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INFORMATION NOTE

from:	General Secretariat
to:	Permanent Representatives Committee / Council
Subject:	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) - Outcome of the European Parliament's proceedings (Strasbourg, 7 to 10 October 2013)

I. INTRODUCTION

The Rapporteur, Ms.Linda McAVAN (S&D, UK), presented a report on the proposal for a directive 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, on behalf of the Committee on the Environment, Public Health and Food Safety (ENVI).

The report contained 86 amendments (amendments 1- 86) to the proposal for a directive. In addition, 90 other amendments (amendments 87 - 189[1]) had been tabled by political groups (EPP, S&D, ALDE, Greens/EFA, ECR, EUL/NGL, EFD) or groups of 40 or more individual MEPs.

II. DEBATE

On 8 October 2013, the Parliament debated the proposal.

The Rapporteur, Ms. Linda McAVAN (S&D, UK) opened the debate by:

- Stating that she hoped that the Parliament today would do the right thing. She appealed for supporting the proposal and for opening negotiations with the Council. Time was running out - the Council had already agreed a common approach and the Parliament itself had called for this legislation.
- Recalling that the proposal was about stopping young people from being recruited as the next generation of smokers. According to the World Health Organisation there is a worrying upward trends of young smokers in a number of Member States. The tobacco companies should be barred from using gimmicky products that were prone to recruit young people (nice pink lipstick products, packaging with flowers and chocolate filter papers) and warnings should be highly visible on the packages.
- Highlighting the key issues for the vote:
  - Size of warnings. She warned against reducing the size to 50 % as demanded by industry, also recalling that the Council had voted for 65 %. In Canada the number of young smokers has been halved after the introduction of large pictorial warnings.
  - The position of the warnings matter, they should be at the top not at the bottom where they will be hidden by the displays.

[1] 13 amendments had been cancelled or withdrawn.

- Flavourings. Tobacco should look like tobacco, smell like tobacco and taste like tobacco. E.g. Menthol in cigarettes acts as a local anaesthetic to reduce coughing and actually allow smokers to inhale more deeply, according to the EU Scientific Committee on health, and they appeal to younger new smokers.
- Slim cigarettes target mainly young women, designed to be smaller, slimmer, less masculine, aimed at the female under-30 market.
- E-cigarettes. Amendments tabled ranged from having no regulation to having some form of regulation. She called for a sensible debate on what kind of regulation to have.

Minister Vytenis Povilas ANDRIUKAITIS, on behalf of the Council:

- Recalled that tobacco use is the largest single avoidable health threat in the European Union. More than 90% start to smoke before they are 25 years old, and 70% even before the age of 18 years. Half of these smokers – around 700 000 people per year – die prematurely. These figures call for live-saving health measures and for democratic responsibility and for public health interest prevailing over the narrow interest of industry.
- Stated that he knew from personal experience how painful death from tobacco-related diseases is. Each early death as a result of tobacco is a personal tragedy and a scourge on our society but there is also a very direct economic consequence. These premature deaths cost the European Union more than EUR 500 billion every year and could be avoided and future generations of children be protected if the necessary actions were taken at European level.
- Therefore welcomed the Commission's proposal and recalled that the Council had demonstrated its determination to take action by agreeing on a general approach under the Irish Presidency. The Presidency was committed to entering into negotiations as soon as the Parliament had adopted its amendments with a view to reaching a first reading agreement as soon as possible. It would send an important signal that Europe is ready to take the lead in tackling the problem of smoking.

Commissioner Tonio BORG:

- Echoed the appeal of the rapporteur to take a decision and to give a mandate for negotiations with the Council in order to deliver this important law to citizens during the current parliamentary mandate. Most citizens in Europe were favourable to the proposed measures.
- Underlined that tobacco products should look like tobacco and taste like tobacco and that was the aim of the proposal, not to ban tobacco or smoking. Therefore it introduces:
  - Large pictorial and text health warnings covering 75 % of the front and the back of cigarette packs placed on the top, so that the warnings are not hidden on the display. The proposal to have them at the bottom is only to serve industry and not the citizens. 75 % is only slightly larger than what is already used in some Member States and other countries use larger warnings (e.g. Mexico and Brazil with 100 % size warnings on one side and Australia with 90 % on one side and 75 % on the other).
  - Measures to ban the attractive look of packaging and characterising flavours that just serve to make tobacco more attractive in particular to young people. With 90 % of those who smoke starting to smoke under the age of 25, there is no place for characterising flavours in tobacco. Commission did not prohibit additives essential for the production of tobacco products, such as sugar.
- Recalled that the overall goal was to reduce smokers by 2 % per year over the next five year (i.e. by 2,4 million people), also in line with the WHO Convention that has been ratified by the Member States and the EU as such. EU was not on the forefront of tobacco control. The rate of smokers in the EU is still 28 %, in the United States it is 18 % and in Canada is as low as 16 %. Those countries have reached these objectives through picture warnings and also limitations on flavours.
- On e-cigarettes, stated that regulation was needed at the EU level. In the absence of that, the Member States had taken different regulatory approaches which hindered the smooth functioning of the internal market. The Commission would assess how to make progress based on the Parliament's and the Council's position.
- Welcomed that the proposed measures against illicit trading (including tracking and tracing systems) had been largely accepted by the ENVI Committee and by the Council.

The following comments from the rapporteurs of the opinions from consulted Committees (International Trade; Industry, Research and Energy; Internal Market and Consumer protection; Agriculture and Rural development and Legal Affairs) could be highlighted:

- Mr. Metin KAZAK (ALDE, BG), on behalf of the Committee on International Trade stated that while it was important to reduce the number of smokers, the proportionality of the proposed measures could be questioned. These could adversely affect industry and competitiveness. In some areas the tobacco industry was the only industry present.
- Mr. Csaba Sándor TABAJDI (S&D, HU), on behalf of the Committee on Agriculture and Rural development supported the measures, arguing that the European tobacco industry could still exist and jobs be kept with these measures, in particular as it had been secured that additives essential to production (e.g. sugar) could still be used.
- Robert GOEBBELS (S&D, LUX), on behalf of the Committee on Industry, Research and Energy complained that the ENVI Committee as usual practically had discarded all the amendments by the five consulted Committees. Large scary pictures would have no affect, it would be better to put information on the package on how to quit smoking.

Karl-Heinz FLORENZ (DE) on behalf of the EPP political group:

- Stated that apart from a couple of amendments, the rapporteur and his group were heading in the same direction. The Commission's proposal was a good basis, although some of its provisions go relatively far.
- Highlighted that against the fact of 700.000 deaths a year, the lobbyists arguments were thin. The aim was not to ban people from smoking but to prevent young people from taking up smoking and from being tricked by tobacco companies.
- Argued that substances in cigarettes needed to be controlled. 800 substances are used by the industry, often 100 are present in each cigarette. When these substances burn they create potentially harmful fumes.

Mr. Andrés PERELLO RODRIGUEZ (ES) on behalf of the S&D group:

- Stated that nobody was able to show that jobs would be suppressed because of the proposed measured but what could be shown scientifically was that 700.000 people each year loose their jobs and lives because of smoking. The objective of the proposed directive was to achieve that these people do not loose their jobs and lives.
- Deplored that before arriving to this debate, the most insidious lobby campaign had taken place. He called upon the Parliament to denounce that and asked what kind of Parliament it would be if MEPs approved objectives that were below those agreed by the Council. What kind of trust could MEPs expect if instead of giving a mandate to the rapporteur, they would be bowing to the lobbyist's agenda? Trust for the Parliament or trust for the lobbyists was the choice that the Parliament was facing.

