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Ammonia releases cost meat company more than just the fine

BY HEIDI SLINKARD BRASHER

A California meat processor who had two reportable ammonia releases from its refrigeration system in 2009 is not only paying \$850,000 in civil monetary penalties, it has also entered a consent decree with the EPA and Department of Justice requiring it to undergo a \$6 million conversion of its ammonia refrigeration system to an ammonia-glycol refrigerant system, among other things.

According to the consent decree, the first release was the result of corrosion of the copper/brass fittings which connected a pressure control switch with stainless steel tubing. After the incident, much of the system was moved from inside the facility to the roof. However, in doing so piping was not properly labeled, management of change (MOC) analysis was not undertaken, and a pre-startup safety review prior to introducing ammonia to the relocated components did not occur.

Six months later, a second release occurred at the same facility – this time on the roof and due to a hydrostatic pressure buildup which caused an access flange of the strainer to fail at the inlet of the evaporator pressure regulator (caused by a valve group configuration design flaw). After the release, a contractor used water in an effort to mitigate the release; however, this increased the vapor cloud, which traveled to adjacent buildings.

The emergency response necessitated evacuation from some buildings and orders to shelter-in-place in others, along with closure of several local roads and entrances/exits to nearby highways for several hours. This second release injured 30, hospitalizing 17.

Following the releases, the EPA inspected another facility within the company and found additional violations. The company and the EPA reached an agreement on February 23, 2010, which the DOJ published notice of in the February 9, 2012 *Federal Register* (77 Fed. Reg. 6822).

- **Government’s January 30, 2012, proposed consent decree (available for download here)**

The consent decree alleges that the company:

- Failed to notify the National Response Center (NRC) or State Emergency Response Committee (SERC) for more than five hours following each reportable release;
- Failed to submit a Risk Management Plan (RMP) for one facility until 11 months after it reached the threshold quantity (10,000 pounds) to be regulated as a stationary source under the Clean Air Act (CAA);



- Established a required Process Hazards Analysis (PHA) in 2007, but failed to establish system to promptly address the 20 recommendations by 2010, in violation of the CAA;
- Failed to establish and implement requisite written operating procedures for performing covered tasks for safe operation of the refrigeration system, and those which were written were maintained off-site and were not readily accessible to employees; and
- Failed to maintain written mechanical integrity procedures onsite.

In addition to the \$658,446 civil penalty, the company has agreed to be bound by injunctive relief estimated to cost more than \$6 million, which requires the company to do the following:

- Convert current ammonia system to an ammonia-glycol refrigerant system, consistent with specified requirements set forth in the consent decree (material deviation from which is prohibited);

- Ammonia to be wholly contained in one building and used only to chill the glycol, which will be circulated through the refrigeration system instead of ammonia;
- Install a scrubber system to treat exhaust due to a release in the building housing the ammonia;
- Meet the CAA's general duty clause to identify potential hazards due to a release using hazard assessment techniques, design and maintain a safe facility by taking steps to prevent releases, minimize accidental release consequences, and comply with various cited industry standards; and
- Conduct approved third-party audits of compliance with Emergency Planning and Community Right-to-Know Act (EPCRA), California Accidental Release Program (CalARP) and the CAA general duty clause within 60 days of converting systems, with follow-up 18-24 months thereafter, and report audit findings and responses to the EPA for approval or disapproval.

Refinery sentenced to pay largest criminal air pollution fine in Louisiana history

BY HEIDI SLINKARD BRASHER

After pleading guilty to felony violations of the Clean Air Act (CAA) and obstruction of justice in October 2011, Pelican Refining Company LLC, a Texas oil company operating in Lake Charles, LA, was sentenced to a \$10 million criminal fine and \$2 million in community service payments for environmental projects in Louisiana.

