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Co-Founder: June 2012

Launched Oct. 8, 2012
First Elected President: 9/12-1/15
President Emeritus: 1/15 -> present

http://www.AEMSA.org/

Launched November 2014

Founder and President

http://E-ResearchFoundation.org/

TC 126/SC3 Vape and Vapor Products
TAG Chair

TAG Administrator:
Brandon Ward (Evolv)

https://www.ANSI.org/

http://www.iso.org/ (vape and vapour products)

About AEMSA

Founded by Consumers
- Lou Ritter and Linc Williams

501c(6)

Launched in October 2012

USA Made e-liquid

3 Highly Credentialed SMEs

Current Membership

Focused on Core Beliefs

The AEMSA standards origin

Established in October 2012

- Is a Living Document
- 2016 Version 2.3.1 (posted on website with full details)

Based on:

- Commercial Food Manufacturing
- GMP principles
- Feedback from Subject Matter Experts
- Practical application from experienced USA made-liquid manufactures

Main Articles

Article I.	• Verifying the accuracy of the nicotine content in products
Article II.	• Ensure the quality of the all ingredients in e-liquid
Article III.	• Clean, Sanitary and Safe Preparation of Products
Article IV.	• Safe Packaging and delivery of products
Article V.	• Transparency into the monitoring and verification process

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

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

Section 2.01 Nicotine Sources / Section 2.02 Nicotine Quality Standard

- 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
  - (iii) Purchase from nicotine suppliers who can provide evidentiary documentation from a certified lab

Section 2.02 Nicotine Quality Standard

- Nicotine quality verifications, and impurities itemized with maximum allowable content, listed on website

Section 2.03 Base liquid ingredients /Section 2.04 Ingredients/ Components other than base liquids

- USP Grade Certified - exclusive use USP base products throughout the manufacturing process

Section 2.05 Listing of items not be added or used in the creation of e-liquids

Section 2.06 Process/Records/Traceability

- Must 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

Article III. Clean, Sanitary and Safe Preparation of Products

- Section 3.02 Manufacturing Environment
- Section 3.03 Hand washing / sanitation
- Section 3.04 Health / illness
- Section 3.05 Eating/Drinking/Vaping
- Section 3.06 Hair Restraints
- Section 3.07 Animals
- Section 3.08 POISONOUS OR TOXIC MATERIALS
- Section 3.09 Employee Safety

Article IV. Safe Packaging and delivery of products

Section 4.01 Child proof caps / Section 4.02 Tamper evident packaging

- Required

Section 4.03 Labeling

- Smear Resistant
- Nicotine content must be clearly displayed
- Safety and health Warning must be clearly displayed
- Nicotine Traceability elements
- (Note): Now supplemented by FDA mandated labeling requirements

Section 4.04 Delivery

- Bagged or wrapped to provide waterproof barrier between packaging and product for spill protection
- Safe handling information must be included in all packaging

Article V. Transparency into the monitoring and verification process

Section 5.01 Within the organization

- Members must provide information (in applications and compliance committee) required to establish compliance including:
- Documented evidence of compliance
  - Photographic and Video evidence
  - Unfettered access to facilities for inspection (scheduled and/or unscheduled)
  - Process and records

Section 5.02 To the consumer

- *Members will provide consumers tracking nicotine test results as far back as the source nicotine*
- *Members will provide answers to consumers on ingredients of products*
  - *Yes/No answers to specific questions as pertains to specific customer sensitivity questions*
- Clearly identified products that are not manufactured by AEMSA Members
  - If the member sells liquid that is manufactured in a non AEMSA compliant facility it must:
    - Clearly identify/ differentiate products that are AEMSA compliant and those that are not AEMSA compliant on a product by product basis

Product (individual and combined) Variables Impact Research, Protocols, RESULTS

- <u>Some Examples:</u>

- User Profiles: Puffing patterns, Puff durations, Puff intervals, Aerosol deposition – Vaping profiles are different from "smoking" profiles (cannot use same for both)
- Power levels and Temperatures?
- Realistic device and atomizer/tank combinations ("Systems") – change "anything" (setting, coil resistance, airflow, etc.) in the system = different results?
- Effective wicking (e-liquid getting to coil) and "dry-puff" phenomenon
- Device Safety Features (which versions are accurate and repeatable?)
- Ohms Law (for mechanical device/atomizer combinations and cigalikes/equivalents)
- Electronics (boost circuits etc., Power Regulation, Temperature Control)
- More… (Please refer to the presentations and slides of John Bellinger and Kurt Kistler)

E-Liquid information (generic)

(chemistry and science will be covered by Kurt Kistler, Ph.D.)

- Skin exposure absorption – watch for nicotine actual content
  - 3 mg/ml is approximately 0.3 % nicotine, 12 mg/ml is approximately 1.2 % …
  - Identifying the real risk(s)

Oral Ingestion: 60 mg of nicotine as lethal? – from an 1856 pharmacology textbook. Current may be 1,000 mg or more. Needs new evaluation/update for Accuracy

- Christensen LB, van't Veen T, Bang J. Three cases of attempted suicide by ingestion of nicotine liquid used in e-cigarettes, Clinical Toxicology. 2013; 51: 290.Clinical Toxicology vol. 51 no. 4 2013
- And: https://www.ncbi.nlm.nih.gov/pubmed/24091634 ("How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century.")