Ms. Frédérique RIES (BE) on behalf of the ALDE group:

- Stated that her group supported most of the ambitious measures in the Commission's proposal, in particular the ban on characterising flavours that give the impression that tobacco is little harmful or not at all. It was the chance for the Parliament to demonstrate its independence from lobbies.
- Argued that it is essential to find a good balance on the key issue of the size of the health warnings. Her group had proposed 65 % on the front and the back but were opposed to neutral packages that leave no freedom of choice for those who have chosen to smoke.
- Believed that the freedom to smoke is also the freedom to quit. That was the reason why her group in amendment 170 had called for e-cigarettes to be accessible. It rejected both the Commission and Council approach. The e-cigarette was not a medicinal product and it was less toxic than normal cigarettes. However, it should be subject to strict conditions along those for other tobacco products (quality, safety, no sale to minors and restrictions on marketing).

Mr. Carl SCHLYTER (SE), on behalf of the Greens/EFA group:

- Recalled that tobacco every year kills four times more Europeans than work place accidents, traffic accidents, murder, AIDS as well as all drugs taken together. The restrictions proposed are in principal of no cost to society but the gains in terms of health could be considerable. To get rid of the situation where 70 % of smokers start as children under 18 is not a question of free choice but about our democratic responsibility to help children not to choose the path of smoking and suffering.
- Against this background, found it scandalous that some people in the plenary, in particular from the EPP group, in all questions of importance to the tobacco industry followed the industry's line despite the fact that their negotiators had taken a reasonable position and had co-operated well with representatives of other groups. As an example he gave the proposal to have health warnings at the bottom. There was no rational for that other than to hide the warning on the display.

Ms. Marina YANNAKOUDAKIS (UK), on behalf of the ECR Group:

- Stated that all seemed to agree on the objective to protect the health of citizens. However, the route that was taken differed.
- On e-cigarettes, argued for her group's amendment on e-cigarettes (i.e. amendment 170 tabled joint with EPP and ALDE), reflecting that they should mainly be seen as a tool to give up smoking and should remain in use for that purpose subject to the same kind of regulation as normal cigarettes. Over-regulating products, such as e-cigarettes, would make it more difficult, not easier, for people to quit. If this amendment was not adopted, her group would vote against giving the rapporteur a mandate to negotiate in first reading.

Ms. Martina ANDERSON (UK), on behalf of the EUL/NGL Group:

- Welcomed the fact that despite the large tobacco companies success in delaying the process, the Parliament was finally ready to vote on this crucial legislation which could help protect generations of young people.

- Believed that the aims of the tobacco industry can never be reconciled with those of public health and spoke out in support of the measures in the proposal. Not only would they result in a reduction in the number of smokers but also in the increase of 2 243 jobs created, due to increased disposable income spent on other goods and services. This would have a positive impact on the 20 % of most deprived areas in EU constituencies where the rate of smoking-related deaths is double that of the least deprived areas.
- Deplored that in spite of the 700.000 people killed each year by tobacco, there are MEPs who still find it difficult to vote in favour of public health measures to combat these avoidable and unnecessary deaths. The measures proposed were necessary and effective. They will prevent the tobacco industry from using attractive gimmicks that serve to getting children and young people addicted to their deadly product.

Mr. Lorenzo FONTANA (IT), on behalf of the EFD group:

- Expressed surprise over the debate he had listened to and the hypocrisy that was displayed. While not doubting the data, he put to the floor that if they were really true than there ought to be a proposal to ban tobacco. However, that was not what was being proposed, instead the measures were banning packs of 10 cigarettes and aromas because these might encourage people to smoke.
- Questioned why then not ban alcohol or fat? If there in the context of smoking was such concern about protecting children in their mother's womb, why was there not the same kind of debate when discussing abortion?

More than 50 speakers then took the floor to comment on the proposal with the rapporteur receiving wide acclaim for her efforts and tenacity. The vast majority of speakers supported the opening of negotiations with the Council. Most of the observations echoed statements made by the speakers above. The key issues raised were thus e-cigarettes, packaging/labelling, flavouring, slim cigarettes and lobbyism/interests of industry. The following comments could be highlighted to provide a flavour of the debate:

A very large number of MEPs commented on which approach to take on e-cigarettes, e.g.:

- Ms. Dagmar ROTH-BEHRENDT (S&D, DE) strongly criticised those in the Parliament that, on one hand, argued that flavouring should be banned in normal cigarettes whilst, on the other hand, allowing this in e-cigarettes. Only to ensure labelling was not enough and therefore the tabled amendment (170) by EPP, ALDE and ECR was damaging, including for what Member States want to achieve. E-cigarettes should not, as proposed by some, be better treated than nicotine sprays or plasters. The position of the Committee would not make them less accessible, as it would be up to the Member States to decide where they could be sold. She dared those colleagues to explain their position to the voters in the context of the next elections.
- The many other supporters of the Committee's position came mostly from the S&D, Greens/EFA and EUL/NGL groups. Ms. Rebecca HARMS (Greens/EFA, DE) called e-cigarettes a new way to become dependant. That view was supported by some speakers from other groups, e.g. Mr. Struan STEVENSON (ECR, UK) who labelled e-cigarettes as gateway to smoking and Ms. Mairead McGUINNESS (EPP, IRL) suspected that they were produced to keep people smoking.
- Mr. Matthias GROOTE (S&D, DE, Chair of the ENVI Committee) stated that the Council's position on e-cigarettes was sensible.
- A large number of MEPs (in particular from the EPP and ALDE groups) defended that e-cigarettes should not be regulated as medicinal products but be regulated more or less as normal cigarettes. Mr. Chris DAVIES (ALDE, UK) stated that e-cigarettes are a potential game changer in the fight against tobacco-related disease. They can save millions of lives and he had received testimony that they were more effective for quitting smoking than e.g. nicotine plasters. Therefore it would be quite wrong to take measures that restrict the availability of e-cigarettes or increase their price. Ms. Antonyia PARVANOVA (ALDE, BG) argued that e-cigarettes should be available as other tobacco products but this did not justify a lighter regulatory framework in comparison with other nicotine-containing products aimed at quitting tobacco. Mr. Peter LIESE (EPP, DE) defended amendment 170 stating that it provided for a strict regulation of e-cigarettes that should not be seen as normal consumer products.

Several MEPs expressed various views on packaging/labelling, flavours and slim cigarettes:

- A number of MEPs underlined that health warnings on 75 % of the front and back of packets were proportionate and necessary, e.g. Ms. Edite ESTRELA (S&D, PT) who stated that despite the measures already taken people still smoke and therefore more restrictive measures were important. Ms. Corinne LEPAGE (ALDE, FR) supported 75% as part of an effective combat against smoking, pointing out that smoking alone in France, in addition to the many deaths, was estimated to cost the country 47 billion EURO or 3 % of BNP.
- Others like Mr. Holger KRAHMER (ALDE, DE) labelled the very detailed packaging rules as disproportionate, questioning whether they could really save lives. The measures were disproportional and irrational. E.g. why would health protection be better with health warning taking up 75 % of the package size instead of 50 %?
- Mr. Richard SEEBER (EPP, AT) pointed out that the proposal of 65 % was a good compromise.
- While many speakers expressed support for the proposed measures on flavours and slim cigarettes, some MEPs were critical. Mr. Georgios KOUMOUTSAKOS (EPP, GR) stated that a balance had to be struck. Measures taken should be discouraging but without distorting competition and not be an ideological crusade. The proposed measures would risk jobs, and he would not vote for many of them, in particular those concerning slims and flavours which would not achieve their objective. Mr. Mario PIRILLO (S&D, IT), while supporting many of the rapporteur's proposals, called the ban on slim cigarettes (and on flavours) disproportionate. Mr. Paul NUTTALL (EFD, UK) stated that 1 million people in the UK smoked menthol cigarettes and a ban would only make them switch to conventional cigarettes and increase the size of the black market.

