UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

SEP 26 2012

MEMORANDUM

SUBJECT: Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs

TO: RCRA Division Directors
EPA Regions I to X

FROM: Suzanne Rudzinski, Director
Office of Resource Conservation and Recovery (ORCR)
Office of Solid Waste and Emergency Response

Many state and local law enforcement agencies, communities, and organizations have established take-back events, mail-back, and other collection programs to collect old, expired, or simply unwanted prescription and over-the-counter pharmaceuticals from households. These programs for household pharmaceuticals have become more prevalent throughout communities that want to reduce the misuse and abuse of drugs, while at the same time stopping the practice of flushing consumer pharmaceuticals which may result in their entry into the environment. Organizers of these household pharmaceutical take-back programs have asked for the Environmental Protection Agency's (EPA) recommendation on how to dispose of and destroy collected household pharmaceuticals. The purpose of this memorandum is to communicate EPA's recommendation that household pharmaceuticals collected by these programs be incinerated. Our preference is that they be sent to a permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor. This guidance only applies to the collection and management of household pharmaceuticals and does not apply to pharmaceuticals that are generated at non-households, such as healthcare facilities.

Background – RCRA Regulations

Pharmaceuticals that are unwanted (e.g., expired or unused) by consumers (households) are not regulated as hazardous wastes and are generally considered municipal solid wastes. While there is a small percentage of pharmaceuticals on the market that meet the definition of hazardous waste under the Resource Conservation and Recovery Act (RCRA), the federal RCRA hazardous waste regulations include an exemption for all hazardous waste generated by households (see the "household hazardous waste" exemption at 40 CFR 261.4(b)(1)). Thus, household pharmaceutical wastes – like other household hazardous wastes - are not subject to the federal RCRA hazardous waste regulations, even when collected at a take-back event or

program. However, the Agency has historically recommended that household hazardous waste collection programs manage their collected waste as hazardous waste, even though it is not required (see memo dated November 1, 1988, from Porter to Regions, RCRA Online #11377). In today's memo, the Agency is clarifying this recommendation as it pertains to pharmaceutical collection programs, since household pharmaceutical wastes are typically collected separately from other household hazardous wastes. Note that household pharmaceutical collection programs are not required to manage collected household pharmaceuticals in accordance with this or earlier Agency recommendations; however, if they choose not to, they must manage the collected pharmaceuticals in accordance with state and/or local environmental regulations for municipal solid waste, as well as applicable federal Clean Air Act (CAA) regulations if they are incinerated.

Background – Controlled Substances Act

A portion of household pharmaceuticals that are collected through take-back events and programs are controlled substances. Controlled substances are drugs or other substances that have the potential for abuse and dependence and are controlled by the Drug Enforcement Administration (DEA) to protect public health and safety. In addition to federal, state and/or local environmental regulatory requirements, collection of pharmaceutical controlled substances through take-back events and programs must be in compliance with the requirements of the Controlled Substances Act (CSA) and its implementing regulations published by DEA (21 U.S.C. 801 – 971 and 21 CFR parts 1300 – 1321). In general, only persons registered with DEA are permitted to possess controlled substances as authorized by their registration and must comply with the applicable requirements associated with their registration. There are exceptions, however; for example, a patient who receives a controlled substance pursuant to a lawful prescription - also known as an ultimate user - is not required to register with DEA in order to receive and possess that controlled substance. Until recently, the CSA did not address disposal of controlled substances by ultimate users. To dispose of their controlled substances, ultimate users were permitted to destroy the substances themselves (e.g., mix the substances with coffee grounds, place in a plastic bag, and throw into the garbage) or surrender the substances to law enforcement, including DEA.

