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Committee on the Environment, Public Health and Food Safety

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COMPROMISE AMENDMENTS 1 - 65

Draft report
Linda McAvan
(PE508.085v03-00)

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

Proposal for a directive
(COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

AM_Com_LegCompr

Amendment 1
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE
Consolidated amendment replacing Amendments 68, 69, 70, 71, 72, 73, 74, ITRE 2, AGRI 3, IMCO 2

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 the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people.	(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people. ***To that end, Member States should promote smoking prevention campaigns, especially in schools and in 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***.

Or. en

Amendment 2

S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing amendment 79 and amendments 393 and 415

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 them.

Or. en

Amendment 3
S&D - EPP - GREENS/EFA - ECR - EFD - GUE
Consolidated amendment replacing Amendments 90, 93, 94

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 on the Union list or used in a manner that does not comply with this Directive should not be placed on the Union market

Or. en

Amendment 4
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments 96, 97, 98, 99, 100, 101, 102, 103, AGRI 6, INTA 2, JURI 4, ITRE 4, IMCO 7

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 .

Or. en

Amendment 5
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments 104, 105, 106, 107, 108, 109, AGRI 8, ITRE 5, IMCO 8, JURI 5

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 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.	***Deleted***

Or. en

Amendment 6
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing 110, 113, 114, 115

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, these 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.

Or. en

Amendment 7
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, IMCO 9, ITRE 6, INTA 3

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.

Or. en

Amendment 8
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE

Compromise amendment replacing Amendments 134, 135, 136, 137, AGRI 9, INTA 4

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 on all sides*** of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Or. en

Amendment 9
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, JURI 6, INTA 5, AGRI 10, IMCO 11, ITRE 9

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	(23) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as

well as regarding certain aspects of the appearance of the tobacco package, ***including the opening mechanism***. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours', 'slim', names, pictures, and figurative or other signs. Likewise, the size and appearance of individual cigarettes can mislead consumers by creating the impression that they are less harmful. A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed.

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. 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. ***Certain packages and products could also mislead by suggesting benefits in terms of social status, social life or qualities such as femininity, masculinity or elegance.*** 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.

Or. en

Amendment 10
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments 155, 156, 157, 158, 159, AGRI 11

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 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	(24) Tobacco products for smoking, other than cigarettes***,*** roll-your-own tobacco products ***and water pipe tobaccos***, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other

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.

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.

Or. en

Amendment 11
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments recital 7, 161, 162, 163, JURI 8, INTA 6, AGRI 12, IMCO 12

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. .

Or. en

Amendment 12
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE
Compromise amendment replacing Amendments recital 166 to 168**,** IMCO 13
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 which 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.

Or. en

Amendment 13
S&D - EPP - ALDE - GREENS/EFA -ECR- EFD - GUE
Consolidated amendment replacing 169, 170, 171, 172, ITRE 11, JURI 10

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	(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.***	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.

Or. en

Amendment 14
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE
Consolidated amendment replacing Amendments: 175-176-177-178-179-180, AGRI 13, INTA 7, IMCO 14

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

on notification of cross-border distance sales of tobacco in this Directive should apply notwithstanding the notification procedure set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services. 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.

Or. en

Amendment 15
S&D-GREENS/EFA -GUE
Consolidated amendment replacing Amendment 192, 193, 194, 195, 196, 197, JURI 12

Proposal for a directive
Recital 33

Text proposed by the Commission	*Amendment*
(33) Nicotine-containing products are sold on the Union market. ***The*** different regulatory approaches ***taken by Member States*** to address health and safety concerns associated with these products ***have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet.***	(33) Nicotine-containing products - ***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, and all nicotine containing products should be regulated through a medicines regime which recognises the well-established use of nicotine. Given the potential of these products to aid with smoking cessation, Member States should ensure that they can be made available outside pharmacies***.