A large number of speakers expressed their discontent with the lobbying by the industry, eg:

- Mr. Hans-Peter MARTIN (NI, AT) stated that as a counter measure to the lobbying against health warnings there should be big warnings against lobbying - "lobbying kills". Those should be put on the doors of Philip Morris and all others that under false pretence tried to convince parliamentarians of something that should be rejected. Parliamentarians were responsible for the health of citizens.
- Ms Françoise GROSSETÊTE (EPP, FR) called it shameful that several of the lobbyists' proposals had been fully taken up by some MEPS that served as a mailbox for the tobacco lobbyists. Since three years the lobbyists had tried to obstruct the directive. The tobacco industry only employed 34.000 people across the EU so she did not buy the argument that the proposal threatened jobs.
- Kartika Tamara LIOTARD (GUE/NGL, NL) informed that she had received hundreds of letters and e-mails from tobacco- and packaging companies and even free packages. She found that the limits had been exceeded with those "deadly packages". She hoped that public health would win over lobbyists in the vote.

However, some speakers objected to what they saw as a one sided debate. Mr. Janusz WOJCIECHOWSKI (ECR, PL) stated that different opinions should be respected and urged not to label anyone who has doubts as a lobbyist on behalf of the tobacco industry. One could be in favour of reducing the number of smokers and want to limit the effects but not be in favour of all these measures. Some of them were hypocritical, e.g. those directed at slims and menthol cigarettes There was no evidence that people started smoking because of that, and jobs would be lost because of those measures. In the same vain, Ms. Renate SOMMER (PPE, DE) complained that the debate on tobacco in the Parliament was very emotional and ideology based, dividing members into good and bad. She also pointed to the influence of the pharmaceutical industry that sponsored some of the NGOs that were active in the debate.

A number of speakers deplored the proposed measures as being hypocritical and paternalistic, e.g.:

- Ms. Suzy DE MARTINI (ECR, IT) called the proposal a mistake that went against workers interest and that would not bring any benefits to health. The imitations proposed made it look like prohibition. She argued that e.g. red meat was known to cause cancer so why not have a directive to turn everybody into vegetarians?
- Mr. Ewald STADLER (NI, AT) was vehemently against proscribing how people should live and against the state forcing moralistic and paternalistic rules on the citizens on something that should not be regulated. Shouldn't then alcohol bottles have shocking pictures on them? This kind of regulation was the reason why the EU was getting even more unpopular.
- Mr Daniël van der STOEP (NI, NL) argued that smoking was a choice like religion. If EU were serious, there should also be warnings on bibles and korans as religion was more deadly than tobacco. Without smokers' contributions to the state coffers, all EU Member States would go bankrupt. Instead of gratitude, smokers are persecuted by health apostles.

Finally, Mr. Olle SCHMIDT (ALDE, SE) supported by Mr. Bendt BENDTSEN (PPE, DK) urged not to ban "snus" that was apart of Swedish culture the same way Alsace wine was part of the culture in Strasbourg.

In his closing remarks, Commissioner BORG inter alia:

- Believed that it was possible to save both lives and jobs, as the funds released by less expenditure on health care and more savings made by those who quit smoking will be invested in the economy, thus also generating jobs. 21 Member States were ready to give up fiscal revenue because health expenditure related to tobacco far exceeds that received from tobacco consumption.

- Countered the argument that there was no scientific evidence by recalling the studies and examples of other countries, adding that the best evidence for the effect of the measures was the opposition by the tobacco industry. Why else would it be against?
- Stated that politics was the art of the possible, acknowledging that the Tobacco Directive would not be the only thing that would help reduce smoking. However, it would be a tool to reach the objective, and he hoped that the Parliament will help the Commission and Council to reach it as well.

In his closing remarks, Minister ANDRIUKAITIS:

- Stated that while he was eagerly awaiting the vote, he was on the basis of the debate hopeful that the Parliament's position and the Council's general approach would be relatively close, particularly on the main points.
- Promised that he would do his utmost to reach the shared goal of having a text which can enter into force as soon as possible.

In her closing remarks, the Rapporteur, Ms.McAVAN inter alia:

- Thanked the Minister for his support, as well as the Commissioner. The support across the Parliament had shown that it was a balanced proposal and that many comments had been taken on board. She hoped that negotiations could start now and a quick resolution could be found in the current parliamentary term.
- Echoed the Commissioner's statement that Europe is lagging behind other countries on tobacco and stated that it was now time to catch up. She urged to choose life today and put the interests of citizens and future generations of citizens first.

III. VOTE

The vote took place on 8 October 2013. The European Parliament adopted 113 amendments to the proposal for a directive.

All but seven of the Committee's amendments (amendments 33, 34, 47, 53, 57, 64 and 65) were adopted, however with several amendments only partly adopted.

In addition, 34 other amendments were adopted, (amendments 87, 141, 148, 149, 153, 154 and 156 by groups of 40 or more individual MEPs; amendments 89 - 92, 95, 96, 100 - 105, 107, 108 and 189 by the EPP group; amendments 111 and 112 by the S&D group; amendments 118, 121, 125 and 185 by the EFD group; amendments 137, 165 and 170 by the EPP, ALDE and ECR groups; amendment 168 by the ALDE group and amendments 181 and 182 (partly) by the ECR group)[1]. A number of these amendments were identical.

The amendments adopted are set out in the Annex.

Upon suggestion by the Rapporteur, the vote on the legislative resolution was postponed to a later session, thereby not closing the European Parliament's first reading and leaving open the possibility of reaching an agreement in first reading. The matter was then referred back to the Committee on the Environment, Public Health and Food Safety, pursuant to Rule 57(2) of the European Parliament's Rules of Procedure.

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[1] To be noted: amendment 95 on prolonging the transitional period for the use of menthol by 5 years; amendments 104/121/148 rejecting the ban of slim cigarettes; amendments 168/181 on having health warning covering 65 % of the front and back of the package; amendment 170 rejecting e-cigarettes having to be authorised as medicinal products but making them subject to certain restrictions.

Manufacture, presentation and sale of tobacco and related products ***I

Amendments adopted by the European Parliament on 8 October 2013 on the proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))[1]

(Ordinary legislative procedure: first reading)

Amendment 1

Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Health warnings serve as part of an organised, effective and long term anti-smoking strategy, with well defined scope and objectives.

Amendment 2

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(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	(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 ***stronger*** legislative action at Union level to achieve the smooth

[1] The matter was referred back to the committee responsible for reconsideration pursuant to Rule 57(2), second subparagraph (A7-0276/2013).

achieve the smooth operation of the internal market.	operation of the internal market.

Amendment 3

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(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***. Of ***relevance are in*** particular its 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.	(7) Legislative action at Union level is also necessary to implement the ***landmark*** WHO Framework Convention on Tobacco Control ("FCTC") of May 2003***. All Member States, and*** the European Union ***itself, have signed and ratified the FCTC and as a result are bound under international law by its provisions***. Of particular ***relevance are*** 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.

Amendment 4

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(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	(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union ("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

the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people.	particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people. ***To that end, Member States should promote smoking prevention campaigns, especially in schools and through the media. In accordance with the principle of producer responsibility, manufacturers of tobacco products should be made responsible for all health costs arising as a consequence of tobacco consumption***.

Amendment 5

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Given that in many Member States large percentages of smokers are unlikely to stop smoking entirely, legislation should take into account their right to know objectively the impact the possible use of tobacco has on their health - information which they also receive through the packaging of the product they are likely to use.

