RISK MANAGEMENT

EnviroScope

ENVIRONMENTAL WHITE PAPER FOR ALLIED WORLD POLICYHOLDERS

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Emerging Environmental Issues

Environmental issues that impact business risk are ever-changing and keeping up with these emerging issues can be difficult for environmental risk managers. This article was developed to provide Allied World policyholders with an update on four emerging environmental issues:

1) United States Environmental Protection Agency (EPA) National Enforcement Initiatives (NEIs)
2) Management of Pharmaceutical Wastes
3) Perflorinated Chemicals: PFOA & PFOS
4) Environmental Justice – Flint, Michigan

Collectively, these emerging issues impact a variety of business classes, such as industrial manufacturing, real estate developers, property managers, the healthcare industry, environmental contractors and risk managers.

United States Environmental Protection Agency (EPA) National Enforcement Initiatives (NEIs) for 2017 – 2019

Every three years, EPA selects NEIs to focus resources on issues that it identified as national environmental problems where there is significant non-compliance with laws, and where it believes federal enforcement efforts can make a difference. According to EPA, NEIs are intended to be in addition to and support EPA's core enforcement work. EPA proposed the 2017-2019 NEIs and solicited public comments on September 15, 2015 and announced the final 2017-2019 NEIs on February 18, 2016. Beginning on October 1, 2016, a new three-year cycle of enforcement initiatives are due to begin. For this new cycle, EPA retained four of its current NEIs, added two new initiatives, and expanded one initiative to include a new focus area. EPA's current NEI for mineral processing operations is not

included in the 2017-2019 NEIs. The new NEIs encompass air, water, hazardous chemicals and energy extraction, specifically addressing:

1) Keeping Industrial Pollutants Out of the Nation's Waters (new initiative)
2) Reducing Risks of Accidental Releases at Industrial and Chemical Facilities (new initiative)
3) Cutting Hazardous Air Pollutants (expanded initiative)
4) Reducing Air Pollution from the Largest Sources
5) Ensuring Energy Extraction Activities Comply with Environmental Laws
6) Keeping Raw Sewage and Contaminated Stormwater Out of the Nation's Waters
7) Preventing Animal Waste from Contaminating Surface and Ground Water

Through the NEIs, EPA has indicated substantial progress toward achieving its goals. For example, more than 98 percent of cities with large combined sewer systems are now reportedly remedying untreated sewage discharges into US waterways.

Management Standards for Hazardous Waste Pharmaceuticals

Many pharmaceutical wastes meet the definition of "hazardous" by the regulations promulgated under the Resource Conservation and Recovery Act (RCRA). Pharmaceutical wastes are included in the P-listed, U-listed, and characteristic hazardous wastes. Examples include epinephrine (P042), nicotine and salts (P075) (e.g., nicotine patches, Nicorette), warfarin and salts (P001, U248) and drugs with thimerosal (D009 – mercury). EPA has estimated that over 600,000 individual facilities in the United States, including retail pharmacies, hospitals, and physicians and dental offices, may be generators of hazardous pharmaceutical wastes.[i] In addition to these healthcare generators, pharmaceutical waste take-back programs and reverse distributors are also subject to the RCRA generator regulations designed to keep pharmaceuticals out of the nation's sewer system and municipal waste landfills.

According to EPA, implementing the RCRA hazardous waste regulations has been difficult for pharmaceutical wastes due to the large number of individual generators, many of which have multiple generation points within their facilities, substantial number of chemicals that render the waste hazardous, and episodic generation where their generator status often changes from month to month. Recognizing these difficulties, EPA initially proposed to regulate pharmaceutical wastes under the regulatory framework of "Universal Wastes". However, the public comment process revealed numerous concerns and, as a result, EPA did not finalize the proposed Universal Waste rule. Instead, EPA proposed to regulate pharmaceutical waste under a separate set of sector-specific standards by adding Subpart P under 40 CFR Part 266 "Standards for the Management of Specific Types of Hazardous Waste Management Facilities".[ii] Under the proposed rule, EPA distinguishes between pharmaceuticals that are being sent off site for disposal and those being returned to a pharmaceutical reverse distributor for a determination or verification of a manufacturer's credit. EPA adopted the term "potentially creditable hazardous waste pharmaceutical" for these materials being sent to a reverse distributor. Healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals, including discounting waste pharmaceuticals managed under RCRA Subpart P toward the site's generator volumetric category, conditional-exemption under RCRA for hazardous

waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances and hazardous waste pharmaceutical residues remaining in containers.

Perflorinated Chemicals

In the 1940s, 3M pioneered the development of a process known as electrochemical fluorination for the manufacturing of perfluorinated chemicals (PFCs). Two common PFCs among this family of compounds are perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), the latter widely used in the production of non-stick cookware (i.e., Teflon) and as a stain repellent in textile fabrics (i.e., Scotchgard). PFCs are also used in the manufacture of plastic coatings, semiconductors, and other industrial processes, and in fire-fighting foam because it is extremely stable, doesn't react with other chemicals and can provide a near frictionless surface. During the manufacturing of these chemicals, the majority is burned off during the process and is not present in significant amounts in the final products. However, many of the primary sources of PFC contamination enter the environment from manufacturing plants, air emissions and from releases resulting in groundwater contamination. Once released, PFCs are persistent in the environment, bioaccumulative in wildlife and humans and in laboratory tests have been shown to be toxic to laboratory animals and wildlife, producing reproductive, developmental, and systemic effects.

