Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2012/0366(COD)
Tobacco and related products: manufacture, presentation and sale Repealing Directive 2001/37/EC 1999/0244(COD) Subject 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.10.06.09 Industrial plants, tobacco, hops 3.40.12 Luxury products industry, cosmetics 4.20 Public health 4.60.02 Consumer information, advertising, labelling 6.20.02 Export/import control, trade defence, trade barriers	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		23/01/2013
	S&D MCAVAN Linda	
	Shadow rapporteur	
	PPE FLORENZ Karl-Heinz	
	ALDE RIES Frédérique	
	Verts/ALE SCHLYTER Carl	
	ECR CALLANAN Martin	
	EFD SCOTTÀ Giancarlo	

Committee for opinion	Rapporteur for opinion	Appointed
INTA International Trade		25/04/2013
	ALDE KAZAK Metin	
ITRE Industry, Research and Energy		06/03/2013
	S&D GOEBBELS Robert	
IMCO Internal Market and Consumer Protection		23/01/2013
	PPE HANDZLIK Małgorzata	
AGRI Agriculture and Rural Development		05/03/2013
	S&D TABAJDI Csaba Sándor	
JURI Legal Affairs		22/01/2013
	PPE LEHNE Klaus-Heiner	

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
JURI Legal Affairs		07/01/2014
	S&D REGNER Evelyn	

Council of the European Union	Council configuration	Meeting	Date
	Transport, Telecommunications and Energy	3303	14/03/2014
	Employment, Social Policy, Health and Consumer Affairs	3247	21/06/2013
European Commission	Commission DG	Commissioner	
	Health and Food Safety	BORG Tonio	
European Economic and Social Committee			

Key events

19/12/2012	Legislative proposal published	COM(2012)0788	Summary
15/01/2013	Committee referral announced in Parliament, 1st reading		
21/06/2013	Debate in Council	3247	
10/07/2013	Vote in committee, 1st reading		
24/07/2013	Committee report tabled for plenary, 1st reading	A7-0276/2013	
08/10/2013	Results of vote in Parliament		
08/10/2013	Debate in Parliament		
08/10/2013	Decision by Parliament, 1st reading	T7-0398/2013	Summary
26/02/2014	Decision by Parliament, 1st reading	T7-0160/2014	Summary
14/03/2014	Act adopted by Council after Parliament's 1st reading		
03/04/2014	Final act signed		
03/04/2014	End of procedure in Parliament		
29/04/2014	Final act published in Official Journal		

Technical information

Procedure reference	2012/0366(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Repealing Directive 2001/37/EC 1999/0244(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/11570

Documentation gateway

Legislative proposal		COM(2012)0788	19/12/2012	EC	Summary
Document attached to the procedure		SWD(2012)0452	19/12/2012	EC	
Document attached to the procedure		SWD(2012)0453	19/12/2012	EC	
Committee draft report		PE508.085	10/04/2013	EP	
Amendments tabled in committee		PE510.712	14/05/2013	EP	
Amendments tabled in committee		PE510.713	14/05/2013	EP	
Amendments tabled in committee		PE510.714	14/05/2013	EP	
Amendments tabled in committee		PE510.715	14/05/2013	EP	
Amendments tabled in committee		PE510.716	14/05/2013	EP	
Amendments tabled in committee		PE510.719	14/05/2013	EP	
Amendments tabled in committee		PE510.720	14/05/2013	EP	
Amendments tabled in committee		PE510.721	14/05/2013	EP	
Amendments tabled in committee		PE510.722	14/05/2013	EP	
Amendments tabled in committee		PE510.717	21/05/2013	EP	
Amendments tabled in committee		PE510.718	21/05/2013	EP	
Amendments tabled in committee		PE510.711	29/05/2013	EP	
Committee opinion	INTA	PE510.734	18/06/2013	EP	
Committee opinion	IMCO	PE508.048	20/06/2013	EP	
Committee opinion	JURI	PE510.591	20/06/2013	EP	
Committee opinion	AGRI	PE507.956	27/06/2013	EP	
Committee opinion	ITRE	PE508.180	08/07/2013	EP	
Specific opinion	JURI	PE516.597	10/07/2013	EP	
Economic and Social Committee: opinion, report		CES0841/2013	11/07/2013	ESC	
Committee report tabled for plenary, 1st reading/single reading		A7-0276/2013	24/07/2013	EP	
Text adopted by Parliament, partial vote at 1st reading/single reading		T7-0398/2013	08/10/2013	EP	Summary
Specific opinion	JURI	PE527.873	24/01/2014	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0160/2014	26/02/2014	EP	Summary
Draft final act		00143/2013/LEX	03/04/2014	CSL	
Commission response to text adopted in plenary		SP(2014)446	20/05/2014	EC	
Follow-up document		COM(2016)0269	20/05/2016	EC	Summary
Follow-up document		COM(2018)0579	08/08/2018	EC	Summary
Follow-up document		COM(2021)0249	20/05/2021	EC	