Or. en

Amendment 16
ALDE-ECR-EFD
Consolidated amendment replacing Amendment 192, 193, 194, 195, 196, 197

Proposal for a directive
Recital 33

Text proposed by the Commission	*Amendment*
(33) Nicotine-containing products are sold on the Union market. The different regulatory approaches taken by Member States to address health and safety concerns associated with these products have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet.	(33) Nicotine-containing products are sold on the Union market. The different regulatory approaches taken by Member States to address health and safety concerns associated with these products have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet. ***Nicotine-containing products can help existing smokers to quit smoking tobacco products and should therefore be as available on the Union market as tobacco products. At the same time nicotine-containing products should comply with specific rules on their safety, marketing and labelling.***

Or. en

Amendment 17
S&D, Greens/EFA, GUE/NGL

Consolidated amendment replacing Amendment 198 to 203**,** JURI 13, ITRE 13, IMCO 16

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	(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 provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. ***Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under*** Directive 2001/83/EC***, to the same legal framework*** clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

November 2001 on the Community code relating to medicinal products for human use 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. ***However, measuring nicotine delivery has proven to be difficult, as it depends on the products and how they are being used. Therefore, subjecting all nicotine-containing products regardless of their nicotine content to*** Directive 2001/83/EC, ***while recognising the well-established use of nicotine***, clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

Or. en

Amendment 18
ALDE-ECR-EFD
Consolidated amendment replacing Amendment 198 to 203, IMCO 16-ITRE 13-JURI 13
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 provides a legal framework to assess the quality, safety and efficacy of	***deleted***

medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

Or. en

Amendment 19
ALDE-ECR-EFD
Consolidated amendment replacing Amendment 205 to 208 JURI 14-IMCO 17-ITRE 14
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.	(35) Labelling provisions should be introduced for nicotine containing products ***falling outside of the scope of Directive 2001/83/EC*** drawing the attention of consumers to potential health risks**,** ***and Member States should be obliged to ensure that national age restrictions for buying nicotine containing products are kept in line with those for the sale of tobacco products.***

Or. en

Amendment 20
S&D-GREENS/EFA-GUE/NGL
Consolidated amendment replacing Amendment 205 to 208 JURI 14-IMCO 17-ITRE 14
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***

Or. en

Amendment 21
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Compromise amendment replacing Amendments 210, 211, 212, 213, 214, 215, ITRE 15, AGRI 15, IMCO 18

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 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 .	(37) In order to ensure uniform conditions for the implementation of this Directive, in 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 .

Or. en

Amendment 22
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, AGRI 16, ITRE 16, JURI 16, IMCO 19

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***	(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

attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco ***and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products***. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

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***, water pipe tobaccos***. 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.

Or. en

Amendment 23
S&D, EPP, ALDE, Greens/EFA, ECR, GUE/NGL, EFD

Compromise amendment replacing Amendment 228 to 232, JURI 17, AGRI 17, ITRE 19, INTA 9

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***	(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 Treaty***. 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.

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.

Or. en

Amendment 24
S&D, EPP, ALDE, Greens/EFA, ECR, GUE/NGL, EFD

Compromise amendment replacing Amendment 14, 234 to 238, AGRI 19, ITRE 20, IMCO 21, JURI 18, INTA 10

Proposal for a directive
Recital 41

Text proposed by the Commission	*Amendment*
(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance, maintain or introduce provisions providing standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information	(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance, maintain or introduce provisions providing standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information

Society services .	Society services .

Or. en

Amendment 25
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments: 15, 17, 247 to 260, INTA 13, IMCO 23, INTA 14

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	in order to ***meet obligations under the WHO Framework Convention for***

products, taking as a basis a high level of health protection.

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***,

Or. en

Amendment 26
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments: 261 to 349, ITRE 22, IMCO 24, JURI 19, INTA 16, JURI 20, ITRE 23, AGRI 21, IMCO 25, INTA 17, IMCO 26, INTA 18, AGRI 22 INTA 19, INTA 20, ITRE 24, AGRI 23, JURI 21, AGRI 25, IMCO 27, IMCO 29, INTA 22, JURI 22, IMCO 30, IMCO 31, ITRE 26, INTA 23, IMCO 32, AGRI 26,

