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EXECUTIVE SUMMARY OF THE 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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1. INTRODUCTION

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.[1] More than ten years have passed since the adoption and it has become necessary to consider and examine options to **update the TPD in line with market, scientific and international developments,** in particular the WHO Convention on Tobacco Control (FCTC) to which the European Union and all the Member States are Party. The initiative to revise the TPD is included in the Commission's Work Plan 2012.[2] The overall objective of the revision is to improve the functioning of the internal market, while ensuring a high level of health protection. Thus, the main objectives are (1) update already harmonised areas to overcome Member States' obstacles to bring their national legislations in line with new market, scientific and international developments,[3] (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[4] and (3) ensure that provisions of the Directive are not circumvented by placing on the market of products not complying with the TPD.[5] A high level of health protection has been considered when defining and choosing between different policy options. In particular, the initiation of tobacco consumption among young people has been taken into account. Most of the measures concentrate, at a first stage, on factory manufactured cigarettes (FMC), roll-your-owns (RYO) and smokeless tobacco products (STP).

2. CONSULTATION, EXPERTISE AND MARKET DESCRIPTION

In the context of the Impact Assessment extensive public and targeted stakeholders' consultations took place. The Impact Assessment also benefited from a number of external studies, opinions from the Commission's independent Scientific Committee (SCENIHR) and Eurobarometer surveys.

The total value of the tobacco market at retail level, including taxes and excise duties, is 136.5 bnEUR. FMC represent almost 90% (121.3 bnEUR) of the total tobacco market value, making up together with RYO close to 95% of the tobacco market. The remaining part of the market is pipe tobacco, cigars/cigarillos and STP. In 2010, excise duties amounted to over 79 bnEUR across the EU.

Tobacco is the largest avoidable health threat in the EU, responsible for almost 700,000 deaths in the EU each year. The revision focuses on initiation of tobacco consumption, in particular among young people, taking into account that 94% of the smokers start before the age of 25.[6] Around 50% of smokers die prematurely, on average 14 years earlier than non-smokers. They have more life years characterised by serious disease. Annual EU public healthcare expenditure on treating six main disease categories related to smoking is estimated around 25.3 bnEUR and society loses 8.3 bnEUR 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 bnEUR every year.

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[1] OJ L 194, 18.7.2001, p. 26–35

[2] http://ec.europa.eu/atwork/programmes/docs/cwp2012_annex_en.pdf

[3] 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.

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

[5] 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).

[6] Special Eurobarometer 385, 2012 : http://ec.europa.eu/health/eurobarometers/index_en.htm. 70% start below the age of 18 years.

3. PROBLEM DEFINITION

3.1. PROBLEM 1: SMOKELESS TOBACCO AND EXTENSION OF THE PRODUCT SCOPE

a) Smokeless tobacco products (STP)

All STP are addictive and associated with a number of adverse health effects. New products with attractive labelling and flavours have reached the market aiming to explore new market opportunities created by national laws prohibiting smoking in public places (smoke-free environments). There are divergent views among stakeholders whether or not the current ban on oral tobacco (snus) is still justified and whether or not the ban on oral tobacco should be extended to other STP. The role of STP in smoking cessation is disputed among stakeholders. STP can act as an entry gate for new tobacco consumers.

b) Nicotine containing products (NCP)

Recent years have seen the emergence of new NCP (including electronic cigarettes), which are put on the market without any prior authorisation or control. In the absence of legislation at EU level, Member States have taken **different regulatory approaches** (ranging from no specific regulation, to tobacco legislation, medicinal products' legislation or ban) to address the uncertainty over the contents and health effects of these products. Nicotine is a toxic and addictive substance and there are also reports of other hazardous substances being used in electronic cigarettes. Producers of NRTs (Nicotine Replacement Therapies) expressed concern over the different treatment of NRTs and NCPs. There is also a risk of an increase in the use of NCP as a consequence of national legislation on smoke-free environment. Others supported that NCP have a potential role in smoking cessation/limitation and argued that NCP should be treated as a consumer product.

c) Herbal products for smoking

Herbal products for smoking are treated differently in national legislations, which negatively affects cross-border trade. Combustion of these products is associated with health risks similar to those of traditional FMC although they do not have the same addictive characteristics and do not contain tobacco. Herbal products for smoking are often perceived as harmless or less harmful products by consumers.

