

February 24, 2020

Sent via: hc.pregs.sc@canada.ca

Dear Mr. Van Loon,

JUUL Labs Canada Ltd. ("JUUL Labs") welcomes the opportunity to participate in the Health Canada Market Research Survey on the proposed change to lower its nicotine concentration ceiling to 20 mg/ml.

JUUL Labs's mission is to transition Canada's five million adult smokers away from combustible cigarettes while combating underage use. Our ability to accomplish that mission is predicated on us earning the trust of society and working cooperatively with regulators, policymakers and stakeholders, including Health Canada, to combat underage use of Vaping Products, while providing viable alternatives to adult smokers.

JUUL Labs believes that the proposed regulatory change to nicotine concentration is counter to these shared public policy goals. To transition smokers away from combustibles, Vaping Products must provide a satisfying alternative, including a nicotine delivery that can compete with cigarettes. A 20 mg/ml cap would result in the removal of the vast majority of such Vaping Products from the market; undermining the risk reduction opportunity for both current adult smokers, as well as former adult smokers who have successfully transitioned to vaping. In addition, the scientific evidence to date does not indicate that a 20 mg/ml cap on nicotine concentration will reduce or combat underage usage. We believe there are more effective youth prevention measures aimed at limiting appeal and restricting access that specifically target underage use while preserving access for adult smokers.

While the survey deals largely with matters of finance and economic impact, we believe it is far more important to consider the public health impact of such a policy. As such JUUL Labs would respectfully request that Health Canada consider the following when reviewing the proposed policy re: 20 mg/ml.

NICOTINE CONCENTRATION AND HARM REDUCTION

100 Canadians die each day from smoking-related illness.¹ According to the World Health Organization, more than eight million people die from tobacco use per year globally, and prior to the recent introduction of vaping technology, cigarette prevalence rates had largely flatlined. From 2013 to 2017, cigarette volume declines in Canada averaged only 3% per year.² Data sourced from Statistics Canada

¹https://www.canada.ca/en/health-canada/services/health-concerns/tobacco/legislation/tobacco-product-labelling/smoking-mortality.html

² Euromonitor



and analyzed in a recent C.D. Howe Institute Intelligence Memo demonstrates a significant decline of 8.5% (population-adjusted) in cumulative past-year sales of cigarettes coinciding with Vaping Products becoming federally legal for sale in June 2018.³

Despite this, over five million Canadians continue to smoke combustible cigarettes. To be clear, nicotine is addictive and can be harmful, and people who do not already use nicotine should not start. Those who do use tobacco and nicotine products should quit. However, JUUL Labs believes those Canadians who cannot or will not quit smoking have a right to access less harmful, alternative products.⁴

In order to maximize the harm reduction potential of Vaping Products, they should be permitted to deliver levels of nicotine comparable to cigarettes to satisfy smokers' cravings and to promote moving away from cigarettes entirely.

Multiple public health authorities have addressed this issue in public statements. For instance, the World Health Organization's 2019 Tobacco Regulation Working Group Report states:

"The nicotine delivery profile of Electronic Nicotine Delivery Systems [ENDS] may be an important determinant of how effectively the product can substitute for a cigarette for a long-term smoker." 5

"As nicotine flux is the primary determinant of the capacity of ENDS to substitute for nicotine from cigarettes, regulators should consider this factor in endeavours to maximize the nicotine substitution potential of ENDS technology."

The Royal College of Physicians in the UK highlights that "the ideal harm-reduction device should deliver nicotine in a manner as similar as possible to cigarettes, while at the same time maximizing palatability and nicotine delivery to approximate the experience of cigarette smoking more closely."

