

UTSFA

Utah Smoke-Free Association



E-Liquid Manufacturing Standards

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These standards are a living document and subject to change based on need, legislative requirements, concerns or membership of the Utah Smoke Free Association.

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Purpose

The purpose of these standards is to create responsible and sustainable “best practice” processes and procedures for the safe manufacturing of e-liquids. Our members believe we have a responsibility to self-regulate for e-liquid manufacturing processes above the requirements of law based on best practices.

The Utah Smoke Free Association aims to accomplish this by creating, implementing and upholding standards for the manufacture of e-liquids. One of our primary goals is to provide consumers and regulators with elevated confidence that our products are manufactured with professionalism, accuracy and safety.

Scope

These standards apply to all Utah Smoke Free Association members that engage in the manufacturing, processing or repackaging of E-liquids.

These standards will serve as a basis for:

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

Inspection Schedule

Inspections are performed twice per year. All manufacturing facilities must be inspected by a member of the Utah Smoke Free Association Board of Directors or Officers Board, agree to the Utah Smoke Free Association Code of Conduct and Terms & Conditions and pay applicable dues before membership into the Association may be granted. After the inspection has been completed, you will receive a door decal signifying your membership and your business will be included on the Utah Smoke Free Association website under the manufacturing directory. Should you have any questions on the above standards or wish to schedule an inspection, please contact a member of our board.

Definitions

Term	Definition
AEMSA (American E-Liquid Manufacturing Standards Association)	Manufacturers' trade association dedicated to creating responsible and sustainable standards for the safe manufacturing of "e-liquids" used in electronic cigarette vapor products.
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.
Business License	Permit issued by the state of Utah that allow companies to conduct business within the respective geographical jurisdiction. It is the authorization to start a business issued by the local government.
Certificate of Insurance	Document issued by an insurance company that certifies an insurance policy has been bought and shows an abstract of the most important provisions of the insurance contract.
Child-resistant Caps	Caps for e-liquid bottles that must be pushed down and turned to open.
Contaminants	An impurity or foreign substance present in a material or environment that affects one or more properties of the material
County Permit	Similar to a business license. Required in most Utah counties in order to operate a dedicated vapor product retail operation.
Dedicated Manufacturing Space	A clean safe environment that is used exclusively for the manufacturing of e-liquid
DIY	Do it yourself
Electronic Age Verification	Smartphone software or a hand-held scanner that verifies through Active Age Verification that the cardholder is of legal age to purchase electronic cigarette vapor products. Electronic methods cannot replace common sense or use good judgment. While the use of these devices can be an excellent tool for age verification, they should not be the only method relied upon for age verification. For instance they machine cannot verify that the person presenting you the card is the actual card holder, be wary of imposters using someone else's ID
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
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
ID Card	A government issued card giving identifying data about a person that contains either a bar code or magnetic stripe on the reverse side. Must include full name, address, age and a photograph.

Leaf Tobacco Products	Tobacco products such as loose tobacco, cigarettes, cigars and shisha
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
PPE (Personal Protection Equipment)	Personal protective equipment (PPE) refers to protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury.
Specialty Retail Outlet	Retail operation specializing in the sale of electronic cigarette vapor products and e-liquid who does not sell leaf tobacco products or accessories.
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 H ₂ O under standard conditions)
Leaf Tobacco Accessories	Products for the consumption of leaf tobacco products. Includes but is not limited to glass pipes, bongs, hookahs, rolling papers, herbal vaporizers, wax atomizers, oil atomizers and leaf atomizers.
Unflavored Base	Nicotine suspended in Propylene Glycol or Vegetable Glycerin into a specific titration meant for direct consumer use or as base to mix with natural and/or artificial flavors for direct consumer use.
USP	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 Pharmacopeia 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
Vapor Product	Also known as VTM (Vapor/Tank/Mods). These are “open” vapor products and generally use refillable tanks, open atomizers or rebuildable atomizers and refillable e-liquid. Vapor products consist of all products after the “first generation” “closed” vapor products.

E-Liquid Manufacturing

If you manufacture liquids in Utah, you need to be working at or above applicable county or state standards *AND* align with standards set forth by the Utah Smoke Free Association. We anticipate the state of Utah to introduce manufacturing regulations statewide in 2015 and we support Smart, Sustainable and Responsible regulations for the safety of the consumers along with the safety of those mixing the liquids. At the time of ratifying these standards, all counties in the state of Utah are working towards or have passed industry regulations requiring the purchase of a manufacturing permit and incorporate much of the manufacturing standards herein.

To be considered as a member manufacturer in Utah, the following minimum standards are required prior to joining. If you sell liquid to the general public, both the Retail and Manufacturing standards apply.

