Results of NJDEP's Inspections of Vape Shops and E-Juice Labs

Presented by: Amy Scaffidi

What is E-Juice?

- E-Juice (also referred to as E-Liquid) in the e-cigarettes typically consist of the following ingredients, with nicotine being the sole active ingredient (P075 - acutely hazardous waste):
- nicotine (1-2.5%)
- flavorings
- propylene glycol (PG) used as food additives and preservatives
- vegetable glycerin (VG) used as food additives and preservatives

NJDEP's Findings: 2 Labs were visited

Lab A	Lab B
Provide co-packaging services, private labels	Provide co-packaging services, private
formulations, along with distribution.	labels formulations, along with distribution.
Manufactures different flavorings by mixing	Manufactures different flavorings by mixing
the vegetable glycerin (VG) and polyethylene	the vegetable glycerin (VG) and
glycol (PG) and nicotine	polyethylene glycol (PG) and nicotine
ISO 7 cleanroom for manufacturing	Designated room for manufacturing
After ingredients are hand mixed they are	Ingredients are mixed in a 600 ml glass jar
poured into a pressure pot. The pressure pot	and baked in an oven. After the E Juice is
cooks the E Juice and then pushes it into the	cooked it is transferred into 30 ml containers
machine where it is bottled into smaller	which are sold to their customers (vape
containers for their customers (vape shops).	shops).
P075 waste includes:	P075 waste includes:
Nicotine River empty containers	Liquid Nicotine Wholesaler empty
The rinsate/residues generated from	containers
cleaning of the mixing instruments and	The rinsate/residues generated from
pressure pot.	cleaning of the mixing instruments and
Rags used to clean up spills	containers.
	Rags used to clean up spills
*Non-notifier - (No EPA ID#)	*Non-notifier - (No EPA ID#)

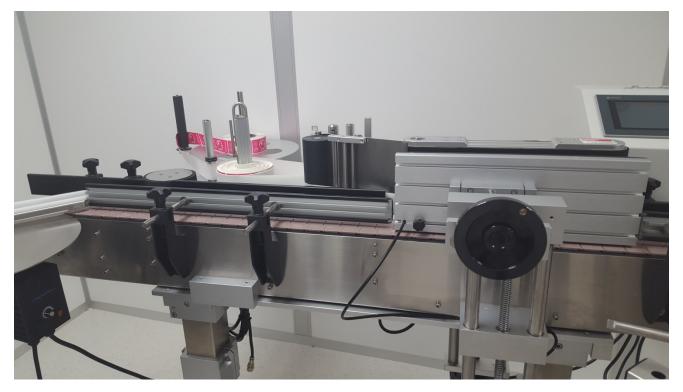
Pictures of Lab A Pressure Pot



Product Dispensing Machine



Bottle Labeling Machine



Nicotine container



Pictures of Lab B



Lab B's equipment



Nicotine Containers



Product: E-Juice



More Product



Various Vape Shops were visited:

- Retailer of vaporizers, heating elements (coil, atomizer, and wicks), E-liquids, authentic mods, and accessories like cases.
- No mixing (no manufacturing) occurs on-site for the e-juice. Possible P075 waste that may be generated on site (which might contain a small amount of nicotine residue) are the small bottles which once held e-juice that are thrown away by their customers into their trash. *A carry in, carry out policy would help with this issue. This idea was developed by another State.
- Shop was determined to be a Conditionally Exempt Small Quantity Generator (CESQG)

One Vape Shop which had a Labwas visited:

*Several vape shops are blending their flavors to make e-juice.

- Retailer of vaporizers, heating elements (coil, atomizer, and wicks), E-liquids, authentic mods, and accessories like cases.
- Facility also performs "blending" of the product, nothing is cooked on-site. 30 ml. bottles of flavors are blended with the nicotine product by use of a syringe. The syringe is used to measure the volume of nicotine being blended into the 30 ml. bottles. Nicotine is being purchased in 16 ounce bottles from a company named Flavor Apprentice. Approximately 4 syringes and 2 empty nicotine bottles per month. These hazardous waste streams (hazardous waste code-P075) have been identified and are being disposed of in their solid waste dumpster. Less than 1 lb. of acutely hazardous waste is being generated per month (or is accumulated on-site any given time). No wick waste is generated on-site because facility does not change the coil or wick

One Vape Shop which had a Lab was visited:

*Several vape shops are blending their flavors to make e-juice. -Continued-

- Shop was determined to be a Conditionally Exempt Small Quantity Generator (CESQG).
- *One empty syringe weighs approximately .005 lbs. and one empty nicotine bottle weighs approximately .068 lbs.

