AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION

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Via Electronic Submission (http://www.regulations.gov)

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, RM. 1061
Rockville, Maryland 20852

Re: Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products; Docket No. ID: FDA-2015-N-1514-0001

The American E-Liquid Manufacturing Standards Association (AEMSA) appreciates this opportunity to respond to the request by the Food and Drug Administration (FDA or Agency) for comments in conjunction with its advance notice of proposed rulemaking (ANPRM) intended to inform regulatory actions FDA might take with respect to nicotine exposure warnings and child-resistant packaging for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, as announced in Docket No. ID: FDA-2015-N-1514-0001.[1]

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 e-cigarettes. AEMSA is an all-volunteer 501(c)(6) 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 professionally responsible and safe manner until such time as FDA promulgates Good Manufacturing Practices (GMPs) for e-liquids. In this regard, AEMSA has developed manufacturing standards for of e-liquids, which are included in **Appendix I** hereto, and may be downloaded from our website at: http://www.aemsa.org/standards/. 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.

[1] *See* 80 Fed. Reg. 37555 (July 1, 2015), available online at: http://www.gpo.gov/fdsys/pkg/FR-2015-07-01/pdf/2015-16151.pdf.

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), but rather are recreational use products. 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.

AEMSA is providing these comments to FDA on behalf of its e-liquid manufacturing Members.

II. FDA's Advanced Notice of Proposed Rulemaking

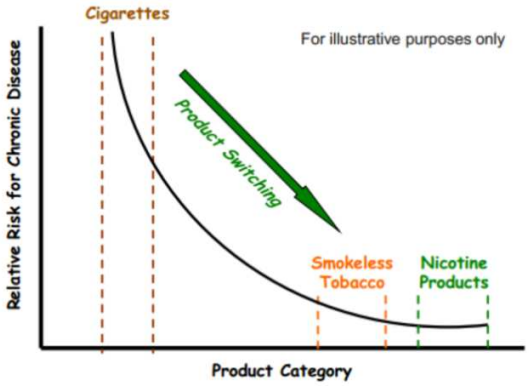
The electronic cigarette is a revolutionary technology that has the ability to greatly benefit the public health, as it provides the first viable recreational alternative to tobacco for cigarette smokers. Assuming solely for the purposes of these comments that e-cigarettes and their e-liquid components (that contain tobacco-derived nicotine) will be deemed to be *regulated* tobacco products,[2] we understand that FDA must weigh the pros and cons of these new products to determine the most effective regulatory scheme. The ANPRM addresses two of FDA's primary areas of concern in this regard: (1) whether and how FDA should warn consumers about the presence of nicotine in products like e-liquids and (2) the need for child-resistant packaging on any nicotine-containing product.

[2] First and foremost, AEMSA's position is that e-cigarettes are technology products, not tobacco products, and that Congress should consider separate legislation specifically giving FDA authority over e-vapor products separate from the Agency's tobacco and drug authorities. We believe that attempting to force the Tobacco Control Act requirements onto these tobacco-free products is not an effective regulatory strategy, and one that could actually harm the public health, as e-cigarettes have proven to be an effective tool for tobacco harm reduction. Nevertheless, for purposes of these comments, we assume, *arguendo*, that e-cigarettes and their e-liquid components will be "covered tobacco products" subject to the Tobacco Control Act requirements, assuming they are used with or contain nicotine derived from tobacco.

III. When Developing Warnings For Deemed Products FDA Should Consider That Tobacco Leaf-Containing Products are Substantially More Harmful that E-Cigarettes That Contain Nicotine

Although e-cigarettes may not be completely "harmless" products and should only be used by adults, there is no doubt that compared to tobacco-leaf products, and especially those that are combusted, e-cigarettes and the e-liquids used in them are dramatically less harmful for individual tobacco users, especially cigarette smokers.

As set forth in AEMSA's comments to the Notice of Proposed Rulemaking (NPRM) for the Deeming Regulation (FDA Docket No. FDA-2014-N-0189), tobacco leaf-containing products, especially those that are combusted, are the most harmful and dangerous products on the "continuum of risk" of nicotine products and should be treated as such. The continuum of risk of nicotine-containing products is a way to visualize the risk disparity between different categories of products. The product that poses the greatest harm and risk of tobacco-related disease (*i.e.*, the traditional, combustible cigarette) is on one end of the continuum, and new product forms (such as e-cigarettes) that do not contain or combust tobacco leaf are on the other end:



Public health organizations recognizing pronounced *continuum of risk*, potential for harm reduction with product switching (e.g., LN-SLT)