The company's admissions include the following:

- Knowing commission of criminal violation of operating permits, which were discovered during a joint LDEQ – EPA inspection, resulting in unsafe operating conditions;
- Obstruction of justice for submission of materially false deviation reports;
- Nonexistent environmental department or budget for the same;
- Nonfunctioning or improperly-maintained pollution prevention equipment;
- Storage of sour crude in faulty tank, continuing after roof sank;
- Bypassing necessary caustic scrubber;
- Nonfunctioning continuous emission monitoring system (CEMS);
- Providing false information to states regarding asphalt testing; and
- Employee use of an emergency flare gun to relight improperly functioning flare used to burn off toxic gasses and for combustion of explosive chemicals.

As the investigation of company practices continues, it is noteworthy that a vice president and a facilities manager have pled guilty to CAA negligent endangerment charges, with the vice president of Lake Charles operations awaiting sentencing which could amount to one year in prison and \$400,000 in fines. Furthermore, the company is prohibited from future operations unless it implements an environmental compliance plan with court oversight of quarterly independent audits, an annual practice of which could have prevented – or at least mitigated – the wrongdoing.



EPA lowers proposed emission limits for chrome electroplating facilities

BY ROBERT JOYCE

In a February 8, 2012, Supplemental Notice of Proposed Rulemaking (the supplemental amendment), the EPA proposed to tighten limits in the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks and for Steel Pickling-HCL Process Facilities and Hydrochloric Acid Regeneration Plants. See *77 Fed. Reg.* 6628 (2/8/12). The EPA had originally proposed revisions to this NESHAP on October 21, 2010 (the original amendment). See *75 Fed. Reg.* 65068 (10/21/10). The supplemental amendment was prompted by a new technology review and residual risk analysis performed in response to comments on the original amendment.

The current NESHAP for chromium electroplating was promulgated on January 25, 1995 (*60 Fed. Reg.* 4963) and is found at 40 CFR Part 63, Subpart N. This NESHAP regulates emissions of chromium compounds from a number of different sources: large hard chromium electroplating, small hard chromium electroplating, decorative chromium electroplating, and chromium anodizing. Large hard chromium facilities are those with a cumulative rectifier capacity at or above 60 million ampere-hours per year (amp-hr/yr); small hard chromium facilities are all those below 60 amp-hr/yr. In the original amendment, the EPA did not require any additional controls on emissions or change emission limits because it “had not identified additional controls that would reduce risk at reasonable costs.” However, because of a concern over residual cancer risk, the EPA initially proposed new housekeeping practices, phased out the use of wetting agent fume suppressants (WAFS) based on perfluorooctyl sulfonates (but not other WAFSs), revised startup, shutdown and malfunction provisions, and revised monitoring and testing requirements. The EPA is not taking additional comments on these issues in connection with the supplemental amendments.

Based on its new data collection and analysis, the EPA is now proposing to lower the current emission control limits for the chromium electroplating category. This decision was based primarily on the fact that the new data show that “most facilities were operating well below the current emission limits,” thus indicating “that more stringent emissions limits could be implemented without significant economic burden to the industry.” The EPA has proposed three alternative compliance options for each category as shown here:



Facility Type	Emissions Limit (mg/dscm)		Surface Tension Limit (dynes/cm)			
			By Stalagmometer		By Tensiometer	
	New	Existing	New	Existing	New	Existing
Large hard chromium	0.006	0.011	40	40	33	33
Small hard chromium	0.006	0.015	40	40	33	33
Decorative chromium	0.006	0.007	40	40	33	33
Chromium anodizing	0.006	0.007	40	40	33	33

The two surface tension options are applicable only if the facility uses a WAFS in its tanks.

Using the above limits, the EPA estimated that the cancer risk to the individual most exposed to hexavalent chromium emissions “is well below 100-in-1 million,” noting that “100-in-1 million is generally considered the upper limit of acceptable risk.” The EPA further stated that the actual cancer incidence is estimated to be “less than 0.05 cases per year (about 1 case in every 20 years).” It is expected that the supplemental amendment will cut hexavalent chromium emissions by an additional 208 pounds per year and chlorine emissions by an additional 15 tons per year, and will cost industry in the neighborhood of \$3.7 million to implement and will add \$3.1 million per year in annual costs.

