



Twelve Crucial Health, Safety, and Environmental Regulations: Will the Obama Administration Finish in Time?

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About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. CPR is grateful to the Public Welfare Foundation for funding this white paper, as well as to the Deer Creek Foundation and the Bauman Foundation for their generous support of its work in general.

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Introduction and Summary

When President Obama came to the White House and put his appointees in place, they faced a long to-do list. For the preceding eight years, the dominant view within the Executive Branch had been that health, safety, and environmental regulation was a nuisance to business, cutting into industry profits in service of objectives that had never been part of President George W. Bush's agenda.

By the time Bush II left office on January 20, 2009, little had been done and a lot of important safeguards had been rolled back. Crucial rules mandated by Congress were delayed or derailed, and enforcement was a shadow of its former self. On global warming, the marquee environmental issue of the day, the Bush Administration simply refused to regulate, while on dozens of smaller issues it delayed, undermined, or decided to do nothing. The nation has paid a high price for this aspect of the Bush legacy. Consider the worst domestic mining disaster in 40 years, toxic imported drywall, poisonous toys, salmonella in peanut products and fresh produce, prescription drugs with fatal side effects, and more.

The Obama Administration came to power promising to reinvigorate protections for public health, worker and consumer safety, and the environment; and, indeed, the Administration has made important progress on several fronts. But the President's first term in office is more than half over, and too much remains to be done. To fulfill the promises he made to the American people, prevent further catastrophes, and save American industry from its own short-sighted opportunism, the President needs to exhort his Cabinet, his political appointees, and the White House staff to get crucial things done. This report identifies 12 such regulatory safeguards, a collection that in the view of the authors represents the 12 most critical environmental, health, and safety regulations still in the pipeline. Too many of them are in serious danger of being stuck in the pipeline long after January 20, 2013.

The agencies responsible for these dozen rules face many challenges, not least of which is a huge amount of work that must be done with shrinking resources. (Many of the agencies charged with protecting people and the environment—especially the Environmental Protection Agency (EPA)—will have to endure particularly tight resource constraints in the near future, since their budgets received among the largest cuts in the recently passed budget bill for funding the federal government through the end of the current fiscal year.) Setting priorities will be essential, especially in the face of congressional wrangling over the next budget, a destructive process that makes it very difficult for the agencies to plan.

Newly energized Republicans, with the active support of polluting industries, have made regulatory issues a centerpiece of their agenda in Congress, and the party's presidential candidates are certain to pursue the same issue, arguing, albeit without evidence, that regulations are stifling economic growth. Already the President and his team have conceded some of the rhetorical battleground, issuing an order calling on regulatory agencies to scour their existing regulations for waste and repetition, and then bragging about regulations delayed or weakened.

These reactions are a bad portent for the remainder of the President's first term because the 2012 presidential campaign will soon begin, and he will surely hesitate to provide fodder for his opponent's anti-regulation arguments during the heat of the campaign. Moreover, rules issued too close to the end of an Administration are in danger of being rescinded by a new President, as the Obama Administration did in the case of some Bush regulations, and the Bush Administration did in the case of some Clinton regulations. In addition, Congress could invoke the Congressional Review Act, allowing it to undo regulations that were completed with less than 60 session days in the Senate or 60 legislative days in the House of Representatives remaining during the current Congress. (Given all the time both Houses of Congress take off for recess, the last 60 session or legislative days of a given session of Congress typically begin about sixth months before Congress formally adjourns in December.) By contrast, rules that have been in place for several months are harder to dislodge, in part because industries have begun to comply and have already footed the bill for any up-front compliance costs.

In short, the practical window for regulatory progress during President's Obama's first term will begin to close soon, probably around June of 2012. When that window closes, will the Administration have accomplished the reinvigoration of sensible safeguards that it set out to achieve?

A careful look at regulations now in the pipeline suggests reason for doubt. The GOP hue and cry over supposed economy-sinking regulation notwithstanding, the Obama Administration has not always displayed a sense of urgency about regulating. It has extended and missed deadlines. It has allowed regulations to be bottled up in the White House Office of Information and Regulatory Affairs (OIRA) for months at a stretch, where they have been subjected to extra rounds of industry lobbying, and eventual watering down.

President Obama must take urgent steps right now to end these self-imposed impediments. If, on January 20, 2013, a Republican president is sworn into office following a campaign season featuring the kind of regulation-bashing that has now become standard Republican fare, it is difficult to imagine that whatever regulations eventually emerge, if any, will be anywhere near as vigorous as those that are likely to emerge from the Obama Administration.

The practical window for regulatory progress during President Obama's first term will close soon, around June of 2012.

The 12 regulations highlighted in this report include:

Rule	Regulatory Benefits	In Danger / On Track
Boiler Hazardous Air Pollutants Rule (EPA)	Save up to 6,600 lives, avoid 4,000 heart attacks, and prevent more than 46,000 cases of aggravated asthma and bronchitis annually; prevent cancer, heart disease, impaired lung function, and IQ loss in children; stop widespread and possibly irreversible environmental damage	ON TRACK SO FAR.
Ozone and Particulate Matter National Ambient Air Quality Standards (EPA)	Prevent harm to respiratory and cardiovascular health; reductions in asthma attacks, impaired lung function, irregular heartbeat, stroke and premature death in people who have underlying heart or lung disease	ON TRACK SO FAR.
New Source Performance Standards to Reduce Greenhouse Gas Emissions from Petroleum Refineries and Power Plants (EPA)	Potentially massive reductions in greenhouse gas emissions; helping to avoid the worst consequences of climate change including increased temperatures, rising sea levels, increased extreme weather events, species extinction, and migration of tropical disease	NO ROOM TO SPARE for the New Source Performance Standards for power plants; EPA cannot afford any delay. The New Source Performance Standards for petroleum refineries is IN DANGER.
Corporate Average Fuel Economy (CAFE) standard for medium- and heavy-duty vehicles; CAFE standard for light duty vehicles, model years 2017-2025 (EPA and NHTSA)	Medium- and heavy-duty vehicles CAFE will reduce oil consumption by 21 billion gallons and GHG emissions by 250 million metric tons; leave Americans less vulnerable to unstable oil prices; spur U.S. automobile manufacturers to innovate	The CAFE standard for medium- and heavy-duty vehicles is ON TRACK SO FAR. The CAFE standard for light duty vehicles is IN DANGER.
Guidance on the Scope of the Clean Water Act (EPA)	Better protection for many wetlands and marginal waters; stronger and more enforcement actions to protect wetlands and marginal waters	IN DANGER, EPA will likely finish the guidance, but is unlikely to codify the guidance through the administrative rulemaking process.
National Stormwater Program Rule (EPA)	Prevent urban pollution runoff (e.g., motor oil, lawn fertilizer, and pet waste) from contributing to the deterioration of our nation's waters; protect aquatic vegetation and habitat	IN DANGER.
Mountaintop Removal Mining Rules (Guidance for Applying Clean Water Act Permits to Mining Operations, Stream Buffer Rule, and Renewal of Nationwide Dredge-and-Fill Permit for Mining Operations) (EPA, Interior OSMRE, and U.S. Army Corps of Engineers)	Protect mountain lands and streams against irreversible damage; protect habitat of many animal species, including several endangered species; safeguard drinking water supplies of Appalachian communities	The guidance for applying Clean Water Act permits to mining operations is IN DANGER; EPA will likely finish the guidance, but is unlikely to codify the guidance through the administrative rulemaking process. The stream buffer rule is IN DANGER. The renewal of nationwide dredge-and-fill permit for mining operations is ON TRACK SO FAR.