Follow-up document		COM(2022)0279	15/06/2022	EC	
Follow-up document		COM(2023)0491	17/08/2023	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2014/40
OJ L 127 29.04.2014, p. 0001 Summary

Corrigendum to final act 32014L0040R(01)
OJ L 150 17.06.2015, p. 0024 Summary

Final legislative act with provisions for delegated acts

Delegated acts

2014/2894(DEA)	Examination of delegated act
2017/3026(DEA)	Examination of delegated act
2022/2739(DEA)	Examination of delegated act

Tobacco and related products: manufacture, presentation and sale

PURPOSE: to revise Directive 2001/37/EC on tobacco products in order to improve the functioning of the internal market and ensure a high level of health protection.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: tobacco is the most significant cause of premature death in the EU, responsible for almost 700 000 deaths every year. More than ten years have passed since the adoption of the Directive 2001/37/EC on tobacco products. In line with market, scientific and international developments, it has become necessary to update and complement this Directive.

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

- update already harmonised areas, in order to overcome obstacles encountered by Member States in bringing their national legislation in line with new market, scientific and international developments;
- address product related measures not yet covered by the Directive;
- ensure that provisions of the Directive are not circumvented by the placing on the market of products not compliant with the Directive;
- ensure a harmonised implementation of international obligations following from the WHO Framework Convention on Tobacco Control (FCTC), which is binding for the EU and all Member States.

With regard to health protection, the proposed revision:

- seeks to regulate tobacco products in a way that reflects their specific characteristics (nicotine has addictive properties) and the negative consequences of their consumption (mouth, throat and lung cancer, cardiovascular problems including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility, impact on the unborn child etc);
- focuses on initiation of tobacco consumption, in particular by young people, taking into account that 70% of the smokers start before the age of 18 and 94% before the age of 25;
- create conditions which allow all citizens across the EU to take informed decisions about the products, based on accurate information on the health consequences of consuming tobacco products.

The Commission's proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme contains measures which have as their direct objective the protection of public health regarding tobacco products and advertisement required by or contributing to the objectives of EU legislation in this field.

IMPACT ASSESSMENT: the Commission undertook an impact assessment which accompanies the proposal. A high level of health protection has been taken as the basic criteria amongst the different strategic options that were considered during the review of the Directive.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT : the revision of Directive 2001/37/CE focuses on the following areas:

1) Ingredients and emissions: the maximum yields of tar, nicotine and carbon monoxide as well as the measurement methods remain the same as in Directive 2001/37/EC.

The proposal:

- keeps in place the mandatory reporting system of ingredients and, in addition, provides that a common electronic format for the reporting and manufacturers are required to provide supporting data (e.g. marketing reports);
- provides that placing on the market of new or modified tobacco products must not take place before the submission of ingredients data. Reported data, excluding confidential information, must be published;
- prohibits tobacco products with characterising flavours, such as fruit flavours or chocolate, and prohibits flavourings in filters, papers or packages;
- forbids additives associated with energy and vitality (e.g. caffeine and taurine), or creating the impression that products have health benefits (e.g. vitamins);
- exempts tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco from some provisions such as the prohibition of products with characterising flavours. The exemption shall be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

2) Labelling and packaging: the proposal seeks to ensure that the appearance of the package reflects the characteristics of the product inside the package - a product that has negative health consequences, is addictive, and is not for the consumption of children and teenagers. In concrete terms, the proposal:

- provides that that combined warnings (picture plus text) of 75% should be displayed on both sides of the packages of tobacco products, presented in rotation;
- replaces tar, nicotine and carbon monoxide (TNCO) levels on the packages with an information message referring to harmful substances of tobacco;
- ensures that display of cessation information (e.g. quit-lines, websites) is added to the packages;
- states that neither packaging of tobacco products, nor the products themselves, shall include any elements that promote tobacco products or mislead consumers into believing that the product is less harmful than others, refers to flavours or tastes or resembles a food product;
- exempts tobacco products other than cigarettes and roll-your own tobacco from larger health warnings;
- provides that in order to increase the visibility of the health warnings on smokeless tobacco products, these will have to be put on both sides of the package according to the proposal, but their size will remain unchanged compared to Directive 2001/37.