In October 2010, however, the Secure and Responsible Drug Disposal Act of 2010 was enacted. DEA is currently drafting the implementing regulations. The Act and implementing regulations will provide the basic framework to allow the public (i.e., the ultimate users) to dispose of their unwanted or expired controlled substance pharmaceuticals in a secure and responsible manner. Until DEA finalizes the implementing regulations for the Act, however, the ultimate users may not deliver their controlled substance pharmaceuticals to any other person for the purpose of disposal other than by surrender to law enforcement, including DEA, for example, through a law enforcement take-back event.

As discussed above, after pharmaceuticals are collected from ultimate users in a take-back event, they must be disposed of in accordance with federal, state and/or local environmental regulations. In addition, DEA or other law enforcement agencies that collect controlled substances during an event are responsible for disposing of the controlled substances they collect. Currently, most, if not all, controlled substances that are collected by take-back programs are destroyed by incineration.

Recommendation for Disposal of Pharmaceuticals from Take-Back Events or Programs

EPA is currently recommending incineration as the preferred disposal method for household drug take-back programs because we believe that incineration will address both environmental and diversion concerns. With regard to environmental concerns, studies have shown active pharmaceutical ingredients are present in some groundwater and drinking water, some portion of which is likely due to flushing. Further, some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems. Incineration of unwanted household pharmaceuticals will reduce the amount of household pharmaceuticals that are disposed by both flushing and landfilling. With regard to diversion, incineration should also address DEA concerns about the diversion of controlled substances by destroying them and thus making them unavailable for diversion. The recommendation to incinerate all collected household pharmaceuticals further reduces diversion concerns by eliminating the need for collection program personnel to sort controlled substances from non-controlled substances. Managing all collected pharmaceuticals together will also reduce collection program costs by eliminating labor costs associated with sorting the controlled substances from non-controlled substances. Please note that until the implementing regulations for the Secure and Responsible Drug Disposal Act of 2010 are finalized, the public may not deliver their controlled substances to any person for the purpose of disposal other than by surrender to law enforcement, including DEA (e.g., a collection program run by law enforcement, including DEA).

EPA has consulted stakeholders, and we are not currently aware of data documenting whether active pharmaceutical ingredients are emitted from combustion units, either hazardous waste combustors or municipal solid waste combustors. We do know, however, based on data from DEA regarding the amount of pharmaceuticals collected during its nation-wide collection days (National Take Back Initiative), that the amounts of collected household pharmaceuticals are extremely small compared to the waste amounts these types of combustors typically burn each day. In addition, these combustion units are subject to carbon monoxide or total hydrocarbon standards, which are widely accepted indicators of combustion conditions in the unit. EPA believes that the combustion conditions present in these regulated units will destroy the organic compounds in collected pharmaceuticals.

Given the lack of emission data from burning pharmaceuticals and because hazardous waste incinerators and cement kilns are subject to comprehensive operating and monitoring controls (40 CFR part 63 subpart EEE), EPA is erring on the side of caution in establishing combustion in a permitted hazardous waste incinerator or cement kiln as the recommended practice for destruction of collected household pharmaceuticals. However, there are roughly 10 commercial hazardous waste incinerators in the U.S. that accept waste from off-site sources and 12 cement manufacturing plants that have a permit to burn hazardous waste (see attached list of RCRA-permitted commercial hazardous waste incinerators and RCRA-permitted cement kilns)[1]. EPA recognizes that due to the limited number of permitted hazardous waste combustors, it may be prohibitively costly to dispose of household pharmaceuticals at hazardous waste combustors; and we do not want that cost to discourage take-back events. Therefore, the Agency is

[1] Note that not all of these permitted hazardous waste incinerators and cement kilns may be permitted to or may choose to accept collected household pharmaceuticals. Contact the individual facility about its policy.

recommending that when hazardous waste combustion is not feasible, at a minimum, collected household pharmaceuticals should be incinerated at a facility that meets EPA's:

- Large Municipal Waste Combustor (LMWC) standards:
  - 40 CFR part 62 subpart FFF for existing LMWCs
  - 40 CFR part 60 subparts Ea and Eb for new LMWCs, or

- Small Municipal Waste Combustor (SMWC) standards:
  - 40 CFR part 62 subpart JJJ for existing SMWCs
  - 40 CFR part 60 subparts AAAA and BBBB for new SMWCs.

