Tobacco International (JTI), the world's third-biggest tobacco manufacturer, planned to close down its cigarette factory in Hainburg in Austria and to move the operations to two plants in Central Europe: in Gostkow Stary near Lodz and in Bucharest, romania.insider.com reported. The relocation is expected to take place by the end of the year.[27] The Hainburg factory with 320 employees had the capacity to make 10 billion cigarettes a year and produced brands such as Benson&Hedges or Memphis. Japan Tobacco built the Gostkow plant in 2009 at a cost of $100m (€70m), creating more than 400 jobs. The company said at the time that its initial annual capacity of 5.5 billion cigarettes would rise to more than 20 billion in 2011. The factory is located near an existing tobacco factory which JTI acquired from Gallaher of the UK as a result of a merger that propelled it to number three cigarette maker in the world.

The **RYO** market consists of a larger number of companies, and, at the moment, is considered less concentrated than the FMC market. Nevertheless, "Big Four" account also for approximately 70% of the RYO market.

In contrast, **cigars, pipe tobacco, nasal and chewing tobacco** are mainly produced by SME's.[28] For cigars and cigarillos in particular, only two companies have a market share of more than 10% and the market share of Big Four is just above 20%.[29] Contrary to common assumptions, about 90% of the EU cigar market is in the hands of EU producers. The production is said to be labour intensive and cigar manufacturing industry employs approximately 5,000 people.[30] In the case of Pipe Tobacco, there are more than 750 different brands available on the EU market; the majority of these are manufactured in Germany or Denmark by small and medium enterprises.[31] Swedish Match is the market leader in snus, but

[27] http://www.romania-insider.com/jti-to-move-cigarette-production-from-austria-to-romania-poland/23187/#
[28] European Cigar Manufacturers Association, ECMA and European Smoking Tobacco Association, EST contributions to DG SANCO
[29] Matrix Report, 2012
[30] Meeting with Industry Stakeholders and DG SANCO, 19th December 2011
[31] ESTA European Smoking Tobacco Industry: Facts and Figures for DG Sanco (ESTA 2011-2012)

it is also engaged in the production of US mass-market cigars and chewing tobacco.[32] The market leader for chewing tobacco in Denmark and Sweden is House of Oliver Twist, with a market share of 82.4%.[33]

There were 48,500 people employed in tobacco manufacturing in the European Union in 2009.[34] Tobacco manufacturing is highly concentrated in geographical terms. Three Member States (United Kingdom, the Netherlands and Germany) account for more than 50% of total EU production.

A.2.1.3. Tobacco growing

As far as **raw tobacco** is concerned, the EU accounts for approximately 280,000 tonnes (4.1%) of world production.[35] Inside the EU, approximately 118,190 hectares are devoted to tobacco growing, according to 2009 estimates, which represents a decrease of 38% from the year 2000.[36] Tobacco production in the EU can be subdivided in four main variety groups; Virginia, Burley, Dark (Dark air-cured and Fire-cured) and Oriental. Virginia varieties represent about 46% of the EU production, Burley 21% and the others together about 33%. The EU counts about 86,000 tobacco farmers.[37] Bulgarian farmers represent 50% of them, followed by Poland and Greece (both 17%). The tobacco production is often limited to small regions carried out by family businesses. The average area (1.6 ha per farmer) differs considerably according to the varieties grown, with Burley and Oriental varieties requiring more labour force than Virginia varieties.[38] As a consequence, 81% of EU tobacco farmers are involved in Burley or Oriental growing, while 15% grow Virginia varieties. According to tobacco producers, certain ingredients, including sugar, are indispensable for the use of certain tobacco varieties (Burley and Oriental). This is because these varieties lose their sugar content during the drying process whereas other varieties, such as Virginia, keep it.

In addition, there are around 100 **first processors** of tobacco in the EU. The first processors collect the raw tobacco cured by the farmers and make a first process before selling it to the industry producing cigarettes, cigars or manufactured tobacco. 44% of the first processors are located in Bulgaria and 22% in Italy. **Second processors** subsequently purchase, process, blend pack, store and ship tobacco to meet each specifications of manufacturers of cigarettes and other consumer tobacco products. Two U.S. based leaf tobacco merchants - Alliance One Int. and Universal Corporation - with substantially similar global market shares, control most of the EU market, e.g. Alliance One delivered in 2011 54% of its tobacco sales to customers in Europe (approx. **800 million EUR**)[39]. Recently, the Commission fined the company's subsidiaries in Spain, Italy and Greece for operating cartels and but the outcome of the appeals process is still ongoing.

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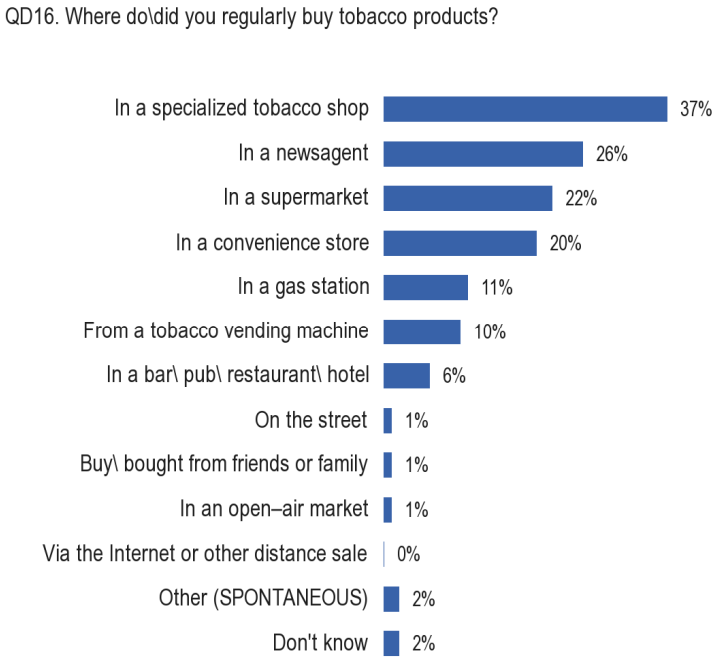
[32] http://www.swedishmatch.com/en/Our-company/Financial-fact-sheet/ (Financial Fact Sheet for Swedish Match , 2010 figures)
[33] Matrix Final Draft Report
[34] Eurostat Statistics 2008/2009
[35] Member States statistics communicated to DG AGRI
[36] http://www.who.int/tobacco/en/atlas41.pdf
[37] Member States statistics communicated to DG AGRI. In addition to the farmers, a number of people (including seasonal workers) are employed on the farms. Copa-Cogeca (European farmers and agri-cooperatives) has estimated this figure to 400 000.
[38] Nomisma report
[39] AOI 2011 Annual Report, http://phx.corporate-ir.net//phoenix.zhtml?c=96341&p=irol-reportsannual, accessed on 29 February 2012

A.2.1.4. Tobacco distribution levels

In terms of distribution, there were 2784 enterprises and 45,900 employees, involved in tobacco **wholesale** in the EU in 2009. In a number of MS's are the wholesale activities, formerly part of national tobacco monopolies, operated by the large tobacco manufacturers. However in other MS's the wholesalers are often involved in distribution of various product categories and therefore only part of their revenue would be impacted.

The tobacco **retailers'** market is quite varied across the EU. For instance, the tobacconists in France need a license, whilst the Belgian newsagents, supermarkets and corner shops do not.

Figure 4: The place of purchase of tobacco products in the EU



Source: Eurobarometer 2012

According to the European Retail Association, in the EU-27 there are almost a million points of sale for tobacco products (988,480 points of sale recorded, excluding vending machines.)[40] For the Member States where such information has been made available, 229,012 of these outlets are recorded as being either kiosks, tobacconists or convenience stores. According to European Confederation of Tobacco Retailers (CEDT) estimation that there are approximately 1.45 employees per point of sale, 332,067 people are said to be employed in the specialised retail of tobacco, although such figures seem to be overstated, particularly in relation to larger retail outlets.[41] Considering the whole added value[42] generated by cigarettes and RYO in the retail sector 7.825 bnEUR (in average 25% margin applied) and the average salary in the sector provided by Eurostat (12,879 EUR), the total number of people involved in the sales of tobacco products should not exceed 600,000 FTE's[43].

40 Tobacco Retailers Figures, CEDT, sent in January 2012
41 According to figures provided by Federazione Italiana Tabaccai
42 This is a hypothetical assumption as besides the labour the whole range of other cost occurs in the retail sector: rent, energy, transportation, furniture, cost of financial transactions etc.
43 Full Time Equivalent

A.2.1.5. Upstream/downstream activities

A number of other upstream- and downstream activities are associated with the tobacco manufacturing process and might be impacted by the proposal considered in this impact assessment. This includes suppliers of flavourings, papers, filters and packaging as well as producers of a number of accessory products such as tobacco vending machines and pipes.

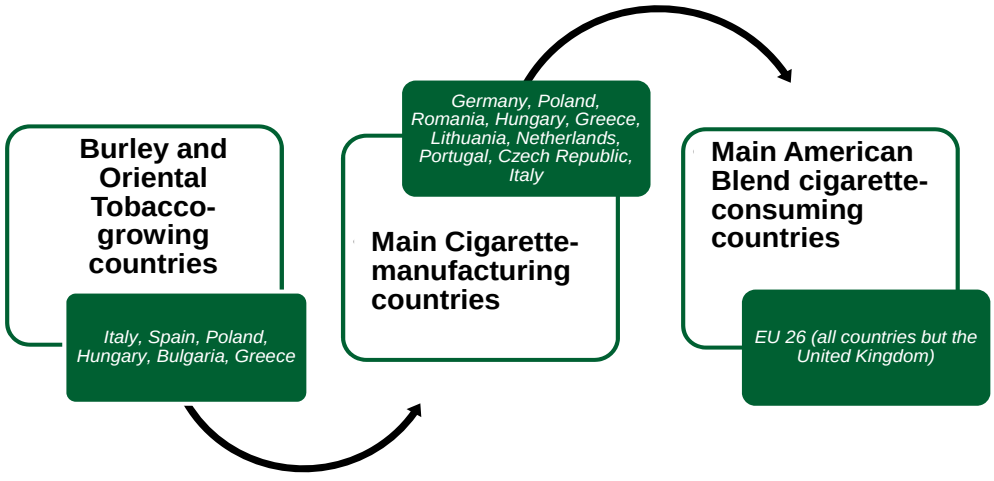
The European Carton Makers Association (ECMA) represent 500 carton producers which account, by volume, for 90% of the European carton market (corresponding to approximately 8.1 bnEUR in turnover). Only 10% of their total turnover (approximately 800 mEUR) is derived from tobacco products and only 6% of employees of companies represented by ECMA work in cigarette carton manufacturing in the EU.[44]

In the case of filters, a prominent manufacturer of filters estimates that 37.5% of their total turnover of 200.7m GBP, (i.e. circa. 75m GBP) came from the EU market.[45] New and more innovative variants of filters are being developed by filter manufacturers, which could potentially make the associated tobacco products more attractive to consumers.[46]

A.2.1.6. Trade

As far as **trade** is concerned, EU imported about 600,000 tonnes of raw tobacco and exported about 170,000 tonnes in 2010.[47] This corresponds to a value of 3,164,087,504 EUR for exports and 2,366,294,046 EUR for imports of manufactured tobacco.[48] There is also substantial intra EU trade with about 268,000 tonnes of raw tobacco being subject to such internal trade between Member States in 2010. The overall value of tobacco products traded within the EU in 2010 was 9.5 bnEUR.[49] Figure 5 illustrates the main trade intra-EU flows in the production of American blend cigarettes.

Figure 5: Trade flows between tobacco-growing, tobacco-producing and tobacco-consuming countries



Sources: Industry respondents, Euromonitor, FAOSTAT, DG AGRI

44 Minute of Meeting of Industry Representatives and DG SANCO, Feb.6th 2012
45 www.filtrona.com
46 http://www.filtronafilters.com/poverview.htm
47 EUROSTAT This figure includes normal trade and inward processing, i.e. tobacco imported and processed in the EU for export to third countries.
48 Eurostat Statistics, 2010
49 Eurostat (Procom), 2008

A.2.2. TOBACCO AND SOCIETY

A.2.2.1. Consumers

While the number of smokers in the EU has been decreasing in the past decades, 28 % of all EU citizens and 29% of young people 15-24 years still smoke.[50] The prevalence levels differs widely between Member States with a range in the proportion of smokers between 13% and 40%. The prevalence levels of smoking also vary between different socio-economic groups differs greatly within the Member States.

It may be useful, for illustrative purposes, to look at the demographic trends as they present themselves on the level of the individual Member States. For example, 2011 estimates by the Bundesministerium für Gesundheit in Germany that 22% of women smoke and this estimation rises to 38% for young women. Smoking prevalence amongst women with lower levels of education and amongst single mothers in Germany is said to be 'remarkably high.'[51] Statistics for certain EU countries suggest that in the last fifteen years, there has been a trend towards **increasing numbers of young people starting to smoke**, although overall statistics suggest that there are less people smoking now than in the 1980s or 1990s. Tobacco consumption among young people in Slovenia increased from 16% in 1993-96 to 26% in 1997-2001.[52] Statistics in Hungary from 2003 show that 38.2% of Hungarian adult males and almost one quarter of Hungarian adult females are smokers and that in spite of more men than women smoking there, school-age girls are far more likely to initiate smoking cigarettes than boys (27.9% for girls as opposed to 15% for boys.)[53] In Slovakia, where the rate of smoking in the adult population in 2003 was 30.1% for men and 17% for women, an increase in occasional smoking amongst women during the 1990s has been attributed to a change in societal attitudes towards women smoking.[54]

On average EU smokers are smoking 14.4 cigarettes a day. The retail price of cigarette packages differs widely between Member States, with a range between 1.48 EUR and 8.45 EUR within the EU.

A.2.2.2. Illicit Trade

The issue of illicit trade in tobacco products has been recognized as fundamental by regulators, enforcement administrations and by tobacco industry. In the EU, the main problem area is the illicit trade in manufactured cigarettes. This illicit trade has to be clearly distinguished from legal non-domestic consumption, for example cross-border shopping in another EU country in legal amounts in order to avoid higher taxation.

In the context of the Tobacco Products Directive, the main problem is that illicit products undermine the existing EU wide regulations as regards, for example, health warnings and maximum yields for tar, nicotine and carbon monoxide, ingredients regulations. Similarly they undermine measures at national level like the prevention of underage smoking.

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[50] Special Eurobarometer 385, May 2012.
http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco_2012_en.pdf
[51] http://www.drogenbeauftragte.de/drogen-und-sucht/tabak/tabak-und-frauen.html
[52] http://www.who.int/tobacco/surveillance/Slovenia%20GYS%20Report-Year2002_2003.pdf
[53] http://www.who.int/tobacco/surveillance/HUNGARY_REPORT_2003--.pdf
[54] http://www.who.int/tobacco/surveillance/Slovakia%20Country%20Report_2003.pdf

As explained in the IA report (section 2.2. problem identification) one needs to distinguish between **genuine products which are *diverted* into the illegal supply chain** (mostly for sale in high tax/price Member States - contraband[55]) – and **falsified products**, which are counterfeits of genuine products, ***made* for the illegal supply chain**[56]. 'Illicit/cheap whites" – often referred to as a third and rapidly growing area of concern – are in principle genuine products, but do not respect the regulatory safeguards of the Tobacco Products Directive nor pay the appropriate taxes and have insofar common features with both contraband and counterfeit.

According to the information collected by **OLAF** (the Commission's antifraud office), the total loss in tax revenues amount to € 10 billion[57] annually, which corresponds to a market value in the legal supply chain (retail level excluding taxes) of € 3 billion. Overall, 50% of these lost sales are attributed to **contraband** and 50% to **counterfeits,** with variations in the Member States.

In all categories, the main threat comes from large-scale smuggling (estimated by Euromonitor of being 70 % of all illicit trade), by highly organised criminal actors. Besides large-scale smuggling there is also "bootlegging", the trafficking of relatively small quantities of contraband by making journeys across the border with small amounts of cigarettes. Another way of illicit supply is the use of internet sites to sell and ship tobacco products by post worldwide to evade taxation. There are also instances of illicit manufacturing of (mostly) cigarettes, without the crossing of a border, therefore not "smuggled" (for example on a site not licensed or registered for manufacturing or an undeclared (over) production on a legal site).

As regards the volume, it lies in the nature of illicit trade that precise figures are difficult to obtain. Although some data are available, generally speaking, transparent, publicly available data on illicit trade are very limited. According to Euromonitor, illicit trade in cigarettes in the EU amounts to **8.25 % of total trade**, with a significant variation across EU countries[58].

The "STAR project" [59], a study carried out by KPMG for PMI International in the context of the legally binding agreement between the company and the EU, comes to the following result: In 2010, **9.9 % of total cigarette consumption** could be regarded as contraband or counterfeit. Similarly, from a study done at global level, the estimate for high income countries (in which category the EU falls) is, that **9.8 % of the cigarette market is illicit**[60].

According to OLAF, in 2010, Member States reported seizures of around 4.6 billion cigarettes. If these seized cigarettes had penetrated the EU markets, it is estimated that the losses to the EU and Member States' budgets in 2010 would have been approximately 1 billion euros. According to OLAF figures, illicit trade represents annual revenue losses of 10 billion euros for the EU and its Member States[61].

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[55] For the purpose of this impact assessment the notion of "contraband" is used to describe all situations in which a genuine product is diverted into the illicit supply chain, i.e. also if the product is produced in the country of destination, but no appropriate taxes are paid.
[56] Falsified (counterfeit) cigarettes also circulate without appropriate taxes having been paid
[57] http://ec.europa.eu/anti_fraud/media-corner/press-releases/press-releases/2011/20110315_01_en.htm
[58] See MATRIX report 2012
[59] http://www.pmi.com/eng/tobacco_regulation/illicit_trade/documents/Project_Star_2010_Results.pdf
[60] Joossens L,Merriman D, Ross H,Raw M. How eliminating the global illicit cigarette trade would increase tax revenue and save lives. Paris; International Union Against Tuberculosis and Lung Disease; 2009
[61] http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1179

A.2.3. MAIN STEPS IN THE MANUFACTURING PROCESS OF CIGARETTES

A.2.3.1. Growing and harvesting

Tobacco is initially grown in outdoor frames called seedbeds. In warm regions, the frames are covered with mulch or a cotton top sheet; in cooler regions, glass or plastic shields are installed to protect the plants. After 8-10 weeks, when the seedlings are almost 10 inches (25 cm) tall, they are transplanted to the fields. Although transplanting machines are available, the vast majority of the world's tobacco plants are still planted manually. As the plants grow, the heads are broken off by hand so the leaves will grow fuller, a process called *topping.* The plants stay in the field 90-120 days before they are harvested.

Tobacco plants are harvested in three times between July and September and in many regions this is done manually. The plants are harvested by one of two methods, *priming* or *stalk-cutting.* In the priming method, the leaves are gathered and brought to a curing bam as they ripen. In the stalk-cutting method, the entire plant is cut and the plants are allowed to wilt in the field before being taken to the curing barn.

Growers are often organized into farmer cooperatives or other producer groups.

A.2.3.2. Curing the leaf

Curing is the process of drying freshly harvested tobacco with partially or fully controlled temperature and moisture schedules. It is done by the growers. Different curing processes are used for different tobacco varieties as illustrated in the table below:

EU variety groups	***Features for curing***	***Main varieties in the EU***	***Final destination***
I	*Flue-cured: tobacco dried in ovens with controlled air circulation, temperature and humidity*	*Virginia, Bright*	*Non blend and American Blend cigarettes*
II	*Light air-cured: tobacco dried in the air under cover, not left to ferment*	*Burley, Mariland*	*American Blend cigarettes*
III	*Dark air-cured: tobacco dried in the air under cover, fermented before being marketed*	*Paraguay,Havana, Badischer, Beneventano*	*Dark cigarettes and cigars*
IV	*Fire-cured: tobacco dried by fire*	*Kentucky, Salento*	*Cigars and Toscany (strong cigars)*
V	*Sun-cured: tobacco dried in the sun "oriental tobacco"*	*Xanti-Yakà, Erzegovina*	*Aromatic for American Blend cigarettes*
VI	*Sun-cured: Basmas varieties*	*Basmas*	*Aromatic for American Blend cigarettes*
VII	*Sun-cured; Katerini varieties*	*Katerini*	
VIII	*Kaba-Koulak (classic) and similar Sun-cured*	*Kaba-Koulak, Elassona*	

Virginia tobacco leaves contain a higher carbohydrate (e.g. sugars) level and lower nitrogen level than Burley leaves. The natural drying of the Burley leaves at relatively low temperatures allows plant respiration which continues to consume sugars during the process, leaving negligible sucrose and (reducing) reduced sugars in the cured leaf. Burley leaves contain higher levels of nitrogen than Virginia leaves. The smoke of Virginia or flue-cured leaves is more aromatic and less alkaline than that of Burley tobacco, with a slight acidic taste resulting from the high levels of natural sugars. Burley tobacco produces a more alkaline smoke than flue-cured tobacco and therefore imparts a bitter aroma and taste to cigarettes. Oriental leaves tend to have a low nitrogen content and moderate levels of carbohydrates, but fewer proteins, than the other varieties.[62] Burley and Oriental varieties require much more labour force and/or investments for curing than Virginia varieties.[63]

A.2.3.3. First processing

Raw tobacco leaves are sorted into grades based on size, color, and quality. Grading is performed by first processors. The first processing step includes the following activities:

- Leaves are sorted by quality to form homogenous lots which are then delivered to manufacturers.
- The leaves are beaten in order to separate the leafy material from the stalks; this is done for some varieties only.
- The tobacco is re-dried to stabilize it and thus enable long-term storage.
- The tobacco is re-sorted to form homogenous lots.
- The tobacco is aged and fermented to assist long terms storage.
- Tobacco strips are prepared ready for industrial use; this is done for some varieties only.
- Packaging for delivery to manufacturers.

