E-cigarette Regulation in the European Union

Progress update on product quality and safety standards

Dr Sudhanshu Patwardhan, Nicoventures

Electronic Cigarettes and the Public Health, FDA-CTP Workshop, Silver Spring, December 11, 2014

Outline

- Nicoventures- Introduction
- European Union's Tobacco Product Directive (TPD)
- Product safety and quality standards initiatives
  - British Standards Institution (BSI)- Publicly available specification
  - French AFNOR Experimental Standards
  - CEN- (European Committee for Standardisation) proposal

nicoventures

Nicoventures

- Nicoventures is part of the BAT Group but is separate from the tobacco business.
- Our focus is the development and production of innovative, high quality inhaled nicotine products that meet relevant regulatory requirements.
- Our aim is to provide adult smokers and users of nicotine products who want to reduce, replace or stop smoking with a range of high quality alternative products, delivering much of the experience they expect from a cigarette, but without the serious health risk of smoking.

nicoventures

A revised Tobacco Product Directive

- European Union's Tobacco Product Directive (TPD) lays down rules governing the manufacture, presentation and sale of tobacco and related products.
  - These include cigarettes, roll your own tobacco, pipe tobacco, cigars, cigarillos, smokeless tobacco, electronic cigarettes and herbal products for smoking.

- The new TPD entered into force on the 19th May 2014
  - EU Member States obliged to transpose the TPD into their national legislation by latest 20th May 2016 (dead line can be extended).

- Article 20 of the TPD relates to e-cigarettes.

Two Options for e-cigarettes in the EU

Article 20 TPD

- 6 months pre- market notification
- Nicotine threshold – under 20 mg/ml
- 10ml max volume refill bottles
- 2ml max volume cartridges /tanks
- Content requirements for E-liquids
- Childproofing
- Health Warnings
- Advertising restrictions
- (No therapeutic claims)

Medicines Route (Med Reg)

- Marketing authorisation (MA) application
- Opportunity to make claims
- Marketing freedoms according to member states' medicines legislation
- Distribution freedoms varies by Member State

nooventures

TPD: What Happens Next

Secondary Regulation (Implementing Act)

Commission:

Pre-Market Notification Template:

- List of ingredients
- Tox data ingredients/emissions
- Production process
- Standards for refill mechanism

Implementing Act Anticipated Q3 2015

Transposition (National Legislation)

Member States:

- Content requirements for E-liquids
- Childproofing
- Health warnings
- Domestic advertising restrictions
- Cross border sales

Impact assessment & National consultation

nicoventures

Current status of standards projects in the EU: BSI

- British Standards Institution (BSI)- a draft standard

- To provide guidance on manufacturing, importing, testing, labelling, marketing and sale of personal vapour inhalers and directly-related products, and
- To specify robust testing methodologies intended to protect consumers from dangerous products on the market.

- Users are expected to be

- manufacturers, distributors and vendors of vaping products
- laboratories and testing houses engaged in, or planning to be engaged in, the testing of e-liquids.

- Source: BSI presentation at the E-cigarette Summit, London Nov 2014
- BSI PAS 54115 for e-cigarettes sponsored by the UK e-cigarette industry trade association (ECITA)

BSI draft Publicly Available Specification (PAS) 54115- outline

- Terms, definitions and abbreviations
- Manufacturing facilities
  - Personal Protective Equipment (PPE)
  - Process control
  - Batch traceability
- E-liquid: ingredients, testing
- General product risk assessment
  - Toxicological risk assessment (TRA) of emissions
  - List of analytes of interest for emissions from hardware
- Technical dossiers
- Substantial modification
- Vaping product labelling, packaging and instructions
- Bottle design for refilling safety
- Test Bed Atomiser design

BSI Publicly Available Specification- sample pages

PAS 54115

PUBLICLY AVAILABLE SPECIFICATION

Manufacture, importation, testing, and labelling of vaping products, including electronic cigarettes, e-shisha and directly-related products – Code of practice

FOR PUBLIC REVIEW

Please submit comments through the online draft review system:
http://drafts.bsigroup.com/Home/Details/53856 by 28 November 2014
Thank you

THIS IS A WORKING DRAFT AND MUST NOT BE REGARDED OR USED AS A PAS
THIS DRAFT IS NOT CURRENT BEYOND 28 NOVEMBER 2014

raising standards worldwide™

Any remaining risks identified should be communicated to consumers as a warning, either as part of the labelling, packaging or accompanying product instructions.

NOTE 1 An example of a risk that is not immediately obvious is the potential choking hazard associated with some small cartomizers.

NOTE 2 Attention is drawn to the General Products Safety Directive.

