European Federation of Allergy and Airways Diseases Patients Associations

EFA briefing **January 2013**

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In view of adopting EFA position paper 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

Purpose

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is a non-profit network of allergy, asthma and chronic obstructive pulmonary disease (COPD) patients' organisations, representing 35 national associations in 22 countries and over 400,000 patients in Europe. EFA is dedicated to making Europe a place where people with allergies, asthma and COPD have the right to best quality of care and safe environment, live uncompromised lives and are actively involved in all decisions influencing their health. This paper includes EFA's first comments on the main issues of the Commission's proposal for the tobacco products directive and was sent out to our network for comments and approval. Members positively responded and especially Norwegian Asthma and Allergy Association (NAAF), Finnish Allergy and Asthma Federation, FEDERASMA and Swedish Heart and Lung Association were actively involved in the development of the document.

Although the directive only applies to tobacco consumption and not to exposure (it does not regulate the smoking banning in public places; the EU has not yet legislated on this topic, only issued non-binding Council recommendation on smoke-free environments)[1], it is fundamental for EFA to advocate for stricter requirements that protect the health of European citizens to be inserted in the text. Tobacco is a proven and classified carcinogen; it causes a great deal of respiratory diseases and is a major source of nuisance and exacerbation for people with asthma, allergy and COPD, leading to social and work exclusion and unnecessary illness. In particular, the World Health Organisation (WHO) estimates that tobacco smoke is the primary cause of COPD in developed countries.[2] Lifelong smokers have a 50%

[1] In some European countries, patients' organisations have been actively involved in protecting European citizens' health by prohibiting smoking in public places. In particular, FEDERASMA in Italy was working hard to promote the so called "Sirchia Law" (Law 3/2003 abolishing smoking in public places) to protect non-smokers, making Italy one of the first countries in Europe to approve such legislations.

[2] WHO, *COPD factsheet*, November 2012, available at: http://www.who.int/mediacentre/factsheets/fs315/en/.

probability of developing COPD during their lifetime; along the same line, there is also evidence that the risk of developing COPD falls by about half with smoking cessation.[3] Research shows that smoking and exposure to second hand smoke is a major factor in provoking allergic responses by babies and young children.[4] A third of adults aged 18-45 with clinical/treated asthma are current smokers.[5] This number is worrying as smoking in asthma is associated with a higher degree of asthma severity, worsening of symptoms, increased hospital admissions, accelerated decline in lung function, limited short-term responses to medicines and poorer asthma control.[6]

Background

On 19 December 2012, the European Commission adopted the proposal to repeal directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.[7]

More than ten years have passed since the adoption of the current directive. During this time, there have been several market, scientific and international developments in the tobacco sector and the existing rules present a number of weaknesses, gaps and loopholes.[8] Therefore, it has become necessary to update and complete the directive. A revision is explicitly foreseen by article 11 of the current directive, was repeatedly called for by the Council and the European Parliament, and was included in the European Commission's work plan for 2012.

The proposal was delayed by the facts surrounding the resignation of former Commissioner for health and consumers, Mr. John Dalli, and the appointment of his successor, Mr. Tonio Borg. The text is currently under ordinary legislative procedure at the European Parliament and the Council of the European Union with the objective of being adopted before next European Parliament's elections (June

[3] Laniado-Laborín L., *Smoking and Chronic Obstructive Pulmonary Disease (COPD). Parallel Epidemics of the 21st Century*, in International Journal of Environmental Research and Public Health, 2009.

[4] Kulig M., Luck W., Lau S., Niggemann B., Bergmann R., Klettke U., Guggenmoos-Holzmann I., Wahn U., *Effect of pre- and post-natal tobacco smoke exposure on specific sensitisation to food and inhalant allergens during the first years of life*, in Allergy, March 1999. Halken S., *Prevention of allergic disease in childhood: clinical and epidemiological aspects of primary and secondary prevention*, in Pediatric Allergy Immunology, June 2004.