There are approximately 85 facilities with LMWCs and SMWCs in 23 states (see attached list of LMWC and SMWC facilities).[2]

The Agency believes that by recommending hazardous waste combustion as the preferred option for disposal and destruction of collected household pharmaceuticals, including controlled substances, and, if not feasible, combustion by small or large municipal waste combustors, as a minimum standard, collection program organizers will have multiple options for disposing and destroying unused, expired, and unwanted pharmaceuticals that will meet both DEA's goal of preventing diversion of controlled substances and EPA's goal of protecting the environment.

The "Contraband Exclusion" Does Not Apply to Burning Pharmaceuticals from Take-Back Programs

EPA has also received a number of inquiries asking whether the exclusion from the Other Solid Waste Incinerators (OSWI) regulations for "units that combust contraband or prohibited goods" (see the exclusion at 40 CFR 60.2887(p) for new OSWIs and 40 CFR 60.2993(p) for existing OSWIs) can be applied to units that combust pharmaceuticals collected in take-back programs. In response, EPA does not consider pharmaceuticals, voluntarily collected from households in a take-back program, to be contraband or prohibited goods. Therefore, if OSWI units are used to combust collected pharmaceuticals, the exclusion does not apply, and the OSWI unit would be subject to 40 CFR part 60 subpart EEEE for new OSWIs or 40 CFR part 60 subpart FFFF for existing OSWIs. However, as discussed above, EPA recommends that pharmaceuticals collected in take-back programs be combusted in either a hazardous waste combustor or a large or small municipal waste combustor, not OSWI units.

Crematoria

Finally, we have received inquiries about burning pharmaceuticals from take-back events in crematoriums. Because crematoriums currently are not regulated units under the Clean Air Act regulations, we recommend that pharmaceuticals from take-back events not be burned in these units. We believe that because they are not regulated units, they may not provide adequate environmental protection when burning pharmaceutical wastes.

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[2] Note that not all of these permitted large or small municipal waste combustors may be permitted to or may choose to accept collected household pharmaceuticals. Contact the individual facility about its policy.

Additional Information & Contacts

Please note that when this letter discusses RCRA hazardous waste regulations, it is in reference to the federal hazardous waste regulations. States that are authorized to implement the RCRA program may have regulations that are different than the federal regulations, provided they are not less stringent than the federal program. Please consult your state regulatory hazardous waste requirements in addition to this memo. For question about the hazardous waste regulations discussed in this memo, please contact Kristin Fitzgerald of the Office of Resource Conservation and Recovery at (703) 308-8286 or fitzgerald.kristin@epa.gov. For questions about the Clean Air Act regulations discussed in this memo, please contact Charlene Spells of the Office of Air Quality Planning and Standards at (919) 541-5255 or spells.charlene@epa.gov.

Attachments:
List of RCRA-Permitted Hazardous Waste Incinerator & Cement Kilns
List of Waste-to-Energy Plants for Municipal Waste Combustion

