

Complaint to the European Ombudsman

Maladministration in the development of the revision of the Tobacco Products Directive with specific reference to Article 18 on electronic cigarettes

- 1. Overview.** This complaint refers to the negotiation of a revision to the Tobacco Products Directive with specific reference to the provisions relating to e-cigarettes (primarily Article 18 of the directive)¹. The complaint focuses on the legislative process followed and argues that this is a case of maladministration because the Commission did not uphold the requirements of the Treaties² with respect to consultation, justification, impact assessment and scrutiny. E-cigarettes represent a very significant public health opportunity as a very low risk alternative to smoking. Regulation of these products is important, but it is essential that such regulation is well designed to balance risks and opportunities. This can only happen if the legislation is properly justified and open to consultation. There are no circumstances in which it is acceptable for the EU to introduce a completely new regulatory framework without consulting experts and the users and businesses affected. There has been no consultation on these proposals. The result is a set of arbitrary, disproportionate and counterproductive measures based on a series of scientific misunderstandings. That could all have been avoided had proper processes been followed.
- 2. Original regulatory proposal changed beyond recognition with no opportunity for stakeholder engagement.** In the course of the Ordinary Legislative Procedure, a set of entirely new measures has been developed. This happened through a fundamental amendment in the European Parliament followed by further development in a secretive trilogue process that completed on 16 December 2013 (see [Annex 1](#) for a chronology). This set of measures differs in *every respect* from the draft measures brought forward in the Commission's legislative proposal of 19 December 2012³. In practice, they amount to a new legislative proposal establishing an entirely new European regulatory framework for these products, and they could easily form a stand-alone directive. The proposals will be presented to the European Parliament plenary for first reading in February or March 2014. If agreed, they are likely to be endorsed by the European Council at its first reading, and become law before May 2014. We argue that these measures should not become law unless and until they are subject to due process: broad consultation; proper justification; impact assessment; and scrutiny by national parliaments. These procedural requirements are not just optional good practice, they are requirements of the main European Union Treaties, and none has happened for these proposals. We contend that at the point where the Commission proposals were amended beyond recognition in the European Parliament, these proposals should have been extracted from the process of revising the Tobacco Products Directive and treated as a new legislative proposal in their own right. This would allow for the necessary consultation, justification, impact assessment, and scrutiny.
- 3. Complaint is against the European Commission.** Our complaint is directed against the European Commission, specifically Commissioner Borg and DG SANCO, as the Commission has

¹ See procedure file [2012/0366 \(COD\)](#)

² 'The Treaties' refers to the [Treaty on European Union](#) (TEU) and the [Treaty on the Functioning of the European Union](#) (TFEU) and their [Protocols](#)

³ [COM\(2012\) 788 Final](#) 19 December 2012

responsibility for upholding EU law and is ‘guardian of the Treaties’⁴. In this case it has not performed this role but has instead participated in the sidestepping of due process in its haste to secure a directive before the May 2014 elections. We contend therefore that this is a case of maladministration; *the Commission has not done what it should have done to uphold EU law.*

4. **A new legislative proposal.** Comparison of the Commission proposal of 19 December 2012 ([Annex 3](#)) and the text emerging from the trilogue on 18 December 2013 ([Annex 4](#)) and comparison of reasoning in the recitals ([Annex 5](#)) shows they are different in every respect. The proposal is now more than five times as long and differs completely in its conceptual approach. The Commission originally proposed to classify most of these products as medicines and regulate them under the medicines directive 2001/83/EC. The proposal emerging from the trilogue specifies detailed obligations, limits and restrictions on the face of the legislation.
5. **Complaint is based on *abuse of process*.** The basis of the complaint is that completely novel legislation has been created in a series of closed negotiations that have the following failings:
 - a. ***The requirement to consult.*** There has been no consultation on the proposed measures with users and businesses affected or appropriate experts. It is a requirement of the Treaties to consult widely on legislative proposals⁵ and it is an extraordinary abuse to bring in an entirely new regulatory framework with no consultation. There was a consultation held in 2010 (see [Annex 2](#)) but the subject of this was whether to include electronic nicotine delivery systems in the revisions of the tobacco products directive. It gave no indication of the measures that might be applied and gave no impression that significant measures like banning advertising or limiting nicotine strength would be applied. That 2010 consultation is not adequate alternative to consulting on the actual proposals under consideration in 2014.
 - b. ***The requirement to give reasons.*** There is no proper evidence-based justification for the measures and to the extent that reasons have been given in recitals (see [Annex 5](#)), these are assertions and are not backed by science and they have changed radically since the Commission published its proposal. The Commission has produced a fact sheet⁶, which does

