AEMSA AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION

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Re: AEMSA Comments to TS/P 251 "Vape and Vapour Products" Submitted by AFNOR (France)

The American E-Liquid Manufacturing Standards Association (AEMSA) appreciates this opportunity to respond to the request by the American National Standards Institute (ANSI), the U.S. Member of the International Organization for Standardization (ISO), for comments on the French Standardization Agency, Association Française de Normalisation (AFNOR), proposal for a new field of technical activity on *Vape and Vapour Products*. On behalf of its e-liquid manufacturing Members, the purpose of this letter is to provide AEMSA's comments on the AFNOR proposal. As discussed below, AEMSA supports the AFNOR proposal to develop a new ISO technical committee (TC) specific to vape and vapor products (hereinafter referred to as "e-vapor" products) with the qualification that nicotine-specific standards for these products, which AFNOR has proposed to leave under the purview of TC 126 on tobacco and tobacco products, should also be the responsibility of the new TC on e-vapor products.

I. Background on AEMSA

AEMSA is the first and only manufacturers' trade association completely dedicated to creating responsible and sustainable standards for the manufacturing of e-liquids used in electronic cigarettes (e-cigarettes). AEMSA is an all-volunteer 501(c)(6) non-profit organization, formed by U.S. manufacturers of e-liquids, to promote safety and responsibility through self-regulation. Our Members believe we have a responsibility to self-regulate the e-liquid manufacturing process using professional criteria. One of AEMSA's primary goals is to provide consumers and government regulators with confidence that our members' products are manufactured in a safe manner until such time as FDA promulgates Good Manufacturing Practices (GMPs) for e-liquids. In this regard, AEMSA has developed manufacturing standards for e-liquids, which are available online at http://www.aemsa.org/standards/ and are attached hereto as **Appendix A.** AEMSA supports reasonable, responsible and science-based regulation of e-cigarettes, including open-system refillable personal vaporizers and the e-liquids used in those products.

In the 2.5 years it has been in operation, AEMSA has been a leading advocate for the vaping industry and community. AEMSA submitted comprehensive comments to the U.S. Food and Drug Administration (FDA) as well as the Office of Management and Budget (OMB) regarding the proposed "Deeming Regulation" which would treat e-cigarettes and their components as regulated tobacco products. AEMSA has also participated in four Listening Sessions with FDA, and submitted comments in conjunction with FDA's public workshops to gather scientific information about the public health impact of e-cigarettes. AEMSA, along with its world-renowned Subject Matter Experts (SMEs), is frequently invited to participate and present as speaker and panelists and industry events sponsored by TMA, and the Global Forum on Nicotine (GFN), among others.

II. AEMSA Supports the AFNOR Proposal With Specific Qualifications

The electronic cigarette (e-cigarette) is a revolutionary technology that has the ability to greatly benefit the public health, as it provides the first viable recreational alternative to tobacco for smokers of traditional cigarettes and other tobacco products. The need for standards that are specific to these "e-vapor" products (*e.g.*, e-cigarettes, e-liquids, and component products) is the reason why AEMSA was formed. For the reasons noted below, AEMSA generally supports the concept proposed by AFNOR that there should be a separate ISO TC for e-vapor products distinct from the existing TC 126 on tobacco and tobacco products, with certain important qualifications discussed below. Furthermore, we do not agree with the position of TC 126 that a separate TC is *unnecessary* because e-vapor products are a subcategory of tobacco products, nor do we agree that TC 126 already has the expertise to develop product-specific standards for e-vapor products.

While AEMSA generally agrees with AFNOR's position that a separate TC for e-vapor products is needed, AEMSA also urges an important modification to the AFNOR proposal. Specifically, AFNOR has proposed a work program for the new TC that includes (1) safety and quality requirements for e-cigarette devices and e-liquids; (2) test methods for devices and e-liquids; (3) testing conditions and equipment, reference products, quantification and qualification of emissions; and (4) user information and services provided by retailing, but would appear to *exclude* "all products that contain tobacco or nicotine." The AFNOR proposal explicitly notes that the determination of nicotine from e-liquids and the field of emissions assessment using routine analytical smoking machines are two areas that could be left to TC 126. We think such a bifurcated system does not make sense would not be effective. As highlighted below, it is AEMSA's view that all e-vapor products – both nicotine-containing products and products without nicotine – should be addressed by a *single* TC on e-vapor products. Moreover, we believe that determination of nicotine content in e-liquids and analysis of e-vapor emissions should be included in the work program of the new e-vapor TC. As discussed in further detail below, studies have demonstrated that smoking machines, as addressed under the existing TC 126 standards, are ill-suited for use with e-vapor products. In addition, the lack of experience of TC 126 in assessing e-liquids would adversely affect the ability of this group to

assess nicotine content in e-liquid products. Of course, AEMSA agrees with AFNOR that the existing TC 126 standards on analysis for nicotine and use of smoking machines can be consulted by the new e-vapor TC in the development of standards for e-vapor products.

Accordingly, AEMSA encourages ANSI to vote in support of the AFNOR proposal for a new TC on e-vapor products with the qualification that the new TC should have purview over *all* e-vapor products, regardless of whether they contain nicotine, and that the new e-vapor TC has the mandate to create standards for determining nicotine levels in e-liquids and analysis of emissions.

a. E-Vapor Products Are Distinct From Tobacco Products

E-vapor products are dramatically different from tobacco-leaf products. These products should be regulated differently by the U.S. Food and Drug Administration (FDA) (as discussed in Section d below), and should be considered distinct from tobacco products by FDA as well as ISO. While FDA has proposed to regulate e-vapor products in the United States under the ambit of the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act"), e-vapor products do not contain tobacco. The e-liquids used in e-vapor devices may contain nicotine, which is often derived from tobacco, but zero nicotine e-liquids have a substantial and growing segment of the market. On the contrary, traditional tobacco products contain leaves of the tobacco plant (*Nicotiana tabacum or Nicotiana rustica*), an agricultural product, along with hundreds of added chemicals and additives. For example, traditional cigarettes involve tobacco leaf, tobacco processing byproducts, and additives wrapped in paper that is sealed with glue and contains a cellulose filter, which is combusted by ignition at one end of the product and inhalation by the consumer at the other end. Such combusted products are the most harmful and dangerous tobacco products on the "continuum of risk" and should be treated as such. It is well established, for example, that the more pyrolyzed tobacco constituents a user inhales from a combustible tobacco product, such as a cigarette, the greater the risk of tobacco-related disease that product poses.[1] Of the approximately 5,300 chemicals identified in tobacco smoke, at least 60 are known human carcinogens, including polycyclic aromatic hydrocarbons (PAHs) and tobacco-specific nitrosamines (TSNAs).[2] E-vapor products are far less risky to individual users than tobacco/combusted products because they do not result in the inhalation of pyrolyzed chemicals.