Rule	Regulatory Benefits	In Danger / On Track
Coal Ash Disposal Rule (EPA)	Protect communities threatened by catastrophic coal ash spills like the one in Kingston, Tennessee; prevent contamination of drinking water supplies	IN DANGER.
Injury and Illness Prevention Program (OSHA)	Prevent workplace injuries and illnesses; compel employers to find and fix all hazards in a workplace	IN DANGER.
Pattern of Violations Policy (MSHA)	Enable MSHA to use its enhanced enforcement authority to hold serial violators of health and safety standards more accountable; compel mines to greatly reduce their significant and substantial violations, reducing nonfatal injuries to miners by at least 150 every year	IN DANGER.
Infant Formula Good Manufacturing Practices Rule (FDA)	Ensure that infant formula meets nutritional needs of millions of babies; prevent health problems and impaired growth and development; prevent contamination of infant formula by <i>Salmonella enterica</i> and <i>Enterobacter sakazakii</i>	ON TRACK SO FAR.
Chemicals of Concern List (EPA)	Provide early warning to the public about the health and environmental problems of several phthalates, several polybrominated diphenyl ethers (PBDEs), and bisphenol A (BPA)	IN DANGER.

In short, for nine of these 12 most critical rules, the Administration is currently on a trajectory that makes it possible, even likely, that it will not complete work on the regulation by the end of the President’s first term. Such an outcome would be particularly distressing because it would not be the consequence of congressional interference or other political opposition, but a flat out failure of the Administration to get its work done in a timely manner – a straightforward unforced error with potentially huge consequences.

Whether the Administration completes its work will depend in great measure on how it handles several delaying factors. Among them:

- **Delays from OIRA.** In the case of three of these 12 rules (Chemicals of Concern List, Guidance on the Scope of the Clean Water Act, and Guidance for Applying Clean Water Act Permits to Mining Operations), OIRA is exceeding its mandate. In the case of the EPA Chemicals of Concern List, it is holding the proposed regulation longer than it is allowed to under the terms of the relevant Executive Order. In the case of the two EPA Clean Water Act guidance documents, OIRA is exceeding its mandate by claiming authority to review something it has no authority to review. In these instances, the agency would be within its authority to simply proceed without OIRA’s approval, although that outcome is unlikely given political considerations. Nevertheless, OIRA should either act or get out of the way.

- **Needlessly protracted deliberation by the agencies themselves.** It is important that agencies give due consideration to the rules they issue and that they allow for comment from the public and consideration of those comments. In the case of several rules (mountaintop removal, NAAQS, infant formula, and Injury and Illness Prevention Program (I2P2)), the agencies themselves are either behind schedule, or setting such leisurely schedules for completing various stages of the process that the entire regulation is in jeopardy. Some rules, such as infant formula and boiler hazardous air pollutants, have been in the works for more than a decade. Further delay at this point is completely unwarranted and impossible to justify. In other cases, agencies may be tempted to undertake unnecessary and time consuming administrative procedural steps, such as publishing an Advanced Notice of Proposed Rulemaking (ANPRM) or a Request for Information (RFI), as precautions designed to alleviate industry opposition later in the rulemaking process or to strengthen their litigation position in the inevitable legal challenges to come. These precautions will do little, if anything, to improve the quality of the rules, however. They are luxuries that the health and safety agencies simply cannot afford at this time.
- **Pressure from anti-regulatory interests.** Political pressure in the form of industry lobbying or congressional interference can slow down and even scuttle almost any rulemaking. Given the current political environment, the danger that regulators and their political appointee supervisors will buckle to such pressure is very real.

In the case of all 12 of these regulations, however, diligence and a sense of urgency on the part of the Administration will be the single most important factor in determining whether or not regulations are issued before the end of the President's first term. So far, that sense of urgency has been lacking in a number of conspicuous instances, and it has been particularly evident in the case of a number of OIRA-imposed delays on regulations.

The Administration has before it critical opportunities to do what the candidate Obama said he would do – reinvigorate the regulatory system so that it provides genuine protections for Americans' health and safety and for the environment. To make good on that commitment, the President and his White House staff must send an unmistakable message to the agencies that needless delays must be avoided, and that vital safeguards must be advanced promptly.

EPA Boiler MACT Rule

The Problem. Industrial and commercial boilers are among the largest sources of mercury, lead, cadmium, polycyclic organic matter (POM), and other toxic air pollutants, spewing thousands of tons of the stuff into the air every year, where it causes hundreds of deaths; imperils the health of millions of Americans by causing cancer, heart disease, impaired lung function, and IQ loss in children; and triggers widespread and often irreversible environmental damage. Boilers are essentially just miniature scale power plants, used to produce energy for large industrial and commercial facilities.

The 1990 Clean Air Act Amendments gave the Environmental Protection Agency (EPA) clear instructions to impose strong safeguards against toxic air pollution from these sources according to a strict timeline. By any reasonable estimate, the safeguards should have been in place by 2000. Tight budgets at the EPA and strong industry pressure, however, have prevented the agency from complying with this statutory command. In 2004, the George W. Bush EPA issued a weak rule, which environmental groups immediately challenged in court. And in 2007, a federal district court struck down the rule for being inconsistent with the Clean Air Act. After years of needless delay, the EPA must now develop new standards for controlling toxic air pollution from industrial and commercial boilers and incinerators. Until these new standards are put into place, both people and the environment will continue to lack adequate safeguards against these harmful pollutants.