⁴ See guidance on the role of the Commission in the application of EU law [[link](#)]: *The Commission's role is to ensure EU law is properly applied - by individuals, national authorities and other EU institutions.* This is derived from Article 17 of the [Treaty on European Union](#): *The Commission shall promote the general interest of the Union and take appropriate initiatives to that end. It shall ensure the application of the Treaties, and of measures adopted by the institutions pursuant to them.*

⁵ For compliance with [Article 11.3 of the Treaty on European Union](#): *11.3. The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent.* Also Article 2 of the [Protocol on the Application of the Principle of Sustainability and Proportionality](#) *2. Before proposing legislative acts, the Commission shall consult widely. Such consultations shall, where appropriate, take into account the regional and local dimension of the action envisaged. In cases of exceptional urgency, the Commission shall not conduct such consultations. It shall give reasons for its decision in its proposal.* There is no exceptional urgency justifying the avoidance of consultation and no reasons have been given.

⁶ European Commission, [E-cigarettes fact sheet](#), December 2013. This cites studies by Konstantinos Farsalinos to draw conclusions that Dr Farsalinos disputes and argues is misuse of his data ,see his letter: [The European Commission has misrepresented my scientific research on nicotine in e-cigarettes](#) (10 January 2014). It also cites a study by Dr Lynne Dawkins who also disputes the accuracy and states that her findings have been taken out of context and misused. It is exactly this sort of error that would be avoided with a more open process and proper consultation that allows for challenge.

cite some studies. It is a requirement of the Treaties to give reasons⁷. Most of the points made are contentious or wrong, and would be disputed by experts, if experts had been asked. The reasoning needs to be framed in terms of the legal base of the proposed directive, in this case as an internal market measure, with departures from the principle of free movement of goods⁸ based on securing a high level of health protection⁹. In other words, good evidence of health benefits is required. It is therefore important that the reasons are based on sound science and the case is based on literature citations, not assertion. The original Commission proposal and impact assessment had a far greater depth of reasoning than the recitals presented with the text and fact sheet¹⁰. Without proper justification it is impossible to assess whether the measures represent an acceptable and proportionate departure from the principle of free movement of goods on health grounds.

- c. **The requirement to provide an impact assessment.** No assessment or statement has been published to demonstrate compliance with principles of subsidiarity and proportionality¹¹ and nothing has been done to assess the financial and other impacts of the measures¹² or that they meet the requirement to impose minimum burdens necessary to meet the objectives of the Treaties¹³. Nor has the Commission shown that the existing directives that cover e-cigarettes – if properly applied and enforced, and, as necessary, enhanced with

⁷ [Article 296 Treaty on the Functioning of the European Union](#), establishes the requirement to state reasons: *Legal acts shall state the reasons on which they are based and shall refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties.* The reasons given should be evidence based and properly justified.

⁸ From legal base [Article 26 TFEU](#). *The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties.*

⁹ From legal base [Article 114 TFEU](#). 1. [...] *The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.* [...] 3. *The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective*

¹⁰ See Commission proposal [COM\(2012\) 788 Final](#) and [Impact Assessment](#) 19 December 2012, showing much greater depth of reasoning.

¹¹ For compliance with Article 5 of the [Protocol on the Application of the Principle of Sustainability and Proportionality](#): *Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality.* [Article 5.4 of the Treaty on European Union](#): 4. *Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.*

¹² For compliance with Article 5 of the [Protocol on the Application of the Principle of Sustainability and Proportionality](#): *This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators.*

¹³ For compliance with Article 5 of the [Protocol on the Application of the Principle of Sustainability and Proportionality](#): *Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved*

appropriate standards – are insufficient to provide proportionate health, safety and consumer protection safeguards¹⁴. These are all requirements of the Treaties and should be an important input to consultation. An impact assessment was produced to support the Commission proposal of 19 December 2012¹⁵, but the proposals have changed completely since then.

