

Environmental Health & Safety Observations

Supreme Court Agrees With Just About Everyone (Except Ninth Circuit) in Recent Clean Water Act Decision...

Welcome

to the inaugural issue of the Environmental Health & Safety Observations, a publication that seeks to provide plainspoken updates concerning the extremely technical and ever-changing laws, rules, and regulations that govern the protection of the environment, health, and safety (EH&S). The Environmental Health & Safety Observations will be published six times a year so we can keep you updated on the most important EH&S developments. This issue highlights some of the recent developments concerning water pollution, water rights, food safety, and product safety in both the US and EU.

It is an odd occurrence when all parties before the US Supreme Court agree on the issue presented. That is particularly so when the issue concerns the interpretation of an environmental statute. Yet such was the case in Los Angeles County Flood Control District v. Natural Resources Defense Council, Inc., et al., No. 11-460, concerning Clean Water Act regulation of stormwater discharges. It should come as no surprise that the Court's opinion was unanimous.

At issue was a citizen suit filed by the Natural Resources Defense Council (NRDC) and Santa Monica Baykeeper against the Los Angeles County Flood Control District (District) and several other defendants. The suit alleged that water-quality measurements taken from concrete channels in the Los Angeles and San Gabriel Rivers that identified elevated concentrations of pollutants demonstrated that the District was in violation of the Clean Water Act. The plaintiffs alleged, that is, that the mere presence of contaminated water in District-controlled structures constituted a violation of the statute. The trial court found that while it was undisputed that water in the District's channels was contaminated, the record was insufficient to demonstrate that the contaminated water had been discharged into the rivers from the District's stormwater control system, which discharge would be necessary to show a violation of the Clean Water Act. NRDC and Baykeeper appealed that holding to the US Court of Appeals for the Ninth Circuit, which has a reputation for taking what might be described as an avant-garde approach to interpreting environmental laws. Ruling on the appeal, a three-judge panel agreed with the lower court's holding that, for a Clean Water Act violation to have occurred, the District must have discharged polluted water; however, the appeals court went on to find that the rerouting of polluted water through in-river concrete channels constituted such a discharge. The District appealed this ruling to the Supreme Court. Interestingly, neither the NRDC nor Santa Monica Baykeeper challenged the appeal, except to once again press their twice-rejected argument that presence of contaminated water in District-controlled structures constituted a violation of the Clean Water Act, notwithstanding the absence of a discharge.

The question taken up by the Court was a narrow one: whether, under the Clean Water Act, a "discharge of pollutants" occurs when polluted water from one portion of a navigable river passes through a concrete channel or other

engineer improvement in the river and then flows back into a lower portion of the same river. Common sense says no, and the Court agreed, citing to the Clean Water Act, which defines a "discharge of pollutants" as "any addition of any pollutant to navigable waters from any point source" (emphasis added). In its decision, authored by Justice Ginsburg, the Court held that no pollutants are added to navigable waters when already-contaminated water is merely transferred between different portions of the same body of water.

Despite what appears to be an uncontroversial opinion from the Court, this is a case that has important implications for the hydropower industry, water control agencies, and dam owners. Had the Supreme Court upheld the Ninth Circuit's decision, owners of improved water control structures could have faced the prospect of liability and onerous

permitting obligations under the Clean Water Act for contaminated water flowing over its dams and through its channels, notwithstanding that such owners and operators may have borne no responsibility for the contamination of the water. In its 2004 holding in South Florida Water Management District v. Miccosukee Tribe, 541 U.S. 95, the Supreme Court found that pumping polluted water from one portion of a body of water to another in the same body of water did not amount to a discharge of pollutants under the Clean Water Act. Coupled with that 2004 decision, the Court's decision in this case makes it clear (if it was not already) that there is no liability under the Clean Water Act for discharges of pollutants into a body of water unless the discharge contributes additional pollution to the water body.

...And a Virginia District Court Agrees with Just About Everyone (Except EPA) that Stormwater Is Not a Pollutant

The US Environmental Protection Agency (EPA) is often criticized by the regulated community for being overly aggressive in its protection of flora and fauna. While EPA administrators typically defend their actions by pointing to their statutory mandate to protect the environment, even the most dedicated agency bureaucrat must have cringed when reading District Court Judge Liam O'Grady's recent opinion issued in the case of Virginia Department of Transportation v. EPA. In another judicial clarification of the obvious. Judge O'Grady, sitting in the US District Court for the Eastern District of Virginia, ruled on January 3, 2013, that the EPA cannot regulate the flow of stormwater into a body of water under the Clean Water Act, because stormwater is not a pollutant. The chortles echoing through the halls of the Chamber of Commerce could be heard for miles.

