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Your ref. TS/P 251 Vape and vapour products
Our ref. TS/P 251
Date 2015-07-02

TO THE ISO MEMBER BODIES

TS/P 251 'Vape and vapour products' submitted by AFNOR (France)

Dear Sir or Madam,

Please find attached a proposal for a new field of technical activity on *Vape and vapour products* proposed by AFNOR (France).

We would like to take this opportunity to inform you that ISO/TC 126 *Tobacco and tobacco products* submitted a request to modify its scope to include smokeless products. The modification of the scope of this TC will be put on hold until the outcome of the member body ballot and comments made on this TS/P are available, in accordance with [TMB Resolution 82/2015](#).

The views of AFNOR (France) and ISO/TC 126 *Tobacco and tobacco products* leadership regarding potential overlaps between the new proposal and the work of the committee are enclosed.

If you have any questions, please contact us at tmb@iso.org.

Yours faithfully,

Sophie Clivio
Secretary to the Technical Management Board

Encl: Position of AFNOR (France) regarding potential overlaps
Position of ISO/TC126 *Tobacco and tobacco products* leadership
TS/P 251 *Vape and vapour products*

Alain COSTES
AFNOR Standardisation Director

Madame Sophie Clivio
Secrétaire du Bureau de gestion
technique de l'ISO
BIBC II
Chemin de Blandonnet 8
1214 Vernier, Genève

Ref.: TMB resolution 82/2015

Subject: Proposal for a new field for vape and vaping products

2015-07-01

Dear Mrs Clivio,

As agreed by the Technical Management Board at its 63rd meeting, I have the pleasure of providing the Members of ISO with more background regarding the proposal to set out a new field of technical activity for vape and vaping products.

I would first like to underline why vape and vaping products should be considered as an emerging technical and economic field. The electronic cigarette devices and their consumables called e-liquids are recognized as a genuinely disruptive innovation. Though taken up mainly by early adopters at first, they have now reached mass market in many countries in just a few years. The use of electronic cigarettes has quickly become popular around the world, especially in North America and in Europe, where, interestingly, its marketing is associated to the development of user communities.

The main characteristics of the now mainstream market for these innovative products are:

- the wide variety of devices and e-liquids,
- the arising of a large number of brand new market players and stakeholders
- the significance of market value and public policies involved.

These facts explain that the e-cigarette industry is set to provide the basis for a new economic sector that covers manufacturing, production as well as retailing of both devices and e-liquid.

The new field of technical activity dedicated to vape and vaping products aims to address the emerging standardisation needs in that field. We believe that the already existing user communities will represent an asset to support the ISO members in the establishment of their mirror committees, along with the industry and retail sectors.

Because of this original model, we are convinced that the standardization tasks at hand warrant the creation of new technical committee. It will naturally work in close cooperation with the related ISO and IEC TCs, first and foremost with ISO/TC 126 on Tobacco and tobacco products. This is the reason why all products containing tobacco or nicotine are excluded from the scope of the new TC as proposed.

These exclusions notwithstanding, the technical committee will have many major standardisation needs to fulfil. The TC work program would therefore focus on:

- safety and quality requirements for electronic cigarette devices and e-liquids,
- test methods for devices and e-liquids,
- testing conditions and equipment, reference products, quantification and qualification of emissions,
- user information and services provided by retailing.

It is quite clear that some of the stakeholders of the new TC may intersect with some of those currently involved in ISO/TC 126 on Tobacco and tobacco products. However, we observe that the vaping community is widely distinct from the tobacco companies in the countries where the practice of vaping has taken off.

This is why we believe that the creation of the new TC would not rule out a modification of scope by TC 126 on Tobacco and tobacco products. The scope of TC 126 could be extended without any problem to nicotine and its measurement in e-liquids. Because ISO TC 126 has a wide expertise in standardization of testing conditions (e.g. routine analytical smoking machines and analytical methods for tobacco components), the new TC could rely on its experience and use as normative reference the work already carried out by the TC 126.

In conclusion, AFNOR proposal is clearly focused on

- devices and their safety,
- e-liquids (excluding the determination of the level of nicotine),
- emissions (excluding the field of routine analytical smoking machines¹)

I am convinced that ISO can at the same time respond the expectation of the new, innovative vape communities and industry, while taking on board the essential part of the proposed extension of scope for TC 126.