Amendment 6

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(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***.	(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 ***Member States and the Commission should actively encourage***

	ongoing efforts ***at international level*** to develop ***such standards or tests***.

Amendment 7

Proposal for a directive
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) Polonium 210 has been shown to be a significant carcinogen in tobacco. Its presence in cigarettes could be eliminated almost completely by a combination of simple measures. It is thus appropriate to set a maximum yield for Polonium 210 that would result in a reduction of 95% of the current average content of Polonium 210 in cigarettes. An ISO standard to measure Polonium 210 in tobacco should be developed.

Amendment 8

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(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.	(11) In relation to the fixing of maximum yields, it might be necessary and appropriate at a later date to ***reduce*** the yields fixed or to fix maximum thresholds for emissions, taking into consideration their toxicity or addictiveness.

Amendment 9

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The current use of different reporting formats makes it difficult for	(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.	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***, in particular the rights of small and medium sized enterprises (SMEs)***.

Amendment 10

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(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	(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.

and vitality or have colouring properties.	***Ingredients that increase addictiveness and toxicity should also be removed.***

Amendment 11

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) In order to protect human health, an assessment should be carried out on the safety of additives for use in tobacco products. Additives should only be allowed in tobacco products if they are included in a Union list of authorised additives. That list should also indicate any conditions or restrictions on the use of allowed additives. Tobacco products containing additives not included in the Union list or used in a manner that does not comply with this Directive should not be placed on the Union market.

Amendment 12

Proposal for a directive
Recital 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) It is important not only to consider the properties of additives as such, but also of their combustion products. Additives as well as their combustion products should not be such that they meet the criteria for classification as hazardous in accordance with 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[1].
	[1] OJ L 353, 31.12.2008, p. 1.

Amendment 13

Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(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.	(15) The likelihood of diverging regulation is further increased by concerns over 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.

Amendment 14

Proposal for a directive
Recital 16

Text proposed by the Commission	*Amendment*
(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	***Deleted***

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.

Amendment 15

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(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***.***	(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. ***In*** order to ensure uniform rules and a high level of health protection***, those additives should not be approved. In addition, additives which impart a characterising flavour should not be approved. This should not result in prohibiting the use of individual additives altogether. Manufactures should, however, be required to reduce the use of an additive or of a combination of additives to such an extent that the additives no longer result in a characterising flavour. It should be possible to approve the use of additives that are essential for manufacturing of tobacco products, as long as those additives do not result in a characterising flavour and are not linked to the attractiveness of such products.***

Amendment 16

Proposal for a directive
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) An increasing number of people, most of them children, suffer from asthma and various allergies. Not all causes of asthma are understood, as indicated by WHO, but it is necessary for risk factors including allergens, tobacco and chemical irritants to be prevented in order to improve people's quality of life.

Amendment 17

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(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.	(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and ***water-pipe*** 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.

Amendment 18

Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) Member States should be encouraged, if they have not already done so, to formulate their national laws on the protection of young people in such a way that tobacco products may not be sold to, or consumed by, young people under the age of 18. Member States should also ensure that such prohibitions are

respected.

Amendment 19

Proposal for a directive
Recital 18 b (new)

Text proposed by the Commission	*Amendment*
	(18b) Article 16 of the FCTC points to the responsibility of Parties to the Convention to address products aimed at underage consumers, such as food products and toys in the form of tobacco products that may be appealing to minors. In recent years, several products, such as shisha vaping sticks, have been placed on the market that do not contain nicotine but have the form of cigarettes and try to imitate the smoking process through vaporising substances, the harmless nature of which is not yet scientifically proven, and through an electric light imitating the burning process of a cigarette. Such products are clearly produced to be appealing to young and underage consumers, and are increasingly popular with minors in several Member States. Increasing concern is expressed at the habits created in young consumers and minors by the use of such imitation cigarettes.

Amendment 20

Proposal for a directive
Recital 20

Text proposed by the Commission	*Amendment*
(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 tobacco products	(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 tobacco products

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

Amendment 21

Proposal for a directive
Recital 22

Text proposed by the Commission	*Amendment*
(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.	(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 ***picture and text*** 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 ***on the field of vision*** of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment 22

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(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,	(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. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful.

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.	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.

Amendment 23

Proposal for a directive
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) Tobacco products have been shown to contain and emit many noxious substances and known carcinogens hazardous to human health when burnt. Scientific studies have clearly proven that passive smoking is a cause of death, illness and disability and that passive smoking is dangerous in particular to unborn children and infants. It can cause or aggravate respiratory problems in persons inhaling smoke. Health warnings should therefore also draw attention to the dangers to health of passive smoking.

Amendment 24

Proposal for a directive
Recital 24

Text proposed by the Commission	*Amendment*
(24) Tobacco products for smoking, other than cigarettes ***and*** roll-your-own tobacco products, which are mainly consumed by	(24) Tobacco products for smoking, other than cigarettes**,** roll-your-own tobacco products ***and water pipe tobacco***, which

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.	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.

Amendment 25

Proposal for a directive
Recital 26

Text proposed by the Commission	*Amendment*
(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 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.	(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 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 ***and any outside transport packaging*** 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**,** ***and to ensure that the unique identifiers of unit packets are linked to the unique identifier on the outside transport packaging***.

Amendment 26

Proposal for a directive
Recital 28

Text proposed by the Commission	*Amendment*
(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.	(28) In order to ensure independence and transparency, manufacturers of tobacco products should conclude data storage contracts with independent third parties. ***The suitability of such contracts should be approved and monitored by the Commission, assisted by*** an ***independent*** 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.

Amendment 27

Proposal for a directive
Recital 29

Text proposed by the Commission	*Amendment*
(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 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. 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	(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 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. 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.***	effects and is attractive to young people.

Amendment 28

Proposal for a directive
Recital 29 a (new)

Text proposed by the Commission	*Amendment*
	(29a) Given the general prohibition of the sale of oral tobacco (snus) in the Union, there is no cross-border interest in regulating the content of snus. The responsibility for regulating the content of snus thus lies with the Member State where the sale of snus is permitted in accordance with Article 151 of the Act of Accession of Austria, Finland and Sweden. Snus should therefore be exempt from the provisions of Article 6 of this Directive.

Amendment 29

Proposal for a directive
Recital 30

Text proposed by the Commission	*Amendment*
(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***	(30) Cross-border distance sales of tobacco ***should be prohibited as they*** facilitate ***young people's*** access to tobacco products and risk ***undermining*** compliance with the requirements ***of*** this Directive.

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. 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 European Parliament and the Council of 25 October 2011 on consumer rights, as of 13 June 2014.

Amendment 30

Proposal for a directive
Recital 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) Directive 2003/33/EC on advertising and sponsorship of tobacco products already prohibits the free distribution of such products in the context of the sponsorship of events. This Directive, which regulates aspects relating to the presentation and sale of tobacco and aims to achieve a high level of health protection and prevention of tobacco consumption among young people, extends the scope of the ban on free distribution to public places and specifically prohibits the distribution of printed material, discount coupons and similar special offers inside packages and wrappings.

Amendment 31

Proposal for a directive
Recital 30 b (new)

Text proposed by the Commission	*Amendment*
	(30b) The Commission and the Member States should commit themselves to the effective implementation of the Protocol to the FCTC to eliminate illicit trade in tobacco products. Efforts should be made to prevent and improve the control of illegal trafficking of tobacco products manufactured in third countries.