One cannot question the absurdity of regulating stormwater – the source of Earth's fresh water – as a pollutant, but the Virginia Department of Transportation (VDOT) case is a little more nuanced, and its result may not be as funny as it first appears. At issue in VDOT was a tributary to the Potomac

River, known as Accotink Creek, which the EPA had listed as having "benthic impairments," meaning that the community of organisms living on the bottom of the creek was not as healthy as it should have been. The EPA determined that one of the reasons for this impairment was the presence of excess levels of sediment, which the Clean Water Act does define as a pollutant.

To address pollutants, the Clean Water Act requires the EPA to determine what are known as Total Maximum Daily Loads (TMDL) of pollutants flowing into impaired bodies of water. A TMDL is often described as something of a pollution diet that, if followed, will result in improvement to the quality of the impaired body of water. In the VDOT case, EPA could have issued a TMDL for sediment, but instead it issued a TMDL limiting the flow of stormwater into the creek as a proxy for sediment, the logic being that the less stormwater entering the creek, the less sediment that stormwater will carry with it. Judge O'Grady's opinion does not address why the EPA chose to issue a TMDL for stormwater flow as a proxy for sediment instead of just issuing a TMDL for sediment, but one

possible reason is that measuring and regulating daily stormwater flow can be easier and cheaper than measuring and regulating daily sediment discharges. Ease and cost of compliance notwithstanding, the

court ruled that the EPA could not regulate pollutants by proxy if that proxy was not also a pollutant, and even the EPA was not prepared to argue that stormwater is a pollutant.

Texas' Water Woes Spur Legislative Action and Supreme Court Proceedings

Dwindling water supplies – not just their contamination - is an issue that regulators and industry alike will need to focus on in the coming years. Take Texas, for example: The second largest state in the country is experiencing one of the most severe and prolonged droughts in its history, with water shortages impacting more than two-thirds of the state. These drought conditions, coupled with a growing population, are already forcing Texas water agencies to make tough decisions about who should receive limited supplies. Texas farmers have been particularly hard-hit to date, and, according to the Texas Water Development Board (TWDB), Texas does not and will not have enough water to meet the needs of its people, businesses, and agricultural enterprises during drought conditions unless significant financial and legislative resources are devoted to the issue. TWDB projects that, if substantial water development and management projects are not implemented over the coming years. water shortfalls will jeopardize public health, safety, and welfare and have a severe impact on economic development in the state, costing Texas businesses and workers roughly \$116 billion per year in income by 2060. In light of these dire projections, Texas is exploring legislative and legal solutions to address the current and projected threats to its water supply.

TWDB's projection that \$53 billion will need to be spent over the coming decades on upgrading Texas' water infrastructure has caught the attention of Texas lawmakers. Allan Ritter, a Republican who chairs the Natural Resources Committee of the Texas House of Representatives, recently introduced bills that would take \$2 billion from the state's Economic Stabilization Fund to establish a water infrastructure bank that

would finance water projects throughout the state on a rolling basis. TWDB's suggested infrastructure upgrades include building new reservoirs, improving existing reservoirs, developing new wells, increasing water reuse, and constructing desalination plants. The bills also mandate that no less than 20 percent of the water infrastructure fund be spent on water conservation, reuse, and education efforts. Funding for conservation-related improvements is crucial, given that TWDB's long-term plan expects 24 percent of the state's future water supply, or 651.6 billion gallons per year, to be sourced through municipal and agricultural conservation.

Texas authorities also are pursuing legal action against New Mexico and Oklahoma in the US Supreme Court in an attempt to secure the allocation of river water they believe their state is entitled to under interstate compacts. On January 8, 2013, the Texas Commission on Environmental Quality filed a complaint with the Court, which has original jurisdiction over matters where two states have a dispute against each other, alleging that New Mexico has violated the 74-year-old Rio Grande Compact by illegally allowing diversions of both surface and underground water. The dispute centers on the Rio Grande Project, a system of dams and canals that impounds water at the Elephant Butte and Caballo reservoirs in New Mexico for delivery for agricultural production in southern New Mexico and West Texas. Texas' complaint alleges that New Mexico changed the conditions that existed in 1938, when the compact was executed, by allowing its residents to sink nearby wells and pump water from the river, which supplies roughly half of El Paso's water supply as well as a significant percentage of the water used for Texas agriculture. New Mexico has asserted through the press that it is meeting its obligations under the Rio Grande Compact. Even if the Court agrees to hear the matter, it could take years to resolve.

