Creating responsible and sustainable practices and process for the safe manufacturing of "e-liquids" used in electronic cigarettes.

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E-LIQUID MANUFACTURING STANDARDS

RESPONSIBILITY • STANDARDS • TRANSPARENCY

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Purpose

The purpose of these Standards is to create a responsible and sustainable practices and process for the safe manufacturing of "e-liquids" 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 e-liquids

(a) Including but not limited to:

(i) Diacetyl

(ii) WTA (whole tobacco alkaloids)

(iii) Medicinal - or prescription medicinal

(iv) Illegal or controlled substances

(v) Caffeine

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

(vii) Acetyl Propionyl (2,3- -Pentanedione)

(viii) 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

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

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 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