[5] To T., Stanojevic S., Moores G., Gershon A. S., Bateman E. D., Cruz A. A., Boulet L., *Global asthma prevalence in adults: findings from the cross-sectional world health survey*, in BMC Public Health, March 2012.

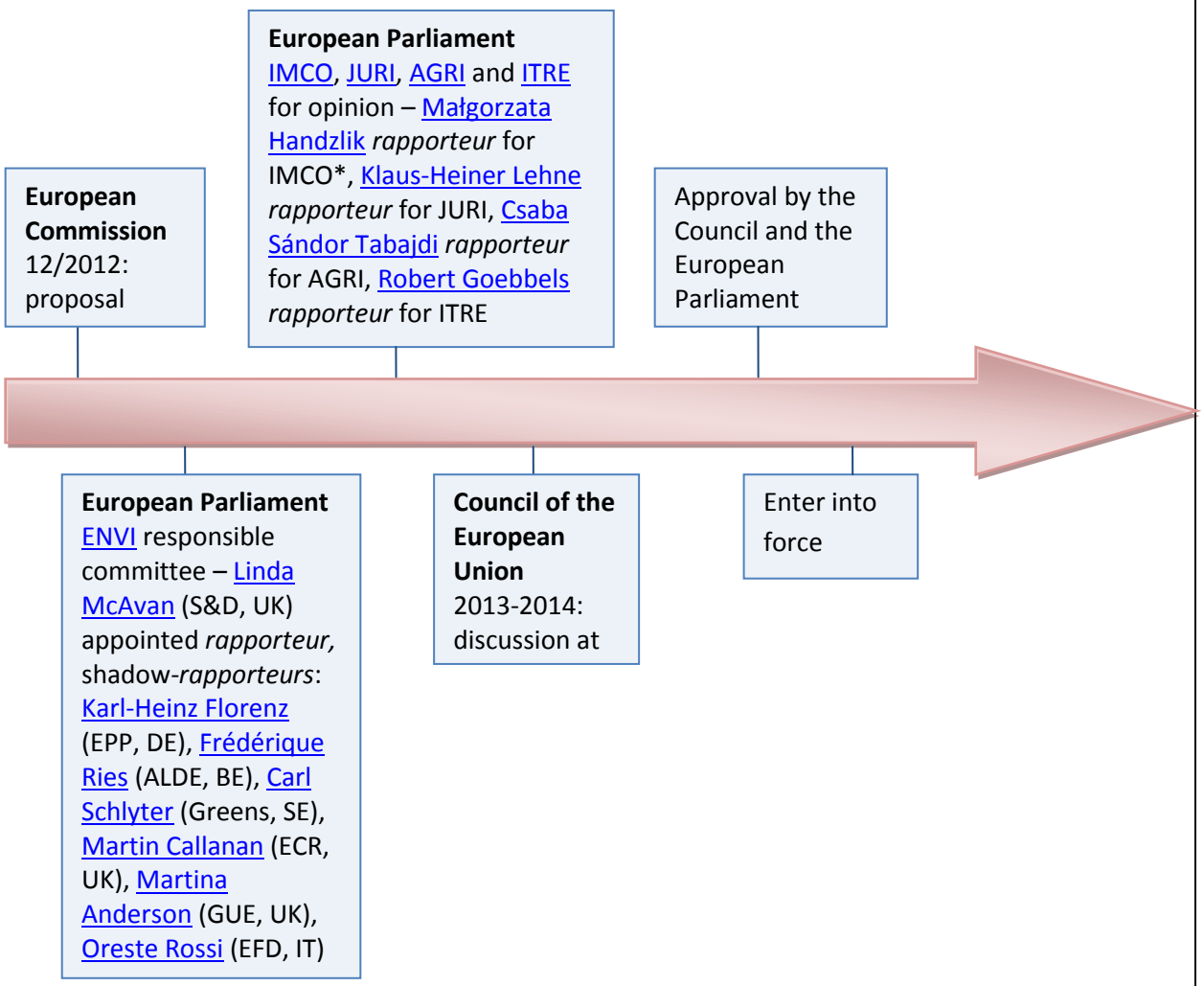
[6] Thomson N. C., Chaudhuri R., Livingston E., *Asthma and cigarettes smoking*, in European Respiratory Journal, November 2004. Fattahi F., Hylkema M. N., Melgert B. N., Timens W., Postma D. S., ten Hacken N.H., *Smoking and nonsmoking asthma: differences in clinical outcome and pathogenesis*, in Expert Review of Respiratory Medicine, February 2011. Polosa R., Thomson N. C., *Smoking and asthma: dangerous liaison*, in European Respiratory Journal, August 2012.

