

Report of Public Hearing
Davis County Board of Health Regulations
Dr. Gary Alexander, Hearing Officer

Pursuant to Utah Code Annotated 26A-1-121(1), the Davis County Board of Health held a public hearing on December 12, 2013, to receive public comments concerning adoption of a new regulation—**Electronic Smoking Device Regulation** and the proposed changes to an existing regulation—**Adjudicative Hearing Procedures Regulation**.

The proposed **Electronic Smoking Device Regulation** will establish practices for the safe preparation, handling and sale of substances used in electronic smoking devices within Davis County. Specifically, the proposed regulation will:

- Formally adopt and incorporate by reference UCA Title 26 Section 38: Utah Indoor Clean Air Act; R392-510: Utah Indoor Clean Air Act; UCA Title 76 Section 10-104: Providing cigar, cigarette, electronic cigarette, or tobacco to a minor; and UCA Title 76 Section 10-105: Buying or possessing a cigar, cigarette, electronic cigarette, or tobacco by a minor.
- Require E-Liquid for sale in Davis County to be clearly and accurately labeled for nicotine content, other ingredients, and safety warnings.
- Require E-Liquid packaging to have child proof caps, be tamper-evident, and be leak proof at the time of sale.
- Require businesses that are mixing E-Liquid to be permitted through the Health Department.

The proposed changes to the existing **Adjudicative Hearing Regulation** include:

- Changing the SCOPE wording from “Environmental Health Services Division programs” to “Davis County Health Department programs” so that the regulation is enforceable throughout the Department.
- Adding PENALTY categories of “Determined by proceedings” and “Variable” to clarify that penalties, if assessed, are based on the hearing procedures.
- Basic formatting changes on pages 7 and 9 with removal of the wording “Failure to File a Timely Appeal” from the beginning of the sections.

Copies of the proposed and existing Regulations were made available to the public at the Department’s website and the Environmental Health Services Division office located at 22 South State, Clearfield, Utah. Notice of the hearing was published in the Davis County Clipper and the Ogden Standard Examiner, papers of general circulation, on November 28, 2013 and December 5, 2013.

Hearing Summary:

The public hearing was held at 5:30 p.m. on December 12, 2013, in Classroom #2021 of the Davis County Health Department, Clearfield, Utah. Written comments were received by the Department at the Environmental Health Services Division until 5:00 p.m. December 19, 2013.

Electronic Smoking Device Regulation:

The Department received several comments during the public hearing and in writing pertaining to the Electronic Smoking Device Regulation. Utah Vapers and other stakeholders were involved throughout the process of writing the regulation and received the proposed regulation prior to the public hearing.

It was estimated that 15 members of the public were in attendance at the hearing. Of those, three requested to speak. Their comments and/or questions include:

Comment 1 - The time period for the regulation to go into effect was questioned by several attendees. In relation to this, several business owners explained that they had purchased a large amount of labels for their products that did not meet the new requirements for labeling. The business owners recommended a time period of 3-6 months to come into compliance with the new regulation.

Response: Staff recommends the board authorizes a phase in period of up to 6 months for businesses to come in compliance with the regulation.

Comment 2 – The need for a single owner to have separate permits for multiple locations in the county was brought up and questioned. A business owner requested that this rule only require one permit per business.

Response: Staff recommends every location regardless of ownership have a permit, consistent with other health department regulations.

Comment 3 - A discussion was held regarding the units for displaying nicotine content—mg/mL vs. percentage (percent by volume). Several attendees commented that both measurement units meet “industry standards” and business owners were worried that they would have to change labeling practices or even change distributors if one unit was required over the other.

Response: Staff recommends the amending the regulation to require the product’s nicotine content be labeled in mg/mL or percent by volume, consistent with industry practices.

Comment 4 - The label size and the amount of wording that will be required on the small bottles were questioned. It should be noted that another business owner informed the group that he has labels and label locations on the bottles that can meet the requirements and he would be willing to help any other owners with this issue.

Response: Staff recommends the labeling requirement be amended to the following:
1) Nicotine content 2) Vendor name 3) Ingredients 4) Safety Warning - Keep Out of Reach of Children and Pets.

Comment 5 - The regulation packaging requirement 5.1.2 currently states that the containers must be “leak-proof” and “tamper-resistant.” A comment was made that alternative wording should be “leak-proof at the time of sale” and “tamper evident.”

Response: Staff recommends the regulation be amended to include “at the time of sale” to “leak-proof. Also recommends “tamper-resistant” be changed to “tamper evident.”

Comment 6 - A business owner in Davis County said he approves of the regulation and his business already meets or exceeds the requirements.

Comment 7 - The director of the Utah Vapers said that the Association “absolutely approves the regulation.”