The U.S. Food and Drug Administration (FDA) has recognized the importance of comparative nicotine delivery as an important factor in helping smokers transition away from cigarettes. In its technical project review of the IQOS PreMarket Tobacco Applications (PMTA), in which the FDA authorized the product for sale in the U.S., the FDA noted:

"PK studies show Marlboro, Smooth Menthol, and Fresh Menthol Heatsticks have nicotine delivery, addiction potential, and abuse liability similar to combustible cigarettes (CC). This is potentially beneficial for smokers trying to switch to IQOS as they are more likely to have satisfactory results and not resume CC smoking. The nicotine levels do pose an addiction risk for non-tobacco users who initiate use of these products; however, the

³ https://www.cdhowe.org/intelligence-memos/ian-irvine---vilification-vaping

⁴ https://www.macleans.ca/news/canada/closing-insite-would-violate-charter-supreme-court/

⁵ WHO's Tobacco Regulatory Study Group (TobReg) 2019 report, pp. 35

⁶ Ibid, pp. 62

⁷ Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP, 2016.



risk is no higher than for other, currently available, tobacco products and initiation is expected to be low generally."8

Our clinical studies of adult smokers have also found that after using a 5.0% JUULpod (59 mg/ml), participants reported a reduction in the urge to smoke cigarettes that, while less than the reduction after smoking their usual brand cigarette, was still statistically significant. In an independent study comparing other Vaping Products with lower nicotine concentrations than a 5.0% JUULpod or at the EU Tobacco Products Directorate limit of 20mg/mL, the use of a 5.0% JUULpod relieved the urge to smoke and was rated significantly higher in several other subjective effects.⁹

JUUL products offered in a range of nicotine strengths have the potential to transition adult smokers away from cigarettes by offering a sufficiently satisfying alternative nicotine delivery system. Based on published research, approximately 50% of survey respondents who were adult smokers fully switched from combustible cigarettes to JUUL products at 6 months after first use. ¹⁰ That number increases over time, up to approximately 55% at 12 months.

We are currently in the process of collecting data about switch rates among users of JUUL products with under 20mg/ml nicotine concentration and look forward to sharing those results when available. A UK study published in the journal Addiction suggested the experience of a JUUL with a JUULpod liquid concentration of 5% may be more effective than NRTs and older types of Vaping Products for switching adult smokers. They explain that the subjective and central effects would contribute to its effectiveness, but that more research must be done in order to understand the magnitude and efficacy in comparison to NRTs.

For Vaping Products, actual nicotine delivery is affected by a combination of factors, including:

- The nicotine content of the liquid;
- The product's characteristics (e.g., ingredients and heating temperature); and,
- User behaviour.

Limiting nicotine concentration in e-liquids may not restrict the amount of nicotine actually delivered and could present additional adverse health consequences. For instance, some Vaping Products allow the device temperature to be increased, which may deliver more nicotine than at lower operating temperatures. But the increased heating temperature may also result in the formation of additional

⁸ FDA Technical Project Lead Review on IQOS PMTA application: https://www.fda.gov/media/124247/download, page 11.

⁹ Hajek *et al.* 2020. Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products. Addiction.

¹⁰ Russell *et al.* 2019. Factors associated with past 30-day abstinence from cigarette smoking in adult established smokers who used a JUUL vaporizer for 6 months. Harm Reduction Journal.

¹¹ Hajek *et al.* 2020. Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products. Addiction.



toxicants.¹² The JUUL device is specifically designed to operate at low temperatures (< 300°C) to minimize the formation of toxicants and produce less aerosol than many other ENDS, while still delivering nicotine at levels to satisfy adult smokers and facilitate their transition from combustible use.

In addition, adult vapers may also modify their behaviour, including increasing their frequency of use, in order to compensate for the lower nicotine yield. Studies show that in lower-strength nicotine Vaping Products, users sometimes engage in behaviours (more or stronger puffs) that allow them to obtain more nicotine, but also increase their exposure to aerosol. Restrictions of nicotine content in e-liquid may therefore not be the ideal mechanism to achieve the government's stated goals.

LOWERING THE NICOTINE CONCENTRATION CEILING AS A YOUTH USE DETERRENT

There remains no definitive scientific evidence that reducing the nicotine concentration limit in vaping liquids will reduce youth use of Vaping Products. This regulatory proposal is heavily influenced by practices observed in the European Union (EU) and more specifically, in the UK. However, it is critical that policymakers examine how various UK policies, particularly comprehensive public education campaigns, impact underage use of Vaping Products.

These include:

- Public Health England remains committed to educating the public on the harms and benefits of Vaping Products, and their role in transitioning adult smokers away from combustible cigarettes.
- The UK has significantly restricted advertising from vaping companies but, unlike Canada, proactively provides public health campaigns/educational tools, encouraging smokers to quit or transition to Vaping Products.
- The UK has a regulatory mechanism in place to keep only approved devices and liquids on the consumer market.