E-Liquid – taste vs. smell (completely different, e-liquids smell nice but taste horrible)

Theories: e-liquid may initiate gag-reflex, swallowing may initiate regurgitation

Systems: device/atomizer (or tank) combinations

Engineering and Technical details will be presented by John Bellinger (Evolv)

- Some basic points which cannot be ignored:

- Temperature (and temperature control features in devices)
- Temperature levels at which harmful constituents may be generated (could vary for different constituents)
- Materials in contact with liquids (tanks and atomizers – which metals, which glass, which plastic(s), plating, 316 stainless, etc.)
- Power levels ***do*** impact nicotine absorbtion: http://www.nature.com/articles/srep04133
- Much more… (see John Bellinger's slides and presentation)

Smoking cessation efficacy evaluations and dynamics

- Reference Device(s) and reference liquids:

- 1st time vaping demands trying many liquids (often 20-30 to find 2 or 3 subjectively satisfactory)
- After 2 or 3 weeks of vaping only (not dual use), olfactory and taste senses restore – tobacco flavors often lose appeal. Finding new flavors - consumers often repeat trying 20 to 30 to find 2 or 3 subjectively satisfactory, trials repeat again and again as consumers seek new subjectively satisfactory flavors
- Smokers tend to stick with one brand ("flavor") while vapers change flavors and brands often (many switch flavors multiple times during a single day)
- Device/atomizer (or tank) combinations ("systems") vary and all variables impact vapor "character"
- Flavors vary – strawberry (any "flavor") is different from one manufacture to another (recipes and ingredients sources vary) = Every "flavor" (e-liquid) is completely subjective for satisfaction
- Single device/liquid pairings may facilitate research consistency but will never replicate real world options that yield substantially higher (anecdotal) cessation levels – true cessation efficacy can only be accurately evaluated by expanding the device/atomizer combinations and e-liquid spectrum options - as all liquids and systems (device/atomizer combinations) are 100% subjective as relates to satisfaction, flavor, physical sensations (throat hit), nicotine delivery (nicotine content and power level combinations can and do vary absorption rates and levels of nicotine delivery)

Lessons from recent years

- Protocols really matter – before commencing studies, some researchers do not learn about the devices, system combinations, user-profiles (puff patterns, puff durations, puff intervals, subjective variations – we rarely, if ever, see any two people vaping the same systems and liquids), wicking issues, airflow, nicotine delivery variances and more - from which all (individually and collectively) impact findings and conclusions
- Uninformed product and usage research has produced some unrealistic results, made sensationalizing headlines and has contributed to misleading regulators, consumers, other researchers, opponents, etc.
- "Use" surveys: "ever tried" vs "actual use" (youth are inherently experimental)
    - <u>While not "science" these cannot be ignored:</u>
- "Gateway" (to tobacco) – so far there is no evidence, merely speculative fears
- Flavors as "marketing to youth" – at the time of the deeming rule (5/10/16) ***48*** States already had laws prohibiting sales to minors. Youth access is no different than tobacco, alcohol and/or any other age-restricted sales. The same flavors are marketed in alcohol (and other products – including NRTs) without these accusations: http://www.biteclubeats.com/flavored-vodkas-from-bacon-to-fruit-loops/ (scroll for list)
- Hopefully you will be able to help separate verifiable facts from confirmation bias and/or invalid assumptions/protocols, non-industry (and industry) knowledgeable SMEs are available to help educate and clarify for information Accuracy

Tobacco Harm Reduction to Harm Minimization (THM)?

- Vaping offers demonstrative (orders of magnitude?) Tobacco Harm Reduction. This provides the opportunity to advance towards *Harm Minimization* – but only if the Science and Regulations facilitate the opportunity: Science can point industry towards issues to address while Regulations need to incentivize (or at least leave room for) such product innovations and refinements
- Accurate, verifiable and replicable Science (with realistic protocols) is imperative
- Motivation and intent, to get past the confusion and use protocols that are representative of **real-world-usage**, are essential to advancing THM
- What about the smokers? Estimates vary – globally 25 million (estimate) smokers have switched to vaping. This is wonderful progress (smoking rates are verifiably declining), and the opportunity to expand these numbers exponentially is on our doorstep. Advancing THM, and reducing smoking deaths, illnesses and correlated suffering (collateral?) – not to mention Health Care - are all realistic and ascertainable goals – but only ***if*** Regulations (guided by consistent, replicable and valid science) and Industry cooperate enough to realize these goals

Thank You

(and some more Resources)

- 900 Studies (most with links): http://www.aemsa.org/existing-research/
- "Direct From The Experts": the ERF website has posted speaker Bios and the individual (video) presentations from 2014 and 2015 Global Forum on Nicotine (GFN) and TMA. GFN 2016 presentation slides can be found here: https://gfn.net.co/2016-presentations - videos here: https://gfn.net.co/gfn2016-videos (TMA 2016 was not recorded). All of these include both individual presentations and Panel discussions. All speaker bios are posted. Please watch GFN 2015 Keynote Speaker Dr. Derek Yach (bio posted) and browse the others – or review them all (others under "Direct From The Experts"): http://e-researchfoundation.org/gfn-2015/
- AEMSA Standards: http://www.aemsa.org/standards/
- AEMSA Public Comment Submissions (all "Public documents" on correlated government websites): http://www.aemsa.org/public-testimony-and-comments/
- Other Resources: http://www.aemsa.org/organizations-blogs-information/