3.2. PROBLEM 2: PACKAGING AND LABELLING

Some of the current TPD provisions in the area of packaging and labelling are **no longer in line with scientific evidence and commitments in the context of the FCTC**. The current harmonised provisions of the TPD do not allow Member States to take action to protect public health and update their legislation in line with their FCTC commitments. For example, Member States cannot remove the display of tar, nicotine and carbon monoxide (TNCO) levels on the package, which are known to be misleading, or introduce pictorial health warnings on both sides of the tobacco packages, which have been shown to be more effective.

Other aspects of packaging and labelling are not harmonised in the current TPD and national developments have led to **discrepancies between Member States**. For example, pictorial health warnings are in use in eight Member States and two more will follow in 2013. Discussions on standardised packaging are on-going in a few Member States. This situation is likely to be aggravated, in particular when Member States implement the FCTC. These divergent approaches will negatively affect the internal market.

3.3. PROBLEM 3: INGREDIENTS

The use of different reporting formats makes it difficult for manufacturers, importers and Member States to fulfil their **reporting obligations** under the current legislation and burdensome for the Commission to compare, analyse and draw conclusions from the data received.

The lack of a harmonised approach on **ingredients regulation** affects the functioning of the internal market and impacts on the free movement of goods across the EU. Some Member States have adopted legislation allowing or forbidding different ingredients given their potential to enhance tobacco consumption or initiation. Without harmonisation, the obstacles on the internal market are expected to increase further in coming years. In order to comply with their obligations under the FCTC, Member States are likely to continue adopting rules unilaterally, in particular to address the attractiveness of tobacco products and considering the marketing development in recent years with more flavoured tobacco products being placed on the market.

3.4. PROBLEM 4: CROSS BORDER DISTANCE SALES OF TOBACCO

Cross-border internet sales of tobacco are - in most cases – illegal, taking into account that the main attraction of these transactions is to evade taxes and/or circumvent age control.[7] From the perspective of the TPD cross-border internet sales implies a risk of circumvention of the **safeguards of the Directive** (e.g. obligation for a tobacco product to feature health warnings in the language(s) of the country of the consumer). Different legal approaches have been taken by Member States in this area and the legal disparities are expected to aggravate as Member States gradually implement FCTC. Cross-border sale has, by definition an impact on the functioning of the internal market. As internet retailers typically offer their products to consumers regardless of their locations, national solutions within the EU have no or little effect.

3.5. PROBLEM 5: TRACEABILITY AND SECURITY FEATURES

The availability of products not complying with the provisions of the Directive (e.g. health warnings and ingredient regulation) undermines the objectives of the Directive. Measures at EU level in the area of traceability based on Article 5(9) TPD have not been taken and in their absence Member States are not in a position to take effective measures. There is currently no level playing field for economic operators on the internal market, as only the four largest tobacco manufacturers have concluded legally binding agreements, including provisions on tracking and tracing, with the EU and the Member States. Sales of illicit products mean that the **consumers do not benefit from the safeguards introduced by the TPD**. Moreover, they are not able to verify the authenticity of the products concerned. Many stakeholders (tobacco industry, but also retailers) have voiced concerns that some of the discussed and intended measures in the revised TPD would increase the illicit trade in tobacco, although compelling evidence to that end was not submitted.

4. EU BASIS TO ACT

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 to ensure a high level of health protection in its proposals envisaged in paragraph 1 of Article 114.

As explained some areas included in the impact assessment are already covered by **harmonisation** in the current TPD, but need to be updated in accordance with scientific and international developments. Other areas relevant for the impact assessment are subject to **different legal approaches** in Member States which has led to obstacles to the free movement of goods.

5. POLICY OBJECTIVES

The overall objective of the revision is to improve the functioning of the internal market, while ensuring a high level of health protection. The proposal aims to update already harmonised areas,

[7] 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.

thereby overcoming the obstacles for Member States in bringing their national legislations in line with new market, scientific and international developments. It also aims to 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. Finally, the proposal seeks to ensure that the provisions of the Directive are not circumvented by placing on the market of products not compliant with the TPD. The proposal will also ensure a harmonised implementation of international obligations following from the 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.