In early January, the Supreme Court agreed to hear another lawsuit regarding Texas' water supply. This suit was filed by the Tarrant Regional Water District (TRWD) against the Oklahoma Water Resources Board. In its lawsuit, the TRWD is seeking to reverse a September 2011 ruling by the Tenth Circuit Court of Appeals, which rejected TRWD's attempt to force an Oklahoma water authority to allow Texas to capture water in Oklahoma, where it is less salty, and pipe the water to communities in northeastern Texas. TRWD alleges that Oklahoma's restrictions on the allocation of out-of-state water permits unconstitutionally restrict interstate commerce under the Commerce Clause of the Constitution. While water rights in the region are governed by a compact negotiated by Texas, Oklahoma, Louisiana, and Arkansas, which was ratified by Congress in 1980, TRWD contends that the compact does not permit a state to discriminate against interstate commerce in water.

Legal and political battles over water are not novel occurrences; however, water supply issues and disputes are taking on greater urgency in the US as hotter, drier conditions affect Western states with growing populations. Moreover, as climate change alters rainfall patterns and freshwater availability worldwide, additional tensions and disputes likely will arise between countries and other stakeholders that share water supplies. While the disputes highlighted above may take years to resolve, Texas' drought conditions should be a wakeup call to prioritize investment in water infrastructure, efficiency, and conservation as well as proactively seek improvements to water-governing instruments before crises emerge.

1 The Rio Grande Compact is an interstate compact between Colorado, New Mexico, and Texas that was signed in 1938 and approved by Congress to equitably apportion the waters of the Rio Grande basin. The compact settled years of litigation by establishing a formula for allocating the river's water to various users.

EU's REACH Registration Deadline Is Approaching

Across the (relatively clean and abundant) pond in the European Union (EU), a key chemical registration deadline is approaching under the EU's legislation on the registration, evaluation, authorization, and restriction of chemicals, known as REACH. REACH applies to most chemicals manufactured or marketed in the EU and was introduced in 2007 to minimize the risks such substances pose to human health or the wider environment. A key innovation of REACH was to make participants in the chemical supply chain, rather than public authorities, responsible for evaluating and reporting the risks. Since its introduction in 2007 there have been a number of important deadlines regarding (1) pre-registration of all chemicals generally and then (2) full registration of chemicals used in large quantities. Another key registration deadline, May 31, 2013, is now approaching.

May 31 is the deadline for businesses that manufacture in, or import into, the EU in quantities exceeding 100 tons per year to register substances with the European Chemicals Agency (ECHA). Registration can involve a considerable amount of work. It requires the submission of detailed technical dossiers containing relevant information about the substance and its use, and the required detail increases along with the tonnage and hazardous nature of the substance concerned. Any party failing to register will be denied access to the EU market for the relevant substance.

Although REACH imposes the registration obligation described above on EU-based manufacturers and importers of chemicals, it has implications for non-EU manufacturers and exporters of chemicals into the EU. Such entities' EU customers are likely to want or need their non-EU supplier's cooperation to satisfy their obligations under REACH. Such customers may need information about the substance to register it successfully, or they may want to take advantage of a REACH provision that allows non-EU manufacturers and exporters to appoint an entity known as an "Only

Representative." Doing so relieves EU customers of their REACH registration obligations by transferring them to the Only Representative.

Most EU businesses affected by REACH should have pre-registered relevant substances some time ago by providing a limited amount of information about the substances to the ECHA. Unless they can qualify for "late pre-registration," failure to pre-register in this way would mean that such businesses' full registration obligations would have been accelerated to December 2008 rather than the upcoming deadline of May 31, 2013, and any failure to comply should already have had an impact on their access to the EU market.

Study Raises Endocrine Disruptor Concerns About Chemical Selected to Replace BPA

Remember all those headlines about the adverse health effects of bisphenol A (BPA), which resulted in manufacturers withdrawing all types of water bottles and containers from the market and government agencies banning the use of BPA? It now seems that the alternative additive chosen by some manufacturers may present its own health concerns.

