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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)

{ SWD(2012) 452 final }

{ SWD(2012) 453 final }

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

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<sup>1</sup>.

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 has been repeatedly called for by Council and Parliament<sup>2</sup>. The initiative to revise the TPD is included in the Commission's Work Plan 2012<sup>3</sup>.

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<sup>4</sup>.
- 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<sup>5</sup>.
- Ensure that provisions of the Directive are **not circumvented** by placing on the market of products not compliant with the TPD<sup>6</sup>.

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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<sup>1</sup> OJ L 194, 18.7.2001, p. 26–35.

<sup>2</sup> 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.

<sup>3</sup> Annex 1 to the Commission work programme 2012 – forthcoming initiatives 2012. COM(2011)777 final

<sup>4</sup> [http://ec.europa.eu/atwork/key-documents/index\\_en.htm](http://ec.europa.eu/atwork/key-documents/index_en.htm) (accessed on 17 December 2012)

<sup>5</sup> 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.

<sup>6</sup> 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).

In line with Article 114 TFEU a high level of **health protection** has been taken as a basis when choosing between different policy options identified in the review of the TPD. In this context, the proposal seeks to regulate tobacco products in a way that reflects their specific characteristics (nicotine has addictive properties) and the negative consequences of their consumption (mouth, throat and lung cancer, cardiovascular problems including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility, impact on the unborn child etc).

Tobacco is the most significant cause of premature death in the EU, responsible for almost 700,000 deaths every year. The proposal 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<sup>7</sup>. This is also reflected in the selection and focus of the proposed policy areas and the products primarily targeted (cigarettes, roll-your-own and smokeless tobacco products). 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).

From a broader perspective, 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, 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 non-complying with the requirements of the Directive may be that the tax revenues of Member States are better protected, as these products often also circumvent national tax legislation.

The revision of the TPD focuses on five policy areas: (1) Smokeless tobacco products and extension of the product scope (i.e. nicotine containing products and herbal products for smoking), (2) packaging & labelling, (3) ingredients/additives, (4) cross-border distance sales and (5) traceability and security features.

While a number of elements can be maintained from the existing Directive (e.g. tar, nicotine and carbon monoxide yields, ingredients reporting and the ban of placing on the market of oral tobacco), in many areas very substantial changes are proposed and some areas are added to the Directive.

## 2. **RESULTS OF CONSULTATIONS WITH INTERESTED PARTIES AND IMPACT ASSESSMENT**

In preparation for this proposal, 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

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<sup>7</sup> Special Eurobarometer 385, 2012: [http://ec.europa.eu/health/eurobarometers/index\\_en.htm](http://ec.europa.eu/health/eurobarometers/index_en.htm)

responses<sup>8</sup> which appear to be the result of several citizen mobilisation campaigns that took place in some Member States<sup>9</sup>. The actions and efforts of these campaigns have affected the overall quantitative data of the public consultation, which indicate that most of the citizens responding to the consultation were against changes to the TPD. This outcome deviates significantly from the latest Eurobarometer survey, published in May 2012. The Eurobarometer survey indicates that EU citizens, including smokers, are largely in favour of tobacco control measures, including the ones hereby proposed such as putting pictorial warnings on all tobacco packages and introducing security features.<sup>10</sup> Unlike public consultations it is important to note that respondents in Eurobarometer surveys 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. A report presenting the outcome of the consultation was published on 27 July 2011, and contributions have been published online<sup>11</sup>.

**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 targeted discussions with NGOs, growers, cigarette producers, other tobacco producers, distributors of tobacco products and upstream suppliers of tobacco products have continued throughout 2011 and 2012<sup>12</sup>. A number of written contributions were also received, which have been carefully considered in assessing the impacts of different policy options. The Commissioner for Health and Consumer Policy met with Health NGOs and economic stakeholders in February-March 2012<sup>13</sup>. The revision of TPD has also been discussed regularly in the **TPD Regulatory Committee** from 2009 to 2012<sup>14</sup>.

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

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<sup>8</sup> 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.

<sup>9</sup> 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.

<sup>10</sup> Special Eurobarometer 385, 2012: [http://ec.europa.eu/health/eurobarometers/index\\_en.htm](http://ec.europa.eu/health/eurobarometers/index_en.htm)

<sup>11</sup> European Commission, Health and Consumer Directorate-General, July 2011, Report on the public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC. The report and contributions are published on:

[http://ec.europa.eu/health/tobacco/consultations/tobacco\\_cons\\_01\\_en.htm](http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm)

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

<sup>12</sup> Minutes for stakeholder meetings can be found at:

[http://ec.europa.eu/health/tobacco/events/index\\_en.htm#anchor4](http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor4)

<sup>13</sup> Idem.

<sup>14</sup> The minutes of the meetings can be found at:

[http://ec.europa.eu/health/tobacco/events/index\\_en.htm#anchor0](http://ec.europa.eu/health/tobacco/events/index_en.htm#anchor0)

or counterfeit products non-complying with the requirements of the Directive is already today a significant problem<sup>15</sup>.

### **3. LEGAL ELEMENTS OF THE PROPOSAL<sup>16</sup>**

#### **3.1. Ingredients and emissions**

The maximum yields of tar, nicotine and carbon monoxide as well as the measurement methods remain the same as in Directive 2001/37/EC.

Directive 2001/37/EC stipulates that Member States require manufacturers and importers of tobacco products to report on the ingredients used in such products. This proposal keeps in place this mandatory reporting system of ingredients and, in addition, foresees a common electronic format for the reporting and manufacturers are required to 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. In addition, the proposal foresees that 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.

The harmonised reporting format and mandatory reporting will create a level playing field and facilitate collection, analysis 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.

The current Directive 2001/37/EC does not harmonise Member States regulation on additives. Some Member States have therefore adopted legislation or concluded agreements with industry allowing or prohibiting certain ingredients. As a result, some ingredients are forbidden in some Member States, but not in others. The proposal foresees that tobacco products with characterising flavours, such as fruit flavours or chocolate, are prohibited. Test panels will 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 ensure that provisions or conditions set out under REACH<sup>17</sup> are applied to tobacco products as appropriate.

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<sup>15</sup> 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 report 2012).

<sup>16</sup> The suggested summary follows the order of Articles in the legislative proposal.

<sup>17</sup> Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p. 1.

The proposal exempts tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco from some provisions such as the prohibition of products with characterising flavours. This exemption is justified considering that these products are mainly consumed by older consumers, while the focus of this proposal is to regulate tobacco products in such a way as they do not encourage young people to start using tobacco. The exemption shall be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people). The proposal addresses the heterogeneous development in Member States in relation to ingredients regulation and takes into account international developments, such as provisions of FCTC on regulation of the contents of tobacco products and guidelines therein. It allows industry to adapt the production lines in one go whilst allowing industry some margin to differentiate between 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 delegated acts.

### **3.2. Labelling and packaging**

The proposal foresees that combined warnings (picture plus text) of 75% should be displayed on both sides of the packages of tobacco products, presented in rotation. Directive 2001/37/EC already makes text health warnings mandatory and picture warnings optional. Eight Member States have already taken the initiative to make pictorial warnings obligatory in their territories (two will follow in 2013). Tar, nicotine and carbon monoxide (TNCO) levels on the packages, as stipulated under Directive 2001/37/EC, are replaced with an information message referring to harmful substances of tobacco. Display of cessation information (e.g. quit-lines, websites) is added to the packages. Packaging of tobacco products, or the products themselves, shall not include any elements that promote tobacco products or mislead consumers to believe that the product is less harmful than others, refers to flavours or tastes or resembles a food product. The proposal also includes requirements for packages, e.g. cuboid shape for cigarette packages and minimum number of cigarettes per package.

Under the proposal, Member States would retain their power to regulate the area of the package not regulated by this Directive or other Union legislation, including implementing provisions providing full standardisation of packaging of tobacco products (including colours and font), 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 Directive five years after its transposition deadline.

