BUSINESS PLAN

CEN/TC 437
ELECTRONIC CIGARETTES AND E-LIQUIDS

The Business Plan is an informational document on the current work program of CEN/TC 437. This document aims to promote the standardization work on the field of electronic cigarettes and e-liquids

EXECUTIVE SUMMARY

CEN/TC 437 is responsible for the development of European Standards for electronic cigarettes[1], e-liquids and emissions.

Electronic cigarettes refer to devices used to transform an e-liquid into an inhalable aerosol. They are disposable or refillable by means of a refill container and a tank, or rechargeable with single use or refillable cartridges.
The e-liquid is a consumable intended for transformation into an aerosol and then inhaled with an electronic cigarette. It may or may not contain nicotine.

[1] also known as e-cigarettes, electronic cigarette devices, personal vaporizers or vaping products

1 BUSINESS ENVIRONMENT OF THE CEN/TC 437

1.1 Description of the Business Environment

Market situation

First imports of electronic cigarettes to Europe started only in 2005. Since then, the e-cigarette and e-liquid sector is rapidly-evolving in terms of product features, market structures and origin of e-liquids with the development of European production.

The electronic cigarette industry is very active in France, Poland, the UK, Germany, Austria, Romania, Italy, Ireland, Hungary, Czech Republic, Greece, The Netherlands, Spain and Portugal.

90% of electronic cigarettes hardware manufacturers are located in Asia, whereas e-liquids sold in Europe are primarily made in Europe first, then in the United States.

Stakeholders

Directly or indirectly involved interested parties in the standardization process:

- Electronic cigarette industry and companies (suppliers, manufacturers, retailers, importers, exporters etc.), their organizations and trade unions
- Users/consumers and their organizations
- Public Health professionals, research institutes and scientists
- Laboratories,
- Suppliers of testing equipment
- EU institutions and public authorities at national (or sub-national) level
- Standardization bodies both international and national
- Liaison organizations

CEN/TC 437 will establish liaisons with organizations where parallel activities are going on.

Political and legal environment

Nicotine-containing electronic cigarettes and e-liquids are covered by various non-specific EU legislations, such as: the REACH regulation[2] (applicable on chemical substances and mixtures), the ROHS directive[3] (Electronic devices), the CLP regulation[4] (classification,

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[3] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

labelling and packaging of dangerous mixtures), the GPSD directive[5] (directive on general products safety) and the legislation on medicines (when applicable).

Moreover, article 20 of the directive 2014/40/EU[6] on tobacco and related products specifically targets nicotine-containing electronic cigarettes and e-liquids. EU Member States have to transpose the Directive by 20 May 2016. The Directive provides only a legal framework and normative efforts are necessary to provide robust and technically sound tools to support reasonable regulations in each member state. These efforts could also be applied to non-nicotine containing products. The directive specifies a number of requirements for "electronic cigarettes and refill containers" placed on the EU market, and that such products continue to comply with "all other relevant Union legislation".

The requirements provided for in the Directive 2014/40/EU include:
• Consistency of nicotine dosing under normal conditions of use;
• Pre-market notification to competent authority 6 months in advance of placing on the market, including:
  a) List of all ingredients and aerosol/vapour produced by the use of the products including quantities;
  b) Toxicological data on the products ingredients and emissions, including when heated;
  c) Information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
  d) Description of product components including opening and refill mechanisms.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the European business environment. The indicators refer to the situation in 2014 or 2015 and are based on figures/estimations from Fivape[7] (France) and other national organizations.

Number of e-liquid references in the EU: above 21 000, not taking into consideration the different levels of nicotine or PG/VG[8] ratio options.
Number of manufacturers of e-liquids in the EU: approximately 200
Overall retail market in the EU (2014): approximately 2 billions euros
Number of users in the EU: around 10 millions users.