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[1] See R.R. Baker, *et al.*, *The pyrolysis of tobacco ingredients*, 71 J. Anal. Appl. Pyrolysis 223-311 (2004).

[2] See Rodgman, A. and Perfetti, T.A., *The Chemical Components of Tobacco and Tobacco Smoke*, Boca Raton, FL: CRC Press (2009).

Furthermore, e-vapor products involve a completely different manufacturing process, completely different ingredients with completely different evaluations and considerations and standards, are manufactured by smaller entrepreneurial manufacturers and in no way resemble the evaluations and/or considerations of combustible tobacco cigarettes, cigars or pipes.

Thus, from a fundamental perspective, e-vapor products do not fall under the charge of TC 126 because they do not directly implicate tobacco or tobacco smoke.

More specifically, the new TC for e-vapor products should focus on establishing product, manufacturing, and testing standards that consider the rapidly evolving technology and the need to improve quality and safety. The primary areas of concern for these products is the safety profile of the aerosol inhaled by the consumer, *i.e.*, its chemical composition and toxicity, and the device design features that are being developed to enhance safety, *i.e.*, power control, temperature control and volumetric air flow rate measurement. In order to be able to predict the safety profile of e-vapor products, regulatory agencies must understand the chemical composition and potential toxicity of the inhaled aerosol, which will depend on a number of factors, including the manufacturing process, ingredients and impurity profile of the e-liquid, the materials and manufacturing methods used for the hardware components, the amount of wattage applied to power the devices and, importantly, the maximum temperature the device and its component parts (*e.g.*, coil) can reach during use. Identifying and establishing product and testing standards for each of these elements should be the goal of the TC for e-vapor products. The safety profile of tobacco products, on the other hand, can vary greatly simply because they are agricultural products, dependent on factors such as growing conditions and other uncontrollable natural variations. This is reflected, for example, by the existing TC 126 standard on pesticide residues in tobacco, ISO 4389:2000. Because e-cigarettes are *technology* products, however, the various processes and chemical reactions that occur during use can be identified and, ultimately, controlled.

b. Rapidly Evolving E-Vapor Technology Indicate the Need for Science-Based Standards and Good Manufacturing Practices

The original, modern e-cigarette was developed in the early 2000s in China and entered the U.S. market between 2007 and 2008. Those early products known as cigarette look-alikes, or "cigalikes," are very different from the vast majority of products on the market today. Compared to today's advanced open-system vaporizers, early disposable cigalikes are rudimentary. E-vapor technology has improved immensely since those first products entered the U.S. A few examples of the types of safety and engineering advancements that have now become common – thanks to the many innovative and entrepreneurial technology companies that make up the e-vaping industry – include improved battery and charger technology, variable power levels, auto-shut off capabilities, short-circuit and over/under-charge protections, temperature limitations, and e-liquid wicking and quality improvements. Moreover, e-liquids are also much less harmful

today (*i.e.*, they contain fewer unintended impurities, etc.) because the quality of ingredients and manufacturing processes have improved.

As the e-vapor industry continues to grow, regulatory agencies, such as FDA, should work with industry and standards-setting bodies, like ISO, and industry knowledgeable and experienced standards professionals with subject matter experts (SMEs) like AEMSA with the mission to develop science-based product standards and specifications for e-vapor products to ensure these products are produced in a safe manner and are not unnecessarily harmful to the health of consumers.

Many other industries have benefitted from this approach, and FDA has worked with standards setting bodies in the past in this very way. For example, in 2006 FDA issued an updated list of consensus standards recognized by the Agency for use in evaluating medical devices prior to receiving premarket approval for entry. The Food and Drug Administration Modernization Act (FDAMA) of 1997 authorized the Agency to recognize standards developed in an open and transparent process, such as those developed by ANSI-accredited standards developing organizations, as well as ISO and the International Electrotechnical Commission (IEC).[3]

Ultimately, with respect to e-liquids, product standards should be designed to ensure that the ingredients used are U.S. Pharmacopeia (USP)-certified (where applicable) and are suitably pure for their intended use (*i.e.*, the amount of impurities/contaminants do not exceed specified levels), that well-known impurities such as diethylene glycol and diacetyl, among others, are not detectable at appropriately sensitive analytical detection limits using standard test procedures, and that the concentrations of nicotine and other baseline ingredients are verifiable and accurate. Specific manufacturing environments, labeling, child-resistant and tamper-evident packaging and traceability should also be mandated for all (nicotine and non-nicotine containing) e-liquids sold to consumers. Furthermore, as detailed below, GMPs for e-liquids should be established based on AEMSA's manufacturing standards to ensure these products are manufactured in a safe manner.

Regarding e-vapor devices (hardware), standards should focus on the following core principles:

- The most important standard for government regulators to establish, using science based evidence, a regulatory maximum temperature limit that a vaporizer device may not exceed during operation, regardless of the e-liquid, airflow, or heater coil used. This is

[3] *See* ANSI, *FDA Issues List of Recognized Consensus Standards for Medical Devices*, available online at: http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=1190.

critically important because the breakdown of consumable e-liquids into potentially harmful substances is primarily a function of temperature. In other words, the chemical composition of the inhaled aerosol will largely depend on the temperature to which the e-liquid and internal vaporizer components (coil) are heated. Excessive heat may result in the formation of unintended impurities/degradation compounds, such as formaldehyde. In developing temperature standards, the new e-vapor TC should work with industry experts to determine if there should be one maximum temperature for all products, or whether it makes sense to have multiple temperature limits for specific product types or e-liquid (*e.g.*, if the e-liquid contains propylene glycol, then the internal temperature of the device should not exceed that which could result in the formation of formaldehyde – alternatively, the diluent ratio (VG/PG) can vary by liquid and differing ratios may also impact potentially considered maximum temperatures – as of yet scientifically undetermined).

- Products should incorporate standard safety features including, but not limited to, auto-shut off capabilities, short-circuit protections, and "smart charging" ability,[4] over/under-charge protections, and consumer safety features to prevent abuse/misuse (*i.e.*, child-proof packaging).

- All e-cigarette devices and components should incorporate electronic protections designed and constructed so that a short-circuit in the atomizer, improperly installed battery, incorrect battery, or any reasonably foreseeable error by the consumer (*i.e.*, using an unauthorized car charger) will not cause unacceptably elevated temperatures, charring, smoke, or fire.

- Batteries and chargers appropriate for use with e-vapor devices should be identified; the use of "smart chargers" designed to ensure devices/batteries will not over-heat or cause electrical damage to the device should be emphasized.

- E-cigarette devices and components should be required to meet standards similar to the European Union's Restriction of Hazardous Substances Directive 2002/95/EC (RoHS or RoHS2), which restricts the use of certain hazardous substances (*e.g.*, lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ether) in electrical and electronic equipment.