The Department also received a number of public comments in writing from three groups— Utah Vapers, National Association of Tobacco Outlets (NATO), and NJOY Electronic Cigarettes (NJOY). Those comments and/or questions include:

Comment 1 (Utah Vapers) - The purpose of the regulation in Section 1.0 indicates this is only for E-Liquid and not devices on any level. The individual recommends changing to the following:

The purpose of this regulation is to protect the public health, safety, and welfare of residents and employees by establishing practices and provisions for the sale of Electronic Smoking Devices (ESDs) and E-Liquid; and the safe preparation and handling of E-Liquid components within Davis County.

Response: Staff recommends amending Section 1.0 by replacing existing wording with the suggested wording.

Comment 2 (Utah Vapers) - In Section 4.1 - Electronic Smoking Device (ESD), recommend using common nomenclature such as ‘electronic cigarettes’ or ‘Electronic Nicotine Delivery System (ENDS) in the definition.

Response: Staff recommends keeping current wording in the definition.

Comment 3 (Utah Vapers) – In Section 4.6 – Manufacturing Facility, recommended changing the definition to the following:

Manufacturing Facility: Any business within Davis County that manufactures, repackages, or resizes E-Liquid for sale or for resale.

Response: Staff recommends amending the wording to include the suggested change.

Comment 4 (Utah Vapers) – In Section 4.7 Nicotine is defined as having many physiological effects and is very addictive. The comment was made that “This is the affect of using nicotine not a definition of the product”.

Response: Staff recommends amending current definition to the following definition to more clearly define nicotine: An alkaloid derived of tobacco and other plants, or produced synthetically which has addictive and other physiological properties when ingested or inhaled.

Comment 5 (Utah Vapers) – In Section 4.8 – Preparation Area, recommended changing the definition to the following:

Preparation Area: Physical location, in which E-Liquid Components are mixed, repackaged or resized for sale to the consumer.

Response: Staff recommends amending wording to include the suggested change.

Comment 6 (NJOY) – Recommended adding the following definition to Section 4:

Child-Proof Caps: Caps that meet the standards of “Child-resistant packaging” under the Poison Prevention Packing Act of 1970.

Response: Staff recommends not adding the Child-Proof Caps definition.

Comment 7 (Utah Vapers) – Regarding Section 5.1.1 – Labeling, recommended allowing nicotine content to be labeled with mg/ml or percent by volume. “Global Standards” accept both.

Response: Staff recommends the regulation be amended allowing the product nicotine content to be labeled in mg/mL or percent by volume, consistent with industry practices.

Comment 8 (Utah Vapers) Regarding Section 5.1.1.1.5 – Safety and Health Warnings, this requirement should be only “if applicable” and it “should be acceptable to have separate sections of the facility along with separate mixing equipment for liquid containing zero nicotine.”

Response: Staff recommends Section 5.1.1.1.5 be removed from the labeling requirements.

Comment 9 (Utah Vapers) Regarding Section 5.1.2 – Packaging, nothing is leak proof. Recommended adding the following:

“leak-proof at the time of sale”

Response: Staff recommends the regulation wording be amended to all containers be leak proof at the time of sale.

Comment 10 (NJOY) Regarding Section 5.1.2 – Packaging, recommended adding the following:

Be leak-proof when used and stored under normal conditions.

Response: *Staff recommends the regulation wording be amended to all containers be lead proof at the time of sale.*

Comment 11 (Utah Vapers) Regarding Section 5.1.2 – Packaging, recommended changing to the following:

Must use tamper-evident packaging such as shrink wrap or break evident cap ring (similar to what is used with 2 liter bottles).

Response: *Staff recommends “tamper-resistant” be changed to “tamper evident.”*

Comment 12 (Utah Vapers) Regarding 5.1.3 – Nicotine level in E-Liquid, national brands such as NJOY, BLU, and others have nicotine content at or exceeding 45mg/mL.

Response: *Staff has evaluated current products on the market and has only found one brand that exceeds the 36 mg/mL maximum requirement. Staff recommends leaving the 36 mg/mL maximum in the regulation.*

Comment 13 (NJOY) Regarding Section 5.1, recommended adding the following:

5.1.5 Section 5.1 shall not apply to liquid sold in pre-fill ESD products, such as disposable single-use products, or sealed pre-filled disposable replacement cartridges for use in ESDs.

Response: *Pre-filled ESD products are currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney’s office, the proposed Section 5.1.5 was added making this regulation consistent with state law.*

Comment 14 (NJOY) Regarding Section 5.2.1, recommended deleting the following:

such as ESDs and/or use of E-Liquid are a healthy alternative to smoking.

Response: *Staff recommends deleting “such as ESDs and/or use of E-Liquid are a healthy alternative to smoking from the regulation.*

Comment 15 (Utah Vapers) Regarding Section 5.3 – Youth Access in Davis County, recommended that section 5.3.1 be more general and changed to the following:

The selling of E-Liquid to any person under the state mandated smoking age is strictly prohibited.

Response: Staff believes the current language is sufficient and also recommends adding possession of E-Liquid by any person under 19 years of age is prohibited to the regulation.

