MEMBER COMPANIES

Clean Harbors Environmental Services
DowDuPont
Eastman Chemical Company
Heritage Thermal Services
INVISTA S.àr.l.
3M
Ross Incineration Services, Inc.
Veolia ES Technical Services, LLC

GENERATOR MEMBERS

Eli Lilly and Company
Formosa Plastics Corporation, USA

ASSOCIATE MEMBERS

AECOM
Alliance Source Testing LLC
B3 Systems
Civil & Environmental Consultants, Inc.
Coterie Environmental, LLC
Focus Environmental, Inc.
Franklin Engineering Group, Inc.
METCO Environmental, Inc.
Montrose Environmental Group, Inc.
O'Brien & Gere
Spectrum Environmental Solutions LLC
Strata-G, LLC
SYA/Trinity Consultants
TestAmerica Laboratories, Inc.
TRC Environmental Corporation
Wood, PLC

INDIVIDUAL MEMBERS

Ronald E. Bastian, PE
Ronald O. Kagel, PhD

ACADEMIC MEMBERS
(Includes faculty from:)

Clarkson University
Colorado School of Mines
Lamar University
Louisiana State University
Mississippi State University
New Jersey Institute of Technology
University of California – Berkeley
University of Dayton
University of Kentucky
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CRWI Update
December 31, 2018

Pharmaceutical waste final rule

On December 11, 2018, Acting EPA Administrator Wheeler signed a final rule setting management standards for hazardous waste pharmaceuticals (HWP). This rule creates a new Part 266 subpart P for the management of HWP by healthcare facilities and reverse distributers. It replaces the requirements in Part 262 for these two groups of generators. Pharmaceutical manufacturers remain subject to Part 262. Farmers, ranchers, and fisheries that create HWP also remain subject to Part 262. The final rule prohibits drain disposal of HWP (flushing or sewering). It eliminates dual coverage of certain compounds by creating a conditional exemption if that material is a Drug Enforcement Agency controlled substance. It keeps the current household hazardous waste exemption for HWP collected during take back programs. It excludes certain Food and Drug Administration approved over-the-counter nicotine replacement therapies from an acute hazardous waste listing when discarded. E-cigarettes, e-liquids, and prescriptions nicotine replacement therapies are not exempted. They remain as P075 when discarded. The rule does not add any pharmaceuticals to the hazardous waste listing or expand the hazardous waste characteristics to include any additional pharmaceuticals. It creates a different definition for RCRA Empty specifically for this subpart.

EPA's policy on reverse logistics has been that items sent through the reverse logistics system are not discarded if they have a reasonable chance of being used or reused. The key is when the decision is made. The rule makes a clear distinction between reverse logistics of prescription pharmaceuticals and over-the-counter retail items. Prescription pharmaceuticals moving through the reverse logistics system are considered discarded at the healthcare facility. Non-prescription pharmaceuticals are not considered as discarded when they enter the reverse logistics system because they have a reasonable expectation of being used/reused. EPA was not persuaded that giving credit for returned prescriptions made a difference since most are discarded even though credit is given. Point of generation for prescription pharmaceuticals is at the healthcare facility. Point of generation for non-prescription

pharmaceuticals is when the decision to discard is made – at a reverse distribution center. Once the reverse logistics facility discards a material, it is governed by the appropriate solid waste provisions.

The rule also establishes a policy on the regulatory status of unsold retail products that are not pharmaceuticals and are managed via a reverse distribution system. The logic behind the policy is similar to what was used for pharmaceutical waste: if the unsold product has a reasonable chance of being reused, the point of generation is at the reverse distributer. If the unsold product is to be discarded, the point of generation is at the retail outlet.

The final rule does not change the status of treatment, storage, and disposal facilities. It does not change how "dual wastes" (RCRA hazardous and biological hazards) or mixed waste (radioactive plus hazardous) are handled. There is one waste code (PHARMA) for this material and it is only used for manifesting and reporting. It is not an official EPA hazardous waste code. This rule does not modify any LDR treatment standards.

The rule becomes effective six months after publication. As of December 31, the rule has not been published in the *Federal Register*. A pre-publication copy can be obtained at https://www.epa.gov/hwgenerators/pre-publication-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075.