Hoping you will find this information helpful, and committing to respond the queries arising from the ISO membership on this topic,

Yours sincerely,

Alain COSTES
AFNOR Standardisation Director



¹ cf. ISO/TC 126 ongoing work on puffing machines for generating and collecting aerosol

From: Laabs, Claudia <claudia.laabs@din.de>
Sent: 2015-07-01 15:02
To: TMB
Cc: Yusuke CHIBA; Lutz Henning Dr.; Baumann, Carola
Subject: Re: AFNOR proposal to establish a new ISO technical committee on vape and vapour products - ISO/TC 126 comments

Dear Francesco

Thank you for giving ISO/TC 126 Chair and Secretary the opportunity to comment on the AFNOR proposal. We have the following comments:

Because e-cigarettes and other vaping products are used by the consumer in a manner similar to tobacco products (which are being smoked), there is profound expertise and experience in ISO/TC 126 "Tobacco and tobacco products" to deal with standard method development in this field.

ISO/TC 126 is already working on the following two projects with regards to vape and vapour products:

- ISO 20714, E-Cigarettes – Determination of nicotine in liquids used in electronic nicotine delivery devices (e-liquids);
- ISO 20768, Routine analytical puffing machine – Definitions and standard conditions (the title will most probably be changed to "Routine analytical machine for e-cigarette aerosol generation and collection – Definitions and standard conditions").

The projects are being dealt with in ISO/TC 126/WG 15 "Determination of substances in e-liquids" and ISO/TC 126/WG 16 "Routine analytical e-cigarette vaping machine", respectively.

Furthermore, ISO/TC 126 has already an established ad-hoc group "Water pipe smoking"(Resolution 300) which is working on preliminary work items for water pipe smoking.

The new CEN/TC 437 "Electronic cigarettes and e-liquids" intends to set up a liaison with ISO/TC 126.

In order to avoid duplication of work and costs, ISO/TC 126 Chair and Secretary – with support of ISO/TC 126 – propose to establish an ISO/TC 126/SC 3 to cover standardization of vape and vapour products. This SC 3 would be of course open to liaison and participation of further associations and experts.

It should be avoided to set up a new ISO/TC because dealing with "Vape and vapour products" could be done within ISO/TC 126 which has the advantages of:

- a profound knowledge of relevant routine analytical methods and machines to set up standards to analyse e-cigarettes, vapour and vaping products.
- an existing organizational structure and a well-established working relationship with relevant liaison partners such as the WHO (World Health Organization), CORESTA (Cooperation Centre for Scientific Research Relative to Tobacco)
- involvement of interested stakeholders (e.g. producer, governmental control laboratories), including e-cigarette and water pipe.

Yours sincerely

DIN – Food and Agricultural Products Standards Committee (NAL)

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PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY	
Circulation date: 2015-05-21	Reference number (to be given by Central Secretariat)
Closing date for voting:	
Proposer AFNOR	ISO/TS/P

A proposal for a new field of technical activity shall be submitted to the Central Secretariat, which will assign it a reference number and process the proposal in accordance with the ISO/IEC Directives (part 1, subclause 1.5). The proposer may be a member body of ISO, a technical committee or subcommittee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the ISO/IEC Directives (part 1, Annex C).

The proposal (to be completed by the proposer)

<p>Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover.)</p> <p>VAPE AND VAPOR PRODUCTS</p>
<p>Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned.)</p> <p>Standardization of requirements and test methods of vape and vapor products, Standardization of product information and services related to the use of vape and vapor products. Note: these products are not intended to be used by children under eighteen.</p> <p>The verb "vape", a word originated as an abbreviation of vapour or vaporize, means 'to inhale and exhale the vapour produced by an electronic cigarette or similar device'. Sign of its popularity, this new word has been elected Word of the Year 2014 by the Oxford Dictionaries.</p> <p>Vape or vapor products refer to devices used to transform a consumable into an inhale aerosol and also to the e-liquids intended for transformation into an aerosol. This definition covers a wide range of devices including electronic cigarettes, e-cigars, e-pipes and e-chichas, which may be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.</p> <p>Most of the current consumables are liquids or gel consumables mainly composed of glycerol and propylene glycol, but considering the fast evolution of this growing market, new kinds of consumables might be reasonably foreseen</p> <p>Are excluded from the scope of this committee:</p> <ul style="list-style-type: none">- tobacco products involving a combustion process (cigarettes, cigars, roll-your-own tobacco products ...),- smokeless tobacco products including chewing tobacco, nasal tobacco and tobacco for oral use,...- all kinds of consumable products containing tobacco or nicotine.- pharmaceutical products.

Proposed initial programme of work (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subject proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.

The work programme will consist of:

1. The development of ISO Standards on vapor products (devices and consumables) and emissions during use
2. The development of ISO Standard on General terminology
3. The development of Standards or other deliverables (to be discussed by the future TC). The standardization work will address risks related to the use of vapor products in view of the safety of the user and surrounding persons.

The main areas in developing standards regarding devices are:

- mechanical hazards: filling procedure, child safety, structural integrity, drop test, tightness,...
- thermal hazards: surface temperatures,...
- chemical hazards (migration of chemical components): skin contact, mouth contact
- user information: marking, use, maintenance, cleaning,...
- ...