The revision will contribute to the overall aim of the EU to promote the well-being of its people (TEU Art. 3) and the Europe 2020 strategy. Keeping people healthy and active longer will have a positive impact on productivity and competitiveness. The revision also fully respects the EU Charter on Fundamental Rights. Whilst unintended, certain measures might also lead to increased tax revenues for Member States.

Reaching these general objectives requires the realisation of the following **specific policy objectives:**

A. To remove obstacles to cross-border trade and ensure a level playing field for manufacturers and other economic operators.

B. To reduce the administrative burden for economic actors and public authorities due to the complexity of the current TPD and remaining disparities in legislation.

A high level of **health protection** has been considered when choosing between different options. In this context, the revision seeks to regulate tobacco products in a way that reflects its characteristics as an addictive product with proven negative health consequences linked to its consumption (including mouth, throat and lung cancer, cardiovascular diseases including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility, impacts on the unborn child). As such the revision aims to ensure that ingredients and packaging do not encourage or facilitate smoking uptake by young people. 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 the safeguards of the TPD (e.g. health warnings and ingredients regulation). In light of this, the following main **health consideration** was taken into account when comparing and choosing between different options:

C. To provide a high level of protection to citizens throughout the EU.

6. POLICY OPTIONS

A substantial number of policy options were considered in the revision. Some measures originally foreseen (e.g. asking the tobacco industry to contribute to health care costs as well as measures to introduce age verification mechanisms in all tobacco vending machines and common provisions on display of tobacco at point of sale) have been dropped.

For policy area "**STP and extension of the product scope**" (i.e. NCP and herbal products for smoking) the options ranged from no change to regulating the products under the TPD (health warnings/ingredients), or phasing out the products (herbal products for smoking). In the area of STP, lifting the current ban on oral tobacco was also assessed and in the area of NCP, setting up a new authorisation system or using the current medicinal products' framework were analysed.

Within the policy area "**packaging and labelling**" policy options included no change, introduction of bigger and mandatory pictorial warnings, plus prohibition of promotional and misleading

elements or introduction of full plain packaging. The measures exempt tobacco products other than FMC and RYO (i.e. cigars, cigarillos, pipe tobacco and STP) from some provisions, but this exemption should be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

In the policy area "**ingredients**" the policy options included mandatory or voluntary reporting in either different formats or based on a common electronic format. Various options in relation to content regulation were also assessed, including regulating additives with attractive, addictive and toxic properties, prohibit products with characterising flavours and with increased toxicity or addictiveness or ban all additives not essential for manufacturing. The measures exempt tobacco products other than FMC, RYO and STP (i.e. cigars, cigarillos and pipe tobacco) from some provisions, but this exemption should be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

In the policy area "**cross-border distance sales**", options range from no change to introducing a notification obligation or prohibiting cross-border distance sales of tobacco.

Finally, the policy area "**traceability and security features**" includes options from no change to the introduction of an EU tracking and tracing system with or without security features. Tobacco products other than FMC and RYO would be granted a transitional period.

7. COMPARING THE OPTIONS AND PREFERRED OPTION

7.1. SMOKELESS TOBACCO PRODUCTS AND EXTENSION OF THE PRODUCT SCOPE

a) Smokeless tobacco products (STP)

Lifting the ban of oral tobacco (snus) and subject STP to stricter rules on labelling and ingredients would remove the current differential treatment between different categories of STP. In economic terms, this option is expected to result in a significant growth for oral tobacco, while sales in other STP are expected to decrease. Economic actors would be faced with some compliance costs to adapt to the regulations on labelling and ingredients, but a harmonised approach at EU level is expected to be advantageous compared to consecutive changes by Member States. As regards health, the degree of harm from oral tobacco is currently being debated, but the overall conclusion is that oral tobacco is an addictive product with adverse health effects. There is no compelling evidence that lifting the ban on oral tobacco would lead to reduced smoking prevalence and it has been suggested that the product can play a role in uptake of tobacco consumption (gateway) or be used in combination with FMC (dual use), in particular in places where smoking is not allowed.