Proposed PCB guidance document

On December 12, 2018, EPA posted a notice on their website of a draft document entitled *Guidance for Applicants Requesting to Treat/Dispose of PCBs Using Incineration or an Alternative Method* (https://www.epa.gov/pcbs/policy-and-guidance-polychlorinated-biphenyl-pcbs). The document is not available from the website but can be found in the docket (Docket ID No. EPA-HQ-OLEM-2018-0305). According to the introduction section, the document creates no new requirements or interpretations but is an update of the 1986 guidance document to include current practices, policies, and regulatory changes since 1986. It only addresses incineration and alternatives to incineration. It does not address disposal, cleanup, or decontamination methods. According to the memo, the comment period closes on January 26, 2019. It is not known whether the current partial government shutdown will impact that date.

Delisting petition granted

On December 14, 2018, EPA granted a delisting petition from Sandvik Special Metals in Kennewick, WA to exclude up to 1,500 cubic yards of F006 wastewater treatment sludge from the list of hazardous wastes. The exclusion is conditional on the sludge passing tests to show it continues to qualify for the exclusion and the material is disposed of in a permitted Subtitle D landfill. The exclusion is effective on the date of publication.

RMP effective date changed

On January 13, 2017, EPA published a final rule adding a number of requirements to Risk Management Plans (RMP). One of the first actions of then EPA Administrator Scott Pruitt was to delay the effective date of this rule. This culminated in a final rule delaying the effective date until February 2019. The purpose of the delayed effective date was to give the Agency time to go through the rulemaking process to remove most of the 2017 provision. The final delay rule was challenged and the court vacated it. After some legal wrangling, the court issued the mandate on September 21, 2018. On December 3, 2018, EPA published a *Federal Register* notice officially removing the February 2019 effective date and made all of the 2017 provisions effective on publication date. This means that certain requirements (hazards reviews, training, compliance audit, incident investigations, coordinate with local emergency planning committees, and others) become effective immediately. Other requirements have compliance deadlines of 2021 and 2022. Meanwhile, the Agency is expected to publish a final rule early in 2019 withdrawing most of the provisions added in 2017.

MATS proposed rule

In the 1990 amendments to the Clean Air Act, Congress put in an extra step for coal-fired utility boilers. Before writing regulations to control emissions from this source category, EPA was required to complete an "appropriate and necessary finding" that showed the benefits of such regulations would outweigh the costs. Only after the Agency decided that the benefits outweighed the costs could emission limitations for this source category be promulgated. Under the Obama Administration, the Agency concluded that the benefits exceeded the costs and proceeded to develop emissions limitations. In estimating the benefits, the Obama Administration included the co-benefit of reducing PM 2.5 emissions. However, PM 2.5 is not a hazardous air pollutant as listed in the Clean Air Act. This was challenged and the U.S. Supreme Court (*Michigan v. EPA*, 2015) remanded the finding to the Agency for failing to properly account for costs and for overestimating the benefits. However, the Supreme Court did not overturn the Mercury and Air Toxic Standards (MATS) rule itself. The rule remained in place and by 2017, the majority of sources had come into compliance.

On December 28, 2018, EPA released their proposed rule to address the Supreme Court remand of the "appropriate and necessary finding." Without the co-benefits of PM 2.5, the annual costs ($7.9 to $9.6 billion) outweigh the benefits ($4 to $6 billion). If this estimate had been used in the first place, EPA would have never promulgated the MATS rule. But the rule has been in place for several years and the industry has come into compliance. This leaves the Agency in an interesting predicament of having no basis for a rule already in place. Industry is divided on how the Agency should proceed. The electric utility groups generally favor leaving the rule in place since they have upgraded their facilities to meet the standards. In contrast, the coal industry suggests that without a favorable cost/benefit basis, the entire rule should be withdrawn. Environmental groups strongly oppose the new finding.

In order to thread this needle, the Agency is proposing that it is not "necessary and appropriate" to regulate hazardous air pollutants under Section 112 of the Clean Air Act for this source category. However, they are not proposing to withdraw the emission standards. They also completed the risk and technology review for the source category and concluded that no changes are needed based on either risk or technology. Once published, the Agency will accept comments for 60 days.