3) Traceability and security features: the proposal:

- provides for an EU tracking and tracing system at packet level for tobacco products throughout the supply chain (excluding retail). Tobacco products other than cigarettes and roll-your-own-tobacco are granted a transitional period of five years;
- provides that technical standards to ensure compatibility between the tracking and tracing systems used as well as for the contracts with third parties shall be adopted by delegated acts. Technical standardisations for security features shall also be adopted through delegated acts.

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

5) Cross-border distance sales of tobacco products: cross-border distance sales of tobacco products fall outside the scope of Directive 2001/37/EC. The proposal:

- includes a notification obligation for retailers of tobacco products intending to engage in cross-border distance sales;
- allows Member States to require the retailer to appoint a natural person, who ensures compliance with the Directive of products delivered to customers in the Member States concerned;
- provides a mandatory age verification mechanism.

6) Novel tobacco products (do not fall within any of the established product categories): these products will have to respect requirements of the Directive (e.g. in terms of labelling and ingredients) to ensure a level playing field, and the applicable rules will depend on whether the product involves a combustion process or not.

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

7) Nicotine containing products (NCP): bearing in mind the novelty and the rapid growth of the market in NCP, the proposal removes current legislative divergence between Member States and the differential treatment between Nicotine Replacement Therapies and Nicotine Containing Products. The proposal provides that:

- NCP that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance;
- NCP with nicotine levels below this threshold can be sold as consumer products provided they feature an adapted health warning.

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

The proposal provides for adapted health warnings for herbal products for smoking to inform consumers about the adverse health effects of

these products. In addition, no promotional or misleading elements are allowed on the packages.

BUDGETARY IMPLICATIONS: the estimated impact on expenditure (operational appropriations, human resources and other administrative expenditure) amounts to EUR 7,888 millions for the period 2014-2018.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU).

Tobacco and related products: manufacture, presentation and sale

The Committee on the Environment, Public Health and Food Safety adopted the report by Linda McAVAN (S&D, UK) 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.

The committee recommends that the European Parliaments position at first reading following the ordinary legislative procedure should amend the Commissions proposal as follows:

Aims of the Directive: according to Members, the Directive should also aim to prohibit cross-border distance sales of tobacco products.

The overall objective is to meet obligations under the WHO Framework Convention for Tobacco Control (FTCT) 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.

Maximum tar, nicotine, carbon monoxide and other yields: Members call for the accuracy of the indications for the other emissions of other combustible tobacco products to be verified in accordance with ISO standard 8243.

Tests verifying the validity of the result supplied by the tobacco companies shall be done on a regular basis by independent testing laboratories monitored by the competent authorities of the Member States.

The Commission shall be empowered to adopt delegated acts to reduce the maximum yields, where necessary, in order to take into account scientific development and internationally agreed standards. In addition, the Commission shall ask the International Organization for Standardization (ISO) to develop a standard to measure Polonium 210 in tobacco.

Ingredients: Members consider that 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. Tobacco products containing additives not included in the Union list or used in a manner that does not comply with this Directive should not be placed on the Union market.

Additives associated with energy and vitality (e.g. caffeine and taurine), or creating the impression that products have health benefits (e.g. vitamins) are prohibited.

Additives which are essential for the manufacture of tobacco products may be approved (such as sugar).

In order to obtain the approval of an additive, manufacturers and importers shall make an application to the Commission.

Labelling and packaging: Members propose that 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.

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 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.

Labels shall not include any information about nicotine, tar or carbon monoxide content.

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.

Traceability and safety: an amendment states that Member States shall ensure that all unit packets and any outside transport packaging of tobacco products shall be marked with a unique identifier. The unique identifier shall determine the intended and actual shipment route from the place of manufacturing to the first retail outlet, including all warehouses used, the shipment date, shipment destination, consignee and point of departure.