In addition to addressing chromium electroplating, the supplemental amendment also addressed emissions from hydrochloric acid regeneration plants at steel pickling facilities. Under the proposal, the EPA will no longer allow such facilities to use site-specific chlorine concentration standards.

The comment period on the EPA’s supplemental notice closed on March 26, 2012.

EPA may use “sustainable development” as route to increase power

BY HEIDI SLINKARD BRASHER

Following a \$700,000 study by the National Academies of Science commissioned by the EPA in 2011, the agency has determined the way of the future is to focus on “sustainable development” – thereby expanding its control over U.S. industry.

The study, “Sustainability and the U.S. EPA,” is referred to as the “Green Book” and is seen by some as the agency’s effort to become an ever-powerful force by asserting that its mission encompasses an anticipatory approach to environmental issues. By shifting its mission unilaterally and without legislative authorization to include social and economic issues, the EPA will focus on sustainability impact statements - instead of environmental impact statements - which will focus on probable effects of the social, economic and environmental segments of “sustainability.” Many believe this move greatly expands the agency’s reach by further focusing on “clean” energy, “environmentally sustainable” communities and economic development, and climate change “controls.”

- “Sustainability and the U.S. EPA” study (available for free download)

EPA delists material from Exxon Mobil’s treating tanks

The EPA is granting a petition by ExxonMobil Refining and Supply Company – Beaumont Refinery to exclude from hazardous waste control certain solid waste generated from the treatment of tank bottoms of several tanks.

The final rule delists the centrifuge solids from the definition of hazardous waste under the Resource Conservation and Recovery Act (RCRA). The centrifuge solids are derived from the management and treatment of several F- and K- waste codes.

The EPA concluded that the petitioned wastes are nonhazardous when disposed of in Subtitle D landfills. The one-time exclusion applies to 8,300 cubic yards of centrifuge solids waste.

SIDEBAR

Nanomaterial regulation

Agencies do not have consensus-based standards to measure nanoparticles, cannot interpret the results of toxicity tests, and do not have agreed-upon names for some nanoparticles, according to Maria Doa, director of the EPA’s Chemical Control Division, who spoke at a nanotechnology workshop organized by the U.S. National Institute of Standards and Technology (NIST) and the American National Standards Institute (ANSI) in December 2011.

The American Chemistry Council’s Nanotechnology Panel said companies need standards to support efforts to test the safety of their products and to protect workers. Workshop participants discussed reasons for the failure to have standards, largely blamed on broad use of the term “nanotechnology.” That word is used in science, engineering and technology dealing with material between approximately 1 nanometer and 100 nanometers. Some workshop attendees indicated that many different types of standards will be needed for diverse applications of nanomaterials. [C. Paul]

Lead-containing tackle

The EPA has been asked by the Center for Biological Diversity, the Loon Lake Loon Association, and Project Gutpile to initiate regulation of lead-containing fishing tackle to swans, loons, turtles and other wildlife. According to the environmental groups, about 4,000 tons of lead fishing sinkers are sold in the United States each year. Based on this, the groups estimated that about one ton of lead was lost in U.S. waters for every 6,000 anglers that fish. [C. Paul]

Canada to withdraw from Kyoto Protocol

Canada plans to withdraw from the Kyoto Protocol, saying the treaty does “not represent the path forward for Canada,” according to Environment Minister Peter Kent. “It is now clear that Kyoto is not the path forward for a global solution to climate change; instead, it is an impediment,” he said. “We believe that a new agreement, with legally binding commitments for all major emitters, that allows us as a country to continue to generate jobs and economic growth, represents the path forward.” Kent said the Kyoto Protocol only covers 13 percent of global emitters and does not include the United States and China, two of the world’s largest emitters. [C. Paul]

