

ENSP/EFA guide to implement the European regulation on e-cigarettes

Helping Member States of the European Union implement Article 20 of the new Directive on the manufacture, presentation and sale of tobacco products (2014/40/EU) which replaces the Directive 2001/37/EU

BACKGROUND

The [special Eurobarometer 385/2012](#)¹ indicates that almost one third of European citizens currently smoke either cigarettes, cigars or pipes. This results in 700,000 deaths per year in the European Union.

Recently, new electronic nicotine delivery systems (ENDS) appeared on the market. The electronic cigarette is the most commonly known device using this new system. The sales of electronic cigarettes are substantial and increasing steadily, leading to legislation being required at European level.

Published in the Official Journal of the European Union on 29 April 2014, the new [Tobacco Products Directive \(TPD\)](#)² dedicates one whole Article to electronic cigarettes (Article 20). The European Network for Smoking and Tobacco Prevention (ENSP) and the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) thank the European Union for their determination in getting a strong Directive and giving priority to health concerns, especially on the electronic cigarette issue. This guide aims at helping Member States to transpose the new Directive into national legislation and to implement it. It clarifies some aspects of the Directive and gives clear recommendations on others.

The **European Network for Smoking and Tobacco Prevention** is an international non-profit association which aims at putting an end to tobacco consumption and to develop a common strategy amongst organisations active in tobacco control throughout Europe, by sharing information and experience, through co-ordinated activities and projects, by creating synergies among public health advocates thus increasing their capacity to direct their actions more effectively. ENSP's two top priority objectives are (i) to have the [Framework Convention on Tobacco Control](#) (FCTC)³ implemented in Europe by 2020 and (ii) to reduce the prevalence of tobacco use in Europe to less than 5% by 2040. ENSP is currently composed of 36 member organisations (including 16 national coalitions and 2 European networks) from the European Union, Switzerland, Georgia, Moldova, Turkey and Ukraine. ENSP acts as the lynchpin for its members, creating a central cohesive force for the European tobacco control movement.

In line with the report on electronic nicotine delivery systems prepared by the FCTC Convention Secretariat, which includes electronic cigarettes, the ENSP General Assembly concluded, during its network meeting of 4 October 2012, that electronic cigarettes, with or without nicotine:

- are another form of smoking and should thus not be allowed where smoking is prohibited;
- must not be considered as an ordinary trading product;
- if allowed on the market, must be regulated;
- if scientifically demonstrated as a safe and effective smoking cessation method, should be licensed as a medical product by the European Medicines Agency and/or a national equivalent.

It is also to be noted that ENSP, in consortium with the [Biomedical Research Foundation of the Academy of Athens](#)⁴, was recently commissioned by the European Commission to support its services in the

¹ http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco_2012_en.pdf

² http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf

³ <http://www.who.int/fctc/en/>

⁴ <http://www.bioacademy.gr/>

development of an EU common reporting format for the submission of data on ingredients contained in tobacco and related products (including electronic cigarettes) for licensing purposes.

The **European Federation of Allergy and Airways Diseases Patients' Associations** (EFA) is an independent non-profit organisation of over 30 allergy, asthma and chronic obstructive pulmonary disease (COPD) patients' associations representing 30% of European citizens currently living with these diseases. EFA is dedicated to making Europe a place where people with allergies and airways diseases have the right to the best quality of care and a safe environment, live uncompromised lives and are actively involved in all decisions influencing their health.

EFA has recommended to ban the use of new products containing nicotine in public places and to limit their uptake. For EFA, if these products are considered as nicotine replacement treatments, they need to be regulated under the medicinal products legislation. Moreover, their availability should be subjected to prescriptions and patients should be educated about their use. Regardless, all electronic cigarettes entering the EU market are to be regulated to ensure appropriate safeguards in terms of quality, safety and efficacy.

Given that the Directive itself specifies that some points are still a matter of national legislation, ENSP/EFA encourage Member States to go beyond the requirements included in the Directive.

Thus, both electronic cigarettes with and without nicotine should be covered by national legislation to avoid renormalisation, as well as all existing, potential and future devices with and without nicotine, all electronic nicotine delivery systems and all refill cartridges. For the same reason, a general advertising ban should apply at the national level and not only when there is a cross-border effect, electronic cigarettes should be banned in all public places where smoking is not allowed, flavours should be prohibited to limit the vaping uptake of children and young people, electronic cigarettes should not be sold to minors, prices should be regulated through taxation, and the FCTC protocol on illicit trade should be applied to electronic cigarette trading.