Comment 16 (NJOY) Regarding Section 5.3.3, recommends the following:

ESDs and E-Liquid shall not be directly accessible to the public. ESDs and E-Liquid on display must be under control of the vendor, such that the product can only be accessed with assistance by the vendor, or behind the counter, or in locked display cases.

Response: In consultation with the county attorney's office, staff believes the current language is consistent with state law.

Comment 17 (Utah Vapers) Concern was expressed regarding Section 5.4.2.4 – “Good Hygienic Practices”, whether these are documented practices or more general statements?

Response: “Good Hygienic Practices” are well defined within the food service industry and can be easily found. Staff feels current wording is sufficient to describe the intent of “Good Hygienic Practices.”

Comment 18 (Utah Vapers) Regarding Section 5.4.2 Sanitation and Safety, recommended that section 5.4.2.8 be changed to the following:

Chemicals not involved in the preparation of E-Liquid shall not be stored in preparation or ingredient storage areas to prevent cross-contamination.

Response: Staff recommends changing the wording in the regulation to the proposed wording.

Comment 19 (NJOY) Regarding Section 5.5.3, recommends adding the following:

Sampling of refillable ESDs and E-Liquid

Response: The sampling of ESDs is currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney's office, Sections 5.5.2 and 5.5.3 were removed making the proposed change not needed or relevant.

Comment 20 (NJOY) Regarding Section 5.5.3, recommended adding the following:

5.5.3.4 Section 5.5.3 shall not apply to pre-fill ESD products, such as disposable single-use products, or sealed pre-filled disposable replacement cartridges for use in ESDs.

Response: The sampling of ESDs is currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney's office, Section 5.5.2 and 5.5.3 were removed making the proposed wording not needed or relevant.

Comment 21 (Utah Vapers) Regarding the ten minute timeframe for sampling in Section 5.5.3.1, sampling can take much longer than this due to variables such as atomizer type and device power. Recommends removing the time limit from the requirement.

Response: The sampling of ESDs is currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney's office, Sections 5.5.2 and 5.5.3 were removed to make this regulation consistent with state law.

Comment 22 (Utah Vapers) Regarding the use of mouthpiece(s) in section 5.5.3.2 and 5.5.3.3, the industry term used is "Drip Tip(s)."

Response: The sampling of ESDs is currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney's office, Sections 5.5.2 and 5.5.3 were removed to make this regulation consistent with state law.

Comment 23 (Utah Vapers) Regarding Section 5.5.3.3, recommended adding the following:

Drip tips shall be cleaned daily using heat or chemical methods of sanitizing.

Response: The sampling of ESDs is currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney's office, Sections 5.5.2 and 5.5.3 were removed to make this regulation consistent with state law.

Comment 24 (NATO) The proposed Electronic Smoking Device Regulation is Pre-Empted by Utah State Law.

Response: Based on recommendations from the county attorney's office, Section 5.1.5 was added and Sections 5.5.2 and 5.5.3 were removed to make this regulation consistent with state law.

Comment 25 (NATO) The Davis County Board of Health may want to consider postponing further consideration of this regulation until the FDA formally adopts and implements nationwide regulations on electronic cigarettes. The FDA is scheduled to release Proposed Federal Regulations on E-Cigarettes this month (December).

Response: Staff recommends moving forward with the adoption of this regulation.

Comment 26 (NATO) Since closed system electronic cigarettes have sealed nicotine cartridges, the proposed labeling and packing requirements should not apply to closed system e-cigarettes.

Response: Pre-filled ESD products are currently regulated under state law and prohibits any requirements that are not essentially the same. Based on recommendations from the county attorney's office, the proposed Section 5.1.5 was added addressing this issue.

Comment 27 (NATO) Concern was expressed regarding the intent of the Davis County Board of Health to apply the proposed regulations to both open system and closed system e-cigarettes? If so the potential impact of the regulations on the closed system electronic cigarettes demonstrates that the proposal exceeds the scope of the authority of the Davis County Board of Health.

Response: Pre-filled ESD products are currently regulated under state law and prohibits any requirements that are not essentially the same. E-Liquid is not currently defined as an ESD and is not pre-empted by state law. Staff recommends the board adopt the revised regulation addressing E-Liquid.

Comment 28 (NATO) The inclusion of various pharmacopeia rules and requirements may be misplaced if manufacturers do not make therapeutic or medicinal claims.

Response: This regulation focuses on the public health concerns surrounding the sanitation and safety of E-Liquid. Requirements set forth in this regulation ensure that those concerns are addressed.

Adjudicative Hearing Procedure Regulation:

No public comments were received at the public hearing or in writing pertaining to the proposed ***Adjudicative Hearing Procedures Regulation*** changes.

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Certification of Hearing:

I, Dr. Gary Alexander, presided over the public hearing for the Davis County Board of Health adoption of the ***Electronic Smoking Device Regulation*** and the adoption of the proposed changes to the ***Adjudicative Hearing Procedures Regulation*** and have approved this Hearing Report Summary.

Signed: 

Date: 2/11/14