The 20mg/ml nicotine concentration ceiling was introduced by the EU Tobacco Products Directive. Recent surveys and research have shown that other EU countries with a 20 mg/ml cap, that have not utilized complementary policies like the UK policies outlined above, have shown increases in youth use

¹² N. Voos, et al., What is the Nicotine Delivery Profile of Electronic Cigarettes?, Expert Opinion on Drug Delivery (2019)

¹³ Kośmider, Leon, et al. "Compensatory Puffing With Lower Nicotine Concentration E-Liquids Increases Carbonyl Exposure in E-Cigarette Aerosols." Nicotine & Tobacco Research, vol. 20, no. 8, 2017, pp. 998–1003., doi:10.1093/ntr/ntx162.

¹⁴ Soar, K., Kimber, C., McRobbie, H., Dawkins, L.E. "Nicotine absorption from e-cigarettes over 12 months." Addictive Behaviors, Vol. 91, April, 2019, pp. 102-105.



of Vaping Products. Germany¹⁵, Spain¹⁶, Italy¹⁷ and Iceland¹⁸ have all shown significant increases in youth use of Vaping Products in the last one to two years. In the case of Italy, peer-reviewed research illustrated that the introduction of the 20mg/ml limit did not have a significant effect on deterring youth uptake.¹⁹

Taken together this data indicates that, utilizing the European model of 20 mg/ml is not a policy that is likely to be effective in deterring youth use of Vaping Products in Canada in the absence of other regulatory tools, especially relative risk communications. This policy does not address the reason youth want to access Vaping Products, which the majority of respondents to the 2019 US National Youth Tobacco Survey identified as curiosity.²⁰

There are a multitude of regulatory tools available which can strongly impact sales to underage users without compromising vaping products for adult smokers. One tool which JUUL Labs believes has been under-examined in Canada is the use of computerized access control at point of sale (POS), where POS hardware will lock out a purchase unless a valid ID is scanned by the terminal. To impact social sourcing, bulk purchase limitations can also be implemented. In a pilot study, the overall failure rate for ageverification compliance fell from 36.8% for JUUL purchases before implementing such a system to 0.2% after implementation.²¹

JUUL Labs continues to support a variety of policies which are more likely to combat youth access and appeal of Vaping Products, including: purchase limits to combat social sourcing, enforcement, social reference pricing, appropriate taxation, and limitations on advertising.

POPULATION LEVEL IMPACT

A 20mg/ml nicotine cap is likely to drive Canadian Vaping Product users back to cigarettes, as well as deter existing adult smokers from transitioning to reduced harm alternatives.

 $^{^{15}} https://www.drogenbeauftragte.de/presse/pressekontakt-und-mitteilungen/2019/iv-quartal/drogen-und-suchtbericht-2019-erschienen.html$

¹⁶http://www.pnsd.mscbs.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2018-19 Informe.pdf

¹⁷ Gorini *et al.* 2019. Prevalence of tobacco smoking and electronic cigarette use among adolescents in Italy: Global Youth Tobacco Surveys (GYTS), 2010, 2014, 2018. Preventative Medicine.

¹⁸ Kristjansson *et al.* 2019. Do population trends in adolescent electronic cigarette use coincide with changes in prevalence of cigarette smoking? Preventative Medicine Reports.

¹⁹ Gorini *et al.* 2019. Prevalence of tobacco smoking and electronic cigarette use among adolescents in Italy: Global Youth Tobacco Surveys (GYTS), 2010, 2014, 2018. Preventative Medicine.

²⁰ Wang *et al.* 2019. Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019. MMWR. Surveillance Summaries

²¹https://newsroom.juul.com/pilot-study-of-racs-program-shows-dramatic-improvement-in-retailer-compliance/



JUUL Labs has approximately 70% market share of the sales of Vaping Products in Canadian Gas and Convenience retailers (C&G).²² Approximately 90% of JUUL Labs' customers use 5.0% (59 mg/ml) and 3.0% (35 mg/ml) JUULpods, which would be removed from the market if this policy is implemented.