- d. **Scrutiny by national parliaments.** The new proposals have not been subject to scrutiny by national parliaments¹⁶. Though the Commission proposal of 19 December 2013 was sent to national parliaments, the amended and completely reconstituted proposals that have emerged from the European Parliament and trilogue process in October-December 2013 have not been sent for scrutiny. It is both logical and a treaty requirement to send *amended proposals* to national parliaments¹⁷. National parliaments have taken a considerable interest in the directive with many submitting reasoned opinions and regarding the directive and politically sensitive¹⁸. As stated above the changes made are not marginal, but fundamental. It is likely that some national parliaments will have a further opportunity to scrutinise before the Council reaches its position at first reading. However, by then there will be little chance of national parliaments having any influence. Given the proposal for Article 18l is completely new, national parliaments should expect to receive it formally and have the requisite eight weeks to respond with reasoned opinions on the new proposal. If they were able to do that for the original proposal it is logical and proper that they should be afforded that right for a completely new proposal generated in the course of the Ordinary Legislative Procedure.
6. **This complaint is not based on challenging *unsatisfactory measures*.** The result of the inadequate process is a number of poorly informed and counterproductive legislative measures that will be harmful to health and impose costs, burdens and restrictions on consumers and business for no reason. We also argue that the legislation is inadmissible under its internal market legal base and in violation of principles of proportionality and non-discrimination. **However, we are not asking the Ombudsman to determine whether these *measures* are acceptable or not within the constraints of the Treaties and scientific understanding.** Our contention is that the legislation is poor because important *process* protections built into the Treaties were sidestepped. The primary issue is therefore one of maladministration. Poor

¹⁴ Derived from [trilogue text](#): *The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with the relevant provisions of this Directive and with all other relevant Union legislation.* This refers to the substantial body of legislation that already applies covering safety, labelling and packaging and consumer protection – see [list of relevant legislation](#).

¹⁵ The Commission published a [package to support its proposal for revision of the tobacco products directive](#) 19 December 2012, including an Impact Assessment and economic and social studies. These cover the entire directive as proposed, but they do not of course cover the entirely new proposals for e-cigarettes created through amendment and trilogue in October-December 2013.

¹⁶ For compliance with [Protocol \(no 1\) on the Role of National Parliaments in the European Union](#)

¹⁷ For compliance with Article 4 of the [Protocol on the Application of the Principle of Sustainability and Proportionality](#): *The Commission shall forward its draft legislative acts and its amended drafts to national Parliaments at the same time as to the Union legislator. The European Parliament shall forward its draft legislative acts and its amended drafts to national Parliaments. The Council shall forward draft legislative acts originating from a group of Member States, the Court of Justice, the European Central Bank or the European Investment Bank and amended drafts to national Parliaments. (emphasis added)*

¹⁸ See Inter Parliamentary Exchange IPEX [SWD/0453/2012](#) -

legislation is an outcome of the closed, insular and unscientific process that has been followed.