Number of users in France: 3 millions[9] (Institut national de prévention et d'éducation pour la santé - INPES, France, February 2015)

Number of users in the UK: 2.6 millions[10], (Action on Smoking and Health – ASH, United Kingdom, May 2015)

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[5] Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety

[6] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC Text with EEA relevance

[7] Fivape: Fédération Interprofessionnelle de la Vape

[8] PG/VG: Propylene Glycol/Vegetable Glycerol

[9] Premiers résultats tabac et e-cigarette - Caractéristiques et évolutions récentes - Résultats du Baromètre santé, INPES, 2014
http://www.inpes.sante.fr/30000/actus2014/048-cigarette-electronique.asp

[10] Use of electronic cigarettes (vapourisers) among adults in Great Britain, ASH, May 2015
www.ash.org.uk/files/documents/ASH_891.pdf

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 437

CEN/TC 437 will develop technical standards for electronic cigarettes and e-liquid products. These standards will provide a common framework for all electronic cigarettes and e-liquid products sold in all EU markets.

The whole standardization work will aim to increase the safety of all the European users, by setting consistent safety and quality standards of the products and improving consumer information across all EU Member States.

These documents, recognized and applicable in all CEN members' countries, will give advice and help manufacturers, importers, exporters and distributors to adhere to standardised safety and quality requirements.

The technical standardization work will support public authorities in their duties and help creating a fair competition environment for the sector with the EU, incl. EEA.

3 PARTICIPATION IN THE CEN/TC 437

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties.
Participation as observers and liaisons is possible under the condition outlined in CEN Regulations.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC 437

CEN/TC 437 aims to develop European Standards for:

- Electronic cigarette devices (mechanical, thermal, electrical and chemical hazards),
- E-liquids (components and its possible impurities, including nicotine),
- Emissions

and the related assessment methods.

The development of standards will be addressed after:

- Considerations and decision on whether or not a common standard for terminology is needed
- Considerations and decision on whether or not manufacturing standards should be developed
- Considerations and decision on whether or not design standards for e-pipes, e-cigars, e-chichas,... should be developed
- Considerations and decision on whether or not services related to the use of electronic cigarettes and consumable products should be developed
- Due consideration will be given to parallel activities ongoing in other organisations.

The work programme of the technical committee will include the following areas;

- Definitions and terminology;
- Risk assessments, manufacturing, safety requirements, labelling, and components;
- Test methods of electronic cigarettes, e-liquids and emissions,

- User information, including product quality and clear instructions for safe handling and use, in order to allow a comparison between products.

Products considered as medicinal products or medical devices and regulated by Directives 2001/83/EC and 93/42/EEC are not a part of the standardization work in CEN/TC 437.

4.2 Identified strategies to achieve the CEN/TC 437 defined objectives.

Once CEN/TC 437 has approved a work programme for the standardization of electronic cigarette devices and e-liquids, relevant working groups will be created in order to develop the standards. The parties interested in this process and involved in these groups shall reflect the stakeholders in their diversity.

The Technical Committee is responsible for ensuring that the national standpoints transmitted by delegations from different countries are taken into consideration. It endeavours to reach consensus[11]. Even though possible, national deviations should be avoided.

The Technical Committee takes into account any ISO/IEC work coming within its scope, together with such data as may be supplied by members and by other relevant international organizations, and work on related subjects in any other Technical Committees (TC).

A plenary meeting of the TC normally takes place once a year. Further voting and exchange of information within the TC takes place by e-mail. Documents are available through electronic committee. All meetings and correspondence are conducted in English.

4.3 Environmental aspects

While the major objective of the committee is the safety of electronic cigarettes and related consumables, the great and growing interest in environmental issues is acknowledged. CEN/TC 437 recognizes the need to reduce as far as possible the potential environmental impacts of electronic cigarettes and e-liquids during all stages (purchase, production, use and disposal). CEN/TC 437 intends to thoroughly consider environmental aspects when drafting its standards.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

A continued active commitment on the part of all stakeholder groups is essential for the completion and implementation of the work programme.

The standardization structures are facing a rapidly-evolving market, a situation which may lead, if not cautiously monitored, to some discrepancies between requirements and product technical features.

Implementing requirements on emissions is highly dependent on the current scientific and technical state of the art. CEN/TC 437 will co-operate with other groups experienced in this complex area.

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[11] Definition of consensus: http://boss.cen.eu/reference%20material/guidancedoc/pages/del.aspx