British American Tobacco Denmark (A/S)
6 April 2022
Case 450
Consultation response

British American Tobacco Denmark A/S (BAT) hereby submits its consultation response to the Althingi Welfare Committee's consultation on the Act on nicotine products, e-cigarettes and refill containers for e-cigarettes, case 450.

Samantekt

BAT styður í grundvallaratriðum stefnumarkmið ríkisstjórnarinnar um að koma í veg fyrir reykingar og notkun barna á nikótínvörum sem eru ætlaðar fullorðnum. BAT fagnar úrræðum eins og heilsuviðvörunum fyrir nikótínpúða, aldurstakmörkum og banni við notkun púðanna á svæðum eins og skólum, sem mun stuðla að minni notkun nikótínpúða meðal ungmenna, án þess þó að draga úr mikilvægi púðanna sem skaðaminnkunarúrræði

Hins vegar er hætta á að sum ákvæði frumvarpsins, eins og bragðbann, grafi undan lýðheilsumarkmiðum frumvarpsins frekar en að efla þau. Bragðefni gegna lykilhlutverki í að auðvelda reykingamönnum að skipta yfir í minna skaðlegan valkost. Nikótínvörur og rafsígarettur með bragðefnum geta þannig skipt sköpum í baráttunni gegn tóbaksnotkun og stutt reykingamenn við að slökkva í sígarettunni. BAT telur því fyrirhugað bragðbann ekki aðeins vinna gegn skaðaminnkunnarhlutverki púðanna heldur að jafnframt sé með öllu óljóst hvaða bragðefni falla þar undir, á hverju það mat hvílir og hvernig það mat fer fram.

Auk þess er mikilvægt að styrleikaþakið sem lagt er til í frumvarpinu, þ.e. hversu mikið nikótín má vera í hverjum púða, vinni í átt að þessu sama skaðaminnkunnarmarkmiði. Til þess að púðarnir gagnist sem tól í baráttunni gegn tóbaksnotkun má ekki takmarka styrleika þeirra um of, ekki síst þegar horft til til stórreykingafólks. Í þessu samhengi bendir BAT á að Staðlastofnun Svíþjóðar, Svenska Institutet för Standarder, hefur úrskurðað að styrleikaþakið skuli vera 20 mg í hverjum púða. BAT styður þessi viðmiðunarmörk, ekki síst í ljósi þess að mörkin gera púðana að handhægum valkosti fyrir reykingamenn.

Ennfremur er mikilvægt að frumvarpið og meðfylgjandi reglugerðir veiti nægan frest til vinna að innleiðingu þeirra, selja núverandi birgðir og breyta framleiðslu. Eins og frumvarpið er nú lagt fram munu veigamiklir hlutar laganna öðlast gildi þegar í stað og veita framleiðendum og seljendum takmarkað svigrúm til að endurskipuleggja starfsemi sína. Það er mat BAT að frumvarpið í heild sinni ætti að taka gildi 12 mánuðum eftir samþykkt þess.

Background.

While BAT's non-combustible products are not authorised cessation devices, and nor are they marketed as such, reduced risk products ("RRP"[1]), such as nicotine pouches and e-cigarettes, can contribute to reducing smoking prevalence. There is therefore a potential public health benefit in eliminating cigarette smoke inhalation for people who continue to use nicotine, and there is a significant risk that this may be jeopardized by disproportionate restrictions.

[1] Based on the weight of evidence and assuming a complete switch from cigarette smoking. These products are not risk free and are addictive. This applies to all references in this document to a "less harmful product" or a "reduced risk product" any variation thereof.

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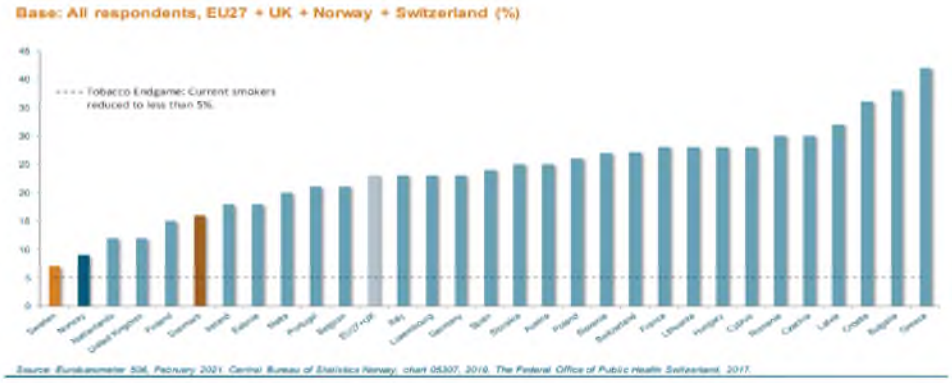
Sweden as an example

Sweden has used tailored marketing and sales regulations towards snus and nicotine products with great success. Sweden reported in 2017 the lowest national level of daily smokers across Europe measured by Eurobarometer.[2] The availability of snus and nicotine pouches in Sweden were a major contributing factor to the reduction in smoking prevalence. Norway has seen similar results with its somewhat recent growth in snus consumption, which has helped to reduce the number of smokers. The market share for snus in Norway rose from 4% in 1985 to 28% in 2012, while total tobacco consumption fell by 20.3% over the same period.