The proposal exempts tobacco products other than cigarettes and roll-your own tobacco from larger health warnings. In order to increase the visibility of the health warnings on smokeless tobacco products, these will have to be put on both sides of the package according to the proposal, but their size will remain unchanged compared to Directive 2001/37. Other tobacco products (e.g. cigars and pipe tobacco) will be subject to rules corresponding to the provisions set out in Directive 2001/37 EC, i.e. text warnings of not less than 30% (front) plus 40% (back) of the

packages<sup>18</sup>. The exemption shall be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

The proposal seeks to ensure that the appearance of the package reflects the characteristics of the product inside the package - a product that has negative health consequences, is addictive, and is not for the consumption of children and teenagers. The proposal provides for an update of current provisions on packaging and labelling in relation to scientific and international development and addresses the current fragmented development in Member States, in particular as regards pictorial warnings. The proposal will both ensure effective display of the health warnings and leave a certain space on the package for display of trademarks. The limitation of the product scope to cigarettes and roll-your-own tobacco in a first stage is justified because other tobacco products (e.g. cigars and pipe tobacco) are primarily used by older consumers. The proposal is based on new evidence showing that bigger and pictorial warnings are more effective<sup>19</sup> and current indications of tar, nicotine and carbon monoxide levels are misleading. The exact size of the warning (75%) has been suggested after thorough analysis of scientific evidence and international experience<sup>20</sup> as well as international developments (Article 11 FCTC and its guidelines call for large double sided picture warnings, and strict rules on misleading information) as well as considerations of the impact on economic stakeholders.

### 3.3. Traceability and security features

Directive 2001/37/EC grants a power to the Commission to adopt technical measures related to traceability and identification, but this power has not been used. As the concept of traceability has developed over the past years, it is necessary to adapt and complete the legislation in terms of traceability and security features. The proposal foresees an EU tracking and tracing system at packet level for tobacco products throughout the supply chain (excluding retail). Member States shall ensure that manufacturers of tobacco products conclude data storage contracts with independent third parties in order to ensure independence of the system and full transparency and accessibility by Member States and the Commission at all times. Processing of personal data should respect relevant data protection provisions, including rules and safeguards laid down in Directive 95/46/EC<sup>21</sup>. In addition to tracking and tracing, visible security features shall be put on all tobacco products placed on the EU market in order to facilitate the identification of authentic products.

Technical standards to ensure compatibility between the tracking and tracing systems used as well as for the contracts with third parties shall be adopted by delegated acts. Technical standardisations for security features shall also be adopted by the use of delegated acts.

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<sup>18</sup> For Member States having more than one official language, the warnings should be increased to 32-35% and 45-50%.

<sup>19</sup> 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).

<sup>20</sup> 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.

<sup>21</sup> OJ L 281, 23.11.1995, p. 31.

Tobacco products other than cigarettes and roll-your-own-tobacco are granted a transitional period of five years.

The proposal ensures compliance with the requirements of the Directive, creates a level playing field between different operators (currently only the biggest four tobacco manufacturers are required to develop and use tracking and tracing systems), facilitates market surveillance and empowers consumers in verifying the authenticity of tobacco products. The proposal does not aim at an integration of the tracking and tracing system with existing excise and customs system (in particular the systems responsible for bulk movement control, such as Excise Movement and Control System (EMCS)).

### **3.4. Tobacco for oral use**

The ban of placing on the market (including cross-border distance sale) of tobacco for oral use (snus) as set out in Directive 2001/37/EC is maintained (except for Sweden which has an exemption in its Accession Treaty<sup>22</sup>).

It is not considered justified to lift the current ban 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 a ban of oral tobacco due to the harmful and addictive effects of the product. 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. The harmful effect of oral tobacco has been confirmed by the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and other studies. Given the continuous development of oral tobacco, in particular oral tobacco flavoured in a significant manner and presented in attractive packages in the Swedish market, there is a risk of uptake (also of other tobacco products) in new users, including young people. The industry confirmed that oral tobacco has huge market potential if the ban on oral tobacco were lifted.

The current ban was seen as proportionate by the Court of Justice of the European Union in 2004 due to the harmful effects, the uncertainty of oral tobacco as a substitute for cigarettes, the addictive and toxic properties of nicotine, oral tobacco's risk potential for young people and the novelty of the product<sup>23</sup>. This reasoning is still valid today.

### **3.5. Cross-border distance sales of tobacco products**

Cross-border distance sales of tobacco products fall outside the scope of Directive 2001/37/EC. The proposal includes a notification obligation for retailers of tobacco products intending to engage in cross-border distance sales. The proposal allows Member States to require the retailer to appoint a natural person, who ensures compliance with the Directive of products delivered to customers in Member States concerned. Mandatory age verification mechanism is also foreseen.

The proposal facilitates legal activity without removing any sales channels, while allowing consumers legitimate access to tobacco products not available on their

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<sup>22</sup> OJ C 241, 29.8.1994 (see Article 151 and Annex XV thereof).

<sup>23</sup> Case C-434/02 Arnold André GmbH & Co. KG v Landrat des Kreises Herford [2004] ECR I-11825.



domestic market. It reinforces the effect on the internal market by preventing purchasing of products not complying with the provisions of the Directive, including health warnings in the right language and ingredients regulation. It also aims at addressing underage purchasing. An unintended side-effect is that the proposal will reduce the availability of cheaper products not respecting national price policies.

### **3.6. Novel tobacco products**

Novel tobacco products are products containing tobacco which do not fall within any of the established product categories (e.g. cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use) and which are placed on the market after the entry into force of the Directive. These products will have to respect requirements of the Directive (e.g. in terms of labelling and ingredients) to ensure a level playing field, and the applicable rules will depend on whether the product involves a combustion process or not.

The proposal also foresees a notification obligation for novel tobacco products and a report on the market development in these products will be issued by the Commission five years after the transposition deadline of the Directive.

The introduction of a notification system for novel tobacco products would contribute to increasing the knowledge base as regards these products for purpose of possible future amendments to the Directive.

### **3.7. Nicotine containing products (NCP)**

NCP fall outside the scope of Directive 2001/37/EC and Member States have so far taken different regulatory approaches to address these products, including regulating them as medicinal products, applying certain provisions that are used for tobacco products or having no specific legislation.

The proposal stipulates that NCP that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance<sup>24</sup>. NCP with nicotine levels below this threshold can be sold as consumer products provided they feature an adapted health warning. The nicotine threshold identified in this proposal has been established by considering the nicotine content of medicinal products (Nicotine Replacement Therapies, NRTs) for smoking cessation which have already received a market authorisation under the medicinal products' legislation.

The proposal removes current legislative divergence between Member States and the differential treatment between Nicotine Replacement Therapies and Nicotine Containing Products, increases legal certainty and consolidates the on-going development in Member States. It also encourages research and innovation in smoking cessation with the aim of maximising health gains. Given the novelty and

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<sup>24</sup> Directive 2001/83 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. 67-128.

rapid increase of the NCP market as well as their addictive and toxic character there is an urgency to act, before more people – unaware of the content and effects of these products – inadvertently develop a nicotine addiction.

The labelling requirement set out in this proposal for NCP containing nicotine below the identified threshold will better inform consumers about the health risks associated with the products.

### **3.8. Herbal products for smoking**

Herbal products for smoking fall outside the scope of Directive 2001/37/EC and Member States regulate these products in different ways.

The proposal foresees adapted health warnings for herbal products for smoking to inform consumers about the adverse health effects of these products. In addition, no promotional or misleading elements are allowed on the packages.

The proposal ensures a more homogenous development in the EU and creates a safety net for consumers. The proposal also provides consumers and potential consumers with more appropriate information about the adverse health effects of herbal products for smoking and thus allows them to make informed choices.

### **3.9. Union competence**

#### *3.9.1. Legal base*

Directive 2001/37/EC was adopted on the basis of Article 95 of the Treaty establishing the European Community, TEC (now Article 114 Treaty on the Functioning of the European Union, TFEU)<sup>25</sup>. The choice of the legal base has been confirmed by the Court of Justice of the European Union<sup>26</sup>. The same legal basis is appropriate for this proposal, aiming at revising Directive 2001/37/EC. 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.

First, this legal basis is appropriate to update, in light of scientific and international developments, the existing level of harmonisation as regards display of tar, nicotine and carbon monoxide levels, the size of the warnings and certain aspects in the area of traceability features<sup>27</sup>. Second, approximation of national legislations on tobacco products under Article 114 is justified when it is necessary to remove obstacles to the

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<sup>25</sup> In addition to Article 95 TEC the TPD was also adopted on the basis of Article 133 TEC.

In 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, 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.

<sup>26</sup> See case C-491/01 *The Queen v Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*.

<sup>27</sup> *Idem*, para 77.

free movement of goods<sup>28</sup>. This is particularly relevant as regards measures related to product scope, labelling and ingredients. Third, harmonisation is justified to ensure that certain provisions concerning the internal market are not circumvented<sup>29</sup>. This is particularly relevant for the areas on cross-border distance sales and traceability and security features. Measures foreseen in these areas will facilitate licit activity and thus prevent sale of tobacco products not complying with the TPD, including health warnings in the right language and ingredients regulation.