New definitions will be voted separately: 285; 291, 296, 308, 309, 310, 322, 332, INTA 15, INTA 21, ITRE 27, AGRI 24, JURI 23, ITRE 25, IMCO 33, AGRI 27, IMCO 34

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,	(4) 'characterising flavour' means a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy,

menthol or vanilla observable before or upon ***intended*** use of the tobacco product;

(5) 'chewing tobacco' means a smokeless tobacco product exclusively designed for the purpose of chewing;

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

(7) 'cigarette' means a roll of tobacco consumed via a combustion process and further defined in Article 3(1) of Council Directive 2011/64/EU;

(8) 'cigarillo' means a small type of cigar ***with a diameter of up to 8 mm***;

(9) 'combined health warning' means a health warning provided for in this Directive and consisting of a combination of a text warning and a corresponding photograph or illustration;

(10) 'consumer' means a natural person who is acting for purposes which are outside his trade, business, craft or profession;

(11) 'cross-border distance sales' means a distance sales service where, at the time the consumer orders the product, the consumer is located in a Member State other than the Member State or the third country where the retail outlet is established; a retail outlet is deemed to be established in a Member State:

(a) in the case of a natural person - if he/she has his/her place of business in that Member State;

(b) in other cases - if it has its statutory seat, central administration or place of business, including a branch, agency or any other establishment in that Member State;

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;

(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;

(8) 'cigarillo' means a small type of cigar ***and is further defined in Article 8 paragraph 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;

(10) 'consumer' means a natural person who is acting for purposes which are outside his trade, business, craft or profession;

(11) 'cross-border distance sales' means a distance sales service where, at the time the consumer orders the product, the consumer is located in a Member State other than the Member State or the third country where the retail outlet is established; a retail outlet is deemed to be established in a Member State:

(a) in the case of a natural person - if he/she has his/her place of business in that Member State;

(b) in other cases - if it has its statutory seat, central administration or place of business, including a branch, agency or any other establishment in that Member State;

(12) 'emissions' means substances that are released when a tobacco product is used as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;	(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 are placed under a customs suspensive procedure or arrangement, as well as their release from a customs suspensive procedure or arrangement;	(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;
(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	(19) 'maximum level' or 'maximum yield' means the maximum content or emission, including 0, of a substance in a tobacco

product measured in grams;	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 outside packaging;	(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;
	(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 equivalent prevalence studies;	(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;
(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	(34) 'tobacco products' means products usable for consumption by consumers and

consisting of, even partly, tobacco, whether genetically modified or not;	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.

Or. en

Amendment 27

S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 18, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, JURI 24, ITRE 29, IMCO 35 (2nd part), AGRI 28

Proposal for a directive
Article 3 – Paragraph 2 - Delegated Acts

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 internationally agreed standards.	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to ***reduce*** the maximum yields laid down in paragraph 1, ***where necessary, in order to take*** into account scientific development and internationally agreed standards.

Or. en

Amendment 28
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 19, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, ITRE 30, JURI 25, IMCO 35 (3rd part), AGRI 29

Proposal for a directive
Article 3 – Paragraph 3 - Delegated Acts

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.***	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. The Commission shall adopt delegated acts in accordance with Article 22 ***to integrate into Union law guidelines agreed by the parties to the FCTC or WHO relating to*** maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes.

Or. en

Amendment 29
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments: 20, 395, 398, 399, 400, IMCO 36 (parts 1-4), part

Proposal for a directive
Article 4 - paragraph 1 and 2

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.

Or. en

Amendment 30
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 401, 402, 403, 404, 405, 406, ITRE 31, AGRI 30, IMCO 36 (5th part)

Proposal for a directive
Article 4 – Paragraph 3 - Delegated Acts

Text proposed by the Commission	*Amendment*
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.