Amendment 32

Proposal for a directive
Recital 31

Text proposed by the Commission	*Amendment*
(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.	(31) All tobacco products have the potential to cause mortality, morbidity and disability and their ***manufacture, distribution and*** consumption should be ***regulated***. 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 ***three*** years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment 165

Proposal for a directive
Recital 33

Text proposed by the Commission	*Amendment*
(33) Nicotine-containing ***products*** are sold	(33) Nicotine-containing products **-**

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***.	***including e-cigarettes -*** are sold on the Union market. ***However Member States have*** taken ***different regulatory approaches*** to address health and safety concerns associated with these products***. There is a need for harmonized rules, therefore all nicotine-containing products should be regulated under this Directive as a related tobacco product. Given the potential of nicotine-containing products to aid smoking cessation, Member States should ensure that they can be made available as widely as tobacco products***.

Amendments 118 and 137/REV

Proposal for a directive
Recital 34

Text proposed by the Commission	*Amendment*
(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[1] 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	***deleted***

2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

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

Amendment 35

Proposal for a directive
Recital 35

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Amendment 36

Proposal for a directive
Recital 35 a (new)

Text proposed by the Commission	*Amendment*
	(35a) Member States should ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products or related products.

Amendment 37

Proposal for a directive
Recital 37

Text proposed by the Commission	*Amendment*
(37) In order to ensure uniform conditions for the implementation of this Directive, in	(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.	particular concerning the format of ingredients reporting, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Amendment 38

Proposal for a directive
Recital 38

Text proposed by the Commission	*Amendment*
(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	(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, ***approving additives and*** setting maximum levels for ***additives as necessary***, 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, ***and*** reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and ***water pipe tobacco***. 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.

appropriate transmission of relevant documents to the European Parliament and Council.

Amendment 39

Proposal for a directive
Recital 39

Text proposed by the Commission	*Amendment*
(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.	(39) The Commission should monitor the developments and submit a report ***three*** years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary***, in particular as regards packaging***.

Amendment 40

Proposal for a directive
Recital 39 a (new)

Text proposed by the Commission	*Amendment*
	(39a) Member States have an important responsibility in protecting public health and taking preventive action, providing public guarantees, monitoring and advice for young people, and carrying out preventive public anti-smoking campaigns, particularly in schools. Universal free access to smoking cessation consultations and corresponding treatments is considered vital.

Amendment 41

Proposal for a directive
Recital 40

Text proposed by the Commission	*Amendment*
(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.	(40) A Member State that deems it necessary to maintain ***or introduce*** more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, ***insofar as such measures are compatible with the TFEU***. 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.

Amendment 42

Proposal for a directive
Recital 42

Text proposed by the Commission	*Amendment*
(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.	(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. ***It is essential that national data protection provisions also be taken into account.***

Amendment 43

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(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.	(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 ***of trademark holders*** (Article 17). ***It is therefore necessary to ensure that the*** obligations imposed on manufacturers, importers and distributors of tobacco products ***not only guarantee*** a high level of health and consumer protection***, but also protect all other fundamental rights and are proportionate with respect to the functioning of the internal market***. The application of this Directive should respect the Union law and relevant international obligations.

Amendment 44

Proposal for a directive
Recital 45 a (new)

Text proposed by the Commission	*Amendment*
	(45a) Member States should respect the right to clean air within the spirit of Article 7 (b) and Article 12 of the International Covenant on Economic, Social and Cultural Rights providing for rights for safe and healthy working conditions and the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. This is within the aim of Article 37 of the Charter of Fundamental rights where a high level of environmental protection and the improvement of the quality of the

environment must be integrated into the policies of the Union.

Amendment 45

Proposal for a directive
Article 1

Text proposed by the Commission	*Amendment*
The aim of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:	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;	(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;	(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;	(c) the prohibition to place on the market tobacco for oral use;
(d) cross-border distance sales of tobacco products;	(d) ***the prohibition of*** cross-border distance sales of tobacco products;
(e) the notification obligation for novel 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;	(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.	in order to ***meet obligations under the WHO Framework Convention for Tobacco Control and in order*** to facilitate the functioning of the internal market in tobacco and related products, taking as a ***base*** a high level of health protection, ***especially for young people***.

Amendment 46

Proposal for a directive
Article 2

Text proposed by the Commission	*Amendment*
For the purposes of this Directive, the following definitions shall apply:	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;	(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;	(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;	(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;	(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 ***which is*** observable before or upon use of the tobacco product;
(5) 'chewing tobacco' means a smokeless tobacco product exclusively designed for the purpose of chewing;	(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;	(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;
(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;	(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***;	(8) 'cigarillo' means a small type of cigar ***and is further defined in Article 8 (1) of***

	Council Directive 2007/74/EC;
(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;	(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;	(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:	(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;	(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;	(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;	(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;	(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;	(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;	(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	(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 placed under a customs suspensive procedure or arrangement, as well as their release from a customs suspensive procedure or arrangement;	are 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;	(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;	(18) 'ingredient' means an additive, tobacco, as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives;
	(18a) 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;
(19) 'maximum level' or 'maximum yield' means the maximum content or emission, including 0, of a substance in a tobacco product measured in grams;	(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;	(20) 'nasal tobacco' means a smokeless tobacco product consumed via the nose;
(21) 'nicotine' means nicotinic alkaloids;	(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;	(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;	(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	(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;	outside packaging;
	(24a) 'outside transport packaging' means any packaging, consisting of an aggregation of unit packets, in which tobacco products are transported from the manufacturer to the subsequent economic operators before being placed on the market, such as cartons, master cases and pallets;
(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;	(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;	(26) 'pipe tobacco' means tobacco consumed via a combustion process and exclusively designed for the purpose of being used in a pipe;
	(26a)'water pipe tobacco' means tobacco intended solely for use in a water pipe;
(27) 'retail outlet' means any outlet where tobacco products are placed on the market including by a natural person;	(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;	(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;	(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	(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 ***five*** 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 ***five*** 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;	equivalent prevalence studies;
(31) 'tar' means the raw anhydrous nicotine-free condensate of smoke;	(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;	(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;	(33) 'tobacco for smoking' means a tobacco product other than a smokeless tobacco product;
(33) 'tobacco for smoking' means a tobacco product other than a smokeless tobacco product;	(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;	(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 occuring over time, usually upon repeated or continuous consumption or exposure;	(35) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occuring 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.	(36) 'unit packet' means the smallest individual packaging of a product that is placed on the market.
	(36a) 'passive smoking' means the involuntary inhalation of smoke from the combustion of cigarettes or cigars or from the exhalation of one or more smokers.

Amendments 89 and 149

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
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	***deleted***

internationally agreed standards.

Amendment 90

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendment 48

Proposal for a directive
Article 4

Text proposed by the Commission	*Amendment*
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.	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	The accuracy of the tar, nicotine ***and carbon monoxide*** indications shall be verified in accordance with ISO standard

with ISO standard 8243.	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.	2. The measurement referred to in paragraph 1 shall be carried out or verified by ***independent*** 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.	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.
	2a. Tests verifying the validity of the result supplied by the tobacco companies shall be done on a regular basis by independent testing laboratories monitored by the competent authorities of the Member States.
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.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to ***supplement or amend*** 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.	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. The Commission shall adopt delegated acts in accordance with Article 22 to ***integrate into Union law methods agreed by the Parties to the FCTC or WHO***.
	4a. The accuracy of the indications for the other emissions of other combustible tobacco products shall be verified in accordance with ISO standard 8243.