Waste-to-Energy Plants for Municipal Waste Combustion*

As of 2010

State	Site Name	Location	Large or Small
AL	Huntsville Solid Waste-to-Energy Facility	Huntsville	L
CA	Commerce Refuse-to-Energy Facility	Commerce	L
CA	Southeast Resource Recovery Facility (SERRF)	Long Beach	L
CA	Stanislaus County Resource Recovery Facility	Crow's Landing	L
CT	Bristol Resource Recovery Facility	Bristol	L
CT	Mid-Connecticut Resource Recovery Facility	Hartford	L
CT	Riley Energy System of Lisbon Connecticut Corp.	Lisbon	S
CT	Southeastern Connecticut Resource Recovery Facility	Preston	L
CT	Wallingford Resource Recovery Facility	Wallingford	S
CT	Wheelabrator Bridgeport Company, L.P.	Bridgeport	L
FL	Bay County Resource Recovery Center	Panama City	S
FL	Miami-Dade County Resource Recovery Facility	Miami	L
FL	Hillsborough County Resource Recovery Facility	Tampa	L
FL	Lake County Resource Recovery Facility	Okahumpka	L
FL	Lee County Resource Recovery Facility	Fort Myers	L
FL	McKay Bay Refuse-to-Energy Facility	Tampa	S
FL	North County Resource Recovery Facility	West Palm Beach	L
FL	Pasco County Resource Recovery Facility	Spring Hill	L
FL	Pinellas County Resource Recovery Facility	St. Petersburg	L
FL	Wheelabrator North Broward, Inc.	Pompano Beach	L
FL	Wheelabrator South Broward, Inc.	Ft. Lauderdale	L
HI	Honolulu Resource Recover Venture (HPOWER)	Honolulu	L
IA	Ames Municipal Electric Utility	Ames	S
IN	Indianapolis Resource Recovery Facility	Indianapolis	L
ME	Maine Energy Recovery Company	Biddeford	L
ME	Mid-Maine Waste Action Corporation	Auburn	S
ME	Penobscot Energy Recovery Corp.	Orrington	L
ME	Greater Portland Resource Recovery Facility	Portland	S
MD	Harford Waste-to-Energy Facility	Joppa	S
MD	Montgomery County Resource Recovery Facility	Dickerson	L
MD	Baltimore Refuse Energy Systems Company (BRESCO)	Baltimore	L
MA	Haverhill Resource Recovery Facility	Haverhill	L
MA	Pioneer Valley Resource Recovery Facility	Agawam	S
MA	Pittsfield Resource Recovery Facility	Pittsfield	S
MA	SEMASS Resource Recovery Facility	West Wareham	L
MA	Wheelabrator Millbury Inc.	Millbury	L
MA	Wheelabrator North Andover Inc.	North Andover	L

*Source: Energy Recovery Council: The 2010 ERC Directory of Waste-to-Energy Plants; http://energyrecoverycouncil.org/waste-energy-resources-a2985

State	Site Name	Location	Large or Small
MA	Wheelabrator Saugus, J.V.	Saugus	L
MI	Greater Detroit Resource Recovery Facility	Detroit	L
MI	Jackson County Resource Recovery Facility	Jackson	S
MI	Kent County Waste-to-Energy Facility	Grand Rapids	L
MN	Great River Energy – Elk River Station	Elk River	L/S
MN	Hennepin Energy Resource Co.	Minneapolis	L
MN	Olmstead Waste-to-Energy Facility	Rochester	S
MN	Perham Resource Recovery Facility	Perham	S
MN	Polk County Solid Waste Resource Recovery Plant	Fosston	S
MN	Pope/Douglas Solid Waste Management	Alexandria	S
MN	Red Wing Resource Recovery Facility	Red Wing	S
MN	Xcel Energy – Red Wing Steam Plant	Red Wing	L
MN	Xcel Energy – Wilmarth Plant	Mankato	L
NH	Wheelabrator Clarement Co, L.P.	Claremont	S
NH	Wheelabrator Concord Company, L.P.	Penacock	S
NJ	Camden Resource Recovery Facility	Camden	L
NJ	Essex County Resource Recovery Facility	Newark	L
NJ	Union County Resource Recovery Facility	Rahway	L
NJ	Warren Energy Resource Company	Oxford Township	S
NJ	Wheelabrator Gloucester Company, L.P.	Westville	L
NY	Babylon Resource Recovery Facility	Babylon	L
NY	Dutchess County Resource Recovery Facility	Poughkeepsie	S
NY	Hempstead Resource Recovery Facility	Westbury	L
NY	Huntington Resource Recovery Facility	East Northport	S
NY	MacArthur Waste-to-Energy Facility	Ronkonkoma	S
NY	Niagara Falls Resource Recovery Facility	Niagara Falls	L
NY	Onondaga County Resource Recovery Facility	Jamesville	L
NY	Oswego County Energy Recovery Facility	Fulton	S
NY	Wheelabrator Hudson Falls Inc.	Hudson Falls	S
NY	Wheelabrator Westchester Company, L.P.	Peekskill	L
NC	New Hanover County – Wastec	Wilmington	L/S
OK	Warren B. Hall Resource Recovery Facility	Tulsa	L
OR	Marion County Solid Waste-to-Energy Facility	Brooks	L
PA	Delaware Valley Resource Recovery Facility	Chester	L
PA	Harrisburg Resource Recovery Facility	Harrisburg	L
PA	Lancaster County Resource Recovery Facility	Bainbridge	L
PA	Covanta Plymouth Renewable Energy	Conshohocken	L
PA	Wheelabrator Falls Inc.	Morrisville	L
PA	York Resource Recovery Center	York	L
UT	Wasatch Integrated Waste Management District	Layton	S
VA	Alexandria/Arlington Resource Recovery Facility	Alexandria	L