Or. en

Amendment 31
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL

Compromise amendment replacing Amendments 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, AGRI 31, ITRE 32, IMCO 36 (6th part)

Proposal for a directive
Article 4 – Paragraph 4 - Delegated Acts

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

Or. en

Amendment 32
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL

Compromise amendment replacing Amendments **21, 23, 24, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, ITRE 33, IMCO 37, ITRE 24, IMCO 38,**

Proposal for a directive
Article 5

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

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

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

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) 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. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt ***and*** unburnt form, ***and that is at least sufficient to classify these substances pursuant to Regulation 1272/2008,*** referring in particular to their effects on health of consumers and taking into account, inter alia, any addictive effects. Regarding the emissions and yields of tobacco products, The list shall be established in descending order of the weight of each ingredient included in the product. ***Manufacturers and importers of tobacco products shall submit the list of ingredients and all the accompanying information referred to above no later than [the date of entry into force of this Directive + 18 months***.

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	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.	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.

Or. en

Amendment 33
S&D - EPP - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments: 25, 26, 27, 28, 29, 442 to 584, 1357, 1358
JURI 26-33, IMCO 39, ITRE 35, INTA 24, AGRI 33-41
Except 537

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	1. ***Additives shall not be used in tobacco products unless they are approved in accordance with this Directive. Approved***

with a characterising flavour.	***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 ***and are not linked to the attractiveness of tobacco products. 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 or increasing attractiveness of tobacco products***
Member States shall notify the Commission of measures taken pursuant to this paragraph.	***deleted.***
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.	***deleted.***
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.	***deleted.***
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	***deleted***.

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:	***deleted***
(a) vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards, or	***deleted***
(b) caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality, or	***deleted***
(c) additives having colouring properties for emissions.	***deleted***
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.***	***deleted***
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.	***deleted***
Member States shall notify to the Commission measures taken pursuant to this paragraph.	***deleted***
8. The Commission shall at the request of a Member State or may on its own initiative determine by means of an	***deleted***

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.

deleted

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 no later than six months 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. 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.

10c. This Article shall apply as from 36 months from the entry into force of this Directive.

Or. en

Amendment 34
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 30 and 586 to 602, IMCO 40, ITRE 36,

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	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.	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 these cannot be removed.***
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.	4. Member States shall ensure that the 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.

Or. en

Amendment 35
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL

Proposal for a directive
Article 7 a (new)

Text proposed by the Commission	*Amendment*
	7 (a) The regulation of other aspects of the packet falls outside the scope of this Directive

Or. en

Amendment 36
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL

Consolidated amendment replacing Amendments**: 604-622, JURI 34-35, INTA 25, ITRE 37, AGRI 42**

Proposal for a directive
Article 8 – Paragraph 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 packaging of tobacco for smoking shall carry the following information message:	2. Each unit packet and any outside packaging of tobacco for smoking shall carry the following information message:
Tobacco smoke contains over 70 substances known to cause cancer	*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.

Or. en

Amendment 37
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL

Compromise amendment replacing Amendments 623 to 634, JURI 35, ITRE 38, IMCO 41, AGRI 43-44

Proposal for a directive
Article 8 – Paragraph 4 – Delegated acts

Text proposed by the Commission	*Amendment*
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:	4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:
(a) to adapt the wording of the ***health warnings*** laid down in paragraph***s 1 and*** 2 to scientific and market developments;	(a) to adapt the wording of the ***information message*** laid down in paragraph 2 to scientific and market developments;
(b) to define the position, format, layout and design of the health warnings laid down in this Article, including their font type and background colour.	***delete***

Or. en

Amendment 38
EPP- ECR

Consolidated amendment replacing Amendments 32 and 635t o 731, IMCO 42, INTA 26-29, JURI 36- 41, AGRI 45-48, ITRE 39

Proposal for a directive
Article 9 – paragraph 1 and paragraph 2

Text proposed by the Commission	*Amendment*
1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The	1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The

combined health warnings shall:	combined health warnings shall:
(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library;	(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library;
(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;	(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;
(c) cover ***75 %*** of the external area of both the front and back surface of the unit packet and any outside packaging;	(c) cover **65 %** of the external area of both the front and back surface of the unit packet and any outside packaging;
(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;	(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;
(e) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging;	(e) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging;
(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;	(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;
(g) for unit packets of cigarettes, respect the following dimensions:	(g) for unit packets of cigarettes, respect the following dimensions:
(i) height: not less than ***64*** mm;	i) height: not less than ***55*** mm;
(ii) width: not less than ***55*** mm.	(ii) width: not less than ***53*** mm;