Amendments 91, 92 and 49

Proposal for a directive
Article 5

Text proposed by the Commission	*Amendment*
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.	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 ***resulting from intended use***. 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)[47] 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[48] . 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	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)[47] 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[48] . 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, ***and that is at least sufficient to classify those substances pursuant to Regulation (EC) No 1272/2008,*** referring in particular to their effects on health of consumers and taking into account, inter alia, any addictive

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.	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.	2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a 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.	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.	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 ***and chronic heavy smokers***, relating to ingredients and emissions, ***as well as working summaries of any market surveys they carry out when launching new products***. 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 request. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.	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 request. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.
	5a. The Commission shall analyse all the information made available under this Article (particularly information relating to the addictiveness and toxicity of ingredients, market research and sales data) and shall produce a regular report to the European Parliament and the Council summarising the main findings.
	5b. The information collected pursuant to this Article shall be taken into account for the purpose of the approval of additives in accordance with Article 6(10a).
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***.	6. ***Proportionate fees may be*** charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article.

Amendments 50, 87 and 95

Proposal for a directive
Article 6

Text proposed by the Commission	*Amendment*
1. ***Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.***	1. ***Additives shall not be used in tobacco products unless they are approved in accordance with this Directive. Approved additives shall be included in the list set out in Annex [-I]. Any conditions or***

restrictions on use of approved additives shall also be indicated in the list. The placing on the market of tobacco products containing additives not listed in Annex [-I] or used not in compliance with any conditions or restrictions laid down in that Annex to this Directive shall be prohibited.

The following additives may not be approved:

(a) vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards;

(b) caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality;

(c) additives having colouring properties for emissions;

(d) additives that meet the criteria for classification as hazardous substances in accordance with Regulation (EC) No 1272/2008, or that result in such substances upon combustion;

(e) additives which, when used, may impart a characterising flavour.

(f) additives that increase at the stage of consumption the toxic or addictive effect of a tobacco product.

Notwithstanding point (e) of the previous subparagraph, where a certain additive or combination thereof typically imparts a characterising flavour only when it exceeds a certain level of presence or concentration, the additive or additives in question may be approved provided that maximum allowed levels are set.

Notwithstanding point (f) of the second subparagraph, where a certain additive amplifies at the stage of consumption the toxic or addictive effect of a tobacco product only when it exceeds a certain level of presence or concentration, including standard safety margins, the additive in question may be approved provided that maximum allowed levels are

	set.
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.	***Additives*** which are essential for the manufacture of tobacco products ***may be approved*** as long as the additives do not result in a product with a characterising flavour***. The reconstitution of sugar compounds in tobacco products up to the levels present in tobacco leaves prior to cutting shall be deemed as not resulting in 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 implemeting 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.	5. 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 ***shall be prohibited***. 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.	10. Tobacco products other than cigarettes, roll-your-own tobacco and ***water pipe tobacco*** shall be exempted from the ***application of point (e) of the second subparagraph of paragraph 1, and*** paragraph 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.
	10a. In order to obtain the approval of an additive, manufacturers and importers shall make an application to the Commission. The application shall be accompanied by the following particulars:
	(a) name or corporate name and permanent address of the applicant;
	(b) chemical name of the additive;
	(c) function of the additive and maximum quantity to be used per cigarette;
	(d) clear evidence supported by scientific data that the additive does not fall under any of the exclusion criteria listed in this Article.
	The Commission may ask the relevant scientific committee whether the additive concerned falls under any of the exclusion criteria listed in this Article as such, or only as of a certain concentration. The Commission shall take a decision on the application after receiving the application.
	The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to approve the additive, with allowed maximum levels where relevant, and amend Annex [-I] accordingly.
	10b. The use of menthol in all its commercial forms known on the date of publication of this Directive shall be exempted from the application of this Article for a period of five years from the

date referred to in Article 25(1).

10c. Oral tobacco (snus) shall be exempt from the provisions of this Article.

10d. This Article shall be without prejudice to the application to tobacco products of the relevant provisions of Regulation (EC) No 1907/2006 or of any conditions set pursuant to that Regulation.

10e. This Article shall apply as from …*.

** **OJ: Please insert date: 36 months from the entry into force of this Directive***

Amendment 51

Proposal for a directive
Article 7

Text proposed by the Commission	*Amendment*
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.	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.	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.	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. ***In the case of tobacco products other than cigarettes, roll-your-own, water-pipe tobacco and smokeless tobacco products, health warnings may be affixed by means of stickers, provided that such stickers cannot be removed.***
4. Member States shall ensure that the	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.	health warnings ***on the fields of vision on all sides*** 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.	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.	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.	7. Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of this chapter.
	7a. The regulation of other aspects of the packet falls outside the scope of this Directive.
	7b. The unit packet and its surrounding packaging shall not include printed vouchers offering discounts, free distribution, two-for-one or other similar offers involving any type of tobacco product covered by this Directive.

Amendment 52

Proposal for a directive
Article 8 – paragraphs 1 to 3

Text proposed by the Commission	*Amendment*
1. Each unit packet and any outside packaging of tobacco for smoking shall carry the following general warning:	1. Each unit packet and any outside packaging of tobacco for smoking shall carry the following general warning:
Smoking kills – quit now	Smoking kills – quit now
2. Each unit packet and any outside	2. Each unit packet and any outside

packaging of tobacco for smoking shall carry the following information message:	packaging of tobacco for smoking shall carry the following information message:
Tobacco smoke contains over 70 substances known to cause cancer	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.	3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets ***in black Helvetica bold type on a white background***. These warnings shall have a width of not less than 20 mm. For roll-your-own tobacco ***in pouches*** the information message shall be printed on the surface that becomes visible when opening the unit packet, ***for cylindrical containers the warnings shall be printed on the lid, and for cuboid containers the warnings shall be printed on the lateral sides.*** Both the general warning and the information message shall cover 50% of the surface on which they are printed.

Amendment 96

Proposal for a directive
Article 8 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Amendments 168 and 181

Proposal for a directive
Article 9 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) cover ***75*** % of the external area of both the front and back surface of the unit packet and any outside packaging;	(c) cover ***65*** % of the external area of both the front and back surface of the unit packet and any outside packaging;

Amendment 111

Proposal for a directive
Article 9 – paragraph 1 – point g – point i

Text proposed by the Commission	*Amendment*
(i) height: not less than ***64*** mm;	(i) height: not less than ***50*** mm;

Amendments 100, 112, 141 and 182

Proposal for a directive
Article 9 – paragraphs 1 – point g –point ii

Text proposed by the Commission	*Amendment*
(ii) width: not less than ***55*** mm.	(ii) width: not less than ***52*** mm.

Amendment 54

Proposal for a directive
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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 ***available for use in any one year*** is displayed as nearly as possible on equal numbers of each brand.

Amendment 101

Proposal for a directive
Article 9 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) define the position, format, layout, design, rotation and proportions of the health warnings;	***deleted***

Amendment 55

Proposal for a directive
Article 9– paragraph 3 – point d

Text proposed by the Commission	*Amendment*
(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	***deleted***

Amendment 56

Proposal for a directive
Article 10 – paragraphs 1 to 4

Text proposed by the Commission	*Amendment*
Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco	Labelling of tobacco for smoking other than cigarettes, roll-your-own, ***and water-pipe*** 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).	1. Tobacco for smoking other than cigarettes, roll-your-own tobacco ***and water-pipe 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.	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.	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 ***more than two*** 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.	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 ***more than two*** official languages.
	3a. In the case of packets whose most visible side has an area exceeding 75 cm², the warnings referred to in paragraphs 2 and 3 must, however, cover an area of at least 22,5 cm² on each side. That area shall be increased to 24 cm² for Member States with two official languages and 26,25 cm² for Member States with three official languages.
4. The general warning and the text warning referred to in paragraph 1 shall be:	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;	(a) printed in black Helvetica bold type on a white background. ***The warnings may be affixed by means of stickers, provided that such stickers are irremovable.*** 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;	(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.	(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.