- Standards for the manufacture and use of the various e-cigarette component parts (*e.g.*, adapters, atomizers, cartomizers, clearomizers, batteries, chargers, tanks, endcaps, tubing, internal microprocessors/motherboards, springs, o-rings, drip-tips/mouth pieces, wicking

[4] Smart charging ability refers to technology typically found in smart phones that stops charging current flow to the battery when fully charged.

materials, and other device components such as internal connectors, buttons, casings, gaskets, seals, internal charging circuitry components, etc.) should be developed.

- Standards should be developed to ensure that the aerosol contains no more than determined maximum levels of identified impurities and/or toxicants.

- Guidelines should be developed for the safe handling of nicotine when mixing e-liquids in the home. Maximum nicotine content levels (*e.g.*, 10% or 100mg/ml) should be considered for direct to consumer Do-it-yourself (DIY) nicotine sales.

The new e-vapor TC may also consider creating manufacturing guidelines[5] for the safe production of e-liquids and devices. Standards for e-liquids should be based on AEMSA's well-established e-liquid manufacturing standards, which are available online (at http://www.aemsa.org/standards/) and included in **Appendix A** hereto.

As the first and only manufacturers' trade association completely dedicated to creating responsible and sustainable standards for the manufacturing of e-liquids, one of AEMSA's primary goals is to provide consumers with higher degrees of confidence that its members' e-liquid products are manufactured with professionalism, accuracy and in a safe manner until such time as formal GMPs are promulgated by government regulators. The core beliefs underlying AESMA's standards are that e-liquid manufacturers have the responsibility to:

- Verify the accuracy of nicotine content in e-liquid products;
- Ensure the quality of all ingredients in e-liquid products;

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[5] ISO has develop GMP-like manufacturing and safe handling guidelines for other product categories regulated by such as cosmetics, food and medical devices. For example, ISO/TS 22008-1:2009 "Prerequisite programmes on food safety – Part 1: Food manufacturing" addresses how to establish, implement, and maintain programs for controlling food safety hazards. Items addressed include a) construction and layout of buildings and associated utilities; b) layout of premises, including workspace and employee facilities; c) supplies of air, water, energy, and other utilities; d) supporting services, including waste and sewage disposal; e) suitability of equipment and its accessibility for cleaning, maintenance and preventive maintenance; f) management of purchased materials; g) measures for the prevention of cross-contamination; h) cleaning and sanitizing; i) pest control; j) personnel hygiene, as well as 1) rework; 2) product recall procedures; 3) warehousing; 4) product information and consumer awareness; 5) food defence, biovigilance, and bioterrorism. There is also ISO 13408-4:2005 on general requirements for clean-in-place processes applied to product contact surfaces of equipment used in the manufacture of sterile health care products. For this standard, the abstract notes that it is not intended to "supersede or replace national regulatory requirements, such as Good Manufacturing Practices (GMPs) and/or compendial requirements that pertain to particular national or regional jurisdictions."

- Prepare e-liquid products in a clean, sanitary and safe environment;
- Ensure e-liquid products are packaged and delivered in a safe manner; and
- Provide a level of transparency into the monitoring and verification process.

To assure that that the public health is protected and that e-liquids are manufactured in compliance with science-based safety standards, the new e-vapor TC should adopt GMPs based on these standards, which will ensure that e-liquids are not contaminated or manufactured in such a way that will result in the products being adulterated or misbranded.

c. Background on FDA Regulation of E-Vapor In the United States Indicating that FDA Should Regulate E-Vapor Products Distinctly From Tobacco-Containing Products

As the U.S. representative to ISO, it is important for ANSI to be familiar with the legal context in which e-vapor products may soon be regulated in the U.S. First and foremost, AEMSA supports FDA regulation of these products but, rather than acting through FDA's authority granted under the Tobacco Control Act, AEMSA believes that Congress should enact new legislation that specifically gives FDA the authority to regulate e-vapor products based on science and the various components, dynamics and considerations specific to e-vapor products, rather than simply treating them as a type of tobacco product. No such legislation is currently pending, however, and FDA appears to be moving forward with its "Deeming Regulation," which will capture all products that contain tobacco-derived substances (including nicotine) as regulated tobacco products subject to the Tobacco Control Act.

By way of background, the Tobacco Control Act amended the Food, Drug and Cosmetic Act (FDCA) to give FDA authority over tobacco products. That law broadly defined "tobacco product," in pertinent part, as anything made or *derived* from tobacco intended for human consumption. But, it only gave FDA immediate authority to regulate certain types of tobacco products (all of which contain tobacco-leaf): cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. Considering the many different types of tobacco products available (*e.g.*, cigars, pipe tobacco, hookah/shisha, etc.), the law also gave FDA the authority to promulgate a regulation to "deem" such other products to be *regulated* tobacco products. On April 25, 2014, FDA published the Notice of Proposed Rulemaking (NPRM) for the Deeming Regulation which, as noted above, will capture anything that contains tobacco-derived substances, potentially including e-vapor products with nicotine, as regulated tobacco products. It is important to recognize, however, that the Tobacco Control Act was established and enacted to limit and control tobacco, and never considered or even contemplated the myriad of relevant factors involved in the manufacture and/or use of e-vapor products (continuum of risk, manufacturing environments and processes, electronics and batteries, safety features, aerosols evaluations, no corporate vertical integrations, entrepreneurial manufacturers and vendors, innovations/safety incentives and considerations, different distributions and sales factors, etc.).

We understand that over 135,000 comments were submitted during the public comment period for the NPRM, and that FDA is still working to finalize the rule.

d. AEMSA Deeming Regulation Comments

It is clear that e-vapor products have only been brought under the Tobacco Control Act based on a strict textual interpretation of the Act's definition of "tobacco product," which broadly includes "any product made or derived from tobacco that is intended for human consumption." It is important to note that not all e-vapor products contain nicotine drawing them outside of the legal definition of "tobacco product" in the United States (similarly, nicotine-derived from non-tobacco sources would also fall outside the ambit of the Tobacco Control Act). Moreover, those e-vapor products that do contain tobacco-derived nicotine involve such vastly different issues than traditional tobacco products that it is inappropriate to group e-vapor products with tobacco products for purposes of ISO's standard-setting work.

AEMSA submitted comprehensive comments to the proposed Deeming Regulation arguing, along with many others, that because e-vapor products are dramatically different from traditional tobacco-leaf containing products, they should be regulated differently even under the Tobacco Control Act. It is for these same reasons that ANSI/ISO should consider e-vapor products separate from tobacco. In fact, as detailed in AEMSA's Deeming Regulation comments, there is much evidence to support the contention that FDA should use its "enforcement discretion" to develop regulations and standards that are *specific* to e-vapor products, rather than applying a "one-size-fits-all" approach to all products that fall under the broad statutory definition of tobacco product. Rather, regulations and standards should be tailored to the product type based on how harmful the product is. In other words, the regulatory burden for a product should be commensurate with its level of harm (*i.e.*, combustible cigarettes should be subject to a higher degree of scrutiny compared to e-cigarettes). In support of FDA taking such an approach, we note the following:

- There is ample statutory authority (both the plain language of the statute as well as its legislative history) to support the view that Congress did not intend FDA to rigidly apply the Tobacco Control Act requirements to those deemed tobacco products that do not contain actual tobacco leaf. Instead of requiring a "one-size-fits-all" approach for all tobacco products, whether or not they contain tobacco leaf, the statute leaves room for the Agency to tailor the requirements for each "other" tobacco product category that it chooses to regulate.