As previously outlined, eliminating these nicotine concentrations will likely result in a reduction in adult smokers transitioning to Vaping Products and an increase in current users returning to cigarettes. Using available data, it can be hypothesized that a reduction to the current nicotine ceiling (66 mg/ml) will cause tens of thousands of adults in Canada who use Vaping Products to return to smoking cigarettes.

- Over a million adults in Canada use Vaping Products.
- Following the introduction of the Tobacco and Vaping Products Act, the proportion of adult Canadian vapers using products above 20mg/ml is estimated at approximately 75%.
- Approximately 90% of JUUL Labs' adult customer-base use products that are over 20mg/ml (which is similar for the sales of all closed systems, across most vaping brands).
- Online sales data has shown that approximately 44% of customers who used 3.0% or 5.0%
 JUULpods and then purchased the 1.5% concentration JUULpods subsequently returned to 3.0%
 or 5.0%.
- If nicotine products are not available for adult users at nicotine levels which they want or need, we estimate that a significant proportion of them would return to combustible cigarettes in an effort to find a satisfying source of nicotine.
- In a conservative estimate, even a 10% "cigarette return rate", of just JUUL Labs' adult customer-base, could result in over 45,000 adults returning to cigarettes. Based on our online sales data, we believe the "cigarette return rate" could be significantly higher.

As such, JUUL Labs strongly cautions Health Canada that a nicotine concentration cap of 20mg/ml could drive a significant number of adult Vaping Product users back to combustible cigarettes. JUUL Labs strongly urges the Government to consider adopting alternative regulatory tools which both assist adult smokers looking to transition off of cigarettes and bar youth from initiating on Vaping Products.

CONCLUSION

Governments can, and should, use regulatory tools granted to further restrict underage access to Vaping Products. In addressing that issue, it is critical that we also preserve adult smoker access to Vaping Products and continue to foster the harm reduction potential these devices can have in helping to continue lower smoking rates in Canada.

As always, JUUL Labs is prepared to work in collaboration with Health Canada to provide adult smokers with an avenue to transition away from cigarettes and reduce underage usage of our and all Vaping Products.

²² Nielsen Syndicated Data, C&G Excluding Newfoundland – Week Ending January 4th



Sincerely,

Michael Nederhoff

President

JUUL Labs Canada Ltd.



Regulatory Option on Limiting Nicotine Concentration in Vaping Products – Consultation on Potential Costs to Manufacturers and Importers of Vaping Products

February 10, 2020

Introduction

Health Canada is currently exploring a regulatory option that would limit the concentration of nicotine permitted in vaping products to 20 mg/g. This follows a public consultation held in spring 2019 on possible approaches to addressing the rapid rise in youth vaping (see https://www.canada.ca/en/health-canada/services/publications/healthy-living/consultation-summary-reducing-youth-access-appeal-vaping-products.html).

This questionnaire is intended to help Health Canada assess the potential impacts this option may have on manufacturers and importers of vaping products. We kindly ask that you provide your input by **Monday, February 24, 2020.** To return the completed questionnaire and/or for enquiries regarding the questionnaire, please email us at: hc.pregs.sc@canada.ca

We thank you in advance for your participation.

Note: If copies of the contributed information are requested under the *Access to Information Act*, personal information will be protected in accordance with the *Privacy Act*. Other information will be subject to the provisions of the *Access to Information Act*.

Self-Identification – Are you a manufacturer or importer? Please select all that apply:

Manufacturer (a business that manufactures finished vaping products, including the labelling, packaging and/or distributing of such products for sale in Canada, e.g. a vaping liquid manufacturer, a vape shop that makes its own vaping liquids, a business that, in addition to importing, also modifies vaping liquids, including by reformulating, repackaging or relabelling.)

Importer (a business that imports finished vaping products for sale in Canada, e.g. a vape shop that imports vaping products from another country directly, an importer that redistributes imported vaping products to Canadian clients)

If you identify as a manufacturer of vaping products in Canada, please complete the questions in SECTION I: MANUFACTURER, starting on page 3.

If you identify as an importer of vaping products in Canada, please complete the questions in SECTION II: IMPORTER, starting on page 6.

Please complete ALL the sections below that apply to you.



Section I: Manufacturers*

*Please only complete this section if you identified as a Manufacturer above.

