Health Canada and JUUL Labs Canada Inc. meeting: Clarification regarding the proposed Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours) – August 5, 2021

Subject:

Clarification regarding the proposed *Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours)*, in particular, with respect to footnote 52 of the related Regulatory Impact Analysis Statement (RIAS).

Date:

August 5, 2021

Participants:

Health Canada (HC)

- Denis Choinière
  - Acting Director General, Tobacco Control Directorate (TCD), Controlled Substances and Cannabis Branch (CSCB) (Chair)
- Acting Manager, International and Regulatory Policy, Office of Policy and Strategic Planning, TCD, CSCB
- Acting Manager, Science Division, Office of Research and Surveillance, TCD, CSCB

- Manager, Vaping Regulations, Tobacco Products Regulatory Office, TCD, CSCB
- Policy Analyst, Office for Policy and Strategic Planning, TCD, CSCB (secretariat)

JUUL Labs Canada Inc. (JUUL):

- Lisa Hutniak
  - Head of External Affairs
- Glenn Thibeault
  - Director of Government Affairs

Introduction:

A meeting was held at the request of JUUL who was seeking clarification on the proposed *Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours)*, in particular with respect to footnote 52 of the RIAS.

The Chair opened the meeting by reminding JUUL representatives that the meeting is subject to disclosure as per Health Canada's Openness and Transparency policies. In the interest of transparency, the Department stated that it would be making a record of the meeting publicly available. The handling of information and privacy notice was mentioned and acknowledged.

The Chair also referred to Article 5.3 of the World Health Organization Framework Convention on Tobacco Control, Health Canada's international obligation to protect tobacco control policies from the vested interests of the tobacco industry. It was acknowledged by JUUL representatives.

The Chair then invited participants to introduce themselves.

Subjects:

In advance of the meeting, JUUL submitted four questions for Health Canada regarding footnote 52 of the RIAS. Footnote 52 reads as follows:

"*Note that interested parties that wish to have the lists of excluded flavouring ingredients amended, once the proposal has come into force, could submit their request to the Department. Those requests would be evaluated based on their alignment with the objective of the proposal.*"

The questions posed by JUUL are:

1. Will the Department be establishing a review committee for such requests, and if not, who specifically will be reviewing and approving the requests? Additionally, will guidance on the complete review process be provided, and by when?
2. How long will the evaluation process take to review requests; is this a one-time request process or can requests be submitted on an on-going basis?
3. If additional flavouring ingredient requests are approved, will the additional flavouring ingredients be publicly available to all manufacturers and the list updated accordingly?
4. What measures will the Department take to protect confidential commercial information, specifically when it comes to trade secrets?

Regarding question #1, Health Canada clarified that any regulated party, stakeholder or member of the public can make a request to Health Canada to suggest amendments to any regulations at any time. When such a request is received, Health Canada asks the requestor for specific information to substantiate the request, and conducts the review internally. It was noted that this would be the process Health Canada would follow *if* the Order Amending

Schedules 2 and 3 to the *Tobacco and Vaping Products Act* (TVPA) were to come into force and such a request was made to Health Canada.

Regarding question #2, Health Canada explained that the amount of time required for the review of any proposed change would depend on the nature of the change requested. Should Health Canada decide to move forward with making such a change, Health Canada would hold public consultations as part of the regulatory process. Health Canada added that there are no limitations on the number of requests an interested party can submit.

Regarding question #3, Health Canada explained that the Department does not currently have a mechanism in place to notify all interested parties when it receives a request to amend regulations. However, if Health Canada proposes any changes to Schedule 2 and 3 of the TVPA to include and/or exclude ingredient(s) or flavours, interested stakeholders would be notified as part of regulatory process and the changes to the Schedules would be made publicly available.

With respect to the last question, Health Canada noted that the Government of Canada has policies on the protection of Confidential Business Information but suggested that manufacturers should discuss confidentiality issues with their legal counsel prior to submission.

In closing, Health Canada indicated that it is the responsibility of manufacturers to ensure that the ingredients they use are safe for their intended use, as indicated in the RIAS. Health Canada invited JUUL representatives to submit any comments they may have regarding ingredients that should or should not be excluded from the proposed prohibition, set out in the proposed Order, before the public consultation ends on September 2, 2021.

Conclusion:

The meeting was then concluded.

Documents:

- Agenda as provided by JUUL