### 3.9.2. *Subsidiarity*

The objectives of the proposed action cannot be sufficiently achieved by the Member States, neither at central nor at regional or local level, but can rather be best achieved at Union level (Article 5(3) TEU).

Some of the areas included in this proposal are already harmonised, but need to be updated in accordance with market, scientific and international developments. Due to the harmonisation which already exists under Directive 2001/37/EC, Member States are prevented from acting unilaterally, for example to increase the size of the health warnings or to remove the display of tar, nicotine and carbon monoxide.

Other areas relevant for this proposal are subject to different legal approaches in Member States which have led to obstacles to the functioning of the internal market. For example, for 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. Only a harmonised approach at EU-level in such areas can remove obstacles to cross-border trade and avoid fragmentation, while ensuring a comparable high level of health protection.

Finally, it is very difficult for a Member State to act unilaterally in some areas 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 regulate tobacco internet sales, e.g. regarding the minimum legal age to purchase tobacco, if such sales are unregulated in other Member States. A legally binding and EU wide measure therefore produces clear benefits. The same holds true for the EU tracking and tracing system, when tobacco products regularly move across borders.

This proposal also contributes to greater consistency, both between and within Member States, and a higher level of legal certainty, for example in the area of nicotine containing products where the legal current situation is complex and unclear, which undermines the level playing field.

### 3.9.3. *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). This proposal provides an appropriate level of margin for implementation by the Member States. It fully respects responsibilities of the Member States to

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<sup>28</sup> Idem, para 64-75.

<sup>29</sup> Idem, para 82-83.

organise, finance and deliver health services and medical care. It is a balanced proposal, which is ambitious while respecting legitimate interests of stakeholders.

#### 3.9.4. *Fundamental Rights*

The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), and the right to property (Article 17). 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 and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union.

#### 3.9.5. *Legal form*

The proposal takes the form of a Directive which will replace as a whole Directive 2001/37/EC.

Even though the proposed changes do not affect all provisions of Directive 2001/37/EC, the text would have to undergo numerous modifications which would change its current presentation. Against this background, it is proposed to repeal Directive 2001/37/EC and, for reasons of clarity, to replace it with a new act modelled on the Directive in force but enriched with new elements and adjustments.

## 4. **BUDGETARY IMPLICATIONS**

The budgetary implications of the proposal are as follows:

- Commission staff to continue to manage and further develop the EU regulatory framework on tobacco products' regulation (functioning of this Directive and drafting of delegated/implementing acts), including Commission bodies or staff to provide scientific opinion and technical support.
- Commission staff to continue to support Member States in ensuring its effective and efficient implementation, including the development of an implementation plan and a network of Member States to discuss implementation.
- Costs for continue organising meetings of the Committee set up under this Directive, including reimbursement of the members appointed by the Member States.
- Costs for further development of a new EU wide electronic format for ingredients reporting.
- Costs for coordination of new test panels approved and monitored by Member States.
- Costs for continuing to keep the health warnings up to date, including testing of new warnings.

- Costs for continuing participation in international cooperation.

Details of the costs are set out in the legislative financial statement. The proposal allows Member States to charge a fee for handling the ingredients reporting.

The budgetary impact is consistent with the MFF 2014-2020 as proposed by the Commission.

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products<sup>30</sup> lays down rules at Union level concerning tobacco products. Due to scientific, market and international developments, substantial changes are to be made to that Directive. For the sake of clarity it is appropriate to repeal Directive 2001/37/EC and to replace it by a new Directive.
- (2) In its reports of 2005 and 2007 on the application of Directive 2001/37/EC, submitted in accordance with Article 11 of that Directive, the Commission identified areas in which further action was considered useful<sup>31</sup>. In 2008 and 2010 the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) provided scientific advice to the Commission on smokeless tobacco products and tobacco

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<sup>30</sup> OJ L 194, 18.7.2001, p. 26.

<sup>31</sup> Reports of the Commission to the European Parliament, the Council and the European Economic and Social Committee: First Report on the Application of the Tobacco Products Directive, COM (2005)339 final. Second Report on the Application of the Tobacco Products Directive, COM (2007)754 final.

additives<sup>32</sup>. In 2010 a broad stakeholder consultation took place<sup>33</sup>, which was followed by targeted stakeholder consultations and accompanied by studies by external consultants. Member States were consulted throughout the process. The European Parliament and the Council repeatedly called on the Commission to review and update Directive 2001/37/EC<sup>34</sup>.

- (3) In certain areas covered by Directive 2001/37/EC Member States are de jure or de facto prevented from effectively adapting their legislation to new developments. This is of relevance in particular for the labelling rules, where Member States cannot increase the size of the health warnings, change their location on the unit packets or replace the misleading warnings on the tar, nicotine and carbon monoxide (TNCO) levels.
- (4) In other areas there are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation, and sale of tobacco and related products which impede the functioning of the internal market. In the light of scientific, market and international developments these discrepancies are expected to increase. This applies in particular to nicotine containing products, herbal products for smoking, ingredients and emissions, certain aspects of labelling and packaging and the cross-border distance sales of tobacco products.
- (5) Those barriers should be eliminated and, to this end, the rules relating to the manufacture, presentation and sale of tobacco and related products should be further approximated.
- (6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for legislative action at Union rather than national level to achieve the smooth operation of the internal market.
- (7) Legislative action at Union level is also necessary to implement the WHO Framework Convention on Tobacco Control (hereinafter: "FCTC") of May 2003 to which the European Union and its Member States are Parties<sup>35</sup>. Of relevance are in particular its

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<sup>32</sup> SCENIHR. Health effects of smokeless tobacco products. 6 February 2008  
[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_o\\_013.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_013.pdf)

SCENIHR. Addictiveness and attractiveness of Tobacco Additives. 12 November 2010  
[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihhr\\_o\\_031.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihhr_o_031.pdf)

<sup>33</sup> European Commission, Health and Consumer Directorate-General, July 2011, Report on the public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC. The report and contributions are published on:  
[http://ec.europa.eu/health/tobacco/consultations/tobacco\\_cons\\_01\\_en.htm](http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm)

<sup>34</sup> 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 invites the Commission to consider strengthening the tobacco control legislation; 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.

<sup>35</sup> Council Decision (2004/513/EC) of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213, 15.6.2004, p. 8.

Articles 9 (regulation of the contents of tobacco products), 10 (regulation of tobacco product disclosures), 11 (packaging and labelling of tobacco products), 13 (advertising) and 15 (illicit trade in tobacco products). A set of guidelines for the implementation of FCTC provisions was adopted by consensus during various Conferences of the Parties to the FCTC with the support of the Union and the Member States.

- (8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people. .
- (9) Directive 2001/37/EC established maximum limits for tar, nicotine and carbon monoxide yields that should be applicable also for products which are exported from the Union. These maximum limits and this approach remain valid.
- (10) For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to ISO standards 4387, 10315 and 8454, which are internationally recognised standards. For other emissions there are no internationally agreed standards or tests for quantifying the yields, but efforts are ongoing to develop them.
- (11) In relation to the fixing of maximum yields, it might be necessary and appropriate at a later date to adapt the yields fixed or to fix maximum thresholds for emissions, taking into consideration their toxicity or addictiveness.
- (12) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on ingredients and emissions to assess the attractiveness, addictiveness and toxicity of tobacco products and the risks to health associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be reinforced. This is consistent with the obligation placed on the Union to ensure a high level of protection for human health.
- (13) The current use of different reporting formats makes it difficult for manufacturers and importers to fulfil their reporting obligations and burdensome for the Member States and the Commission to compare, analyse and draw conclusions from the information received. In this light there should be a common mandatory format for the reporting of ingredients and emissions. The greatest possible transparency of product information should be ensured for the general public, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the manufacturers of tobacco products.
- (14) 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 or entered into binding agreements with the industry allowing or prohibiting certain ingredients. As a result, some ingredients are regulated in some Member States, but not in others. Member States are also taking different approaches as regards additives integrated in the filter of cigarettes as well as additives colouring the tobacco smoke. Without harmonisation, the obstacles on the



internal market are expected to increase in the coming years taking into account the implementation of the FCTC and its guidelines and considering experience gained in other jurisdictions outside the Union. The guidelines on Articles 9 and 10 FCTC call in particular for the removal of ingredients that increase palatability, create the impression that the tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

