Internetconsultatie Rookwarenbesluit
Reactie Martijn Voncken.

Op Europees niveau heeft er geen consultatie plaatsgevonden m.b.t artikel 20 van de TPD (e-sigaret). Ik vind dit zeer ondemocratisch. Daarom dien alsnog een reactie op artikel 20 van de TPD in.

Clive Bates, (Ex directeur van ASH UK , een anti rook organisatie) heeft vele bezwaren tegen artikel 20 in de EU TPD samengevat in de onderstaande bijlage, ik sta achter al zijn bezwaren.

In een van de laatste alinea's stelt hij: "***De facto ban on tanks/mods?*** Does the combination of several provisions create a de facto ban on tanks and mods" Dit is mijn grootste angst, TPD artikel 20 geeft lidstaten de ruimte om effectief alle hervulbare e-sigaretten(open systemen) te verbieden.

Het huidige wetsvoorstel geeft het ministerie de ruimte om via een AMVB alle hervulbare e-sigaretten(open systemen) effectief te verbieden zonder dat de 2e kamer kan ingrijpen.

http://www.clivebates.com/?p=3026

What is wrong with the Tobacco Products Directive for vapour products?

The European Union directive governing e-cigarette regulation is a catalogue of poorly designed, disproportionate and discriminatory measures that will achieve nothing useful but do a great deal of harm. Let's review the main issues:

From 20 May 2016, e-cigarettes and other nicotine vapour products will be regulated in Europe under Article 20 of the Tobacco Products Directive (2014/40/EU). The main issues with the directive are that in several areas harmful unintended consequences (usually meaning more smoking) are likely to far exceed any intended benefits, where these can be identified at all. The public health community has been very slow to understand how 'tough' regulation of e-cigarette and vaping easily amounts to regulatory protection of the cigarette trade – discussed here: Turning the tables on public health – let's talk about the risks *they* create and here Big Tobacco's Little Helpers. What does tough regulation of harm reduction actually mean? The directive provides a number of specific cases of this problem – costs, burdens or restrictions with little

benefit and huge unintended consequences that reduce the appeal of e-cigarettes relative to cigarettes. Main examples:

- *A ban on almost all advertising sponsorship and promotion of e-cigarettes.* The anti-competitive e-cigarette advertising ban protects the incumbent cigarette trade from a disruptive challenger and is unjustified in a directive with a single market legal base, and disproportionate relative to tobacco. Most tobacco advertising is banned in the EU, but that's because tobacco kills 700,000 per year. In contrast, vaping is likely to *reduce* premature deaths. Banning advertising hampers the development of trusted brands, communication of innovation and the aspirational messages that help new products succeed. Limitations on advertising similar to those applied to alcohol are justified – as implemented by the UK Committee on Advertising Practice [broadcast / non-broadcast codes for e-cigarettes] but the directive goes far beyond these.
- *Limiting the strength of nicotine liquids to 20mg/ml (2%) nicotine.* Approximately 25-30% of consumers use liquids stronger than this. There are four downsides to this limit: (1) stronger liquids may be more important for more heavily dependent smokers; (2) they are important for smokers in the process of switching – new users may not have acquired the skill or familiarity to find vaping a satisfactory alternative to smoking in the early days – the strength limit will cause more to relapse; (3) in a market that values miniaturisation it may be a barrier to innovation – allowing more nicotine to be kept in a smaller volume may be important in future product design; (4) for those users who would prefer stronger e-liquids, it will mean they will need to inhale more vapour to get the nicotine they want – if there are any hazardous substances in vapour, this policy will *increase*exposure (hat tip). No argument exists for actually doing this. If the concern is poisoning then child-resistant containers are the answer.
- *Limiting size of e-juice containers to 10ml and tanks or cartridges to 2ml.* No purpose to this other than bureaucratic harassment – though it is probably based on wild misunderstandings of nicotine toxicity and overstated LD50 (lethal dose). It actually means more fiddling about, more frequent refilling, more spillage possibilities more chance of running out, high costs for users etc. Again, we solve problems of hazardous liquids, like bleach for example, not by insisting that they are held in thimble sized containers, but by having child resistant packaging – as in ISO8317. This issue is compounded by the limit on strength – how do smaller tanks of weaker liquid help in the competition for smokers?