[7] In order to avoid numerous modifications of the current directive that would change its presentation, and for reasons of clarity, the Commission proposed to repeal directive 2001/37/EC, that is to replace it with a new act modelled on the text in force, but enriched with new elements and adjustments.

[8] In particular, the World Health Organisation's Framework Convention on Tobacco Control (WHO FCTC), the world's first international health treaty, was adopted in 2003 and entered into force in 2005. The EU became a party to the FCTC in 2005 and as of 2012 all the EU Member States have ratified the FCTC.

2014).[9] Otherwise, the process will be stopped and the final approval of the new directive will be deferred.

Timeline of the directive



* Shadow *rapporteurs*: Catherine Stihler (S&D, UK), Olle Schmidt (EPP, SE), Christian Engstrom (Greens, SE), Adam Bielan (ECR, PL)

[9] A more complete overview of the legislative procedure is available at: http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0366%28COD%29&l=en. Basically, the Commission proposes; the European Parliament has to identify a responsible committee that will draft the report and several committees that will give an opinion on this proposal; the Council will discuss the issue in its responsible configuration. Because of the complexity and political weight of the directive, it is highly possible that the European Parliament and the Council do not agree on the text during the first reading and therefore a second reading is expected.

Legal basis

Article 114 of the Treaty on the Functioning of the European Union (TFEU): harmonisation of national laws, regulations and administrative provisions concerning the manufacture, presentation and sale of tobacco and related products (first paragraph) aimed at ensuring a high level of health protection (third paragraph)

Subsidiarity: the proposed action cannot be sufficiently achieved by the Member States, neither at central nor at regional or local level, but can rather be best achieved at the EU level – article 5 (third paragraph) of the Treaty on European Union (TEU)

Proportionality: the proposal does not exceed what is necessary to achieve the objectives of the Treaty as it provides an appropriate level of margin for implementation by the Member States and fully respects their responsibilities to organise, finance and deliver health services and medical care – article 5 (fourth paragraph) of the TEU

→ The Commission is empowered by the regulation to adopt delegated (article 290 of the TFEU) and implementing acts (article 291 of the TFEU). The former ensures uniform application of the proposed directive; the latter complements the regulatory framework for tobacco products over time.[10]

The proposed regulation applies to all 27 EU Member States[11] and to the three countries of the European Economic Area (EEA: Norway, Liechtenstein and Iceland).

While the overall objective of the proposal is to improve the functioning of the internal market, it is expected that citizens in all Member States will benefit from improved public health. In particular, the revision will contribute to the overall aim of the EU to promote the well-being of its people (article 3 of the TEU) and the Europe 2020 strategy, as keeping people healthy and active longer, and helping people to prevent avoidable diseases and premature death will have a positive impact on productivity and competitiveness.

[10] Delegated acts may be adopted regarding the adoption and adaptation of maximum yields for emissions and their measurement methods, the setting of maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, the definition of key elements for contracts on data storage with independent third parties, the review of certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and of the nicotine levels for nicotine containing products.
The Commission is empowered to adopt implementing acts 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.