- (15) The likelihood of diverging regulation is further increased by concerns over tobacco products, including smokeless tobacco products, having a characterising flavour other than tobacco, which may facilitate uptake of tobacco consumption or affect consumption patterns. For example, in many countries, sales of mentholated products gradually increased even as smoking prevalence overall declined. A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people. Measures introducing unjustified differences of treatment between flavoured cigarettes (e.g. menthol and clove cigarettes) should be avoided<sup>36</sup>.
- (16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a characterising flavour.. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.
- (17) Certain additives are used to create the impression that tobacco products have health benefits, present reduced health hazards or increase mental alertness and physical performance. These additives should be prohibited in order to ensure uniform rules and a high level of health protection.
- (18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco which are mainly consumed by older consumers, should be granted an exemption from certain ingredients requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people.
- (19) Disparities still exist between national provisions regarding the labelling of tobacco products, in particular with regard to the use of combined health warnings consisting of a picture and a text, information on cessation services and promotional elements in and on packets.
- (20) Such disparities are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated. Also, consumers in some Member States may be better informed about the health risks of

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<sup>36</sup> WTO Appellate Body, AB-2012-1, United States – Measures Affecting the Production and Sale of Clove Cigarettes (DS406).

tobacco products than in others. Without further action at Union level, the existing disparities are likely to increase in the coming years.

- (21) Adaptation of the labelling provisions is also necessary to align the rules at Union level with international developments. For example the guidelines on Article 11 FCTC call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information. The provisions on misleading information will complement the general ban on misleading business to consumer commercial practices laid down in Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market<sup>37</sup>.
- (22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.
- (23) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, including the opening mechanism. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours', 'slim', names, pictures, and figurative or other signs. Likewise, the size and appearance of individual cigarettes can mislead consumers by creating the impression that they are less harmful. A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed.
- (24) Tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other tobacco products should follow specific rules. The visibility of the health warnings on smokeless tobacco products needs to be ensured. Warnings should therefore be placed on the two main surfaces of smokeless tobacco product packaging.
- (25) Member States apply different rules on minimum number of cigarettes per packet. Those rules should be aligned in order to ensure free circulation of the concerned products.
- (26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that

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<sup>37</sup> OJ L 149, 11.6.2005, p. 22-39.

these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not products are authentic.

- (27) An interoperable tracking and tracing system and a common security feature should be developed. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the security features. This would allow producers of other tobacco products to benefit from the experiences gained in the meantime.
- (28) In order to ensure independence and transparency, manufacturers of tobacco products should conclude data storage contracts with independent third parties, under the auspices of an external auditor. The data related to the tracking and tracing system should be kept separate from other company related data and be under the control of and accessible at all times by the competent authorities from Member States and the Commission.
- (29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use<sup>38</sup> prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition<sup>39</sup>. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people. For other smokeless tobacco products that are not produced for the mass market, a strict labelling and ingredients regulation is considered sufficient to contain market expansion beyond their traditional use.
- (30) Cross-border distance sales of tobacco facilitate access to tobacco products of young people and risk to undermine compliance with the requirements provided for by tobacco control legislation and in particular by this Directive. Common rules on a notification system are necessary to ensure that this Directive achieves its full potential. The provision on notification of cross-border distance sales of tobacco in this Directive should apply notwithstanding the notification procedure set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services<sup>40</sup>. Business to consumer distance sale of tobacco products is further regulated by Directive 97/7/EC of the European Parliament and the Council of 20 May 1997 on the protection of consumers in respect of distance contracts, which will be replaced by Directive 2011/83/EU of the

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<sup>38</sup> OJ L 359, 8.12.1989, p. 1.

<sup>39</sup> OJ C 241, 29.8.1994.

<sup>40</sup> OJ L 178, 17.7.2000, p. 1-16.

European Parliament and the Council of 25 October 2011 on consumer rights, as of 13 June 2014.<sup>41</sup>

- (31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.
- (32) In order to ensure a level playing field, novel tobacco products, which are tobacco products in the sense of this Directive, should respect the requirements provided for in this Directive.
- (33) Nicotine-containing products are sold on the Union market. The different regulatory approaches taken by Member States to address health and safety concerns associated with these products have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet.
- (34) 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<sup>42</sup> provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.
- (35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of consumers to potential health risks.
- (36) The regulation of herbal products for smoking differs between Member States and these products are often perceived as harmless or less harmful despite the health risk caused by their combustion. In order to ensure the proper functioning of the internal market and improve information to consumers, common labelling rules should be introduced at Union level.

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<sup>41</sup> OJ L 144, 4.6.1997, p. 19-27 and OJ L 304, 22.11.2011, p. 64-88.

<sup>42</sup> OJ L 311, 28.11.2001, p. 67, as last amended by Directive 2011/62/EU, OJ L 174, 1.7.2011, p. 74.

- (37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting, the determination of products with characterising flavours or with increased levels of toxicity and addictiveness and the methodology for determining whether a tobacco product has characterising flavour, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011<sup>43</sup>.
- (38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, , the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.
- (39) The Commission should monitor the developments and submit a report 5 years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary.
- (40) A Member State that deems it necessary to maintain more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, on grounds of overriding needs relating to the protection of public health. A Member State should also be allowed to introduce more stringent provisions, applying to all products alike, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. More stringent national provisions should be necessary and proportionate, not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.
- (41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance, maintain or introduce provisions providing standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of

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<sup>43</sup> OJ L 55, 28.2.2011, p. 13-18.

information in the field of technical standards and regulations and on rules on Information Society services<sup>44</sup>.

- (42) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>45</sup>.
- (43) The provisions of this Directive are without prejudice to Union legislation governing the use and labelling of genetically modified organisms.
- (44) In accordance with the Joint Political Declaration of Member States and the Commission of 28 September 2011 on explanatory documents, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (45) The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), and the right to property (Article 17). 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 and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union. The application of this Directive should respect the EU law and relevant international obligations.

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<sup>44</sup> OJ L 204, 21.7.1998, p. 37-48.

<sup>45</sup> OJ L 281, 23.11.1995, p. 31.

HAVE ADOPTED THIS DIRECTIVE:

## TITLE I – COMMON PROVISIONS

### *Article 1*

#### **Aim**

The aim of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

- (a) the ingredients and emissions of tobacco products and related reporting obligations including the maximum yields for tar, nicotine and carbon monoxide for cigarettes;
- (b) the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features to ensure compliance with this Directive;
- (c) the prohibition to place on the market tobacco for oral use;
- (d) cross-border distance sales of tobacco products;
- (e) the notification obligation for novel tobacco products;
- (f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely nicotine-containing products and herbal products for smoking;

in order to facilitate the functioning of the internal market in tobacco and related products, taking as a basis a high level of health protection.

### *Article 2*

#### **Definitions**

For the purposes of this Directive, the following definitions shall apply:

- (1) 'addictiveness' means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control behaviour typically by instilling a reward or a relief from withdrawal symptoms, or both;
- (2) 'additive' means substance contained in a tobacco product, its unit packet or any outside packaging with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants;
- (3) 'age verification system' means a computing system that unambiguously confirms the consumer's age in electronic form according to national requirements;

- (4) 'characterising flavour' means 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;
- (5) 'chewing tobacco' means a smokeless tobacco product exclusively designed for the purpose of chewing;
- (6) 'cigar' means 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<sup>46</sup>;
- (7) 'cigarette' means a roll of tobacco consumed via a combustion process and further defined in Article 3(1) of Council Directive 2011/64/EU;
- (8) 'cigarillo' means a small type of cigar with a diameter of up to 8 mm;
- (9) 'combined health warning' means a health warning provided for in this Directive and consisting of a combination of a text warning and a corresponding photograph or illustration;
- (10) 'consumer' means a natural person who is acting for purposes which are outside his trade, business, craft or profession;
- (11) 'cross-border distance sales' means a distance sales service where, at the time the consumer orders the product, the consumer is located in a Member State other than the Member State or the third country where the retail outlet is established; a retail outlet is deemed to be established in a Member State:
  - (a) in the case of a natural person - if he/she has his/her place of business in that Member State;
  - (b) in other cases - if it has its statutory seat, central administration or place of business, including a branch, agency or any other establishment in that Member State;
- (12) 'emissions' means substances that are released when a tobacco product is used as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;
- (13) 'flavouring' means an additive that imparts aroma and/or taste;
- (14) 'health warning' means a warning provided for in this Directive, including text warnings, combined health warnings, general warnings and information messages;
- (15) 'herbal product for smoking' means a product based on plants or herbs which contains no tobacco and is consumed via a combustion process;
- (16) 'import of tobacco and related products' means the entry into the territory of the Union of such products unless the products upon their entry into the Union are