7. **Requested remedy.** We would like the Ombudsman to require the European Commission to introduce a new legislative proposal for e-cigarettes, or otherwise to ensure there is consultation, proper evidence based justification, impact assessment, and scrutiny of the measures proposed, as required by the Treaties. It is possible for the European Parliament to amend the proposal to do this at first reading (at the end of February), while securing those parts of the directive that have not been radically altered – the majority of the directive that deals with tobacco products.
8. **Raising concerns with the institutions.** These concerns have been raised with the Commission (email Clive Bates to Dominic Schnichels, Joanna Darmanin, DG Sanco 23 October 2013)¹⁹; with the European Parliament negotiators (email to rapporteur and shadows, 12 December 2013)²⁰; with the Council health representatives (email Clive Bates to Health attachés and secretariat, 12 December 2013). No replies were received to any of these communications.
9. **Complainants.** This complaint is brought by consumers, producers and public health experts:
 - a. ECCA (UK) on behalf of consumers. The proposals would force a number of perfectly satisfactory and safe products from the market, limiting consumer choice and appeal, and potentially causing regress to smoking. We have not been consulted on the concepts of details of the proposals and what they would mean for users.
 - b. ECITA (UK) on behalf of businesses which will face unnecessary burdens and restrictions, with no justification will have their competitive position relative to cigarettes weakened, through for a example a ban on advertising. Many of the measures proposed are counterproductive or excessive given the risks. We should have been consulted properly.
 - c. AIDUCE (France) on behalf of users. Electronic cigarettes are deemed by France's health professionals to be infinitely less dangerous than smoked tobacco. The growth in the number of smokers who are adopting them is exponential. According to their testimony on our user forums, well over half eventually quit tobacco altogether. The proposed measures would severely restrict the attractiveness of e-cigarettes for smokers; and indeed for many vapers who would return to tobacco. They are absurd in terms of public health policy.
 - d. Villanypara Egyesület (Hungary) on behalf of users. The proposal as it stands would be a big mistake in the fight against tobacco and prevent adoption of a healthier alternative. We are vapers not smokers and we are much healthier thanks to e-cigarettes!
 - e. DADAFO - Dansk e-Damper Forening - Danish Vaping Society - wholeheartedly supports the complaint issued by Clive Bates to the EU-ombudsman. The ignorance from the legislators, the denial from the Council and the Commission to understand what the European people wants, is horrendous. Vaping has nothing to do with tobacco, and even less to do with being a form of medicine. And trying to deny other smokers in the EU (and for that matter, in the whole world) the chance to choose a much safer alternative to smoking, will cause millions of premature deaths.
 - f. Acvoda (Netherlands) on behalf of consumers. The proposals would force a number of perfectly satisfactory and safe products from the market, limiting consumer choice and

¹⁹ See <http://www.clivebates.com/?p=1586>

²⁰ See <http://www.clivebates.com/?p=1700> (also sent to the Council)

appeal, and potentially causing regress to smoking.

- g. ABVD (Belgium) on behalf of users. ABVD.be (Belgium) on behalf of users. We are strongly convinced that ecigs must be taken out of the tobacco directive. According to us, ecigs devices and e-liquids should be considered in another specific regulation, elaborated in accordance with public health fair principles and in close collaboration with genuinely independent experts and scientists. Also users' opinions and experiences should ideally be taken into account. We, ABVD.be, do not accept, or can't agree with, this unfair proposed directive, written in a hurry, lacking any scientific background or evidences and obviously influenced by lobbies.
- h. IG-ED (Germany / Austria) on behalf of users. German speaking vapers will not tolerate to be forced back into smoking tobacco, therefore we support this complaint.
- i. LIAF (Italy) Italian League Anti Smoking on behalf of those who would benefit from improved health with the widespread use of non-combustible nicotine containing products.
- j. FIESEL (Italy) LIFE (Italy) e-cigarette retailers associations on behalf of Italian retailers, which strongly believe that these negotiations behind closed doors will bring unnecessary burdens and restrictions to their business.
- k. SUEP (Polish Vapers Association) - on behalf of the users. We do not want to be forced to use tobacco cigarettes again - e-cigarettes are much less harmful alternative. It is our right to choose!
- l. World Vaping Organisation (global) on behalf of EU users wishes to add support to this complaint to safeguard the right of the EU vapers regarding current and future regulation for electronic cigarettes.
- m. Norsk Dampselkap (NDS) on behalf of Norwegian users. We also wish to add our support to this complaint, as the proposed Directive is a text with EEA relevance. The proposed regulation will greatly restrict ecigs/personal vaporizers and make them far less attractive as an alternative product for smokers of tobacco product.
- n. This complaint is also supported by members of the expert community in the field of e-cigarettes: Clive Bates (UK); Professor Gerry Stimson (UK); Dr Konstantinos Farsalinos (Greece); Professor Riccardo Polosa (Italy); Dr Jacques LeHouezec (France); Dr Lynne Dawkins (UK); Professor Jean François Etter (University of Geneva) on behalf of those who would benefit from wider public health objectives. The proposals include numerous statements that are without foundation and measures that will prove harmful to human health at individual and population level. Public health experts have also written to the Financial Times to express their concerns^{21 22}

10. **For correspondence**, please contact Clive Bates [address information removed] Disclosure: no competing interests. Transparency Register entry: 810709012348-60

²¹ Letter to the Financial Times, [E-cigarettes are helping smokers](#), 1 December 2014.13 specialists in public health raise concerns about the proposals.