A.2.3.4. Preparation of basic blends and making of cigarettes

This is performed by second processors and cigarette manufacturers.

Blending is the selection and thorough mixing of the tobacco-based components plus any associated casings, humectants and flavouring required for a particular product or brand. The tobacco based components may include the leaf lamina, cut and rolled stem, reconstituted sheet and expanded tobacco. The tobaccos stored in bales are broken up, cut into specific dimensions, and combined with other blend components such as casing and top dressing, and the moisture content is adjusted.

The final shredded tobacco is dispersed over a continuous roll of cigarette paper. A machine rolls the shredded tobacco into the paper and cuts it to the desired length. A device then grabs each cigarette and fastens a filter in one end. Modern cigarette machines can produce 25-30 cigarettes a second.

[62] Addictiveness and Attractiveness of Tobacco Additives, SCENIHR Opinion of 12 November 2010

[63] Factsheet on the Production of Raw Tobacco in the EU: European Commission DG AGRI, Directorate C.3. : Wine, alcohol, tobacco, seeds and hops.

The process for the manufacture of cigarettes incorporates the use of 'Fine Paper Products', such as cigarette paper, plug wrap paper and tipping paper.[64]

A.2.3.5. Adding of humectants, flavors and flavourings

There are no fixed rules as to where humectants, flavourings and other additives are added to the processed tobacco but generally the more volatile additives are added as late as possible in the production process in order to prevent losses.

Tobacco blends that contain flavourings are usually held in a bin to allow for equilibration across the blend before it is passed to the making machine as the final blend. Top flavourings are generally applied to the total tobacco blend as one of the last steps in processing. They are usually carried in an alcohol base. They are used to improve quality of smoke and to impart a pleasant pack aroma and side-stream aroma. Flavourings are used to enhance the taste of tobacco smoke, to make the product more desirable to consumers.[65] Menthol may be added at any of the following stages; spraying onto the final blend, through addition to the filter via a thread, or by application to the cigarette paper or the foil used to wrap the cigarettes. Due to the high level of volatility of menthol, different manufacturers have over the years developed a variety of methods for producing mentholated products that are as consistent as possible in terms of their finished product menthol levels. [66]

Casing refers to the sauce composed of a variety of ingredients such as humectants, sugars, cocoa, liquorice and fruit extracts.[67] Additives such as cocoa may be used as a means of dilating the airways, which allows the smoker to inhale the smoke deeper into their lungs, which leads to a more intense exposure to nicotine and to tar.[65] The basic material of casing for reducing harshness is sugar. A commercial solution of tannin also sweetens and softens the smoke of tobacco. The best known example of an additive that changes markedly and even masks the taste of tobacco is the use of cloves. Addition of menthol is another example, but in this case the tobacco taste is still discernible. Burley leaf has the ability to absorb up to 25% of its weight of added material. [68]

Casings are usually applied to tobacco strips or leaf early in the primary processing scheme to tone down or mute the strength or harshness of tobacco smoke, enhance the processing potential of tobacco and add deep flavour notes to the smoke. Casings are traditionally added to US blended styles of product that contain significant proportions of Burley type tobacco blends. These casings are added to the Burley tobacco line through the means of the casing cylinder or Cased Leaf Dryer.

Ammonia technology has been used mainly in American blend products containing cased Burley tobacco. Ammonium salts could be added at the Cased Leaf Dryer (CLD) stage or with the manufactured reconstituted tobaccos.

In cigarettes, flavours may be added to tobacco, cigarette paper, or the filter, in a plastic pellet placed in the filter or the foil wrapper, in an attempt to enhance the tobacco flavour, mask

[64] Factsheet 'Fine Paper Industry': Meeting with DG SANCO, Feb 6th 2012 (Benkert, B. and Brinker, A.)
[65] MATRIX report, 2012
[66] Response submitted to the SCENIHR Committee "call for information" by British American Tobacco; 2010. Accessed 22 June 2010 from: http://ec.europa.eu/health/scientific_committees/consultations/calls/scenihr_call_info_08_en.htm
[67] Hoffmann D, Hoffmann I. The changing cigarette, 1950-1995. J Toxicol Environ Health 1997;50:307-64.
[68] Akehurst BC. Tobacco. 2nd ed. London: Longman; 1981.

unpleasant odour, and deliver a pleasant cigarette-pack aroma. Internal industry documents reveal additional flavour technologies such as flavour microencapsulation in the paper, carbon beads, and polymer-based flavour fibres inserted into the filter, flavoured tipping etc. (WHO 2007b).

A.2.3.6. Packaging

Packaging contributes to the overall costs of producing and marketing cigarettes and is the final stage of cigarette manufacture. The completed cigarettes are normally packed 20 to a package. The packs are mechanically sealed in cellophane and hand-placed in cartons. The size of cigarette packages, in terms of the quantity of cigarettes contained therein, is regulated by some of the Member States. Current TPD bans misleading terms such as 'light', 'mild', or 'low tar' and requires that all tobacco products sold in the EU display two text warnings: the first compulsory warning is either "tobacco kills" or "tobacco can seriously harm you and others around you". The second warning is selected from a list of 14 warnings (text and a corresponding picture) developed by the European Commission.

Cigarette carton manufacturing follows a very specific process, which produces the cartons in 'flat form', which are then sent to the cigarette manufacturers for assembly to be completed. According to information from one major manufacturer, **pre-printed flat packages are purchased from suppliers** generally at a price around 0.02 EUR, however costs differ significantly between different types of packages and between packages used in different countries.

The proposed mandatory use of pictorial health warnings on cigarette packages would involve the use of three standard process colours; cyan, magenta and yellow plus black. Overall, the labelling of branded cigarette cartons involves the use of complex process colours (so called 'spot colours'.) There are also metallic finishes and structural varnishes which can be used in the manufacturing of cigarette cartons. Compared to the colours needed to produce a graphic health warning, it is claimed by industry representatives that ten to twelve colours are used in the production of typical hinged lid or soft packet packaging. According to the ECMA, specifications for particular colours have very tight 'control tolerances.' The process of foil stamping and embossing takes place after the carton has been manufactured.[69]

A.2.4. THE MARKET FOR RELATED NON-TOBACCO PRODUCTS

In addition to the traditional tobacco market, recent years have seen a diversification of nicotine containing- and other novel and niche products which can be associated with tobacco use.

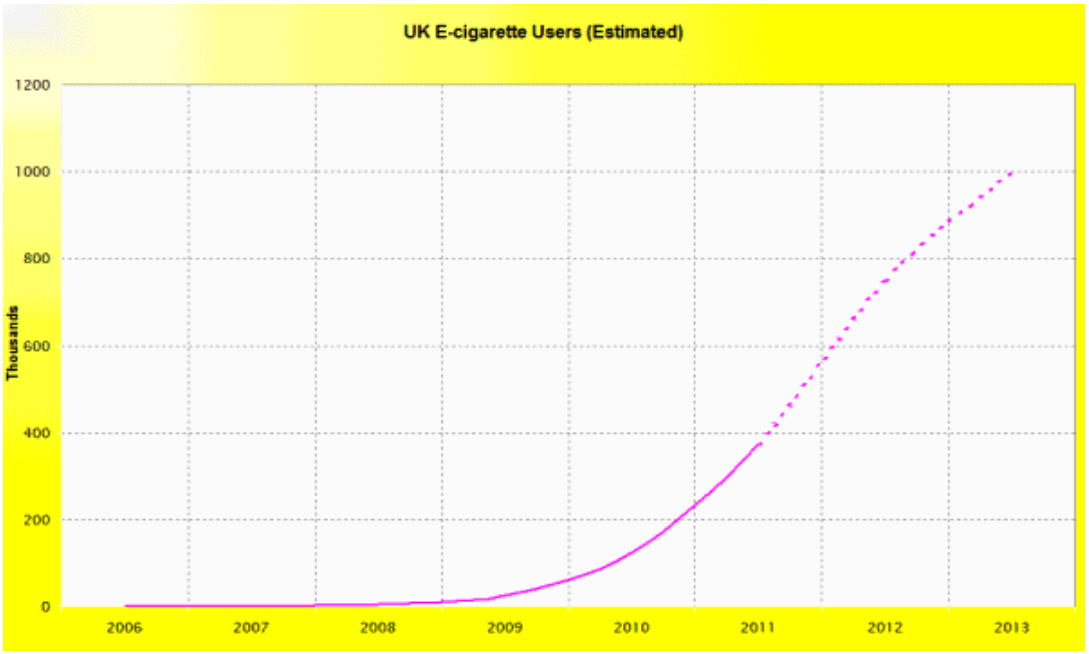
A.2.4.1. Electronic cigarettes and other nicotine containing products for consumer use

Electronic cigarettes appear to be the most commonly available nicotine containing consumer/leisure product in the EU. The EU **electronic cigarette** market is growing rapidly and it is difficult to estimate the total value. The electronic cigarette supplier, Red Kiwi, estimates that the current value of the German market is around 100 mEUR and that the total value of the EU27 e-cigarette market (including devices and refills) is between 400 and 500

[69] Document from European Carton Makers Association; *Production Explained*

mEUR.[70] The Electronic Cigarette Industry Trade Association (ECITA) estimates that they represent 60-70% of the volumes sold on the UK market and reports that the market is growing 20-30% monthly.[71] ECCA UK estimates that in 2012 there will be 750,000 electronic cigarette users (see the figure below).[72] Red Kiwi estimates the figure for Germany to be 1.2 million for the year 2011.[70]

Figure 5: Estimation of the use of electronic cigarettes in the UK



Graph adapted from http://www.eccauk.org/index.php/uk-sitrep.html

For non-electronic cigarettes, the brand "Similar" has reported sales of one million packs per annum in 2010.[72] Other nicotine containing consumer products (such as nicotine drinks and sweets) appear, at this stage, to be less common in the EU, but it cannot be excluded that a further market development will take place in coming years.

Many of the nicotine containing consumer products are manufactured in third countries (most electronic cigarettes are produced in the Shenzhen region of China) and the EU market is characterised by a large number of distributors rather than manufacturers.[72] Many of these are SMEs, but there is a growing interest from bigger companies to enter into this business. For example, British American Tobacco has recently launched its own subsidiarity company "Nicoventures" for the purpose of developing non-tobacco nicotine products, with similar moves from Philip Morris International.[73] Electronic cigarettes are most often bought in bulk from the manufacturers and sold, via the internet or in physical shops, re-branded in the EU. Once imported to the EU market, these products are subject to significant cross-border trade.

[70] Matrix insight. 2012. (Interview with Red Kiwi, 16 December 2011)
[71] DG SANCO meeting with ECITA, 20 June 2012: http://ec.europa.eu/health/tobacco/docs/ev_20120703_mi_en.pdf
[72] Matrix Report 2012
[73] http://www.nicoventures.co.uk/; http://online.wsj.com/article/SB10001424052702304066504576347513991162274.html

A.2.4.2. Herbal products for smoking

The overall size of the market of herbal cigarettes has grown in recent years, from around 40,603,000 units in 2000 to 49,953,000 in 2010.[74] These products are available from numerous internet sites and health food stores (e.g. Holland and Barrett in the UK). The products are marketed in a range of different flavours, including vanilla and ginseng and are often suggested as a help for quitting smoking.

[74] Matrix report, 2012

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Part 4

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]

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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 use[3] 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 safety[5], 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

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[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 warining 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 States[15] (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 packages[16]. 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 offic- languages and 35% & 50% in MS with 3 offic- 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 paranthesis

[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 202.[19] A Belgian MP tabled a proposal for plain tobacco packaging in May 2011[20] 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 2012[22] 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.

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[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 guidelines[25] 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 UK[28]) 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, Bulgaria[29] 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 2008[33] 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 completely[36] 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 Netherlands[37] 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 UK[38]) 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 States[42] 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 manufacturers[43]. 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	**Article 2(1) tobacco products** STP fall inside the scope of FCTC. NCP and herbal products fall outside the scope of the FCTC.	**Article 1c tobacco products** STP fall inside the scope of FCTC. 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."	**WHO Technical Report, 1988** -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] **WHO Study Group on Tobacco Product Regulation (TobReg) 2009** -**STP:** Recommendations on limits for carcinogenic components for carcinogenic components: Tobacco specific N-nitrosamines (TSNA) and polycyclic aromatic hydrocarbons (PAH).[2] **-Electronic cigarettes:** Recommendation to regulate as combination drug and medical devices and not as tobacco products. -Report by the Convention Secretariat to Conference of the Parties (CoP) to the FCTCand CoP5: no conclusive guidance on how to regulate the products.	**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.** -Stricter than current TPD. -In line with WHO Technical Report 1988 -In line with general principle in FCTC Article 4 (4) adopt measures to reduce consumption of all tobacco products. **NCP (option 3):** Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements -Outside current TPD -In line with WHO TobReg recommendation. -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. **Herbal products for smoking (option 1): Health warning** -Outside both TPD and FCTC.
Packaging and labelling	**TPD Article 5** All tobacco products must carry one general text	**FCTC Article 11** Large, clear, visible and legible health warnings should be **50% or more of the**	**The FCTC guidelines Article 11** -Parties should consider using health warnings covering **more than 50%** of the display areas.	**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**

[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)
	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. Packages of manufactured cigarettes should display the results of tar, nicotine and carbon monoxide (TNCO) yield measurements. 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). The pictorial warnings should, together with the additional text warning, cover 40% of the other most visible side of the package.[3] **TPD Article 7** Text, names, trade marks and figurative and other signs suggesting that a tobacco product is less harmful than others should	**principal display areas but no less than 30%.** They may be in the form of or include pictures or pictograms. -information on relevant constituents and emissions of tobacco products as defined by national authorities. -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". **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'.	-Parties should consider **pictorial health warnings on both principal display areas.** -Health warnings and messages should in addition to harmful effects address different issues such as **advice on cessation**. -Parties should prohibit the display of figures for emission yields such as **TNCO**. -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. **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. **FCTC guidelines Article 9 and 10** –Parties should prohibit or restrict ingredients that have colouring properties in tobacco products.	**the Treaty:** -Stricter than current TPD -In line with FCTC Article 11. -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)

[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	**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. **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.)	**FCTC Article 9** Guidelines shall be proposed for the regulation of ingredients. Parties shall adopt and implement effective measures for such regulation. **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.	**FCTC guidelines Article 9 and 10** -Parties should regulate, by prohibiting or restricting, ingredients that may be used to **increase palatability** in tobacco products and that have **colouring properties**. -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. -Parties should consider making information about the toxic constituents and emissions disclosed to governments publicly available.	**Option 2: Ban products with characterising flavours, common reporting and information publicly available.** -Stricter than current TPD. -In line with FCTC Article 9 and 10 -In line with FCTC guidelines for Article 9 and 10
Cross-border distance sale	**TPD** No provisions **Council Recommendation 2003/54/EC** recommends that Member States restrict tobacco distance sale for general retail such as sales via the internet.	**FCTC Article 16 (1d)** 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.	**FCTC guidelines Article 13FCTC** -**Internet sales of tobacco** should be banned as they inherently involve tobacco advertising and promotion.	**Cross-border distance sale (option 1): Notification of retailers:** -Outside current TPD. -In line with Illicit Trade Protocol. -Less strict than FCTC guidelines for Article 13. -

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	**TPD Article 5(9)** 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. Technical measures shall be adopted by "comitology". (This has not been done).	**FCTC 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. **FCTC Article 15** 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." **Protocol on illicit trade** The provisions relevant for the TPD revision relate to a tracking and tracing regime. (Part III of the Protocol on Supply Chain Control)		**Preferred option 2: Tracking and tracing system plus security feature** -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 (whith an external or internal imitative chacteristics 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 aproved 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)
		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.	
Cyprus	Chewing tobacco non-banned by Dir 2001/37 is permited to be marketed in Cyprus. Although such product are only popular among ethnic groups.	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.	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).	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. 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 yers old) is prohibited. (since July 2010).	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	Covered by Law on Tobacco Products. https://www.retsinformation.dk/Forms/R0710.aspx?id=121336 and https://www.retsinformation.dk/Forms/R0710.aspx?id=135884	With nicotine regulated as pharmaceuticals due to the pharmacological function of the nicotine.	Not regulated by Law on Tobacco Products but herbal cigarettes are like tobacco cigarettes covered by Law on smoke-free environment. https://www.retsinformation.dk/Forms/R0710.aspx?id=11388
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.	Treated as pharmaceutical products but with problems. Nicotine cartridges are classified as medicinal products by function. Possible ban coming on all nicotine products other than medicine and pesticides. 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.	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)
		The product cannot be sold in Finland without license. 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. 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.	
France	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. Nasal tobacco products are authorized	If presented as cessation treatment, whatever the nicotine dosage, the product is regarded as a medicinal product. 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 concentratioon equal or above 20 mg/ml. If not medicinal products according to the description above, the General Product Safety Directive applies. French consumer code provides rules of security.	Some plants are regulated upon pharmaceutical monopoly and as such are medicinal products by presentation. Herbal cigarettes presented as tobacco cessation treatment are also medicinal products. 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.
Germany		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. There are currently court proceedings pending regarding the classification of electronic cigarettes as medicinal products.	Taxed as tobacco products. Exception: products containing no tobacco and used exclusively for medical purposes under German drug law are exempt from taxation.
Greece	Common Minister Decision 266/2001, art.8. According this decision chewing tobacco is	Prohibited under the new tobacco legislation unless approval by the Ministry of Health.	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

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	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."	received approval by the National Medicines Organization that they can be used as a tool for smoking cessation 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."
Hungary	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)	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 undoubtely. 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.	Not regulated explicitly, they are considered as consumer products as long as they do not fall under the definition of pharmaceutical products by function. 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.

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 at 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 whose design imitates tobacco products or packaging	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 whose design imitates tobacco products or packaging
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 (*Art. 7 of the Health Protection Act against the Consequences of Tobacco Use of 9 November 1995*)	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 permited to be marketed. Although such product are not very popular among the Portuguese population.	According to a Informative Provision by the portuguese National Autority 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 smokless tobacco products.	No specific regulation. Electronic cigarettes have not been considered medicinal products,unless the intented 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 intented use falls under the definition of medicinal product. Protection of consumers' interests Directive and General Product Safety Directive applies.
Sweden	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. 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. 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. The production of chewing and sucking tobacco (i.e. snus) has further to comply with	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). 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.	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. 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. 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.

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.	New products with tobacco or nicotine are prohibited Regulations no. 1044 of 13 October 1989 concerning the prohibition against new tobacco and nicotine products **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. **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). 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. Electronic cigarettes and waterpipe/shisha tobacco are banned under this regulation. There is a limited derogation for private import of electronic cigarettes under medicinal products legislation.	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. 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.
Turkey			

A.3.3.2. Packaging and labelling

Member State	**Pictorial warnings: state of implementation** *(please include info (e.g. name, date) and weblinks to relevant legislation)*	**Pictures on cigarettes + required size of the warning** *(please specify, e.g. starting date of actual use of pictures)*	**Pictorials on other smoked tobacco products** e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	**Pictures used** *(how many? rotation, please specify)*	**Are cessation services* included in warnings?** *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	**Other packaging or labelling requirements** (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	**Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC)**
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 2011and 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** *(please include info (e.g. name, date) and weblinks to relevant legislation)*	**Pictures on cigarettes + required size of the warning** *(please specify, e.g. starting date of actual use of pictures)*	**Pictorials on other smoked tobacco products** e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	**Pictures used** *(how many? rotation, please specify)*	**Are cessation services* included in warnings?** *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	**Other packaging or labelling requirements** (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	**Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC)**
Bulgaria (02/07/12)	Work on the introduction of pictorial health warnings is ongoing. 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. 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	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.	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. [The website www.aznepusha.bg provides lists of free-of- charge and paying cessation services. Free of charge services have been run by the MoH since 2005 in the regional Health Inspections of the 28 administrative districts in Bulgaria. The costs of the services (private, in hospitals etc.) where the clients pay depend	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). The internal labelling of the packages would also be banned.	Article 5.9 of Directive 2001/37/EC has been transposed by: 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; 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

Member State	Pictorial warnings: state of implementation *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC)
	MoH for approval. 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. 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/.				on the methods of the services and are between 10-20 levs to 300-400 levs.]		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.
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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	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.retsinformation.dk/Forms/R0710.aspx?id=135884 and https://www.retsinformation.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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	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** *(please include info (e.g. name, date) and weblinks to relevant legislation)*	**Pictures on cigarettes + required size of the warning** *(please specify, e.g. starting date of actual use of pictures)*	**Pictorials on other smoked tobacco products** e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	**Pictures used** *(how many? rotation, please specify)*	**Are cessation services* included in warnings?** *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	**Other packaging or labelling requirements** (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	**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 1st 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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	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 circu lation 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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	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_lilt.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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC)
					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 Cabinet Regulation No. 868 (Adopted 21 October 2008) Regarding Addition of Colour Photographs or Illustrations to Tobacco Packaging Units	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]

[13]Health 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.
[14]In 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** *(please include info (e.g. name, date) and weblinks to relevant legislation)*	**Pictures on cigarettes + required size of the warning** *(please specify, e.g. starting date of actual use of pictures)*	**Pictorials on other smoked tobacco products** e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	**Pictures used** *(how many? rotation, please specify)*	**Are cessation services* included in warnings?** *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	**Other packaging or labelling requirements** (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	**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 *Seimas* of the Republic of Lithuania [15] However, this proposal was not approved by the *Seimas* 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 fount , 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** *(please include info (e.g. name, date) and weblinks to relevant legislation)*	**Pictures on cigarettes + required size of the warning** *(please specify, e.g. starting date of actual use of pictures)*	**Pictorials on other smoked tobacco products** e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	**Pictures used** *(how many? rotation, please specify)*	**Are cessation services* included in warnings?** *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	**Other packaging or labelling requirements** (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	**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, 1ière 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

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	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	It is not mandatory to display a quitline on packaging or labelling. [The National Health Service offers a few Smoking cessation consultations at hospitals – specialty in Respiratory diseases services. In December 2007 the General Directorate of Health approved a National Programme to normalize the smoking cessation services offered by the Portuguese NHS. 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.	Minimum 20 cigarettes in a pack.	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. 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.