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<sup>46</sup> OJ L 176, 5.7.2011, p. 24.



placed under a customs suspensive procedure or arrangement, as well as their release from a customs suspensive procedure or arrangement;

- (17) 'importer of tobacco and related products' means the owner or a person having the right of disposal over tobacco and related products that have been brought into the territory of the Union;
- (18) 'ingredient' means 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;
- (19) 'maximum level' or 'maximum yield' means the maximum content or emission, including 0, of a substance in a tobacco product measured in grams;
- (20) 'nasal tobacco' means a smokeless tobacco product consumed via the nose;
- (21) 'nicotine' means nicotinic alkaloids;
- (22) 'nicotine-containing product' means a product usable for consumption by 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;
- (23) 'novel tobacco product' means 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 this Directive;
- (24) 'outside packaging' means any packaging in which products are placed on the market and which include a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;
- (25) 'place on the market' means to make products available to consumers located in the Union, with or without payment, including by means of distance sale; in case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;
- (26) 'pipe tobacco' means tobacco consumed via a combustion process and exclusively designed for the purpose of being used in a pipe;
- (27) 'retail outlet' means any outlet where tobacco products are placed on the market including by a natural person;
- (28) 'roll-your-own tobacco' means tobacco which can be used for making cigarettes by consumers or retail outlets;
- (29) 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;
- (30) 'substantial change of circumstances' means an increase of the sales volumes by product category, such as pipe tobacco, cigar, cigarillo, by at least 10% in at least

10 Member States based on sales data transmitted in accordance with Article 5(4); or an increase of the prevalence level in the consumer group under 25 years of age by at least 5 percentage points in at least 10 Member States for the respective product category based on \_\_\_\_ [this date will be set at the moment of adoption of the Directive] Eurobarometer report or equivalent prevalence studies;

- (31) 'tar' means the raw anhydrous nicotine-free condensate of smoke;
- (32) 'tobacco for oral use' means 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;
- (33) 'tobacco for smoking' means a tobacco product other than a smokeless tobacco product;
- (34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco, whether genetically modified or not;
- (35) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually upon repeated or continuous consumption or exposure;
- (36) 'unit packet' means the smallest individual packaging of a product that is placed on the market.

## **TITLE II – TOBACCO PRODUCTS**

### **Chapter I: Ingredients and emissions**

#### *Article 3*

##### **Maximum tar, nicotine, carbon monoxide and other yields**

1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than:
  - (a) 10 mg per cigarette for tar,
  - (b) 1 mg per cigarette for nicotine,
  - (c) 10 mg per cigarette for carbon monoxide.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the maximum yields laid down in paragraph 1, taking into account scientific development and internationally agreed standards.
3. Member States shall notify the Commission of the maximum yields that they set for other emissions of cigarettes and for emissions of tobacco products other than

cigarettes. Taking into account internationally agreed standards, where available, and based on scientific evidence and on the yields notified by Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes that increase in an appreciable manner the toxic or addictive effect of tobacco products beyond the threshold of toxicity and addictiveness stemming from the yields of tar, nicotine and carbon monoxide fixed in paragraph 1.

#### *Article 4*

##### **Measurement methods**

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

The accuracy of the tar and nicotine indications shall be verified in accordance with ISO standard 8243.

2. The measurement referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the methods of measurement of the tar, nicotine and carbon monoxide yields, taking into account scientific and technical developments and internationally agreed standards.
4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. Based on these methods, and taking into account scientific and technical developments as well as internationally agreed standards the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement.

#### *Article 5*

##### **Reporting of ingredients and emissions**

1. Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a

product is modified affecting the information provided under this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified tobacco product.

The list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. The list shall indicate their status, including whether the ingredients have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>47</sup> as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures<sup>48</sup>. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health of consumers and taking into account, *inter alia*, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product. Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4 paragraph 4, the manufacturers and importers shall indicate the measurement methods used. Member States may also require manufacturers or importers to carry out other tests as may be laid down by the competent national authorities in order to assess the effects of substances on health, taking into account, *inter alia*, their addictiveness and toxicity.

2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a dedicated website, which is available to the general public. In doing so Member States shall take due account of the need to protect information which constitutes a trade secret.
3. The Commission shall, by means of implementing acts, lay down and if necessary update the format for the submission and dissemination of the information specified in paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.
4. Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups, including young people, relating to ingredients and emissions. Member States shall also require manufacturers and importers to report the sales volume data per product, reported in sticks or kilograms, and per Member State on a yearly basis starting from the full calendar year following that of the entry into force of this Directive. Member States shall provide alternative or additional sales data, as appropriate, to ensure that information on sales volume requested under this paragraph is reliable and complete.
5. All data and information to be provided to and by Member States under this Article shall be provided in electronic form. Member States shall store the information electronically and shall ensure that the Commission has access to the information at all times. Other Member States shall have access to this information upon justified

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<sup>47</sup> OJ L 396, 30.12.2006, p. 1.

<sup>48</sup> OJ L 353, 31.12.2008, p. 1–1355.

request. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

6. Fees charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article, if any, shall not exceed the cost attributable to those activities.

## *Article 6*

### **Regulation of ingredients**

1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products, as long as the additives do not result in a product with a characterising flavour.

Member States shall notify the Commission of measures taken pursuant to this paragraph.

2. The Commission shall at the request of a Member State or may on its own initiative determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

3. In case the experience gained in the application of paragraphs 1 and 2 shows that a certain additive or a combination thereof typically impart a characterising flavour when it exceeds a certain level of presence or concentration the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives or combination of additives that cause the characterising flavour.
4. Member States shall prohibit the use of the following additives in tobacco products:
  - (a) vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards, or
  - (b) caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality, or
  - (c) additives having colouring properties for emissions.
5. Member States shall prohibit the use of flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing

modification of flavour or smoke intensity. Filters and capsules shall not contain tobacco.

6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.
7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.  
  
Member States shall notify to the Commission measures taken pursuant to this paragraph.
8. The Commission shall at the request of a Member State or may on its own initiative determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall be based on the latest scientific evidence.
9. In case scientific evidence and the experience gained in the application of paragraphs 7 and 8 shows that a certain additive or a certain quantity thereof amplify in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives.
10. Tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

## **Chapter II: Labelling and packaging**

### *Article 7*

#### **General provisions**

1. Each unit packet of tobacco products and any outside packaging shall carry health warnings in the official language or languages of the Member State where the product is placed on the market.
2. Health warnings shall occupy the entire surface reserved for them and they shall not be commented on, paraphrased or referred to in any form.
3. In order to ensure their graphic integrity and visibility, health warnings shall be irremovably printed, indelible and in no way hidden or interrupted, including by tax stamps, price marks, tracking and tracing marks, security features or by any type of wrapper, pouch, jacket, box or other device or by the opening of the unit packet.

4. Member States shall ensure that the health warnings of the main surface of the unit packet and any outside packaging are fully visible, including not being partially or totally hidden or interrupted by wrappers, pouches, jacket, boxes or other devices when tobacco products are placed on the market.
5. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.
6. Member States shall not increase the size of the health warnings including by introduction of an obligation to surround the health warnings by a border. The actual size of the health warnings shall be calculated in relation to the surface on which they are placed before the unit packet is opened.
7. Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of this chapter.

#### *Article 8*

#### **Text warnings for tobacco for smoking**

1. Each unit packet and any outside packaging of tobacco for smoking shall carry the following general warning:

*Smoking kills – quit now*

2. Each unit packet and any outside packaging of tobacco for smoking shall carry the following information message:

*Tobacco smoke contains over 70 substances known to cause cancer*

3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets. These warnings shall have a width of not less than 20 mm and a height of not less than 43 mm. For roll-your-own tobacco the information message shall be printed on the surface that becomes visible when opening the unit packet. Both the general warning and the information message shall cover 50% of the surface on which they are printed.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:

- (a) to adapt the wording of the health warnings laid down in paragraphs 1 and 2 to scientific and market developments;
- (b) to define the position, format, layout and design of the health warnings laid down in this Article, including their font type and background colour.