Examples of different types of e-cigs and vape modifications







Examples of different types of e-cigs and vape modifications





Enforcement Actions were issued (Notice of Violation) to the non-notifiers for the following 6 requirements:

- 1. Failure of generator of solid waste to determine if waste is hazardous. Specifically, the Laboratories failed to determine that their nicotine waste (empty containers and rinsate) was an acutely hazardous waste (hazardous waste code-P075). [40 CFR 262.11]
- 2. Failure of generator to have EPA identification number before it treats, stores, transports, offers for transportation, or disposes of hazardous waste. Laboratories failed to obtain an EPA identification number. [40 CFR 262.12(a)]
- Failure of a generator to submit hazardous waste report of manifest activities by March 1. Laboratories failed to submit a Biennial Report by March 1, 2016.
 [40 CFR 262.41(a)]

Enforcement Actions continued:

- 4. Failure of facility owner or operator to provide required classroom or on-the-job training for facility personnel. Laboratories were unable to provide any training documentation relating to the management of hazardous waste. [40 CFR 265.16(a)(1)]
- Failure of facility owner or operator to make required arrangements with police or fire departments, emergency response contractors, equipment suppliers, or local hospitals, or to document any such authority's refusal of such arrangements. Laboratories failed to make required arrangements with all of the entities listed above. [40 CFR 265.37(a)]
- Failure of facility owner or operator to have a contingency plan designed to minimize hazards to human health and the environment. Specifically, Laboratories failed to prepare and retain a hazardous waste contingency plan. [40 CFR 265.51(a)]

Status of Enforcement Actions:

The Laboratories were not aware they generated a hazardous waste and were not well educated on the hazardous waste regulations. In the beginning it was a steep learning curve. NJDEP provided several guidance materials to the facilities and helped them come into compliance. Compliance with these 6 violations took approximately 6 months.

Additional Findings:

- During a colleagues inspection of a Rite Aid, the inspector ran across a business called "Knightshade" who claims to recycle Nicotine from Smoking Cessation Products. Knightshade is located at 14601 Country Road 212, Suite K in Ohio. There is
 - an EPA Letter regarding the recycling of nicotine by Knightshade LLC (OH).
- https://yosemite.epa.gov/osw/rcra.nsf/ea6e50 dc6214725285256bf00063269d/42F79D357D B8199885257E810070F6B0/\$file/14851.pdf

Moving forward...

NJDEP's Bureau of Hazardous Waste C&E has drafted an Enforcement Alert which will be posted the NJDEP's website.

DRAFT DOCUMENT



Enforcement Alert Making You Aware of Anticipated Enforcement Activities

ompliance and Enforcement

#2017-00

DEP to Conduct Compliance and Enforcement Inspections at Vape and e-Cigarette Shops and **Manufacturers**

Issued:

Who is affected by this initiative?

All retailers and manufacturing facilities that are engaged in the sale or manufacturing of ejuice and e-cigarettes that contain nicotine.

Why is DEP focusing on e-cigarette and vape shops and manufacturers?

The DEP wants to ensure that facilities that sell or manufacture e-cigarette and vape products are properly managing the waste, primarily nicotine, generated from the production of e-juice and e-cigarette cartridges. Nicotine is a commercial chemical product (CCP) that is regulated as an acutely hazardous waste (waste code-P075) under the Resource Conservation and Recovery Act (RCRA) when disposed. If a facility generates or accumulates on site at any given time >2.2 lbs. of an acutely hazardous waste, they are considered a Large Quantity Generator (LQG) of hazardous waste.

What is DEP doing?

The DEP's Bureau of Hazardous Waste Compliance and Enforcement has begun a thorough review of the accumulation and disposal of nicotine waste at vape shops and manufacturers. The department will investigate and take appropriate enforcement action against facilities where the hazardous waste regulations are being violated.

What should I do?