Maintaining the ban of oral tobacco, subjecting all novel tobacco products to a notification obligation and all STP to stricter labelling and ingredients regulation (i.e. health warnings on both sides of the packages and a ban of STP with characterising flavours) is the preferred option. This option would provide a common framework for STP in terms of ingredients and labelling while keeping the current ban on oral tobacco untouched. The introduction of a notification system for novel tobacco products would also contribute to increasing the knowledge base as regards these products for the purpose of possible future amendments to the Directive. The preferred option is well in line with FCTC guidelines on ingredients and labelling. Maintaining the ban on oral tobacco is considered to be the only effective measure to contain the use of this product and discourage the uptake of STP and nicotine addiction among non-smokers and by young people. As other STP have still very small markets in the EU and their growth potential is limited banning products with characterising flavours and making health warnings more visible is considered proportionate.

Maintaining the ban of oral tobacco, restrict the sale of other STP to areas of traditional use only and subject all STP to stricter labelling and ingredients rules (i.e. health warnings on both sides of the packages and a ban on STP with characterising flavours) would allow for equal

treatment of all STP and provide a high level of health protection, but considering the more limited growth potential of STP other than oral tobacco, at this stage, this option was discarded mainly because it was considered unnecessarily strict.

An even more far reaching option would have been to **ban all STP with the exception of oral tobacco in Sweden, which would have to respect stricter labelling and ingredients rules** and without allowing Member States to exempt products for traditional use. This option was discarded as it was considered disproportionate.

b) Nicotine containing products (NCP)

Regulating NCP under the TPD could contribute to improving the safety of these products. However, this option does not correspond to the current regulatory development in Member States, based on the function of these products.

Setting up of a separate authorisation scheme for NCP would imply high administrative costs for national authorities, involve complex considerations in terms determining the criteria to be used in the evaluation and imply a risk of overlap with the pharmaceutical framework.

Subjecting those NCP which fall above a predetermined nicotine threshold to the medicinal products' legislation and allowing the remaining NCP to be sold as consumer products provided they feature health warnings is the preferred option. It would remove the current differential treatment between NCP and Nicotine Replacement Therapies (NRT), increase legal certainty and consolidate the on-going development in Member States based on the function of these products. Authorised products could circulate freely in the EU, others only if their nicotine content is below the identified threshold and they comply with the labelling rules. The option encourages R&D in smoking cessation with the aim of maximising health gains.

Subjecting all NCP to medicinal products' legislation is the most stringent option identified, but this option was rejected for proportionality reasons.

c) Herbal products for smoking

Regulating herbal products for smoking under the TPD (labelling requirements) is the preferred option. It would contribute to a homogenous development in the EU facilitating free circulation, provide a common safety net for consumers and address the misleading potential of the products.

Phasing out the marketing of herbal products for smoking would be most beneficial from a health perspective, but result in a negative impact on the economic stakeholders involved. The solution was discarded mainly because it would not be proportionate, taking into account that the main concern relates to the misperception about adverse health effects. In addition herbal products do not present the same characteristics in terms of addictiveness as traditional cigarettes or other nicotine containing products.

7.2. PACKAGING AND LABELLING

Introducing **bigger and mandatory pictorial warnings** on both sides of tobacco packages would bring coherence to the currently fragmented situation (picture warnings are already in use in eight Member States and two more will follow from 2013), be in line with international commitments (FCTC), and facilitate cross-border trade. The adoption of EU wide measures would lead to cost savings for the industry compared to the current situation where the industry has to adapt consecutively to many different legal systems. From a health point of view, bigger and mandatory pictorial warnings would increase awareness about the negative health consequences of tobacco consumption in all EU Member States (while now consumers in the Member States that use picture and text health warnings are better informed than consumers in the countries that only use text

warnings), motivate behavioural change, and prevent smoking initiation, in particular among young people.

