



To:

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Unit B2 'Prevention of technical barriers',
Directorate-General 'Internal Market, Industry, Entrepreneurship and SMEs'
Grow-Notif-Infractions@ec.europa.eu

Ministry of Social Affairs
Suur-Ameerika 1, 10122 Tallinn
E-mail: info@sm.ee, triinu.taht@sm.ee, el.teavitamine@mkm.ee

REGARDING THE DRAFT AMENDING THE ESTONIAN TOBACCO ACT

Lithuanian Confederation of Industrialists (LCI) is concerned regarding the draft amending the Estonian Tobacco Act (notification No 2019/280/EE-X00M) and expresses a strong opinion that Estonia should not ban heated tobacco products with characterising flavours.

According to the draft, a heated tobacco product cannot have a characterising flavour and the ingredients of a heated tobacco product must be without flavours. Banning heated tobacco products with characterising flavours would violate Articles 7(1), 7(12), 24(1) of the Tobacco Products Directive (TPD)¹. Article 7(1) and 7(12) of the TPD provide that Member States shall ban all cigarettes and roll-your-own tobacco with a characterising flavour. However, all other tobacco products, including heated tobacco products, are specifically exempted from this ban by Article 7(12) of the TPD. According to the Article 24(1) of the TPD, Member States shall not prohibit or restrict the placing on the market of tobacco products which comply with the TPD requirements. Heated tobacco products with characterising flavours comply with all TPD requirements and therefore their freedom of movement on the internal market should not be restricted by individual Member States.

Furthermore, banning novel tobacco products such as heated tobacco products with characterising flavours would undermine the competencies and procedure provided by Articles 7(12), 2 (28), 27 of the TPD. According to the Article 7(12) of the TPD, the European Commission shall under certain conditions and following a certain procedure have the power to adopt a delegated act to withdraw the exemption for a particular product category. National bans of products with characterising flavours would interfere with the competence of the Commission and undermine the procedure foreseen by the TPD. The above was confirmed by EU COM – DG SANTE in the meeting of the Group of Experts on Tobacco Policy on 21 March 2019².

¹ Directive 2014/40/EU of the European Parliament and the Council of 3 April 2014.

² https://ec.europa.eu/health/sites/health/files/tobacco/docs/ev_20190321_sr_en.pdf

What is more, LCI perceive a risk of distortion of competition. The proposed flavour ban would distort competition by putting heated tobacco products at a competitive disadvantage vis-a-vis other tobacco products, subject to the exemption of the Article 7(12) of the TPD, including other Novel Tobacco Products. The flavouring rules of these other tobacco products have been fully harmonised under the TPD, and as stated above, individual Member States should not further restrict these products. Where the TPD allows Member States to further regulate specific products, it is explicitly stated in the TPD rules – for instance, the flavouring rules for electronic cigarettes have explicitly not been fully harmonised and are subject to individual Member State regulation. Recital 47 of the TPD: “This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States.” However, this is not the case for heated tobacco products.

Furthermore, the statement that flavourings are prohibited in electronic cigarettes sold in Estonia, is not fully true. In reality flavourings can still be sold separately, mixed with e-cigarette liquid and then used in open tank e-cigarettes. In other words flavours are allowed for open tank e-cigarettes and banned for closed tank e-cigarettes. In the light of recent developments in US one should have in mind that the risk of possible intoxication is bigger in case consumers are mixing the liquid by themselves (open tank) vs the mixture of the liquid is controlled by manufacturer, reported to EU according to Directive and packed in a separate capsule, which can not be opened and closed again (closed tank). In other words the current situation in Estonia already distorts the competition and does not serve the public health agenda. Ultimately, the proposed flavour ban for heated tobacco would further distort the competition by putting also heated tobacco products at a competitive disadvantage vis-a-vis open tank electronic cigarettes sold in Estonia.

Also, according to the draft, similar restrictions, in terms of the consumption of tobacco products, are extended to heated tobacco products—consumption by people under the age of 18 is prohibited, a list of locations where their consumption is prohibited or restricted is extended to heated tobacco products. We would like to grab your attention that heated tobacco products are meant for adult smokers. The variety of available research demonstrates that heated tobacco products are used predominantly by adult smokers while non-intended audiences (non-smokers or youth) present negligible intention to use them. For instance, in the Technical Project Lead Review³, the U. S. Food and Drug Administration concluded that “although the data for IQOS uptake by never smokers, former smokers, and youth is limited, there are some data from countries where IQOS is marketed - Italy and Japan - which show low uptake by youth and current nonsmokers. In these countries, the likelihood of uptake is slightly higher in former smokers, but still low. Appropriately, the population most likely to use IQOS are current CC [combustible cigarettes] smokers.” Also, the independent studies by Swiss researches confirm negligible use of heated tobacco products by non-intended audiences⁴. Next, the results of an online survey conducted by the researchers from the Institute of Global Health, Faculty of Medicine, University of Geneva demonstrated that heated tobacco products were used only by

³ <https://www.fda.gov/media/124247/download>, page 12

⁴ Addiction Suisse, La consommation de substances psychoactives des 11 à 15 ans en Suisse – Situation en 2018 et évolutions depuis 1986, 28 March 2019 https://www.hbsc.ch/pdf/hbsc_bibliographie_342.pdf



smokers, mainly to replace cigarettes⁵. Additionally, researchers from American Cancer Society, using 2014-2018 monthly retailer data from Japan, analysed whether different dates of IQOS introduction across Japan's regions are reflected in the patterns of cigarette sales in those regions. The researchers concluded that "The example of IQOS in Japan demonstrates a circumstance in which cigarette consumption has likely been reduced via the introduction of an alternative non-combustible tobacco product. Definitively identifying that the introduction of a novel tobacco product is significantly changing the marketplace for tobacco products is important information for policymakers and public health proponents as they consider how to alter existing tobacco control policies to accommodate these new products"⁶.

Sincerely,
Executive Director

Ričardas Sartatavičius

U. Radžiūnaitė-Šutjevienė, ugne.radziunaite@lpk.lt

⁵ Queloz, Sébastien & Etter, Jean-François An online survey of users of tobacco vaporizers, reasons and modes of utilization, perceived advantages and perceived risks <https://bmcpublihealth.biomedcentral.com/articles/10.1186/s12889-019-6957-0>

⁶ Stoklosa et al. Effect of IQOS introduction on cigarette sales: evidence of decline and replacement. <https://tobaccocontrol.bmj.com/content/early/2019/06/11/tobaccocontrol-2019-054998?rss=1>