 Under <u>40 CFR 262.11</u>, a person who generates a solid waste, as defined in 40 CFR 261.2. must determine if that waste is a hazardous waste. Nicotine waste, including empty containers that once held nicotine or other wastes that have been contaminated by nicotine (e.g. rinsate, rags used to clean up drips or spills, cotton coils from vapes, etc.), contains nicotine residue and must be managed as an acutely hazardous waste when discarded.

• Ensure that your facility is in compliance with the Federal Regulations for hazardous waste which is regulated by the EPA under the Resource Conservation Recover Act (RCRA). Hazardous waste generators are required to determine their generator status and abide by the applicable Federal and State hazardous waste requirements. A summary of the regulatory citations and a description of the requirements can be found within the Compliance Assistance Packet for Hazardous Waste Generators which was developed by the DEP.

Who should I contact with guestions?

Bureau of Hazardous Waste Compliance and Enforcement – Southern Field Office	856-614-3658
Bureau of Hazardous Waste Compliance and Enforcement – Central Field Office	609-943-3019
Bureau of Hazardous Waste Compliance and Enforcement – Northern Field Office	973-656-4470

Where can I get more information?

For more information, visit:

NJDEP Compliance Assistance Packet for Hazardous Waste Generators http://www.nj.gov/dep/enforcement/CAVPacket Master.pdf

Instructions and Form for Hazardous Waste Generators, Transporters, and Treatment, Storage and Disposal Facilities to Obtain an EPA Identification Number https://www.epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-andtreatment-storage-and

EPA's Determination Regarding the Hazardous Waste Status of E-Cigarettes Under RCRA https://yosemite.epa.gov/osw/rcra.nsf/ea6e50dc6214725285256bf00063269d/EE5AE44ACEE473B585257E 810070F655/\$file/14850.pdf

EPA's Evaluation of P-Listed Pharmaceutical Residues in Empty Pharmaceutical Containers

https://cfpub.epa.gov/si/si public record report.cfm?direntryid=310610&keyword=land%20and%20waste%2 0management&subject=land%20and%20waste%20management%20research&showcriteria=2&fed_org_id= 111&datebeginpublishedpresented=12/24/2011&dateendpublishedpresented=12/24/2016&sortby=pubd ear

Please note this advisory is intended to be a summary explanation of a department initiative. It does not include all potentially applicable requirements. If you have any questions related to compliance with this initiative, please contact the Enforcement number listed above.

What other agencies are these facilities regulated by? NEW JERSEY DEPARTMENT OF HEALTH

- The 2006 NJ Smokefree Air Act ("Act") and 2007 Regulations promulgated by the NJ Department of Health and Senior Services
- The NJ Department of Health issued regulations in May and October 2007 to help implement the 2006 Act, and in 2014 to revise one definition, add in a definition for "hookah" (new) and "electronic smoking device" (electronic smoking devices was already added in 2010 as an amendment to the 2006 Act)...

There are always exceptions

Tobacco Retail Establishment (TRE) exception requirements:

N.J.S.A. 26:3D-57 defines a 'tobacco retail establishment' as 'an establishment in which at least 51 percent of retail business is the sale of tobacco products and accessories, and in which the sale of other products is merely incidental.'

 To be granted a TRE waiver, certain requirements must be met: such as ventilation, revenue, sales and registration requirements.

What other agencies are these facilities regulated by? US Food & Drug Administration

- In 2016, FDA finalized a rule (21 CFR Parts 201, 801, and 1100) extending their regulatory authority to cover all tobacco products, including vaporizers, vape pens, hookah pens, electronic cigarettes (E-Cigarettes), epipes, and all other Electronic Nicotine Delivery Systems (ENDS). FDA now regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS. This includes components and parts of ENDS* but excludes accessories.
- Manufacturing ENDS and E-Liquids: If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import ENDS, you must comply with these requirements for

manufacturers.

Some examples of the FDA's requirements are as follows: • Report user fee information and pay user fees;

- Submit tobacco health documents;
- Register your establishment and submit list of products, including labeling and advertisements;
- Submit ingredient listing;
- Include Required Warning Statements on Packages and Advertisement;
- Submit a premarket application for "new" tobacco products (this would mean each

flavor).

Where can I find more information on the FDA Tobacco Regulations...

 https://www.fda.gov/TobaccoProducts/Guidan ceComplianceRegulatoryInformation/Manufac turing/default.htm

QUESTIONS?