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**From:** Charles Hamshaw-Thomas [Charles@e-lites.co.uk]  
**Sent:** 05 March 2013 18:46  
**To:** SCHLYTER Carl  
**Cc:** EVANS Jill OFFICE  
**Subject:** your 21 February email, last week's ENVI hearing and e-cigs  
**Follow Up Flag:** Follow up  
**Flag Status:** Completed  
**Attachments:** E lites briefing\_note re EUTPD e-cigs February 2013.pdf; E-cigs\_the\_regulatory\_framework\_Feb2013.pdf; E-cigs\_what\_the\_public\_health\_experts\_are\_saying\_Feb2013.pdf

Dear Carl

I refer to my earlier email and last week's Environment, Public Health and Food Safety Committee meeting.

I was at the meeting and would have tried to introduce myself afterwards - but recognised you had far more pressing priorities?!

While I was heartened to hear comments from some MEPs about the possible role e-cigs might be able to play in terms of tobacco harm reduction – it being widely recognised they are a safer alternative to cigarettes – I'm very worried about the seemingly wide discrepancy in the levels of understanding amongst Committee Members about e-cigs. That means we've got a big education programme to do ..... and as soon as possible in terms of the timetable for the Directive.

The Directive's proposal has some enormous implications. It will require removal from the market of virtually all e-cigs despite their being proven to be capable of being a satisfactory alternative to cigarettes. I attach:

- . a briefing note which summarises the facts about e-cigs and the market, our concerns and who we are
- . details of the Regulatory Framework we have been successfully operating under and
- . a summary of what the public health experts are saying about e-cigs.

We fervently believe e-cigs are an exciting, breakthrough and potentially 'transforming' product. We believe raising awareness is critical. We are though very worried common sense may get overlooked and vested interests (of other much bigger and more powerful companies) be allowed to 'strangle at birth' a new, innovative and flourishing industry (in Germany and UK over 2million and 700,000 regular e-cig users respectively). The current proposal makes it seem as if we're being prevented from competing against tobacco companies and it's going to be harder to sell e-cigs than the harmful products they are designed to replace.

Regarding your question about nicotine, please note e-cigs deliver levels of nicotine directly comparable to cigarettes (which is part of the reason why they are proving popular to smokers as an alternative to cigarettes) and nicotine is widely regarded as not being the harmful element in cigarettes – please see the quote from Dr Karl Fagerstrom in the attached note. For your information we do sell an e-cig with no nicotine in it but to date that has not proved popular with smokers.

I understand the next public meeting of ENVI on the Directive is 20/21 March. I've also heard Linda McAvan is arranging a meeting for representatives of the e-cig industry on the 19<sup>th</sup> which is great news. So perhaps we could organise a brief meeting on one of those dates? With the first meeting of the Shadow Rapporteurs I understand being 12 March, my immediate priority is to make sure I've made good contact with all of their offices/assistants so please do let me know if you need any more information before then.

Please note I met Jill Evans and her assistant last week who were most helpful and particularly interested to learn more about e-cigs having been contacted by a number of constituents who were expressing their concerns. I've copied this email to Jill's office accordingly

With thanks in advance and I look forward to meeting you soon.

All best  
Charlie

Charles Hamshaw-Thomas | Director of Legal & Corporate Affairs  
+ 44 (0) 7723 031358 | + 44 (0) 1527 573492 | [www.E-Lites.co.uk](http://www.E-Lites.co.uk)  
Zandera Ltd, 18 Buntsford Park Road, Bromsgrove, Worcestershire B60 3DX



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**From:** SCHLYTER Carl [<mailto:carl.schlyter@europarl.europa.eu>]

**Sent:** 21 February 2013 11:08

**To:** Charles Hamshaw-Thomas

**Subject:** RE: re EU Tobacco Product Directive 2012/0366 (COD), draft Article 18 and electronic cigarettes (e-cigs)

I assumed you have nicotine in your e-lites. You write " e-cigs are not an nrt product" so, of course if it contains no nicotine we do not need to regulate it as a nrt. I was however totally convinced that all e-cigs did contain nicotine.