Section 1 – Licensing / Insurance

- a. All manufacturers must have proper business licenses to operate in the city/county/state of incorporation. Additional business permits may be required by your county health department depending on the county of incorporation. Copies of all licenses and permits must be provided to the Utah Smoke Free Association and to any specialty retail outlet upon request.
- b. Adequate insurance to protect both yourself and your resellers in the event of injury or illness as a result of product usage. Copies of insurance certificate(s) must be provided to the Utah Smoke Free Association and to any specialty retail outlet upon request.
- c. Retail resellers must have insurance to protect their business against loss and liability for injury/illness brought on by products manufactured. Insurance certificate must indicate the manufacturer is insured for the manufacturing and sales of e-liquid. Recommendations of providers are available upon request.

Section 2 – Facilities

All Utah Smoke Free Association certified manufacturing facilities must be constructed as a standalone or shared facility with adequate separation from publicly accessible spaces. Manufacturing facilities may not be constructed in a private or shared residence. All manufacturing facilities are to maintain cleanliness standards to meet or surpass health department food service regulations, including:

- a. Stainless or other solid surface mixing tables (excluding wood)
- b. Shelving to be of stainless or solid material (excluding wood)
- c. Use of 3 compartment stainless steel sink system for wash, rinse and sanitize
- d. Proper hand washing sink separate from bathroom facilities
- e. Floors, walls and ceiling must be solid surface that are easily cleanable.
- f. Cleaning chemicals and equipment are to be stored outside the mixing facility
- g. No wood, cardboard or paper (excluding order slips) may be present in the mixing facility at any time.
- h. Negative air-flow ventilation must be present when nicotine above 48mg is in use within the mixing facility.
- i. 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.

Section 3 – OSHA (Occupational Safety & Health Administration) Requirements

Employers must be committed to the elimination of safety and health hazards. With the commitment of eliminating safety and health hazards in the workplace and establishing a safety and health program, employers benefit from increased productivity, better morale and decreased workers' compensation and health care costs. For more information:

<http://laborcommission.utah.gov/divisions/UOSH/>

Material Safety Data Sheets

- a. OSHA requires all employers to maintain a physical binder containing all Material Safety Data Sheets (MSDS) for every chemical stored on site. Binder location must be known and be accessible by all employees. Examples of chemicals can include, e-liquid components, air deodorizers, cleaning chemicals, window cleaner, soaps, etc.

Safety Training

The Utah Smoke Free Association is happy to assist in organizing consultation training at no cost to our members on OSHA safety and the necessary requirements a business owner must follow to remain in compliance with the law. Please contact the Board of Directors if you require assistance.

Nicotine

Nicotine solutions should be stored in a dry, cool, dark location that is secured from untrained personnel. Containers storing Nicotine solutions must always be labeled properly with the content and appropriate warning language and/or symbols. Labeling should include the chemical name, and bear the words Danger, or Poison. DO NOT store Nicotine solutions in unlabeled containers. Recommendations on labeling available upon request.

Section 4 – Personal Protection Equipment

To enter or work within the mixing facility, everyone must have:

- a. Smock / lab coat
- b. Gloves
- c. Eye / face covering
- d. Hair covering
- e. Foot covering
- f. Mask / face covering

Section 5 – Ingredients

- a. Use of USP grade PG, VG & Nicotine only
- b. No direct use of artificial food coloring. Where food coloring is used by flavoring supplier, exact food coloring number identifier must be included on label
- c. Ingredient such as pharmaceuticals, marijuana, marijuana extracts, caffeine, vitamins, dietary supplements, herbs, essential oils or anything beyond traditional flavorings are forbidden.
- d. Flavoring bases must be of PG, VG, water or alcohol only. Flavorings suspended in oil may not be used.
- e. Water used (if any) will be either deionized or distilled
- f. Propylene Glycol (PG), Vegetable Glycerin (VG) and Nicotine shall be stored in a location free of wood and paper products to reduce the risk of dust contamination.

Section 6 – Mixing Equipment

- a. Where not mixing per bottle, use of laboratory grade mixing vessels
- b. When using graduated pipettes or syringes, must be disposed of after each batch
- c. Separate mixing equipment for all zero nicotine liquids
- d. When not in use, open mouth mixing equipment is to be suspended upside down so rim of equipment does not make contact with storage surfaces.

Section 7 – Storage Equipment

- a. All storage equipment for parts, supplies & ingredients must be of stainless steel or appropriate plastics with lids to ensure cross-contamination risks are minimized. The use of wood, wood composites, paper or cardboard are strictly prohibited within all areas ingredients are stored or mixed into a final consumable product.