Amendment 102

Proposal for a directive
Article 10 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendment 58

Proposal for a directive
Article 11 – paragraphs 1 and 2

Text proposed by the Commission	*Amendment*
1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:	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	This tobacco product ***damages*** 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:	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;	(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.	(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 ***more than two*** official languages

Amendment 59

Proposal for a directive
Article 11 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraph***s*** 1 ***and 2*** taking into account scientific and market developments.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraph 1 taking into account scientific and market developments.

Amendments 60, 103 and 153

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The labelling of a unit packet and any outside packaging and the tobacco product itself shall not include any element or feature that:	1. The labelling of a unit packet and any outside packaging and the tobacco product itself ***and / or its brand name*** 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;	(a) promotes a tobacco product ***and encourages its consumption*** by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions. ***Labels shall not include any information about nicotine, tar or carbon monoxide content;***
(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;	(b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health effects;
(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;	(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;
(d) resembles a food product.	(d) resembles a food ***or a cosmetic*** product;
	(da) aims to reduce the effect of some harmful components of smoke or increase the biodegradability of tobacco products.

Amendments 104, 121 and 148

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission	*Amendment*
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.***	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.

Amendment 61

Proposal for a directive
Article 12 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In the case of filter cigarettes, the tipping paper shall afford sufficient protection against product counterfeiting by means of its complexity. To this end it shall, at least possess the following characteristics:
	(a) several visible print colours and production using gravure printing;
	(b) all white areas are coated;
	(c) complex printing with partially thin structures;
	(d) printing on white base paper;
	(e) pre-perforation situated sufficiently far from the end of the cigarette.

Amendment 62

Proposal for a directive
Article 12 – paragraph 2 – subparagraph 1 b (new)

Text proposed by the Commission	*Amendment*
	The cigarette paper shall include watermarks.

Amendment 63

Proposal for a directive
Article 12 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The variety of tobacco used to manufacture the product, its country of origin, or both, may be indicated on the unit packet.

Amendment 105

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. 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 ***20*** g.

Amendment 66

Proposal for a directive

Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendments 107, 125 and 154

Proposal for a directive
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to make either cuboid or cylindric 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.	***deleted***

Amendments 156, 67, 185, 189 and 108

Proposal for a directive
Article 14

Text proposed by the Commission	*Amendment*
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	1. Member States shall ensure that all unit packets ***and any outside transport packaging*** of tobacco products shall be marked with a unique identifier ***with the aim to trace the products through the whole supply chain***. In order to ensure their integrity, unique identifiers shall be

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.	***secure,*** 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.
	1a. Member States shall ensure that the unique identifiers of unit packets are linked to the unique identifier on the outside transport packaging. Any changes in links between unit packs and the outside transport packaging shall be recorded in the database mentioned in paragraph 6.
2. The unique identifier shall allow determining:	2. The unique identifier shall allow determining:
(a) the date and place of manufacturing;	(a) the date and place of manufacturing;
(b) the manufacturing facility;	(b) the manufacturing facility;
(c) the machine used to manufacture the products;	(c) the machine used to manufacture the products;
(d) the production shift or time of manufacture;	(d) the production shift or time of manufacture;
(e) the product ***name***;	(e) the product ***description***;
(f) the intended market of retail sale;	(f) the intended market of retail sale;
(g) the intended shipment route;	(g) the intended ***and actual*** shipment route ***from the place of manufacturing to the first retail outlet, including all warehouses used, the shipment date, shipment destination, consignee and point of departure;***
(h) where applicable, the importer into the Union;	(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;	(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.	(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	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***.	tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit ***and outside*** packets into their possession, as well as all intermediate movements and the final exit from their possession***, and transmit the data electronically to a data storage facility pursuant to paragraph 6***. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging.
	3a. The technology used for tracking and tracing should belong to and be operated by economic entities without any legal or commercial link to the tobacco industry.
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.	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***, as determined by those Member States,*** 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	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.	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.	6. Member States shall ***verify*** 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 independent third party shall be free from commercial and other vested interests of the tobacco industry and other related industries.*** The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored ***by the Commission, assisted*** by an ***independent*** external auditor, who is 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.	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 cm², 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.	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 ***and invisible***, tamper proof security feature of at least 1 cm², 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. ***In those Member States where tax stamps are applied on tobacco products and the tax stamps applied***

	comply with the requirements of this paragraph, no additional security feature is required.
9. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:	9. ***Taking into consideration the practices, technologies and existing commercial operating aspects, as well as global standards of tracking, tracing and authentication of consumer goods and the corresponding requirements set by the WHO Protocol on Illicit Trade of Tobacco Products,*** 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;	(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	(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 ***in line with international standards.***
(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.	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 ***seven*** years following the date referred to in paragraph 1 of Article 25.

Amendment 68

Proposal for a directive
Article 16

Text proposed by the Commission	*Amendment*
Chapter IV: ***Cross-border*** distance sales of tobacco products	Chapter IV: ***Promotional distribution*** and distance sales of tobacco products
Article 16	Article 16
Cross-border distance sales of tobacco	***Distance*** sales of tobacco products

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:***	1. Member States shall ***prohibit*** retail outlets ***established on their territory*** from engaging in cross border distance sales.
(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 ©vices;	
(c) the address of the website/-s used for that purpose and all relevant information necessary to identify the website.	
	1a. Member States shall retain the power to decide whether to widen the scope of the above-mentioned prohibition to include national distance sales. Where Member States allow national distance sales, they shall ensure that retail outlets are equipped with an age verification system.
	1b. A Member State may, for public health reasons, impose restrictions on imports of tobacco for personal use. A Member State must be able to apply such restrictions in particular when the price in the Member State where the product is purchased is significantly lower than the price in the Member State of origin or if the health warnings are not in its official language(s).
2. ***The competent authorities of the*** Member States ***shall publish the complete***	2. Member States ***which have implemented a national anti-smoking***

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.	***strategy may set quantitative limits on cross-border movements***.
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.	

Amendment 69

Proposal for a directive
Article 16 a (new)

	Article 16a

	Member States shall prohibit retail outlets established on their territory from distributing free or discounted tobacco products through cross border distance channels or through any other channel.

Amendment 70

Proposal for a directive
Article 17

Text proposed by the Commission	*Amendment*
Notification of novel tobacco products	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:	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 ***any proposed labelling, instructions for use, details of the product's composition, the manufacturing process and associated controls and*** 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;	(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	(b) ***working summaries of the*** available studies and market research on preferences of various consumer groups, including young people and ***chronic heavy smokers;***
(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	(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.	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.	2. ***After the placing on the market of a tobacco product,*** 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.	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.

Amendment 170

Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
1. ***The following*** nicotine-containing products may only be placed on the market ***if they were authorised pursuant to Directive 2001/83/EC:***	1. Nicotine-containing products may only be placed on the market ***in accordance with the notification procedure set out in Article 17 of this Directive.***
	Member States shall ensure that nicotine-containing products comply with all relevant Union legislation, and in particular with Directive 2001/95/EC on general product safety.
(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.

2. ***Nicotine-containing products that are presented as having properties for treating or preventing disease may only be placed on the market if they were authorised*** pursuant to Directive 2001/83/EC.