Member State	**Pictorial warnings: state of implementation** *(please include info (e.g. name, date) and weblinks to relevant legislation)*	**Pictures on cigarettes + required size of the warning** *(please specify, e.g. starting date of actual use of pictures)*	**Pictorials on other smoked tobacco products** e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	**Pictures used** *(how many? rotation, please specify)*	**Are cessation services* included in warnings?** *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	**Other packaging or labelling requirements** (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	**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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC)
						advierten:", placed in both sides over the main warnings with specific requirements 2)"PROHIBIDA LA VENTA A MENORES DE 18 AÑOS", 13% on one side with specific requirements. Plain packaging is under consultation. Minimum pack size of 20 cig.	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.
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	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) This is regulated by the Swedish National Institute of Public Health regulation; FHIFS 2002:4 Sök hjälp för att sluta röka: fråga din läkare, på apotek eller	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. Other tobacco products than cigarettes are not regulated with regard to pack size. 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	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. Nevertheless, the implementation of article 5.9 in Dir.2001/37/EG awaits further regulation from the Regulatory Committee and the European Commission. However, tracking and tracing, with regards to sucking and chewing tobacco, is regulated according to LIVSFS 2012:6.

Member State	Pictorial warnings: state of implementation *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	Tracking and tracing and/or authenticity marks (including implementation of Article 5.9 of Dir 2001/37/EC)
					Sluta röka-linjen 020-840000. [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).]	The Swedish National Institute of Public Health is regulatory agency regarding pack size and shape. 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. According to practice, it is not possible to have advertising on the package, in an onsert, insert etc. The Swedish Consumer agency is regulatory agency regarding marketing etc. 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.	
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 *(please include info (e.g. name, date) and weblinks to relevant legislation)*	Pictures on cigarettes + required size of the warning *(please specify, e.g. starting date of actual use of pictures)*	Pictorials on other smoked tobacco products e.g. RYO, cigar, cigarillos, pipe, water pipe *(please indicate which products and specify, including starting date of actual use)*	Pictures used *(how many? rotation, please specify)*	Are cessation services* included in warnings? *(please specify)* **[Further details on cessation services.]** *All MS have cessation services in some form (e.g. website, quitline).	Other packaging or labelling requirements (including minimum number of cigarettes per pack, plans on standardised/ plain packaging, pack shape and appearance etc.) **Legislation/Plan** *(please specify)*	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 publshed 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?)
				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.
France (13/06/12)	Yes (ministerial order (arrêté) of the first of December 2011 : http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025596638)	Electronic	Not yet, but intend to make it compulsory	Positive list of ingredients classified by categories ministerial order (Arrêté) of the 12th of September 1995 Code de la Santé Publique : Article L3511-2 Modifié par LOI n°2009-879 du 21 juillet 2009 - art. 98 (V) 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 Article D3511-16 Créé par Décret n°2009-1764 du 30 décembre 2009 - art. 1 The maximal content of ingredients giving a flavour sweet or acidulated to flavoured cigarettes, mentioned at article L. 3511-2, 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. http://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006688201&dateTexte=&categorieLien=cid
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	Positive and negative list 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 Over 10 pages positive list and 1 page negative list Ingredients in filter and other paraphernelia like paper are regulated.

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 tabaksingrëdienten 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. 7*a 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?)
				En la elaboración de tabaco, cigarros y cigarrillos se permite utilizar o adicionar: a) Agua, amoníaco, ácido acético, láctico, cítrico y tartárico. b) Azúcar de caña, de higos, de arce o invertida, glucosa, melaza, miel, regaliz, sustancias aromáticas autorizadas y agua de rosas. 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. 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. f) Glicerina, etilenglicol o propilenglicol. 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. h) En la elaboración de cigarros y cigarrillos, el empleo de adhesivos a base de agua con caseína, almidón, dextrina, goma tragacanto o arábiga y otros productos inofensivos. **Papers** 3.25.80. Papeles para cigarrillos. Reunirán fundamentalmente las siguientes condiciones: a) Serán elaborados con fibra de lino, cáñamo, cereales, algodón, «cargas» autorizadas, y los edulcorantes artificiales incluidos en las listas positivas de este Código. b) Estarán exentos de sustancias nocivas. c) No producirán en la combustión olor o gusto desagradable. d) Contendrán solamente indicios de acidez, cloruros y nitratos. **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
Sweden	Not mandatory but recommended using EU's practical guide.	Both.	No.	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. 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. 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

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: ➢ 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: ➢ 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)
				athletes, prominents including their comments on smoking; ➢ 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	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. Advertising banned except for the display of trademarks in tobacco shops and newsagents.	None	Display of the trademark permitted at point of sale Art 7 § 2bis. Of following law http://www.sante.belgique.be/internet2Prd/groups/public/@public/@dg1/@mentalcare/documents/ie2law/15748531_fr.pdf
Bulgaria	18	Ban 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;	Ban 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. 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	Permitted. 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. 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. The scientific results of Ireland are very positive and inspiring after ban at point of sale.

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	Ban Article 9 of the Law providing for the taking of measures to restrict smoking states that: A person who- (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 (b) Uses or puts in operation any tobacco vending machine, or (c) Imports or manufactures for local use any automatic vending machine for the sale of tobacco, 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.	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	Restriction. 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." Act no. 379/2005 Coll. on measures for protection against the harmful	Restriction 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)	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)
		effects of tobacco products, alcohol and other addictive substances and on the amendment of related laws stipulates it in Division 1 – Section 4 : (§ 4) 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: http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=379/2005&typeLaw=zakon&what=Cislo_zakona_smlouvy http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=225/2006&typeLaw=zakon&what=Cislo_zakona_smlouvy http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=274/2008&typeLaw=zakon&what=Cislo_zakona_smlouvy http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=305/2009&typeLaw=zakon&what=Cislo_zakona_smlouvy	…. 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: http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=379/2005&typeLaw=zakon&what=Cislo_zakona_smlouvy http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=225/2006&typeLaw=zakon&what=Cislo_zakona_smlouvy http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=274/2008&typeLaw=zakon&what=Cislo_zakona_smlouvy http://aplikace.mvcr.cz/sbirka-zakonu/SearchResult.aspx?q=305/2009&typeLaw=zakon&what=Cislo_zakona_smlouvy	
Denmark	18	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. https://www.retsinformation.dk/Forms/R0710.aspx?id=121329 Advertising, besides that on the cigarette package, is prohibited.	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. https://www.retsinformation.dk/Forms/R0710.aspx?id=13234	Ban on all Tobacco Product Advertisements and sponsoring. The ban does not cover neutral display at point of sale that does not give rise to a promotional effect. https://www.retsinformation.dk/Forms/R0710.aspx?id=121329
Estonia	18	Ban Tobacco Act Passed 4 May 2005 (RT[2] I 2005, 29, 210), entered into force on 5 June 2005: § 22. Prohibitions upon retail trade in tobacco products (2) Retail trade in tobacco products is prohibited… 2) from automatic vending machines; …	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	Restriction. Advertising on TVM is banned. Ban of TVM to be introduced from 2015. 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.	No specific restriction, but - 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	Banned from 2012 onwards Act amending the Tobacco Act Section 8a of the Tobacco Act (693/1976), as it appears in Act 698/2010: "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."
France (13/06/12)	18	Ban Code de la Santé Publique : Article L3511-2 Modifié par LOI n°2009-879 du 21 juillet 2009 - art. 98 (V) … Sales of tobacco products by vending machines is forbidden	Ban http://www.douane.gouv.fr/page.asp?id=34 Code général des impôts	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

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)
			Article 568 ter The remote sale of tobacco products is forbidden in metropolitan France and in French overseas departments.	price lower than that mentioned in the article 572 of the general taxes code are forbidden. 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.
Germany (16/07/2012)	18	Restriction (ID verification card) The selling machine has to be installed at a location not accessible for *Children* and for *Adolescents* or The selling machine has to be furnished with mechanical devices or has to be permanently guarded to ensure that *Children* and *Adolescents* cannot take tobacco products out of them. Protection of Young Persons Act, §10: http://www.gesetze-im-internet.de/juschg/ 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.	Restriction. 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." http://www.gesetze-im-internet.de/lmg_1974/__21a.html 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. Tobacco tax law, Art. 22 (1) / (2) and Art. 23 (1) / (3): http://www.gesetze-im-internet.de/tabstg_2009/BJNR187010009.html	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):**

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		Law 3730/23.12.08, art. 2, par. 2. Art. 2 ..... 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.	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	Ban 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	Ban 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.	Tobacco display is permitted. 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.
Ireland (18/07/12)	18	Restriction Section 43 (3) of the Public Health (Tobacco) Act 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	None	Ban 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. 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".

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		concerned)." The Public Health (Tobacco) (Self Service Vending Machines) Regulations 2009 outline the procedures for selling tobacco products by means of a vending machine. 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.		
Italy (18/07/12)	16	Restriction All vending machines should be equipped with electronic devices to control the age of the purchaser. Advertising is forbidden but cigarette packs may be displayed on the TVM. The packages displayed have health warnings.	Ban	National legislation permits tobacco display at the point of sale.
Latvia	18	Ban Law On Restrictions Regarding Sale, Advertising and Use of Tobacco Products Section 7. Procedures for Trade in Tobacco Products and Herbal Smoking Products It is prohibited to sell tobacco products: 5) Utilising vending machines.	Ban 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.	Restriction 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. Displays (without any promotional cigarettes' brand names or slogans) itself are allowed.
Lithuania	18	Ban	Ban Law On Tobacco Control	Display of tobacco products at point of sale is allowed. Advertising of tobacco products at points of sale, except

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		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	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	an information specified in paragraph 3 of Article 17 of the Law on Tobacco Control is prohibited, i.e. only the following information may be presented on showcases used to display tobacco products at tobacco sales outlets: 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. 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. 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. No other visual or graphic information concerning tobacco products not specified in the Law of Tobacco Controll may be displayed in tobacco product sales outlets. It is prohibited also: 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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				7) organise games or competitions and lotteries, which would promote acquisition and (or) consumption of tobacco products; 8) to manufacture and (or) sell toys, food products and other goods, whose design imitates tobacco products or packs; 9) to sell other (non tobacco) products, marked with tobacco goods trademarks and etc.
Luxemburg	16	Restriction Article 9 de la Loi du 11 août 2006 relative à la lutte anti-tabac, article 9(2) : "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.» (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)	No regulation	Display limited to the name and the price of the tobacco product as well as the logo of the brand. (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. »)
Malta (18/07/12)	18	Restriction TVM need to be supervised at all times. TVMs are only allowed to sell cigarettes and tobacco products. Decoys should include the health warning.	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	Advertising ban
Netherlands (16/07/2012)	16	Restriction. Besulit van 26 januari 2004 houdende uitvoering van artikel 9, vierde lid, van de Tabakswet (Besulit tabaksautomaten) Vending machines have to be placed in a spot where personnel of the	None	Restricted

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)
		location where they are situated in can supervise them to make sure age restrictions are respected. Outdoor vending machines are not allowed. 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.		
Poland	18	Banned since 1996	None	Tobacco promotion and advertising is banned. Display at point of sale is allowed.
Portugal (16/07/12)	18	Restriction 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. Vending machines should have an electronic system or other kind of system in order to prevent the access of minors (under 18 years old). 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. Advertising on TVM is prohibited.	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	Ban 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.	Ban	
Slovenia	18	Ban	Restriction	Allowed.

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)
Spain (18/07/12)	18	Restriction Art 3.1 & 4.b of the Ley 28/2005 amended by Ley 42/2010 and Real Decreto-Ley 14/2011 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. The machines must include a technical device to block the access to minors. 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). 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.	Ban Art.3.1 of the Ley 28/2005 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. Art. 3.6 of Ley 28/2005 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 forbiddden.	Art. 10.Tres of the Real Decreto 1199/1999 Only indoor. Views from outside is forbidden.
Sweden (16/07/12)	18	Restrictions apply. 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". The Swedish National Institute of Public Health is regulatory agency regarding sales. 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.	Restrictions apply. 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 in vending machines**,** postal order and similar ways". The Swedish National Institute of Public Health is regulatory agency	Marketing etc. are as a general rule banned. 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. This is regulated by the Swedish Consumer Agency regulation KOVFS 2009:7. The Swedish Consumer Agency is regulatory agency for marketing etc.

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			regarding sales.	
United Kingdom	18	**Prohibition of the sale of tobacco from vending machines** **England - t**he sale of tobacco products directly from an automatic vending machine was prohibited from 1 October 2011 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 **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 **Northern Ireland** – prohibted 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) **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)	Restriction based on transposition of Advertising Directive	**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:- (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). 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.
Norway	18	Ban **Act No. 14 of 9 March 1973 relating to Prevention of the Harmful**	None	Ban Act No. 14 of 9 March 1973 relating to Prevention of the

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		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. 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. 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. The Ministry may lay down further rules to implement and supplement these provisions.		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. At points of sale neutral information may be given regarding prices and the tobacco products sold there. The same also applies to smoking accessories. The Ministry may issue regulations regarding implementation and supplementation of these provisions and may allow exemption from them.

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COMMISSION

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Part 5

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)

{COM(2012) 788 final}
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A.4 ASSESSMENT CRITERIA & COMPARING THE OPTIONS

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A.4.1. ASSESSMENT CRITERIA OF IMPACTS

ASSESSMENT CRITERIA	IMPACTS
ECONOMIC IMPACTS	
Functioning of the internal market	*-Facilitate cross border trade by removing national discrepancies for product specific measures* *-Create/maintain a level playing field for economic stakeholders (including SMEs), in particular for imported and domestic products* *-Allow the adaptation of the level of harmonisation in light of market, scientific and international developments.* *-Remove unjustified differential treatment of products*
Impact on economic players (farmers, manufacturers, wholesalers, retailers, others)	*-Cost/benefits for the industry concerned when envisaged measure is implemented (one off/fixed costs, running/variable costs, comparison with status quo)* *-Cost/benefits for the upstream suppliers/downstream distributors* *-Redistribution effects (input/output model)*[1] *-Indirect impacts associated with expected change in consumption* *-Innovation and research*
Impact on Government	*-Costs/benefits for the public authorities when envisaged measure is implemented: administrative burden* *-Indirect impacts associated with the expected change in consumption (macroeconomic environment): public health (as monetised in line with IA guidelines), health care costs, productivity/absenteeism, taxes (even though no macroeconomic impact)* *-Illicit trade*
Impact on consumers	*-Consumer choice, price, quality* *-Consumer protection*
Third countries and international relations	*-Import, export* *-International agreements (WTO, including TRIPs and TBT)* *-WHO Framework Convention on Tobacco Control (FCTC)*

[1] Whilst money not spent on tobacco will be spent on other goods and services, the "redistribution effects" based on the input/output model will not be used in the comparison tables, as it would mean not show the expected impact on the tobacco industry and would always be neutral or positive (for details see explanations below).

SOCIAL IMPACTS	
Employment and labour markets	*-Employment, including upstream/downstream and specific regions* *-Redistribution effects (input/output model)* *- Impact on SMEs*
Equality of treatment and opportunities	*-Young people* *-Vulnerable groups* *-Equality*
HEALTH IMPACTS	
Awareness and appeal	
Prevalence, smoking cessation and initiation	
Morbidity and mortality	
ENVIRONMENTAL IMPACTS	
Waste, water, soil	

A.4.2. COMPARING THE OPTIONS

In order to evaluate the relative effectiveness and efficiency of the options identified in the impact assessment, consideration has to be given to their positive and negative impacts and how well each option will meet the objective identified in section 3.

Policy option 0, status quo, has been taken as a baseline and therefore the potential positive and negative impacts associated with the other options will be measured against the status quo.

To help comparisons between options the impacts have been rated: +++: fully achieves the objectives; ++: mostly achieves the objectives; +: partly achieves the objectives 0: no impact on the achievement of the objectives; -: partly impedes the achievement of objectives; - -: mostly impedes the achievement of objectives; ---: fully impedes the achievement of the objective.

Two **important explanations** are warranted: (1) For the purpose of the scoring exercise, the impacts on economic players and on employment have been limited to the **tobacco sector**, although it is expected that money not spent on tobacco will be spent on other products and services and will benefit the economy and employment in these other sectors. This is described in more details in Annex 5, which suggests that – from a macro-economic

perspective – measures impacting strongly on the tobacco industry are positive for the economy as a whole.

(2) When comparing the status quo (national discrepancies) with a situation in which industry has to adapt its production lines to one EU standard (e.g. on labelling and content/ingredients) it is generally accepted that **cost savings** are achieved for the "one off costs" (familiarisation etc.). Also economies of scale are possible if industry has to comply with one EU standard. For the running/variable costs the impact will also depend on the envisaged measure. However, these (positive) direct impacts could be outweighed by "**indirect impacts**" linked to the decrease in tobacco consumption (for details see Annex 5), which explains in the table below why the impact on the tobacco industry could be negative.

A.4.2.1. STP and extension of the product scope

A.4.2.1.1. Smokeless tobacco products (STP)

A.4.2.1.1.1. Comparison table

Impacts	**Specific criteria**	**Option 0:** No Change	**Option 1:** Lift the ban or oral tobacco and subject all STP to general product standards	**Option 2:** Lift the ban on oral tobacco and subject all STP to stricter labelling and ingredients regulation	**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**	**Option 4:** Maintain the ban on oral tobacco and subject all STP to the same treatment	**Option 5:** Remove the current circumvention potential of STP
Economic	***Internal market***	0	+	+ +	+ +	+ + +	+
	Economic players	0	+ +	+	-	- -	- - -
	Governmental	0	0	0	0	0	0
	Consumers	0	+	+	+ +	+	0
	International	0	0	+	0	+	0
Social	***Employment***	0	+ +	+	-	- -	- - -
	Equality	0	- -	-	+ +	+ +	+
Health	***Awareness/Appeal***	0	- -	-	+ +	+ +	+ +
	Prevalence	0	- -	-	+	+ +	+ +
	Morbidity	0	-	-	+	+	+
Envi	***Waste, water, soil***	0	0	0	0	0	0

A.4.2.1.1.2. Reference

Detailed explanations can be found in section 5.2.1. of the main report.

A.4.2.1.2. Nicotine containing products (NCP)

A.4.2.1.2.1. Comparison Table

Impacts	Specific criteria	**Option 0:** No Change	**Option 1:** Subject all NCP to labelling and ingredients requirements under TPD	**Option 2:** Establish a new authorisation scheme for NCP	**Option 3:** Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements	**Option 4:** Subject all NCP to the medicinal products' legislation
Economic	***Internal market***	0	+	+	++	+
	Economic players	0	-	-	-	- -
	Governmental	0	+	-	+	+
	Consumers	0	+	+ +	+	+
	International	0	0	0	0	0
Social	***Employment***	0	-	0	0	0
	Equality	0	+	-	++	+ +
Health	***Awareness/Appeal***	0	+	-	+	+
	Prevalence	0	0	0	+	+
	Morbidity	0	+	+ +	+++	+ + +
Envi	***Waste, water, soil***	0	0	0	0	0

A.4.2.1.2.2. Reference

Detailed explanations can be found in section 5.2.2. of the main report.

A.4.2.1.3. Herbal products for smoking

A.4.2.1.3.1. Comparison table

Impacts	Specific criteria	**Option 0:** No Change	**Option 1:** Subject all herbal products for smoking to labelling requirements under TPD	**Option 2:** Phase out marketing of herbal products for smoking
Economic	*Internal market*	0	+	-
	Economic players	0	-	- -
	Governmental	0	0	0
	Consumers	0	+	-
	International	0	0	0
Social	*Employment*	0	-	- -
	Equality	0	++	+++
Health	*Awareness/Appeal*	0	++	n.a.
	Prevalence	0	++	+ ++
	Morbidity	0	++	+ ++
Envi	*Waste, water, soil*	0	0	0

A.4.2.1.3.2. Reference

Detailed explanations can be found in section 5.2.3. of the main report.