Or. en

Amendment 39
S&D - ALDE - GREENS/EFA -ECR- GUE/NGL

Consolidated amendment replacing Amendments: 32 and 635 to731**,** IMCO 42, INTA 26-29, JURI 36- 41, AGRI 45-48, ITRE 39

Proposal for a directive
Article 9 – paragraph 1 and paragraph 2

Text proposed by the Commission	*Amendment*
Combined health warnings for tobacco for smoking	Combined health warnings for tobacco for smoking

1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall:	1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined picture and text health warnings. The combined health warnings shall:
(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library;	(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library ***in Annex II***;
(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;	(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;
(c) cover ***75 %*** of the external area of both the front and back surface of the unit packet and any outside packaging;	(c) cover ***75 %*** of the external area of both the front and back surface of the unit packet and any outside packaging. ***Cylindrical containers shall display two combined health warnings, equidistant from each other, covering 75% of their respective half of the curved surface;*** ;
(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;	(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;
(e) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging;	(e) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging;
(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;	(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;
(g) for unit packets of cigarettes, respect the following dimensions:	(g) for unit packets of cigarettes, respect the following dimensions:
(i) height: not less than ***64*** mm;	i) height: not less than ***55*** mm;
(ii) width: not less than ***55*** mm.	(ii) width: not less than ***53*** mm;
2. The combined health warnings shall be divided into three sets rotating on an annual basis. Member States shall ensure that each combined health warning is displayed as nearly as possible on equal numbers of each brand.	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.

Or. en

Amendment 40
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 733 to 754, AGRI 49-51, JURI 42, ITRE 43

Proposal for a directive
Article 9 – paragraph 3 – Delegated acts

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:
(a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments;	(a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments;
(b) ***establish and*** adapt the picture library ***referred to in point (a) of paragraph 1 of this Article*** taking into account scientific and market developments;	(b) adapt the picture library ***in Annex II to this Directive,*** taking into account scientific and market developments;
(c) define the position, format, layout, design, rotation and proportions of the health warnings;	(c) define the position, format, layout, design, rotation and proportions of the health warnings;
(d) by way of derogation from Article 7(3), lay down the conditions under which health warnings may be broken during unit packet opening in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.	***delete***

Or. en

Amendment 41
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 755-782 except 774 and 775. And IMCO 43, INTA 30-32, AGRI 52, ITRE 44

Proposal for a directive
Article 10 – Paragraph 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**
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).	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	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.	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.

Or. en

Amendment 42
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments **783-794, AGRI 43, JURI 43, ITRE 44**

Proposal for a directive
Article 10 – Paragraph 5 – Delegated Acts

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.	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 ***to Council and the European Parliament***.

Or. en

Amendment 43
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 795-806 **IMCO 44, AGRI 54, ITRE 45**

Proposal for a directive
Article 11 – Paragraph 1 to 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

Or. en

Amendment 44
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 808-811, AGRI 55, ITRE 46

Proposal for a directive
Article 11 – Paragraph 3 – Delegated Acts

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

Or. en

Amendment 45
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 812-833, JURI 44 and 45, IMCO 45 lett b, INTA 33, AGRI 56, ITRE 47

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 or ***lifestyle*** 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.

Or. en

Amendment 46
S&D - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 834 -856, JURI 46, IMCO 45 (Para 2), INTA 34, AGRI 57, ITRE 47

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. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

Or. en

Amendment 47
S&D - EPP - ALDE - ECR
Consolidated amendment replacing Amendments 862 to 886, INTA 35, AGRI 59, IMCO 46, JURI 47

Proposal for a directive
Article 13 – Paragraph 1

Text proposed by the Commission	
Article 13	Article 13
Appearance and content of unit packets	Appearance and content of unit packets
1. ***A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have the form of a pouch, i.e. a rectangular pocket with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet.*** A unit packet of cigarettes shall ***include*** at least 20	1. A unit packet of cigarettes shall ***contain*** at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.