Age limit: Member States should be encouraged, if they have not already done so, to formulate their national laws on the protection of young people in such a way that tobacco products may not be sold to, or consumed by, young people under the age of 18. They should also ensure that such prohibitions are respected.

Member States shall report every two years to the Commission, in particular with regard to age limits set in national legislation, as well as their plans to increase the age limit to achieve the goal of a "smoke-free generation".

Electronic cigarettes: the report stresses that Members States have taken different different regulatory approaches to address health and safety concerns associated with these products. There is a need for harmonised 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 such products to aid with smoking cessation, Member States should ensure that they can be made available outside pharmacies.

Tobacco and related products: manufacture, presentation and sale

The European Parliament adopted by 560 votes to 92, with 32 abstentions, amendments to 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.

The issue has been referred back to the committee responsible. The vote has been postponed to a later date.

The main amendments adopted in plenary are the following:

Objectives of the Directive: the general objective should be to meet obligations under the WHO Framework Convention for Tobacco Control and 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.

The Directive stipulated that Member States should prohibit cross border distance sales of tobacco products.

Maximum yields of tar, nicotine and carbon monoxide and other substances: the accuracy of the tar, nicotine and carbon monoxide indications shall be verified in accordance with ISO standard 8243. Tests verifying the validity of the result supplied by the tobacco companies shall be done on a regular basis by independent testing laboratories monitored by the competent authorities of the Member States.

Members suggested setting a maximum yield of Polonium 210 which has been shown to be a significant carcinogen in tobacco. This would result in a reduction of 95% of the current average content of Polonium 210 in cigarettes.

Ingredients: an assessment should be carried out on the safety of additives for use in tobacco products. Additives should only be allowed in tobacco products if they are included in a Union list of authorised additives. That list should also indicate any conditions or restrictions on the use of allowed additives. Tobacco products containing additives not included in the Union list or used in a manner that does not comply with this Directive should not be placed on the Union market.

The following additives may not be approved: vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards; caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality; additives which, when used, may impart a characterising flavour (fruit, spice, herb, alcohol, candy, menthol or vanilla). Additives essential to produce tobacco, such as sugar, would be authorised.

In order to obtain the approval of an additive, manufacturers and importers shall make an application to the Commission.

Labelling and packaging: Members requested that the health warnings should appear on all sides of the unit packet and any outside packaging and that they cover 65 % of the external area of both the front and back surface of the unit packet and any outside packaging.

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 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.

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

Members rejected the banning of slim cigarettes.

Traceability and security: Member States should ensure that all unit packets and any outside transport packaging of tobacco products shall be marked with a unique identifier.

The unique identifier should determine the date and place of manufacturing, the manufacturing facility, the intended and actual shipment route from the place of manufacturing to the first retail outlet, including all warehouses used, the shipment date, shipment destination, consignee and point of departure.

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

Member States should report every two years to the Commission on the enforcement of the measures taken on the prevention of smoking and on initiatives to improve tobacco control, in particular with regard to age limits set in national legislation, as well as their plans to increase the age limit to achieve the goal of a smoke-free generation.

Imitation tobacco products: products aimed at underage consumers, such as food products and toys in the form of tobacco products that may be appealing to minors should be banned.

E-cigarettes: E-cigarettes should be regulated, but not be subject to the same rules as medicinal products unless they are presented as having curative or preventive properties. Those for which no such claims are made should contain no more than 30mg/ml of nicotine, should carry health warnings and should not be sold to anyone under 18 years old.

Manufacturers and importers would also have to supply the competent authorities with a list of all the ingredients that they contain. E-cigarettes would be subject to the same advertising restrictions as tobacco products.

Given the potential of nicotine-containing products to aid smoking cessation, Member States should ensure that they can be made available as widely as tobacco products. These products should be available to be sold outside pharmacies.

Tobacco and related products: manufacture, presentation and sale

The European Parliament adopted by 514 votes to 66, with 58 abstentions, a legislative resolution 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.

The issue had been referred back to the committee responsible during the session of 8 October.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise between Parliament and Council. The main amendments are the following:

Objectives of the Directive: the general objective should be to meet obligations under the WHO Framework Convention for Tobacco Control and 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.