"Once in, always in" litigation

In 1995, EPA developed a policy that major sources for air toxics would have to comply with MACT rules even though they reduced their emissions below the levels that made them a major source in the first place. This was called the "once in, always in" policy. Early in 2018, EPA revised that policy. Under the new policy, sources can accept enforceable limits to restrict its potential-to-emit and then apply for area source designation. A number of environmental groups and the state of California challenged this in federal court. They filed their opening brief on October 2018. EPA filed their response brief on December 21, 2018. Predictably, the Agency argued that the memo was neither a legislative rule that required notice and comment under the Administrative Procedures Act nor a final action subject to judicial review. The memo was simply a communications of a revised reading of the plain language of the law. As such, the lawsuit should be dismissed. The brief went on to argue that should the court wish to proceed to the merits of the case, the Clean Air Act does not contain any language that restricts when a source can change their status. As such, sources can change from being a major source to being an area source anytime they can show they meet the criteria.

Petitioner's reply brief is due on February 8, 2019. Oral arguments have not been scheduled.

Enforcement

On December 18, 2018, the Department of Justice announced a proposed consent decree with Tradebe Treatment and Recycling Northeast LLC. The complaint lists 23 separate claims for both Clean Air Act and RCRA violations at the Meriden, CT and Bridgeport, CT facilities. These violations were identified in 2015 during multiple inspections by Region 1 and Connecticut Department of Energy and Environmental Protection personnel. Violations listed in the complaint include:

- Visible holes, cracks or gaps in fixed roof tanks;
- Failure to submit notice of compliance reports;
- Failure to obtain a Title V permit;
- Operating without a Title V permit;
- Failure to secure trailer storage areas;
- Storing hazardous waste in areas not authorized for storage;
- Failure to report spills;

- Failure to properly inspect and correct cracks in concrete in the trailer storage area;
- Tank overfill protection systems were not operating properly;
- Failure to certify tank integrity;
- Failure to comply with RCRA Subpart CC tank and closed vent requirements;
- Failure to conduct equipment leak monitoring under RCRA Subpart BB;
- Failure to properly train personnel; and
- Failure to maintain protocol or QA/QC plans for on-site waste analysis.

The proposed consent decree has a $525,000 civil penalty. It requires Tradebe to install, test, and operate a thermal oxidizer to replace the current carbon absorption controls for their closed vent system. They have 270 days to install the thermal oxidizer system. In addition, they are required to correct all violations identified in the complaint. All comments on the proposed decree must be submitted by January 17, 2019.

EPA shutdown

President Trump and Congress could not come to an agreement on funding levels for approximately one third of the federal government (including EPA) before the temporary funding ran out on December 21, 2018. EPA had enough funding to allow operations until December 28, 2018. After that, most EPA employees were furloughed. The issue that is causing the impasse is President Trump's insistence on Congress appropriating $5 billion to fund the construction of a wall between the U.S. and Mexico. While the House had passed appropriations legislation with that funding, the Senate Democrats refused to agree. Since the Republicans do not have the votes to limit debate, there was no chance that the House passed appropriations legislation would ever get approved by the Senate. In the past President Trump has threatened to veto any appropriations that did not contain the requested $5 billion but backed down, not wanting to shut down the government. This time he did not back down. The new Congress will be seated on January 3, 2019. At that time, the Democrats will control the House. It is likely that they will quickly pass appropriations legislation that would fund the rest of the government at 2018 levels and send it to the Senate. Republicans still control the Senate. Senate Majority Leader Mitch McConnell (R-KY) has publically stated he will not bring up any appropriations legislation in the Senate unless President Trump agrees to sign it. Both Republicans and Democrats are trying to place the blame on the other party. Who knows how long this stalemate will last or who will blink first.

CRWI meeting

The next CRWI meeting will be on February 27-28, 2018, in Anahuac, TX. It will feature a tour of Paragon Southwest medical waste combustion units. For additional information, contact CRWI (mel@crwi.org or 703-431-7343).