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

Or. en

Amendment 48
S&D - ALDE - ECR - EFD
Consolidated amendment replacing Amendments 872 to 896, JURI 48, AGRI 60, ITRE 48

Proposal for a directive
Article 13 – Paragraph 1a and 2

Text proposed by the Commission	*Amendment*
	1a. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have a cuboid or a cylindrical shape, or have the form of a pouch i.e. a rectangular packet with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet.
2. A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after the opening is first opened, other than the flip-top lid. ***The*** flip-top lid ***of a cigarette packet*** shall be hinged only at the back of the packet.	2. A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after the opening is first opened, other than the flip-top lid ***or a shoulder box hinged lid***. ***For packets with a*** flip-top lid opening, ***the lid*** shall be hinged only at the back of the packet.

Or. en

Amendment 49
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 898-914 and 36, JURI 49, AGRI 61

Proposal for a directive
Article 13 – Paragraph 3 – Delegated Acts

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.	***delete***

Or. en

Amendment 50
S&D - ALDE - GREENS/EFA - GUE/NGL
Consolidated amendment replacing Amendments 915-930, JURI 50, AGRI 62

Proposal for a directive
Article 13 – Paragraph 4 – Delegated Acts

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.	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.

Or. en

Amendment 51
S&D - GREENS/EFA - GUE/NGL
Consolidated amendment replacing Amendments 34 and 897

Proposal for a directive
Article 13 – Paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. All outer surfaces of the unit packet and any outside packaging of cigarettes and roll-your-own tobacco not regulated by Articles 7, 8 and 9 shall be standardised in the following way:
	a) not contain any trade mark or any other mark, apart from the brand name and any variant name for the tobacco products;
	b) be of a dark, unattractive colour set by the Commission;
	c) the brand name, and any variant name shall:
	i) not appear more than once on any one surface;
	ii) appear horizontally below, and in the same orientation as, the combined health warning, in the centre of the space remaining on the front and back surfaces of the unit packet and any outside packaging;
	iii) comply with any more detailed rules set out in paragraph 3;

Or. en

Amendment 52
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 931- 996 and 1009, JURI 51-59**,** IMCO 47, INTA 36-40, **ITRE 50-55**

Proposal for a directive
Article 14 – Traceability and Security Features

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,	1. Member States shall ensure that all unit packets ***and any outside transport packaging*** of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers

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.	shall be ***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 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;	***delete***
(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	(k) the invoice, order number and

payment records of all purchasers from manufacturing to the first retail outlet.

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, ***provided that tracking and tracing of unit packets remains possible***.

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies with the necessary equipment allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

5. Recorded data cannot be modified or deleted by any economic operator involved in the trade of tobacco products, but the economic operator that introduced the data and other economic operators directly concerned by the transaction such as the supplier or the recipient can comment on previously introduced data. The economic operator concerned shall add the correct data and a reference to the previous entry which requires rectification in their view. In exceptional circumstances and upon

payment records of all purchasers from manufacturing to the first retail outlet.

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit ***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***, determined by the 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 registered.

6. Member States shall ***ensure*** that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who is ***proposed and*** paid by the tobacco manufacturer and approved by the Commission. Member States shall ensure full transparency and accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. In duly justified cases Member States or the Commission can provide manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations.

7. Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.

8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible,

submission of adequate evidence, the competent authority in the Member State in which the recording took place or if the recording took place outside the Union the competent authority in the Member State of importation, can authorise the modification or deletion of data previously registered.

6. Member States shall ***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.

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***

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.	***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.***

Or. en

Amendment 53
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 997-1008, JURI 60

Proposal for a directive
Article 14 – Paragraph 9 – Delegated Acts

Text proposed by the Commission	*Amendment*
9. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:	9. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:
(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
(c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.	c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.

Or. en

Amendment 54
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 1015 - 1026, IMCO 48-50, INTA 43-44, **JURI 62, ITRE 57**

Proposal for a directive
Article 15 – Tobacco for Oral Use

Text proposed by the Commission	*Amendment*
Article 15	Article 15
Tobacco for oral use	Tobacco for oral use
Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.	Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.
Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.	Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Or. en

Amendment 55
S&D - EPP - ALDE - GREENS/EFA - EFD - GUE/NGL
Consolidated amendment replacing Amendments 42-47, 1028-1108**,** AGRI 65, INTA 45-54, IMCO 51 all parts, AGRI 66 1st -9th part, AGRI 67,
The amendments concerning import restrictions will be voted separately (1045, 1108, 1081).