- **Institute of Medicine (2001)**
- **American Council on Science and Health (2006)**
- **Royal College of Physicians (2002, 2007)**
- **Scientific Committee on Emerging and Newly Identified Health Risks (2007)**
- **Life Sciences Research Office (2008)**
- **American Association of Public Health Physicians (2008)**
- **World Health Organization (2008)**
- **Strategic Dialogue on Tobacco Harm Reduction Group (2009)**

Tobacco leaf-containing products, especially those that are combusted, are the most harmful and dangerous 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.[3] Of the approximately 5,300 chemicals identified in tobacco smoke, at least

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

60 are known human carcinogens, including polycyclic aromatic hydrocarbons (PAHs) and tobacco-specific nitrosamines (TSNAs).[4] Electronic cigarettes are far less risky to individual users than combustible cigarettes because they do not result in the inhalation of pyrolyzed chemicals.

When developing regulatory requirements for deemed tobacco products, including e-cigarettes and e-liquid, FDA must consider how the different product types compare to each other, and the potential benefit to the public health of allowing consumers (*e.g.*, cigarette smokers) to choose less harmful products as a means of tobacco harm reduction. Establishing a "one-size-fits-all" regulatory scheme, for example, could do considerably more harm than good. Rather, as AEMSA outlined in its comments to the proposed Deeming Regulation, FDA should use its enforcement discretion to establish appropriate regulatory requirements and procedures – including warning language – for the different types of deemed product, that are commensurate with the harm that requires regulation.

This is true, in particular, with regard nicotine warning language. Excessive warning language on e-cigarettes and e-liquids, for example, could be misleading by cause consumers to view these products as actually being *more* harmful than tobacco – which could not be farther from the truth. While warnings are absolutely necessary, accentuating the risks of vaping when there is little public health reason for doing so may actually deter cigarette smokers and tobacco users from trying significantly less harmful products like e-cigarettes. Indeed, some have argued that "Big Tobacco" companies have pushed for *more* warnings on e-cigarettes not because they are concerned about the risk to consumers, but because hefty warnings and other regulatory requirements assist in neutralizing the threat that e-cigarettes pose to their core tobacco business.[5] The warnings placed on Altria's MarkTen e-cigarette, for example, are far more elaborate than those placed on its most deadly Marlboro cigarettes.[6]

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

[5] *See* Geller, Martinne, *Special Report: When it comes to e-cigs, Big Tobacco is concerned for your health*, Reuters, available online at: http://www.reuters.com/article/2015/03/23/us-ecigarettes-regulations-specialreport-idUSKBN0MJ0GN20150323.

[6] *See* Richtel, Matt, *Dire Warnings by Big Tobacco on E-Smoking*, New York Times, available online at: http://www.nytimes.com/2014/09/29/business/dire-warnings-by-big-tobacco-on-e-smoking-.html.

According to a recent poll conducted by the Action on Smoking Health (Ash), a growing number of smokers are failing to understand the relative risks of cigarette smoking versus vaping and may, as a result, put off switching to e-cigarettes. Specifically, between 2013 and 2015, the proportion of respondents to the Ash survey who believe e-cigarettes were as harmful as regulated, tobacco-combusting cigarettes, increased from 6% to 20%.[7] This is a staggering result that will have grave consequences for the public health, and makes clear the need to have appropriate warning language that alerts consumers to the appropriate correlative potential risks of nicotine, but does not mislead and/or potentially scare them away from these products altogether.

Accordingly, when developing warning language for nicotine containing e-cigarettes and e-liquids, FDA should consider the impact that such warnings could have on consumer behavior and the potential that excessive warning language or graphics may be a factor in preventing smokers from attempting to switch to lower correlative risk e-cigarettes.

IV. Nicotine Risks Can be Mitigated with Appropriate Warnings and Child-Resistant Packaging

a. Safety of Nicotine

We understand that appropriate, non-confusing and science-based warnings are needed to ensure that consumers are fully aware of all potential health risks. AEMSA acknowledges that nicotine, which is used in many, but not all, e-liquids, is a substance of concern, and that a warning should be placed on product labels, advertising, marketing materials and websites.