5.5 Toxicological risk assessment (TRA) of emissions

A TRA should be carried out by a qualified toxicology specialist of the emissions from every atomizer, or hardware product which includes an atomizer. Hardware should be assessed under the TRA with a test solution of 76% propylene glycol ("PG"), 18% vegetable glycerine or glycerol ("VG"), 2% purified water , and 2% nicotine. All the ingredients for the test solution should be of pharmaceutical grade. The material composition of the device should inform the TRA.

Where an analyte of interest is identified in the emissions from the product, at a level of toxicological concern, the source of these levels should be identified. Attempts should be made to alter the structure, components or design to reduce the levels present to a level that is toxicologically supportable. This should be verified by further TRA of emissions from the modified product. However, in identifying a supportable level, comparators may be assessed, such as workplace exposure levels, etc.

5.6 List of analytes of interest for emissions from hardware

Substances which should be monitored for emission by the hardware during VP use are listed in Table 3.

Table 3 – List of analytes of interest which should be quantified in the emissions from the activation of hardware

Substance and CAS number	Recommendations
Formaldehyde (50-00-0), acetaldehyde (75-07-0), acrolein (107-02-8) and acetone (67-64-1)	These should be measured with a view to minimising the emissions. Care should be taken when testing for formaldehyde, however, since it is a ubiquitous chemical.
Determine the device composition and test for these materials	Testing for emissions generated by the device should be informed by the composition of the device, however attention is drawn to the following analytes:
Metals, to include lead (7439-89-6), cadmium (7440-43-9), mercury (7439-97-6), chromium (7440-47-3), nickel (7440-02-0) and iron (7439-89-6) Silicon (7440-21-3)	Some of these metals are likely to be present in the emissions from hardware, so should be quantified and toxicologically evaluated to ensure that they are not present at levels of toxicological concern. The level of silicon in the emissions should be measured, since this is likely to provide an indication of the level of degradation of the wicking material. If levels of emitted silicon are high, the wick should be examined to ensure that needles or other dangerous small particles are not being generated. Changing the wicking material grade or supplier may be warranted if dangerous particles are separating.

5.7 Substantial modification

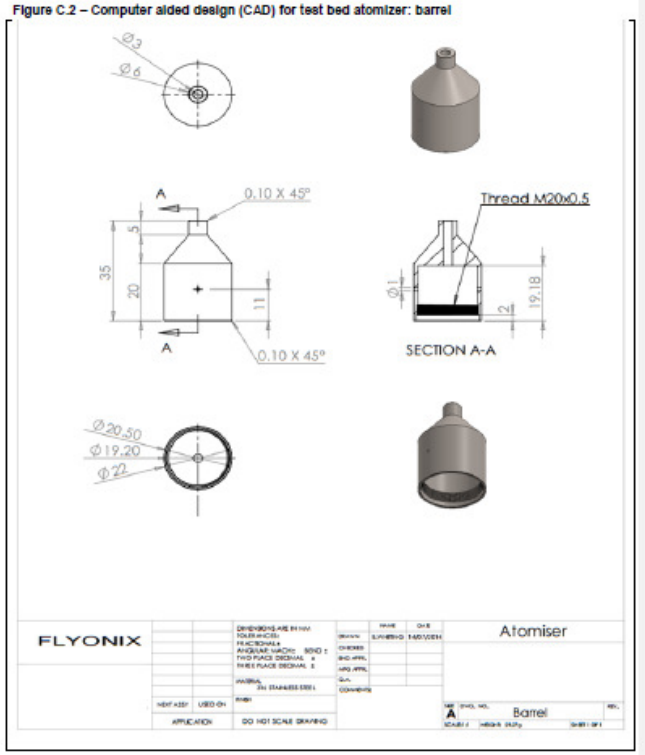
If a producer modifies a hardware product so that it performs differently from the original, then a new technical dossier should be produced by the producer for the modified product.

NOTE 1 Examples of substantial modification include:

a) Changes in the voltage/wattage to the atomizer, or resistance of the heating element.

b) A change of any of the device materials that are in contact with the liquid or aerosol.

Figure C.2 – Computer aided design (CAD) for test bed atomizer: barrel



Current status of standards projects in the EU: AFNOR and CEN

- AFNOR - the French standards body- has an e-cigarette standards initiative (similar to the BSI) to draw up proposed 'Experimental standards' by early 2015

- The European Commission has stated that they are considering developing technical standards for e-cigarettes with CEN (the EU standards body) in 2015

- AFNOR submitted an application to CEN to establish a Technical Committee for the development of a European standard
  - CEN circulated a Technical Committee proposal among its 33 members
  - A decision expected in January 2015.