Best regards,

carl

-----Original Message-----

From: Charles Hamshaw-Thomas [<mailto:Charles@e-lites.co.uk>]

Sent: Wed 2/20/2013 8:01 PM

To: SCHLYTER Carl

Subject: RE: re EU Tobacco Product Directive 2012/0366 (COD), draft Article 18 and electronic cigarettes (e-cigs)

Dear Carl

Thank you for your email.

Our visit next week will be the first to Brussels and we will be attending to all requisite registration requirements then.

I note what you say regarding cigarettes and nicotine replacement (nrt) products. Please note we believe it's vital and in the interests of wider public health across the EU as a whole for all MEPs on the ENVI Committee to be aware that:

- e-cigs are not a tobacco product (as sold by the cigarette companies)
- e-cigs are not an nrt product (as sold by the pharmaceutical companies)
- e-cigs are a consumer product, designed as a much safer alternative to smoking and proven to be capable of being satisfactory to smokers as an alternative to cigarettes and
- the effect of the proposed Directive, as drafted, will be to restrict their availability and make it very much harder to sell e-cigs, the safest product which are already making an enormous contribution to tobacco harm reduction across Europe, than the considerably more harmful cigarettes they are designed to replace. So perversely it will be counter-productive and stifle tobacco harm reduction progress.

While I note your comments about the Framework Convention Tobacco Control, please be aware that we are not a tobacco company, there is no tobacco in our products and we have no associations with the tobacco industry. Correspondingly there are no industry or other meetings of which I'm aware and at which we'll be present. I'd therefore like to request, particularly so as you are Shadow Rapporteur for the Group of the Greens/European Free Alliance, an opportunity to meet separately.

I look forward to hearing from you as to when may be convenient.

With many thanks and kind regards

Charlie

<<http://www.e-lites.co.uk/>>

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From: SCHLYTER Carl [<mailto:carl.schlyter@europarl.europa.eu>]  
Sent: 19 February 2013 17:15  
To: Charles Hamshaw-Thomas  
Subject: RE: re EU Tobacco Product Directive 2012/0366 (COD), draft Article 18 and electronic cigarettes (e-cigs)

Dear Charles,

Thank you for your letter. I could not find E-lites in the Commission's transparency register, are you registered there?

To my view, e-cigarettes should not have an easier authorisation route than other tobacco replacement products. They are all cessation products and too easy access and a mindset that would give people the impression that they are harmless would be bad. Even though e-cigarettes are less hazardous for smokers as compared to normal cigarettes, nicotine is a rather heavy drug and a harmful substance, so e-cigarettes are not "healthy" as such and their usage needs to be reduced.

I am usually very restrictive with meeting lobbyists on this issue in order to comply fully with the FCTC. I am not able to meet with you but will attend hearings where your industry will be represented and you are welcome to send written information if you wish.

Best regards,

Carl Schlyter

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From: Charles Hamshaw-Thomas [<mailto:Charles@e-lites.co.uk>]  
Sent: 15 February 2013 17:48  
To: SCHLYTER Carl  
Subject: re EU Tobacco Product Directive 2012/0366 (COD), draft Article 18 and electronic cigarettes (e-cigs)

Dear Carl

I have tried to contact your office today. And having been unsuccessful, I thought it best to firstly send you an email.

I propose attending the ENVI public hearing on Monday 25 February relating to the above and would like to be able to meet with you, particularly as I understand you are Shadow Rapporteur for the Group of the Greens/European Free Alliance. Our interest in Article 18 relates to our being one of Europe's leading providers of e-cigs.

We're a flourishing business, headquartered in the UK and I would like to both understand the intention of the proposal regarding e-cigs and also the process. I'd also like to make sure you have to hand all the information you require relating to e-cigs and particularly the contribution they are already making (and can continue to make) to tobacco harm reduction. E-cigs are proving to be an increasingly popular alternative to cigarettes and you may find this recent piece from BBC news helpful - <http://www.bbc.co.uk/news/health-21408502> - with the eminent Professor John Britton (of the UK Royal College of Physicians) identifying the product's capabilities to 'save millions of lives'.