Furthermore, we invite Member States to consider the [WHO report prepared for the Sixth session of the Conference of the Parties to the FCTC \(COP6\)](#)⁵ as a key reference document, and especially bear the following Articles in mind:

36. When designing a regulatory strategy for ENDS, governments should bear in mind the following general regulatory objectives:

- (a) impede ENDS promotion to and uptake by non-smokers, pregnant women and youth;*
- (b) minimise potential health risks to ENDS users and non-users;*
- (c) prohibit unproven health claims from being made about ENDS; and*
- (d) protect existing tobacco-control efforts from commercial and other vested interests of the tobacco industry.*

37. Because the product, the market and the associated scientific evidence surrounding ENDS are all evolving rapidly, all legislation and regulations related to ENDS should be adaptable in response to new scientific evidence, including evaluation of different models for ENDS regulation, as evidence accumulates.

38. Governments should consider that if their country has already achieved a very low prevalence of smoking and that prevalence continues to decrease steadily, use of ENDS will not significantly decrease smoking-attributable disease and mortality even if the full theoretical risk reduction potential of ENDS were to be realised.

Finally, a close collaboration between Member State and European Commission services would strongly support the legislative transposition process.

⁵ http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf

RECOMMENDATIONS

Article 20.1. The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with this Directive and with all other relevant Union legislation. This Directive does not apply to electronic cigarettes and refill containers that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

These paragraphs mean that electronic cigarettes as regulated by this Directive are not intended as a smoking cessation device.

ENSP/EFA recommend that all the following aspects should be taken into account during the transposition of this Directive into national legislation:

- electronic cigarettes with and without nicotine, and any relative devices (current and future ones) with and without refill containers should be considered;
- Member States should regulate electronic cigarettes with and without nicotine in the same way because:
 - a) the electronic cigarette by itself may contribute to renormalising tobacco and advertising smoking;
 - b) a distinct control system for nicotine and non-nicotine containing electronic cigarettes will be inefficient in practice.

Article 20.2. 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 notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

- (a) the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;***
- (b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;***
- (c) toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;***
- (d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;***
- (e) a description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;***
- (f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;***

(g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

Where Member States consider that the information submitted is incomplete, they shall be entitled to request the completion of the information concerned.

Member States may charge manufacturers and importers proportionate fees for receiving, storing, handling and analysing the information submitted to them.

The European Commission is preparing a new electronic reporting format for applying and licencing reporting tobacco products ingredients, including electronic cigarettes, which is expected to be available in 2015. Therefore ENSP/EFA recommend that Member States do not to use or develop any other national reporting system.

Concerning (b), ENSP/EFA strongly recommend Member States to require the development of a European standard to measure emissions.

ENSP/EFA recommend that the body preparing the notification to be submitted by the manufacturer or the importer be an independent accredited body.

Article 20.3. Member States shall ensure that:

(a) nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml;

(b) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;

(c) the nicotine-containing liquid does not contain additives listed in Article 7(6);

(d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the second subparagraph of paragraph 2 of this Article are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture;

(e) except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;

(f) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;

(g) electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

ENSP/EFA recommend Member States to start immediately developing strong control mechanisms to monitor the exact content of nicotine in electronic cigarettes and refills. ENSP/EFA underline that impurities included in the electronic cigarette liquid may pose a risk to human health and that pure nicotine is a strong poison.

In addition, referring to (d), ENSP/EFA recommend that e-liquid should contain no allergens, as defined by annex II of regulation 1169/2011 and in the 2012 Opinion of the Scientific Committee on Consumer Safety.

Article 20.4. Member States shall ensure that:

(a) unit packets of electronic cigarettes and refill containers include a leaflet with information on:

(i) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;
(ii) contra-indications;
(iii) warnings for specific risk groups;
(iv) possible adverse effects;
(v) addictiveness and toxicity; and
(vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union;

(b) unit packets and any outside packaging of electronic cigarettes and refill containers:
(i) include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;
(ii) without prejudice to point (i) of this point, do not include elements or features referred to in Article 13, with the exception of Article 13(1)(a) and (c) concerning information on the nicotine content and on flavourings; and
(iii) carry one of the following health warnings:
'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.
or
'This product contains nicotine which is a highly addictive substance.'
Member States shall determine which of these health warnings is to be used;
(c) health warnings comply with the requirements specified in Article 12(2).

ENSP/EFA recommend that:

- the leaflet should contain a general message, common to all products, prepared by a public health European umbrella organisation with stakeholder consultation and complemented by more specific messages prepared by the manufacturer, and should receive the approval of an independent body;
- part of the leaflet content should be repeated and printed on the refill container;
- the same product in different countries should have the same leaflet content;
- the electronic version of the complete leaflet, together with the license number, should be made available on the license provider's website or equivalent;
- a unique and simple anti-poison center phone number should be clearly indicated on the leaflet and on the refill container;
- a leaflet should be included in any device manufactured for the delivery of nicotine or a non-nicotine electronic delivery system.

