AEMSA AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION

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Via Electronic Mail

Steven P. Cornish
Senior Director – International Policy
American National Standards Institute
25 West 43rd Street, 4th floor
New York, New York 10036

Re: Response to ANSI Proposal for E-Vapor Subcommittee Under TC 126

Dear Mr. Cornish:

The purpose of this letter is to provide you with our comments regarding the suggested ANSI position on the AFNOR proposal for a new field of technical activity at ISO on vape and vapor products ("e-vapor products"). Based on your August 19, 2015 e-mail, we understand that ANSI is proposing to support standard-setting for e-vapor products under a subcommittee of ISO/TC 126 on tobacco and tobacco products, as opposed to a separate ISO/TC for these products as AFNOR suggested. In our view, the proposed position ignores the substantive input that the ANSI ISO Council (AIC) received from U.S. stakeholders. AEMSA does not support the formation of an e-vapor subcommittee of ISO/TC 126, and instead reasserts its support for a separate ISO/TC for e-vapor products that has jurisdiction over standards for devices, e-liquids, and assessing nicotine in e-vapor products.

Based on our review of the comments received by the AIC, the proposed position of ANSI does *not* align with the position of the relevant stakeholders. In addition to AEMSA's, the majority of comments received by AIC support the formation of a new ISO/TC for e-vapor products. The most significant input comes from the Food and Drug Administration (FDA) – the federal agency that ultimately will control the regulation of e-vapor products in the U.S. – which has urged ANSI to support the creation of a separate ISO/TC for e-vapor products. FDA has clearly delineated the many ways in which it perceives e-vapor products to be "fundamentally different" from conventional cigarettes, both in design and use. To illustrate, FDA's comments to ANSI listed 11 engineering parameters for conventional cigarettes and 19 engineering parameters for e-vapor products that are *completely divergent*. It is clear that FDA views e-vapor products as being substantially different from tobacco products. This is critical for ISO to also recognize by creating a new, completely separate ISO/TC for e-vapor. Moreover, the Agency has discouraged ANSI from aligning the work with ISO/TC 126 due to its criticisms of the e-vapor standards this group has developed until now. FDA specifically pointed out that the fundamental stages of the work on the ISO/TC 126 e-vapor standards were critically lacking in

technical expertise. The Agency's comments, in fact, highlighted that e-vapor standards involve unique considerations and require expertise that differs from that found on ISO/TC 126.

Brief comments from Phillip Morris International (PMI), Richard Gast of Deere & Company (Deere & Company officially abstained from commenting), and the ISO/TC 126 Technical Advisory Group (TAG) appear to support developing e-vapor standards under the ambit of ISO/TC 126. We point out that Lauterbach and Associates, LLC has separately dissented from the TAG position, although it is a member of this group, to state that ISO/ TC 126 does *not* have the resources to develop the standards that will be needed for e-vapor products, and this work should be conducted under a separate ISO/TC. On the whole, the comments submitted to ANSI – most significantly FDA's – reflect the view that a separate ISO/TC should be developed for e-vapor products. ANSI appears to be following the recommendations of groups that have *not* fully substantiated or defended the rationale for a subcommittee under ISO/TC 126, while it has, essentially, ignored the well-reasoned and comprehensive arguments for a separate ISO/TC provided by FDA and AEMSA, the U.S. trade association that has been most prominently active at the federal level on e-liquid manufacturing standards.

Contrary to your August 19 email, ANSI's support for the creation of a subcommittee under ISO/TC 126 in no way reflects a compromise between those that prefer creation of a separate ISO/TC for e-vapor products and those that prefer creation of a subcommittee under ISO/TC 126. Moreover, given that ANSI appears to be advancing the idea that standards under the ISO/TC 126 subcommittee on e-vapor products would be developed "with distinct separation from other standards developed in other ISO/TC 126 subcommittees or working groups," it is unclear why the subcommittee approach is expected to be more efficient for stakeholders that have an interest in conventional tobacco products and e-vapor products. It would seem that interested members of ISO/TC 126 could just as easily contribute to a separate ISO/TC as they could to a subcommittee of ISO/TC 126.

In any event, the risks of creating a subcommittee under ISO/TC 126 far outweigh any benefits conferred by the approach. Any e-vapor standards developed under ISO/TC 126 are likely to be unduly influenced by the existing standards for traditional cigarettes and tobacco products. As FDA has suggested, a new ISO/TC is needed to facilitate the development of standards that are attuned to the technology of e-vapor products. There is no logical connection between e-vapor products and tobacco and tobacco products other than the fact that both products involve the consumption of nicotine (and e-vapor products do not always contain nicotine). In fact, as discussed in AEMSA's August 13, 2015 comments to ANSI, e-vapor products are more akin to medical devices than convention cigarettes. In this light, e-vapor standards development work may be just as appropriately housed under an ISO/TC dedicated to medical devices as under ISO/TC 126. Because e-vapor standards development will necessarily involve technical experts from a variety of fields besides those covered by ISO/TC 126 (e-vapor products entail electronic elements such as pressure sensors and activation buttons, heating coils, atomizers/cartomizers, and batteries) it is well-suited for its own ISO/TC.

Finally, in addition to AFNOR's proposed work on any ISO/TC (or subcommittee thereof) for e-vapor products, AEMSA is interested in actively participating on the committee as a knowledgeable expert stakeholder. AEMSA has demonstrated its qualifications to assist in standard setting for e-vapor products through its work on the AEMSA e-liquid standards that have been in place for nearly three years, and have been presented to FDA, the Office of Management and Budget (OMB), and at industry conferences around the world. Indeed, the AEMSA standards were explicitly referenced in AFNOR's original proposal on the e-vapor ISO/TC.

In sum, AEMSA does *not* support ANSI submitting comments to ISO indicating that a subcommittee of ISO/TC 126 will suffice, as this is in direct contradiction with the substantive comments that were received. AEMSA appreciates the opportunity to submit these comments to ANSI, and would be glad to discuss this matter further.

Respectfully Submitted,

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On behalf of:

AEMSA General Members:

1. 180 Vape – Travis Pharr
2. Chuckin' Clouds – Trishcia Braden
3. Ecigcharleston – Joe Atwell
4. EC Blend – Carol Williams
5. Eclipse Liquids – Steve Mazurek
6. Firebrand – Brian Gage
7. Hot Vapes – Tim Roche
8. J Vapes – Jourdan Wheeler
9. Madvapes – Scott Church
10. Mister E-Liquid – Dan Lawitzke
11. Molecule Labs – Michael Guasch
12. Mountain Oak Vapors – Steve Nair
13. NicVape – Richard Henning
14. NicQuid – Adam Knudsen
15. Purilum – Bianca Iodice
16. Tampa Vapor – John Synychak
17. Texas Select Vapor – Brett Coppolo
18. The Vapor Bar – Schell Hammel
19. The Vaper's Knoll – Richard Gue
20. Two Peas in a Pod – Orlan Johnson
21. VaporHQ – Adam Black
22. VaporShark – Brandon Leidel
23. Virgin Vapor – Annette Rogers

Subject Matter Experts:

1. Kurt Kistler, Ph.D.
2. Gene Gillman, Ph.D.
3. Konstantinos Farsalinos, M.D.
4. Richard Soltero, Ph.D.

Consumer Advocates:

1. Lou Ritter (President Emeritus)
2. Linc Williams (Secretary)
3. Jesse Ray
4. Matt Allen