Introducing **bigger and mandatory pictorial warnings and in addition prohibiting promotional and misleading elements is the preferred option.** This would further advance the functioning of the internal market and imply cost savings compared to multiple national changes. This option would also reinforce the positive impacts on health by increasing further awareness about the product and its health related consequences. It would also contribute to discouraging, in particular young people, from taking up smoking. Member States would remain free to introduce plain packaging, as far as this is compatible with the Treaty.

Introduction of **plain packaging** at EU level would maximise the effects on the internal market and further reduce compliance costs for the industry. This option would provide the most positive impact from a health point of view. However, given the current lack of real life experience in the EU, pending legal disputes and concerns expressed by some stakeholders, it appears preferable to choose a less stringent option at this stage and report on this issue 5 years after transposition to assess developments.

7.3. REPORTING AND REGULATION OF INGREDIENTS

Introducing a **mandatory reporting in harmonised electronic format** would ensure a level playing field, facilitate analysing and monitoring of data and provide cost savings for industry compared to the current fragmented situation with different reporting formats in Member States.

Obliging Member States to regulate toxic, addictive and attractive additives in tobacco products would provide Member States with limited guidance and only result in limited positive impacts on the internal market. For economic stakeholders, the measure would lead to legal uncertainty and only limited cost savings compared to the current situation where the industry has to adapt to different national measures. This option is not expected to have any significant impact on smoking initiation.

Prohibiting tobacco products with characterising flavours and with increased toxicity or addictiveness is the preferred option.[8] This option would prevent a patchwork of national regulations and facilitate cross-border trade. The option would also imply a cost saving compared to the current situation where more and more multiple national changes can be expected. This option does not prohibit the use of all additives, but focus on products that have characterising flavours (e.g. vanilla and chocolate), as well as additives associated with energy and vitality (e.g. caffeine and taurine), or additives creating the impression that products have health benefits (e.g. vitamins). The number of affected products would be limited as well as the effects for the farmers, including those involved in Burley and Oriental growing, as this option does not regulate additives which are essential for the manufacture of tobacco products. This option would contribute to discouraging young people (attracted by flavoured products) from taking up smoking. Test panels will assist in the decision making process. The option also allows for further measures when scientific advances on toxicity and addictiveness arise.

Prohibiting all additives not essential for manufacturing would constitute the most stringent option.[9] This option would further improve the internal market and similarly to the option of prohibiting products with characterising flavours, could result in economies of scale. However, the measure would remove most additives, even those used in smaller quantities that do not give products a distinctive taste. Therefore this option would affect practically all products on the market, requiring reformulations and possibly leading to product withdrawals. Burley and Oriental tobacco growers could be particularly affected as more additives are used in the manufacturing of

[8] This option is similar to the current US approach.
[9] This option is similar to the Canadian and Brazilian approaches.

tobacco products using these types of tobacco varieties. In terms of health, this option would further reinforce the effect on consumption/prevalence, but not to the extent justifying the additional costs.

7.4. CROSS-BORDER DISTANCE SALES

The preferred option is to regulate cross-border distance sales in terms of notification obligations and age verification mechanisms. This option is expected to ensure better compliance with TPD and improve the situation for retailers engaged in legal activities, while continuing to allow purchasing of products not available in all Member States. Age verification and higher prices (legal sale) are expected to have a positive impact on prevalence/consumption. Setting up the system would imply some limited additional costs for national administrations, but these costs are considered proportionate considering the positive impacts on legal sales and reduced consumption. The costs are also largely compensated by improved enforcement possibilities.

A **prohibition of cross-border distance sale** would address the current distortions and facilitate traditional retailers to carry out their legal activity. It would also make it easier for Member States that have adopted stricter rules to enforce these and it would further reinforce the effect of the TPD by preventing purchasing of products not complying with the Directive. On the other hand, this option would fully remove one of the sales channels. Given that better compliance with the TPD can be achieved with an alternative less strict option, a full prohibition of cross-border distance sale was not considered necessary.