The regulatory framework should therefore mirror the relative risk of tobacco-free nicotine pouches compared to combustible cigarettes and more harmful products. A flexible regulatory landscape like Sweden and Norway supports the concept that smokers can transition to alternative nicotine delivery system with associated decreases in smoking prevalence.

On contents and flavours, Article 9.

For nicotine pouches and snus products to become a successful tool to lower smoking prevalence a variety of flavours must be present in the market, to allow for smokers to find a suitable alternative. A ban on flavoured nicotine pouches could therefore have unaccounted negative effects and discourage smokers from choosing a reduced risk product. Flavour variety is thus critical to provide all types of smokers with a suitable alternative to the consumption of cigarettes. Instead, to prevent use by youth, the use of nicotine products and e-cigarette descriptors on the packaging should be regulated so that they do not mislead, relate to lifestyle, appeal to youth or encourage trial and experimentation. Only factually descriptive flavour names should be allowed.

Adding to that, Vedoy & Lund from the Norwegian Institute of Public Health found that daily smokers and former daily smokers were more likely to use flavoured snus products compared to snus users without any prior history of smoking. A hypothetical ban or limitation of flavoured snus might then come to affect smokers more than non-smokers[3].

By removing flavours, the Government is essentially making a reduced risk product less favourable to combustible cigarettes which is not in line with the health policy objectives.

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[2] Eurobarometer, report 458, issued May 2017: March 2017 survey data.

[3] https://harmreductionjournal.biomedcentral.com/track/pdf/10.1186/s12954-020-00419-7.pdf

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On maximum strength and size of nicotine products, Article 8.

BAT supports setting a maximum level of nicotine in nicotine pouches. BAT suggests that the legislation should set a maximum level for nicotine content of 20 mg. per pouch, when it comes to nicotine pouches. As nicotine pouches are a new and, in many places, not specifically regulated but subject to general consumer safety regulation, there are examples of nicotine pouches from other manufacturers available in other countries with extremely high nicotine levels, which is neither responsible nor desirable.

It is worth noting that 20 mg per pouch is also the ceiling set in Sweden by the Svenska Institutet för Standarder and thus constitutes the Swedish standard for nicotine content in nicotine pouches.

A nicotine ceiling of 20 mg. per pouch is also what the Belgian Federal Agency for Medicines and Health Products provides as a rule of thumb[4].

In BAT's view, a ceiling of 20 mg. per pouch and 20mg/ml of nicotine-containing liquid constitutes a similar amount of nicotine to cigarettes to be a valid alternative to heavy smokers.

BAT also wants to highlight the need for separate regulations when establishing maximum nicotine for nicotine products such as nicotine pouches and for e-cigarettes because nicotine pouches do not contain electrolyte liquid.

Therefore BAT proposes a focus on "dose per serving (pouch) instead, for products without e-liquids.

This is because a maximumconcentration is easily manipulated by simply adding weight to the pouch. If the maximum nicotine is defined by concentration, as currently proposed, it would be possible to change the concentration solely by changing the weight of the nicotine pouch.

For example, a 6mg. nicotine per pouch would be banned because the weight of the pouch is relatively small, while a 30 mg. nicotine per pouch could be allowed by adding grams of weight to the pouch.

As not all ingredients from a fresh pouch are extracted during use, the concentration of nicotine in the extract is greater than originally in the pouch.

Therefore, BAT believes that nicotine products, such as nicotine pouches, should have limit of 20 mg. pr. pouch/serving

BAT proposes the following wording: *Ráðherra skal í reglugerð kveða á um leyfilegan hámarksstyrkleika nikótíns í nikótínvöru, að hámarki 20 mg. í hverjum nikótínpúða.* ~~*Við ákvörðun um hámarksstyrkleika skal líta til þess að upptaka nikótíns úr vöru sé ekki meiri en fæst af leyfilegum hámarksstyrkleika í rafrettuvökva.*~~

On commencement of the act, Article 21.

BAT proposes that the act enters into force on 12 months after adoption. Several of the proposed changes to the Act will require BAT to change production while also require time to sell what has already been produced.

This process usually takes 9-12 months including a market-cleaning period for producers and retailers to empty stocks without taking significant losses.

[4] https://www.famhp.be/en/news/nicotine_pouches_are_no_longer_considered_to_be_a_medicinal_product

Furthermore, it's important that the regulation provides due time to sell current stock and change of production for the sake of local retailers. As the bill is currently proposed, important parts of the legislation will enter into force immediately and provides no planning ability for the manufactures. In consequence this means months of out of stock on all nicotine products for retailers for months. The bill in its entirety should therefore enter into 12 months after adoption.