3***. As regards nicotine-containing products to be placed on the market in accordance with paragraph 1, Member States shall ensure that:***

(a) nicotine-containing products with a nicotine level exceeding 30 mg/ml are not placed on the market;

(b) manufacturers and importers of nicotine-containing products submit to the competent authorities a list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof, as well as any changes. Member States shall then ensure the dissemination of this information on a website with due regard to the protection of trade secrets. Manufacturers and importers shall also report to the authorities about national sales volumes by brand name and type;

(c) nicotine-containing products with additives listed in Article 6(4) are not placed on the market;

(d) the unit packet of nicotine-containing products includes a leaflet with instructions for use, including that the reference that the product is not

	recommended for use by non-smokers, contra-indications, warnings for specific risk groups, reporting of adverse reactions, place of manufacture and contact details of the manufacturer or importer;
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*****".**	(e) each unit packet and any outside packaging of nicotine-containing products carry the following health warning: "This product ***is intended for use by existing smokers. It*** contains nicotine ***which is a highly addictive substance*****";**
	(f) the sale of the product is restricted in line with the legal age for sale of tobacco products in the relevant Member State; in any case it should not be allowed under the age of 18;
	(g) the products are available to be sold outside pharmacies;
	(h) flavourings are allowed in the products;
	(i) the limitations on advertising, sponsorship, audiovisual commercial communication and product placement for tobacco products as set out in Directive 2003/33/EC and Directive 2010/13/EC shall apply to nicotine-containing products;
	(j) cross-border distance sales of nicotine-containing products are regulated in accordance with Article 16;
	(k) tobacco trademarks, brand names and symbols are not used on nicotine-containing products.
4. The health warning referred to in ***paragraph 3*** shall comply with the requirements specified in ***Article 10(4). In addition, it shall:***	4. The health warning referred to in ***paragraph 3(e)*** shall comply with the requirements specified in ***Article 10.***
(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***	5. ***Member States shall monitor the development of the nicotine-containing products market, including any evidence of gateway use among young people and report their findings to the Commission. Based on the evidence submitted as well as scientific studies the Commission shall submit a report to the European Parliament and the Council on nicotine-containing products five years after entry into force of this Directive. The report shall assess if amendments to this Directive or any further legislation are necessary.***

Amendment 72

Proposal for a directive
Article 19

Text proposed by the Commission	*Amendment*
Herbal products for smoking	Herbal products for smoking
1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:	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	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.	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	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.	languages and 35 % for Member States with ***more than two*** official languages.

Amendment 73

Proposal for a directive
Article 19 a (new)

Text proposed by the Commission	*Amendment*
	Article 19a
	Imitation tobacco products
	Imitation tobacco products which appeal to minors and consequently form a potential gateway to using tobacco products shall be prohibited.

Amendment 74

Proposal for a directive
Article 20 – Paragraph 3

Text proposed by the Commission	*Amendment*
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.	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. ***Any financial penalties applicable to intentional infringements shall be such as to offset the economic advantage sought through the infringement.***

Amendment 75

Proposal for a directive
Article 22

Text proposed by the Commission	*Amendment*
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	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]*.	2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6***(10a)***, 8(4), 9(3), 10(5), 11(3), 13(4) ***and*** 14(9) shall be conferred on the Commission for ***a*** period of ***five years*** from [Office of Publications: please insert the date of the entry into force of this Directive]. ***The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of five-year period. The delegation of power shall be tacitly extended for periods of identical duration unless the European Parliament or Council opposes such an extension not later than three months before the end of each period.***
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.	3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(***10a***), 8(4), 9(3), 10(5), 11(3), 13(4) ***and*** 14(9) 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.	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	5. A delegated act pursuant to Articles 3(2), 3(3), 4(3), 4(4), ***6(10a),*** 8(4), 9(3), 10(5), 11(3), 13(4) ***and*** 14(9) shall enter into force only if no objection has been expressed either by the European

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.	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.

Amendment 76

Proposal for a directive
Article 23 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	No later than ***three*** 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.

Amendment 77

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) evaluation of the addictive effects of those ingredients which encourage addiction;

Amendment 78

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide;

Amendment 79

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – point c c (new)

Text proposed by the Commission	*Amendment*
	(cc) toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use;

Amendment 80

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – point c d (new)

Text proposed by the Commission	*Amendment*
	(cd) development of standards concerning products other than cigarettes.

Amendment 81

Proposal for a directive
Article 23 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States shall report every two years to the Commission on the enforcement of the measures taken pursuant to Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives

	to improve tobacco control, in particular with regard to age limits set in national legislation, as well as their plans to increase the age limit to achieve the goal of a "smoke-free generation".

Amendment 82

Proposal for a directive
Article 24

Text proposed by the Commission	*Amendment*
1. Member States shall not prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive.	1. ***Subject to paragraphs 2 and 3,*** 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.	2. However, a Member State may maintain ***or introduce*** more stringent national provisions in areas covered by the Directive, ***insofar as such measures are compatible with the Treaty***. Such national provisions ***shall apply equally to all products, including those imported from another Member State or a third country. They 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	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.	of Member States to maintain or introduce national provisions concerning aspects not regulated by this Directive, ***insofar as they are compatible with the Treaty.*** They ***shall apply equally to all products, including those imported from another Member State or a third country,*** 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.

Amendment 83

Proposal for a directive
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by …* ***and in the case of Article 6 by…**** at the latest. They shall forthwith communicate to the Commission the text of those provisions.
	_____
	**** Publications Office, please insert the exact date: entry into force + 18 months.***
	***** Publications Office, please insert the exact date: entry into force + 36 months***

Amendment 84

Proposal for a directive
Article 26

Text proposed by the Commission	*Amendment*
Transitional provision	Transitional provision
Member States may allow the following products, which are not in compliance with	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]:	this Directive, to be placed on the market until …*:
(a) tobacco products;	(a) tobacco products;
(b) nicotine containing products below the threshold set out in Article 18(1);	
(c) herbal products for smoking.	***(b)*** herbal products for smoking.
	Member States may allow nicotine containing 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.
	***** Publications Office, please insert the exact date: entry into force + 36 months.***

Amendment 85

Proposal for a directive
Annex -I (new)

Text proposed by the Commission	*Amendment*
	Annex -I
	Additives approved for use in tobacco products
	Chemical name of the additive - function - maximum level permitted

Amendment 86

Proposal for a directive
Annex I

Text proposed by the Commission	*Amendment*
List of text warnings	List of text warnings
(referred to in Article 9 and Article 10(1))	(referred to in Article 9 and Article 10(1))
(1) Smoking causes 9 out of 10 lung	(1) Smoking causes 9 out of 10 lung

cancers	cancers
(2) Smoking causes mouth and throat cancer	(2) Smoking causes mouth and throat cancer
	(2a) Smoking causes bladder cancer
(3) Smoking damages your lungs	(3) Smoking damages your lungs
(4) Smoking causes heart attacks	(4) Smoking causes heart attacks
(5) Smoking causes strokes and disability	(5) Smoking causes strokes and disability
(6) Smoking clogs your arteries	(6) Smoking clogs your arteries
(7) Smoking increases the risk of blindness	(7) Smoking increases the risk of blindness
(8) Smoking damages your teeth and gums	(8) Smoking damages your teeth and gums
(9) Smoking can kill your unborn child	(9) Smoking can kill your unborn child
10) Your smoke harms your children, family and friends	10) Your smoke harms your children, family and friends
(11) Smokers' children are more likely to start smoking	(11) Smokers' children are more likely to start smoking
(12) Quit smoking – stay alive for those close to you	(12) Quit smoking – stay alive for those close to you
(13) Smoking reduces fertility	(13) Smoking reduces fertility
(14) Smoking increases the risk of impotence	(14) Smoking increases the risk of impotence
	(14a) Smoking can cause cot death
	(14b) Smoking during pregnancy causes premature birth
	(14c) Passive smoking can worsen asthma or meningitis in children.