The Regulatory Solution. In June of 2010, the EPA proposed new rules for limiting toxic air pollution from industrial and commercial boilers and incinerators to replace the one that had been struck down in 2007. (One rule proposes standards for boilers that are “area sources,” or small boilers, and the other proposes standards for boilers that are “major sources,” or large boilers; the Bush era rule addressed both types of boilers together.) Together, the proposals are commonly referred to as the Boiler MACT rule, because they establish very stringent emission standards for industrial and commercial boilers that are based on maximum achievable control technology (MACT).¹ After the rules were proposed, industry groups and their anti-regulatory allies in Congress immediately began attacking them, particularly the Boiler MACT rule for major sources, claiming their regulatory costs were too high. In response to this pressure, the EPA sought to significantly revise the rules in order to weaken them. The agency sought an extension of the tight judicial deadline it was under for completing these rules, but the federal district court denied its request. Accordingly, when the deadline came in February of 2011, the EPA issued a final Boiler MACT rule that was significantly different from the proposed version.² Some of the changes that the EPA made to the proposed rule relied on “sub-categorization,” which enabled the agency to set different emission limits for different kinds of large boilers and to eliminate pollution limits for certain small boilers altogether. Despite these changes, the final Boiler MACT still produces massive regulatory benefits, including saving up to 6,600 lives, avoiding 4,000 heart attacks, and preventing more than 46,000 cases of aggravated asthma and bronchitis every year.³

The final Boiler MACT rule would save up to 6,600 lives, avoid 4,000 heart attacks, and prevent more than 46,000 cases of aggravated asthma and bronchitis annually.

Current Status of the Regulatory Solution. Even though the EPA has issued a final rule, the journey for the Boiler MACT rule is far from over. Citing the huge substantive changes between the proposed and final versions of the Boiler MACT rule, the EPA has said it will begin a formal reconsideration process, provided for in the Clean Air Act, which will entail another public comment period.⁴ The reconsideration process would allow the EPA to stay the effective date of the Boiler MACT, May 20, 2011, for an additional three months. That means a truly final version of the Boiler MACT may not be completed until as late as August of 2011.

Required Action. Industry will likely use the reconsideration period as another opportunity to continue attacking the Boiler MACT rule, urging EPA to weaken it even more. Not only must the EPA resist these efforts, it should also explore other opportunities for strengthening the rule so that it better safeguards people and the environment from the harmful effects of toxic air pollution released by industrial and commercial boilers.

EPA Ozone and Particulate Matter NAAQS

The Problem. In 2010 alone, the reductions in particulate matter and ozone mandated by the 1990 Clean Air Act amendments prevented 160,000 premature deaths and 13 million lost work days, according to a recent report by the Environmental Protection Agency (EPA). But, more work needs to be done. These pollutants are linked to a number of respiratory and cardiovascular health effects, including asthma, impaired lung function, irregular heartbeat, stroke, and premature death in people who have underlying heart or lung disease.



Photo was taken prior to installation of emission controls equipment for removal of sulfur dioxide and particulate matter. Source: U.S. National Park Service

The Clean Air Act categorizes particle matter and ozone as criteria air pollutants, and thus requires the EPA to set uniform national ambient air quality standards (NAAQSs) for them at levels that are protective of public health with “an adequate margin of safety.” The Clean Air Act further requires the agency to review existing standards every five years, and to revise them as necessary, ensuring that these goals are still being met. During the George W. Bush administration, the EPA’s Clean Air Science Advisory Committee (CASAC), the agency’s top science adviser on clean air issues, advised the agency that it was necessary to strengthen both standards. EPA disregarded this advice on both occasions, and instead issued standards that were weaker than what CASAC had recommended. Environmental groups challenged the particulate matter standard issued in 2006, and a federal district court agreed that the agency had failed to explain how the less stringent standards would adequately protect public health. Similarly, the ozone standard was so bad that soon after it was issued in 2008, CASAC took the unusual step of publicly criticizing the EPA for ignoring its advice.

The Obama administration, which began before the ozone standard could take effect, delayed its implementation, and in September of 2010, the EPA began a formal reconsideration process to revise the ozone standard.

The Regulatory Solution. The EPA is reviewing the NAAQS for particulate matter, but it has not made any public announcement about whether it will revise the current standard. At a minimum, EPA should strengthen the current annual standard for fine particulate matter (*i.e.*, particulate matter with an aerodynamic diameter less than or equal to 2.5 micrometers) in accordance with CASAC's recommendation. Also, as CASAC recommended, the EPA should strengthen the existing standard for protecting the environment—known as a secondary NAAQS—for fine particulate matter. The EPA should also strengthen other elements of the NAAQS for particulate matter—especially the 24-hour standard for coarse particulate matter (*i.e.*, particulate matter with a diameter less than or equal to 10 micrometers)—if the best available science indicates that further reductions are needed to protect public health.

In January of 2010, the EPA proposed to revise the NAAQS for ozone. EPA has proposed to lower the allowable 8-hour ozone NAAQS to between 60 and 70 parts per billion, down from 75 parts per billion, and would change the multi-year averaged, seasonally-adjusted limit to an annual seasonally-adjusted limit. These revisions are consistent with CASAC's current recommendations.

Current Status of the Regulatory Solution. The EPA is currently working toward a proposed rule for revising the NAAQS for particulate matter and had projected that it would issue a proposal in March of 2011,⁵ though this date has already passed. The comment period for the EPA's proposed rule for reconsidering the ozone NAAQS ended in March of 2010,⁶ and the agency is currently working toward a final rule. The EPA projects that it will issue a final rule in August of 2011.⁷

Required Action. The EPA has already missed its March of 2011 deadline for issuing a proposed rule to revise the particulate matter NAAQS. The agency must issue the proposal as soon as possible, since it currently projects that it will issue a final rule by November of 2011. While ambitious, this is exactly the kind of urgent pace that the EPA must maintain. On ozone, the EPA has already delayed issuing a final rule for revising the NAAQS once, but it can afford no more delays. The agency must complete the rule in August of 2011 as it has projected.

