



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products  
**Substances of human origin and Tobacco control**

Brussels, 12 June 2015

## **MEETING WITH CEN-CENELEC ON EUROPEAN STANDARDISATION AND LEGISLATION ON “E-CIGARETTES AND E-LIQUIDS”**

### **Participants:**

**CEN-CENELEC: Cinzia Missiroli, CEN -CENELEC; Karolina Krzystek, CEN -CENELEC; Remi Parola, FIVAPE; Henrik Brostrom, Nicoventures; Sandra Costigan, Nicoventures.**

**SANTE D4: Dominik Schnichels, Anna-Eva Ampelas, Isabel Holmquist, Patricia Murray**

**Date: 10 June 2015**

### **Summary**

The meeting took place following a request from CEN -CENELEC Management Centre to discuss their new Committee (CEN/TC 437) that will work to develop European standards for electronic cigarettes and e-liquids. The main aim of the meeting was to present the rapidly developing e-cigarette market and initial thoughts on the possible standards that could be developed for e-cigarettes.

The Committee will be chaired by Remi Parola (FIVAPE) and will bring together members from 20 CEN member countries. The first meeting is planned for 22 June in Paris.

#### ***1. The e-cigarette market and need for quality standards***

Henrik Brostrom (Nicoventures) presented data on the e-cigarette market (mainly in the UK), including product development, user profiles and flavour preferences. The e-cigarette market shows continued growth with a number of product developments. At the same time, the market shows increasing balance between male and female users with small changes in the age profile among young adult users. As regards flavours, tobacco, mint and fruit are the most popular.

It was stressed that European standards are needed to assure regulators and consumers that the products on the market are safe and of high quality. The CEN Committee will also decide how best to coordinate with ISO on their development of international standards for e-cigarettes. CEN stressed that they endeavour to include all stakeholders in their work (Industry, public authorities, NGOs and consumer groups).

#### ***2. Scientific challenges***

Sandra Costigan (Nicoventures) outlined the market and scientific challenges when elaborating standards for e-cigarettes and refill liquids. There is currently a lot of innovation in e-cigarettes which makes developing technologically neutral standards all the more important. Flexibility is also needed to account for new ways of using the products coming on the market.

It was proposed to develop standards in two waves. As a first step, the Committee should work to lay down minimum standards for process and quality control, rules for e-liquid ingredient selection and comparisons with existing standards. As a second step, emissions assessments, further quality assurance (such as ISO 9001 compliance) and a full toxicological risk assessment could be required. The programme of work of CEN/TC 437 will be agreed upon in their first plenary meeting on 22 June 2015 by all members.

DG SANTE explained that emissions measurement methods were a key priority, as reliable emissions reporting under the notification required under Article 20 of the Tobacco Products Directive was crucial. Standards for consistent dosing and measuring uptake of nicotine may also be beneficial. Sandra Costigan added that, in Nicoventure's opinion, CEN should work on requirements for e-liquids (purity, food and pharmaceutical grade ingredients, exclusion of compounds with CMR properties or respiratory sensitisers).

DG SANTE reported that they will develop technical specifications for refill bottles and refill mechanisms. This work will be independent of the CEN Committee. Henrik Brostrom stressed that industry would need sufficient time to adapt to any specifications developed by the Commission.

### ***3. Closing remarks***

Sandra Costigan explained that the CEN Committee will be able to bring together standards developed across the Member States, including the AFNOR (FR) and BSI (UK) standards that were developed by different stakeholder groups.

The Committee will look at many different issues in parallel and four or five working groups are currently planned. CEN expects that it will take about 20 months to develop the first standard. CEN explained that more will be known after the first Committee meeting on 22 June. The process will be followed closely by the Commission through the Joint Research Centre.