As you may recall, BPA is an additive that was used in a variety of products, most notably in many rigid plastics, such as polycarbonate water bottles and baby bottles, and as a protective interior coating for metal food and drink cans. For many years environmental groups called on the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) to ban the use of BPA in food contact articles and consumer products with which infants and small children come into frequent contact. In addition to BPA's alleged effects on hormones, these groups also cited studies linking BPA to diabetes, asthma, altered prostate, and heart and kidney disease.

For years, federal regulators declined to ban the substance and continued to study its potential effects.

By contrast, any EU business that has already successfully pre-registered a substance will have been obliged to join a Substance Information Exchange Forum (SIEF) for that substance. SIEFs exist to facilitate the sharing and joint commissioning of data required to register a substance with the ECHA. An Only Representative as described above may participate in a SIEF on behalf of the entities that have transferred their obligations to it. SIEFs, under the guidance of a lead registrant, are responsible for submitting a joint registration dossier in advance of the May 31 deadline, which is crucial for their participants' continued access to the EU market.

Undeterred, environmental groups continued to press the issue and were more successful in getting other countries (notably Canada and some EU countries) to act. Some states and municipalities passed laws banning the use of BPA in certain products. In 2012, FDA banned BPA from use in baby bottles and sippy cups, but continued to allow its use in other products. By that time, however, many industrial users had moved away from BPA to alternative substances, and BPA was prohibited in children's food and beverage containers by some state and local laws. In fact, the 2012 FDA regulation was adopted at the urging of industry, which wanted to assure consumers that their products were now BPA-free.

Among the alternatives for BPA in some products was bisphenol S (BPS), which is now found most often as a developer in thermal papers, including sales receipts and printouts from ultrasound machines and other medical devices. Scientists at the University of Texas recently linked low concentrations of BPS to disruption of estrogen in rats. According to a recent article in the journal Environmental Health Perspectives, researchers exposed rat cells to BPS concentrations similar to those humans are exposed to and found that BPS disturbs the body's response to natural estrogen hormones. It should be noted that the Texas study cautioned that BPS effects in laboratory animals do not necessarily translate into similar effects in humans. And the study does not

suggest that BPS is present in children's food and beverage containers.

Ironically, the use of BPS has grown in recent years in part because it has been seen as an effective replacement for the more ubiquitous BPA, which had been under intense scrutiny due to substantially similar health concerns. It likely won't be long before environmental groups call for the banning of BPS as well. But the manner in which BPA fell out of favor provides some lessons about how not to effectively regulate and phase out a potentially hazardous substance.

This tortured regulatory history should provide a cautionary tale. From the perspective of environmental activists, FDA and CPSC dragged their feet on BPA and were too easily influenced by industry. From the regulators' perspective, however, most of the early BPA studies did not conclusively link the presence of BPA to human health effects and did not show that BPA persisted in the body or in the environment. After Health Canada designated BPA for listing as a "hazardous substance" in 2008, Wal-Mart unilaterally declared that its Canadian stores would cease selling BPA-containing food containers and that its US stores would phase out baby bottles with BPA by early 2009. Toys 'R' Us and other retailers soon followed suit. Nalgene, a leading maker of reusable water bottles, announced that it would stop using BPA, as did some of its competitors. In 2009 Sunoco, which produced BPA and other chemicals, announced it would no longer sell BPA to companies that make children's food and beverage containers.

The regulation of phthalates – a group of additives used to make plastics more flexible – followed a similar path. Most manufacturers voluntarily removed the leading types of phthalates from baby bottle nipples and teethers long before Congress banned them from children's products in a 2008 law designed to update and reform the CPSC's handling of product recalls. By that time California and some other states had already banned certain phthalates in some products. As with BPA, the impetus for change came from pressure – some would say Internet-fed hysteria – from publicinterest groups, hastened by a marketplace reaction of

retailers and manufacturers that was fueled by the fear of potential and actual lawsuits.

Action by political branches of government (namely, Congress and its state and local counterparts) contributed to the momentum for prompt replacement of the additives and bypassed the more methodical risk-assessment approach employed by regulatory agencies. The problem with this approach is the risk of unintended consequences, as evidenced by the new findings on BPS. Indeed, the pressure on manufacturers brought by public outcry, politicians, and retailers led to an accelerated and hasty selection of replacements. As more becomes known about the possible hazards associated with BPS and other compounds that replaced BPA and phthalates, this process will likely repeat itself. A better approach would be to let regulatory agencies work with scientific experts and industry to assess the risk, identify feasible alternatives, and establish reasonable phaseout schedules.