- Neither e-cigarettes nor e-liquids are mentioned anywhere in the Tobacco Control Act or its legislative history.

- The Tobacco Control Act is not a standalone piece of legislation, but amended the FDCA – a statute with a rich history, and one that FDA has always interpreted as providing

much rulemaking and enforcement flexibility. There are numerous examples of FDA using its rulemaking authority to find ways around strictures in the statute.

- FDA has displayed a willingness to exercise enforcement discretion with respect to implementing the Tobacco Control Act for products that are currently regulated.

- Strictly Applying the Tobacco Control Act's requirements to e-cigarettes and e-liquid products would result in the vast majority of these products being removed from the market, which will be tantamount to a ban which Congress did not intend.

- The primary purpose of the Tobacco Control Act is to reduce tobacco-related disease and death; the continued availability of e-vapor products as an alternative to much more harmful tobacco-leaf containing (and combusted) products is critical to achieving this public health goal.

AEMSA's Deeming Regulation and other public comments are available online on our website here: http://www.aemsa.org/public-testimony-and-comments/.

III. Establishing E-Vapor Product Standards: Role of ANSI/ISO

a. E-Vapor Products Are More Closely Associated with Medical Devices than with Traditional Tobacco Products

While recreational e-vapor products do not meet FDA's statutory definition of "medical device,"[6] because they are not *intended* for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animal,[7] it is clear that e-vapor products are more closely related to medical devices than traditional tobacco products, and FDA has shown that it shares in this assessment, as discussed below. This further makes clear that ISO should not consider these products to be a subcategory of tobacco products.

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[6] The definition of "device" is found in Section 201(h) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 321(h).

[7] We note that although e-liquid and e-cigarette products manufactured by AEMSA's Member companies may have the corollary benefit of helping tobacco cigarette smokers quit smoking or nicotine use altogether, these products are not intended to be smoking cessation devices or nicotine replacement therapies (NRTs), and are not marketed as such; rather these are recreational use products. See *Sottera Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). Although the available evidence demonstrates that most current e-cigarette users are using these products as an aid to help them quit or cut down on their use of traditional cigarettes, no claims to this effect are being made by AEMSA or any of its Member companies about their products.

FDA's view that e-vapor products are most similar to medical devices is evidenced by its earliest actions toward these products immediately following passage of the Tobacco Control Act. Specifically, FDA initially classified e-vapor products as drug delivery devices – a "combination product" that is comprised of a drug (here, nicotine) and a medical device. Based on this, FDA and Customs had several e-cigarette shipments from China seized at the border for being unapproved combination products/drugs. Those e-cigarette companies filed a lawsuit against FDA arguing that their products were actually not unapproved combination products/drugs at all, but tobacco products under the new Tobacco Control Act, which had just become law. The argument that the court ultimately agreed to in *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010) is that if an e-cigarette contains nicotine derived from tobacco and is "customarily marketed" for recreational use and not for any intended therapeutic benefit (such as to treat nicotine addiction or for smoking cessation), then such e-cigarette would fall under the broad "tobacco product" definition[8] under the new law, and would *potentially* be subject to FDA's tobacco authority if deemed to be regulated by the Agency. Since FDA issued its April 2014 proposed rule that would extend its Tobacco Control Act authority to cover e-vapor products (the Deeming Regulation discussed above), the Agency has continued to demonstrate its view that e-vapor products are most similar to medical devices – and *not* tobacco products. This further supports that ISO should consider e-vapor products distinct from tobacco.

In this regard, FDA's Center for Tobacco Products held a public workshop on "Electronic Cigarettes and the Public Health" where various stakeholders gathered to discuss the regulation of e-vapor products.[9] Throughout the public workshop, members of the e-vapor industry, researchers studying e-vapor products, and FDA regulators alike pointed out the distinctions between e-vapor products and traditional tobacco products. Moreover, there was substantial discussion of the similarities between e-vapor products and medical devices, including comments from a number of participants from FDA's Center for Device and Radiological Health (CDRH).[10] Below, we summarize several conclusions from FDA's workshop regarding the

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[8] The definition of "tobacco product" is found in Section 201(rr) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 321(rr).

[9] The public workshop was held December 10-11, 2014 at FDA's White Oak facility in Silver Spring, Maryland. The transcript for the workshop is available on FDA's website at http://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM429315.pdf (December 10, 2014) and http://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM429316.pdf (December 11, 2014).

[10] The participants from CDRH included the Director of CDRH, the co-leader of CDRH's Battery-Powered Medical Devices Working Group, and an official from the Office of Center Director for CDRH involved with medical device labeling initiatives.

differences between e-vapor products and traditional tobacco products, and the need to separately address the standards for these products.

1. E-vapor products are consumed differently from traditional tobacco products

During FDA's December 2014 Workshop, academic researchers specifically pointed out that the ISO standard for testing conventional cigarettes is not applicable to e-vapor devices due to differences in use behavior for these products.[11] Specifically, assumptions regarding the volume and duration of puff that are used to test conventional cigarettes are not considered to be consistent with the use of e-vapor products. Specialized research is currently underway to identify how to best model the amount of aerosol inhaled and the emissions involved with the use of e-vapor products.

Standards developed in this area will require specialized expertise, not just pertaining to the biological gas pathways of breathing circuits, but also related to the atomizer/cartomizer design, heating element coil design, pressure sensors, and electronic circuitry of e-vapor devices, as well as the chemical composition of e-liquid products. This work is best housed under a TC that is composed of experts from the e-vapor industries.

For this reason, AEMSA is urging a modification to the AFNOR proposal to make clear that the assessment of e-vapor emissions should be addressed by the new e-vapor TC, not TC 126. In this regard, specialized understanding of the consumption and composition of e-vapor products is needed to adequately analyze e-vapor emissions.

2. E-vapor devices implicate design issues that are different from traditional tobacco products

As highlighted above, design issues around e-liquid cartridges and wicking elements must be considered in standard-setting for e-vapor products. However, this work falls completely outside of the realm of traditional tobacco and tobacco product standards.