A.4.2.2. Packaging and labelling

A.4.2.2.1. Comparison table

Impacts	Specific criteria	**Option 0:** No Change	**Option 1:** Mandatory enlarged picture warnings	**Option 2:** Option 1 plus harmonise certain aspects of pack and FMC appearance and prohibit promotional and misleading elements	**Option 3:** Option 2 plus full plain packaging
Economic	***Internal market***	0	+	++	++
	Economic players	0	-	-	- -
	Governmental	0	0	+	+
	Consumers	0	+	++	+
	International	0	+	+ +	+
Social	***Employment***	0	-	-	--
	Equality	0	+	+++	++
Health	***Awareness/Appeal***	0	+	++	+++
	Prevalence	0	+	++	+++
	Morbidity	0	+	++	+++
Envi	***Waste, water, soil***	0	0	0	0

A.4.2.2.2. Reference

Detailed explanations can be found in section 5.3. of the main report.

A.4.2.3. Reporting and regulation of ingredients

A.4.2.3.1. Comparison table

Impacts	Specific criteria	**Option 0:** No change	**Option 1:** Common reporting format on a voluntary basis. Prohibit toxic, addictive and attractive additives in tobacco products.	**Option 2:** Mandatory reporting in harmonised format. Prohibit products with characterising flavours.	**Option 3:** Mandatory reporting in harmonised format. Prohibit all additives not essential for manufacturing.
Economic	***Internal market***	0	--	++	+++
	Economic players	0	+	0	---
	Governmental	0	+	+	+
	Consumers	0	0	0	--
	International	0	0	0	--
Social	***Employment***	0	0	0	-
	Equality	0	0	+	+
Health	***Awareness/Appeal***	0	-	+	+
	Prevalence	0	0	+	++
	Morbidity	0	0	+	++
Envi	***Waste, water, soil***	0	0	0	0

A.4.2.3.2. Reference

Detailed explanations can be found in section 5.4. of the main report.

A.4.2.4. Cross-border distance sales of tobacco

A.4.2.4.1.1. Comparison table

Impacts	Specific criteria	**Option 0:** No change	**Option 1:** Minimum harmonisation requiring notification and age verification system	**Option 2:** Prohibit cross border distance sale of tobacco products
Economic	***Internal market***	0	++	+
	Economic players	0	+ +	+
	Governmental	0	+	+ +
	Consumers	0	+++	+
	International	0	+	+ +
Social	***Employment***	0	++	+
	Equality	0	+	+
Health	***Awareness/Appeal***	0	+	+ +
	Prevalence	0	+	+
	Morbidity	0	+	+
Envi	***Waste, water, soil***	0	0	0

A.4.2.4.1.2. Reference

Detailed explanations can be found in section 5.5. of the main report.

A.4.2.5. Traceability and security features

A.4.2.5.1. Comparison table

Impacts	Specific criteria	**Option 0:** No change	**Option 1:** EU tracking and tracing system	**Option 2:** Tracking and tracing system, complemented by security features
Economic	***Internal market***	0	+ +	+++
	Economic players	0	+ +	++
	Governmental	0	+++	+++
	Consumers	0	++	+++
	International	0	+++	+++
Social	***Employment***	0	+	++
	Equality	0	+	+ +
Health	***Awareness/Appeal***	0	++	+++
	Prevalence	0	++	+ ++
	Morbidity	0	++	+ ++
Envi	***Waste, water, soil***	0	0	0

A.4.2.5.2. Reference

Detailed explanations can be found in section 5.6. of the main report.

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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)

{COM(2012) 788 final}
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A.5 SOCIO-ECONOMIC IMPACT OF THE OPTIONS

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A.5.1. INTRODUCTION

This Annex outlines the expected **socio-economic impacts** of the policy options on economic stakeholders active in the tobacco supply chain as well as on Governments and society at large. It analyses how a **reduction of tobacco consumption** will impact on the stakeholders (e.g. loss of revenues). This is referred to as the *indirect* impact of the envisaged measures. The main part of this Annex consists of four sections.

Section 1 outlines the methodological approach taken for the analysis. **Section 2** describes the expected impact on the revenues and profits of the economic stakeholders. The analysis focuses on the tobacco industry, its upstream suppliers and its downstream distributors. The section also describes how a negative impact on these stakeholders will be compensated by a positive impact on other sectors, taking into account that money not spent on tobacco is spent on other economic activities.

Section 3 deals with the impact on Governments and society at large. It explains the positive impacts of reduced tobacco consumption on public health, on costs for medical treatment and smoking related absenteeism. These positive impacts are also contrasted with the anticipated negative impact on tax revenues associated with a decline of tobacco consumption, even though the tax reductions are not really a cost to society, but rather a transfer of resources within the society.

Section 4 analyses the impact of reduced tobacco consumption on employment in the tobacco industry, its upstream suppliers and downstream distributors, as well as in other economic sectors (redistribution effect). A particular focus will be placed on the input/output model which outlines how money not spent on tobacco would be spent on other economic activities. This section also addresses regional issues.

A.5.2. SOCIO-ECONOMIC IMPACT ASSOCIATED WITH A REDUCTION OF TOBACCO CONSUMPTION

A.5.2.1. Methodological approach

The main objective of the analysis in this annex is to quantify socio-economic impacts linked to a drop in cigarette/RYO prevalence and consumption, as a result of the implementation of the proposed preferred policy options. For this, our analysis was based on the assumption that the **combination of the envisaged policy options would lead to a drop of tobacco consumption of 2% for cigarettes and RYO**[1] beyond the baseline in 5 years. In absolute figures, such a drop in tobacco consumption corresponds to **2.4 million Europeans** that would either not start smoking or successfully manage to quit smoking.

The expected impacts are analysed for the **fifth year after transposition** of the envisaged directive, i.e. at a time when the measures are expected to develop their major impact in terms of decreased consumption. This should not be understood to mean that there are no **impacts on consumption** before or after "year five". On the contrary, the drop in tobacco consumption is expected to develop gradually, starting already in year one and continuing

[1] The focus on cigarettes and RYO is due to the fact that the preferred policy options focus on these segments and concrete measures are proposed for them whilst for other tobacco products (pipe and cigars) the preferred options foresee delegated powers. For smokeless tobacco and herbal products intended for smoking, the reference is made to the analysis on policy area 1 (scope).

beyond year five. This is for example due to the fact that some provisions (e.g. new mandatory picture warnings) are expected to initially affect actual and potential smokers awareness before leading to a change in smoking behaviour, while other provisions (e.g. the ban of characterizing flavours) may have a more direct/immediate effect on smoking behaviour. Overall, the measures are expected in particular to affect the uptake of smoking in young people leading to a continuous reduction in smoking consumption in the long run. This effect develops and reinforces itself over time[2].

Some **benefits of reduced tobacco consumption on public health** will also only develop over time. While improvement for certain tobacco related acute diseases (e.g. respiratory illnesses) are expected to be seen within short time period, the effect on some other diseases (e.g. cancer) may take several decades to fully materialise. A scientific study from 1997 suggests that maximum health benefits from tobacco control policies are observed five years after a tobacco control measure is introduced[3]. In this light, "year five after transposition" was selected as a good proxy for the analysis of the effects. The long term benefits (e.g. reduced cancer rates) are anticipated to allow for a fair comparison. Social discounting is used where appropriate.

As indicated the preferred policy measures are – in combination - expected to lead to a **decrease of consumption of 2% compared to the baseline**[4]. This assumption is in line with expectation and experiences of other tobacco control agencies which have observed similar drops for comparable policy measures. According to these, the main contributions are expected from the policy areas on packaging and labelling and ingredients. Whilst the details how each policy area contributes to the decrease of consumption are set out in the introductory part of section 5.7 of the IA report, the following table contains an overview:

Table 2.1: Contributions of individual policy areas to the projected decrease of cigarette/RYO consumption

Policy area		Foreseen contribution to the decrease in %
Scope	(STP)	0.2-0.3
	NCP	
	(Herbal)	
Packaging & Labelling		1-1.5
Ingredients		0.5-0.8
TOTAL		**1.7-2.6%**
Cross-border distance sales + Illicit trade		Additional decrease of consumption, however not in the legal supply chain. (Decreases in illicit consumption is expected to partially mitigate the decrease in the legal chain).

[2] In this respect it is considered that more than 80% of smokers start smoking when they are under age (teenagers) and that nicotine contained in tobacco has addictive properties, which makes smoking cessation a challenge. It is also considered that people, who do not start smoking under age, are less likely to start smoking at a later stage and that children of smokers are significantly more likely to start smoking
- Anne Charlton, Youth and Cigarette Smoking, http://www.globalink.org/en/youth.shtml, accessed on 11 March 2012
- Meg Riordan, Campaign for Tobacco-Free Kids; www.tobaccofreekids.org/research/factsheets/pdf/0127.pdf, accessed on 11 March 2012
- U.S. Department of Health and Human Services, Preventing tobacco use among young people; http://profiles.nlm.nih.gov/ps/access/NNBCLQ.ocr, accessed on 11 March 2012

[3] Jan J. Barendregt, M.A., Luc Bonneux, M.D., and Paul J. van der Maas, Ph.D. N Engl J Med 1997; 337:1052-1057

[4] For description of the base line see section 2.3 of the main report.

The figures in the above table should be interpreted with caution. Firstly, the proposed measures are mutually reinforcing. For example, improved health warnings and an improved ingredients policy both have the public health objective of making it less attractive for young people to start smoking[5]. The combination of these measures is expected to have a better effect than the sum of each individual measure. Secondly, from an *ex post* perspective it is sometimes not straight forward to fully disentangle the impact of the different measures. Typically **tobacco regulators introduce a variety of measures at the same time**. This is due to the fact that there is not one single policy measure that could make the introduction of all other tobacco control measures redundant. Tobacco control policy measures include among others price/tax policies, smokefree environments, information campaigns, advertising bans/limitations, health warnings. The task to say with precision which measure contributed to the success and to which degree is further complicated by the fact that certain measures require time to take full effect (see above). Lastly, the success of many of the policy measures implemented in other jurisdictions needs to be judged against the backdrop of existing measures, national/cultural differences and the economic situation of the country concerned. The same applies to the situation in the different Member States.

In the light of the arguments above, it seems preferable to work on the basis of the assumption that the **combination of the envisaged measures will lead to a drop of consumption of 2% in 5 years' time**.

For the sake of clarity and transparency, annex 5 provides not only the calculations for a 2% reduction, but also **calculations based on higher and lower impact scenarios**. This is done to show that more stringent measures could have even bigger impact (e.g. plain packaging, full ban of additives, full ban of displays, which could lead to a reduction of consumption of up to 5%), but also to show - if the current expectations prove not to be correct - that even smaller decreases in tobacco consumption are beneficial and therefore make sense from an impact assessment point of view. This simplified sensitivity analysis did **not suggest any significant variation of qualitative outcomes within the broad range of the assumed consumption drop**.

In order to bring our range into perspective, a comparison can be made with various global targets. For example, the WHO envisages a 40% relative reduction in prevalence of current tobacco smoking by the year 2025, taking 2010 as a base year. In comparison to these figures, the projected consumption drop is not overly ambitious, even if tobacco product regulation is just one tool of many and other tobacco control measures may also contribute to decreasing smoking prevalence.

One last **important caveat** should be remembered, **collecting data and presenting it in a coherent form was a challenge** when preparing the IA report. Whilst all possible efforts were made to gather the most comprehensive data, some challenges remain. For example, some stakeholders either did not provide the requested information or did not provide the information in a usable format. Furthermore, information received from economic stakeholders could not always be reconciled with publicly available data (e.g. Eurostat). The data sets received from industry were also not always fully consistent when comparing data of different market participants (here every effort was made to reconcile the data to the extent possible). In order to ensure overall quality, some key data was verified with associated

[5] Although the main objective of the revised directive is the improvement of the internal market, when it comes to the assessment of the effects of the proposed options, the drop of consumption needs to be assessed in line with the objective of a high level of public health.

services (e.g. tax revenues) and/or industry (e.g. turnover generated with tobacco products and the allocation of shares across stakeholders along the value chain). Finally, information on the illicit part of the market was difficult to establish in a robust form taking into account the nature of these activities.

As explained above, this annex addresses the expectation of how reduced tobacco consumption impacts on various stakeholders. It does not address other (for example direct) impacts associated with a change of regulation (e.g. costs/benefits associated with implementing the new regulatory requirements on labelling). These are described in the respective sections of section 5.5 of the IA report.

A.5.2.2. Impact on the revenues and profits of the economic stakeholders

This section describes the impact that a decrease in tobacco consumption is expected to have on the **revenues and profits of the tobacco industry, its upstream suppliers and its downstream distributors**. It concentrates on **factory manufactured cigarettes (FMC) and roll your own tobacco (RYO)**, as the different policy options focus on these categories of tobacco products[6].

The analysis focuses on the **legal part of the supply chain**. This is not to mean that policy options cannot have an impact on the illicit supply sector. However for the purpose of this impact assessment, the impact of the illicit part of the sector is only relevant to the extent that the illicit market takes away additional revenues from the legal supply chain or that revenues previously attributed to the illicit trade return to the legal supply chain. Moreover, the illicit sector does not deserve any protection in its own right. To the contrary, law enforcement needs to ensure that the illicit part of the market is reduced to the extent possible.

With respect to **illicit trade,** it is also worth noting that none of the preferred options are expected to lead to a (noteworthy) increase in illicit trade beyond the baseline and will therefore not shift additional revenues from the legal to the illicit supply chain. On the other hand, the preferred options in policy areas 4 (cross border (including distributors) 5 (tracking & tracing, security features) are expected to lead to a decrease in illicit trade, which will subsequently lead to part of these revenues returning to the legal supply chain. These effects have, however, not been analyzed in this section in order to ensure full transparency of the impact of the preferred policy options on consumption and to provide a conservative estimate of these impacts[7]. In this respect the analysis below thus amounts to a "**worst case/conservative scenario**" for economic stakeholders.

The analysis is also a "conservative scenario" for economic stakeholders for another reason, when applying the **input/output model** presented in detail in section 5.2.4 for the impact on employment, it appears that money not spent on tobacco will be spent on other goods and services. This will not necessarily benefit the tobacco industry, but will benefit certain parts of the distribution chain (retailers in particular) or upstream suppliers. Accordingly, the effects presented below are maximum negative impacts for the tobacco industry, but not for the economy as a whole (including distributors).

---

[6] For pipe tobacco and cigars/cigarillos only delegated powers are foreseen, in particular if they develop into a smoking initiation products.

[7] See however section 5.6 of the main report.

The **main factors taken into account** in the analysis were (1) revenues generated by the economic stakeholders as well as the added values of the individual sectors in the overall supply chain, (2) the profit margins of the individual sectors and (3) the dependence of different sectors/stakeholders on the revenues generated with tobacco products.

Shares of the stakeholders in the value chain

As explained in Annex 2, in 2010 the **EU-27 market for FMC and RYO was worth 130.6 bEUR at retail level including VAT and excise duties**[8]. Thus, a 1% reduction in tobacco consumption would mean that a 1.3 bEUR decrease in spending on tobacco. However, in order to establish the impact on economic stakeholders the part of turnover associated with taxes (VAT and excise duties) must be removed[9]. Accordingly the total market at retail level accounted for 31.36 bEUR. Of this, 90.4% (i.e. 28.34 billion EUR) are generated from the sales of FMCs, and 9.6% (or 3.02 billion EUR) from RYO. The value generated from other tobacco products[10] are not further considered in this assessment, in particular because the envisaged policy measures are proposed to be currently suspended for these products.

If one assumes a 1% reduction in tobacco consumption, the company revenues from FMC and RYO at retail level would lead to a reduction of 313.6 mEUR, this would double with a 2% reduction and so on. The breakdown for the two product categories considered is 283 mEUR for FMCs and 30 mEUR for RYO if a 1% reduction is observed. Table 2.2 below summarises the revenue loss that all the companies within the tobacco supply chain face when overall tobacco consumption decreases by 1, 2, 3, 4 or 5%.

Table 2.2: Reduction of sales (mEUR)

	Reduction of consumption translated into reduction of tobacco sales at retail level				
	1%	**2%**	**3%**	**4%**	**5%**
Reduced spending on tobacco	1306	2612	3918	5224	6530
- Tax revenue lost	992.4	1984.8	2977.2	3969.6	4962
- Company revenue loss[11]	313.6	627.2	940.8	1254.4	1568

Source: own calculations

The concept of value added

In figure 2.1 below we present the **production/supply chain for cigarettes** in a simplified form. It sets out the main categories of suppliers, the activities of the tobacco companies and the distribution chain.

[8] Matrix report 2012, Euromonitor figure - consist of overall EU market value of FMC (121,3 bEUR) and RYO (9.3 bEUR); see also Annex 2

[9] Euromonitor, DG TAXUD, Matrix report 2012; see also Table 2 in Annex 2

[10] Cigars and cigarillos, pipe tobacco; for EU market shares of these products see Table 1 in Annex 2

[11] Overall tobacco suply chain losses

Figure 2.1: Supply and value chain of tobacco products

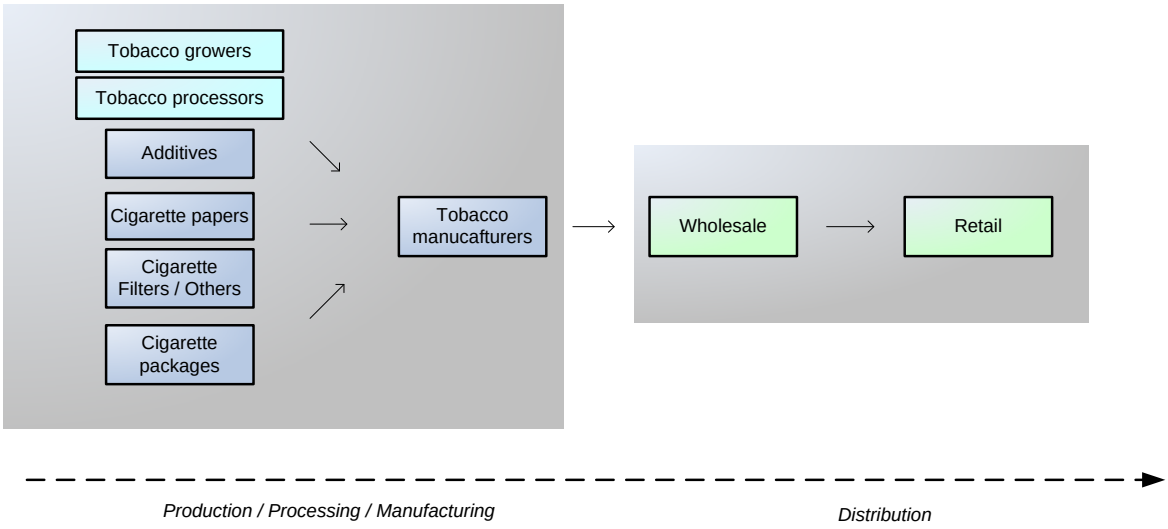

Table 2.4: Revenues (sales to tobacco industry or of tobacco products) and profits (in billion EUR)

	Upstream suppliers						Tobacco industry	Downstream Distribution	
	Leaf production		*Additives*	*Fine Paper*	*Filters/ Others*	*Carton*		*Wholesale*	*Retail*
	Farmers	*Processors*							
Revenue (bEUR)	0.68	2.56	0.61	0.61	1.38	0.91	18.82	23.25	31.36
Profit margin	8.0%	8.0%	6.8%	6.8%	6.8%	6.8%	14.4%	1.5%	1.5%
Profit (bEUR)	0.04	0.22	0.04	0.04	0.09	0.06	2.71	0.35	0.47

Source: own calculation for turnover, S&P Index 500 Stocks margins by sectors

The subsequent sections explain what a drop of consumption in the region of 2% would mean for the different stakeholders along the tobacco supply chain. The analysis starts with the tobacco industry, then turns to upstream suppliers and concludes with downstream distributors.

A.5.2.2.1. Impact on tobacco manufacturing industry

From Table 2.4 we can derive that the **tobacco manufacturing industry generated a turnover of 18.8 billion EUR** in year 2010 with the sale of FMCs and RYO at an ex-factory level excluding taxes[12].

Table 2.5 shows the impact on **revenues and profits** as a result of a declining consumption of FMCs and RYO. The projected decrease of 2% in consumption is expected to lead to total revenue losses for tobacco manufacturers of approximately 376 mEUR, which represents a reduction of profits in the region of 54 mEUR. The profit margins are based on industry averages[13].

[12] Excise duty and VAT
[13] S&P Index 500 Stocks margins by sectors; 3Q/2011; http://mobile.bloomberg.com/news/2011-10-28/summary-of-third-quarter-margins-for-s-p-500-stocks-by-sectors (accessed on 14/3/2012) – subsequently compared with the reported margins of the industry in their publicly available P/L accounts

Table 2.5 Reduction in revenues and profits for tobacco industry

Tobacco manufacture	Reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Revenue loss in sector (mEUR)	188	376	564	753	941
Profit loss in sector (mEUR)	27.1	54.2	81.3	108.4	135.5

Source: own calculation

As indicated previously, the presented reduction in revenues and profits is a "**conservative estimate**" for the industry. For example, that certain sales of the illicit supply chain are expected to return to the legal supply chain as a result of the measures proposed under policy areas 4 (cross border internet sales) and 5 (dealing with measures against illicit trade) has not been considered.[14]

When comparing the expected reduction in revenues and profits with the **actual turnover and profits of the industry for the year 2010** (Table 2.5) as reported by the big four tobacco companies in their P/L accounts (accounting for 80-90% of the EU market), it can be concluded that the impact in relative terms would not be major and the measures are therefore not disproportionate.