²² See also Dr Farsalinos, [EU regulating e-cigarettes based on ideology and theories, but not science](#). 20 December 2013.

Annex 1: Chronology

- 24 September 2010** The Commission consults on a revision of the Tobacco Products Directive. For nicotine containing products the focus of the consultation is on whether these should be included in the revised directive. It does not address what measures would be applied.
- 19 December 2012** Commission proposal published. This favours regulating e-cigarettes and other nicotine containing products as medicines, subject to a very low threshold for strength of nicotine liquid. This text is shown at [Annex 2](#).
- 11 July 2013** The ENVI committee of the European Parliament endorsed a simplified version of the Commission's approach (regulating e-cigarettes as medicines).
- 21 June 2013** Under the Irish presidency, Council agrees a General Approach that is similar to the Commission proposal – regulating most e-cigarettes as medicines. The [Council General Approach](#) is an informal agreement between representatives of the member states.
- 8 October 2013** European Parliament plenary rejects medicine regulation on the grounds that it will be unduly burdensome and restrictive and is probably not lawful. A new proposal for regulating e-cigarettes had been drawn up by MEPs in the form of an amendment and passes in the Parliament. The amendment is a political compromise agreed behind closed doors a week before the plenary.
- October 2013** A trilogue process begins in order to close differences between the European Parliament's amendments to the Commission proposal and the Council's General Approach
- 22 November 2013** The Commission and Presidency introduce a new proposal for regulating e-cigarettes. This is five times longer than the initial Commission proposal. In detail and conceptually it is completely different to the original proposal.
- 16-18 December 2013** A final trilogue meeting is held and political agreement reached on a new text. This is endorsed by COREPER on behalf of the Council two days later. This is five times longer and completely different in concept to the initial Commission proposal and can be viewed at [Annex 3](#).
- March 2014** European Parliament first reading (likely). The directive is likely to be settled at first reading as the Council via COREPER has already agreed the trilogue text.

Annex 2. Text of Commission Consultation 2010 that refers to Nicotine Containing Products

1. SCOPE OF THE DIRECTIVE

1.1. Problem definition

Since the adoption of the Directive in 2001, the tobacco products market has increasingly diversified. The Directive does not cover electronic nicotine delivery systems (ENDS), such as electronic cigarettes. Yet they are generally marketed as alternatives to smoking.

Some Member States classify electronic cigarettes that contain nicotine as pharmaceutical products. This means they cannot be put on the market unless they have proven efficacy, safety and quality. However, in many Member States electronic cigarettes (with and without nicotine) are marketed as consumer products with no prior authorisation or safety checks. This results in a legal uncertainty.

In addition, nicotine drinks are in the market in some Member States, and are likely to enter other Member States' markets. There is also an emerging market of nicotine sweets worldwide. However, by definition these products are covered by food legislation.¹¹

Furthermore, the Directive does not cover cigarette-like products which do not contain tobacco, such as herbal cigarettes, that have similar harmful effects as regular cigarettes.

The legislation of Member States to classify or regulate these products varies. There are no uniform conditions for regulating ENDS and herbal cigarettes. This might imply both a distortion of the internal market and a failure to ensure a high level of health protection in the EU.

1.2. Possible options

Option 1 - No change

Tobacco and nicotine products that are not covered by the Tobacco Products Directive, or other EU legislation (food, pharmaceutical) would remain subject to different legislations in different Member States. The same would be true for products that are smoked, but do not fall under any of the above legislations (such as herbal cigarettes).

Option 2 - Extend of the scope of the Directive

An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS.

Annex 3. Text of Commission Proposal for Article 18 19 December 2012

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

(a) products with a nicotine level exceeding 2 mg per unit, or

(b) products with a nicotine concentration exceeding 4 mg per ml or

(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC.

3. each unit packet and any outside packaging of nicotine containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

“This product contains nicotine and can damage your health”.

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

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

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

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

Annex 4. Text of the proposal emerging from trilogue 17 December 2013

1. The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with the relevant provisions of this Directive and with all other relevant Union legislation.