1.	Do you manufacture vaping products in Canada, for sale in Canada, that contain greater than 20mg/g[1] of nicotine? If yes, please complete the remaining questions in Section I. If no, you do not need to complete the remaining questions in Section I.			
	Yes	No		
2.	. In 2019, of the nicotine-containing vaping products you manufactured in Canada, for sale in Canada, what percentage of units contained 20 mg/g of nicotine or less? What percentage of units contained greater than 20 mg/g of nicotine? A range is acceptable.			r less? What percentage of
	20 mg/g of nicotine or le	ess:		_ (% units)
	Greater than 20 mg/g o	f nicotine:		_ (% units)
 In 2019, how many vaping products did you manufacture in Canada, for sale in Canada, that a nicotine concentration greater than 20mg/g per product type? Pre-filled cartridge/pod: (quantity produced) E-liquid refill bottle: (quantity produced, by bottle size) Pre-filled device: (quantity produced) 			a, for sale in Canada, that had	
	Other, please specify:		- (quantity produc	ed)
4.	Since June 2018, what is greater than 20mg/g pe		r vaping products w	vith a nicotine concentration
	Pre-filled cartridge/pod E-liquid refill bottle: (mo Pre-filled device: (mont Other, please specify:	onths)	- (months)	
5.	one considered here co	mes into force. If a decis	ion is taken to ado	ed before a measure like the pt a measure that limits the , do you believe you would be

able to distribute/sell all your vaping products with a nicotine concentration greater than 20mg/g within 6 months? If yes, please go to question 7. If no, please go to question 6.



Yes

No

6.	(a) If a decision is taken to adopt a measure that limits the concentration of nicotine permitted in vaping products to 20 mg/g and you are unable to distribute/sell all of your vaping products containing a concentration greater than 20 mg/g nicotine within 6 months, what do you anticipate you will do with your remaining stock?				
	port it her, please specify:	Reformulate it	Dispose of it		
		et associated with your res ovide details on how you a	sponse in 6(a)? If so, how much our in arrived at this estimate.	do you estimate	
	Answer:				
7.	If a decision is taken to vaping products to 20	·	its the concentration of nicotine	permitted in	
(a)	Do you expect any loss	in total sales to your adul	t customers?		
	Yes No				
	If yes, what percentage swer with market resear		cted? Please explain why and su	pport your	
	Answer:	(% loss)			
	Explain:				
8.	margins between your		on profits if there are difference bove 20 mg/g and those at 20 mg ping products?	•	
	20 mg/g of nicotine or	less:	(%)		
	Greater than 20 mg/g	of nicotine:	(%)		



9. (a) Do you currently test nicotine concentration in your vaping products?				
Yes	No			
vaping products	s to 20 mg/g, would you	sure that limits the concentration of nicotine permitted in have to develop a testing methodology, or change the way in to ensure you are in compliance?		
Yes	No			
(c) If yes, how i	(c) If yes, how much do you expect this to cost? A range is acceptable.			
Answer:				
10. If a decision is taken to adopt a measure that limits the concentration of nicotine permitted in vaping products to 20 mg/g, are there other possible cost considerations to your business? Answer:				
11. Are there a Canada?	ny other matters related	to this proposal that you wish to highlight to Health		
Answer:				
ection II: Im	norters*			

Section II: Importers

*Please, only complete this section if you identified as an Importer above.

12. Do you import vaping products in Canada, for sale in Canada, that contain nicotine? If yes, please complete the remaining questions in section II. If no, you do not need to complete the remaining questions in Section II.