## Article 9

### **Combined health warnings for tobacco for smoking**

1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall:
  - (a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library;
  - (b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;
  - (c) cover 75 % of the external area of both the front and back surface of the unit packet and any outside packaging;
  - (d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;
  - (e) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging;
  - (f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;
  - (g) for unit packets of cigarettes, respect the following dimensions:
    - (i) height: not less than 64 mm;
    - (ii) width: not less than 55 mm.
2. The combined health warnings shall be divided into three sets rotating on an annual basis. Member States shall ensure that each combined health warning is displayed as nearly as possible on equal numbers of each brand.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:
  - (a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments;
  - (b) establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments;
  - (c) define the position, format, layout, design, rotation and proportions of the health warnings;
  - (d) by way of derogation from Article 7(3), lay down the conditions under which health warnings may be broken during unit packet opening in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.



## Article 10

### **Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco**

1. Tobacco for smoking other than cigarettes and roll-your-own tobacco shall be exempted from the obligations to carry the information message laid down in Article 8(2) and the combined health warnings in Article 9. In addition to the general warning specified in Article 8(1), each unit packet and any outside packaging of these products shall carry a text warning listed in Annex I. The general warning specified in Article 8(1) shall include a reference to the cessation services in accordance with Article 9(1)(b).

The general warning shall be printed on the most visible surface of the unit packet and any outside packaging. The text warnings listed in Annex I shall be rotated in such a way as to guarantee their regular appearance. These warnings shall be printed on the other most visible surface of the unit packet and any outside packaging.

2. The general warning referred to in paragraph 1 shall cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.
3. The text warning referred to in paragraph 1 shall cover 40 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 45 % for Member States with two official languages and 50 % for Member States with three official languages.
4. The general warning and the text warning referred to in paragraph 1 shall be:
  - (a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;
  - (b) centred in the area in which they are required to be printed, parallel to the top edge of the unit packet and any outside packaging;
  - (c) surrounded by a black border not less than 3 mm and not more than 4 mm in width inside the surface reserved for the text of the warning.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22, to withdraw the exemption laid down in paragraph 1 if there is a substantial change of circumstances as established in a Commission report.

## Article 11

### **Labelling of smokeless tobacco products**

1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

*This tobacco product can damage your health and is addictive*

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(4). In addition, it shall:
  - (a) be printed on the two largest surfaces of the unit packet and any outside packaging;
  - (b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 1 and 2 taking into account scientific and market developments.

### *Article 12*

#### **Product description**

1. The labelling of a unit packet and any outside packaging and the tobacco product itself shall not include any element or feature that:
  - (a) promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
  - (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or social effects;
  - (c) refers to flavour, taste, any flavourings or other additives or the absence thereof;
  - (d) resembles a food product.
2. Prohibited elements and features may include but are not limited to texts, symbols, names, trade marks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

### *Article 13*

#### **Appearance and content of unit packets**

1. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have the form of a pouch, i.e. a rectangular pocket with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the

packet. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.

2. A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after the opening is first opened, other than the flip-top lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to define more detailed rules for the shape and size of unit packets in so far as these rules are necessary to ensure the full visibility and integrity of the health warnings before the first opening, during the opening and after reclosing of the unit packet.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to make either cuboid or cylindrical shape mandatory for unit packets of tobacco products other than cigarettes and roll-your-own tobacco if there is a substantial change of circumstances as established in a Commission report.

#### *Article 14*

#### **Traceability and security features**

1. Member States shall ensure that all unit packets of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.
2. The unique identifier shall allow determining:
  - (a) the date and place of manufacturing;
  - (b) the manufacturing facility;
  - (c) the machine used to manufacture the products;
  - (d) the production shift or time of manufacture;
  - (e) the product name;
  - (f) the intended market of retail sale;
  - (g) the intended shipment route;
  - (h) where applicable, the importer into the Union;
  - (i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used;
  - (j) the identity of all purchasers from manufacturing to the first retail outlet;

- (k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.
3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.
  4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies with the necessary equipment allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.
  5. Recorded data cannot be modified or deleted by any economic operator involved in the trade of tobacco products, but the economic operator that introduced the data and other economic operators directly concerned by the transaction such as the supplier or the recipient can comment on previously introduced data. The economic operator concerned shall add the correct data and a reference to the previous entry which requires rectification in their view. In exceptional circumstances and upon submission of adequate evidence, the competent authority in the Member State in which the recording took place or if the recording took place outside the Union the competent authority in the Member State of importation, can authorise the modification or deletion of data previously registered.
  6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. Member States shall ensure full transparency and accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. In duly justified cases Member States or the Commission can provide manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations.
  7. Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.
  8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible, tamper proof security feature of at least 1 cm<sup>2</sup>, which shall be irremovably printed or affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation.

9. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:
  - (a) to define the key elements (such as duration, renewability, expertise required, confidentiality) of the contract referred to in paragraph 6, including its regular monitoring and evaluation;
  - (b) to define the technical standards to ensure that the systems used for the unique identifiers and the related functions are fully compatible with each other across the Union and
  - (c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.
10. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraph 1 to 8 during a period of 5 years following the date referred to in paragraph 1 of Article 25.

### **Chapter III: Tobacco for oral use**

#### *Article 15*

#### **Tobacco for oral use**

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

### **Chapter IV: Cross-border distance sales of tobacco products**

#### *Article 16*

#### **Cross-border distance sales of tobacco products**

1. Member States shall oblige retail outlets intending to engage in cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State where the retail outlet is established and in the Member State where the actual or potential consumer is located. Retail outlets established outside the Union have to register with the competent authorities in the Member State where the actual or potential consumer is located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities:
  - (a) name or corporate name and permanent address of the place of activity from where the tobacco products are supplied;
  - (b) the starting date of the activity of offering tobacco products for cross-border distance sales to the public by means of information society services;

- (c) the address of the website/-s used for that purpose and all relevant information necessary to identify the website.
2. The competent authorities of the Member States shall publish the complete list of all retail outlets registered with them in accordance with the rules and safeguards laid down in Directive 95/46/EC. Retail outlets may only start placing tobacco products on the market in form of distance sales as of the moment the name of the retail outlet is published in the relevant Member States.
3. If it is necessary in order to ensure compliance and facilitate enforcement, Member States of destination may require that the retail outlet nominates a natural person who is responsible for verifying the tobacco products before reaching the consumer comply with the national provisions adopted pursuant to this Directive in the Member State of destination.
4. Retail outlets engaged in distance sales shall be equipped with an age verification system, which verifies at the time of sale, that the purchasing consumer respects the minimum age foreseen under the national legislation of the Member State of destination. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system.
5. Personal data of the consumer shall only be processed in accordance with Directive 95/46/EC and not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to any other third parties. Personal data shall not be used or transferred beyond the purpose of this actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products.

## **Chapter V: Novel tobacco products**

### *Article 17*

#### **Notification of novel tobacco products**

1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:
  - (a) available scientific studies on toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;
  - (b) available studies and market research on preferences of various consumer groups, including young people and
  - (c) other available and relevant information, including a risk/benefit analysis of the product, the expected effects on cessation of tobacco consumption, the

expected effects on initiation of tobacco consumption and other predicted consumer perception.

2. Member States shall require that manufacturers and importers of tobacco products inform their competent authorities of any new or updated information referred to in point (a) to (c) of paragraph 1. Member States shall be entitled to require tobacco manufacturers or importers to carry out additional tests or submit additional information. Member States shall make available to the Commission all information received pursuant to this Article. Member States shall be entitled to introduce an authorisation system and charge a proportionate fee.
3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

### **TITLE III – NON TOBACCO PRODUCTS**

#### *Article 18*

##### **Nicotine-containing products**

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:
  - (a) products with a nicotine level exceeding 2 mg per unit, or
  - (b) products with a nicotine concentration exceeding 4 mg per ml or
  - (c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.
3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

*This product contains nicotine and can damage your health.*
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:
  - (a) be printed on the two largest surfaces of the unit packet and any outside packaging;

- (b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

#### *Article 19*

#### **Herbal products for smoking**

1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:

*This product can damage your health*

2. The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.
3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than 30 % of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.
4. Unit packets and any outside packaging of herbal products for smoking shall not include elements or features referred to in points (a), (b) and (d) of Article 12 and shall not state that the product is free of additives or flavourings.

### **TITLE IV – FINAL PROVISIONS**

#### *Article 20*

#### **Cooperation and enforcement**

1. Member States shall ensure that manufacturers and importers provide competent national authorities and the Commission with complete and correct information requested pursuant to this Directive and within the time limits set. The obligation to provide the requested information lies primarily with the manufacturer, if the manufacturer is established in the Union. The obligation to provide the requested information lies primarily with the importer, if the manufacturer is established outside the Union and the importer is established inside the Union. The obligation to provide the requested information lies jointly with the manufacturer and the importer if both are established outside the Union.