Halliburton evidence on Deepwater Horizon

BP accused Halliburton of destroying evidence that could be important in the litigation over responsibility for the Deepwater Horizon oil spill (*In re: Oil Spill*, E.D. La., No. 2:10-md-2179, 12/5/11). BP questioned whether a cement slurry that contractor Halliburton pumped into the Macondo well was strong enough to do its job and asked the court to impose sanctions on Halliburton for discarding cement that Halliburton tested in the weeks following the blowout. BP also asked for an order compelling Halliburton “to deliver to a third party forensic electronic firm reasonably acceptable to BP the computer that Halliburton used to produce proprietary 3D modeling results that it now inexplicably claims are gone.” Halliburton denied the allegations. [C. Paul]

Industry comments on high consequence area (HCA) expansion

BY HEIDI SLINKARD BRASHER

PHMSA's Advance Notice of Proposed Rule Making (ANPRM) in August 2011 (76 *Fed. Reg.* 53086, August 25, 2011), posed several questions on numerous pipeline safety issues, including possible expansion of HCAs. However, the January pipeline safety legislation addressed some of the issues raised by the agency's ANPRM.

As a result many, including the Interstate Natural Gas Association of America (INGAA) which commented on January 20, 2012, argue the HCA definition adequately protects people and property based on prioritized risks and does not warrant further expansion. Expansion, INGAA argued, would increase industry costs and not increase public safety because many already voluntarily extend additional integrity management measures to areas outside of the HCAs, and it estimates that by 2030 all areas within the potential impact radius of all pipelines will have integrity management principles applied, thereby making expansion of HCAs unnecessary at this time.

It remains to be seen how PHMSA will respond to stakeholder comment.

\$16.8 million fine for public utility

BY HEIDI SLINKARD BRASHER

Despite the requirement that gas distribution systems conduct leak surveys pursuant to 49 CFR 192.723 (annually in business districts, every three years for bare steel lines, and every five years for the remaining lines), Pacific Gas & Electric (PG&E) found it had not properly leak surveyed 13.83 miles of suburban distribution mains and 1,125 service lines and that some of the mileage had not been tested for 19 years.

Unclear company standards and a lack of quality control were cited as the potential cause. PG&E, which is one of the largest combination natural gas and electric utilities in the United States, self-reported its discovery and that it had repaired the 22 leaks found during their post-discovery survey, including 14 Grade 3 leaks, five Grade 2 leaks, two Grade 2+ leaks, and one Grade 1 leak. Regardless, the California Public Utility Commission (CPUC) proposed a \$16.76 million fine for this failure because of the duration and seriousness of the violation.

SIDEBAR

Safe Drinking Water Act enforcement

The former mayor of Stover, Missouri, was sentenced in December 2011 to 10 years of probation and five months of home confinement, 30 days in a halfway house, and a \$10,000 fine on charges related to violations of the Safe Drinking Water Act (*United States v. Beckmann*, W.D. Mo., No. 2:10-CR-04021, sentenced 12/1/11). Scott A. Beckmann had been convicted in March of misprision of a felony and of making a false statement to a federal agent. Beckmann's co-defendant, Richard R. Sparks, former superintendent of the city's public works department, was sentenced in April to five years of probation and ordered to pay a \$5,000 fine for submitting a false record to the Missouri Department of Natural Resources (DNR). Beckmann and Sparks allegedly misled the DNR as to the levels of bacteriological contaminants, lead and copper in the Stover water supply. [C. Paul]