FDA Issues Proposed Rules to Prevent Outbreaks of Foodborne Illnesses

Recent headlines suggest that the FDA is taking action to better protect the public food supply and reduce the risk of foodborne illnesses, which the Centers for Disease Control says sicken approximately one in six Americans each year, send more than 128,000 people to the hospital, and result in 3,000 deaths annually. Because the proposals have garnered attention, even in the local media, this article attempts to explain just what the FDA has proposed and what it means.

The FDA is acting pursuant to the Food Safety Modernization Act (FSMA), which Congress enacted in 2010 in response to several well-publicized nationwide food poisoning outbreaks. In that legislation, Congress directed the FDA, which is charged with ensuring the safety of nearly 80 percent of the national's food supply, to promulgate rules addressing five areas of food safety. The FDA's recent proposals address two areas of food safety: preventive controls for human food and standards for produce safety. The agency

hopes these rules, when implemented, will prevent approximately 1.75 million illnesses a year. The FDA will eventually roll out other regulations mandated by the FSMA, including foreign supplier verification for importers, preventive controls for animal food, and accreditation of third-party auditors.

First, the FDA has proposed that facilities that process, package, or store food for human consumption develop a written plan that: (1) evaluates reasonably anticipated hazards (such as diseasecausing organisms); (2) outlines the controls that will be put in place to avoid such hazards; and (3) establishes a plan for monitoring these controls, as well as a plan for correcting problems when they arise. The agency will evaluate these plans during routine facility inspections. Currently, industry employs a variety of voluntary standards and procedures. Large producers likely will only need to modify their existing policies to adapt to the rules when they go into effect. For smaller producers, however, compliance may be more burdensome. Nevertheless, some in industry believe the rules will level the playing field and promote standard safety practices.

Second, the FDA has proposed standards that apply to the harvesting and production of fruits and vegetables, including standards for irrigation, farm worker hygiene, intrusion of animals in the growing fields, and sanitation of buildings, tools, and equipment. This rule is intended to prevent contamination from biological organisms, such as E. coli, which has been an increasing source of foodborne illness associated with raw produce. Unlike processed foods, which usually involve cooking at temperatures that kill bacteria, fresh produce that is consumed raw poses unique food safety challenges, since contamination is not easily detected or treated.

Experts claim that had these rules been in place sooner, two recent foodborne illness outbreaks might have turned out differently. They contend that the rules could have prevented a 2012 episode involving contaminated organic peanut butter that sickened 41 people in 20 states. Additionally, experts claim that a

2011 outbreak stemming from listeria in cantaloupes, which killed at least 29 people, could have been prevented if contaminated rinse water had been detected.

Response from industry to the proposed rules has been supportive but equivocal. The Grocery Manufacturers Association said: "We are pleased that implementation of FSMA is moving forward and look forward to working with the FDA by continuing to share our food safety expertise and best practices and by evaluating and commenting on the proposed rules." Similarly, the Produce Marketing Association released the following statement: "We're pleased to see the proposed rules released and are eager to review and assess them. Throughout the regulatory process, we've worked diligently with and will continue to inform key decision makers to help guide these regulations in a direction that will best serve public health and our industry's food safety needs."

Notwithstanding the media hype, it may take several years for the rules to have a practical effect on food safety. The public has 120 days to comment on the proposed rules. The FDA may revise the rules based on input from stakeholders before promulgating final rules. Food establishments would have to comply with the preventive controls requirements within 60 days of that rule becoming final, but smaller facilities would have more time to comply. The FDA is proposing that larger farms be in compliance with most of the produce safety requirements 26 months after the final rule is published in the Federal Register. Small and very small farms would have additional time to comply, and all farms would have additional time to comply with some of the water quality requirements. Despite this, the FDA has already shown that it will use its enhanced enforcement powers under the new food safety law. In November 2012, the FDA shut down the Sunland Inc. processing plant in New Mexico that was the reported source of the tainted peanut butter. The agency allowed the plant to reopen only after the company agreed to retain an outside food safety expert and obtain FDA approval of a comprehensive sanitation plan.

As always, Weil will continue to monitor and report on litigation, legislation, and regulation impacting the environment, health, and safety.

Environmental, Health & Safety Observations is published by the Environmental practice group of Weil, Gotshal & Manges LLP, 767 Fifth Avenue, New York, NY 10153, +1 212 310 8000, http://www.weil.com.

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