Table 2.6: Revenues and profits reported by the industry in 2010[15]

	Data for the "big four" representing almost 90% of the total EU market			
	PMI*	**BAT**	**JTI***	**IT***
Revenues in the EU (in mEUR)	-	4,460	-	-
Profits reported for EU (in mEUR)	-	1,331	-	-
Revenues worldwide (in mEUR)	13,476	17,964	7,857	6,578
Profits worldwide (in mEUR)	5,586	5,212	2,463	2,192

Source: Company financial reports 2010; Companies internet websites[16]

Furthermore, it is important to underline that the relationship between FMC/RYO sales and profits of the tobacco companies is not perfectly correlated[17]. A decrease in cigarette does not necessarily lead to a reduction in relative, or even absolute, profits. It seems that companies, on the basis of their substantial market power, have been able to maintain profits at high levels in recent years despite a decline in sales.

[14] Further details in section 5.5 of the main report.

[15] Financial reports of "big four" tobacco companies; companies internet websites; data converted in EUR with ECB exchange rate as of 16/02/2012; data for EU

[16] Data on revenues and profits derived from sales within the EU were not available (neither made public nor provided by companies on request)

[17] Over last 10 years, Germany and France had a larger sales volume reduction than average, whilst Italy and the UK saw a smaller sales volume reduction than average. The French rise in tobacco profits coincided with a (larger than the EU average) -34% fall in the volume of cigarettes sold in France, and could be explained by both a resistance to the squeezing of profit margins despite rising taxes *and* strong growth in the volume of RYO tobacco (+36%) and cigarillos (+10%) sales; Matrix report 2012

A.5.2.2.2. Impact on tobacco growers and other upstream suppliers

A reduction of tobacco consumption is also likely to impact the **upstream suppliers** to the tobacco industry, as the tobacco industry will reduce its purchases from upstream suppliers in the light of declining sales. For the purpose of this impact assessment, these effects were estimated and are presented below. It is assumed that a 2% reduction in consumption will lead to a linear reduction in purchases of the tobacco industry (FMC/RYO) from upstream suppliers.

Tobacco growers and processors

In 2010, EU based tobacco **growers produced 294,000 tonnes of raw tobacco and generated revenues of 682 mEUR**[18] in sales to the tobacco industry. This includes sales for products other than FMCs and RYO, without adjusting for product exemptions (leading to an overestimation of the overall reduction considering all tobacco products).

Table 2.7 shows the revenue and profit losses in the tobacco growing and processing sector as a result of a declining consumption of FMCs and RYO. The projected decrease of 2% consumption would lead to **total revenue losses for tobacco farmers in the EU** of approximately **13.6 mEUR,** representing an overall sector net profit loss of approximately 1.1 mEUR. This assumes, conservatively, that all sales of raw tobacco were made to EU tobacco manufacturers, which cannot be compensated through other sales.

Table 2.7: Reduction in revenues and profits for tobacco growers and processors

	Reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Tobacco growers					
Revenue loss in sector (mEUR)	6.8	13.6	20.4	27.2	34
Profit loss in sector (mEUR)	0.54	1.09	1.63	2.18	2.72
Tobaco processors					
Revenue loss in sector (mEUR)	25.6	51.2	76.8	102.4	128
Profit loss in sector (mEUR)	2.05	4.10	6.14	8.19	10.24

Source: own calculation

Whilst it is reasonable to assume that a significant number of growers are able to, and actually do, generate at least some **additional revenues with other products**, it was not deemed appropriate to consider these revenues in this impact assessment. In order to maintain a "conservative scenario", it was assumed that no additional revenues were generated by growers. If the overall reduction in profits is distributed over all 86,133 farmers[19] in the EU, the **annual reduction in an individual farmers' turnover amounts to 158 EUR per year**.[20] This appears to be an acceptable burden. In particular, it does not appear that certain types of farmers (Burley or Oriental growers) would be affected in particular manner. Obviously it is unlikely that each farmer will produce 2% less tobacco. Taking into account past experience,

[18] DG AGRI data

[19] Sources: Member States' communications (Commission Regulation (EC) No 2095/2005) ; DGAGRI.

[20] As the EU tobacco consumption is composed by 1/3 of EU production and 2/3 of EU imports, we have also performed a sensitivity analysis assuming that the reduction of 2 - 3%, will affect only the EU production or will affect only the imports into EU. Taking in account these extreme scenarios, the theoretical loss of income for the EU tobacco growers should lie between 0 - 711 EUR/grower.

it is more likely that certain farmers will discontinue their activities whilst other will continue at previous levels.

In this respect it should also be noted that in the past in the EU, the market for growers has decreased faster than the market for FMCs (with sales of RYO even growing).[21] There is thus **no linear correlation between the reduction in smoking consumption and EU farming output**. If this negative trend for growers continues, it is important to distinguish between the baseline scenario (which would predict a negative trend for farmers irrespective of the measures foreseen) and the relatively moderate effects that can be associated with the reduced consumption of FMCs and RYO following the revised TPD.

Finally, table 2.8 below shows that the European market for growers and processors has developed differently from the **world market**. The EU market has seen a decline of 31% from 2000 to 2009 in volume terms, whilst the world market has grown by 7%. It is therefore fair to assume that the underlying cause for the negative trend for European growers is at least partly of a structural nature, including decoupling of subsidies from production in 2004.[22]

Table 2.8: EU production and trade of unmanufactured tobacco (000, tonnes)

	2000	**2009**	**change**	Trade in unmanucatured tobacco (2010)			
				import		Export	
				(000 t)	(mEUR)	(000 t)	(mEUR)
EU 27	439	304	-31%	597	2170	167	686
World Total	6676	7122	7%				

Source: Matrix / Euromonitor; Faostat, Eurostat

In 2010, there were 88 **first processors**[23] of tobacco in the EU. These were located close to tobacco growing regions, with the majority located in Bulgaria and Italy. Two U.S. based leaf tobacco merchants[24] with similar market shares control the major part of the EU market of **second processors.**[25] In 2011, Alliance One delivered 54% of its tobacco sales to customers in Europe (approx. **800 mEUR**).[26]

Table 2.6 above shows the revenue and profit losses in the tobacco processing sector as a result of a declining consumption of FMCs and RYO. The projected decrease of 2% consumption would lead to **total revenue losses for tobacco processors in the EU** of approximately **51 mEUR** which represent overall sector net profit loss of 4mEUR.

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[21] Between 2000 and 2009, the total production of unmanufactured tobacco in the EU decreased by 31%, from 438.7 thousand tonnes annually to 303.8 thousand tonnes annually. The volume of the EU cigarettes market in 2010 (608.8 billion sticks) declined by 23.3% in comparison to 2000. The market size of RYO tobacco in 2010 (75.500 tonnes) increased in comparison to 2000 by 42.2 %. Thus, overall FMC+RYO market decreased by 19.2 % (assuming that 1g of RYO tobacco corresponds to one cigarette).

[22] Negative effect of the reform was the growth of raw tobacco's prices which brings significant competitive disadvantage of EU tobacco growers in the global market.

[23] The first processors collect the raw tobacco cured by farmers and undertake the first process before selling it to the second processors (see also Annex 2), cf. DG AGRI.

[24] Alliance One Int.; Universal Corporation

[25] The second processors subsequently purchase, process, blend, pack, store and ship tobacco to meet each specifications of manufacturers of cigarettes and other tobacco products (see Annex 2).

[26] AOI 2011 Annual Report, http://phx.corporate-ir.net//phoenix.zhtml?c=96341&p=irol-reportsannual, accessed on 29 February 2012. Recently, the Commission fined the company's subsidiaries in Spain, Italy and Greece for operating cartels, but the outcome of the appeal is not yet known.

Other upstream suppliers

Table 2.9 below shows the reduction in revenues and profits of other industries/sectors supplying the tobacco manufacturers as a result of decline in the consumption of tobacco products.

Table 2.9: Reduction in revenues and profits of suppliers to FMC/RYO producers

	Reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Tobacco additives					
Revenue loss in sector (mEUR)	6.1	12.1	18.2	24.3	30.3
Profit loss in sector (mEUR)	0.41	0.83	1.24	1.65	2.06
Cigarette papers					
Revenue loss in sector (mEUR)	6.1	12.1	18.2	24.3	30.3
Profit loss in sector (mEUR)	0.41	0.83	1.24	1.65	2.06
Cigarette packages					
Revenue loss in sector (mEUR)	9.1	18.2	27.3	36.4	45.5
Profit loss in sector (mEUR)	0.62	1.24	1.86	2.48	3.09
Cigarette filters / Others					
Revenue loss in sector (mEUR)	13.8	27.6	41.5	55.3	69.1
Profit loss in sector (mEUR)	0.94	1.88	2.82	3.76	4.70

Source: own calculation; based on data received from industry

The EU based suppliers of **tobacco additives** generated an estimated 610 mEUR of revenue [27] from sales to producers of FMC/RYO in the EU in 2010. The projected decrease of 2% in consumption would lead to total revenue losses for the sector of approximately 12.1 mEUR which represents an overall sector net profit loss of 0.83 mEUR. Given that the **dependence of additives/flavours production sector on tobacco industry is rather limited** (possibly with the exception of some specialised SMEs), the impact of decreasing tobacco consumption on revenues and profit losses within the sector would be marginal.

The EU based suppliers of **cigarette fine papers** generated revenues of 610 mEUR[28] from sales to the tobacco industry in the EU in 2010. Sales to tobacco industry often represents close to 100% of these suppliers total revenue, but only approximately 50% of the sector production is reported as sales within the EU. The projected decrease of 2% in tobacco consumption would lead to total revenue losses for the sector of approximately 12.1mEUR which represents an overall sector net profit loss of 0.83 mEUR. Similarly to suppliers of additives, the 2% decrease in cigarette consumption would have a relatively small impact on overall revenues and profits of the cigarette paper industry representing 1% of the profits taking into account exports.

The EU based suppliers of **cigarette packages** generated revenue of 910 mEUR[29] from sales to the tobacco industry in EU in 2010. The sales to the tobacco industry represent approximately 10% of the sector total revenue. The projected decrease of 2% in cigarettes consumption would lead to total revenue reduction for the sector of approximately 18.2 mEUR which represents an overall sector net profit loss of 1.24 mEUR. Since the dependence

[27] Reconciled from the data obtained from additive and cigarette manufacturers
[28] Reconciled from the data obtained from industry - fine paper producers and cigarette manufacturers
[29] Reconciled from the data obtained from industry – ECMA industry association and cigarette manufacturers

of cigarette package producers on the tobacco industry is low, the overall impact of a decrease in tobacco consumption by 2% on **reduction in revenues in the sector will be an insignificant 0.2%** of total sector turnover.

It is estimated that **other EU based suppliers** to tobacco industries including acetate tow / cigarette filter producers generated revenues of 1.38 billion EUR[30] from sales to the tobacco industry in the EU in 2010. The projected decrease of 2% in cigarette consumption would lead to total revenue losses for the sector of approximately 27.6 mEUR which represents an overall sector net profit loss of 1.88 mEUR. There is insufficient information available on how much the industries concerned rely on sales to the tobacco industry located in the EU[31], but in line with the explanations above it is assumed that the impact on these industries is significantly less than the respective decrease in consumption.

A.5.2.2.3. Impact on wholesalers and retailers

The reduction in consumption will also affect the **downstream distributors** of the tobacco industry, i.e. wholesalers and retailers (which range from specialist retailers to hypermarkets). This section aims at summarizing the expected impacts of reduced consumption on these stakeholders.

Wholesale

The EU based **wholesalers of tobacco products** generated revenues of 23.25 billion EUR[32] from sales of FMC and RYO in the EU in 2010. As shown in the table 2.10, the projected decrease of 2% in consumption would lead to total revenue losses for the sector of approximately 465 mEUR which represents an overall sector net profit loss of 7 mEUR.

Table 2.10: Reduction in revenues and profits of wholesalers

Wholesale	Reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Revenue loss in sector (mEUR)	232.5	465	697.5	930	1162.5
Profit loss in sector (mEUR)	3.49	6.98	10.46	13.95	17.44

Source: Euromonitor; own calculation

In a number of Member States wholesale activities, formerly part of national tobacco monopolies, are operated by large tobacco manufacturers.[33] In other MS the wholesalers are often involved in the distribution of various product categories, and therefore only part of their revenue would be impacted[34].

[30] Reconciled from the data obtained from industry – GAMA industry association
[31] The acetate tow producers are part of big multinational cooperations which generate only a very small fraction of their revenues with acetate tows
[32] Reconciled from the data obtained from industry. Obviously, the wholesalers would have proportionally reduced purchasing costs of 18.82 bEUR. In this regard the sector added value is estimated at 4.4 bEUR.
[33] Case No COMP/ M.4424 JT / Gallaher; Case No COMP/ M.4581 Imperial Tobacco / Altadis. Article 6(2) non-opposition
[34] e.g. Cash and carry warehouses, European Tobacco Wholesalers Association

Retail

The **turnover generated at retail level from tobacco products** (FMCs and RYO) amounted to 31.36 bEUR in 2010.[35] The table below shows the revenue and profit reductions of the retail distributors of tobacco products as a result of declining consumption. The projected decrease of 2% in consumption would lead to total revenue loss for the sector of approximately 627 mEUR (cooresponding to the sector added value of 162 mEUR) which represents an overall sector net profit loss of 9.4 m EUR.

Table 2.11: Reduction in revenues and profits of wholesalers

Retail	Reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Revenue loss in sector (mEUR)	313.6	627.2	940.8	1254.4	1568
Profit loss in sector (mEUR)	4.70	9.41	14.11	18.82	23.52

Source: Euromonitor; own calculation

It is evident that the dependence of retailers on turnover generated with tobacco varies quite significantly. On the one hand, there are specialist tobacco retailers, which generate a significant part of their turnover from tobacco. On the other hand big super markets sell a great variety of products and tobacco products only account for a minor share of their revenues. Table 2.12 below shows the proportion of sales of tobacco products in the EU across the different retail channels and allocates the total revenues at retail level to them. The subsequent column shows the impact of declining consumption for each type, if consumption decreases by 2%. Similarly to previous sections the net profit margin was applied for each of the sectors[36].

Table 2.12 : Shares of retail sale of tobacco products in EU and impact on revenue/profit

Place of sale	Share of retail sales in EU (2010)	Impact of 2% decline in consumption (mEUR)	
		Revenues	Profits
Tobacco specialists	23.8%	149.27	2.24
Newsagent-tobacconists/kiosks	24.7%	154.93	2.33
Supermarkets/discounters	14.6%	91.60	1.37
Hotels/restaurants/bars	1.3%	8.13	0.12
Vending machines	8.6%	53.93	0.81
Small grocery retailers	10.8%	67.73	1.01
Convenience stores	4.9%	30.73	0.46
Forecourt retail / gas stations	8.9%	55.80	0.84
Others	2.4%	15.07	0.23
	100.0%	627.20	9.41

Source: Matrix report 2012; Euromonitor, own calculation

[35] Obviously, the wholesalers would have proportionally reduced their purchasing costs in the range of 23.25 bEUR. In this regard the sector added value is estimated at 8.1 bEUR.
[36] S&P Index 500 Stocks margins by sectors; 3Q/2011

The **retailers most dependent on selling tobacco products**[37] generate an aggregated revenue from selling tobacco products of 15.2 bEUR, which is almost 50% of the total retail revenues from the sales of tobacco products. Assuming that their revenues from tobacco products account for between 45-60% of their total revenues[38], the projected decrease of 2% in cigarettes consumption would lead to revenue losses of 304.2 mEUR, representing 0.9-1.2% of their total revenues. Overall the profit reduction for the retailers most dependent on tobacco would account for 4.57 mEUR.

As discussed in more detail in Section 4, **money not spent on tobacco products will be spent on other products and services**. This will also partially benefit retailers specializing in tobacco (e.g. bars, newsagents, snacks).

All other retailers, which are less dependent on tobacco products, generated revenues from tobacco products in the region of 16 bEUR. Since these revenues form only a fraction of their total revenues, the projected decrease of 2% in cigarettes consumption would influence these retailers only in an insignificant manner.

Whilst the **general trend** in tobacco sales has been downward, the distribution channels through which tobacco is sold changed only slightly between 2000-2010. Declining sales in cigarettes have affected all retail channels, but to different degrees.[39] Furthermore, in recent years, the number of very small mixed businesses in the EU have in general been on the decline. This has resulted mainly from overall consumer behavior changing (e.g. longer working hours and extended shopping hours for supermarkets and major shopping centers). Thus, regardless of public policies on tobacco, the continuing decline in profitability of small corner stores in EU is likely to lead to **concentration of cigarette and tobacco sales by larger retailers**.

A.5.2.2.4. Input output model

As explained, money not spent on tobacco is spent on other goods and services (e.g. food, cloths, holidays, cinemas among others). This additional expenditure is expected to benefit the economic operators concerned (**re-distribution effect**). In order to fully capture the macroeconomic effects, a so-called **input/output model** was used. Whilst this model is explained in more detail in section 4 below (employment), the attached table shows which sectors are expected to benefit from a reduction in tobacco consumption and which sectors are expected to lose revenues (for more detailed explanations see A5.2.4.1 below).

[37] Tobacco specialists, Newsagents-tobacconists/kiosks
[38] Data provided by European Federation of Tobacco Retailers
[39] Over last 10 years, sales have dropped more in specialised stores than in larger supermarkets/hypermarkets or discounters (Matrix report 2012).

Table 2.13: The impact on output of different sectors associated with a reduction in consumption of tobacco by 1% (in billion EUR)

Industry	Monetary impact of reduction in tobacco consumption	Monetary impact of increase in expenditure for other goods	Net effect on output
TOTAL	**-0.574**	**0.634**	**0.059**
Agriculture	-0.025	0.017	-0.008
Mining and petroleum	-0.002	0.006	0.005
Food industries	-0.012	0.067	0.054
Tobacco	-0.197	0	-0.196
Textile	-0.002	0.022	0.019
Wood and wood products	-0.003	0.018	0.015
Paper products and printing	-0.018	0.007	-0.011
Chemical products	-0.011	0.014	0.003
Rubber products	-0.003	0.005	0.002
Metal and non metal products	-0.004	0.009	0.005
Basic metal products	-0.004	0.008	0.004
Machinery	-0.005	0.009	0.004
Transport devices	-0.025	0.057	0.033
Housing and Electricity	-0.011	0.07	0.059
Finance and trade and insurance	-0.018	0.018	0
Wholesale and retail	-0.033	0.044	0.011
Services	-0.095	0.136	0.041
Compensation of employees	-0.093	0.108	0.014

Source: Matrix report 2012

A.5.2.3. Impact on society and Government budgets

For the society as a whole, a reduction in tobacco consumption has mostly **positive implications** (improved public health, reduced health care costs and less absenteeism). However, it might also have some adverse impacts on budgets (reduction in **tax revenues**), even if in the past a reduction in tobacco consumption has not lead to a decrease of revenues and from a macro-economic perspective represents only redistribution of the resources to other stakeholders with the society.

This section describes the effects outlined above in more details. It starts with the positive effects associated with a reduction in tobacco consumption and then turns to the budgetary implications of this reduction. The subsequent section balances both effects and comes to the conclusion that the positive effects outweigh the negative effects. In order to cater for the benefits and costs that occur in different time periods, social discounting is applied in the last part of this Section.

A.5.2.3.1. Positive impacts of reduced consumption

The main positive impact of reduced tobacco consumption is that **public health is significantly improved**. People, who do not smoke/stop smoking in time, live significantly longer with better health. It is evident that across society and individuals, as well as for their families and those close to them, a gained (healthy) life year is a very significant and precious value in its own right. This effect will be outlined in the first subsection, which also monetises

the value in line with the Commission's Impact Assessment guidelines to allow for comparisons to be made.

Apart from improved public health (i.e. decreased mortality and longer healthy life years), reduced tobacco consumption will also lead to **lower health care costs** and to **improved productivity** due to fewer cases of absenteeism and premature retirements. These impacts will be described in the second and third subsections.