This Directive does not apply to products that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

2. Manufacturers and importers of electronic cigarettes and refill containers shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For products already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 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. name and contact details of the manufacturer, a responsible legal or natural person within the European Union, and, if applicable, the importer into the European Union;
- b. 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 these ingredients and their emissions, including when heated, referring in particular to their effects on health of consumers when inhaled and taking into account, inter alia, any addictive effect;
- d. information on nicotine dosing and uptake when used under normal or reasonably foreseeable conditions;
- e. description of the components of the electronic cigarette; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;
- f. description of the production process including series production and declaration that the production process ensures conformity with the requirements in this article;
- g. 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 data are incomplete, they are entitled to request the completion of such data.

Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.

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, disposable electronic cigarettes or in single use cartridges. The cartridges or tanks

shall not exceed a volume of 2 ml;

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

c) the liquid does not contain additives listed in paragraph 4 of Article 6;

d) only ingredients of high purity and free from contaminants are used in the manufacture of the liquid; substances other than the ingredients referred to in paragraph 2(b) are only present in trace levels, if they are technically unavoidable during manufacture;

e) only ingredients are used in the liquid that are not toxic hazardous to human health in heated or unheated form, with the exception of nicotine;

f) electronic cigarettes deliver the nicotine doses consistently;

g) electronic cigarettes and refill containers are child- and tamperproof;

h) electronic cigarettes and the refill containers are protected against breakage and leakage and have a mechanism ensuring leakage free refilling.

4. Member States shall require manufacturers and importers to ensure that:

(a) unit packets of electronic cigarettes and refill containers include a leaflet with information instructions for use and storage, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, on addictiveness and toxicity, and contact details of the manufacturer or importer and a legal or natural contact person within the European 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, and an indication of nicotine content and delivery per dose, the batch number and a recommendation to keep out of reach of children;

ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content

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 are used.

(c) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

5. Member States shall ensure that:

a) commercial communications with the aim or direct or indirect effect of promoting electronic

cigarettes and refill containers are prohibited in information society services as defined in Article 1(2) of Directive 98/48/EC, in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of the products and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market;

- b) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited in the radio;
- 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 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 falling under Directive 2010/13/EU are prohibited for electronic cigarettes and refill containers;
- f) cross-border distance sales of electronic cigarettes and refill containers are regulated in accordance with Article 16.

6. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market as well as the market for refill containers, including any evidence of gateway use among young people and non-smokers.

7. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.

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

8. Member States shall require that manufacturers, importers or distributors establish and maintain a system to collect information about all suspected adverse effects. If any of these operators considers or has reason to believe that electronic cigarettes or refill containers, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to 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 operator, for example on safety and quality aspects or any adverse effects.

9. The Commission shall report on the potential risks to public health associated with the use of refillable electronic cigarettes at the latest on the date referred to in Article 25(1) and whenever needed thereafter.

In the case of products meeting the requirements of this Article, where a competent authority ascertains or has reasonable grounds for concerns that a given electronic cigarette or a refill container, or a type of electronic cigarettes or refill containers, could present a serious risk to human health, it shall may take all appropriate measures and shall immediately communicate to the Commission and the competent authorities of other Member States the measures taken and any supporting data. The Commission shall determine, as soon as possible, whether the provisional measure is justified [following whenever possible appropriate consultations]. The Commission shall inform the Member State concerned, which will ensure appropriate follow-up.

Where, in the application of the first subparagraph of this paragraph, a given type of electronic cigarette or refill container, or a type of electronic cigarettes or refill containers has been banned on justified ground by at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to extend such a ban to all Member States, if that measure is justified and proportionate.

10. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the wording of the health warning in paragraph 4(j). When adapting that health warning, the Commission shall ensure that it is factual.

11. The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2 and the technical standards of the refill mechanism.

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Annex 5: Recitals to related to e-cigarettes

1. Recitals related to nicotine containing products: Commission Proposal 19 December 2012

(33) Nicotine-containing products are sold on the Union market. The different regulatory approaches taken by Member States to address health and safety concerns associated with these products have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet.

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁴² provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

(35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of consumers to potential health risks.

