

EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Deputy Director General for Consumers and Health

Brussels, Sanco.ddg1.d.4/IPK/ed (2014)124951

Dear Dr Le Houezec and colleagues,

Subject: Scientific declaration on TPD

Thank you for your mail of 17 January addressed to Commissioner Borg. I reply in my function as responsible Deputy Director General.

Before I reply to the issues raised, let me underline that I appreciate your active engagement in the discussions on e-cigarettes. Also I would like to clarify that the final text agreed is essentially the compromise found by the co-legislators, i.e. the European Parliament and the Council. The role of the Commission is limited to facilitating the negotiations, but we fully support the agreement reached. In particular we welcome the efforts to establish high quality and safety standards for electronic cigarettes.

In your mail you suggest that the established maximum nicotine threshold is not an appropriate one for a smoker trying to give up smoking. In this respect I would like to emphasise that various studies — including from scientists that signed the letter - indicate that electronic cigarettes with such a nicotine threshold or below help the vast majority of smokers. Also when setting the threshold, the co-legislators took other considerations into account, such as the need to protect children against exposure to nicotine etc.

In your letter you also argue that nicotine is less dangerous than often perceived. However, the co-legislators considered that nicotine is not a harmless substance. As a matter of fact nicotine is classified as a toxic substance under existing EU law. I would also point out that under the new Tobacco Products Directive (TPD) refill bottles containing up to 200 mg of nicotine will be allowed. This also explains the need for child and tamper proof opening mechanisms.

As regards the consistent nicotine dosing of electronic cigarettes, I would like to clarify that only puffs of the same strength would have to deliver the same amount of nicotine. Diverging degrees of nicotine intake depending on the puff strength would thus remain possible – similar to normal cigarettes. The co-legislators wanted the consumers to be informed of the nicotine dose and uptake and wanted to provide the authorities with a basis to assess the risk profile of a product.

Jacques Le Houezec

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¹ Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

Last but not least I would like to point out that the consumption pattern for electronic cigarettes seems to be rapidly changing. Already today we see that their consumption is no longer limited to established smokers. We also observe a high and increasing degree of experimentation by young people. This is why there was a consensus on the part of the co-legislators on the need to remain vigilant to prevent the product from developing into a gateway product.

For the sake of completeness we would like to ask for clarification whether the scientists that have signed the mail have undertaken research, provided consulting or received funding/travel support from electronic cigarettes companies. I think Honourable Members of the European Parliament would appreciate full transparency on potential conflicts of interest. Also they might be interested to know whether there are dissenting views to the opinions expressed in your letter.

Yours sincerely,

Martin Seychell

Cc: Rapporteur and shadow rapporteurs for the TPD in the EP