Gulf spill update – air issues

In the year following the Gulf of Mexico oil spill, research scientists have concluded that all methane from the spill was metabolized by bacteria, resulting in essentially no release of the greenhouse gas to the atmosphere, according to Paul Sandifer, senior science adviser to the National Oceanic and Atmospheric Administration (NOAA). About 40 percent of surface oil spewed from the Macondo well evaporated within two days, according to Sandifer. But researchers found evidence of genetic damage in fish, contamination of beaches, toxicity issues in microbial and plankton, and injuries to coral that appear to be from contact with subsurface oil, he said. There also appears to be an increased incidence of disease among fisherman and oil spill response workers, because of "impacts to both physical and mental health, a story yet to be completed," Sandifer said. [C. Paul]

\$38 million fine for Pacific Gas & Electric 2008 explosion

California applied a \$38 million penalty against Pacific Gas & Electric Co. for a 2008 gas explosion in which one person died and five were injured, caused by a faulty pipeline installation and failed oversight. The National Transportation Safety Board determined the probable cause was use of a section of unmarked and out-of-specification polyethylene pipe with inadequate wall thickness that allowed gas to leak from a mechanical coupling installed in September 2006. A two-hour, 47-minute delay in arrival at the site of a PG&E crew that was properly trained and equipped to identify and classify outdoor leaks and conduct response activities was cited as a contributing cause. [C. Paul]

Storage tanks

Owners of land on which petroleum underground storage tanks are located are responsible for the cleanup of gasoline released (*In re Huntington and Kildare Inc. v. Grannis*, N. Y. App. Div., No. 512100, 11/3/11). Huntington and Kildare Inc. argued that because it does not own the storage tanks on the property, it cannot be held liable as a discharger. The court, citing the ruling in *New York v. C.J. Burth Services Inc.*, 915 N.Y.S.2d 174 (N.Y. 2010), said that liability was based on capacity to prevent spills or clean up contamination rather than on ownership. Huntington and Kildare knew for years that the property had a petroleum contaminant plume and that the storage tanks were not properly abandoned in place. [C. Paul]

Washington State not liable as arranger for disposal of hazardous waste

Between 1937 and 1940, the state of Washington entered leases with mining companies for the purpose of mining and removing ore. As part of the metal extraction process, waste rock and tailings are necessary byproducts. This waste eventually became the subject of a Superfund action against Teck Cominco Metals, Ltd. under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for the disposal of the waste directly into the Columbia River. Teck filed a counterclaim against the state, alleging that Washington was liable as an arranger.

The court found that the subject leases fell in the grey area between transactions for the sole purpose of discarding a used hazardous substance, and transactions for a new product that eventually becomes used and disposed in a way that leads to contamination. Nevertheless, the court found that “the physical nature of ore and the need to obtain access to the metals within does not indicate the state intended the disposal of mining waste, but at most was indifferent to whatever disposal method was chosen by the mining companies.” Thus, the court found the state not liable as an arranger.

The court noted that the foreseeability of the substance becoming waste is insufficient to subject an entity to arranger liability. Indeed, not only was Washington aware that waste would inevitably result from the operation, but it earned a royalty based on the successful extraction of sellable product. Instead, the court focused on the fact that naturally occurring ore deposits did not have the “characteristic of waste” when they were “delivered” to the mining companies.

The court differentiated from other instances in which a seller was found liable as an arranger. In such circumstances, the items were already hazardous before being sent off to the buyer. In contrast, the state of Washington never owned or possessed “hazardous waste,” nor was the purpose of the leases to treat hazardous waste. Rather, the purpose was to generate revenue for the state, and waste was merely a byproduct of the transaction.

