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Public Consultation Nicotineproducten zonder tabak

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Dutch initiative to ban nicotine pouches is not based on proper assessments of health risks and might prevent smokers from using alternative products

Despite a comparatively stringent tobacco control, smoking prevalence in the Netherlands is still approximately 20%[1]. Although lower than in Germany, the proportion of smokers in the adult population is higher than in the United Kingdom (13%). Perhaps, one of the reasons is a notable difference regarding the use of alternative products. While the prevalence of electronic cigarette users in the Netherlands was only 1,1% in 2020[1], it is much high higher (7.1%) in the United Kingdom[2]. The comparatively low vaping prevalence in the Netherlands reflects a generally skeptical view of the Dutch government on e-cigarettes, accompanied with initiatives to ban flavors even in zero nicotine products. Consequently, e-cigarettes might become even less appealing as alternatives to smoking.

The proposed ban of oral nicotine products is fully in line with the official rejection of tobacco harm reduction. Again, there are notable parallels to e-cigarettes.

Firstly, e-cigarettes and nicotine pouches are considered to be less harmful than combustible cigarettes. For example, RIVM concluded in its recent report (RIVM-report 2020-0152: Nicotineproducten zonder tabak voor recreatief gebruik) that nicotine pouches are probably a less harmful alternative to smoking. The German Federal Institute for Risk Assessment (BfR) came to the same conclusion (BfR statements 042/2021, dated December 21st 2021 and 023/2022, dated October 7th 2022). Further, the BfR demonstrated that apart from traces of tobacco specific nitrosamines (TSNA) pouches contain no other harmful compounds except for nicotine (Mallock *et al.* Tob Control 2022, doi:10.1136/tobaccocontrol-2022-057280). In fact, TSNA have only been found in parts of the sample and only at levels much lower than in conventional tobacco products. Consequently, substantially lower risks are expected in respect to cancer, as well as cardiovascular and respiratory diseases in relation to combusted tobacco products. Most likely, nicotine pouches are the least harmful option to consume nicotine.

Secondly, use of e-cigarettes is limited in the Netherlands[1]. The same is true for nicotine pouches in all age groups (Havermans *et al.*, Drug Alcohol Depend 2021, 229:109136). Consequently, there is little reason to tighten the regulation of these products or to keep up a *de facto* ban by way of food classification.

The latter option is as questionable as an explicit ban. In food regulation, nicotine is limited to an insignificant level in order to protect the general population from an unintended uptake through ingestion (NB, assessing pouches from an ingestion perspective is already flawed, since the nicotine from pouches is taken up through the oral mucosa route). To define such "nonhazardous" ingestion, the European Food Authority (EFSA) had derived an Acute Reference Dose (ARfD: 0.0008 mg nicotine per kg body weight) based on the Lowest Observed Adverse Effect Level (LOAEL: 0.0035 mg Nicotine per kg bw). Importantly the underlying effect was a very mild and transient increase of the heart rate that might not be

considered adverse. The RIVM approach is even more stringent by estimating a ten-fold lower No Observed Adverse Effect Level (NOEAL: 0.00035 mg per kg bw) based on the LOAEL. According to this calculation, only an ingestion of 0.021 mg nicotine can be considered "nonhazardous" for a 60 kg person (although this was slightly increased to 0.035 mg, because only 60% of the ingested nicotine becomes bioavailable, i.e. reaches the blood[3]). Notably, the Dutch government is even more restrictive than EFSA, as calculations based on the ARfD would set such limit to 0.08 mg per pouch.

Again, these extremely low limits for nicotine are not meant to protect from toxicity, but to prevent any measurable effect due to an unintended ingestion *via* food. Importantly, this assessment framework is fundamentally flawed for pouches and any other nicotine product because it is not adaptable to an intended consumption of nicotine. Notably, the German BfR took reference to the more recent assessments by European Committee for Risk Assessment (RAC)/ECHA[4]. Accordingly, pouches could be considered as comparatively safe when properly regulated as nicotine product under tobacco legislation. Further, an Acute Toxicity Estimate (ATE) of 5 mg nicotine per kg bw (or 300 mg for a 60 kg person) was defined by RAC. Serious or lethal poisonings are not to be expected as typical pouches might contain up to 20 mg nicotine. RIVM did also confirm in its report that lethal poisonings are not expected for adults.

In fact, RIVM had initially considered regulation of nicotine pouches through the Tobacco Act, but not a ban. An appropriate regulation could for example impose an upper limit for nicotine and implement further measures of consumer and health protection.

The restrictive approach by the Dutch government towards alternative products could be obstructive to further efforts to reduce cigarette smoking. A very recent study has confirmed that smoking is less prevalent in countries with high adoption of alternative nicotine products (Fagerström, Harm Reduction Journal 2022, 19:131).

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Footnotes:

1 https://www.trimbos.nl/wp-content/uploads/2021/11/AF1898-Smoking-in-the-Netherlands-key-statistics-2020.pdf

2 https://ash.org.uk/uploads/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2021.pdf

3 https://www.nvwa.nl/onderwerpen/roken-en-tabak/verbod-op-nicotinezakjes-snus-zonder-tabak link: : onderzoek van het RIVM.

4 Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of Nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-yl]pyridine EC Number: 200-193-3 CAS Number: 54-11-5, CLH-O-0000001412-86-68/F.