The design considerations for e-vapor devices are more akin to considerations for medical device products than considerations for cigarettes, which are composed of agricultural material. For example, stakeholders have identified extractables and leechables from e-liquid cartridges as a chief concerns for e-vapor devices. None of the standards housed under TC 126 are directly relevant to this concern. On the other hand, ISO 10993-17:2002 ("Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable

[11] ISO 3308:2012 defines the smoking parameters and standards conditions for routine analytical machine smoking of cigarettes.

substances") addresses the determination of substances that may leach from medical devices, and describes a process for quantifying the toxicological risks from hazardous substances present in a medical device. ISO 10993 is managed by ISO/TC 194 on the biological and clinical evaluation of medical devices.

Another factor related to e-vapor product design is determining the shelf life of the e-liquids in light of exposure conditions, including misuse of the products. While TC 126 has not dealt with shelf-life issues for tobacco and tobacco products, other ISO TCs have dealt with this issue for medical device and other consumption oriented products. In this regard, TC 172 has developed ISO 13212:2014 ("Ophthalmic optics – Contact lens care products – Guidelines for determination of shelf-life"), and TC 212 has developed ISO 23640:2011 ("In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents").

It also bears noting that many e-vapor companies report selecting ISO 13485 ("Medical devices – quality management systems – requirements for regulatory purposes") certified manufacturers to produce e-vapor products.

The work carried out by TC 126 bears no relevance to standards for the design of e-vapor devices.

3. E-vapor products, unlike traditional tobacco products under the purview of ISO/TC 126, involve the presence of electronic circuitry

In addition to the design issues around e-liquid cartridges/tanks, e-vapor products entail electronic elements such as pressure sensors and activation buttons, heating coils, atomizers/cartomizers, and batteries. Researchers involved with e-vapor products have identified the need to account for the relationship between voltage, current, resistance, and power in designing these device. As discussed at FDA's December 2014 workshop, with respect to battery-powered devices, available voltage and current vary depending on the design, manufacture, load, temperature, storage time, and the depth of discharge and recharge cycles (for rechargeable batteries). Challenges involve overheating that can cause fires or explosions. The e-vapor industry has been engaged in the complex process of engineering devices that can be actuated in a way to promote safety and effectiveness.

Medical devices ranging from electronic thermometers and toothbrushes to automated external defibrillator (AED) and pacemakers involve the use of battery-powered electronic circuitry. Within ISO, TC 150 has developed ISO 11318:2002 ("Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements") dealing with connecting implantable defibrillator leads to implantable defibrillator generators. Likewise, TC 173 has developed ISO 7176-25: 2013 ("Wheelchairs – Part 25: Batteries and chargers for powered wheelchairs"). In addition, the considerations in developing standards for e-vapor devices are similar to the considerations for aerosolized drug delivery systems, such as

nebulizers. In this regard, ISO TC 121/SC 2 on airways and related equipment has developed standards such as ISO 27427:2013 "Anaesthetic and respiratory equipment – Nebulizing systems and components."

Necessarily, standards developed for electronic devices entail specialized engineering capabilities, and any standards established for e-vapor products will require this knowledge-base. Traditional tobacco products do not involve the use of electronic circuitry and, thus, the TC 126 is ill-equipped to address standards related to the engineering of e-vapor devices.

4. E-vapor products pose different packaging and labeling consideration than traditional tobacco products

As noted above, the use of child-resistant packaging has been identified as an important consideration for e-vapor products. Currently, TC 122 maintains ISO 13127:2012 ("Packaging – Child resistant packaging – Mechanical test methods for reclosable child resistant packaging systems"). However, TC 126 does not appear to have undertaken any work in this area.

With respect to labeling of e-vapor products, FDA's December 2014 workshop focused on the activities of CDRH with respect to Unique Device Identifiers (UDI) as a means to assist with surveillance activities for e-vapor products. In addition, as with medical devices, proper operation and maintenance of the device is critical to the safe and effective operation of e-vapor devices. The ability to address proper labeling of e-vapor products requires specialized understanding of the wide variety of e-vapor devices and liquids on the market.

b. Existing National Standards for E-Vapor Products Further Demonstrate the Distinction Between E-Vapor Products and Traditional Tobacco Products

Thus far, two national standard setting organizations have developed standards for e-vapor products: AFNOR in France and the British Standards Institute (BSI) in the United Kingdom. The content of these standards, which have been developed through a consensus-based standard-setting process, further indicate the vast differences between the international standards that will be required for e-vapor products and the international standards that TC 126 has developed for traditional tobacco and tobacco products.

On the April 2, 2015, AFNOR was the first to publish two voluntary standards related to e-vapor products, including a standard for e-cigarettes (XP D90-300-1), and a standard for e-liquids (XP D90-300-2). Both standards set out a list of safety and quality criteria for the relevant products. With regard to e-cigarettes, the XP D90-300-1 standard details precautionary measures to prevent overheating of the device, as well as proper maintenance recommendations, coating requirements, chemical risk prevention, and drop-tests. The XP D90-300-2 standard on e-liquids includes requirements for the refill containers (bottle safety, label and information leaflet, etc.) and lists various substances that can and cannot be used in e-liquids (it includes a list

of banned ingredients, grades of ingredients, nicotine dosage, etc.). A third standard on the subject of characterizing emissions is expected to be published by the end of the year.[12]

BSI has published a Publicly Available Specification (PAS)[13] 54115:2015. The standard provides guidance for the manufacture, import, labeling, marketing and sale of vapor products, including e-cigarettes, e-shishas and do-it-yourself (DIY) e-liquid mixing kits. PAS 54115:2015 covers, among other things (1) the purity of e-liquid ingredients, potential contaminants from device materials and potential emissions from device operation; (2) a test solution-liquid, and an outline for the toxicological and chemical analysis of emissions; and (3) safety of batteries and chargers.

Based on certain concerns that have been identified with respect to the existing AFNOR and BSI e-vapor standards, AEMSA does not believe that these standards should be wholly adopted by the new TC on e-vapor products, but that these standards, along with AEMSA's e-liquid manufacturing standards should serve as a starting point for the new e-vapor TC. The considerations highlighted in the AFNOR and BSI standards illustrate that consensus-based standard-setting at the international level will focus on issues of composition and purity of formulated e-liquids, and engineering and performance standards for e-vapor devices and their components. This issues stand in stark contrast to the existing standards for TC 126 on tobacco and tobacco products, which have focused on determining the composition of an agriculture product and estimating emissions related to the product, as detailed below. The national standards established thus far provide further evidence that international standard-setting for e-vapor products is best achieved separately from ISO's tobacco and tobacco product standard-setting work.

c. ISO TC for Tobacco Products Does Not Have the Needed Experience to Develop Standards for E-Vapor Products

The existing standards under direct responsibility of TC 126 cover the determination of silicated residues, alkaloid content, organochlorine pesticide residues, maleic hydrazide residues,

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[12] See AFNOR publishes the world's first voluntary standards for electronic cigarettes and e-liquids, AFNOR (April 7, 2015), http://www.afnor.org/en/news/news/2015/avril-2015/afnor-publishes-the-world-s-first-voluntary-standards-for-electronic-cigarettes-and-e-liquids.