A.5.2.3.1.1. Morbidity and mortality caused by tobacco

The risks associated with smoking

From a scientific/medical perspective, it is by now generally acknowledged that smoking harms nearly every organ of the human body, causing a broad range of diseases.[40] At least 24 of these smoking induced diseases are fatal, whereas others lead to chronic illnesses. The long-term risks of smoking have been extensively quantified in a cohort study of British doctors that compared the overall survival of smokers and non-smokers over time. This **study showed that at least 50% of smokers die prematurely.**[41]

Another study based on Danish data compared the **average lifetime in good health** of smokers and non-smokers and found that, in addition to the years lost from dying earlier, smokers suffer from poor health conditions for a greater number of years compared to non-smokers. Men who smoked heavily (defined here as at least 15g of tobacco per day) had 8 years more of poor health than people who never smoked. Women who smoked heavily had an average of 12 years more of poor health, in addition to their earlier loss of life.[42] A number of studies have also found similar results.[43,44,45]

Peto et al[46] have estimated that in the EU27 smokers who die in middle age as a result of their tobacco consumption lose an average of 22 years of life. Even those who die at age 70 or older as a result of their smoking at lose on average 8 years of life. Peto et al estimates that, on average, **smokers who die as a result of their tobacco consumption die 14 years earlier than people who never-smoked**. Other studies come to similar conclusions.[47]

These findings also allow for a comparison between different risk factors that lead to premature mortality, for every 1000 individuals who smoked regularly across all EU countries (reference year 2000), 500 will die from smoking related illness, whilst only seven will be

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40 US Department of Health and Human Services. The health consequences of smoking: a report of the Surgeon General.Washington, Government Printing Office, 2004.
41 Doll R, Peto R, Boreham J, Sutherland I. (2004). "Mortality in relation to smoking: 50 years' observation on male British doctors". BMJ 328 (7455): 1519.
42 Bronnum-Hansen H, Juel K. Abstention from smoking extends life and compresses morbidity: a population based study of health expectancy among smokers and never-smokers in Denmark. Tobacco Control 2001; 10: 273-278.
43 Nusselder WJ, Looman CW, Marang-van de Mheen PJ, van de Mheen H, Mackenbach JP. Smoking and the compression of morbidity. J Epid Comm Health 2000; 54: 566-574.
44 Klijs B et al. Obesity, smoking, alcohol consumption and years lived with disability: a Sullivan life table approach. BMC Public Health. 2011; 11: 378.
45 Bronnum-Hansen H, Juel K, Davidsen M, Sorensen J. Impact of selected risk factors on expected lifetime without long-standing, limiting illness in Denmark. Prev Med. 2007;45(1):49–53.
46 Peto R, Lopez AD, Boreham J,Thun M. Mortality from Smoking in Developed Countries 1950-2010. 2nd Edn. Imperial Cancer Research Fund, World Health. Data updated November 2011. Organization. Oxford, Oxford University Press,
47 http://www.cpinternet.com/~mdmagree/smokers_2006-01-19.html

killed in road accidents and only one will be murdered.[48] Smoking is generally seen as the largest avoidable health threat in Europe and the rest of the world.

Healthy life years as a value to society

Every civilised society **strives to avoid premature death of its citizens and to maintain a high level of public health**. For example, EU Member States build hospitals and medical research centres, finance the education of doctors and nurses, and provide public health insurance that reimburses medical treatments, pharmaceuticals and medical devices. Even outside the healthcare sector, many measures are introduced to improve public health and/or ensure a high level of public health. Some examples of Member State actions, across different sectors, that demonstrate these societal efforts towards a high level of public health forcefully are the obligation to wear seat belts in cars, the prohibition of dangerous pesticides that could potentially enter the food chain and the introduction of legislation that requires the removal of asbestos in public buildings.

The underlying reason for all these policies is that Member States governments and societies in general attribute a high value to the avoidance of premature death and a high level of public health. **Life in general and healthy life years in particular are a value in their own right** and in most constitutions of Western societies the right to live and the right to have access to medical treatment is recognised as human right of highest importance. With the same token societies do not allow companies to put their profits above public health as repeated scandals in health care sector show (e.g. Mediator case in France[49]).

Traditionally, the **question whether a public measure improving public health makes sense from an economic perspective is of secondary nature**. Nobody seriously raises the question whether society should stop medical treatment of people who are no longer part of the active workforce or whether citizens should be obliged to wear seat belts. However in times of economic crisis it is important to ensure that measures are not only beneficial to society but also cost effective. A good example, is the approach of the UK public body NICE, which evaluates whether a new medicine should reimbursed based on both its cost and the number of healthy life years gained from the treatment.

The attempt to monetise

In light of the above, economists have repeatedly attempted to **monetise the value of life** in order to provide regulators with a tool to decide whether certain policy measures are beneficial for society (e.g. because the measures are cost-effective). Concretely at least two approaches are discussed: (1) the loss of productive capacity (a tangible cost) and (2) the psychological effects borne by the deceased and others (an intangible cost).

The first method focuses on the loss of productive capacity. The approach is known as the **human capital approach**. It involves estimating and monetising the loss of the expected productive capacity. The second method also looks at the psychological costs of premature death/avoidable illness. This approach is also known as the **willingness-to-pay approach**, in which researchers identify how much people would be willing to pay to reduce the risk of

[48] ASPECT 2004 study

[49] http://www.afssaps.fr/Dossiers-thematiques/Mediator-R/Mediator-R-et-accompagnement-des-personnes/(offset)/0

death in a particular period of time. Generally, intangible costs (willingness-to-pay) are more difficult to establish than tangible costs, for which conventional markets (market prices) exist.

If regulators merely take into account the human capital approach, the **premature deaths of people above workforce age** could be considered to have no cost/limited costs to society since no productive capacity is lost. Indeed, when such an approach is taken, it can be argued that some "benefits" accrue to society as a whole from the premature death of old people, since certain resources (such as pension payments), which would have be needed to meet the needs of the deceased, are now saved. **It can thus be concluded that looking only at the human capital approach would not be in line with the Europe's values**.

As indicated above, European societies and Member States actions (including the allocation of substantial health care resources to the aged) demonstrate that **lives of people/healthy life years are valuable in their own right, irrespective of whether the persons concerned are part of the work force.** Thus, while it is important to evaluate the loss of productive capacity, it is not appropriate to ignore the social costs of premature deaths.

The analysis method used by the European Union considers the **value that is attributed to each life year gained**, not the value of a lost life itself (which can involve the loss of many years of living or just a few months). The values used in the Commission's impact assessment guidelines are based on surveys or observations of the research project ExternE, which established a 'typical' range of €50,000 to €100,000 for the **value of one life year (VOLY)**. The median of estimates of intangible value of the loss of one year's living (as included in the Commission's Impact Assessment guidelines), is **€52,000** irrespective of the age or country of residence of the victim.

Table 3.1 shows that premature deaths in the population due to smoking is a very significant burden associated with tobacco consumption. In total, **almost 700,000 premature deaths** (i.e. 15% of all deaths in the EU for those over 35) can be attributed to smoking, out of almost 5 million total deaths annually observed in the EU (year 2005).

Table 3.1: Overall estimated mortality attributable to smoking in the EU27 in 2005

Gender	Total mortality	Attributable to smoking	As % of total mortality
Males	2,404,508	522,267	21.7
Females	2,408,625	176,557	7.3
Total	4,813,133	698,824	14.5

Source: R. Peto, 2011

Expressed in life years, it is calculated that in 2010, **about 9.94 million years are lost prematurely**. Applying the estimate from the ExternE project, the **loss to society caused by premature deaths associated with smoking thus amounts to a monetised value of 517 bEUR for the EU**, which corresponds to about 4.7% of the GDP (Table 3.2).

Table 3.2: Estimated monetary value of years of life lost (YLL) due to smoking

	Total YLL due to smoking	Monetary value of loss (mEUR)	As % of EU	GDP (mil.EUR at PPS[50])	Loss as % of GDP (at PPS)
Austria	132,411	6,885	1.3	244,796	2.8
Belgium	226,637	11,785	2.3	298,464	3.9
Bulgaria	179,103	9,313	1.8	78,424	11.9
Czech Republic	219,861	11,433	2.2	202,557	5.6
Denmark	157,613	8,196	1.6	159,410	5.1
Estonia	25,989	1,351	0.3	19,993	6.8
Finland	65,266	3,394	0.7	144,259	2.4
France	1,116,577	58,062	11.2	1,639,459	3.5
Germany	1,563,453	81,300	15.7	2,224,648	3.7
Greece	206,717	10,749	2.1	249,870	4.3
Hungary	434,458	22,592	4.4	152,259	14.8
Ireland	67,451	3,507	0.7	133,871	2.6
Italy	992,332	51,601	10.0	1,469,877	3.5
Latvia	48,974	2,547	0.5	27,152	9.4
Lithuania	66,660	3,466	0.7	42,754	8.1
Luxembourg	5,582	290	0.1	31,102	0.9
Malta	4,900	255	0.0	7,978	3.2
Netherlands	365,121	18,986	3.7	511,825	3.7
Poland	1,080,437	56,183	10.9	543,816	10.3
Portugal	130,191	6,770	1.3	199,839	3.4
Romania	511,757	26,611	5.2	237,224	11.2
Slovakia	98,134	5,103	1.0	92,359	5.5
Slovenia	37,966	1,974	0.4	41,781	4.7
Spain	721,281	37,507	7.3	1,112,893	3.4
Sweden	122,421	6,366	1.2	260,683	2.4
Unit. Kingdom	1,355,499	70,486	13.6	1,606,081	4.4
Total	**9,936,789**	**516,713**			**4.7**

Source: GHK; 2012 data[51], Cyprus excl.

Application of the methodology to the expected reduction of tobacco consumption

The above methodology can be applied to the expected drop in tobacco consumption. Table 3.3 shows how the estimated losses to society caused by premature deaths would decrease, if tobacco consumption is reduced by 1, 2, 3, 4, or 5%. For example, a 2% decline in consumption would result in a **net benefit to society of 10.3 bEUR per year**.

Table 3.3: Estimated monetary benefit of decreased mortality

	Premature mortality decrease with different percentage reduction in tobacco consumption				
	1%	**2%**	**3%**	**4%**	**5%**
Premature mortality cost due to smoking (mEUR)	511,546	506,379	501,212	496,044	490,877
Net benefit (mEUR)	5,167	10,334	15,501	20,669	25,836

Source: GHK 2012, own calculation

[50] Gross domestic product adjusted for the size of an economy in terms of population and also for differences in price levels across countries

[51] A Study on Liability and The Health Costs of Smoking. GHK, revised report published in June 2012.

It is important to underline again that the above approach is merely an **attempt by economists to express in monetary terms how much society values life in general and (healthy) life years in particular**. It is a proxy for the fact that people do not wish to die prematurely. It is also important to underline again that a good part of the benefits associated with reduced tobacco consumption will accrue only in a few years time (e.g. when a drop in cancer treatments are observed).

Implications for social security system

As indicated above, **certain studies,** including one study from the tobacco industry which was later withdrawn, have argued that smokers subsidise non-smokers' pensions, at least in some countries.[52] Society would thus benefit from premature deaths caused by smoking.

In this respect, it is first important to underline that **other studies**[53] have argued that smokers' greater disabilities (fewer healthy life years) lead to net pension payments to them. It has also been argued in more general terms that the net lifetime costs of smokers are superior for the State than the costs for non-smokers, in particular if one includes indirect costs. Evidence from Sweden shows that smokers use the social welfare systems more than non-smokers, and that smoking leads to net lifetime external costs for men and women currently smoking, and even for former male smokers.

Furthermore it should be noted that **people above the official workforce age actively participate in the economy**, be it as consumer, as investor or as provider of often unpaid services, e.g. taking care of children. The pension age in most Member States is also currently being increased. It can therefore be expected that the current work force will work much longer than in the past, increasing potential productivity losses in the future, in particular considering the demographic development of Europe.

In any event, it is important to underline that the arguments developed in the studies mentioned above are contrary to the approach foreseen by the Commission's impact assessment guidelines, which **attributes a value to each (healthy) life year** irrespective of the fact whether the person is still an active member of the active work force or not. This is due to the fact, as previously mentioned, that life has a value in its own right.

A.5.2.3.1.2. Health care budget

Another major benefit for society and Governments is that a reduction in tobacco consumption is expected to lead to reduced health care costs.

The health care costs associated with treating smoking related diseases

Governments/societies incur very significant costs associated with **smoking-related diseases**. The size of these costs depends on the extent to which healthcare, prevention and public health services are covered by public funds. Indirectly, the burden on Governments also appears in the form of smoking related disabilities and social benefits payments, lost income

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[52] Arthur D. Little International Inc. Public finance balance of smoking in the Czech Republic, 1999. http://www.mindfully.org/Industry/Philip-Morris-Czech-Study.htm (accessed 15 February 2012).

[53] - Atkinson AB, Skegg JL*(1973) Anti-smoking publicity and the demand for tobacco in the UK. The Manchester School of Economic and Social Studies* ***41****:265–282.*

- Anneli Taala, Raul Kiivet,b and Teh-Wei Huc (2004); The Economics of Tobacco in Estonia

tax and lost contributions to social benefits funds. This section focuses on health care costs, whereas the issue of absenteeism is addressed in the next subsection.

With respect to **health care costs,** it has been well documented through clinical evidence that smoking increases the risks of individuals contracting certain diseases requiring health treatment. For the purposes of the analysis, the **direct costs** to European public healthcare systems were considered in terms of the estimated amount of healthcare expenditure attributable to the treatment of diseases caused by smoking in a given year. Direct costs represent the costs of in-patient and out-patient treatment and the cost of medication.

There are **six main disease categories** that are associated with smoking. This includes respiratory and cardiovascular diseases or cancers. In order to estimate the expenditure on health attributable to smoking, a standard smoking attributable factor (SAF) for each six disease categories was used[54]. Table 3.4 presents these diseases and the total treatment costs per disease that is attributable to smoking.

The calculation on the expenditure is based on the annual EU public healthcare expenditure for diseases, which might be caused by smoking and the subsequent attribution of this total expenditure to different causes (including smoking) on the basis of available statistical data. In conclusion, **healthcare expenditure on treating smoking attributable diseases is estimated to be around 25 bEUR** which corresponds to 2.89% of total healthcare spending in the EU27 and 0.22% of GDP.

Table 3.4 EU-wide health care expenditures on treatment of smoking attributable diseases

Disease category	Costs (bEUR)
Cardiovascular diseases	9.113
COPD	5.081
Lung cancer	3.641
Other cancers	3.063
Other respiratory diseases	2.662
Upper aerodigestive cancers	1.740
Total	**25.300**

Source: GHK, 2012

Benefits from a decline in smoking consumption

Declines in smoking consumption will lead to a **reduction in health care costs**. The extent of the reduction will depend on the success of the envisaged measures.

For certain diseases there will be a **time lag** before the reduced heath care costs are observed (e.g. cancer treatments), whereas for other diseases (e.g. respiratory and cardiovascular) the savings will be more immediate. Regarding respiratory diseases many ex-smokers feel immediate positive effects when they stop smoking, with smokers frequently suffering from coughing, headache, eye irritation, sore throat, sneezing and runny nose, nausea, breathing

[54] The estimates of the costs to public healthcare systems of treating smoking attributable diseases are based on incidence data and average of per case expenditure based on data from the UK, Germany and the Netherlands (data 2008-2010).

problems, and irregular heartbeat.[55] Lightwood and Glantz estimated that **each new non-smoker** as a result of the Californian anti-smoking campaign **reduced anticipated medical costs** associated with acute myocardial infarction and stroke by $47 in the first year and by **$853 during the next 7 years**.

In order to present the figures for one single year (year 5 after transposition), the costs for the long term treatments were anticipated. In this light it is expected that the annual net benefit of a reduction in tobacco consumption by 2% amounts to **506 million EUR** per year. The current value of this benefit should be the same or even higher considering the inflation of the health care costs above the average.

Table 3.5: Estimated savings in health care expenditures

	Health care expenditures with different percentage reduction in tobacco consumption				
	1%	**2%**	**3%**	**4%**	**5%**
Projected Total EU health care expenditures (mEUR)	19,628	19,430	19,232	19,034	18,836
Net benefit (mEUR)	198	396	594	792	990

Source: GHK, 2012, own calculation

Lifetime costs of smokers and non-smokers

Smoking is a major health hazard, and since non-smokers are healthier than smokers, it is only natural that health care systems spend less money on non-smokers compared to smokers, which is confirmed by a number of studies.[56,57,58] Not smoking saves money spent on health care.[59] In each age group, the annual per capita health care costs for smokers are higher than for non-smokers and they rise sharply with age. The difference varies according to age group, but according to some sources the costs for smokers among 65-to-74-year-olds are as much as 40 percent higher for men and as much as 25 percent higher for women.

[55] Lightwood JM, Glantz SA. Short-term economic and health benefits of smoking cessation: myocardial infarction and stroke. Institute for Health Policy Studies, Department of Medicine, University of California, San Francisco 94143-0124, USA. Circulation. 1997;96:1089-1096

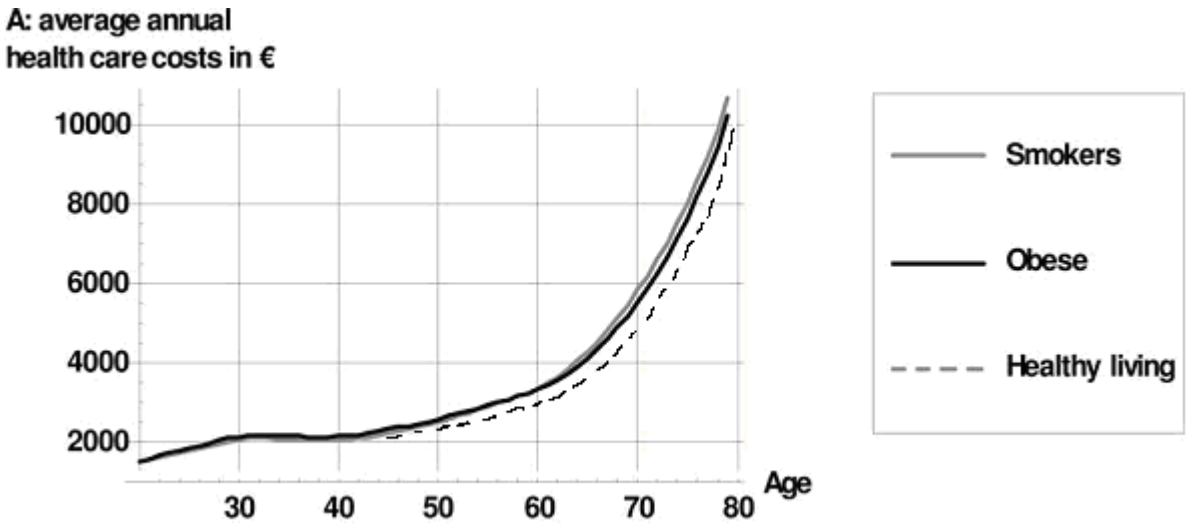
[56] Paul A Fishman, Zeba M Khan, Ella E Thompson, and Susan J Curry:Health Care Costs among Smokers, Former Smokers, and Never Smokers in an HMO

[57] Manning, W. G., *et al*. (1989). The taxes of sin: Do smokers and drinkers pay their way? *Journal of the American Medical Association, 261*, 1604-1609.

[58] Milbank Q. 1992;70(1):81-125. Cigarette smoking and lifetime medical expenditures.

[59] Despite the fact that the link between the consumption of tobacco products and health cost savings is not necessarily linear as smoking and other risky health behaviours, such as drinking alcohol or food disorders, could be to some extent substitutable. However there is no evidence that the population of non-smokers is more prone to any kind of behaviour linked to increased health risks than smoker's population.

Figure 3.1: Average annual health care cost in Netherlands



Source: Van Baal et al, 2008[60]

However some recent studies[61,62] in this field have argued that the non-smoking population as a whole is more expensive than the smoking population because the annual cost per capita ignores the differences in longevity between smokers and non-smokers. Non-smokers live longer and therefore incur more costs over their lifetime due to diseases not related to smoking, particularly in old age, when these costs are the highest. As the differences in life expectancy are substantial, more non-smokers live to old age than smokers. In the age group of 70 and above, the lower per capita cost of non-smokers is outweighed by the greater number of non-smokers requiring treatments of age related, mostly chronic, diseases.

In this context, it is noteworthy that, within a longer evaluation period, the reduction of health care costs attributable to reduced smoking gradually decreases. According to this study the break-even year, when the initial benefit is balanced by the eventual cost at the society level, has been estimated to occur after 26 years of follow-up[63].

Ageing is one of the greatest social and economic challenges of the 21st century for European societies. The EU strives to help citizens age in good health, and live active and independent lives[64]. Our society is clearly willing to spend money on not only on additional life years but also on healthier life years. Therefore, the evaluation of interventions within tobacco control policy should not be restricted to a comparison of "total costs", but it should rather, or at least also, look at cost-effectiveness. The analysis reveals the costs per gained life year. In this respect it is important to note that in the area of smoking cessation, favourable **cost-**

[60] Van Baal et al. Lifetime Medical Costs of Obesity: Prevention No Cure for Increasing Health Expenditure PLoS Med. 2008 February; 5(2): e29.
[61] The Health Care Costs of Smoking, Jan J. Barendregt, M.A., Luc Bonneux, M.D., and Paul J. van der Maas, Ph.D.N Engl J Med 1997; 337:1052-105
[62] van Baal PHM, Polder JJ, de Wit GA, Hoogenveen RT, Feenstra TL, et al. (2008) Lifetime medical costs of obesity: Prevention no cure for increasing health expenditure. PLoS Med 5(2): journal.pmed.0050029
[63] Discounting of the projected costs and benefits has a greater impact as the costs become more distant in time and brings the "break-even" further into the future.
[64] http://ec.europa.eu/health/ageing/policy/index_en.htm

effectiveness results have been shown even if increased medical costs in life-years gained are taken into account[65].

Thus, even if recent studies are correct when arguing that over their lifetime the total health care costs of non-smokers are higher than those of smokers, any intervention leading to reduced smoking would beneficial, as it would yield a **very high return in health for the money invested**. An effective antismoking policy is thus cost-effective.[66]

In conclusion, it is fair to say that a reduction of consumption by 2% would result in savings to EU Governments of 506 mEUR per year. Whilst over a longer time period and presupposing a very successful tobacco control policy the benefits of smoking cessation are expected to reduce/diminish, it is important to underline that tobacco control policy is certainly a very cost-effective measure to improve public health.