Studies have found that PFCs are present worldwide at very low levels in just about everyone's blood. Higher PFC levels have been found in plant occupational workers and community residents where local water supplies have been contaminated by PFOA.

Is PFOA a carcinogen? Many studies in recent years have looked at whether PFOA causes cancer and have suggested possible links to kidney, testicular and thyroid cancer, but the increases in risk have been small. As a result, the International Agency for Research on Cancer (IARC), part of the World Health Organization (WHO), has classified PFOA as "possibly carcinogenic to humans" (Group 2B).

The long-term effects of PFOA and related chemicals are largely unknown, but there has been sufficient international concern to prompt legislation to phase out industrial emissions of them. In 2006, the EPA and the eight manufacturers who used PFOA at the time agreed to reduce factory emissions and product content levels of PFOA by 95% by the year 2010 and to eliminate PFOA from emissions and product contents by the end of 2015.

The EPA does not regulate the levels of PFOA or related chemicals in drinking water at this time. However, in 2009 and 2016 the EPA released provisional health advisories (PHAs) for PFOA and PFOS in drinking water. These advisories recommend that actions should be taken to reduce exposure when contaminants exceed 0.4 µg/L (micrograms per liter) for PFOA and 0.2 µg/L for PFOS in drinking water. On May 19, 2016, EPA established health advisories for PFOA and PFOS based on the agency's assessment of the latest peer-reviewed science. These advisories provide drinking water system operators, state, tribal and local officials with information on the health risks of these chemicals so that they can take appropriate actions to protect their residents. To provide a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water, EPA has established the health advisory levels at 70 parts per trillion (Federal Register Vol. 81 No. 101. May 25, 2016). Although, these advisories are not legally enforceable federal standards, they are typically precursors to developing enforceable

standards in the future and are subject to change as new information becomes available. A link to the recent EPA advisory has been included in the reference section of this Enviroscope paper. [iii]

Environmental Justice – Flint, Michigan

In 1994 President Clinton signed Environmental Justice Executive Order 12898 for the fair treatment and meaningful involvement of all people regardless of race, color, national origin or income with respect to the implementation and enforcement of environmental laws and regulations. Through "fair treatment", no group of people should bear a disproportionate share of the negative environmental consequences resulting from industrial, governmental and commercial operations. The federal government was acknowledging that some communities of color in both urban blighted industrial areas, or in rural 'poverty pockets,' have been subject to disproportionately adverse human health or environmental effects. Current laws and statutes in place give EPA and state agencies the authority to consider and address environmental justice concerns, and the EPA has developed an Environmental Justice 2020 Action Agenda to integrate environmental justice to "improve on-the-ground results, and chart a path forward for achieving better environmental outcomes and reducing disparities in the nation's most overburdened communities."

As a result of the 1994 Executive Order, the EPA has incorporated guidance principles for Environmental Justice into the National Environmental Policy Act (NEPA) in 1997, Risk Management Plans under Section 112R and Clean Air Act 309 Reviews, requiring Environmental Impact Statements (EIS) to assess the potential effects on soil, water or air prior to the construction of new industrial facilities which may have a significant effect on the environment. Other statutory provisions under the Toxics Substances Control Act (TSCA) explicitly direct the Agency to target low-income populations for assistance. There are many Environmental Justice cases underway, including the most recent occurrence at Flint Michigan with lead contamination in the public water supply.

Flint Michigan made a public policy decision based on economic factors that became an environmental disaster. Since April 2014, residents of Flint had been drinking and bathing in water that contains lead exceeding EPA primary and secondary drinking water standards. Between 1967 and 2014, the City of Flint had been receiving its water from the City of Detroit, when it decided to change back to using the Flint River as the drinking water supply source.

The lead contamination in Flint is a well-documented case where the state and federal government contributed to long delays in addressing the lead contamination. Public documents and articles describe this as a classic case supporting the need for Environmental Justice. The working class and communities like those in Flint are far more likely to be exposed to toxic substances like lead. Documented cases in the U.S. and throughout the world indicate that environmental problems, pollution, disasters and health threats often take longer to be acknowledged in communities of color, indigenous peoples and low-income communities. Evidence in Flint documents that state officials in Michigan and regional EPA officials responded to the Flint crisis by either trying to avoid responsibility or minimizing the extent of the damage, further documenting the case and need for Environmental Justice equally among all communities.

References

i. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals; Proposed Rule, Environmental Protection Agency, 73 FR 73520, December 2, 2008.

ii. Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule, Environmental Protection Agency, 80 FR 58014, September 25, 2015.

iii. https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos

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