7.5. TRACEABILITY AND SECURITY FEATURES

An **EU wide tracking and tracing system** would ensure a homogenous approach, which means significant cost savings for industry and the creation of a level playing field for all operators on the internal market. It would also reinforce the effects of the TPD in terms of health warnings and ingredients regulation, by reducing the availability of illicit and non-compliant products. Taking into account that a large part of the market already has contractual obligations to have a tracking and tracing system in place, the compliance costs for the industry are expected to be proportionate, even if one considers that data storage should be outsourced to an independent third party. The measure is expected to contribute to a drop in consumption following increased awareness and reduced availability of cheap illicit FMC and RYO. 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").

An EU wide tracking and tracing system, **complemented by security features is the preferred option.** The option would maximise the effect of the TPD, facilitate market surveillance and empower consumers in verifying the authenticity of products. It also addresses the (unsubstantiated) concerns of some stakeholders who claim that revision of the TPD would result in an increase in illicit trade.

7.6. OVERALL CONCLUSION OF THE IMPACTS

7.6.1. Overview of preferred options

Following the conclusions in previous section, 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	**Maintain the ban on oral tobacco, subject all novel tobacco**	Maintain the ban on oral tobacco, restrict the sale of other	Ban all STP with the exception of oral tobacco in Sweden. Subject	-harmonised labelling and ingredients regulation for all STP. -facilitated level playing field. -proportionate to prevent the

	STP to stricter labelling and ingredients regulation	**products to notification obligation and all STP to stricter labelling and ingredients regulation**	STP to areas of traditional use only and subject all STP to stricter labelling and ingredients regulation.	oral tobacco in Sweden to stricter labelling and ingredients regulation.	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.
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	-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	-facilitates the free circulation of products -remove current misperception on health - Trade-off: Removes misperceptions while minimising compliance costs.

PA / Options	**1**	**2**	**3**	**Justification**
2. Packaging and labelling	Mandatory enlarged picture warnings	**Mandatory 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	-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 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 and addictiveness.**	Mandatory reporting in harmonised format. Prohibit all additives not essential for manufacturing.	-removes disparities on the internal market and facilitates free circulation -reduces administrative burden (reporting) -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	-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**	-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 protection. As far as the **internal market** is concerned, all 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** is concerned, the envisaged revision focuses on discouraging young people from taking up smoking, but would also allow adult consumers to take informed decisions. The revision would also allow smokers to benefit from the protective measures set by the TPD.

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 may, however, be outweighed by lost revenues due to a decrease in consumption.

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).

7.6.2. Overall impacts

It is expected that the combination of the preferred policy options will lead to a reduction of consumption of around 2% within a five year period beyond the baseline for FMCs and RYO. This corresponds to a **reduction of 2.4 million smokers in the EU.**

The impacts on **economic stakeholders** of complying with the preferred options (direct costs) are expected to be positive compared to the baseline scenario. On the other hand, the indirect impacts following from an expected decrease in consumption will lead over time to a loss of revenue for the FMC and RYO manufacturers of around 376 mEUR. This negative impact on FMC and RYO manufacturer might outweigh the benefits from the cost savings in terms of direct costs. However, money not spent on tobacco is expected to be spent on other sectors which in turn benefit economically from increased expenditure.

In terms of **employment** it is estimated that jobs lost in tobacco will be off-set by jobs in other sectors and that, overall, the measures will lead to a net gain in employment estimated to around 2,200 jobs. Possible regional employment impacts, as well as the specific situations of SMEs and micro-enterprises, have been carefully considered when formulating the preferred options.

The main benefit for **Governments** following the drop in consumption/prevalence is the improvement of health which is a value in its own right. 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 around 9.4 bnEUR even if one deducts reduced tax revenues. The table below provides a breakdown of the overall net costs and benefits.

On the other hand, social discounting 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.[10] This is particularly 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. 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 bnEUR.

Figure 1: Overall net costs and benefits (m EUR)

	Different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Decrease in excise tax revenues[11]	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

[10] 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.

[11] Disregarding measures taken against illicit trade and possibility to increase tax levels.

8. MONITORING AND EVALUATION

The following measures will ensure effective implementation of the revised TPD:

- Transposition meetings between the Commission and Member States.
- Setting up an implementation plan.
- Monitoring of a number of indicators relevant for the objective of the proposal.
- Setting up a network of Member States to discuss the implementation of the revised TPD.
- Commission Report on the implementation of the Directive five years after transposition.