[11] Croatia will join the European Union in July, becoming the 28th Member State.

General content

Tobacco is the most significant cause of premature death in the EU, responsible for almost 700,000 deaths every year. The proposal focuses on **initiation of tobacco consumption, in particular by young people**, taking into account that 70% of the smokers start before the age of 18 and 94% before the age of 25 years.[12]

EFA comment: although the objective of preventing youth from starting smoking is valuable and should be encouraged, this should not be the only aim of the proposal. Indeed, this strategy reflects in some provisions of the text that are less strict regarding some products (because deemed to be consumed by an older audience). EFA representing people with asthma, allergy and COPD, our main objective is to ensure that the rights of all these people, independently from their age, are guaranteed.

At the same time, however, EFA acknowledges that reducing the number of people that start smoking will be an important contribution towards reaching all other aims. To this extent, a special attention should be paid to water-pipe (non-tobacco water-pipe is indeed excluded from the scope of the directive). This is particularly used by young people[13] and extremely harmful as it releases combustion products in the air at a much higher concentration than cigarettes. Especially, CO_2 levels are five times higher, tar levels 46 times and other carcinogens' levels 50 times higher. As a consequence, the risk of lung cancer and respiratory symptoms increases, oral health problems occur and special issues regarding pregnancy, most notably lower birth weight, happen.

The revision focuses on **five policy areas**:

1. Smokeless tobacco products and extension of the product scope
2. Packaging and labelling
3. Ingredients/additives
4. Cross-border distance sales
5. Traceability and security features

Novel tobacco products are those products containing tobacco that do not fall within any of the established product categories (e.g.: cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use) and that are placed on the market after the entry into force of the proposed directive. These products will have to respect the requirements of the directive, a notification obligation is introduced and a report on the market development in these products will be issued by the Commission five years after the transposition deadline of the directive.

[12] Special Eurobarometer, *Attitudes of Europeans towards tobacco*, May 2012, available at: http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco_2012_en.pdf.
[13] In Sweden, 65% of 17-year old people use water-pipes.

1. Smokeless tobacco products and extension of the product scope

All smokeless tobacco products must carry health warnings on the main surfaces of the package and products with characterising flavours cannot be sold (see below for more details on packaging).

Oral tobacco: as it is in the current directive, the ban on oral tobacco products is maintained, except for Sweden which has an exemption.

Nicotine containing products (NCP): these products (e.g.: chewing-gums, some electronic cigarettes[14]) fall outside the scope of the current directive and Member States have so far taken different regulatory approaches, such as regulating them as medicinal products, applying certain provisions that are used for tobacco products or having no specific legislation.

As this hinders the EU single market, the proposal addresses the issue as follows. Below certain nicotine thresholds, these products are allowed on the market, but they must feature health warnings. Above these thresholds, they are only allowed if authorised as medicinal products, like nicotine replacement therapies (NRT).

Herbal products for smoking: if these products were not regulated by the current directive, the proposal now requires that they have to carry health warnings to be placed on the EU market.

EFA comment: EFA welcomes the maintenance of the ban on oral tobacco due to its harmful and addictive effects that have been confirmed by the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and other studies.

EFA is against the use of electronic cigarettes for several reasons. Firstly, electronic cigarettes are not suitable for addiction control and withdrawal as smokers continue to have the habit of smoking and keeping a cigarette in their hands, and, on the contrary, they might be an outpost to reintroduce smoke habit in public places (as it is currently the case in some airlines). In addition, electronic cigarettes were proven to be harmful for people. They contain propylene glycol (E1520) and glycerol (E422), but the remaining composition of their fluids is mainly unknown and no one is properly controlling their safety (this is particularly the case for non-nicotine containing e-cigarettes' liquids as they are not regulated by any EU piece of legislation). A study conducted in 2011 reported the following side effects: mouth irritation increased by 21%, sore throat by 32%, dry cough by 32%. In the case of people with respiratory diseases, it was proven that in the short-term these electronic cigarettes have immediate adverse physiologic effects that are similar to some of the effects seen with tobacco smoking. Exposure to propylene glycol can induce respiratory irritation and increase the likelihood of developing asthma.[15] As a result, if they have to be sold, these products should be regulated under the medicinal products' legislation. If electronic cigarettes were used as a remedial care, they ought to be supplied like

[14] Not all electronic cigarettes contain nicotine.