2. Member States shall ensure that products which do not comply with this Directive, including its implementing and delegated acts, are not placed on the market.
3. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive.

#### *Article 21*

##### **Committee procedure**

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

#### *Article 22*

##### **Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [*Office of Publications: please insert the date of the entry into force of this Directive*].
3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act pursuant to Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament

and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### *Article 23*

##### **Report**

1. No later than five years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.

With a view to drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available.

2. In the report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:
  - (a) the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments;
  - (b) market developments in novel tobacco products considering, *inter alia*, notifications received under Article 17;
  - (c) market developments which amount to a substantial change of circumstances.

The Member States shall provide the Commission with assistance and all available information for carrying out the assessment and preparing the report.

3. The report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco and related products, to the extent necessary for the operation of the internal market, and to take into account any new developments based on scientific facts and developments on internationally agreed product standards.

#### *Article 24*

##### **Import, sale and consumption of tobacco and related products**

1. Member States shall not prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive.
2. However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation

of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

3. This Directive shall not affect the right of Member States to maintain or introduce, in accordance with the Treaty, national provisions concerning aspects not regulated by this Directive. These national provisions must be justified by overriding reasons of public interest and be necessary and proportionate to their aim. They must not be a means of arbitrary discrimination or a disguised restriction on trade between the Member States and must not jeopardise the full application of this Directive.

#### *Article 25*

#### **Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + 18 months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.
2. When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### *Article 26*

#### **Transitional provision**

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + 24 months]:

- (a) tobacco products;
- (b) nicotine containing products below the threshold set out in Article 18(1);
- (c) herbal products for smoking.

*Article 27*

**Repeal**

Directive 2001/37/EC is repealed.

References to the repealed Directive shall be construed as references to this Directive and read in accordance with the correlation table in Annex II.

*Article 28*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

*Article 29*

**Addressees**

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## **ANNEX I**

### **LIST OF TEXT WARNINGS (referred to in Article 9 and Article 10(1))**

- (1) Smoking causes 9 out of 10 lung cancers
- (2) Smoking causes mouth and throat cancer
- (3) Smoking damages your lungs
- (4) Smoking causes heart attacks
- (5) Smoking causes strokes and disability
- (6) Smoking clogs your arteries
- (7) Smoking increases the risk of blindness
- (8) Smoking damages your teeth and gums
- (9) Smoking can kill your unborn child
- (10) Your smoke harms your children, family and friends
- (11) Smokers' children are more likely to start smoking
- (12) Quit smoking – stay alive for those close to you
- (13) Smoking reduces fertility
- (14) Smoking increases the risk of impotence

**ANNEX II**

CORRELATION TABLE		
Directive 2001/37/EC	This Directive	
Article 1	Article 1	
Article 2	Article 2	
Article 3	Article 3	
Article 4(1) and (2) and Article 9(1)	Article 4	
Article 6 and Article 4(3)-(5)	Article 5	
Article 12	Article 6	
Article 5	Article 7	
Article 5(1) and (2)	Article 8	
Article 5(3) and Article 9(2)	Article 9	
Article 5	Article 10	
Article 5(4)	Article 11	
Article 7	Article 12	
	Article 13	
Article 5(9)	Article 14	
Article 8 and Article 9(3)	Article 15	
	Article 16	
	Article 17	
	Article 18	
	Article 19	
	Article 20	

Article 10	Article 21	
	Article 22	
Article 11	Article 23	
Article 13	Article 24	
Article 14	Articles 25 and 26	
Article 15	Article 27	
Article 16	Article 28	
Article 17	Article 29	
Annex I	Annex I	
Commission Decision 2003/641/EC and Commission Decision C(2005) 1452 final	Annex II	
Annex III	Annex III	

## LEGISLATIVE FINANCIAL STATEMENT

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management method(s) envisaged

### **2. MANAGEMENT MEASURES**

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
  - 3.2.1. *Summary of estimated impact on expenditure*
  - 3.2.2. *Estimated impact on operational appropriations*
  - 3.2.3. *Estimated impact on appropriations of an administrative nature*
  - 3.2.4. *Compatibility with the current multiannual financial framework*
  - 3.2.5. *Third-party participation in financing*
- 3.3. Estimated impact on revenue



## LEGISLATIVE FINANCIAL STATEMENT

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

#### 1.1. Title of the proposal/initiative

Proposal for a directive of the European Parliament and the Council on the approximation of laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products
--

#### 1.2. Policy area(s) concerned in the ABM/ABB structure<sup>49</sup>

Health for Growth
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#### 1.3. Nature of the proposal/initiative

- The proposal/initiative relates to **a new action**
- The proposal/initiative relates to **a new action following a pilot project/preparatory action**<sup>50</sup>
- The proposal/initiative relates to **the extension of an existing action**
- The proposal/initiative relates to **an action redirected towards a new action**

#### 1.4. Objectives

##### 1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

The overall objective of the revision is to improve the functioning of the internal market, while ensuring a high level of health protection.
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##### 1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

The proposal aims to:
-----------------------

- |  |
|--|
| <ol style="list-style-type: none"><li>(1) Update already harmonised areas to overcome Member States' obstacles to bring their national legislations in line with new market, scientific and international developments.</li><li>(2) Address product related measures not yet covered by the Tobacco Product Directive (TPD) insofar as heterogeneous development in Member States has led to, or is likely to lead to, fragmentation of the internal market.</li><li>(3) Ensure that provisions of the Directive are not circumvented by placing on the market of products not compliant with the TPD.</li></ol> |
|--|

<sup>49</sup> ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

<sup>50</sup> As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

The Commission's Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme for the period 2014-2020 (COM[2011]709) lists supporting measures which have as their direct objective the protection of public health regarding tobacco products and advertisement required by or contributing to the objectives of EU legislation in this field.

*1.4.3. Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

The impacts of the proposal on all relevant stakeholders (economic stakeholders including the tobacco farmers, the manufacturers of tobacco products, their upstream suppliers and the distribution chain, governments, society, consumers, employers) are summarised in Chapter 6.2 of the impact assessment report.

*1.4.4. Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

Key indicators for achievement of the proposal's objectives are outlined in section 7 of the impact assessment report.

**1.5. Grounds for the proposal/initiative**

*1.5.1. Requirement(s) to be met in the short or long term*

More than ten years have passed since the adoption of the current TPD. In line with market, scientific and international developments it has become necessary from an internal market perspective to update and complete the TPD. From a health perspective the revision aims to ensure that the ingredients and packaging of the products do not encourage or facilitate initiation, in particular by young people. This should lead to a drop of tobacco consumption.

*1.5.2. Added value of EU involvement*

Section 2.4.2 of the impact assessment report describes the added value of the EU involvement. The assessment is further exemplified for each policy area.

*1.5.3. Lessons learned from similar experiences in the past*

Not applicable.

*1.5.4. Coherence and possible synergy with other relevant instruments*

The proposal provides for a consistent implementation of obligations stemming from the WHO Framework Convention on Tobacco Control (FCTC) and a harmonised approach to non-binding FCTC commitments. Enhanced coherence is expected with other legislation concerning tobacco policy and other areas (e.g. medicinal products, GPSD, REACH, food).

## 1.6. Duration and financial impact

Proposal/initiative of **limited duration**

- Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

- Implementation with a start-up period from YYYY to YYYY,
- followed by full-scale operation.

## 1.7. Management mode(s) envisaged<sup>51</sup>

**Centralised direct management** by the Commission

**Centralised indirect management** with the delegation of implementation tasks to:

- executive agencies
- bodies set up by the Communities<sup>52</sup>
- national public-sector bodies/bodies with public-service mission
- persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

**Shared management** with the Member States

**Decentralised management** with third countries

**Joint management** with international organisations (*to be specified*)

*If more than one management mode is indicated, please provide details in the "Comments" section.*

### Comments

The Commission will centrally manage the administrative, technical and scientific support to the Regulatory Committee and its technical working groups.

<sup>51</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

<sup>52</sup> As referred to in Article 185 of the Financial Regulation.

## **2. MANAGEMENT MEASURES**

### **2.1. Monitoring and reporting rules**

*Specify frequency and conditions.*

The monitoring and reporting rules are set in section 7 of the impact assessment report. In addition the use of certain delegated acts calls for a prior Commission report (see Art. 22 of the legislative proposal).