A.5.2.3.1.3. Increased productivity

Smoking also has an important impact on the productivity of the paid workforce. Smoking reduces the size of the available workforce as a result of smoking-attributable deaths and illnesses causing premature retirement. It also increases the absenteeism resulting from smoking-attributable sickness or injury. **A reduction in smoking consumption is expected to reduce these productivity losses**.

Premature retirements and deaths

Table 3.6 presents estimates of the **loss of productivity from premature retirements and deaths** in the EU which are caused by smoking. The total annual costs for the economy in the EU caused by absenteeism due to smoking are 6.1 bEUR. These losses are estimated for the paid workforce. The calculations are based on estimates of years lived with disability (YLD),[67] estimated inactivity due to smoking related diseases (number of people in retirement due to smoking) and average labour costs in business economy.[68] As with the preceding cost estimates for health care, these are net estimates, and show the amount of resources which would have been available if there had been no tobacco-attributable productivity losses.

65 David Hoeflmayr, Reiner Hanewinkel. (2008) Do school-based tobacco prevention programmes pay off? The cost-effectiveness of the 'Smoke-free Class Competition'. Public Health 122:1, 34-41.
66 Jacobs-van der Bruggen MA, Bos G, Bemelmans WJ, Hoogenveen RT, Vijgen SM, et al. (2007) Lifestyle interventions are cost-effective in people with different levels of diabetes risk: results from a modeling study. Diabetes Care 30: 128–134.
van Baal PH, Hoogenveen RT, de Wit GA, Boshuizen HC (2006) Estimating health-adjusted life expectancy conditional on risk factors: results for smoking and obesity. Popul Health Metr 4: 14.
van Baal PH, Feenstra TL, Hoogenveen RT, Ardine de Wit G, Brouwer WB (2007) Unrelated medical care in life years gained and the cost utility of primary prevention: in search of a ''perfect'' cost-utility ratio. Health Econ 16: 421–433.
67 WHO estimates, 2004
68 Eurostat data, 2009

Table 3.6: Estimated number of retirements due to smoking

Disease category	Total inactive persons due to long-term sickness or disability	Inactive due to smoking-related diseases	Of which: attributable to smoking	Economic loss due to smoking-related incapacity (million EUR)
Lung cancer	n.a.	11,482	9,664	359
Upper aerodigest. cancers	n.a.	5,694	3,027	109
Other cancers	n.a.	153,392	10,617	390
Cardiovascular diseases	n.a.	214,922	141,131	3,929
COPD	n.a.	235,804	22,560	780
Other respirat. diseases	n.a.	156,868	15,127	514
Total	**8,017,872**	**778,162**	**202,127**	**6,081**

Source: GHK, 2012

Table 3.7 shows how the estimated losses caused by premature retirement and deaths would decrease with the different percentage reductions in tobacco consumption. The net annual benefits resulting from a 2% decline in consumption are expected to amount to **122 million EUR (productivity gains)**.

Table 3.7: Estimated productivity losses caused by early retirements due to smoking

	Economic losses (caused by early retirement, deaths) with different percentage reduction in tobacco consumption				
	1%	**2%**	**3%**	**4%**	**5%**
Economic loss form early retirement and deaths due to smoking (mEUR)	6,020	5,959	5,898	5,837	5,776
Net benefit (mEUR)	61	122	183	244	305

Source: own calculation

Absenteeism during active work life

Decreased on-the-job productivity and employee absence because of smoking related diseases result in an additional cost factor to employers.

It has been well documented[69] that smokers have a higher rate of workplace absenteeism than non-smokers. Based on GHK calculations[70], an estimated **93 million days were reported as being missed** by adults in the EU due to smoking-related diseases in 2009. The smoking attributable fraction was calculated based on estimates of the number of days lost to disease (DLD) suffered by smokers that could be directly attributed to their smoking.

Absenteeism costs were calculated using the "**lost wages method**" (based on the average daily earnings rate for employed persons), the most frequently used method to measure

[69] The health consequences of involuntary exposure to tobacco smoke: a report of the Surgeon General", 2006 for a summary of clinical evidence (U.S. Department of Health and Human Services 2006) Bush and Wooden (1994)

[70] Eurostat data; calculation based on absenteeism data from 3 countries (AT, NL, DE) during 2007-2010

productivity loss[71], suggesting productivity loss of € 2.2 billion in the EU from absenteeism due to smoking. Table 7 provides a detailed breakdown of smoking attributable absenteeism per MS and diagnosis.

Table 3.8: Estimated loss from smoking-induced absenteeism in 2009 (mEUR)

Country	Neoplasms	Respiratory diseases	Cardiovascular diseases	Total
Austria	3.3	18.3	6.3	28
Belgium	14	60.4	36.5	111
Bulgaria	0.4	2.7	1.2	4
Cyprus	0.2	0.8	0.4	1
Czech Republic	3	18.2	9	30
Denmark	9.5	56.9	35.4	102
Estonia	0.2	1.8	0.6	3
Finland	5	23.1	12.6	41
France	43.5	194.4	105.7	344
Germany	38.6	157.4	132.8	329
Greece	2.9	12.8	6.9	23
Hungary	2.7	18.8	8.2	30
Ireland	2.5	16.4	8.9	28
Italy	25.7	112.7	53.6	192
Latvia	0.3	2.7	0.9	4
Lithuania	0.4	3.4	1.2	5
Luxembourg	0.3	1.3	1	3
Malta	0.1	0.2	0.2	0
Netherlands	30.4	160.4	95.1	286
Poland	9.2	55	29.9	94
Portugal	3.6	13.8	7.5	25
Romania	0.9	7.3	2.5	11
Slovakia	1.2	7.1	3.2	11
Slovenia	1.4	6	3.7	11
Spain	16.7	54.8	29.8	101
Sweden	6.5	37.3	23.6	67
United Kingdom	26.4	158.8	94.2	279
EU 27 total	**249**	**1203**	**711**	**2162**

Source: GHK, 2011

Table 3.9: Reduction of loss from smoking-induced absenteeism (mEUR)

	Economic losses due to absenteeism with different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Economic loss from absenteeism due to smoking (mEUR)	2140.4	2118.8	2097.1	2075.5	2053.9
Net benefit (mEUR)	21.6	43.2	64.9	86.5	108.1

Source: own calculation

Table 3.9 shows how the estimated **losses caused by absenteeism** would decrease, if tobacco consumption decreased. More specifically, the net annual benefits of 2% decline in consumption would result in savings of **43 million EUR**.

[71] Mattke S. Balakrishnan A. Bergamo G. Newberry SJ. A review of methods to measure health-related productivity loss. *Am J Managed Care*. 2007;13:211–217.

Production losses in the household sector

Smoking-attributable sickness or death causes production losses not only in the paid workforce but also in the unpaid household sector. The total economy of a nation consists of both market and non-market sectors. The non-market sector uses through an unpaid capacity considerable human resources for the production of goods and services which are directly consumed by households without going through the market. These activities, though productive, are in almost all cases not included in conventional national accounts statistics and thus not considered for this analysis. For the purpose of this impact assessment they are just mentioned, but not monetised.

Conclusion

Smoking causes a loss of national productive capacity in the paid workforce as a result of smoking-attributable death and sickness. As a result of a 2% decline in tobacco consumption, **smoking related productivity losses to the EU economy would decrease by € 165 million annually**. Taking into account that the retirement age is expected to increase in the years to come, this figure is expected to increase significantly, but to maintain a conservative approach, the figures have not been amended.

A.5.2.3.1.4. Conclusion on the advantages

The overall benefits for Governments and society resulting from a reduction of tobacco consumption are summarised in the table below:

Table 3.10: Overall benefits for Governments and society (in million EUR)

	Different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Decrease in health care expenditures	253	506	759	1,012	1,265
Increased productivity	83	165	248	331	413
- due to less early retirement / deaths	61	122	183	244	305
- due to less absenteeism	22	43	65	87	108
Decrease in premature mortality costs	5,167	10,334	15,501	20,669	25,836

Source: own calculation based on the above described analysis

A.5.2.3.2. Budgetary impact

Sales of tobacco products allow Member States to generate significant tax revenues. Governments collect **excise duties, VAT** and upon importation customs duties on tobacco products.[72] For the purpose of this Section, it was considered appropriate to concentrate on the excise duties collected. Custom duties are negligible considering minimal market share of manufactured tobacco products imported from third countries. Disregarding VAT appears justified as money not spent on tobacco products is expected to be spent on other goods and/or services, which in turn generate VAT. From this perspective, a reduction in tobacco consumption should be "VAT neutral".

Conventional wisdom would suggest that a decline in tobacco consumption will lead to a decline in Governments' revenues. Accordingly, tax revenues of Member States would

[72] EU legislation allows Member States to exclude customs duties from the basis for calculating the ad valorem excise duty on cigarettes.

decline when tobacco consumption decreases. However, in reality, Member States' tax revenues increased over recent years despite decreasing tobacco consumption. This is due to the fact that Member States have introduced higher tax levels over recent years. This will be further explained in this section.

Table 3.11: EU-27 revenues from excise duty (cigarettes + RYO) in 2010

Member State	Pack of 20 cigarettes				2010 Excise duty collected incl. RYO (mEUR)
	Weighted average retail price incl. taxes	Excise duty	All duties (excise + VAT)	Net retail price excl. Taxes	
IE	8.47 €	5.23 €	6.65 €	1.82 €	1,160
UK	6.27 €	4.61 €	5.65 €	0.62 €	10,153
FR	5.40 €	3.47 €	4.35 €	1.05 €	10,359
SE	4.97 €	2.81 €	3.80 €	1.17 €	852
NL	4.73 €	3.12 €	3.88 €	0.86 €	2,407
DK	4.65 €	2.82 €	3.75 €	0.90 €	1,105
DE	4.60 €	2.82 €	3.63 €	0.96 €	13,478
BE	4.53 €	2.69 €	3.48 €	1.05 €	1,987
FI	4.32 €	2.60 €	3.41 €	0.92 €	691
IT	4.10 €	2.39 €	3.07 €	1.03 €	10,622
AT	3.79 €	2.27 €	2.90 €	0.89 €	1,502
MT	3.76 €	2.33 €	2.90 €	0.86 €	70
LU	3.60 €	2.06 €	2.53 €	1.07 €	2,099
PT	3.45 €	2.28 €	2.66 €	0.79 €	1,429
ES	3.33 €	2.15 €	2.66 €	0.67 €	8,023
CY	3.27 €	2.11 €	2.54 €	0.73 €	199
EL	3.13 €	2.04 €	2.62 €	0.51 €	2,913
CZ	2.78 €	1.65 €	2.12 €	0.66 €	1,616
SK	2.66 €	1.72 €	2.17 €	0.49 €	614
SI	2.64 €	1.60 €	2.04 €	0.60 €	391
RO	2.39 €	1.60 €	1.88 €	0.51 €	1,345
PL	2.32 €	1.53 €	1.97 €	0.35 €	4,250
BG	2.25 €	1.55 €	1.93 €	0.32 €	777
LV	2.21 €	1.46 €	1.86 €	0.36 €	130
HU	2.21 €	1.34 €	1.78 €	0.43 €	925
EE	2.21 €	1.49 €	1.86 €	0.34 €	115
LT	2.16 €	1.30 €	1.68 €	0.48 €	160
EU 27					**79,369**

Source: EC, DG Taxud, 2010

The expected reduction of excise duties applying conventional wisdom

Revenue from excise duty on the sale of tobacco products in EU was about € 79 billion in 2010, contributing almost 3% to total Government revenues. Most of these revenues were generated by cigarettes (€72 billion).

Table 3.12: Loss revenues from excise duties

	Excise tax revenues with different percentage reduction in tobacco consumption				
	1%	**2%**	**3%**	**4%**	**5%**
Projected excise tax revenues (mEUR)	78,575	77,781	76,987	76,193	75,399
Decrease in excise tax revenues (mEUR)	794	1,588	2,382	3,176	3,970

Source: DG TAXUD, own calculations

As consumption of FMC and RYO is expected to decline, fewer tobacco products will be purchased and excise duty will decline (Table 3.12). Applying a linear approach, the **projected decrease in consumption of 2% would lead to lower excise tax revenues of 1.6 billion EUR**.

It should be underlined that this is a conservative/**worst case scenario** as the calculations do not take into account that – as a result of measures proposed in PA4b (cross border internet sales) and PA5 (measures addressing illicit trade) - certain sales currently occurring in the illicit part of the market are expected to return to the licit part of the market.

Possible tax increases

The calculations are also a "worst case scenario" for another reason. They do not take into account that Member States can react to decreased tax revenues with tax increases. In fact, **Member States are expected to take action to mitigate the negative impact on public budgets caused by lower tobacco consumption**, as they have done in the past.

Table 3.13: Excise duty from tobacco products collected by MS's

Member State	2002	2003	2004	2005	2007	2008	2009	2010
AT	1296.9	1328.7	1317.9	1339.7	1446.2	1424.5	1457.6	1502.0
BE	1255.0	1395.7	1409.4	1425.2	1559.5	1532.0	1529.5	1686.6
BG					687.4	875.3	901.9	762.9
CY			142.6	131.1	180.4	191.4	185.1	186.5
CZ			658.6	827.0	1666.9	1410.6	1375.1	1576.3
DE	13205.5	13353.0	12544.9	12386.9	12861.9	12260.6	11950.8	11991.6
DK	923.5	937.2	856.7	894.8	913.9	912.1	935.9	1042.8
EE			58.7	70.1	96.3	95.9	131.1	110.9
EL	2126.8	2248.1	2241.5	2257.1	2581.3	2516.2	2566.2	2913.0
ES	5144.9	5537.1	5836.3	6150.8	7169.7	7371.3	7452.8	7689.6
FI	535.1	528.1	538.0	544.2	563.7	570.1	614.0	628.6
FR	8628.6	8828.0	9244.0	9851.0	9380.0	9550.4	9894.5	9393.2
HU			681.1	675.7	956.8	1000.7	1055.4	787.7
IE	1121.0	1137.1	1042.9	1067.1	1177.5	1156.6	1201.9	1145.5
IT	7790.0	7993.0	8636.0	8912.0	9938.3	10256.9	10341.0	10426.4
LT			62.4	74.4	117.5	197.6	199.0	159.0
LU	352.0	381.5	458.8	372.4	415.0	439.1	413.2	406.7
LV			40.5	62.0	105.7	204.8	160.0	126.6
MT			57.3	60.2	56.7	60.4	62.9	68.2
NL	1380.3	1439.1	1597.6	1409.4	1717.0	1767.0	1809.0	1869.0
PL				2408.3	3521.6	3737.6	3856.5	4249.7
PT	1153.0	1215.2	1016.6	1309.8	1209.2	1276.1	1115.4	1395.6
RO					918.7	1081.2	1261.5	1345.3
SE	751.6	740.6	717.6	731.0	823.8	799.3	739.4	798.7
SI			226.0	247.0	299.6	341.8	362.0	389.1
SK			188.8	289.6	685.8	388.5	507.3	610.1
UK	12237.4	11608.9	10813.0	10741.6	11147.7	10232.0	8374.6	9257.4
EU-25				**64238.2**	**72198.0**	**71649.8**	**70453.7**	**72518.8**
EU-xx total	57901.7	58671.3	60387.1	64238.2	72198.0	71649.8	70453.7	72518.8

Source: EC, annual reports published by DG Taxud

The relatively low price elasticity of cigarette demand implies that a tax increase will in most cases secure higher revenues, and which is supported by research in a variety of contexts. In developed countries, demand for tobacco products decreases at around half the rate of price

increases.[73] Therefore, **price and/or tax increases normally result in the generation of additional revenues**.

The fact that tax revenues of Member States from tobacco have been stable in the past or even increasing can also be seen from the table 3.13. **While the number of FMC released for consumption in the EU 27 (ex RO) declined by 24% between 2002 and 2010, the revenues increased by more than 28% in the same period** (EU 27, ex RO and BG).[74] Reducing tobacco consumption does therefore not necessarily lead to a negative impact on public budgets in form of reduced excise duties (for VAT see above).

A.5.2.3.3. Summary

Taking into account the four main socio-economic factors (public health, health care expenditures, productivity loss and tax revenues), the **annual net benefits to the EU would amount to 9.4 billion EUR**, based on the assumption that smoking consumption will decrease by 2% (Table 3.14). The table includes estimates of both true economic benefits (i.e. reductions in health care expenditures, productivity losses, and premature mortality) as well as changes in excise tax revenues collected by Governments. Reductions in excise tax revenues do not, however, represent an actual benefit to society as a whole but rather a transfer of resources from one sector of society to another (i.e. from consumers to the state, or vice versa). A reduction in excise tax revenues (which is moreover very unlikely, see explanation above) does not thus constitute a true cost to society. However, it still represents a significant economic effect for the government and therefore it is included in the summary table below.

Table 3.14: Overview of costs and benefits from the societal and Governmental perspective (mEUR)

	Different percentage reduction in tobacco consumption				
	1%	**2%**	3%	4%	5%
Decrease in excise tax revenues[75]	-794	**-1,588**	-2,382	-3,176	-3,970
Decrease in health care expenditures	253	**506**	759	1,012	1,265
Decrease of productivity loss	83	**165**	248	331	413
- due to early retirement / deaths	61	**122**	183	244	305
- due to absenteeism	22	**43**	65	87	108
Decrease in premature mortality costs	5,167	**10,334**	15,501	20,669	25,836
Overall net benefit	4,709	**9,417**	14,126	18,836	23,544

Source: own calculations

A.5.2.3.4. Social discounting

Discounting is used to allow comparisons between benefits and costs that occur in different time periods by expressing their values in present terms. In the analysis above, it is assumed that the costs and benefits of the policies occur simultaneously and their relative values do not change over time. All amounts are expressed in the present value, e.g. changes of the health care costs are calculated from the actual present values and are thus in principle expressed in

[73] Curbing the Epidemic: Governments and the Economics of Tobacco Control, World Bank Development in Practice series. 1999. Washington DC.
[74] Calculation, based on unpublished data, provided by DG TAXUD
[75] Disregarding measures taken against illicit trade and possibility to increase tax levels.

current prices.[76] Therefore, in order to calculate the future value of current health care costs in year 5 after the implementation of the revised TPD (using the appropriate discount rate), the current cost would need to be increased to accommodate for inflation in the health care sector. This figure would then subsequently need to be discounted back to the present value, using a general inflation rate. For these reasons, the basic calculations are non-discounted. However, in order to account for individual or social rates of time preference, present values of the future benefits and costs can be calculated by employing the appropriate social discount rates.

The discount rate is not likely to affect the present value of the benefits and costs for those cases in which costs and benefits of a policy occur simultaneously and their relative values do not change over time. On the other hand, social discounting is applied in order to compare benefits and costs that occur at different times based on the rate at which society is willing to make such trade-offs. Discounting may substantially affect the present values of costs and benefits when there is a significant difference in the timing of realisation of costs and benefits. As this might be the case in tobacco control policies, which usually deliver some of their expected benefits with a certain time delay, three scenarios have been developed. The table below gives an overview of the scenarios in terms of time delays for two major benefits (i.e. decrease in morbidity induced costs and mortality).

Table 3.15 Alternative scenarios of time delays for morbidity and mortality benefits

Scenario 1	All the costs and benefits realised in year 5 are plainly discounted to the net present value.
Scenario 2	All the costs and benefits are discounted for the period of 5 years except the benefits from reduced premature mortality which are discounted for the period of 25 years[77]
Scenario 3	The costs from decrease in excise tax revenues are discounted for 5 years, the benefits from decrease in health care costs and productivity loss are discounted for 10 years and the benefits from reduced premature mortality are discounted for the period of 40 years[78]

Discount rate

Considering that costs and benefits can be represented as changes in consumption profiles over time, discounting should be based on the rate at which society is willing to postpone consumption today for consumption in the future. Thus, the rate at which society is willing to trade current for future consumption, or the social rate of time preference, is the appropriate discounting concept[79]. One common approach to estimating the social rate of time preference is to approximate it from the interest rates for **long-term, risk-free assets such as**

[76] Assuming their nominal increasse in line with general inflation rate.
[77] While the evidence suggest that the health consequences of smoking occur in relatively short period, the change in mortality rates is usually observed two decades later.
Lopez AD, Collishaw NE, Piha T.A descriptive model of the cigarette epidemic in developed countries. Tobacco Control 1994; 3: 242-247.www.who.int/tobacco/statistics/country_profiles/en/Introduction.pdf
[78] As incidence of some smoking related diseases increases with age, it can be argued that the social benefits of smoking cessation could be observed with additional delay if only the youngest population would be responsive to the proposed measures.
[79] EPA, Guidelines for Preparing Economic Analyses, December 2010.
http://yosemite.epa.gov/ee/epa/eerm.nsf/vwAN/EE-0568-06.pdf/$file/EE-0568-06.pdf

government bonds. The rationale behind this approach is that this market rate reflects how individuals discount future consumption and Government should value policy-related consumption changes as individuals do. In other words, the social rate of discount should equal the consumption rate of interest.

The overall net benefit of reduction in tobacco consumption by 1% for different scenarios and for various discount rates is calculated in table 3.16. The interests of the long term government bonds of Germany, UK and France fluctuate in the range of 2-3%.[80] We approximate the social rate of time preference at the level of 3%, which is for the purposes of our analysis a rather conservative assumption.