[15] Vardavas C. I., Anagnostopoulos N., Kougias M., Evangelopoulou V., Connolly G. N., Behrakis P. K., *Short-term Pulmonary Effects of Using an Electronic Cigarette: Impact on Respiratory Flow Resistance, Impedance, and Exhaled Nitric Oxide*, in CHEST, June 2012.

prescription drugs and not in shops, which are fast increasing and available to any age. If nicotine is used as a medical treatment, it is advisable that patients understand it and get it through products known as drugs.

The provisions forbidding characterising flavours for smokeless tobacco products are welcomed, as well as those requiring that nicotine containing products and herbal products for smoking carry health warnings. However, as explained below, no different treatment should exist between smoking and smokeless tobacco products in terms of size of these warnings.

2. Packaging and labelling

Health warnings: the current directive makes text health warnings mandatory (30% on the front and 40% on the back) and picture warnings (only on the back) optional. There are now 10 EU countries requiring pictorial warnings: Belgium (2006), Romania (2008), UK (2008), Latvia (2010), Malta (2011), France (2011), Spain (2011), Denmark (2012), Hungary (2012) and Ireland (as of 2013). In the wider European region, Switzerland (2008), Turkey (2010), Norway (2011) and Ukraine (2012) have adopted pictorial warnings. Worldwide, at least 50 jurisdictions have required pictorial warnings.

The new proposal foresees that combined warnings (picture plus text) of 75% should be displayed on both sides of the packages of tobacco products. 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.

Warnings on tar, nicotine and carbon monoxide (TNCO): as tar, nicotine and carbon monoxide levels on the packages stipulated under the current directive are misleading; they will be replaced with an information message referring to harmful substances of tobacco.

Cessation information: display of cessation information (e.g.: quit-lines, websites) is added to the packages.

Plain packaging: packaging of tobacco products, or the products themselves, shall not include any elements that promote tobacco products or mislead consumers to believe that the product is less harmful than others, refers to flavours or tastes or resembles a food product. For example, “mild”, “smooth”, “light” wording is prohibited; cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

The proposal also includes requirements for packages, e.g.: cuboid shape for cigarette packages, and the number of cigarettes per package (20). However, the proposal does not harmonise at the EU level the packages as regards for example colours and font. Therefore, Member States would retain their power to regulate these areas of the package not regulated by the text, including implementing provisions providing full standardisation of packaging of tobacco products (including colours and font), as far as these provisions are compatible with the EU treaties and other legislations.

→ Exception: the proposal exempts tobacco products other than cigarettes and roll-your own tobacco from larger health warnings and from warnings on harmful substances of tobacco. For smokeless tobacco products, these health warnings will have to be put on both sides of the package, but their size will remain unchanged compared to the current directive. The exemption shall be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

EFA comment: once again, the text should be streamlined and the same provisions apply to all tobacco products at the same way. In addition, plain packaging should become a compulsory element of the proposal. As it is now, it is still possible for Member States to introduce national legislations requiring plain packaging, but this is left to their initiative and they need to justify that these provisions do not hinder the EU single market. This could easily lead to a situation where in some Member States there are these provisions in place and in others not, therefore creating inequalities as regards EU citizens health's protection.[16]

3. Ingredients/additives

Electronic reporting format for ingredients and emissions: the maximum yields of tar, nicotine and carbon monoxide as well as the measurement methods remain the same as in the current directive. Manufacturers and importers of tobacco products continue (as in the current legislation) to be required to report on the ingredients used in these products. The proposal introduces a new common electronic format for such report and requires manufacturers and importers to provide supporting data (e.g.: marketing reports), a statement setting out the reasons for the inclusion of such ingredients, and their status under the regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) as well as their classification under the regulation on the classification, labelling and packaging of substances and mixtures. New or modified tobacco products cannot be placed on the market before these data on the ingredients are submitted. All reported data, excluding confidential ones, should be published and available for the public.