*Source: Energy Recovery Council: The 2010 ERC Directory of Waste-to-Energy Plants; http://energyrecoverycouncil.org/waste-energy-resources-a2985

State	Site Name	Location	Large or Small
VA	Hampton-NASA Steam Plant	Hampton	S
VA	Harrisonburg Resource Recovery Facility	Harrisonburg	S
VA	I-95 Energy-Resource Recovery Facility (Fairfax)	Lorton	L
VA	Wheelabrator Portsmouth, Inc.	Portsmouth	L
WA	Spokane Regional Solid Waste Disposal Facility	Spokane	L
WI	Barron County Waste-to-Energy & Recycling Facility	Almena	S
WI	Xcel Energy French Island Generating Plant	LaCrosse	S

Note that not all of these permitted hazardous waste incinerators and cement kilns may be permitted to or may choose to accept collected household pharmaceuticals. Contact the individual facility about its policy.

Disclaimer: This is a list of all Waste-to-Energy plants in the U.S. that are regulated as either Large or Small Municipal Solid Waste Combustors under the Clean Air Act. Inclusion on this list does not imply endorsement or recommendation to use any particular facility.

*Source: Energy Recovery Council: The 2010 ERC Directory of Waste-to-Energy Plants; http://energyrecoverycouncil.org/waste-energy-resources-a2985

RCRA-Permitted Commercial Hazardous Waste Incinerators

State	Site Name
AR	Reynolds Metals Company
AR	Clean Harbors El Dorado, LLC
IL	Veolia ES Technical Solutions LLC
MO	General Dynamics Ordnance and Tactical Systems, Joplin Operations
NE	Clean Harbors Environmental Services
OH	Ross Incineration Services, Inc.
OH	Heritage – WTI, Inc.
TX	Veolia ES Technical Solutions LLC
TX	Clean Harbors Deer Park LP
UT	Clean Harbors Aragonite LLC

RCRA-Permitted Cement Kilns that Burn Hazardous Waste

State	Site Name
AR	Ash Grove Cement Co.
IN	Buzzi Unicem USA
IN	ESSROC Corporation
KS	Ash Grove Cement Co.
MO	Buzzi Unicem USA
MO	Continental Cement Company
OH	Lafarge North America, Inc.
OK	Lafarge North America, Inc.
PA	Giant Cement Holding Inc.
SC	Giant Cement Holding Inc.
SC	Holcim (US) Inc.

Note that not all of these permitted hazardous waste incinerators and cement kilns may be permitted or may choose to accept collected household pharmaceuticals. Contact the individual facility about its policy.

Disclaimer: This is a list of commercial hazardous waste incinerators that are permitted under RCRA and a list of cement kilns that burn hazardous waste as fuel that are permitted under RCRA. Inclusion on this list does not imply endorsement or recommendation to use any particular facility.