Nicopure Labs LLC Comments to the Draft Commission Implementing Decision on Technical Standards for the Refill Mechanism of Electronic Cigarettes ("Proposed Decision")

January 5, 2016

Nicopure Labs LLC is a leading, U.S. based manufacturer of e-liquids and vaping devices, with sales in over 65 countries. Nicopure Labs LLC American-made Halo and eVo liquids are distributed worldwide, and the company's leading e-liquid brand is distributed in the United Kingdom under the brand name Purity. The company also offers for sale the Reactor, Tracer, Triton and G6 vaping devices, which are refillable devices. Nicopure Labs LLC EU subsidiary is currently based in the Netherlands and an England-based subsidiary will be incorporated soon. Due to Nicopure Labs LLC's prominence among manufacturers, the company has a legitimate interest in the outcome of any EU legislative initiative, including the Proposed Decision.

Nicopure Labs LLC respectfully submits the following comments to the Proposed Decision.

1. General Comments

Nicopure Labs LLC welcomes harmonization and legislative efforts that provide consumer benefits while allowing innovation, consumer choice and support tobacco harm reduction. Nicopure Labs LLC is determined to lead the way with reasonable, constructive product standards that prioritize the greatest product concerns and do not unreasonably stifle innovation. As such, we will support clearly formulated and communicated initiatives that define the regulators' expectations of the industry and are clearly communicated. We also urge the Commission to ensure that all EU member states are aligned as to product standards, in support of the free circulation of goods and services and in the spirit of transparency and trust.

Any implementing act should allow sufficient technical feasibility that does not unduly burden the industry, taking into consideration the prevailing technology, practices and consumer preferences at present. Implementing acts should not mandate a specific technology, rather they should outline pass/fail tests carried out in accordance with accepted published standards that several design variations of the same product could meet. As an example, for packaging several standards organizations publish testing methods for package testing (such as the International Organization for Standardization and the European Committee for Standardization (CEN)). A general description of device characteristics such as the one in the Proposed Directive may be unclear to manufacturers and may yields vastly different safety outcomes with respect to consumers.

We therefore urge the Commission to defer the Proposed Decision implementation until such time that at least CEN develops a standardized test for leak-minimized refill under normal conditions of use. At that time the Commission's Implementing Decision could reference the respective testing method(s) available for compliance.

2. Specific Proposals

a. Preamble

Paragraph (3) should be amended to read: "Given the range of toxicological profiles and potential for dermal exposure to, or accidental ingestion of nicotine-containing liquids used in electronic cigarettes and refill containers [….]"

b. Article 2 – Requirements for the refill mechanism, paragraph 1

With respect to the requirement that the container nozzle be non-detachable, this requirement does not necessarily further the goals of the Proposed Decision, while at the same time placing undue restriction and burdens on container and e-liquid manufacturer. Furthermore, a non-detachable nozzle combined with a flow control mechanism results in a de facto ban on tempered glass containers, which are among the safest and most desirable containers, as they maintain e-liquid properties longer, prevent leakage and offer recycling alternatives. A snuggly-fitting nozzle would accomplish the same consumer protection goals without limiting manufacturing options. To be noted that various medicinals available in liquid form in the EU are distributed in glass bottles fitted with a detachable, yet tightly fitting plastic dropper. E-liquid product packaging requirements should not be more stringent than medicinals requirements.

Thus, the relevant language in Article 2 (1) (a) should read: "it entails the use of a refill container possessing a snuggly (or tightly)-fitting nozzle [...]"

With respect to device compatibility, it is our suggestion that the Commission take into consideration the likely scenario that consumers may choose to use e-liquids with different tank systems offered by various manufacturers, and therefore any design standards should strictly be applicable to the container and device that the respective e-liquid manufacturer recommends to be used together, not to any combination device/e-liquid.

Thus, the relevant language in Article 2 (10 (a) should read: "[…] into the opening of the tank of the electronic cigarette(s) that the manufacturer recommends the respective refill liquid to be used with […]"

With respect to the liquid flow when the container is placed vertically upside-down, we suggest that the paragraph be further clarified to ensure consistent application among manufacturers, as follows:

"[…] and possessing a flow control design that prevents the nozzle from emitting more than 20 drops of refill liquid per minute when placed vertically, in an idle state, and not squeezed, shaken or otherwise manipulated."

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We trust that our comments will support the Commission and national authorities in their decision-making process by providing a leading industry participant's practical view of the subject matter. We remain at your disposal should you require additional explanations.

Respectfully submitted on behalf of Nicopure Labs LLC,

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