EFA comment: EFA welcomes the provision on the common electronic format as it harmonises the situation in all EU Member States, therefore ensuring the same level of people's health protection everywhere in the European Union. It is positive that new or modified tobacco products cannot be placed on the market before the data on the ingredients have been submitted as this enhances controls and contributes to public health concerns. EFA welcomes the transparency provision that requires these data to be publicly available.

Additives: as the current directive does not harmonise Member States regulation on additives, some of them have adopted legislation or concluded agreements with industry allowing or prohibiting certain ingredients. As a result, some ingredients are forbidden in some Member States, but not in others.

[16] In April 2012, the UK Department of Health launched a public consultation on the introduction of standardised packaging of tobacco products, available at: http://consultations.dh.gov.uk/tobacco/standardised-packaging-of-tobacco-products/consult_view.

The proposal foresees that tobacco products with characterising flavours, such as fruit flavours or chocolate, are prohibited. Additives associated with energy and vitality (e.g.: caffeine and taurine) or creating the impression that products have health benefits (e.g.: vitamins) are also prohibited. No flavourings are allowed in filters, papers or packages and tobacco products with increased toxicity or addictiveness shall not be placed on the market. Additives that are essential for the manufacture of tobacco products are not prohibited.

→ Exception: tobacco products other than cigarettes, roll-your own tobacco and smokeless tobacco products, such as cigars, cigarillos and pipe tobacco, are exempted from this provision that prohibits characterising flavours. This is justified by the fact that these products are mainly consumed by older consumers, while the focus of this proposal is to regulate tobacco products in such a way as they do not encourage young people to start using tobacco. The exemption shall be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

EFA comment: as previously stated, the line that should be followed by EFA and our members in our advocacy efforts is to obtain a full ban of all additives (and not only those considered as characterising) in all tobacco products, irrespectively of the average age of people consuming them.

4. Cross-border distance sales

While cross-border distance sales fall outside the scope of the current directive, the proposal allows these distance sales and requires retailers to **notify** their willingness to engage in cross-border distance sales. Mandatory **age verification mechanism** is foreseen to ensure that tobacco products are not sold to children and adolescents. Therefore, it is possible to buy tobacco products by means of information society services, but these products will need to respect the provision of the proposed directive (including health warnings in the right language, understandable by the consumer, and ingredients regulation).

EFA comment: in principle those products should not be sold by means of information society services as they are particularly harmful and, although the compulsory age verification mechanism is inserted, it is difficult to verify whether it really works and which one is the right method to use to ensure that tobacco products are not sold to underage people. The proposed directive defines age verification system as "a computing system that unambigouisly confirms the consumer's age in electronic form according to national requirements", but it does not specify how to do it.

5. Traceability and security features

Although the current directive empowers the Commission to adopt technical measures related to traceability and identification, this power has not been used. The proposal introduces a new EU **tracking and tracing system** at packet level for tobacco products throughout the supply chain (excluding retailers). Visible **security features** (e.g.: holograms) should be put in all tobacco products to facilitate

the identification of authentic products and ensure that only products complying with the directive are sold in the EU.

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

EFA comment: all tobacco products should receive the same treatment and no exception should be foreseen for those other than cigarettes and roll-your-own-tobacco. Invisible security features should be added to visible ones as holograms are easy to counterfeit.