ENSP/EFA recommend that the short sentence "This product contains nicotine which is a highly addictive substance." proposed in the Directive is used.

ENSP/EFA underline that the Directive does not make any recommendation for products that may be used with and without nicotine. In this case, we recommend that the sentence should be slightly modified to "This product may be used to deliver nicotine which is a highly addictive substance." Thus, all potentially ENDS should be labelled with one or the other sentence.

Article 20.5. Member States shall ensure that:

(a) commercial communications in Information Society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market;
(b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;
(c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers is prohibited;
(d) any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;
(e) audiovisual commercial communications to which Directive 2010/13/EU of the European Parliament and of the Council⁶ applies, are prohibited for electronic cigarettes and refill containers.

In line with the WHO FCTC tobacco restrictions, ENSP/EFA recommend all Member States to implement a comprehensive ban on the advertising, promotion and sponsorship of all electronic cigarette devices, relative devices and refill containers. This ban should apply to all forms of commercial communication, recommendation or action and all forms of contribution to any event, activity or individual with the aim, effect, or likely effect of promoting these products or their use either directly or indirectly (as it the case for tobacco products).

Article 20.6. Article 18 of this Directive shall apply to cross-border distance sales of electronic cigarettes and refill containers.

In accordance with Article 18, ENSP/EFA recommend all Member States prohibit cross-border distance sales of electronic cigarette and refill containers to consumers.

Article 20.7. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit, annually, to the competent authorities:
(i) comprehensive data on sales volumes, by brand name and type of the product;
(ii) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;
(iii) the mode of sale of the products; and
(iv) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.
Member States shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers.

ENSP/EFA recommend that:

⁶ Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

- concerning the monitoring process, tobacco control groups from the public health sector should be commissioned with this responsibility (cf art 5.3 FCTC);
- a standardised electronic reporting format should be developed;
- pan-European conclusions should be extracted from the collected data at national level;
- Member States may impose further specific studies at national level for reasons of public health;
- the results of the studies should be publicly available.

Article 20.8. Member States shall ensure that the information received pursuant to paragraph 2 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available.

Member States shall, upon request, make all information received pursuant to this Article available to the Commission and other Member States. The Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

ENSP/EFA recommend that:

- trade secrecy should be abandoned when serious health problems have been identified;
- a clear definition of trade secrets applicable to electronic cigarette should be provided;
- Member States should without delay start developing the publication mechanisms provided above;
- the European Commission should develop a unique European website.

Article 20.9. Member States shall require manufacturers, importers and distributors of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.

Should any of these economic operators consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with this Directive, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with this Directive, to withdraw or to recall it, as appropriate. In such cases the economic operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

Member States may also request additional information from the economic operators, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

ENSP/EFA recommend that:

- all the collected information systems should be supervised by the EMA at European level and/or a national equivalent health body at Member State level;
- the European Commission should help Member States by providing a uniform monitoring system involving users;
- Member States reporting systems should be connected with other ones (e.g.: Rapace) to avoid double declarations;
- all data should be centrally collected and analyzed at the European level;
- all data should be published online.

Article 20.10. The Commission shall submit a report to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes by 20 May 2016 and whenever appropriate thereafter.

ENSP/EFA recommend that:

- the European Commission should scientifically assess all available literature as well as all relevant data collected under Article 20.9.;
- the report should be published.

Article 20.11. In the case of electronic cigarettes and refill containers that comply with the requirements of this Article, where a competent authority ascertains or has reasonable grounds to believe that specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, could present a serious risk to human health, it may take appropriate provisional measures. It shall immediately inform the Commission and the competent authorities of other Member States of the measures taken and shall communicate any supporting data. The Commission shall determine, as soon as possible after having received that information, whether the provisional measure is justified. The Commission shall inform the Member State concerned of its conclusions to enable the Member State to take appropriate follow-up measures.

Where, in application of the first subparagraph of this paragraph, 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 adopt delegated acts in accordance with Article 27 to extend such a prohibition to all Member States, if such an extension is justified and proportionate.

ENSP/EFA recommend that, in case any follow-up measures should be taken by Member States. These measures should be taken without any delay.

Article 20.12. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the health warning in paragraph 4(b) of this Article. When adapting that health warning, the Commission shall ensure that it is factual.

No specific comment for the implementation of the Directive

Article 20.13. The Commission shall, by means of an implementing act, lay down a common format for the notification provided for in paragraph 2 and technical standards for the refill mechanism provided for in paragraph 3(g).

No specific comment for the implementation of the Directive

ENDS

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