Considering the social discount rate corresponding with market interest rates of long term risk-free governmental bonds issued by major Member States, the annual net overall discounted benefit arising from a reduction in tobacco consumption by 2% would amount to 4.0 bEUR under the most likely scenario, i.e when decrease in tax revenues and health care/absenteeism savings are observed during the 5 years after implementation, while on average the benefits from reduced premature mortality accrue only in 25 years.

Table 3.16: Net present values of future benefits and costs (corresponding with 1% decrease in consumption) for different scenarios and discount rates

Overall benefits	Discount rate				
	1%	2%	3%	4%	5%
Non-discounted	4,709	4,709	4,709	4,709	4,709
Scenario 1	4,471	4,250	4,038	3,834	3,638
Scenario 2	3,578	2,700	2,016	1,486	1,077
Scenario 3	3,000	1,857	1,092	584	245

Source: own calculation

The conservative scenario 3 can cater for sensitivity analysis and even with the highest considered discount rate the **cost/benefit ratio remains positive**, with a corresponding net present benefit of 0.49 bEUR.

A.5.2.4. Impact of the reduction in consumption on employment

A.5.2.4.1. Input-output model

In order to evaluate how the reduction in consumption impacts on employment, the so called input-output model[81] was used. Input-output analysis is a means **of examining relationships within an economy**, both between businesses and between businesses and final consumers. The analysis captures all monetary market transactions for consumption in a given time period. The resulting mathematical formula allows the examination of the effect of a change in one or several economic activities on the entire economy. The core of the analysis is the

[80] Rates as of May 2012; www.bloomberg.com/markets/rates-bonds/government-bonds;

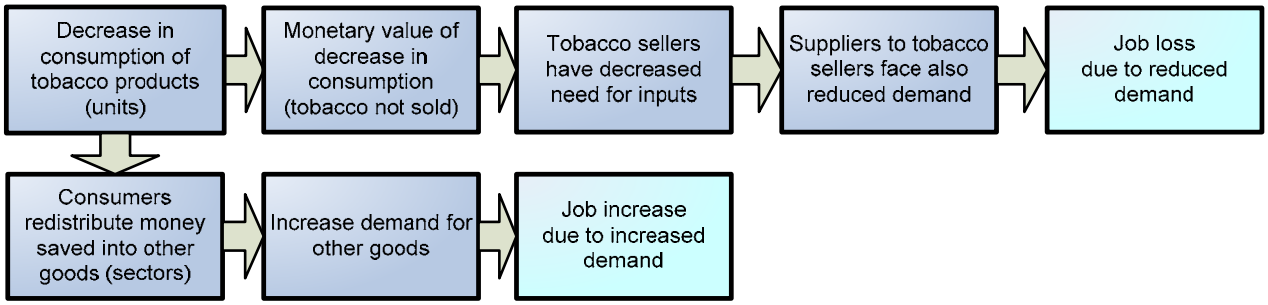
[81] I-O analysis is a well-established method for estimating economy-wide effects from a change in demand from one particular industry (Beyer et al, 2000). Conceptually, the I-O model estimates the direct and indirect effects associated with a change in demand for a particular industry. Economics of Tobacco Control Toolkit, Worlbank 1999. http://web.worldbank.org/wbsite/external/topics/exthealthnutritionandpopulation/extetc/0,,contentmdk:20365047~menuPK:478898~pagePK:148956~piPK:216618~theSitePK:376601,00.html

creation of input-output tables. These tables describe the flow of goods and services in the economy in a matrix form.

The **World Bank recommends** the input/output model as one of the preferred methodologies for estimating economy-wide effects from a change in demand from one particular industry while acknowledging its limitations, including the static nature of the model. For example, it does not account for technological development leading to increased production in a certain industry sector without increased the employment. Cigarette manufacturing is highly automatized, and numerous examples have shown that jobs in cigarette manufacturing have fallen dramatically as a result of upgrading to new more capital-intensive technology, even with increases in production levels.[82] Conversely, service oriented industries are more work intensive and employment levels follow to a larger sector output.

Three different matrices are used for a standard input-output model. The inter-industry transaction matrix describes the flow of goods and services between all individual sectors of an economy in a given year. The direct requirement matrix indicates the requirements for a particular industry to produce an average unit output. The total requirement matrix indicates the total requirements of all industries necessary for that industry to deliver a unit of output to final demand.

Figure 4.1: Conceptual I/O model



Source: Matrix 2012

The model assumes that **money not spent on tobacco is spent on other goods and services** according to consumers' existing (average) expenditure patterns. To simulate the change in employment from a reduction of tobacco consumption, the amount of expenditure released from tobacco spending is distributed according to an assumed expenditure pattern and then applied to the static input/output (I/O) model. The model contains interdependencies or relationships between industry sectors in the economy and is used to simulate the impact of an external policy change (i.e. change of which the consequence is a reduction of tobacco consumption) on outputs and employment of each sector of the economy (Figure 4.1).

Calculations

If consumers forgo tobacco products they will spend the money they would have spent on tobacco products on other goods and services (for example on food, beverages, clothing, cinemas, and hotels). These sectors will therefore see an increase in demand for their products/services and thus increase their expenditure on inputs. This has a knock-on effect in all associated industries. The **overall impact on the economy** of a reduction in tobacco

[82] http://ec.europa.eu/health/archive/ph_determinants/life_style/tobacco/documents/world_bank_en.pdf

consumption is therefore the net effect on employment due to both reduced demand/consumption of tobacco products and increased demand/consumption of non-tobacco products.

Table 4.1: Increased spending on other products as a result of a reduction in tobacco consumption (mEUR, 2010)

Expenditure categories	Spending pattern of a recent ex-smoker	Increase in consumption of non-tobacco products with different reductions in tobacco consumption				
		1%	2%	3%	4%	5%
Food products and beverages	22.90%	43.1	86.2	129.3	172.4	215.5
Clothing; furs	7.80%	14.7	29.4	44.1	58.8	73.5
Housing, electrical energy, gas, steam and hot water	24.40%	46	92	138	184	230
Furniture; other manufactured goods n.e.c.	6.50%	12.2	24.4	36.6	48.8	61
Health and social services	5.60%	10.5	21	31.5	42	52.5
Motor vehicles, trailers and semi-trailers	6.10%	11.6	23.2	34.8	46.4	58
Other transport equipment	6.10%	11.6	23.2	34.8	46.4	58
Post and telecommunication services	2.50%	4.7	9.4	14.1	18.8	23.5
Recreational, cultural and sporting services	6.10%	11.5	23	34.5	46	57.5
Education services	0.70%	1.4	2.8	4.2	5.6	7
Hotel and restaurant services	5.70%	10.7	21.4	32.1	42.8	53.5
Other services	5.60%	10.5	21	31.5	42	52.5
Total	**100%**	**188.5**	**377.0**	**565.5**	**754.0**	**942.6**

Source: Matrix report 2011; data on spending pattern by York (1995)

As stated in Section 2, the **EU-27 tobacco market at retail level including taxes is worth 130.6 bEUR.**[83] Thus, a 1% reduction in tobacco consumption would mean 1.3 bEUR less spent on tobacco. However in order to establish the impact on the economic stakeholders it is essential to remove the part of the turnover associated with taxes not least as it is assumed that Member States might use the possibility to increase the tax rates to maintain the revenues (VAT and excise duties).[84] Additionally, the distribution margin of wholesalers and retailers cannot be attributed to the tobacco manufacturers (in total 40%). In this light, the calculations are based on the assumption that the tobacco industry experiences reduced revenues of about 188 mEUR for each per cent of reduced consumption.

[83] The value of the domestic tobacco market is based on the value of consumed cigarettes and roll your own tobacco. A large proportion of this comprises tax payments.

[84] It is true that once consumers forgo tobacco products, they will save and consequently spend total amount of money including taxes. However, similarly the governments would use/spend/redistribute the taxes which ultimately will end up in the economy.
For the purpose of this impact assessment it was considered that - on a weighted average basis - taxes (excise + VAT) account for 77.4% of the final retail price across the EU-27; DG Taxud data + VAT rates in MS

Table 4.1 shows how **consumers are expected to spend the money they save on tobacco**. Like in previous sections, the presentation is based on different scenarios from a drop in consumption of 1 to 5%, i.e. between 188 to 942 mEUR. The table outlines corresponding increases in expenditure by sector due to a reduction in tobacco consumption.

The York study provides the most extensive insight into actual spending patterns of recent ex-smokers and shows how they spend their additional money (not spent on tobacco) on day to day products such as food and beverage, clothing, recreational activities, restaurants, and other services. Considering the fact that spending patterns have probably further evolved since 1995, the impact of the various spending patterns on the overall results of the model was tested using several different scenarios of expenditure patterns, i.e. for general consumer (Eurostat data, 2009), for recent ex-smoker adjusted[85] and for consumers with a hypothetical spending pattern[86]. Table 4.2 shows how the net impact on output and employment changes for the different spending scenarios. The sensitivity analysis confirms that the choice of spending patterns in the sensitivity testing do not significantly alter the outcomes of the overall analysis.

Table 4.2: Economy-wide impact on output & employment using different spending patterns (mEUR, 2010 prices)

Spending patterns	**Impact on production** (reduction in tobacco consumption)	**Impact on production** (increase in non-tobacco consumption)	**Net effect on production**	**Employment impact** (reduction in tobacco production)	**Employment impact** (increase in non-tobacco production)	**Net effect on employment**
Ex-smoker	- 290	+ 320	+30	-1,426	+ 1,984	+558
General consumer	- 290	+310	+20	-1,425	+ 2,002	+577
Ex-smoker adjusted	- 290	+340	+50	-1,430	+ 2,237	+807
Hypothetical scenario	- 290	+310	+20	-1,433	+ 2,413	+980

Source: Matrix report, 2012

The above change in the **pattern of consumption** will cause a corresponding change in the pattern of production (input-output model used) which is shown in tables 4.3 and 4.4. It demonstrates that a 188 mEUR reduction in tobacco consumption results overall in 575 mEUR reduction in production in the economy[87], whilst the corresponding increase in consumption of other goods and services amounts to 634 mEUR (net positive effect: around 59,4 million EUR). The impact on overall production in the economy due to a reduction in consumption of tobacco products by 2% thus leads to net gains of 119 mEUR.

[85] The spending patterns for the York study had a significant percentage allocated to housing, electricity, and healthcare. To test the impact of this distribution, the spending pattern was adjusted to remove these categories

[86] The hypothetical spending pattern was based on assuming consumers would spend their additional money only on day to day products, i.e. food and beverages, clothing, recreational activities, restaurants, and other services

[87] The fact that 188 million EUR loss to the tobacco industry generates a 575 million EUR loss overall is due to the fact that the input/output model accounts for direct and indirect effects.

Table 4.3: Production patterns (mEUR, 2010 prices)

	Different percentage of reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Monetary impact of reduction in tobacco consumption	-575.0	-1150.0	-1725.0	-1725.0	-2875.0
Monetary impact of increase in expenditure for other goods	634.4	1268.7	1903.1	1903.1	3171.9
Net effect on output	59.4	118.9	179.6	239.0	298.5

Source: Matrix report 2012; I-O model calculations

The fact that spending on non-tobacco goods and services results in an increase in net production is partially explained by the fact that the tobacco sectors are less input intensive[88].

A.5.2.4.2. Impact on employment

The impact on employment levels is estimated by applying the employment-output ratios for different industries to the changes in production in each industry. The employment-output ratio provides an estimate of the value of each employee within an industry. It is calculated by taking the total market value for each industry across EU-27 and dividing by the total number of employees in that industry across EU-27.

Table 4.4 below shows the change in employment in each industry associated with a 1% reduction in tobacco consumption. It demonstrates that the reduction in production caused by the fall in tobacco consumption will result in a loss of 2,854 jobs. The corresponding increase in consumption on non-tobacco products results in a gain of 3,972 jobs. The impact on employment due to a reduction in tobacco consumption by 1% is thus equivalent to an increase of 1,118 jobs. When comparing production and employment together it is clear that the relationship between production and employment is not linear. The analysis shows that a small gain in production within non-tobacco sectors results in a larger gain in employment. This observation is explained by the fact that non-tobacco sectors which have an increase in production are associated with smaller employment output ratios (i.e. are less capital and more labour intensive).

As explained above, the economy will adjust over time, and broad-scale long-term impacts are unlikely. In this respect, it is important to recall that tobacco consumption will not decrease overnight, but over a longer period of time. By the same token the additional expenditure in other sectors will only be felt over time.

[88] The value added of an industry refers to things such as fixed capital and operating surplus. It would be expected that industries such as tobacco which are heavily dependent on machinery would invest more in items such as fixed capital. In comparison industries which are less machinery dependent most likely rely more on raw inputs such as agriculture to produce food and beverage products. Within the I-O model industries which are less input intensive result in smaller multipliers. As the non-tobacco sectors are more input intensive than the tobacco industry, spending on these goods results in larger multipliers generating an output gain.

Table 4.4: The sectoral impact on production/employment associated with a reduction in consumption of 1%[89]

Industry	Monetary impact of reduction in tobacco consumption (mEUR)	Monetary impact of increase in exp. for other goods (mEUR)	Net effect on output (mEUR)	Employment impact of reduction in tobacco expenditure	Employment impact of increase in exp. for other goods	Net effect on employment
Agriculture	-24.8	16.9	-7.9	-589.8	399.2	-190.6
Mining and petroleum	-1.8	6.4	4.6	-8.4	33.6	25.8
Food industries	-12.1	66.6	54.5	-67.2	366.9	299.7
Tobacco[90]	-196.6	0.2	-196.5	-731.9	0.6	-731.3
Textile	-2.3	21.6	19.3	-22.6	280.4	258.4
Leather products	-0.5	0.9	0.5	-3.9	7.1	3.9
Wood and wood products	-3.3	18.0	14.7	-32.3	206.7	174.4
Paper products and printing	-17.9	7.2	-10.7	-68.5	27.8	-40.7
Chemical products	-11.2	14.4	3.3	-17.4	21.3	3.9
Rubber products	-3.3	5.0	1.7	-20.7	31.0	11.0
Metal and non metal products	-4.1	9.1	5.0	-16.2	35.5	18.7
Basic metal products	-4.0	7.9	3.9	-29.7	59.4	29.1
Machinery	-5.4	9.2	3.9	-28.4	48.5	20.0
Transport devices	-24.5	57.3	32.8	-138.9	288.1	149.9
Miscellaneous	-1.5	2.9	1.4	-28.4	60.7	32.3
Electricity	-11.0	70.2	59.2	-36.8	214.5	177.7
Construction and maintenance	-10.3	13.4	3.0	-97.5	127.3	29.1
Finance and trade and insurance	-18.0	17.8	-0.1	-98.8	98.2	-1.3
Wholesale and retailing	-33.2	44.3	11.1	-355.3	432.2	76.9
Services	-95.2	136.4	41.3	-436.7	1204.1	767.4
Private households with empl. persons	-0.5	0.6	0.1	-25.2	29.1	3.9
TOTAL	**-575.0**	**634.4**	**+59.4**	**-2854**	**3972**	**+1118**

Source: Matrix report 2011

As can be expected, the **tobacco, agriculture, and pulp/paper industry** are the most negatively affected by a reduction in tobacco consumption. It is estimated that within these industries 731, 191, and 41 jobs are lost respectively, with possible short- to medium-term economic disruption in areas that would bear the highest share of adverse employment impacts.

However, the loss of jobs in these industries is offset by an increase in employment in a variety of industries such as **food products and beverages, clothing and furs, furniture,**

[89] The changes associated with a 2% reduction in tobacco consumption are proportionally higher.

[90] The I-O model estimates the direct and indirect effects associated with a change in demand for a particular industry The combination of the direct and indirect effect is known as the I-O multiplier. The I-O multipliers used in the analysis are derived from the Eurostat input-output matrix (Eurostat, 2007). The I-O multiplier for tobacco products sector equals to 1.043.

electrical energy, gas, steam and hot water, health and social work services, hotel and restaurant services and other services. For example, it is estimated the other services, food and beverage, and textiles will see an increase in employment of 767, 300, and 258 jobs respectively. The changes associated with a 2% reduction in tobacco consumption are proportionally higher.

A.5.2.4.3. Redistribution and regional effects

Overall, as shown in the analysis, a reduction in tobacco use will have a positive effect on the total output and employment in the EU. However, reducing tobacco consumption might lead to a change in employment among different sectors and regions. Job losses might occur in (1) those sectors immediately associated with tobacco production, such as tobacco farming and processing, manufacturing, paper products and printing, wholesale and retail services, or in (2) those regions dependent on tobacco growing and manufacturing. However, these losses are generally outweighed by increases in employment in all other industries or in non-tobacco dependent regions. For any country or region, the estimated net change of employment depends on specific assumptions and the structure of the economy.

Production and processing of tobacco takes place in 12 EU Member States. The main tobacco farmers within the EU are Italy, Bulgaria, Poland, Spain, and Greece. These countries, together with France, produce over 90% of the total EU production of unmanufactured tobacco. It is thus estimated that the loss of 1178 jobs in agriculture sector due to a 2% decrease in tobacco consumption would be the jobs of tobacco farmers located in the above-mentioned countries. This corresponds to a reduction of 1.4% of the workforce currently working in this sector[91]. The regions specialised in growing burley, oriental or dark varieties are located in Bulgaria (all regions producing tobacco), southern Poland (Lubelskie, Lodzkie, Mazowieckie, Podlaskie), Northern Greece (Macedonia and Thrace), Italy (Tuscany, Campania, Lazio), but also France, Romania and Spain. In most of these regions tobacco growers are small farmers and tobacco consists of their main revenue. Virginia is mainly grown in Italy (Veneto, Umbria), Spain (Extremadura), southern Poland, Bulgaria, France and Hungary.[92] Compared to the previous restructuring of the sector, the impact is considered small, although non-negligible in some areas. Between 2005 and 2006, partially as a result of the discontinuation of direct subsidies for growing tobacco, the production of raw tobacco in EU25 dropped from 345,600 to 232,400 tonnes.[93]

In 2009, there were overall 48.500 persons employed in **the manufacturing of tobacco products in the EU**. The main tobacco manufacturers are located in Germany (27% of tobacco employment), Poland (17%), Bulgaria (11%), UK (10%), France, Spain and Netherlands (8-9%). It is thus estimated that a 2% decrease in tobacco consumption will ultimately lead to the loss of 1462 jobs in manufacturing sector mainly affecting the countries listed above. However, the overview of employment trends in Germany, France and UK indicates that employment is not to the same extent directly linked to falls in sales in all countries. Furthermore, in order to tackle the challenge of falling sales, there has been a fundamental restructuring of tobacco companies over the past ten years[94]. Some relocations of

[91] Euromonitor; 84228 persons employed in sector
[92] DG AGRI, January 2012 as cited by Matrix 2012
[93] Evaluation des measures de la PAC relatives au secteur du tabac brut, COGEA, August 2009
[94] Euromonitor data, Matrix report 2012

manufacturing premises have also taken place, as shown in the case study below while other two case studies with examples of such restructuring are given in Annex 2.

It can be concluded that further market developments would clearly affect tobacco companies in different countries in different ways and thus the exact impact of further falls in tobacco sales on costs, profits and employment within the tobacco manufacturing sector will differe from country to country.

In 2009, there were **45,900 individuals** employed in the **wholesale** of tobacco products[95] and according to the European retailer association (CEDT), there are almost 990,000 retail premises selling tobacco in the EU, with around 230,000 of these specialised shops which typically generate 45-50% of their turnover from tobacco.[96] In total, **retailers** generate 7.84 bEUR added value which would correspond to maximum of **600,000 FTE's**[97] assuming the average salary in the sector[98] and neglecting any other costs (housing/rent, energies, furniture, communication, transportation etc.). The I/O model predicts that the indirect impact of a 2% decrease in tobacco consumption will ultimately result in the loss of 710 jobs in the wholesale and retail sector of tobacco, representing a 0.11% decline.

A.5.2.4.4. Conclusion

Table 4.4 below shows the impact on overall economic production and employment associated with reduction in tobacco consumption between 1-5%. Overall, the net impact on employment is positive, i.e. the reduction in tobacco consumption is likely to result in an increase in employment. This is due to the fact that, although a reduction in tobacco consumption leads to job losses in the production of tobacco, this is more than compensated by the gain in employment in sectors producing goods and services purchased by former smokers.

Table 4.5: The impact on production/employment associated with a reduction in consumption between 1-5%

Reduction in tobacco consumption (%)	Employment impact of reduction in tobacco expenditure	Employment impact of increase in expenditure for other goods	Net effect on employment
1%	-2854	3972	1118
2%	-5708	7943	2235
3%	-8562	11915	3353
4%	-11416	15886	4470
5%	-14270	19858	5588

Source: Matrix 2012, own calculation

In any event it is very important to underline that it is the tobacco industry itself which is responsible for more lost jobs in a given country's domestic tobacco industry than the most successful tobacco control policies. **Industry induced job losses derive** among other from

[95] Eurostat 2010. Bulgarian farmers represent 50% of the EU tobacco farmers, followed by Poland and Greece (both 17%)
[96] Tobacco Retailers Figures. CEDT (Confédération Européenne des Détaillants en Tabac). sent to DG SANCO in January 2012
[97] Full Time Equivalents
[98] 12879 EUR, Eurostat 2010

(1) mechanisation of tobacco production plants, in which technology replaces factory workers; and (2) purchase of imported tobaccos, replacing domestically grown tobaccos raised by local farmers.