Would it be possible to fix a very brief meeting (15-20 minutes maximum) either on the Monday or Tuesday 26th?

With thanks and I look forward to hearing from you as soon as possible.

Kind regards

Charles

<<http://www.e-lites.co.uk/>>

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**Strictly Private & Confidential – February 2013**  
**Briefing Note re European Tobacco Products Directive 2012/0366(COD) (EUTPD)**  
**and electronic cigarettes (e-cigs)**

*"... nicotine containing products that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 mg per ml may be placed on the market only if they have been authorised as medicinal products..."*

**Chapter V Article 18**

**The effect of the above (the Proposal) will be to require removal from the market of virtually all e-cigs pending their authorisation as medicinal products, despite being proven to be capable of being a satisfactory alternative to cigarettes.**

- 1. Why would governments restrict their availability and make it harder to put e-cigs on the market than the harmful products they are designed to replace?**
- 2. Removing existing e-cigs from the market would be detrimental to the overall aim of the European Union (EU) to promote the well-being of its people, it would do more harm than good and it would be counter-productive.**

**WHAT ARE E-CIGS?**

- an electrical **consumer product proving popular with smokers as an alternative to cigarettes**
- battery powered, the smoker inhales a vapourised liquid solution containing nicotine to simulate the act of smoking
- **e-cigs are widely recognised as being safer than cigarettes**
- the benefits of e-cigs:
  - **no tobacco, smoke or tar ie no exposure to the 4,000 toxins and carcinogens found in tobacco smoke** (the e-cig's liquid solution has four ingredients: pharmaceutical grade nicotine, propylene glycol, food grade flavourings and water)
  - **no risk posed to non-smokers from environmental tobacco smoke/'passive smoking'**
  - **no smell, no litter, no fire risk**
- they are widely **recognised by leading public health experts and bodies as being able to reduce the harm caused by smoking**

*"... if all the smokers in Britain stopped smoking cigarettes and started smoking e-cigs we would save 5 million deaths .... a massive potential public health prize ... "*

**Professor John Britton, Leader of Tobacco Advisory Group Royal College of Physicians February 2013**

*".... there is little real world evidence of harm from e-cigs to date, especially in comparison to smoking... consequently they represent a safer alternative to cigarettes ...."*

**UK Action on Smoking & Health (ASH) January 2013**

*"... informing smokers about e-cigarettes and increasing access to these products is the best way we have to save millions of lives ...."*

**Dr Gilbert Ross, Executive Director American Council on Science and Health (ACSH)**



- e-cigs are marketed and sold only to adults who are smokers
- **described by UK Trading Standards as ‘... a code any industry would be proud to have .’ the Electronic Cigarette Industry Trade Association (ECITA)’s Industry Standard of Excellence (ISE) provides a regulatory framework for e-cigs;** ISE certification (with a bi-annual audit process) ensures compliance with (and in many cases surpasses) all relevant consumer protection legislation, rules and regulations relating to product/quality/safety & marketing standards and is being used and reviewed for adoption and formal recognition in certain Member States
- e-cigs are **designed as an alternative to smoking cigarettes** - they don’t contain tobacco and they deliver levels of nicotine directly comparable to cigarettes which, with the ‘hand to mouth’ behavioural component, provides an overall product **acceptable to smokers**
- **e-cigs are not nicotine replacement therapy (nrt) products** – those products are designed by pharmaceutical companies and are presented as aides to help smokers stop smoking cigarettes (which necessitates medicinal authorisation)

