



Received

OCT 25 2012

BSHW

OCT 25 2012

October 21, 2012

Mr. Anthony Tripp

Florida Department of Environmental Protection
2600 Blair Stone Road, MS 4560
Tallahassee, FL 32399-2400

Mr. Jim Byer

Florida Department of Environmental Protection
160 Government Center
Pensacola, FL 32502-5794

Re: Regulatory Status of Electronic Cigarettes

Dear Sir or Madam:

Veolia ES Technical Solutions, L.L.C. (Veolia), a leader in the hazardous and universal waste service industry, operates a universal waste facility in Tallahassee, FL that has recently received questions from several of its customers regarding the proper management, recycling, and disposal of electronic cigarettes (e-cigarettes). Veolia is seeking confirmation of our interpretation of the regulatory requirements for the proper classification of e-cigarettes, as it applies to the nicotine containing portion of the e-cigarette, when offered for treatment and disposal. Based on our research of the Federal Resource Conservation and Recovery Act (RCRA) regulations, the Florida Administrative Code (F.A.C.), and EPA issued interpretation letters, it is our understanding that e-cigarettes are NOT regulated as a hazardous waste, due to the presence of the nicotine, under 40 CFR Part 261 or as adopted by reference in 62-730.030 F.A.C. However, due to the presence of the lithium battery, the e-cigarettes would be subject to the requirements of the universal waste rules under 40 CFR Part 273 as adopted in 62-730.185 F.A.C. An electronic cigarette is an electric inhaler that vaporizes a propylene glycol-, glycerin-, or polyethylene glycol-nicotine based liquid solution into an aerosol mist, simulating the act of tobacco smoking. An e-cigarette contains three components: a battery, an atomizer, and a cartridge/mouthpiece. The cartridge contains the liquid propylene glycol-, glycerin-, or polyethylene glycol-nicotine mixture.

Three types of e-cigarettes are currently marketed to consumers: Disposable, Rechargeable, and Refillable.

- Disposable e-cigarettes - the battery, circuitry, heating element and fluid cartridge are contained in one unit and when completely used the entire unit is discarded.

- Rechargeable e-cigarettes – the rechargeable battery and circuitry are combined in one unit and the fluid cartridge and heating element are in a separate removable component. Following use the battery is recharged to allow reuse of the device and the consumed fluid cartridge is discarded and replaced with a new one.
- Refillable e-cigarettes – may be all-in-one or have separate components, but the fluid containing cartridges are refillable.

The e-cigarettes that may be received by Veolia for management and disposal are either:

- Off-Specification Unused Products being discarded by the manufacturer;
 - Unused Returned Products being discarded by the manufacturer, distributor, or retailer;
- or
- Used Returned Products from the consumer

To make a hazardous waste determination for the e-cigarette the primary focus is on the presence of the nicotine in the liquid solution and whether its presence results in the classification of the e-cigarette as a listed hazardous waste. EPA provided guidance on the hazardous waste listing of unused nicotine containing dermal patches to Charlotte A. Smith, Director, PharmEcology Services, in a letter dated August 23, 2010. In the letter, EPA states that the unused nicotine patches when discarded would meet the definition of a P075 (nicotine and salts) listed hazardous waste because the patches meet the definition of an unused commercial chemical product. “Nicotine in finished dosage forms, such as tablets or capsules, is regulated under RCRA, because it is a commercial chemical product formulation containing nicotine as the sold active ingredient. We view transdermal patches as an analogous dosage form; therefore, unused patches are also listed P075 when discarded.”

In addition, the August 2010 letter EPA further discusses the regulatory status of “commercial chemical products” by stating, “EPA considers the definition of commercial chemical product in 40 CFR 261.33 to exclude manufactured articles such as batteries or fluorescent lamps. Manufactured articles that happen to contain a chemical listed in 261.33 are not generally known by a generic chemical name; therefore, manufactured articles that contain one of the listed chemicals would not be considered a listed waste when discarded in an unused form.” In addition, an August 1996, Monthly Hotline Report, discusses off-specification mercury thermometers and states that, “For the purposes of the P and U lists of hazardous waste, however, EPA intended to include in the P and U lists only those commercial chemical products and manufacturing chemical intermediates known by the generic chemical name listed in 261.33. EPA considers the P and U list definition of commercial chemical product to exclude manufactured articles such as thermometers or fluorescent lamps. Therefore, manufactured articles that contain a P or U listed chemical would not be considered a listed waste when discarded in an unused form.”

By applying this EPA interpretation to the e-cigarettes, Veolia believes that the e-cigarettes meet the definition of a “manufactured article” as described above and would not be regulated as a commercial chemical product. This is supported by the fact that e-cigarettes are currently:

- Not classified as stop smoking aids and therefore not currently regulated as a medicine;
- Not classified as a tobacco product and therefore not currently regulated by the Food and Drug Administration as tobacco; and
- Are not known by the generic chemical name nicotine.

Should Florida DEP not agree with our interpretation that the e-cigarettes are a manufactured article, but rather consider them to meet the definition of a commercial chemical product, then for the e-cigarettes to be considered a P075 listed hazardous waste the nicotine in the e-cigarettes would need to be considered the “sole active ingredient” as defined in 40 CFR 261.33.

In a May 19, 1988 letter to Michal Fox, Chemical Engineering Services, EPA stated that, “Discarded commercial chemical products are hazardous wastes if they are listed in 40 CFR 261.33 (the “p” and “U” lists) or if they exhibit one or more of the hazardous waste characteristics of Part 261, Subpart C. A comment in Section 261.33(d) clarifies that the listing applies to commercial and technical grades of the product, and to formulations in which the chemical is the sole active ingredient. ‘Sole active ingredient’ means the active ingredient is the only chemically active component for the function of the product. If the discarded product is a formulation with more than one active ingredient, it would not be within the scope of the listing in Section 261.33.”

Veolia believes that e-cigarettes do not meet the definition of a “sole active ingredient” for the following reasons:

- The propylene glycol-, glycerine-, or polyethylene glycol- is used as a carrier for the nicotine and an e-cigarette will not function without the carrier. Therefore, the e-cigarette essentially has several active ingredients and therefore the nicotine would not be considered to be the sole active ingredient.
- Heat must be applied to the carrier and nicotine for an e-cigarette to function as intended, therefore, the heating element is also an active component of the e-cigarette.
- Flavorings are also added to e-cigarettes. The flavorings are not added for medicinal purposes, but are essential to the functioning of the e-cigarettes for the enjoyment of the user.
- E-cigarettes are also available in non-nicotine versions, further implying that the presence of the nicotine in the e-cigarette is not essential for the device to function.

We are seeking your written concurrence that e-cigarettes are not regulated as a hazardous waste due to the presence of nicotine according to 40 CFR Part 261 or as adopted by reference in 62-730.030 F.A.C.



Upon review of this letter should you require additional information from Veolia, please contact Kevin McGrath at (402) 991-6666 (e-mail; kevin.mcgrath@veoliaes.com), or Tom Baker at (973) 691-7330 (email; tom.baker@veoliaes.com). Veolia greatly appreciates your time and assistance in responding to this request.

Sincerely,

A handwritten signature in black ink that reads 'Thomas M. Baker'.

Thomas M. Baker
Veolia ES Technical Solutions, L.L.C.
Director, Environment and Transportation