As FDA reviews comments to the ANPRM and develops warning language, it must acknowledge that it is not starting from a *tabula rasa* when it comes to understanding the safety of inhaled nicotine aerosols. It is well established that while nicotine is not, *per se*, harmless, it is *not* the substance that kills smokers. This is important for FDA to acknowledge as it develops nicotine-specific warning language for deemed products. As Mitch Zeller, the Director of FDA's Center for Tobacco Products has stated on several occasions, people may smoke cigarettes for the nicotine, but die from inhaling the smoke and tar from combusting tobacco. The safety and toxicological profile of nicotine has been studied extensively in both animals and man, and a comprehensive survey of this literature will not be presented here. We do note that, importantly, nicotine itself is not a carcinogen. The long-term inhalation effects of nicotine have

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[7] Public Health England, *E-Cigarettes: an evidence update*, available online at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

been studied over a two-year period in 68 female Sprague-Dawley rats (34 control animals).[8] After being exposed to pure nicotine aerosol for 20 hours a day for five days a week for over two years, no tumorigenic effects of nicotine were found in any organ in the body. No tumors were detected on either microscopic or macroscopic examination of the lungs. There were also no changes evident in the macroscopic examination of the hearts, including atherosclerotic lesions (although some nicotine-exposed animals did develop pituitary tumors).

Studies on the long-term use of nicotine-replacement therapies (NRTs) have similarly made clear that nicotine is also not a carcinogen in humans. Specifically, a connection between nicotine and cancer was not found in a 5-year study of 5,887 subjects.[9] In that study, the researchers concluded that "[t]he absence in general of a relation between nicotine replacement therapy and cancer across the models adds credence to our conclusion that nicotine replacement therapy does not cause cancer." FDA itself has confirmed this in its Notice of Findings published in 2013 for "Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use".[10] In that notice, FDA cites a growing body of evidence that demonstrates the safety of long-term nicotine use as well as that NRT products sold over-the-counter (OTC) do not appear to have significant potential for abuse or dependence. Considering this, FDA requested NRT manufacturers to submit supplemental New Drug Applications to change the labeling of their current NRT products to make clear that, among other things, it is safe for consumers to use such products beyond the 8-12 weeks on the label in order to quit smoking.

Of course, we recognize that nicotine does pose some acute hazards if swallowed or absorbed through the skin (see Section V below re child-resistant packaging) and, as a result of the increasing market share of refillable "open-system" vaporizers, the growing presence of e-liquids on the marketplace, and in the home, expands the population that may be inadvertently exposed to nicotine at levels that pose an acute toxicity risk. But it is first important to recognize

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[8] *See* Waldhum, H.L. et al., *Long-term effects of inhaled nicotine*, 58(16) Life Sciences 1339-1346 (1996).

[9] See Murray, R.P et al., *Does nicotine replacement therapy cause cancer? Evidence from the Lung Health Study*, Nicotine Tob Res. 2009 Sep; 11(9): 1076–1082, available online at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2725009/.

[10] *See* 78 Fed. Reg. 19718 (April 2, 2013).

that, contrary to popular belief, the lethal dose of nicotine for adults (when ingested) is between 500-1000 mg (not 50-60 mg as many still believe).[11]

a. Recommendations for Warning Language

Keeping the above context in mind, AEMSA believes that appropriate nicotine warning for labels on e-liquid bottles (considering the size of standard label for 18 mL bottle) should read as follows: **"This product is for adults (over 18) only and contains nicotine, which is potentially addictive. Do not use if you are pregnant or breastfeeding. Keep out of reach of children and pets. In case of accidental ingestion, call [poison control hotline]."** Such language is sufficient to warn consumers of the acute health risks nicotine can pose, and give them a resource for emergency assistance. Cramming additional legalese about oral, ocular and dermal exposures risks of nicotine, or including graphic images or illustrations, on the label would do nothing more than promote fear-mongering of e-cigarettes. Additional information about nicotine can be provided in package inserts or on the manufacturer's website.

Companies should have the freedom to place more comprehensive warnings on their labels, advertising, marketing materials and websites if they choose, if they feel that doing so is necessary from product liability or other commercial reasons. Such additional warning language, however, should not be mandated by the government, especially when such warnings could actually be a detriment to the overall public health.

V. Need for Child-Resistant Packaging

As noted above, although nicotine is not a carcinogen and has been unfairly demonized by many in the anti-tobacco lobby, we recognize that, at least in its undiluted form, it does pose a potential acute hazard if large quantities come into contact with skin or is ingested. To understand the magnitude of this risk, FDA should first recognize that nicotine is *not* the main ingredient in e-liquids (in terms of amount, it is generally the lowest concentration in e-liquid), which are composed primarily of excipients such as propylene glycol and/or vegetable glycerin (glycerol), which act as carriers for the flavoring compounds and nicotine. Nevertheless, e-liquids are often mischaracterized in the media as "liquid nicotine" – and in the ANPRM itself – which implies that these products consist *mostly* of nicotine. It is such *pure* liquid nicotine that, if swallowed, could be deadly (see footnote 11). In reality, however, nicotine is only a component

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[11] See Farsalinos, KE, *Nicotine lethal dose in humans: a common argument by regulatory authorities, based on poor science*, available online at: http://ecigarette-research.com/web/index.php/2013-04-07-09-50-07/132-nicotine-lethal-dose-in-humans.

of some e-liquids and, in those products, is present at concentrations ranging between 0.2% and 2.4%.