	ı			
	Yes	No		
13.	3. In 2019, of the nicotine-containing vaping products you imported in Canada, for sale in Canada, what percentage of units contained 20 mg/g[3] of nicotine or less? What percentage of units contained greater than 20 mg/g of nicotine? A range is acceptable.			
	20 mg/g of nicotine or less: 5.88% (% units)			
	Greater than 20 mg/g	of nicotine:	94.12% (% units)	
14. In 2019, how many vaping products did you import in Canada, for sale in Canada that nicotine concentration greater than 20 mg/g per product type?				
	Pre-filled cartridge/pod: (quantity imported) 11,323,910 packs containing 4 JUULpods each E-liquid refill bottle: (quantity imported, by bottle size) Pre-filled device: (quantity imported)			
	Other, please specify:		- (quantity imported)	
15.	Since June 2018, what greater than 20mg/g] of your vaping products with a nicotine concentration	
	Pre-filled cartridge/pod: (months) 3.2million packs per month E-liquid refill bottle: (months)			
	Pre-filled device: (mor Other, please specify:	· · · · · · · · · · · · · · · · · · ·	- (months)	
16.	considered here come concentration of nico able to distribute/sell	es into force. If a tine permitted in all your vaping p	s is usually provided before a measure like the one decision is taken to adopt a measure that limits the vaping products to 20 mg/g, do you believe you would be roducts with a nicotine concentration greater than go to question 18. If no, please go to question 17.	
	Yes	No		
17.	in vaping products to	20 mg/g and you	asure that limits the concentration of nicotine permitted are unable to distribute/sell all of your vaping products n 20 mg/g nicotine within 6 months, what do you	

Export it Reformulate it **Dispose of it**Return it to supplier Other, please specify: _____

anticipate you will do with your remaining stock?



(b) Do you anticipate a cost associated with your respons	se in 17(a)? If so, how much do you
estimate this cost will be? Please provide details on how y	you arrived at this estimate.

Answer: We estimate the cost of disposing 3.5 million packs of pods to be approximately \$100,000.

- 18. If a decision is taken to adopt a measure that limits the concentration of nicotine permitted in vaping products to 20 mg/g:
- (a) Do you expect any loss in total sales to your adult customers?

Yes No

(b) If yes, what percentage loss in total sales is expected? Please explain why and support your answer with market research, if available.

Answer: 82.4% loss (% loss)

Explain: Currently, products containing over 20mg/ml sales make up 87.1% of total sales. A recent consumer insights survey of adult JUUL users showed only 35% of 5% users and 70% of 3% users said they would be willing to try 1.5%. An E-Commerce study of JUUL user purchasing behaviour showed of the 5% users that bought 1.5% JUULpods, 6/7^{ths} returned to 5%, while 2/3rd of the 3% users returned to 3%. If we assume these trends are sustained, and 5 and 3% users could not find satisfaction in 1.5%, the percentage loss could be 82.4%.

19. We would also like to know the potential impact on profits if there are differences in profit margins between your products with nicotine above 20 mg/g and those at 20 mg/g or less. What is the average profit margin for the following vaping products?

20 mg/g of nicotine or less: Same margin (%)

Greater than 20 mg/g of nicotine: Same margin (%)

20. (a) Do you currently test nicotine concentration in your vaping products?

Yes No



(b) If a decision is taken to adopt a measure that limits the concentration of nicotine permitted in vaping products to 20 mg/g, would you have to develop a testing methodology, or change the way you currently test nicotine concentration to ensure you are in compliance?

	Yes	No		
(c) If yes, how much do you expect this to cost? A range is acceptable.				
	Answer:			
21.		adopt a measure that limits the concentration of nicotine permitted in ng/g, are there other possible cost considerations to your business?	1	
	smokers, this regulatory at costs close to C\$19M	ada Ltd. projects that, due to reduced demand from current adult change would necessitate the layoff of approximately 100 employee. It would also necessitate the reduction of spending in multiple el, spending with Canadian suppliers and vendors, etc. We estimate range of C\$17M.	s,	

22. Are there any other matters related to this proposal that you wish to highlight to Health Canada?

Answer: Comments provided in attached letter

^[1] The concentration of nicotine in mg/g is the amount of nicotine in mg per mass (g) of vaping liquid. It is sometimes expressed as a percentage, i.e. 20%. If you use mg/ml to characterize your products instead of mg/g or percentage, please use 20 mg/ml as a proxy for this questionnaire.

^[2] Turnover is defined as the average amount of time (months) it takes to distribute/replace inventory.

^[3] The concentration of nicotine in mg/g is the amount of nicotine in mg per mass (g) of vaping liquid. It is sometimes expressed as a percentage, i.e. 20%. If you use mg/ml to characterize your products instead of mg/g or percentage, please use 20 mg/ml as a proxy for this questionnaire.

^[4] Turnover is defined as the average amount of time (months) it takes to distribute/replace inventory.