2. Recitals related to nicotine containing products: Amendment / Trilogue text 16 December 2013

(a) Electronic cigarettes and refill containers should be regulated within this Directive, unless they are due to their presentation or function subject to Directive 2001/83/EC or to Directive 93/42/EEC. Diverging legislation and practices including on safety require Diverging legislation and practices including on safety requirements exist in Member States as regards these products requiring action at Union level to improve the functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to allow Member States to exercise their functions of surveillance and control, manufacturers and importers of electronic cigarettes and refill containers should be required to notify their products before the intended placing of the market

(b) Responsibility for ensuring that the products comply with the essential requirements should rest with manufacturers. If manufacturers are not established in the European Union, the natural or legal person who imports electronic cigarettes into the European Union should bear the responsibility.

(c) Nicotine containing liquid should only be allowed under this Directive where the nicotine concentration does not exceed 20 mg/ml. This level of concentration is similar to the dose of nicotine derived from a standard cigarette during the same duration of smoking. In order to limit risks associated with nicotine, maximum sizes for containers, cartridges and tanks are set.

(d) Only electronic cigarettes that deliver the nicotine doses consistently should be allowed under this Directive. Consistent delivery of the nicotine doses under normal use is necessary for health, safety and quality purposes including to avoid the risk of accidental consumption of high doses.

(e) Electronic cigarettes and refill containers may create a risk when they are in the hands of children. Therefore, it is necessary to ensure that these products are childproof including child-proof

labelling, design, fastenings and opening mechanism.

(f) Given that nicotine is a toxic substance and considering the potential risks also to those for whom the product is not intended, nicotine-containing liquid should be placed on the market in electronic cigarettes or in refill containers that meets certain safety and quality requirements.

(g) The labelling and packaging of these products should display sufficient and appropriate information on safe use, in order to protect human health and safety, should carry appropriate health warnings and should not include any misleading elements or features.

(h) Disparities existing between national legislations and practices on advertising and sponsorship impede the free movement of goods and the freedom to provide services and create an appreciable risk of distortions to competition. Without further action at Union level, the existing disparities are likely to increase in the coming years, considering also the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national rules on advertising and sponsoring, taking as a base a high level of health protection. Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising of electronic cigarettes and refill containers.

(i) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on market developments in electronic cigarettes and refill containers. To this end reporting obligations on sales volumes, preference of various consumers groups and mode of sales should be put on manufacturers and importers of these products. The transparency of this information should be ensured for the general public with due regard for trade secrets.

(j) In order to ensure appropriate market surveillance by Member States, it is necessary that manufacturers, importers and distributors have an appropriate system for monitoring, recording and informing the competent authorities about suspected adverse effects, so that appropriate action can be taken. A safeguard clause is warranted allowing Member States to act against serious risks to public health.

(k) This Directive does not harmonise all aspects of electronic cigarettes or refill containers, and leaves for example the regulation of flavours to the Member States. It may be useful for Member States to consider allowing flavours in the products. However, they should be mindful of the potential attractiveness for young people and non smokers. Such prohibitions of flavours would need to be justified and notified according to Directive 98/34/EC.

(l) Moreover, this Directive does not harmonise rules on smoke-free environments, or on domestic sales arrangements or advertising, brand stretching, nor does it introduce an age limit for electronic cigarettes or refill containers. In any case, the presentation and advertising of the products should not be used to promote tobacco consumption or give rise to confusion with tobacco products. Member States are free to regulate such matters in their own domain and are encouraged to do so.

(m) In the context of an emerging market on electronic cigarettes, it is possible that, although conforming to the provisions of this Directive, a given electronic cigarette or refill container, or a type of electronic cigarettes or refill containers, placed on the market could pose an unforeseen risk to human health. It is therefore advisable to provide for a procedure intended to address this risk, which should include the possibility for a Member State to adopt provisional appropriate measures. Such provisional measures could involve the prohibition on the placing on the market of a given electronic cigarette or refill container, or of a type of electronic cigarettes or refill containers. In this context, the Commission should be empowered to adopt delegated acts in order to prohibit a given electronic cigarette or refill container, or a type of electronic cigarettes or refill containers, when at least three Member States have prohibited these products on justified grounds and it is necessary to extend this prohibition to all the Member States in order to ensure the smooth functioning of the

internal market for compliant products not presenting the same safety concerns.