While ingestion of and extensive dermal exposure to e-liquids is an avoidable risk, the fear-mongering in the media and by some in the public health community about the dangers of these products continues to inappropriately convince many would-be vapers to avoid these products rather than explore them as an alternative to smoking. For example, recent media reports about the rising dangers of nicotine exposures from e-liquids greatly exaggerate the level of harm. According to the National Poison Data System (NPDS), e-cigarettes account for only 0.1% of exposures reported to Poison Control Centers (*i.e.*, 200 of 194,500 monthly calls). In 2012, there were 2,275,141 exposures reported to Poison Control Centers, or 189,595 exposures per month.[12] Considering this in light of the CDC's announcement in 2014 that up to 200 e-cigarette calls per month were being reported to Poison Control Centers, it is clear that e-cigarettes account for only a tiny fraction (0.1%) of reported exposures (*i.e.*, 200 of 189,595 monthly calls).[13] Other common household goods result in far more reported poisoning cases. According to NPDS's annual report from 2012, the top five substance classes most frequently involved in all human exposures were analgesics (11.6%), cosmetics/personal care products (7.9%), household cleaning substances (7.2%), sedatives/hypnotics/antipsychotics (6.1%), and foreign bodies/toys/miscellaneous (4.1%). Analgesic exposures as a class increased the most rapidly (8,780 calls/year) over the last 12 years. The top five most common exposures in children aged 5 years or less were cosmetics/personal care products (13.9%), analgesics (9.9%), household cleaning substances (9.7%), foreign bodies/toys/ miscellaneous (7.0%), and topical preparations (6.3%).[14]

Despite these exaggerations about the frequency of e-liquid poisonings, since its inception nearly three years ago, AEMSA's standards have promoted the safe handling of all e-

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[12] *See* James Mowrey *et al*., *2012 Annual Report of the American Association of Poison Control Centers ' National Poison Data System (NPDS): 30th Annual Report*, (2013), https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2012_NPDS_Annual_Report.pdf.

[13] *See* CDC, *Notes from the Field: Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014*, (2014), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s_cid=mm6313a4_e.

[14] *See* Mowry, *et. al.*, 2012 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 30th Annual Report, 51(10), Clin. Toxicol. 949-1229 (2013). *See* CDC, 2012 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 30th Annual Report.

liquids and mandated the use of child-resistant (and tamper evidence) packaging for products sold directly to consumers (*e.g.*, e-liquid bottles). AEMSA's e-liquid manufacturing standards, which are available online (at http://www.aemsa.org/standards/) and included in Appendix I hereto.

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

Respectfully Submitted,

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President
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Lou Ritter
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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
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Subject Matter Experts:

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Consumer Advocates:

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2. Linc Williams (Secretary)
3. Jesse Ray
4. Matt Allen

Enclosures:
Appendix I – AEMSA E- Liquid Manufacturing Standards

Appendix I

AEMSA E- Liquid Manufacturing Standards (Version 2.3 – September 4, 2015)

E-LIQUID MANUFACTURING STANDARDS

AEMSA advocates electronic cigarette products for ADULT USE ONLY.
AEMSA supports ban on sales to minors.

Version 2.3 - September 4, 2015

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 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 Eliquids. 2015 E-Liquid Manufacturing Standard will be used as a basis for:

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

CONTENTS

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

(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 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%*

(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 the 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

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

(vi) Artificial 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

(vii) 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 after any 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 of production 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 hands to 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 IV. 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

APPENDIX A: TERMS AND DEFINITIONS

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, side-by-side) with the molecular formula $C_4H_6O_2$. Diacetyl occurs naturally in alcoholic beverages, other natural sources and is added to some foods to impart a buttery flavor. Diacetyl, while not problematic for ingestion via digestion, has been identified as a potential inhalation risk and has been reported in some flavorings. As a preventative and good product stewardship measure, many e-liquid manufacturers are now testing, reformulating and/or removing identified flavors from inventory to avoid potential inhalation risks.

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". 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

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For more information or to become a member, please visit:

AEMSA.org