The standards covering consumables may address the following items:

- requirements on liquid composition, black listed components, heavy metals, allergens, ...
- requirements on packaging: child-resistant and tamper-evident packaging, sealing,...
- user information
- ...

One of the major areas to be considered is the emission testing which aims to analyse and quantify the substances released during the process of vaping. The standard has therefore to address the definition of a "vaping" cycle, a standard reference flavouring, standard reference liquids. It will also determine testing facilities and propose methods for measurement/quantification of the emissions.

The standards will define test methods, relying as far as possible on existing methods already in use in other sectors (e.g. lighters, tobacco products, batteries and power supply devices, child-resistant packaging...).

It is suggested that the Technical Committee should consider the setting up of different Working groups covering the major items.

It is proposed to hold the first TC plenary meeting at the beginning of 2016.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient.)

ISO Standards: terminology, requirements and test methods

Technical reports: common safety requirements to be referred to in the development of the subsequent specific standards

A listing of relevant existing documents at the international, regional and national levels. (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)

The following illustrates some of the major standards identified to date in the case of vape and vaping products.

USA:

E-liquid manufacturing standards (American E-liquid Manufacturing Standards Association - AEMSA) - 2012

United Kingdom:

PAS 54115 "Manufacture, importation, testing, and labelling of vaping products" (to be published)

France:

XP D90-300-1 Electronic cigarettes and e-liquids – Part 1: Requirements and test methods for electronic cigarettes - 2015

XP D90-300-2 Electronic cigarettes and e-liquids – Part 2: Requirements and test methods for e-liquids - 2015

XP D90-300-3 Electronic cigarettes and e-liquids – Part 3: Requirements and test methods for emissions (under development).

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. (The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

The purpose of establishing this Technical Committee is:

1. to establish, based on the existing national and regional standards, safety requirements and test methods to increase the safety of users;
2. to offer consumers the necessary information, for instance instructions for use;
3. to promote consistency (use, testing, terminology) when dealing with risks for vapor products;
4. to ensure consistency with standards already developed by existing TCs: ISO/TC 126 "Tobacco and tobacco products", IEC/TC 89 "Fire hazards of electrotechnical equipment".

A listing of relevant countries where the subject of the proposal is important to their national commercial interests.

China, France, Germany, Poland, Spain, United-Kingdom, USA,...

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)

ISO/TC 126 "Tobacco and tobacco products"

ISO/TC 146 "Air quality"

IEC/TC 89 "Fire hazards of electrotechnical equipment".

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).

The stakeholders are suppliers, manufacturers, distributors, purchasers, testing laboratories and consumers.

For suppliers and manufacturers, ISO standards can mitigate the difficulties in product design, in consumable products composition and marketing of safe products. ISO standards also contribute to lower costs all around the world and to prevent incidents related to product safety.

For distributors and importers, ISO standards decrease risks in the downstream supply chain.

For consumer/end user associations, ISO standards are expected to improve safety and knowledge of the safe use of products.

For public authorities, ISO standards facilitate market surveillance and foster the fairness of the market.

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.
AFNOR is willing to perform the duties of the secretariat of the proposed Technical Committee and to propose a Chair.

Purpose and justification for the proposal. (The purpose and justification of the standard to be prepared shall be made clear and the need for standardization of each aspect (such as characteristics) to be included in the standard shall be justified. Clause C.4.12.1 through C.4.12.10 of Annex C of the ISO/IEC Directives, Part 1 contain a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)

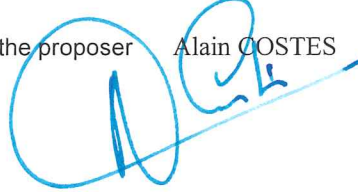
In 2013 vapor products have been considered by Goldman Sachs as one of the secular disruptive themes that they believe possess the potential to reshape their categories and command greater attention in the coming years. According to the analysts, being less harmful than cigarettes, but providing a similar experience and better economics, vapor products can alter the status quo of the tobacco market and accelerate the volume decline of traditional cigarettes.

The vape development is based on disruptive innovation and total creativity, which supports the idea of creating a field of activity devoted to vapor products.

The quick evolving market of vapor products is transforming the habits of millions of people. For example, within Europe, estimates give between 12 and 15 millions of end users of vapor products.

The standardization work will aim to increase the safety of users and surrounding persons, by setting safety and quality requirements of the devices, consumables and emissions and by improving consumer information.

Signature of the proposer Alain COSTES



Further information to assist with understanding the requirements for the items above can be found in the Directives, Part 1, Annex C.

Comments of the Secretary-General (to be completed by the Central Secretariat)

Signature