Section 8 – Packaging

All certified manufacturers agree to include within the printable space on their label the Utah Smoke Free Association seal (located on the “Organization Standards” page of the Association website) to indicate compliance and participation with organization standards.

- a. All bottles are to be new unused bottles, tips, caps and/or droppers.
- b. Labeling to meet most rigorous standards in the state but must contain:
 - i. Nicotine content in mg or percentage by volume (12mg/mL)
 - ii. Ingredients listed in order of volume
 - iii. Warning statement (Nicotine is a poison, keep out of reach of children and pets)
 - iv. Company name/City & State of manufacture
 - v. Flavor
 - vi. Volume of bottle (10mL, 15mL, etc)
 - vii. Batch number
 - viii. Association manufacturing seal
 - ix. Smudge-proof labels
- b. Use of child-resistant caps
- c. Tamper-evident packaging is required

Section 9 – Product Testing

Nicotine

- a. Each liquid batch must be tested within 10% +/- of the target base nicotine levels. Signed certificate of testing must be obtained for each test and copies of each test maintained for a period of not less than 24 months and be made available for inspection upon request.
- b. 1-10mL sample of each batch must stored under refrigeration for a period of not less than 24 months with proper batch numbering identifying the testing results.

Diacetyl and Acetyl Propionyl

All products must be tested for Diacetyl and Acetyl Propionyl (2,3-pentanedione). The testing may be performed on each raw ingredient or on the final product for consumption. This test must be performed each time raw ingredient batch numbers change to ensure the ingredient formulation has not changed. Additional tests may be required in the future as required by industry standards or local regulations.

- a. Tests for diacetyl and acetyl propionyl must use testing methods that are equal to or better than quantitative GC-MS with LOD of 5 ug/mL or less. Signed certificate of testing must be obtained for each test and copies of each test maintained for a period of not less than 36 months and be made available for inspection upon request.
- b. 1-10mL sample of each batch must stored via refrigeration for a period of not less than 24 months with proper batch numbering identifying the testing results.

Section 10 – Penalties

Penalties may be assessed against manufacturing facilities that fall out of compliance with the published standards. If after the yearly or surprise audits, any deficiencies are noted; adequate time to correct the issues and come into compliance will be given. If after a re-inspection, the issues remain, the following penalties will apply:

First offence

1. Financial penalty of \$750

Second offence

Within 12 calendar months:

1. Financial penalty of \$1200

Third offence

Within 12 calendar months:

1. Six-month suspension from organization, removal of Utah Smoke Free Association seal of certification, forfeiture of dues and benefits and removal from trusted manufacturing directory.
2. Re-entry into the organization will require all fees to be repaid and full inspections to be taken.

Code of Conduct

As a Utah Smoke Free Association member manufacturer, by signing this you agree to these terms below:

1. It shall be prohibited to sell, give or furnish in any manner, vapor products to minors under the age of "19". Minors shall not be allowed to sample any product at any time, nor will they be allowed into any vapor specialty retail establishment unless accompanied by a parent or legal guardian (not a friend) above the age of "21".
2. Members shall not at any time engage in unlawful or illegal activity including but not limited to, the sale or distribution of illegal and or controlled substances. Members agree not to sell any equipment that can be used or to facilitate illegal drug activity.
3. Members shall not have in their inventory or sell any solid leaf tobacco products such as but not limited to; cigarettes, cigars, loose tobacco, etc. Members also may not sell tobacco accessories designed for the smoking of leaf tobacco such as but not limited to; glass pipes, water pipes, hookahs, rolling papers, herbal vaporizers, etc.
4. Members shall operate their businesses in a professional and ethical manner at all times as an active member of the Utah Smoke Free Association and agree to uphold ethical standards of the organization.
5. Member manufacturers shall provide to the Utah Smoke Free Association a copy of its sales tax permit, a copy of business entity filing on file with the state of Utah and a copy of any applicable county permits.
6. We believe in ethical, fair and vigorous competition. Any unethical or unprofessional actions towards other shops; or actions which may harm the reputation of the Utah Smoke Free Association, membership as a Utah Smoke Free Association retailer may be prohibited or revoked at the discretion of the Utah Smoke Free Association Board of Directors.

Any illegal activity witnessed or reported, the Utah Smoke Free Association will work diligently with local, county and state officials to take the appropriate action; membership as a Utah Smoke Free Association retailer may be revoked at the discretion of the Utah Smoke Free Association Board of Directors.

Any violations of the above code of conduct will result in revocation of membership, benefits, advertising, and any dues set forth for a period of not less than 6 consecutive months.

By signing, you are accepting these terms of the Utah Smoke Free Association "Code of Conduct" and agree to operate your business in a professional and ethical manner.

Signature _____

Print Name _____

Store name _____

Date _____