EPA New Source Performance Standards for Petroleum Refineries and Power Plants

The Problem. In addition to increased temperatures and rising sea levels, global climate change is likely to bring an increased number of droughts and heat waves, more intense hurricane events, accelerating rates of animal and plant species extinction, and the rapid migration of malaria and other vector-borne diseases to previously unaffected regions of the world. Without decisive action by the United States and the global community, global climate change will almost certainly harm every human society and ecosystem on the planet. And, decisive action must be taken immediately; greenhouse gases (GHGs) have long residence times in the atmosphere, so delays cannot be compensated for later. One critical step the United States must take is to reduce GHG emissions produced by fossil fueled power plants and petroleum refineries, which account for about 40 percent of our total emissions. A modest two percent reduction in emissions from these sectors would achieve the same amount of GHG reductions as would the existing or proposed fuel efficiency standards for light- and heavy-duty vehicles.

The Environmental Protection Agency (EPA) can regulate GHG emissions from stationary sources—which include power plants and refineries—using the Clean Air Act’s New Source Performance Standards (NSPS) program. With a strongly divided Congress, effective comprehensive climate legislation has no chance of passing for the foreseeable future. In the meantime, the EPA must move forward with an effective regulatory program for limiting our GHG pollution, including the establishment of well-designed and sufficiently stringent NSPSs for limiting GHG emissions from fossil fueled power plants and petroleum refineries.

The Regulatory Solution. In December of 2010, the EPA announced plans to issue an NSPS limiting GHG emissions from fossil fueled power plants by May of 2012 and an NSPS limiting GHG emissions from petroleum refineries by November of 2012, as part of a settlement agreement with several environmental groups and state and local governments.⁸ The agency has not yet issued any proposed rules, so the precise details of the NSPSs are not clear. The Clean Air Act requires the EPA to set NSPSs based on the best demonstrated technology for controlling emissions, and to review and revise existing NSPSs to account for advances in emissions control technology. The EPA has provided no information about its assessment of the potential emissions control technology, or whether it will consider controversial control technologies like carbon capture and sequestration. The EPA should consider efficiency and process improvements, particularly in the petroleum refining sector, to reduce the need for flaring. Unfortunately, the EPA has emphasized that it intends to develop NSPSs that are “flexible” and “cost effective.” Intense pressure from industry and its anti-regulatory allies in Congress may compel the agency to develop NSPSs that are weaker than what the law and best available science call for.

Fossil fueled power plants and petroleum refineries account for about 40 percent of U.S. greenhouse gas emissions. The EPA can regulate these sources under the Clean Air Act.

Current Status of the Regulatory Solution. The EPA is currently working toward developing proposed rules that would establish NSPSs limiting GHG emissions from fossil fueled power plants and petroleum refineries. Under the settlement agreement, the EPA must complete the proposal for the power plant NSPS by July of 2011, and the proposal for the petroleum refineries NSPS by December of 2011. As part of this process, the agency recently held five public listening sessions to gather input from major stakeholders including the industries, environmental groups, state and tribal groups, and coalitions.⁹

Required Action. Because the EPA is just beginning the rulemaking process, it still has much work to do, including issuing proposed rules, accepting public comment, and developing final rules. The settlement agreement establishes an adequately quick timeline for completing the power plant NSPS (May of 2012 deadline), and the EPA must adhere to it; the agency cannot afford any delays. The timeline for the petroleum refineries NSPS (November of 2012 deadline) is not quick enough, however. The EPA must adopt an even quicker pace for completing the petroleum refineries NSPS to prevent partisan politics from jettisoning this vital rule.

CAFE Standards

The Problem. The harmful effects of climate change are far reaching, including sea level rise, food shortages, more frequent and severe droughts, heat-waves and floods, increases in insect-borne diseases like malaria, and reduced biodiversity.¹⁰ Though the threat of catastrophic climate change looms ever larger, neither the United States nor the global community is making much progress toward significantly reducing carbon pollution. Transportation sources emitted 29 percent of all U.S. greenhouse gas (GHG) emissions in 2007 and have been the fastest-growing source of U.S. GHG emissions since 1990.

To have any hope of addressing the impending climate crisis, the United States must establish fuel economy and GHG emissions standards for vehicles that are well designed and sufficiently stringent. We have already started down this path, albeit meekly. The Environmental Protection Agency (EPA) and the National Highway Traffic Safety Administration (NHTSA) set fuel economy and GHG emissions standards for light-duty vehicles for model years 2012-2016 that are expected to reduce gasoline consumption by 61 billion gallons and GHG emissions by 655 million metric tons over the lifetime of new vehicles sold.¹¹ These standards lag behind those of China and should have been much stronger. Making our fuel economy and GHG emissions standards even stronger would leave Americans less vulnerable to unstable oil prices, and spur U.S. automobile manufacturers to develop and produce better fuel efficient and alternative fuel vehicles, so that they don't fall further behind their foreign competitors.

The Regulatory Solution. In November of 2010, the EPA and NHTSA jointly proposed the first ever fuel economy and GHG emissions standards for medium- and heavy-duty vehicles ("the Truck Rule"). The Truck Rule establishes different kinds of performance standards for three main classes of diesel engines based on types of usage. These standards would apply to newly-built vehicle engines for the 2014-2018 model years. The standards will reduce oil consumption by 21 billion gallons and GHG emissions by 250 million metric tons, and help to prevent the worst effects of climate change. However, the standards could be stronger. They fail to regulate trailers, which could capture substantial efficiency gains from improved aerodynamics. They also impose only modest efficiency standards on tractor-trailer engines, even though the National Academy of Sciences concluded that much larger gains would be technologically achievable.

In October of 2010, the EPA and NHTSA began work on their next set of fuel economy and GHG emissions standards for light duty vehicles, applicable to model years 2017-2025 ("the Car Rule"). The Notice of Intent to regulate presented a range of options, which focused on reducing GHG emissions between 3 and 6 percent per year to reach an average between 190 and 143 grams of carbon dioxide per mile for the entire light-duty vehicle fleet. Fuel economy standards would rise to between 47 and 62 miles per gallon (mpg).

Transportation sources account for around 29 percent of U.S. greenhouse gas emissions and have been the fastest-growing source of U.S. emissions since 1990.

Current Status of the Regulatory Solution. The EPA and NHTSA accepted comments on the proposed Truck Rule through January of 2011, and are working toward a draft final rule.