EPA proposes national uniform emission standards for heat exchange systems

BY ROBERT JOYCE

On January 6, 2012, the EPA issued a Notice of Proposed Rulemaking (proposed rule) in which it proposed amendments to the NESHAP/NSPS standards applicable to hydrocarbon emissions from heat exchange systems for petroleum refineries. However, most significantly, the EPA’s notice includes a proposal to create national uniform standards for heat exchange systems that would apply to many facilities other than refineries. The EPA plans to “reference” these new uniform standards as it “revise[s] in the future NESHAP or source performance standards for individual source categories that have heat exchange systems.” As such, *the uniform standards could affect many different types of manufacturers, including manufacturers of petrochemicals, chemicals, polymers, plastics and specialty chemicals – not just refineries.*

In addition to creating the new uniform standards, the proposal provides refineries with an alternative option for complying with the standards for heat exchange systems, and would allow refineries to reduce monitoring frequency by meeting a more stringent definition for “leaks.”

The EPA first published its MACT (maximum achievable control technology) standards for petroleum refineries (40 CFR Part 63 Subpart CC) in 1995. 60 *Fed. Reg.* 43620 (8/18/1995). These standards were amended in 2009 with the adoption of the MACT standards for heat exchange systems at petroleum refineries. 74 *Fed. Reg.* 55670 (10/28/2009). The proposed rule would amend 40 CFR Part 63 Subpart CC, and create a new section – 40 CFR Part 65, subpart L - containing the uniform standards for heat exchange systems. As noted above, the EPA’s plan is to reference these uniform standards “as appropriate ... [in] future NESHAP for major or area source categories” in 40 CFR Parts 60, 61, and 65.

The proposed rule was prompted by a December 29, 2009, request from the American Petroleum Institute (API) for the EPA to reconsider 10 sections of the 2009 MACT standards for heat exchange systems at petroleum refineries. Of the issues raised, the

View of the Columbia River dividing Washington and Oregon

Continued on next page



EPA only agreed to reconsider three: 1) 63.640(n) – overlap provisions for storage vessels, 2) 63.646 – deck fitting control requirements for vessels with internal floating roofs, and 3) reports for storage vessels also subject to 40 CFR Part 61, subpart Y.

As for other refinery-specific changes in the proposed rule, the EPA stated that it would continue to require monthly leak monitoring for heat exchange systems at existing sources, with an action level of 6.2 ppmv total strippable hydrocarbons in stripping gas collected via the TCEQ Modified El Paso Method, Revision 1 (El Paso Method); for new sources, the action level of 3.1 ppmv would also remain. However, the EPA proposed alternative leak action levels based on analysis of total strippable hydrocarbons in cooling water collected and analyzed according to certain SW-846/ASTM methods. The new alternative action levels are 80 ppbw for existing sources and 40 ppbw for new sources. The EPA also retained the “delay of repair” action level of 62 ppmv total strippable hydrocarbons collected via the El Paso Method, and proposed an 800 ppbw action level for total strippable hydrocarbons in the cooling water collected and analyzed by the SW-846/ASTM methods. In addition, the EPA proposed that refineries be allowed to monitor on a quarterly basis instead of monthly if they use the lower leak action levels of 3.1 ppmv via the El Paso Method or the 40 ppbw via the SW-846/ASTM methods.

As for the new uniform standards, the EPA proposed adding two new subparts to 40 CFR Part 65: Subpart H – National Uniform Emissions Standards General Provisions, and Subpart L - National Uniform Emissions Standards for Heat Exchange Systems. Subpart H contains provisions that would apply to all sources subject to current or newly promulgated uniform standards such as definitions and provisions for incorporation by reference, as well as determining whether a uniform standard applies to a particular regulated source. Subpart L of the proposed uniform standards is directed at heat exchange systems, and applies to “the control of air emissions from heat exchange systems for which another subpart references the use of this subpart for such air emission control.” A heat exchange system is defined as “a device or collection of devices used to transfer heat from process fluids to water without intentional direct contact to of the process fluids with the water. . . and to transport and/or cool the water in a closed loop recirculation system (cooling tower system) or a once through system (e.g. river or pond water).” The proposed subpart sets forth the required monitoring and repair requirements including monitoring locations, methods, frequency, and action levels. The new regulations also set forth the recordkeeping, notification and reporting requirements applicable to covered heat exchange systems.

