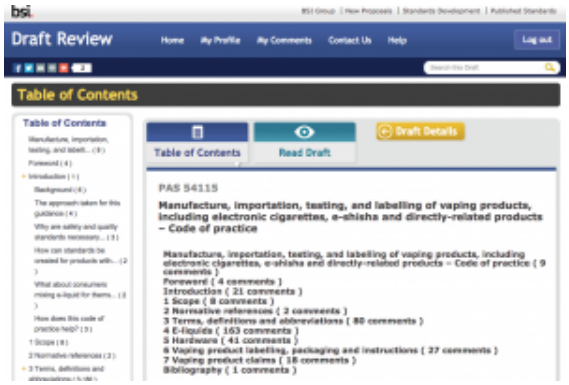
Comments on draft BSI standard for vaping products

written by Clive Bates | 30 November 2014



Make your views known: if you aren't at the table, you're probably on the menu

I provided some comments on the draft British Standards PAS 54115, Manufacture, importation, testing, and labelling of vaping products (closing 30 Nov). A PAS is an industry-led Publicly Available Standard, brokered but not imposed by the British Standards Institute, and designed to quickly set norms in an industry. I'm broadly pretty positive about this, not least as it could give a basis for more rational regulation if the EU directive Article 20 is annulled in court, which it should be. However, I think the current draft PAS leans towards costly overkill in some areas – we need to keep the likely risks in proportion and remember the damaging and distorting effects of subjecting these products to greater testing burdens than cigarettes. There are many worthwhile proposals, but the excesses have been my focus in comments.

What I hope this does is open a conversation – that would be the one that was never had while the EU directive was being drafted.

Overall comment

Comment: The PAS should not attempt to incorporate the requirements of the TPD – many of which have no evidence base and are counterproductive for both health and the functioning of the single market, and may be overturned following

challenge in the Court of Justice of the European Union. The PAS should only set standards that a proportionate and likely to create material benefits for users that justify the costs. The PAS as drafted does meet tests of proportionality – yet it would impose high and disruptive costs and tend to favour the large companies in the market at the expense of SMEs.

The PAS does not adopt a proportionate risk based approach to regulation. The big health impacts arise from people switching from smoking to vaping products, not by marginal improvements in vaping products. To the extent that the latter compromises the former, the PAS will be harming health. This could arise if the effect of the PAS was to drive good products and small firms out of the market simply because of the weight of compliance. The process of PAS development should include an impact assessment. If firms are going to be put at risk, then there needs to be a good reason.

The PAS has a tendency to demand excessive testing and toxicological risk assessment, when the tests themselves would say little useful about the product. Rather than trying to measure toxic emissions, it would be better and cheaper to address the causes of toxicity 'upstream'.

Remedy. 1. Embrace the concept of proportionality – this is vital if these products are not going to be subject to regulatory 'barriers to entry' that distort competition with tobacco products (that do not require any of this testing) and favour large companies within the category.

2. Conduct a limited impact assessment before finalising the PAS and be more aware of what sort of business models are at risk if the PAS becomes a de facto standard.

3. Focus on tackling *precursors* to health and safety risk rather than make arbitrary measures of vapour.

– Specify liquids to pharma standard and flavours to food standard;

– Require devices to be capable of use in a food processing environment and specify materials that can or cannot be in contact with liquids;

– place constraints on the operating regime – or provide warnings about running too hot or too dry. It is these abnormal operating conditions that cause most toxic

emissions – it would be better to address these directly, than indirectly through testing vapour.

Comments on some specific sections

4.6.5 Toxicological Risk Assessment for flavourings

> *All flavourings including natural extracts should be additionally subject to a toxicological risk assessment (TRA)*

Comment: A toxicological risk assessment for all flavourings is hugely excessive and burdensome, and will involve large scale duplication and across the industry. This would potentially close down most of the flavours industry and may have harmful effects of removing low-volume niche flavours from the market.This is an area where the PAS needs to be subject to a proportionality test and impact assessment.

Remedy: Toxicological risk assessment should be considered strictly on a risk basis – where it is justified by some form of novelty or anticipated risk. Otherwise a simple chemical analysis should suffice. Some sort of listing arrangement could be used to validate flavours across the industry as a whole – it is essential to avoid large and unnecessary compliance burdens, especially given the structure of this industry

4.8 Toxicological Risk Assessment for ingredients

> *A TRA should be carried out by a competent toxicology specialist taking into account every ingredient used in the manufacture of e-liquids.*

Comment: What is the purpose of an expensive TRA if there is already a requirement that the flavours are food grade and the nicotine and diluents are pharmaceutical grade? If none of the ingredients are toxic, what is there for a toxicological risk assessment to find? Leachables should be addressed by specifying device standards – for example excluding toxic metals. Thermal breakdown products are an artefact of the operating regime and become

problematic when devices are operated in unrealistic conditions. Again, this has been proposed without a sense of proportionality or estimation of the regulatory impact. It is important to consider what effect this would have on the businesses in the market if it became a de facto standard, rather than optional.

Remedy The ideal proportionate approach should focus on setting standards that avoid or control the precursors to the formation of toxins, not on measuring toxins in the emissions. This means specifying pharmaceutical grade nicotine and diluents, food grade flavours and standards for devices equivalent to those used in food processing.

4.10.5 Emissions testing for liquids

> *E-liquids should be tested for the production of inhalation toxicants produced during the vapourization process.*

Comment. This is exceedingly burdensome for no obvious return in health and safety terms. The formation of toxins in the vapour depends on what is in the initial liquids, the manufacturing specification of the device and – most importantly – the operating regime. These issues can be more pragmatically addressed 'upstream' by specifying standards. This is an area where proportionality is necessary and an impact assessment is required to judge the damage it would do to small firms if this becomes a de facto standard.

Remedy. There is no reason to have extensive emissions testing, which will produce largely arbitrary results at great cost. The real focus should be on addressing the precursors to the formation for toxins in the emissions – standards for liquids, stability of device surfaces in contact with liquids and, if necessary, by limiting the operating parameters to prevent especially hot or dry use – or by warning that the products should not be used in that way.

5.5 Toxicological risk assessment (TRA) of emissions for devices

Comment: An excessive and disproportionate way of addressing risks arising from the device. Some test of proportionality is necessary here and a proper impact assessment done to understand the damage that such a burdensome

regime might to do SMEs in the sector. It is difficult to see what this would achieve that could not be more directly realised by setting standards for device construction.

Remedy: It would be better to address risks from devices 'upstream' by setting standards for the materials and construction rather than testing emissions. Why not prohibit toxic metals from construction and have a white list for approved materials. A good analogy might be to ensure that it would be safe to use in the food industry.

5.7.2 Batteries

> *Batteries and chargers should be further tested to ensure they can function safely during use (see Annex G for test methods).*

Comment. Batteries and chargers are now pervasive thanks to mobile technologies. Surely this issue should be addressed generically rather than having a specific testing regime in the PAS. If practical there would be valuable consumer benefit in being able to interchange chargers with mobile phones. Given there is a process to standardise mobile phone chargers, it would be sensible where possible to align with that.

Remedy. It would be better simply to refer to compliance with BS EN 62133:2013 on secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications and the Low Voltage Directive 2006/95/EC. Unless there is some insurmountable technical reason that prevents it, the PAS should align with emerging standards for a common mobile phone charger – if necessary as an option.

Comment on contribution by the Association of Directors of Public Health

Comment. The Association of Directors of Public Health has provided unsubstantiated opinions on unrelated issues that have no bearing on the PAS.

Remedy. Delete or ignore contribution from ADPH.