The EPA and NHTSA accepted comments on their Notice of Intent to issue the Car Rule through October of 2010, and, in December of 2010, they issued a supplemental Notice of Intent that provided an updated technical analysis of potential fuel economy and GHG standards.¹² The agencies are currently working toward a proposed Car Rule, which they expect to issue in September of 2011. To be effective, this proposed rule must at least aim to require the most stringent fuel economy and GHG emissions standards contemplated in the Notice of Intent. It must also seek to improve on the existing standards for vehicles in model years 2012-2016, by applying a full fuel cycle analysis to electric and hybrid electric vehicles to account for greenhouse gas emissions from electric power generation. Finally, when developing the Car Rule, the EPA must not adopt NHTSA's approach to standard setting, as it did for the 2012-2016 standards, since NHTSA operates under statutorily imposed economic constraints that do not apply to EPA's program under the Clean Air Act.

Required Action. The Administration has committed to issuing a final Truck Rule by July of 2011,¹³ which suggests that it is approaching this rulemaking with the proper amount of urgency. But, to meet this goal, the EPA and NHTSA must work quickly to finish the draft final rule so that it has plenty of time to get through centralized review at the Office of Information and Regulatory Affairs.

The EPA and NHTSA have committed to issuing a final Car Rule by July of 2012. This schedule is not quick enough, however. The EPA and NHTSA must commit to issuing the final Car Rule no later than June of 2012, which may require the agencies to issue the proposed rule earlier than September of 2011 and to employ an expedited notice-and-comment period.

EPA Guidance on the Scope of the Clean Water Act

The Problem. Wetlands are crucial for both humans and the environment, controlling flooding, filtering pollutants from water, and serving as important habitat and breeding grounds for aquatic species. Thanks to the Supreme Court’s muddled opinion *Rapanos v. U.S.*, the Clean Water Act now leaves many of these important waters and wetlands unprotected. That decision has thrown into confusion the scope of waters subject to jurisdiction under the Clean Water Act, and indeed handcuffed the EPA and the U.S. Army Corps of Engineers (USACE). This case involved determining whether a developer was required to obtain a Clean Water Act permit to fill wetlands that were connected, although distantly, to traditional navigable waters covered by the Act. Without a majority opinion, the Court established two tests to determine Clean Water Act jurisdiction: Justice Scalia interpreted the Act narrowly to cover only those wetlands with a continuous surface water connection to a navigable water, which excludes many wetlands and waterbodies; and Justice Kennedy established a broader “significant nexus” test that covers more wetlands, by including those that “significantly affect the chemical, physical, and biological integrity” of traditional waters covered by the Act. The divided opinion has left lower courts with no clear standard to apply, creating confusion over the jurisdiction of the EPA and the USACE in wetlands cases.

As a result of the *Rapanos* decision and subsequent guidance issued by the EPA under the George W. Bush Administration, a 2007 congressional oversight memorandum concluded that “[h]undreds of violations have not been pursued with enforcement actions and dozens of existing enforcement cases have become informal responses, have had civil penalties reduced, and have experienced significant delays.”¹⁴ In addition, EPA regional offices have complained that assessing waters on a case-by-case basis poses a significant drain on personnel and financial resources, resulting in reduced effectiveness of the Clean Water Act enforcement program. The EPA must act quickly to clarify the scope of the Clean Water Act, so that it can more effectively protect wetlands from irreversible damage that will harm the environment and humans alike.

The Regulatory Solution. The EPA is currently preparing to release guidance to further clarify its interpretation of Justice Kennedy’s “significant nexus” standard, which as noted above encompasses more waterbodies and is arguably more consistent with the Clean Water Act. According to a draft of the guidance, which has not been formally made public, the number of waters subject to Clean Water Act jurisdiction will increase significantly as compared to past guidance documents—a welcome development. Moreover, the draft guidance would shift the burden of proof in jurisdictional disputes from the government to the private sector, where it belongs. Unfortunately, the draft guidance fails to clarify

whether other more marginal waters, such as prairie potholes or vernal pools, fall within the Clean Water Act's protective jurisdiction. Because these waters play vital roles in different ecosystems, and thus arguably should be covered by the statute, the EPA should ensure that the final guidance explicitly includes them.

Despite a push by environmental groups and parties subject to regulation under the Clean Water Act for the EPA to formalize its interpretation of "waters of the United States" through administrative rulemaking, the EPA has not indicated that it will follow its guidance with a proposed rule. The EPA must codify its final guidance through the rulemaking process, so that future administrations that are hostile to the protection of wetlands and marginal waters cannot easily dispense of this important guidance.

Current Status of the Regulatory Solution. The EPA has completed a draft of the guidance clarifying the scope of the Clean Water Act, and sent it to the Office of Information of Regulatory Affairs (OIRA) for centralized review on December 20, 2010. OIRA has already hosted two meetings regarding this rule with several industry groups, including representatives of the agriculture, mining, land development, and oil industries.¹⁵ This review violates Executive Order 12866, which exempts guidance documents from the centralized review process. But if OIRA is going to conduct such a review, it must at least complete it no later than April 20, 2011, under the deadlines set forth in Executive Order 12866.

Required Action. The EPA must not allow its draft guidance clarifying the scope of the Clean Water Act to be indefinitely delayed by OIRA's centralized review. Executive Order 12866 authorizes agencies to publish a rule once the time limit for centralized review has expired, and the EPA should exercise this authority if necessary, so that it can finalize the guidance as soon as possible. As noted above, once the guidance has been finalized, the EPA must then work quickly to codify the document through the rulemaking process. The agency will need to develop and closely follow a highly expedited rulemaking timeline to ensure that the final rule is issued no later than the June of 2012.

EPA National Stormwater Program Rule

The Problem. Stormwater is a ubiquitous source of water pollution, channeling a highly polluted cocktail of motor oil, lawn fertilizer, pet waste, and other contaminants directly into lakes, rivers, and estuaries around the country. The stormwater runoff from urban areas, which constitute a mere 3 percent of the total landmass in the United States, is estimated to be the primary source of impairment of 13 percent of assessed rivers, 18 percent of assessed lakes, and 32 percent of assessed estuaries.¹⁶ As vegetation and topsoil are replaced by asphalt roads and parking lots, concrete buildings, and other impervious urban infrastructure, the local hydrology changes. Where the natural vegetation and soil once retained water that could then percolate into the water table or enter the atmosphere, that water now directly and rapidly flows across urban surfaces into waterways. Channeled stormwater arrives in episodic and forceful bursts that contain the pollutants found in urban areas and that erode aquatic vegetation and habitat.