[13] As stated by the BSI: "A Publicly Available Specification (PAS) is a sponsored fast track standard driven by the needs of the client organisations and developed according to guidelines set out by BSI. Key stakeholders are brought together to collaboratively produce a BSI-endorsed PAS that has all the functionality of a British Standard for the purposes of creating management systems, product benchmarks and codes of practice. In not more than two years from the date of publication a PAS is reviewed to determine whether amendment or revision is required or whether it should be considered for conversion to a formal British Standard."

dithiocarbamate residues, nitrosamines, acetate, and benzo[a]pyrene in tobacco products; a good number of these standards expressly deal with cigarettes, which, as noted above, are vastly different from e-vapor products. Several of the standards deal with the measurement of tobacco leaf and stem. The TC 126 standards also deal with the measurement of cigarette smoke in terms of consumption and content. Absent from the existing TC 126 standards is any work that would indicate particular expertise in addressing the unique issues surrounding the consumption, design, electronic circuitry, e-liquid formulation, or packaging/labeling issues germane to e-vapor products. All-in-all, the TC 126 standards do not address the considerations that are most salient for e-vapor products.

There is a risk that e-vapor standards developed under TC 126 will be unduly influenced by the existing standards for traditional cigarettes and tobacco products. While experts from the e-vapor industry could be engaged to help modify existing standards to the needs of the e-vapor products, this type of re-assessment is not expected to be the most efficient or productive path forward. The more appropriate means of establishing standards for e-vapor products is under a new TC comprised of appropriate subject matter experts and knowledgeable and informed advocates who have been integrally involved with these products. A new TC is needed to facilitate standards development that is not constrained by the existing paradigm for tobacco and tobacco product standards under TC 126.

* * *

In summary, AEMSA supports the AFNOR proposal to develop a new TC on vape and vapor products that is separate and apart from ISO's existing TC 126 on tobacco and tobacco products, provided that the new e-vapor TC is granted responsibility for both nicotine-containing and nicotine-free e-vapor products, including standards on nicotine-content of e-liquids and assessment of e-vapor emissions. The relevant considerations for e-vapor products greatly diverge from those for traditional tobacco products, and grouping e-vapor products under existing TC 126 would gravely impair ISO's ability to establish effective standards for e-vapor products. Developing a separate TC on e-vapor products is the most appropriate way for ISO to address these products. In this regard, the TC on e-vapor products would not need to be constrained by the existing paradigm for tobacco and tobacco product standards – which are largely incongruous with the issues specific to e-vapor products – and it could involve stakeholders with particular interest and expertise in the e-vapor industry.

* * *

AEMSA appreciates the opportunity to submit these comments to ANSI, and would be glad to discuss these comments at its earliest convenience.

Respectfully Submitted,

Jeff Hammel
President, AEMSA

Lou Ritter,
President Emeritus, AEMSA

Enclosure: Appendix A – AEMSA E-Liquid Manufacturing Standards

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. Firebrand – Brian Gage
6. Eclipse Liquids – Steve Mazurek
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

Appendix A

AEMSA E-Liquid Manufacturing Standards

(attached)

Version 2.2 5/20/2015

E-LIQUID MANUFACTURING STANDARDS

Purpose

The purpose of these Standards is to create a responsible and sustainable practices and process for the safe manufacturing of "eliquids" used in electronic cigarettes. Our members believe we have a responsibility to self---regulate the e---liquid manufacturing process based on professional criteria. AEMSA aims to accomplish this by creating, implementing and upholding standards for the manufacture of e---liquids. One of AEMSA's primary goals is to provide consumers with higher degrees of confidence our members' products are manufactured with professionalism, accuracy and safety **AEMSA standards are established based on the following Core Beliefs:**

- We have a responsibility to verify the accuracy of any nicotine content in the products we distribute.
- We have a responsibility to ensure the quality and safety of all ingredients in our e---liquids.
- We have a responsibility to prepare our products in a clean, sanitary and safe environment.
- We have a responsibility to ensure our products are packaged and delivered in a safe manner.
- We have a responsibility to provide a level of transparency into the monitoring and verification process.

The 2012 AEMSA Standards are living documents and subject to changes according to the AEMSA corporate structure and procedures.

Scope

These standards apply to all AEMSA general members that engage in the manufacturing or processing of E---liquids. 2012 E---Liquid
Manufacturing Standard will be used as a basis for:

- Evaluating compliance for membership acceptance
- Confirming compliance of existing membership

Definitions

Term	Definition
Active Age Verification	Taking active measures to ensure that all customers are of legal age. Can be accomplished in many ways including Photo Identification and 3rd party verification systems. Note: Having pop up box asking the person to indicate they are over a specified age is not Active Age Verification
ASTM --- American Society for Testing and Materials	An international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services
Chain of custody	The chronological documentation or, showing the custody, control, transfer, analysis, and disposition of physical component; tracking a product along the supply chain to the point of sale
Components	A part or element of a larger whole; a substance that forms part of a mixture. Any substance, material or the tangible substance that goes into the manufacturing of e---liquid
Contaminants	An impurity or foreign substance present in a material or environment that affects one or more properties of the material
Custard Notes	Flavor compounds that impart a buttery, creamy, or custard taste or sensation. Most commonly used are acetoin, acetyl propionate and diacetyl
Dedicated Manufacturing Space	A clean safe environment that is used exclusively for the manufacturing of e---liquid

Diacetyl	A natural byproduct of fermentation. It is a vicinal diketone (two C=O groups, sideby---side) with the molecular formula C4H6O2. Diacetyl occurs naturally in alcoholic beverages and is added to some foods to impart a buttery flavor. It has been eliminated from many commercial flavorings due to risk of lung damage
Direct Operation	A facility or process where Full time employees for an organization directly supervise and oversee production and process
DIY	Do it Yourself

Electronic cigarette	Also known as an e---cigarette (e---cig) is an electrical inhaler that vaporizes a propylene glycol and/or glycerin---based liquid solution into an aerosol mist simulating the act of tobacco smoking
E---liquid	Liquid for producing vapor in electronic cigarettes, known as e---juice or e---liquid
E---liquid manufacturing	Fabrication: the act of making something (a product) from raw materials; to include all processes from supply acceptance to the point of customer delivery
Free---base	An amine or nitrogen---containing organic compound, such as nicotine, in its basic (high pH) form, in contrast to its acidic (low pH) form, which is often called the "salt" form. Unless an acid has been added to nicotine, or it is purchased as the salt, it is in the freebase form. Free---base describes the form of the compound, not its purity
Generally Recognized as Safe (GRaS)	Generally recognized as safe (GRAS) is an American Food and Drug Administration (FDA) designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements
Indirect Operation	A facility or process where supervision and/or oversight of production and/or process for an organization is conducted by a 3rd party or contractor (subcontractor)
Mg / ml	Milligrams per Milliliter – a scale (or ratio) for measuring an ingredient component, in liquid form, where accuracy is measured in mg per ml --- or a percentage equivalent
Nicotine	Nicotine is an alkaloid found in the nightshade family of plants (Solanaceae) that acts as a nicotinic acetylcholine agonist. The biosynthesis takes place in the roots and accumulation occurs in the leaves of the Solanaceae. It constitutes approximately 0.6–3.0% of the dry weight of tobacco and is present in the range of 2–7 µg/kg of various edible plants