## OUR POSITION RE THE PROPOSAL

- **we are not selling a tobacco product** (there’s no tobacco in an e-cig)
- **we are not selling a medicinal product** (we don’t present e-cigs as having health benefits and they are not functionally a medicine)
- **we are selling a consumer product** (a proven alternative to cigarettes)
- **e-cigs are an exciting, breakthrough and potentially ‘transforming’ product which are increasingly widely being recognised as making a very significant contribution to tobacco harm reduction (THR)**
- we want smokers to have access to an alternative and be able to make an informed choice between cigarettes and e-cigs; we also believe all smokers have the right to benefit from technological advances that provide an alternative to cigarettes which is widely recognised as being safer
- **regulation as a medicine is not necessary and will stifle THR progress across Member States**
  - existing consumer protection legislation and other regulations, proven by ISE to be capable of codification and adoption, provide the necessary regulatory framework
  - removing already popular e-cig products from shelves would eradicate the contribution they are making to THR (sales of E-Lites in 2012 reduced consumption of cigarettes by 200million), it could drive millions of smokers back to cigarettes and provide impetus to an illicit trade in e-cigs
- we want freedom to compete against cigarette companies - **limitations on the wider availability of e-cigs will give cigarette companies an unfair competitive advantage and perversely ‘protect’ their existing markets**
- **in the best interests of public health across the EU we believe it is important:**
  - **e-cigs and nrt products are made as widely available as possible (ideally wherever cigarettes are sold and consumed)**
  - **to have a framework of different regulations to accommodate 1.harmful cigarettes (as tobacco products), 2. pharmaceutical nrt products (as medicinal products) and 3. e-cigs (as consumer products)**

## ABOUT US

- Since 2007 we have made significant investment in R&D, consumer research and new product development, to enable trading to start in 2009
- E-Lites G9 (9th generation) range is recognised as the world’s most technologically advanced e-cig
- Based in Bromsgrove England, employing 128 people (58 employees in head office and 70 full and part-time sales & merchandising agents and franchisees) across the UK
- 300-500% yr on yr sales growth for the three years ending 03/2013
- +£20m forecast sales for 2012/13; one of the UK’s fastest growing companies with **sales, into 26 European markets, replacing equivalent of +200million cigarettes in 2012**

25 February 2013

## **E-CIGS – THE REGULATORY FRAMEWORK**

**The UK Electronic Cigarette Industry Trade Association (ECITA) and its increasingly highly regarded Industry Standard of Excellence (ISE) provides an important and widely recognised regulatory framework for e-cigs**

*“...a code any industry would be proud to have ....” UK Trading Standards, 2011*

**ISE certification mandates a bi-annual audit and ensures compliance with (and in many cases imposes a higher regulatory burden than) all relevant consumer protection legislation, rules & regulations relating to product quality, product safety & marketing standards.**

### **These include:**

- General Product Safety Regulations 2005
- Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP) 2009
- Weights & Measures (Packaged Goods) Regulations 2006
- Plugs and Socket (Safety) Regulations 1994
- The Waste Electronic and Electrical Equipment Regulations 2006 (WEEE)
- The Batteries and Accumulators (Placing on the Market) Regulations 2008
- The Waste Batteries and Accumulators Regulations 2009
- Consumer Protection (Distance Selling) Regulations 2000
- Electronic Commerce (EC Directive) Regulations 2002
- Data Protection Act 1998
- Health and Safety at Work Act 1974
- Control of Misleading Advertising Regulations (1998)
- Business Protection from Misleading Marketing Regulations (2008)
- Enterprise Act (2002),
- Unfair Trading Regulations (2008)
- Advertising Standards Agency Code

### **ECITA's audit checks inter alia:**

- CE Certification (required for electronic products and use of hazardous substances)
- e-liquid laboratory analysis at a UK accredited public analyst's laboratory
- the detailed analysis of nicotine, propylene glycol and glycerol
- CHIP/CLP and Reach Compliance
- child-proof testing
- product labelling to ensure not sold to minors under 18
- (unique to E-Lites) batch coding for every cartridge/tip and
- product liability insurance

**ECITA has worked with UK Trading Standards and the National Measurement Office in the development of the ISE and is in discussions with the regulatory authorities in Hungary regarding formal recognition of the ISE. The ISE has been formally adopted in States of Guernsey.**

25 February 2013





# E-Lites™

## E-CIGS – WHAT THE PUBLIC HEALTH EXPERTS ARE SAYING

*“... if all the smokers in Britain stopped smoking cigarettes and started smoking e-cigs we would save 5 million deaths .... a massive potential public health prize ...”*

**Professor John Britton, Leader of Tobacco Advisory Group Royal College of Physicians**

*“... there is little real world evidence of harm from e-cigs to date, especially in comparison to smoking... consequently they represent a safer alternative to cigarettes ...”*