Section 402(p) of the Clean Water Act requires the Environmental Protection Agency (EPA) to regulate stormwater from municipal separate storm sewer systems (MS4s), from industrial activity, and from certain construction sites. These discharges must be covered by National Pollutant Discharge Elimination System (NPDES) permits. Hundreds of thousands of sources require permits, putting a heavy burden on the EPA and state and local governments that develop, implement, and manage stormwater programs. In 2008, the National Research Council (NRC) issued a report¹⁷ that concluded that the EPA's existing national stormwater program for MS4s¹⁸ is inadequate. For example, the report found that "EPA's program has monitoring requirements that are so benign as to be of little use for the purposes of program compliance. Most dischargers have no measurable, enforceable permit requirements." Stormwater permits leave wide discretion to the regulated community, allowing it to set standards, develop control schemes, and self-monitor. As a result, the report called for "an entirely new permitting structure."¹⁹

The Regulatory Solution. In response to the NRC report, the EPA began the rulemaking process to strengthen the national stormwater program. In 2009, the EPA issued a request for public input on how stormwater should be regulated.²⁰ The EPA has not issued a proposal, so the details of the new stormwater regulation are not yet clear. At the very least, the EPA's proposed rule should:

- **Expand the areas subject to stormwater regulations.** Under the Clean Water Act, the EPA has "residual designation authority" to regulate additional areas. For example, the current Phase II MS4 regulations (*i.e.*, the stormwater regulations for smaller MS4s) only require regulation for the Census-designated urbanized area. Moving toward a watershed approach to regulation—letting hydrologic boundaries guide regulations rather than political boundaries—would result in more holistic regulations and better integrate the regulations with science.

- **Establish strict standards for controlling stormwater from new development and redevelopment.** For example, these standards could require projects to incorporate features to retain water on the property or to otherwise mimic natural systems.
- **Employ the use of volume and flow indicators.** The regulation should focus on flow and the volume of water discharged following storm events, rather than focusing on removing the chemical pollutants in stormwater.

Current Status of the Regulatory Solution. The EPA is working on developing a proposal for strengthening the national stormwater program rule.²¹ On December 28, 2009, the EPA issued a notice in the Federal Register to solicit input, and the public comment period ended on February 26, 2010. The agency is under a judicial timeline to issue a proposal by September of 2011.

Required Action. The EPA is still in the early stages of the rulemaking process, and must still issue a proposal and complete the notice-and-comment process before it can issue a final rule to strengthen the national stormwater program. The agency is potentially under too slow a timeline for completing these steps—the judicial timeline only requires that the EPA issue a final rule by December of 2012. If the EPA is to finish this rule by June of 2012, then it must quicken its pace, starting by committing to issuing a proposed rule by no later than June of 2011, followed by an expedited notice-and-comment period.

Mountaintop Removal Mining Regulations

The Problem. Since the 1960s, mountaintop removal mining has decimated perhaps more than a million acres of land (an area the size of Rhode Island) and buried more than 2,000 miles of streams and headwaters (more than the twice the length of the entire Ohio River), irretrievably destroying entire ecosystems, damaging the habitat of countless wildlife (including many endangered species), and contaminating drinking water supplies for millions of people. Most commonly practiced in the central Appalachian Mountains, the process begins with the removal of hundreds of acres worth of trees and plants from the targeted mountaintop. Next, using several high powered explosives, the mining company literally blows away the top of the denuded mountain—much like pulling the top off of a muffin—in order to expose a coal seam. Large earth moving machines called draglines push the spoil—that is, the exploded remains of the mountaintop—into nearby valleys and streams. Federal law requires mining companies to restore the damaged mountain to its original “contour,” but gaping loopholes ensure that this command is rarely ever heeded.



Source: Image by Flickr user nrdc_media, used under a Creative Commons license. Photo source for attribution: http://www.flickr.com/photos/nrdc_media/2964379829/.

While in office, the George W. Bush Administration took several steps to facilitate mountaintop removal mining, including weakening the stream buffer rule (a rule that limits the ability of mining companies from dumping spoil and other mining waste within 100 feet of streams). In addition, mountaintop removal mining is subject to two different Clean Water Act permitting requirements—National Pollution Discharge Elimination System

(NPDES) permits, issued by the states for discharges from mining operations, and Section 404 dredge-and-fill permits, issued by the U.S. Army Corps of Engineers (USACE) for valley fills—that historically have not been implemented strictly enough to minimize the environmental harms caused by mountaintop removal mining. The Obama Administration should treat mountaintop removal mining as the environmentally ravaging activity it is and regulate it accordingly by adopting stronger environmental safeguards as required under both the Surface Mining Control and Reclamation Act and the Clean Water Act..

The Regulatory Solution. In June of 2009, the Environmental Protection Agency (EPA), the Department of the Interior’s Office of Surface Mining Reclamation and Enforcement (OSMRE), and the USACE entered into a memorandum of understanding in which each of the agencies agreed to review their existing standards for mountaintop removal mining, and to strengthen them so that they are more consistent with existing law and better able to protect public health and the environment. Consistent with this memorandum, these agencies are taking the following coordinated actions:

- In April of 2010, the EPA issued an interim Clean Water Act guidance directing states to enforce applicable water quality standards in the NPDES permits they issue to mining companies for their surface mining operations. This guidance tells the states to translate the vague narrative standards they have been relying on into firm numeric limits, enforced through permit restrictions that are based on the most recent science about the harmful effects of mining pollution on aquatic life in Appalachian streams. The guidance also directs the USACE to consider water quality impacts independently when issuing section 404 permits. In the past, USACE has argued that it does not need to consider these impacts, since the NPDES permits (though woefully inadequate) are sufficient on their own for safeguarding water quality.
- In November of 2009, the OSMRE formally began work on a new stream buffer rule that would impose stricter limits on the circumstances under which companies engaged in surface coal mining—including mountaintop removal mining—may disturb areas within 100 feet of streams. The agency is considering various options for replacing the Bush rule. One option would restore an earlier version of the stream buffer rule, which prohibited the disturbance of land within 100 feet of covered streams unless the proposed activity would not harm water quality or violate any water quality standards.
- In February of 2011, the USACE proposed to modify or eliminate a key nationwide general permit—Nationwide Permit 21—governing Section 404 dredge-and-fill permits for surface coal mining operations including mountaintop removal mining, which expires in March of 2012. The USACE’s preferred option would be to reissue the permit, but to eliminate from its coverage mountaintop valley fills. Instead, the USACE would issue individual Section 404 permits for these activities, allowing the USACE and the EPA to apply more vigorous oversight to mountaintop removal projects.