### **2.2. Management and control system**

#### **2.2.1. Risk(s) identified**

No major risks in particular with respect to budgetary implications were identified. At this stage the main risk for the Commission is of reputational nature.

#### **2.2.2. Control method(s) envisaged**

A network of Member States representatives will provide a regular platform to discuss issues related to the implementation of the Directive. Complaints of the citizens and non-governmental organisations which could identify possible weaknesses in the implementation of the new directive will be carefully analysed.

Article 23 of the draft legislative proposal requires the Commission to submit a report on the application of this Directive not later than five years from transposition.

### **2.3. Measures to prevent fraud and irregularities**

*Specify existing or envisaged prevention and protection measures.*

The proposal foresees antifraud measures which are described and assessed in section 5.6 of the impact assessment.

In addition to the application of all regulatory control mechanisms, the responsible Commission's services will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure inter alia that its internal anti-fraud related controls are fully aligned with the CASF and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing implementing activities of the Tobacco Product Directive will be set up. In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing implementing activities of the Tobacco Product Directive will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;

- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);
- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;
- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

Moreover, the Commission will control a strict application of the rules on conflict of interests provided in the proposal.

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description...Health for Growth]	Diff./non-diff. ( <sup>53</sup> )	from EFTA <sup>54</sup> countries	from candidate countries <sup>55</sup>	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
3	17.0301 <sup>56</sup>	Diff/non -	YES/NO	YES/NO	YES/NO	YES/NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading.....]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
			YES/NO	YES/NO	YES/NO	YES/NO

<sup>53</sup> Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations.

<sup>54</sup> EFTA: European Free Trade Association.

<sup>55</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

<sup>56</sup> Budget line 17.0301 relates to the new nomenclature for MFF 2014-2020. It corresponds to the same budget line in MFF 2007-2013. This budget line is indicative and could be changed following the annual procedure.

### 3.2. Estimated impact on expenditure

#### 3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

Heading of multiannual financial framework:		Number	Health for Growth Programme							
DG: SANCO			Year 2014	Year 2015	Year 2016	Year 2017	Years 2018 and esq			TOTAL 2014-2018
• Operational appropriations										
Number of budget line 17.03.XX	Commitments	(1)	0.900	0.900	0.900	0.900	0.900			4.500
	Payments	(2)	0.450	0.900	0.900	0.900	1.350			4.500
Number of budget line	Commitments	(1a)								
	Payments	(2a)								
Appropriations of an administrative nature financed from the envelope for specific programmes <sup>57</sup>										
Number of budget line		(3)								
<b>TOTAL appropriations for DG SANCO</b>	Commitments	=1+1a +3	0.900	0.900	0.900	0.900	0.900			4.500
	Payments	=2+2a +3	0.450	0.900	0.900	0.900	1.350			4.500
• TOTAL operational appropriations										
	Commitments	(4)	0.900	0.900	0.900	0.900	0.900			4.500
	Payments	(5)	0.450	0.900	0.900	0.900	1.350			4.500

<sup>57</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADING 3</b> of the multiannual financial framework	Commitments	=4+ 6	0.900	0.900	0.900	0.900	0.900			<b>4.500</b>
	Payments	=5+ 6	0.450	0.900	0.900	0.900	1.350			<b>4.500</b>

**If more than one heading is affected by the proposal / initiative:**

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADINGS 1 to 4</b> of the multiannual financial framework (Reference amount)	Commitments	=4+ 6								
	Payments	=5+ 6								



<b>Heading of multiannual financial framework:</b>	<b>5</b>	" Administrative expenditure "
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EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Years 2018 and esq		TOTAL
DG: SANCO								
• Human resources		0.571	0.571	0.571	0.508	0.508		2.729
• Other administrative expenditure		0.018	0.165	0.168	0.172	0.136		0.659
<b>TOTAL DG SANCO</b>	Appropriations	<b>0.589</b>	<b>0.736</b>	<b>0.739</b>	<b>0.68</b>	<b>0.644</b>		<b>3.388</b>

<b>TOTAL appropriations under HEADING 5 of the multiannual financial framework</b>	(Total commitments = Total payments)	<b>0.589</b>	<b>0.736</b>	<b>0.739</b>	<b>0.68</b>	<b>0.644</b>		<b>3.388</b>
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EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Years 2018 and esq		TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework</b>	Commitments	1.489	1.636	1.639	1.58	1.544		7.888
	Payments	1.039	1.636	1.639	1.58	1.994		7.888

### 3.2.2. Estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs  ↓			Year 2014	Year 2015	Year 2016	Year 2017	Year 2018 and sq years						TOTAL					
	OUTPUTS																	
	Type of output <sup>58</sup>	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1 <sup>59</sup> ...			Establish mechanisms to ensure harmonised implementation of the rules by all Member States with a sustainable, efficient and credible management at EU level with access to internal and external technical and scientific expertise, allowing improved coordination and resource-sharing between Member States (applicable for both main objectives in Section 1.4.2)															
- Output	Technical, market and scientific reports	0.233	3	0.800	3	0.800	3	0.800	3	0.800	3	0.800						

<sup>58</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>59</sup> As described in Section 1.4.2. "Specific objective(s)..."

- Output	Up-to date IT tool for analysis of ingredients data	0.100	1	0.100	1	0.100	1	0.100	1	0.100	1	0.100						
Sub-total for specific objective N°1																		
SPECIFIC OBJECTIVE No 2...																		
- Output																		
Sub-total for specific objective N°2																		
<b>TOTAL COST</b>			4	0.900	4	0.900	4	0.900	4	0.900	4	0.900					20	4.500

### 3.2.3. Estimated impact on appropriations of an administrative nature

#### 3.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Years 2018 and esq			TOTAL
--	-----------	-----------	-----------	-----------	--------------------	--	--	-------

HEADING 5 of the multiannual financial framework								
Human resources	0.571	0.571	0.571	0.508	0.508			2.729
Other administrative expenditure	0.018	0.165	0.168	0.172	0.136			0.659
<b>Subtotal HEADING 5 of the multiannual financial framework</b>	<b>0.589</b>	<b>0.736</b>	<b>0.739</b>	<b>0.68</b>	<b>0.644</b>			<b>3.388</b>

Outside HEADING 5 <sup>60</sup> of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
<b>Subtotal outside HEADING 5 of the multiannual financial framework</b>								

<b>TOTAL</b>	<b>0.589</b>	<b>0.736</b>	<b>0.739</b>	<b>0.68</b>	<b>0.644</b>			<b>3.388</b>
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<sup>60</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

### 3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full amounts (or at most to one decimal place)*

	Year 2014	Year 2015	Year 2016	Year 2017	Years 2018 and esq		
<b>• Establishment plan posts (officials and temporary agents)</b>							
XX 01 01 01 (Headquarters and Commission's Representation Offices)	4.5	4.5	4.5	4	4		
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
<b>• External personnel (in Full Time Equivalent unit: FTE)<sup>61</sup></b>							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
<b>XX 01 04 yy<sup>62</sup></b>	- at Headquarters <sup>63</sup>						
	- in delegations						
XX 01 05 02 (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>	4.5	4.5	4.5	4	4		

**XX** is the policy area or budget title concerned.

The human resources required will be met by staff from DG SANCO who are already assigned to the management of the action and who will be redeployed within DG SANCO, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints (estimated needs: 4.0 AD/FTE and 0.5 AST/FTE).  
Description of tasks to be carried out:

Officials and temporary agents	
External personnel	

<sup>61</sup> CA= Contract Agent; INT= agency staff ("*Intérimaire*"); JED= "*Jeune Expert en Délégation*" (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert.

<sup>62</sup> Under the ceiling for external personnel from operational appropriations (former "BA" lines).

<sup>63</sup> Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

### 3.2.4. Compatibility with the current multiannual financial framework

- Proposal/initiative is compatible with the new multiannual financial framework 2014-2020. The actions will be covered by the proposed Health Programme 2014-2020.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

...

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework<sup>64</sup>.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

...

### 3.2.5. Third-party contributions

- The proposal/initiative does not provide for co-financing by third parties
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
<i>Specify the co-financing body</i>								
TOTAL appropriations cofinanced								

<sup>64</sup> See points 19 and 24 of the Interinstitutional Agreement.

### 3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
  - on own resources
  - on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative <sup>65</sup>								
		Year N	Year N+1	Year N+2	Year N+3	... insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)				
Article .....										

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

...

Specify the method for calculating the impact on revenue.

<sup>65</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.