**UK Action on Smoking & Health (ASH)**

*“... informing smokers about e-cigarettes and increasing access to these products is the best way we have to save millions of lives ....”*

**Dr Gilbert Ross, Executive Director American Council on Science and Health (ACSH)**

*“.. [e-cigs are] very safe relative to cigarettes and also safe in absolute terms on all measurements we have applied..”*

*“.. e-cig vapour is not toxicant free, but is free of most smoke toxicants particularly of the leading carcinogen in cigarette smoke, 1,3 butadiene, and the leading cardiovascular toxicant, hydrogen cyanide. Importantly, e-cigs directly substitute for the habit as well as the nicotine, without the smoke. As persistent smokers face a one in two risk of dying early (they are on death row so to speak) they need to get out jail card and substitutes can provide it. To deny them such relief is inhumane and unconscionable ...”*

**Dr Murray Laugesen, Founder and Managing Director Health New Zealand & Chair of End Smoking NZ**

*“..there is no question that any risks associated with e-cigs are dwarfed by those caused by smoking and second-hand smoke exposure. Thus, e-cigs are a viable alternative to cigarettes that drastically reduce health risks ..”*

**Professor Michael Siegel, Community Health Sciences, Boston University School of Public Health**

*“.. e-cigs are a rival consumer product to cigarettes. In a couple of respects, [they've] got spectacularly better characteristics – in terms of the health impact, in terms of the nuisance and passive smoking effect on other people..”*

**Clive Bates, former Director ASH**

*“..the death and disability toll from cigarette smoking is far too high not to be doing all that we can. The rise of a consumer movement, as I understand almost entirely consisting of ex-smokers, supporting the use of e-cigs is the first social-level evidence that there might now be substitutes for cigarettes that will be readily taken up by smokers. These and other strategies should be actively considered ..”*

**Professor Ron Borland, Distinguished Fellow in Cancer Prevention Cancer Council Victoria & Professorial Fellow School of Population Health & Dept Information Systems University of Melbourne**

*“..harm reduction strategies which allow smokers to substitute cigarettes with less hazardous sources of nicotine have the potential to prevent millions of avoidable deaths ... new nicotine containing devices such as e-cigs have the potential to provide an even less hazardous, and more effective, substitute for tobacco smoke. It is important that nicotine products are regulated rationally, affording market freedom in inverse relation to their hazard, rather than the status quo, in which the most dangerous product is freely available but less hazardous alternatives are not..”*

**Professor John Britton, Leader of Tobacco Advisory Group Royal College of Physicians**

*“..if one believes that tobacco/nicotine is here to stay, and nicotine is not a big health problem by the way, how can one not want the least harmful forms to be used..”*

**Dr Karl Fägerström, Founding Member Society Research on Nicotine & Tobacco & Deputy Editor Nicotine & Tobacco Research Journal**

*“.. around a billion people are addicted to nicotine in deadly cigarettes and many have no immediate plans to quit. Young people will also continue to try dangerous and addictive products. We believe it is preferable that, if people become addicted to cigarettes or decide to try tobacco, they can use a product that is markedly less harmful than cigarettes. [...] ...we should be prepared to accurately inform smokers about the relative risks of cigarettes ... e-cigs and approved smoking-cessation medications. In light of all the available evidence, banning or exaggerated opposition to e-cigs in cigarette-rife environments is not sound public-health policy..”*

**Professor Jonathan Foulds, Professor of Public Health Sciences & Psychiatry, Penn State University, College of Medicine**

*“.. cigarette smoking is a huge cause of death due almost entirely to the repeated inhalation of the products of combustion. There are products currently available that can substitute for cigarettes without inhalation of smoke ..”*

**David Swenor, Adjunct Professor (Law Faculty of Law) University of Ottawa & Special Lecturer, Division of Epidemiology and Public Health, University of Nottingham**

*“..THR is still the best kept secret in global public health and hundreds of millions of lives could be saved if THR strategies, science and products were to be adopted ..”*

**Dr Delon Human, President & CEO Health Diplomats**

25 February 2013