Current Status of the Regulatory Solution. The EPA was supposed to issue the final Clean Water Act guidance for mountaintop mining operations on April 1, 2011. Instead, the agency has unnecessarily delayed the release of this document by submitting it for centralized review at the Office of Information and Regulatory Affairs (OIRA), even though OIRA has no authority under Executive Order 12866 to review guidance documents. The guidance could remain stuck at OIRA for at least several months.

The comment period on the OSMRE's Advanced Notice of Proposed Rulemaking for its stream buffer rule ended in December of 2009, and the agency is currently working toward a proposed draft of the rule, which had a projected release date of February of 2011.²²

The USACE is currently accepting public comment on its proposed changes to Nationwide Permit 21 through April of 2011.

Required Action. Since the EPA's Clean Water Act guidance for mountaintop mining operations is now stuck at OIRA for the indefinite future, it is unlikely that the agency will be able to finalize the document any time soon. Given the importance of this guidance, however, the agency should also codify this document through the standard rulemaking process. To ensure that a final rule is issued no later than June of 2012, the EPA must begin this process even before the guidance emerges from OIRA.

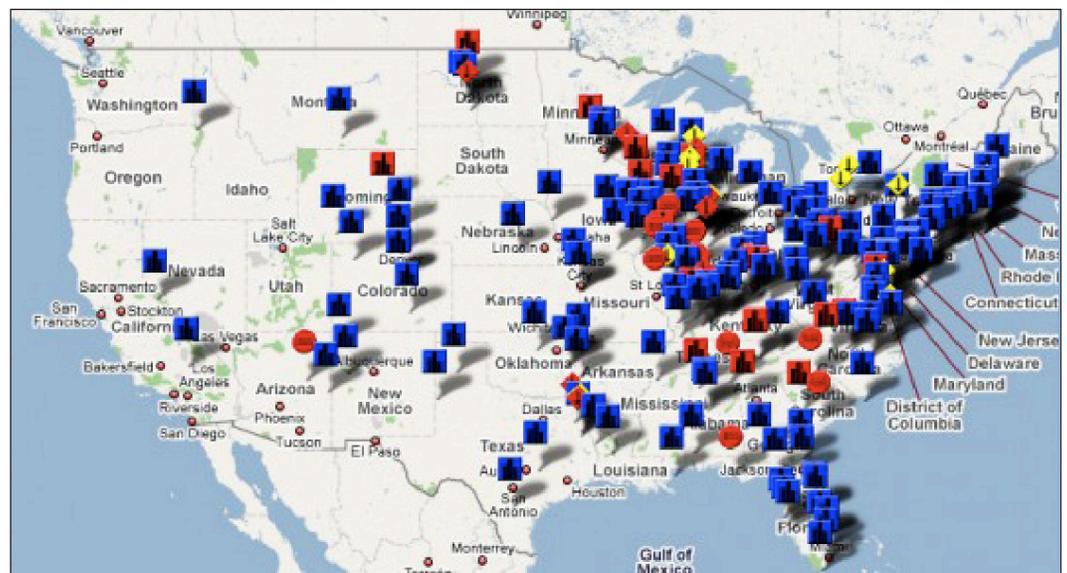
The OSMRE must release its proposed stream buffer rule as soon as possible, so that it is able to complete the notice-and-comment process and issue a final rule by no later than the June of 2012. At a minimum, this rule must prohibit activities that disturb lands within 100 feet of streams, unless it can be shown that such disturbance would not harm water quality or violate any water quality standards.

The USACE must work quickly to finalize its plans for whether and how it will replace Nationwide Permit 21 after the comment period ends. These plans ought to be at least as strong as the agency's preferred option of eliminating general permit coverage for mountaintop valley fills. The USACE expects to have a plan in place for how it will address Section 404 permits for surface coal operations before the current Nationwide Permit 21 expires in March of 2012. This would be an adequately quick timeline.

Annually, 94 million tons of coal is dumped into huge pits, many behind dams. The EPA has identified 50 of these pits as likely to cause loss of life if they failed.

EPA Coal Ash Rule

The Problem. U.S. coal-fired electric utility plants generate about 140 million tons of coal ash each year, over three times the total amount of industrial hazardous waste produced each year. Byproducts of burning coal include toxic metals such as arsenic, cadmium, lead, selenium, and mercury. Ironically, the installation of scrubbers to make sure these toxics do not go up the smokestack has meant they are concentrated in ash at dangerous levels. Some of this coal ash waste is recycled in products like concrete and wallboard. But about 70 percent—94 million tons per year—is dumped into colossal dump sites, including wet “surface impoundments” (a glorified term for man-made pits in the ground that hold coal ash mixed with water, often behind massive dams) and dry landfills. Of 629 surface impoundments nationwide, one-third were not designed by a professional engineer, and 96 impoundments are at least 40 feet tall and at least 25 years old. On December 22, 2008, a surface impoundment at a Tennessee Valley Authority (TVA) facility near Kingston, Tennessee burst, ultimately spilling 1.1 billion gallons of inky sludge across 300 acres of the town at depths of three feet—a spill larger in quantity than the Deepwater Horizon catastrophe in the Gulf of Mexico this past summer. The Environmental Protection Agency (EPA) has identified 50 “high-hazard” surface impoundments likely to cause loss of life if they failed. The Pennsylvania Department of Environmental Protection predicts that the failure of the Little Blue Run ash basin in Western Pennsylvania could kill 50,000 people. In addition to spill hazards, dump sites leak chronically, contaminating underground water supplies with toxic heavy metals. About 140 cases of such contamination have already been documented.



The various points in this map represent coal ash disposal sites throughout the United States. For more information on these sites, please visit the Center for Public Integrity’s website at <http://www.publicintegrity.org/articles/entry/1144/>. Source: Center for Public Integrity

The Regulatory Solution. Following the Kingston disaster, the EPA decided to resurrect its long stalled efforts to regulate the disposal of coal ash waste under the Resource Conservation and Recovery Act (RCRA). (For the last 25 years, the agency has taken up this effort in fits and starts.) In its original draft proposal, the EPA proposed treating coal ash as a “special waste” so that utilities would be required to build more secure landfills to contain such toxic byproducts. The landfills would be equipped with liners to prevent leakage, detection systems to alert operators if the liners are breached, and groundwater monitoring equipment. EPA would write these standards and the states would be compelled to enforce them. The standards would deal with the safety of *both* existing and new landfills. Electric utilities and coal ash recycling companies vehemently opposed this “Subtitle C” proposal (after the section of RCRA that authorizes it) and lobbied the White House so strenuously that the Office of Information and Regulatory Affairs (OIRA) forced the EPA to modify the rulemaking notice to include a far weaker “Subtitle D” proposal (based on a separate section of RCRA meant to address household garbage and other non-hazardous wastes). Under the weak option, states would be in charge of writing requirements, and might or might not do so. While 48 percent of coal ash is disposed of in states that require some degree of groundwater monitoring, only 12 percent is disposed of in states that require monitoring for both new *and* existing surface impoundments. The rest of the 48 percent (36 percent of the total) is disposed of in states that require monitoring only for new surface impoundments. No state imposes the full measure of protections that would be required by the strong option.