Maximum yields of tar, nicotine and carbon monoxide and other substances: the accuracy of the tar, nicotine and carbon monoxide indications shall be verified in accordance with ISO standard 8243. Tests verifying the validity of the result supplied by the tobacco companies shall be done on a regular basis by independent testing laboratories that are not owned or controlled directly or indirectly by the tobacco industry.

Priority list of additives and enhanced reporting obligations: in addition to the reporting obligations laid down regarding the reporting of ingredients and emissions, enhanced reporting obligations shall apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list.

The Commission shall adopt implementing acts laying down and subsequently updating such a priority list of additives. A first list of additives shall be adopted containing at least 15 additives within 2 years of entry into force of the Directive.

Manufacturers and importers of cigarettes and roll-your-own tobacco containing an additive that is included in the priority list must carry out comprehensive studies, which shall examine for each additive whether it contributes to the toxicity or addictiveness of the products concerned, or results in a characterising flavor, facilitates inhalation or nicotine uptake or leads to the formation of substances that have CMR properties.

Ingredients: the amended text prohibits the placing on the market of tobacco products containing a characterising flavour (a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla). Also prohibited are additives such as vitamins, caffeine or taurine, additives having colouring properties for emissions, additives that facilitate inhalation or nicotine uptake, and additives that have CMR properties in unburnt form.

The use of additives necessary for the manufacture of tobacco products, for example sugar, is allowed.

These provisions shall not apply to tobacco for oral use.

Labelling and packaging: the health warnings on a unit packet and any outside packaging are irremovably printed, indelible and fully visible. They shall remain intact when opening the unit packet other than packets with a flip-top lid. All unit packets of tobacco products, which are placed on the market, must carry a tamper proof security feature, composed of visible and invisible elements.

Members want the combined health warnings to cover 65 % of both, the external front and back surface of the unit packet and any outside packaging. The warnings must contain a corresponding colour photograph specified in the picture library in Annex II.

The labelling shall not include any element or feature that: (i) promotes a tobacco product or encourages its consumption; (ii) suggests that a particular tobacco product has properties or has other health or lifestyle benefits; (iii) resembles a food or a cosmetic product; (iv) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

Packets of less than 20 are forbidden.

Cross-border distance sales of tobacco products: the amended text states that Member States may prohibit cross-border distance sales of tobacco products to consumers. Member States shall cooperate to prevent such sales. Retail outlets engaging in cross-border distance sales of tobacco products may not supply such products to consumers in Member States where such sales have been prohibited.

Electronic cigarettes: in accordance with Parliaments wishes, E-cigarettes should be regulated, either as medicinal products for stopping smoking or tobacco products. In the second case, the nicotine concentration must be no more than 20mg/ml. E-cigarettes should carry health warnings and should not be sold to children.

They would be subject to the same advertising restrictions as tobacco products.

Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market.

The Commission shall submit a report on the potential risks to public health associated with the use of refillable electronic cigarettes within 2 years after entry into force of the Directive and where appropriate thereafter.

Tobacco and related products: manufacture, presentation and sale

Corrigendum to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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 and repealing Directive 2001/37/EC (Official Journal of the European Union L 127 of 29 April 2014)

On page 19, point (f) of Article 10(1):

for:

?(f)be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;?,

read:

?(f)be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 4;?.

Tobacco and related products: manufacture, presentation and sale

PURPOSE: to improve the functioning of the internal market for tobacco and related products, taking as a base a high level of protection of

human health, especially for young people.

LEGISLATIVE ACT: Directive 2014/40/EU 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 and repealing Directive 2001/37/EC.

CONTENT: this Directive replaces Directive 2001/37/EC and aims to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, that is, electronic cigarettes and refill containers, and herbal products for smoking.

Maximum emission levels for tar, nicotine, carbon monoxide and other substances: by virtue of the new Directive, the emission levels from cigarettes placed on the market or manufactured in the Member States shall not be greater than: a) 10mg of tar per cigarette; b) 1mg of nicotine per cigarette; c) 10mg of carbon monoxide per cigarette.

The accuracy of the measurements shall be determined in accordance with ISO standard 8243.

The measurements shall be verified by laboratories which are approved and monitored by the competent authorities of the Member States. Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

Reporting of ingredients and emissions: the Directive shall require manufacturers and importers of tobacco products to declare the ingredients contained in all tobacco products, as well as the tar, nicotine and carbon monoxide emissions of cigarettes. Additional enhanced reporting obligations should be provided for in respect of additives contained in cigarettes and roll-your-own tobacco included on a priority list. A first list of additives, containing at least 15 additives, shall be adopted no later than two years after the entry into force of the Directive.