NIST ---The National Institute of Standards and Technology	A non---regulatory agency of the United States Department of Commerce. The institute's official mission is to: Promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life
OSHA	The United States Occupational Safety and Health Administration (OSHA) is an agency of the United States Department of Labor. Congress established the agency under the Occupational Safety and Health Act, was signed into law on December 29, 1970. OSHA's mission is to "assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance"[2]. The agency is also charged with enforcing a variety of whistleblower statutes and regulations
PPM	Parts Per Million
SINGLE---USE ARTICLES	Utensils, containers and tools designed and constructed to be used once and discarded
Tamper Evident	Tamper---evident describes a device or process that makes unauthorized access to the protected object easily detected. Seals, markings or other techniques may be tamper indicating
Titration	Also known as titrimetry, is a common laboratory method of quantitative chemical analysis that is used to determine the concentration of an identified component; the determination of rank or concentration of a solution with respect to water with a pH of 7 (the pH of pure H2O under standard conditions)
USP (US Pharmacopoeia)	The United States Pharmacopeia (USP) is the official pharmacopeia of the United States, published dually with the National Formulary as the USP---NF. The United States Pharmacopeial Convention (usually also called the USP) is the nonprofit organization that owns the trademark and copyright to the USP---NF and publishes it every year. Prescription and over–the–counter medicines and other health care products sold in the United States are required to follow the standards in the USP---NF. USP also sets standards for food ingredients and dietary supplements
WTA (whole tobacco alkaloids)	A full---spectrum mixture of all alkaloids extracted from whole tobacco. WTA can contain, in addition to nicotine, anabasine, cotinine, myosmine, anatabine, and/or nornicotine, in varying compositions, largely dependent on the tobacco species

E---Liquid Manufacturing Standard

Article I. Verifying the accuracy of the nicotine content in products

Section 1.01 .....Accuracy of nicotine

(a) All manufactures must confirm the accuracy of nicotine content upon delivery from supplier

Section 1.02 .....Titrated/verified after dilution

(a) All nicotine must be titrated/verified for content accuracy after dilution to working level

Section 1.03 .....Measuring nicotine equipment

(a) All equipment used in measuring nicotine from working level to final product must be either

(i) NIST (calibrated)

(ii) ASTM compliant (calibrated)

Section 1.04 .....Tolerance level

(a) All products produced will be within the tolerance level of +/---10% nicotine content in final product

Section 1.05 .....Maximum allowable nicotine content

(a) The maximum allowable nicotine content in final flavored product will be no greater than 36 mg / ml

Section 1.06 .....Retail nicotine sold for unflavored/DIY nicotine

(a) Will follow the same criteria for verifying the nicotine content and quality on all batches when received and titrated after dilution at various sales levels

(b) Is not subject to maximum allowable nicotine content in final flavored product

Article II. Ensure the quality and safety of the all ingredients of in e---liquid

Section 2.01 .....Nicotine Sources

(a) All manufacturers must purchase and comply with at least one of the following:

(i) USP CERTIFIED nicotine (with evidentiary documentation from a certified lab)

(ii) Free---base nicotine from suppliers who can provide source evidentiary documentation from a certified lab confirming (batched) nicotine conforms to the Nicotine Quality Standard (see Section 2.02)

(iii) Purchase from nicotine suppliers who can provide evidentiary documentation from a certified lab confirming the incoming
(batched) free---base nicotine conforms to the Nicotine Quality Standard (see Section 2.02) **Section 2.02 .....Nicotine Quality Standard**

(a) All nicotine used in manufacturing must meet the following nicotine quality standards:

(i) Nicotine purity greater than or equal to 99.0% *

(ii) Total combined of all other possible contaminants less than or equal to 1.0%

(iii) Per existence of any solvent must not exceed 0.06%

(iv) Per existence nicotine oxide less than or equal to 1%

(v) Per existence nicotine---N---oxides less than or equal to 1%

(vi) Cumulative heavy metals *content* cannot exceed 10ppm

(vii) Cumulative Arsenic *content* cannot exceed 1ppm

(viii) All diluents after source pure must be USP certified thru chain of custody

Section 2.03 .....Base liquid ingredients

(a) Base liquid diluent ingredients such as Propylene Glycol, Vegetable Glycerin, Glycerol, or any other e---liquid bases (either regularly or exclusively) will be at a minimum level of USP (US Pharmacopoeia) grade certified

(i) Material must maintain full certification throughout chain of custody on raw materials used in manufacturing process (ii)
Manufacturer must exclusively use certified base products throughout the manufacturing process

Section 2.04 .....Ingredients/ Components other than base liquids

(a) Ingredients/ Components other than base liquids will contain only safe or highest grade base materials

(i) Flavorings (including menthol) used will be at a minimum of food grade and/or Generally Recognized as Safe (GRAS) standard certifications whenever the ingredient is produced at those standards

(ii) Flavorings containing artificial food coloring will identify food coloring information to include coloring number in advertising and product descriptions

(iii) Flavorings containing Custard Notes will identify advertising and product descriptions(iv) Water used (if any) will be either deionized or distilled (v) Alcohol and additional additives (if any) will be:

1) Used in the purest form commercially available and safe for human consumption
2) Minimum of US Food grade standards

Section 2.05 The following will not be added or used in the creation of eliquids

(a) Including but not limited to:

(i) WTA (whole tobacco alkaloids)

(ii) Medicinal --- or prescription medicinal

(iii) Illegal or controlled substances

(iv) Caffeine

(vi) Vitamins or Dietary supplements (other than for preservative purposes)

(vii) Artifical Food Coloring

1) AEMSA members will not add any artificial coloring or dyes during the e---liquid manufacturing process. Non vendor manufactured flavorings containing artificial food coloring will identify food coloring information to include coloring number in advertising and product descriptions

(viii) AEMSA reserves the right to review, evaluate and deny/approve any potential substance used in the creation of e---liquids at any given time

**Note: Diacetyl and Acetyl Propionyl (2,3 ------ Pentanedione) standards are undergoing active re---evaluations. All standards amendments are posted immediately after ratifications.*

Section 2.06 .....Process/Records/Traceability

(a) Manufactures will maintain sufficient process and records to enable the manufacturer to trace any individual product distributed to the test results for nicotine content to include source nicotine (see section 2.02)

Article III. Clean, Sanitary and Safe Preparation of Products

Section 3.01 .....General

(a) All Lab/Mixing employees are required to be fully familiar with all AEMSA standards