SIDEBAR

Asbestos violations for demolition company result in criminal convictions for individual owners

A salvage and demolition company and three of its employees were charged and convicted in federal court in Tennessee for conspiracy and for purposefully violating national emission standards for hazardous air pollutants when they illegally removed asbestos and demolished a facility still containing asbestos.

These Clean Air Act (CAA) convictions resulted from the improper handling, removal and disposal of asbestos during renovation and demolition activities, including scattering it in piles exposed to the elements such that emissions traveled to nearby homes, businesses and a child care center. [H. Brasher]

Hydrocarbon refrigerants

The Environmental Protection Agency approved three hydrocarbon refrigerants – propane, isobutene, and the chemical R-441A – as substitutes for the chlorofluorocarbon CFC-12 and the hydrochlorofluorocarbon HCFC-22. The EPA approved use of isobutane and R-441A in household refrigerators and freezers, and propane is approved for use in retail standalone refrigerators and freezers. The rule is to address ozone depletion in the upper atmosphere, believed to result from reactions with CFCs. [C. Paul]

PHMSA advisory bulletin clarifies reporting requirement for pipeline facilities

On January 13, 2012, PHMSA issued an advisory bulletin (ABD-12-01) explaining that while 49 CFR 195.2 defines “pipeline facility” to include pipe, for the purposes of notification pursuant to sections 195.64(c)(1)(iii) and 195.64(c)(2)(v), pipe is excluded. Therefore, required electronic notification to PHMSA through the National Registry of Pipeline and LNG Operators of construction of a new “pipeline facility” or of acquisition or divestiture of an existing “pipeline facility subject to this part” is not intended to include “pipe” in the definition of “pipeline facility” for these reporting purposes. [H. Brasher]

EPA proposes to delist Conoco Phillips’ residual solids from processed stormwater tank sludge

The EPA is proposing to grant a petition by the ConocoPhillips Billings, Montana, refinery to exclude (or “delist”) certain residual solids from the list of hazardous wastes. The proposal would exclude the waste from the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

The exclusion would apply to residual sludge from two stormwater tanks that is dewatered and de-oiled using a filter press and portable centrifuge.

The EPA agreed with ConocoPhillips that the waste does not meet the criteria for F037 waste and that it is nonhazardous. F037 wastes are wastes that are generated in the separation of oil, water and solids from petroleum refinery process wastewaters and oily cooling wastewaters.

FDA sued for not responding to rulemaking petition on nanoparticles

BY ROBERT JOYCE

The Food and Drug Administration has been sued by a group of consumer safety and environmental advocates concerned over possible health and environmental effects of engineered nanomaterials. In this first-of-a-kind lawsuit, the group alleges that the FDA failed to adequately respond to the group's May 16, 2006, petition under the Administrative Procedures Act (APA) seeking amendment of FDA regulations regarding such materials. According to a statement issued by one of the plaintiffs, Friends of the Earth, "The agency's unlawful delay unnecessarily places consumers and the environment at risk."

In 2006, the group petitioned the FDA to enact new regulations which would better define the materials at issue, treat them as new substances distinct from their bulk forms, require them to have detailed labeling, and subject them to "nano-specific paradigms of health and safety testing." The petition also requested the FDA to prepare an Environmental Impact Statement under the National Environmental Policy Act to assess the impacts of nanotechnology in products regulated by the FDA. According to the complaint filed on December 21, 2011, with the U.S. District Court for the Northern District of California (*International Center for Technology Assessment v. Hamburg*, Case No. CV-11-6592-MEJ), "The FDA has not meaningfully responded to or taken action on the 2006 petition in violation of the Administrative Procedure Act" and, "in the interim, nanomaterial consumer products have proliferated." Plaintiffs have requested the court to declare the FDA to be in violation of the APA and to order the FDA "to respond to the 2006 petition as soon as possible."