Ingredients: the Directive prohibits the placing on the market of tobacco products containing characterising flavour (perfume of fruit, spices, aromatic plants, alcohol, sweets, menthol or vanilla). Furthermore, additives such as vitamins, taurine or caffeine, as well as additives having colouring properties for emissions, as well as additives that facilitate inhalation or nicotine uptake, and that have CMR properties in unburnt form.

Additives which are essential for the manufacture of tobacco products, for example, sugar, shall, however, be authorised.

In the case of tobacco products with a characterising flavour, whose Union-wide sales volumes represent 3% or more in a particular product category, the provisions of this Directive shall apply from 20 May 2020.

The prohibition on tobacco products with a characterising flavour shall not apply to other tobacco products such as cigars, cigarillos and smokeless tobacco products. In addition, this Regulation shall not apply to tobacco for oral use (snus).

Labelling and packaging: cigarette packets shall carry combined health warnings containing a colour photograph and a text warning covering 65% of both the external front and back surface of the unit packet and any outside packaging. Health warnings will also cover 50% of the lateral surfaces of packets (such as Smoking kills quit now or Tobacco smoke contains over 70 substances known to cause cancer.)

Unit packets of cigarettes shall have a cuboid shape and shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30g.

The health warnings should be irremovably printed, indelible and fully visible in the official language or languages of the Member State where the product is placed on the market.

Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message and the combined health warnings In that event, they will be required to ensure that a general warning with reference to smoking cessation services and one of the text warnings appears on the products.

Each unit packet of smokeless tobacco products shall carry the following health warning: This tobacco product damages your health and is addictive. In addition, each unit packet of herbal products for smoking shall carry the following health warning: Smoking this product damages your health.

The labelling of unit packets shall not include any element or feature that: i) promotes a tobacco product or encourages its consumption; ii) suggests that a particular tobacco product has other health or lifestyle benefits; iii) resembles a food or a cosmetic product; iv) suggests that a certain tobacco product has improved biodegradability.

Traceability: Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier. This identifier shall allow the following to be determined, among others, the date and place of manufacturing, the manufacturing facility, the product description, the intended market of retail sale, and the intended shipment route. All unit packets of tobacco products, which are placed on the market, should carry a tamper proof security feature.

Tobacco for oral use and cross-border distance sales: the Directive provides that the Member States prohibit the sale of tobacco for oral use, without prejudice to the Act of Accession of Austria, Finland and Sweden. Member States should, therefore, be allowed to prohibit cross-border distance sales. Member States should cooperate with each other in order to prevent such sales.

Notification: the Directive requires the manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of Member States of any such product they intend to place on the national market concerned.

Electronic cigarettes: electronic cigarettes should be regulated like medicinal products if they permit smoking cessation or as tobacco products. In the second case, their nicotine concentration should not exceed 20mg/ml.

Manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.

Electronic cigarettes should be banned for children and carry health warnings. They shall be subject to the same restrictions as tobacco products as regards advertising.

The Commission shall submit a report on the potential risks to public health associated with the use of refillable electronic cigarettes by 20 May 2016 and whenever appropriate thereafter.

Where the placing on the market of specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container has been

prohibited on duly justified grounds in at least three Member States, the Commission shall be empowered to extend such a prohibition to all Member States.

ENTRY INTO FORCE: 9.05.2014.

TRANSPOSITION: no later than 20.05.2016. The measures shall apply from this date.

DELEGATED ACTS: the Commission may adopt delegated acts in order to adapt the Directive to technical, scientific and international developments in tobacco manufacture, consumption and regulation. The power to adopt such acts shall be conferred on the Commission for a period of five years from 19 May 2014. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification (this period can be extended for two months). If the European Parliament or the Council make objections, the delegated act will not enter into force.

Tobacco and related products: manufacture, presentation and sale

The Commission presents a report on the potential risks to public health associated with the use of refillable electronic cigarettes in accordance with Directive 2014/40/EU.

The report identifies the particular risks that may be associated with refillable e-cigarettes and their refill containers. It does not consider the potential public health impact of e-cigarettes in general.