(i) There will be a special emphasis placed on nicotine handling, storage and clean---up

(b) Each member will create and maintain written lab/mixing protocol and make accessible to all lab/mixing employees

(c) All Persons allowed in process area must comply with applicable protection/ safety and standards

(d) All products will be created and/or bottled in dedicated manufacturing space reserved exclusively for e---liquid

Section 3.02 .....Manufacturing Environment

(a) Manufacturing processes will meet food preparation standards to include

(i) Non---porous sanitized preparation work surface

(b) All surfaces in lab/mixing area (floors, counters, etc.) shall be cleaned with anti---bacterial agents at least once each day and afterany spill of any mixing ingredient or any possible---contaminants

(c) Equipment will be cleaned by FDA Approved Chemical Sanitation or autoclave

(d) All supplies and material will be disposed of in a manner that is appropriate to component disposal --- proper disposal ofproduction material

(e) There shall be no open fans, dusty boxes and/or other potential sources of airborne contaminants etc. in dedicated space (f) All bottles and materials unpacked outside of dedicated lab/mixing space

Section 3.03 .....Hand washing / sanitation

(a) Not in sink used for cleaning mixing utensils, and/or other e---liquid materials

(b) Minimum 20 seconds with commercial (food handler's grade) antibacterial hand washing agent and warm water

(c) Hands washed each and every time entering mixing room

(d) After bathroom use, coughing, sneezing, eating and/or drinking, engaging in any other activities which potentially expose handsto any form of potential contaminants

(e) During mixing as often as necessary to remove any mixing products on hands

(f) Before proceeding to a subsequent mixing session ---> to prevent any cross contamination from one batch to the next

Section 3.04 .....Health / illness

(a) All open wounds or abrasion will be properly covered

(b) Any/All mixing employees report any illness/abrasion(s)/lesions to person in charge before entering the process

(c) Employees must report to person in charge if exposed to any contagion or infection --- viral or bacterial --- from anywhere

(including others in their homes, other work environments, other domiciles, etc.) before entering lab/mixing area (i) Such exposure/conditions excludes said individual from entering mixing room for a period of three (3) asymptomatic days have passed and/or cleared with medical documentation (equivalent to commercial food handling) (ii) Discharge from eyes, nose and/or mouth:

(iii) Report to business any persistent discharge from eyes, nose, and/or mouth. Any employee exhibiting such symptoms shall not enter the mixing room until such symptoms cease

Section 3.05 .....Eating/Drinking

(a) No eating, drinking, vaping and/or smoking in the lab/mixing area at any time

Section 3.06 .....Hair Restraints

(a) Each member must establish written hair and beard standards

Section 3.07 .....Animals

(a) No animals shall be permitted in the mixing room at any time for any reason

Section 3.08 .....POISONOUS OR TOXIC MATERIALS

(a) POISONOUS OR TOXIC MATERIALS shall be stored so they cannot contaminate PRODUCT COMPONENT, FOOD, EQUIPMENT, UTENSILS, and SINGLE---USE ARTICLES by:

(i) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning

(ii) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above PRODUCT COMPONENTS, FOOD, EQUIPMENT, UTENSILS, or SINGLE---USE ARTICLES

(iii) This does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of PRODUCT COMPONENT, FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE---SERVICE and SINGLE---USE ARTICLES

(iv) All POISONOUS OR TOXIC MATERIALS will be disposed of in a safe manner

(v) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a lab/mixing area, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a lab/mixing area (kept sealed and separate --- never above --- from any/all mixing supplies)

(vi) A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense any other substance

Section 3.09 .....Employee Safety

(a) Employers MUST provide their employees with a workplace that does not have serious hazards and follow all relevant OSHA safety and health standards including --- but not limited to --- the following mandatory personal protective equipment (P.P.E.): (i) Eye protection

(ii) Lab Coat / Apron

(iii) Fully covered footwear

(iv) All manufacturing spaces must have easily accessible

1) First aid kit

2) Emergency eye wash kit

Article IV. Safe Packaging and delivery of products

Section 4.01 .....Child proof caps

(a) Child proof caps required for all consumer level e---liquid products

(b) Zero Nicotine Products do not require child proof caps

Section 4.02 .....Tamper evident packaging

(a) All Products require tamper evident packaging once leaving vendor chain of custody

Section 4.03 .....Labeling

(a) Smear Resistant Labeling is required on all e---liquid products

(i) Must pass “30 second submerged” test for all required elements

(b) Nicotine content must be clearly displayed

(c) Safety and health Warning must be clearly displayed

(i) Contains Nicotine

(ii) Keep away from Children and Pets

(d) Nicotine Traceability elements (i.e. Batch ID or nicotine batch ID or production date)

Section 4.04 .....Delivery

(a) All shipped liquid must be bagged or wrapped to provide waterproof barrier between packaging and product for spill protection

(b) Safe handling information must be included in all packaging

Section 4.05 .....Active age verification

(a) All Vendors must use Active age verification for all sales (retail and/or online) (

b) AMESA Members will not knowingly sell products to any persons under the legal smoking age

Article V. Transparency into the monitoring and verification process

Section 5.01 .....Within the organization

(a) Members must provide information to applications and compliance committees required to establish compliance including: (i)

Documented evidence of compliance

1) Photographic and Video evidence
2) Unfettered access to facilities for inspection (scheduled and/or unscheduled) 3) Process and records

(b) Member to member profiles will contain only minimal information for the identification and communication amongst and between members

(i) Current status of compliance --- by facility (ii) Contact Information

1) Name
2) DBA
3) Email
4) Phone
5) Location(s)/ Facilities of production

Section 5.02 .....To the consumer

Note: Subsections (a) and (b) are already posted on AEMSA website. **Subsections (c) and (d) are intended for specific information warranted situations ONLY; these may include --- but not limited to --- allergy sensitivities, other specific medical conditions/sensitivities, etc.** Subsection (e) shall be available on member's web site

(a) A substantive version of the AEMSA Standards be published on Website

(b) AEMSA Membership Status

(c) **Members will provide consumers tracking nicotine test results as far back as the source nicotine**

(i) Information on the supplier may be redacted to protect intellectual property and trade secrets

(ii) The member may charge a reasonable and fair fee for said tracing requests

(d) **Members will provide answers to consumers on ingredients of products**

(i) Yes/No answers to specific questions as pertains to specific customer sensitivity questions

(ii) No intellectual property or trade secrets of the e---liquid ingredient has to be revealed

1) This includes revealing the source supplier and trademarked/brand name ingredient

(e) Clearly identified products that are not manufactured by AEMSA Members

1) If the member sells liquid that is manufactured in a non AEMSA compliant facility it must:
2) Clearly identify/ differentiate products that are AEMSA compliant and those that are not AEMSA compliant on a product by product basis

Section 5.03 .....To potential regulators

(a) To be decided on case by case basis