Of particular concern to plaintiffs is that, because of their small size, nanomaterials have unique properties, functions and effects. Nanoparticles are typically between 1 and 100 nanometers in size (a nanometer is one-billionth of a meter), while "a red blood cell is approximately 7,000 nanometers wide." As such, nanoparticles have novel "electrical, optical, magnetic, toxicity, chemical, photoreactive, persistence, bioaccumulative and explosiveness" properties that are alleged to pose hazards to humans and the environment. The small size of the particles purportedly results in "unprecedented mobility in the body and environment" and allows them to "enter the body and pass through biological membranes – like cell walls, cell tissues, and organs – more easily than larger

particles." Consequently, when inhaled, ingested or absorbed, the particles are said to be able to accumulate in cells, organs and tissues and even make their way into cell mitochondria and nuclei "where they can interfere with cell signaling and induce structural damage, including DNA damage."

The fundamental concern is that the FDA's existing information on bulk forms of the materials from which the particles are made is inadequate to characterize them. According to the complaint, the FDA's belief that "particle size is not an issue... is a loggerheads with the consensus view of the scientific community, which is that the adverse effects of nanoparticles cannot be reliably predicted or derived from the known toxicity of the bulk material." Consequently, the groups want the FDA to treat nanoparticles and nanotubes as new chemicals with properties distinct from their bulk forms.

According to plaintiffs, there are well over 1,300 products containing nanoparticles that are intended for human consumption or application. Of immediate concern to plaintiffs are sunscreens containing nanoparticles of zinc oxide and titanium oxide. Plaintiffs point out that there are "several hundred sunscreen products containing manufactured nanoparticles... currently on the market in Australia." They maintain that FDA's "first and only words" on such sunscreens was that it "considered manufactured nanoparticle ingredients in these sunscreens a mere reduction in size and not a new drug ingredient, permitting manufacturers to sell [them] based



on the agency's safety assessment of bulk material sunscreens." However, plaintiffs fear that zinc oxide and titanium oxide nanoparticle ingredients in sunscreens pose new and distinct risks not associated with their bulk forms. In particular, they cite early studies that link these ingredients with damage to colon cells and brain stem cells, and that purport to affect gene expression in the

brains of mice fetuses in ways that have been associated with autism, epilepsy and Alzheimer's disease. Plaintiffs also cite studies which indicate that nanoparticles smaller than 240nm can pass through the human placenta to the fetus, "meaning that the toxicity of manufactured nanomaterials could extend across generations."

Not limiting themselves to potential effects of human exposure, the plaintiffs' complaint also raises various environmental issues. They characterize nanomaterials as "a new class of non-biodegradable pollutants" which can enter the environment by being sprayed on, washed off, or disposed of. They claim the potential environmental issues include: "mobility, reaching places that larger particles cannot, moving through aquifers and soils; transport, the ability to absorb or bond to harmful chemicals and carry them places they would not otherwise reach; reactivity, interacting with natural substances to develop toxic compounds; fate and persistence; and bioaccumulation." Plaintiffs even cite the EPA for the proposition that "there is a significant gap in our knowledge of the environmental, health, and ecological implications associated with nanotechnology."

The complaint chastises the FDA for the fact that its only response to the 2006 petition has been a November 9, 2006, letter stating that the EPA could not address the petition "because it raises complex issues requiring extensive review and analysis by agency officials, and in relation to which the agency is seeking public input." Further, despite having had the petition before it for more than five years, the EPA issued several guidance documents and proposed rules regarding sunscreens in 2011, which purportedly "ignored the 2006 petition and issues it tabled."

By stipulation, the FDA has been granted an extension of time until April 23, 2012 to respond to the complaint.

- » **FDA's docket for the petition**
- » **Citizens' Petition to the United States Food and Drug Administration**
- » **Citizens' Complaint for Declaratory and Injunctive Relief**
 - **Part 1**
 - **Part 2**

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