Proposal for a directive
Chapter IV– Cross-Border Distance Sales - 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 products	***Distance*** sales of tobacco products
1. Member States shall ***oblige*** retail outlets intending to engage in cross-border distance sales ***to consumers located in the Union to register with the competent authorities in the Member State where the retail outlet is established and in the Member State where the actual or potential consumer is located. Retail outlets established outside the Union have to register with the competent authorities in the Member State where the actual or potential consumer is located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities:***	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 services;	
(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.
2. The competent authorities of the Member States shall publish the complete list of all retail outlets registered with them in accordance with the rules and safeguards laid down in Directive 95/46/EC. Retail outlets may only start placing tobacco products on the market in form of distance sales as of the moment the name of the retail outlet is published in the relevant Member States.	***deleted***
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.	***deleted***
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.	***deleted***
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.	***deleted***
	Article 16a (new) 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.

Or. en

Amendment 56
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments 48-53, 1111 to 1141. IMCO 52-58, JURI 63-64, AGRI 68, ITRE 58-63

Proposal for a directive
Article 17 - Novel Tobacco Products

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***

	and
(c) other available and relevant information, including a risk/benefit analysis of the product, the expected effects on cessation of tobacco consumption, the expected effects on initiation of tobacco consumption and other predicted consumer perception.	(c) other available and relevant information, including a risk/benefit analysis of the product, the expected effects on cessation of tobacco consumption, the expected effects on initiation of tobacco consumption and other predicted consumer perception.
2. Member States shall require that manufacturers and importers of tobacco products inform their competent authorities of any new or updated information referred to in point (a) to (c) of paragraph 1. Member States shall be entitled to require tobacco manufacturers or importers to carry out additional tests or submit additional information. Member States shall make available to the Commission all information received pursuant to this Article. Member States shall be entitled to introduce an authorisation system and charge a proportionate fee.	2. ***After the placing on the market,*** 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.

Or. en

Amendment 57
S&D-Greens/Efa-GUE/NGL
Consolidated amendment replacing Amendments: 1146 to 1248, 1360, JURI 65, IMCO 59, INTA 55, AGRI 69, ITRE 64-65
Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
1. ***The following*** nicotine-containing	1. Nicotine-containing products may only

products may only be placed on the market if they ***were*** authorised pursuant to Directive 2001/83/EC***:***	be placed on the market if they ***are*** authorised pursuant to Directive 2001/83/EC***, taking into account the well-established use of nicotine.***
a) products with a nicotine level exceeding 2 mg per unit, or	***deleted***
b) products with a nicotine concentration exceeding 4 mg per ml or	***deleted***
c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.	***deleted***
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.	***deleted***
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:	***deleted***
This product contains nicotine and can damage your health.	
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:	***deleted***
(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	***deleted***

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.

Or. en

Amendment 58
ALDE-ECR - EFD
Consolidated amendment replacing Amendments 1146 to 1248, JURI 65, IMCO 59, INTA 55, AGRI 69, ITRE 65
Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
	1. Nicotine-containing products may only be placed on the market in accordance with the provisions for tobacco products as laid out in articles 5, 17, 20, 21, 22, 23, 24, 25 and 26 of this Directive.
	Member States shall ensure that nicotine containing products comply with all relevant EU legislation.
	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. For all nicotine-containing products notified in accordance with the procedure set out in article 18 (1), Member States shall ensure that:
	(a) the product is clearly labelled with the nicotine content, instructions for use, instructions for reporting adverse reactions, and details of the manufacturer;
	(b) each unit packet and any outside packaging shall carry the following health

warning:

"**This product is intended for use by existing smokers above the legal smoking age as an alternative to tobacco products. It contains nicotine which is a highly addictive substance. Consult your doctor if you are pregnant, breast feeding, allergic to nicotine or propylene glycol, or have high blood pressure."**

(c) the sale of the product shall be restricted in line with the legal age for sale of tobacco products in the relevant Member State;

(d) the products shall be available to be sold outside pharmacies;

(e) advertising and promotion shall be appropriately regulated;

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10. In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages.