The document was prepared with input from the PRECISE study prepared by an external contractor, and analysed 277 cases of nicotine poisoning reported to poison centres in eight EU Member States (Austria, Hungary, Ireland, Lithuania, Netherlands, Portugal, Sweden and Slovenia) from January 2012 to March 2015.

The contractor performed chemical analysis on e-cigarette samples. It also conducted a survey amongst the e-cigarette industry to determine what they believed to be the main risks associated with refillable e-cigarettes

The Commission identified four main risks related to the use of refillable e-cigarettes, these being:

- accidental ingestion of e-liquid (particularly with young children);
- dermal contact, where e-liquid contains nicotine and other products irritating to the skin (propylene glycol and flavours);
- mixing or customisation of liquids, where users blend their own e-liquid at home by purchasing ingredients separately;
- risks due to using untested combinations of e-liquid and device or hardware customisation.

Possible risks to health: the report concludes that the use of refillable electronic e-cigarettes, and the potential exposure to e-liquids containing nicotine in high concentrations, may pose risks to public health. Based on the limits set out in the Tobacco Products Directive, refillable e-cigarette devices can contain up to 40 mg nicotine and refill containers can hold up to 200 mg nicotine. There is, therefore, a particular risk for young children if they accidently ingest e-liquid especially from a refill container.

Measures to reduce risk: in the context of current scientific knowledge, the Commission considers that the measures relating to refillable e-cigarettes provided for in the Tobacco Products Directive and secondary legislation, combined with national regulation, provide an adequate and proportionate framework for the mitigation of such risks. This does not, however, preclude the need for further study of these products and their safety for consumers (in particular concerning poisoning from accidental ingestion of e-liquid and the hazard profile of flavours).

The rather high percentage of poisonings involving adults over the age of 18 (57%) also suggests the need to increase awareness amongst citizens on the toxicity of the e-liquids containing nicotine, perhaps through national educational campaigns.

Member States and the Commission should carefully monitor the market of refillable e-cigarettes, as well as the notifications received under Article 20(2) of the TPD.

Lastly, the report suggests that further research on certain aspects of e-cigarettes relevant to refillables, such as emissions testing and the safety of flavours or mixtures of flavours, should also be carried out. Additional research on these topics would benefit all users of e-cigarettes (whether they are disposable, rechargeable and refillable).

Tobacco and related products: manufacture, presentation and sale

The Commission presents a report on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Directive 2014/40/EU on the approximation of the laws and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (Tobacco Products Directive). Under the terms of the Directive, the Commission is required to draw up a report in respect of the delegation of power conferred on the Commission for a period of five years from 19 May 2014.

The Commission reports that it adopted two delegated acts based on Articles 10(3)(b) and 15(12) of the Tobacco Products Directive.

Delegated act adopted under Article 10(3)(b): this provision empowers the Commission to adopt delegated acts to establish and adapt a picture library. The pictures contained in that library are an integral part of the combined health warning which is required to appear on each unit packet and outside packaging of tobacco products for smoking placed on the EU market. Commission adopted Delegated Directive 2014/109/EU amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products.

Delegated act adopted under Article 15(12): the relevant provisions of Article 15 require Member States to ensure that:

- all unit packets of tobacco products are marked with a unique identifier, in order to enable their movements to be recorded by all economic operators involved in the trade of tobacco products;
- manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant traceability data recorded in this context

The Commission may adopt delegated acts to define the key elements of the data storage contracts, such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts.

Accordingly, the Commission adopted Delegated Regulation (EU) 2018/573 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products, in order to ensure the effective functioning of the traceability system in general and the interoperability of the data storage system in particular.

Procedure: the two draft delegated acts were submitted to the Expert Group on Tobacco Policy prior to their adoption. The European Parliament has been systematically invited to the meetings of this Expert Group. The documents relevant to these consultations were transmitted simultaneously to the European Parliament and to the Council, as provided for in the Common Understanding between the European Parliament, the Council and the Commission on Delegated Acts. The European Parliament or the Council raised no objection to either of the delegated acts adopted by the Commission within the 2-month period provided for in the Directive.

As regards the other delegated powers conferred, the preconditions for their exercise have not yet been met.

The Directive states that the five-year duration of the delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period. The Commission considers that the delegation of powers should be extended, since the rationale for the delegation has not changed and the powers granted are essential for achieving the objective of the Tobacco Products Directive.