- *Excessive warnings***.** By design the mandatory warnings required will be unmistakably similar to those used on cigarettes – bold black and white cover 30% or more of the main pack surfaces – yet there is nothing like equivalent risk. The only warning needed is reference to nicotine along with an age restriction 18+ and keep out of children's reach – just like they have on off-the-shelf medications.In addition each pack will need to contain a leaflet – even though nothing similar is required for cigarettes. As with marketing, alcohol warnings would offer a proportionate benchmark.
- *Notification regime*. Before a product can be put on the market a dossier of information has to be provided to the Commission followed by a 6 month wait. It is a notification regime – if the information required is provided the product can be placed on the market. There's devilment in this – the Commission has delegated authority to define what information is required. It could require extensive testing of thousands of product combinations in many different operating conditions. None of this is required to place a cigarette on the market – this needs only minimal testing of crude metrics (tar, nicotine and carbon monoxide) with long established protocols. At the time of writing, the e-cigarette notification regime is under discussion: see draft data dictionary. And it is very demanding, though fortunately it does not go as far as requiring pharmacokinetic studies. However, it does introduce numerous wasteful burdens that have no real purpose – like a lot of EU regulation it appears indifferent to costs and burdens, yet these will break some of the smaller, more agile companies. For example:
    - Measurement of TSNAs measurements in aerosol is pointless given that pharma grade nicotine is specified elsewhere. The same applies for ethylene glycol and DEG.
    - Measurement of aerosol particulate matter is irrelevant: what are the implications? It's just make-work.
    - The EU admits their inability to develop a standard testing protocol, so they just specify any old scheme and then require them to redo it once the Commission does know what it is doing: "*In the absence of agreed standards/protocols, emissions measuring should be performed for both the medium range wattage and the maximum wattage. All other settings (i.e. airflow, puffing etc.) are to be described within the next item, Item #6.31 (methods). After the unified standards/protocols for emission measuring have been developed, the stakeholders will have to repeat the tests using the standardised protocol…*"
    - They specify testing for atomisers with the "most commonly sold liquid and battery". For battery testing, use the most commonly sold atomiser and liquid. For liquid, the most

commonly sold atomiser and battery. It should be obvious that these 'most commonly sold' products are different in all markets and change all the time. So what use will the data be?

- *Leak free filling*. The Commission, though not a manufacturer or designer of anything, is to specify a leak free filling mechanism. Depending what these civil servants come up with, it is possible that this will create a *de facto* ban on 'tank' products – requiring a cartridge approach (supporting the razor-blade business model favoured by some vendors). This being the most individually personalisable and most likely to function as a successful alternative to smoking. This provides a 'solution' to a non-problem or one that could be left to the market to address for those who want it. This provision could also make it impossible to have rebuildable or replaceable coils – effectively mandating disposable products. However, the technical standard will not be settled until 2nd quarter 2016, even though the directive applies from 20 May 2016 – so some fudge will be needed in the short term (see Peter Becket's comment below). Documentation on this issue:Commission's Letter (PDF); Consultant's questionnaire (Word).
- *Medicine regulation mandatory*. Some member states, for example Sweden, will interpret the directive as allowing them to *require* all e-cigarette to be regulated as medicines. This regulatory regime applies the restrictive, costly and immensely burdensome medicines regime to what is in reality a fast moving consumer good. The will create very high barriers to entry and dramatically contract the range of products on the market, favour the high volume commodity products, and ensure that only the largest players (i.e. major tobacco companies) can participate. It will destroy the industry's model of innovation in which new products are coming into the market every six months – nothing like the pharma model, which relies on a stable patent-protected market. It was a huge fight to persuade the European Parliament to reject mandatory medicines regulation – see arguments here and here – why has it crept back in by stealth? The language was intended to recognise a 'twin track', in which a manufacture could seek a marketing authorisation if they *wished to* make a therapeutic claim.
- *Power to ban certain types of vapour product*. Para 11 of Article 20 was introduced to appease member states who wished to ban refillable tank systems. The language has been made reasonable – there has to be clear danger to health and a ban has to be a proportionate and justified response – but the intention is the troubling part of this.

- *Bans and other extreme measures*. Even though the directive is supposed to approximate laws with a view to developing the single market it contains at Article 24 a general provision allowing member states to go further than the directive and to impose bans. This provision allows member states to contemplate 'plain packaging' for example. This article could be used by the more zealous member states to ban flavours, impose plain packaging etc.
- ***De facto ban on tanks/mods?*** Does the combination of several provisions create a de facto ban on tanks and mods, without actually specifying it? In other words is the regulation geared to work with, and only with, high volume commoditised products using sealed units or cartridges? Several measures may simultaneously combine to lead to this: the burdensome notification and testing regime; the leak-free filling mechanism; tamper-proofing; limits on tank size; member state unilateral action. The latest data from ASH (UK) show these products to be now the most popular (most often used by 66% of users in 2015, up from 40% in 2014); that most users have migrated to them from lower specification devices (only 28% start with these devices but by 2015 they were most popular for 66% of users). Those figures show the market 'voting' for the higher spec tanks and mods products.

Implementation plan: see the Commission's tracking document – three items concern e-cigarettes:

1. Report on potential health risks to public health from refillable electronic cigarettes – due 2Q 2016. By PRECISE consortium.
2. Technical standards for the refill mechanism for electronic cigarettes – due by 2Q 2016. By PRECISE consortium.
3. Reporting format for electronic cigarettes – due by 4Q 2015. By EUREST consortium.

Note that PRECISE and EUREST are led by Biomedical Research Foundation,Academy of Athens (BRFAA).

Bad process: the directive is as bad as it is mainly because the process of making it breached most principles of good policy-making. A full account of the shoddy, secretive and unaccountable process is set out in my complaint to the EU Ombudsman (background), which she declined to consider.

Martijn Voncken.