5. Member States shall monitor the development of the nicotine-containing products market, including any progress made in harm reduction, as well as any evidence of gateway use amongst young people. Based on the evidence, the Commission shall report back to the European Parliament and the Council 5 years after the transposition date of this Directive. The report shall assess whether amendments to this Directive are necessary;

	6. The Commission shall request an opinion from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) within 24 months of the entry into force of the Directive in order to obtain reliable scientific and toxicological data to determine the health effects of the main ingredients of electronic cigarettes as well as suggestions for potential measures to regulate this tobacco-related product.

Or. en

Amendment 59
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments: 1251 to 1261, IMCO 60-61, AGRI 70,

Proposal for a directive
Article 19– Herbal Products for Smoking

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 languages and 35 % for Member States with ***three*** official languages.	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 ***more than two*** official languages.

Or. en

Amendment 60
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments: 1268 to 1278, AGRI 71, IMCO 62

Proposal for a directive
Article 22 – Paragraph 2

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(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 ***a*** period of ***5 years from (...). (Publications*** Office ***is to fill in*** the date of entry into force of this ***amending Act). 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 3 months before the end of each period***.

**This list will be automatically aligned to the results of the vote on the substantive articles.*

Or. en

Amendment 61
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments: 55, 1310 to 1321, AGRI 77, JURI 71, IMCO 66, INTA 56, ITRE 71-72

Proposal for a directive
Article 24 - Review clause

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	1. ***Subject to paragraphs 2 and 3,*** Member States shall not prohibit or restrict the import, sale or consumption of tobacco or

with this Directive.

2. However, a Member State may maintain more stringent national provisions, ***applicable to all products alike,*** in areas covered by the Directive, ***on grounds of overriding needs relating to the protection of public health***. ***A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health.*** Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

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

related products which comply with this Directive.

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 to all products alike, 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 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 to all products alike, 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.

Or. en

Amendment 62
S&D-GREENS/EFA -GUE/NGL
Consolidated amendment replacing Amendments: 1324 to 1330, IMCO 68-71, INTA 57, JURI 73, ITRE 73-75

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 this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + 24 months]:	Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + 24 months]:
(a) tobacco products;	(a) tobacco products;
(b) nicotine containing products below the threshold set out in Article 18(1);	***deleted***
(c) herbal products for smoking.	***(b)*** herbal products for smoking.
	Paragraph 1a (new) 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 + 36 months]:

Or. en

Amendment 63
ALDE ECR -EFD
Compromise amendment replacing Amendments: 1324 to 1330, IMCO 68-71, INTA 57, JURI 73, ITRE 73-75

Proposal for a directive
Article 26

Text proposed by the Commission	*Amendment*
Transitional provision	Transitional provision
Member States may allow the following	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]:	products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + 24 months]:
(a) tobacco products; (b) nicotine containing products ***below the threshold set out in Article 18(1)***; (c) herbal products for smoking.	(a) tobacco products; (b) nicotine containing products; (c) herbal products for smoking.

Or. en

Amendment 64
S&D - EPP - GREENS/EFA - ECR - EFD - GUE/NGL
Consolidated amendment replacing Amendments: 1337

Proposal for a directive
Annex 1 a (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

Or. en

Amendment 65
S&D - EPP - ALDE - GREENS/EFA - ECR - EFD - GUE/NGL
Compromise amendment replacing Amendments: 1338 to 1355

Proposal for a directive
Annex 1 (List of Text Warnings)

Text proposed by the Commission	*Amendment*
LIST OF TEXT WARNINGS (referred to in Article 9 and Article 10(1))	LIST OF TEXT WARNINGS (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
	(2 a) 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
	(14 a) Smoking can cause cot death
	(14 b) Smoking during pregnancy causes premature birth
	(14 c) Passive smoking can worsen asthma or meningitis in children.

Or. en