Current Status of the Regulatory Solution: In June of 2010, the EPA issued a Notice of Proposed Rulemaking that “co-proposed” the strong and weak options for regulating coal ash described above. The comment period for this proposed rule ended in November of 2010.²³ EPA Administrator Lisa Jackson has announced that the agency will not complete work on the rule until 2012, at the earliest.

Required Action. The EPA should issue a rule adopting the strong Subtitle C option no later than December of 2011. Meeting this quick deadline may be challenging, given the agency’s resource constraints and the large number of comments it received from very well-organized industry opponents. Nevertheless, these comments are largely repetitive, and promulgation of strong safeguards is urgent from an environmental and public health standpoint.

In the United States, 4,000 to 5,000 people die every year from workplace injuries.

OSHA Injury and Illness Prevention Program Rule

The Problem. In an average year in the United States, 4,000-5,000 people die at work. Tens of thousands more die from the long-term consequences of injuries or illnesses that began on the job. These deaths are preventable. So, too, are nurses' and doctors' aides' wrenched backs, and crab pickers' chemical rashes. Congress created the Occupational Safety and Health Administration (OSHA) 40 years ago to eliminate health and safety hazards in the workplace, but following early declines in occupational fatalities and injury and illness rates, the agency's headway toward Congress's goal has slowed. OSHA's focus on particular hazards, rather than the safety of a workplace as a whole, has ultimately limited its effectiveness.

The Occupational Safety and Health Act (OSH Act) requires that employers bear the responsibility of providing safe and healthy workplaces, with appropriate guidance and assistance from OSHA. But unscrupulous employers have slowly shifted their burden onto OSHA's shoulders by ignoring workplace hazards until an OSHA compliance officer points them out. OSHA and its state-plan partners only have the resources to inspect a tiny fraction of workplaces each year, and they are hampered by a limited set of health and safety standards. As a result, occupational fatality, injury, and illness rates are not declining as much as they were when OSHA first came into existence. OSHA can shift the burden back to where it belongs by providing employers with better guidance on the basic principles of health and safety management. The goal would be to have all employers create health and safety (H&S) management programs that are designed to find and fix all hazards in a workplace.

The Regulatory Solution. OSHA published voluntary guidelines on H&S management programs in 1989 and undertook a major effort to publish a mandatory rule in the mid- to late-1990s, only to abandon the rulemaking when finalizing the ill-fated ergonomics rule²⁴ took precedence. In 2009, OSHA began work again on a mandatory H&S management programs rule, which it now calls the Injury and Illness Prevention Program (I2P2) rule. Because OSHA has not issued a proposal, the details of what the I2P2 rule might include are still not clear. At a minimum, the rule should provide for all the core elements of a good H&S management program, which include:

- Giving workers a voice by establishing H&S committees;
- Identifying hazards;
- Fixing hazards;
- Education and training;
- Regular review of the program to ensure it's working; and
- Effective enforcement by OSHA.

Current Status of the Regulatory Solution. OSHA is presently working toward a proposed I2P2 rule. Unfortunately, OSHA faces several unique procedural hurdles before it can issue a proposed rule, which often serve only to delay the rulemaking process without actually enhancing the quality of the proposed rule. In particular, OSHA must conduct a small business panel review of the I2P2 rule, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA), which is set to begin in June of 2011.

Required Action. Having published notice of its intent to begin this rulemaking and held several stakeholder meetings, OSHA need not waste time with additional precautionary administrative procedural steps, such as publishing an Advanced Notice of Proposed Rulemaking (ANPRM) or a Request for Information (RFI). OSHA should set a short timeline for the statutorily mandated SBREFA review panel and strive to issue a proposed rule by the end of this year. Otherwise, the agency will have no chance of completing a final rule by the summer of 2012.

In 2009 alone, MSHA cited Massey Energy's Upper Big Branch Mine for 515 different safety violations, around 200 of which the agency deemed to be "significant and substantial."

MSHA Pattern of Violations Policy

The Problem. On April 5, 2010, a massive explosion ripped through Massey Energy's Upper Big Branch Mine in Raleigh County, West Virginia, killing 29 miners—the worst mining catastrophe in the United States in almost 40 years. Between 2005 and the time of the explosion, the Mining Safety and Health Administration (MSHA) had cited the Upper Big Branch Mine for 1,342 violations. In 2009 alone, the agency cited the mine for 515 different safety violations, around 200 of which MSHA deemed to be “significant and substantial,” or violations that could reasonably be expected to lead to a serious injury or illness.

The “pattern of violations” provision of the Federal Mine Safety and Health Act of 1977 provides MSHA with enhanced enforcement authority to address scofflaw mines like the Upper Big Branch. Once MSHA has issued to a mine “a pattern of violations notification,” then the agency can order the mine to withdraw workers from any part of the mining operation that it subsequently finds to have a significant and substantial violation. The workers may not return to work in that part of the mine until the violation has been corrected. Unfortunately, however, the existing regulations for implementing the pattern of violations provision, issued in 1990, establish overly complex criteria for identifying mines to which pattern of violations notifications should be issued. Mines can avoid a pattern of violations status simply by appealing their violations, since the regulations exempt violations under appeal from being considered in a pattern of violations determination. (While nearly all mining companies employ this tactic, Massey Energy has been the most aggressive, appealing 34 percent of their safety violations, as compared to the national average of 27 percent.) These regulations have been so ineffective that the agency has never been able to put a single mine under a pattern of violations status. MSHA must revise these regulations so it can use its enhanced enforcement authority to hold serial violators of health and safety standards more accountable as the law intended.

The Regulatory Solution. In February of 2011, MSHA proposed revisions to its pattern of violations regulations to simplify the criteria used for identifying those mines that repeatedly fail to maintain healthy and safe working conditions for their workers. The proposed rule would require the agency to post online the specific criteria (*e.g.*, the number of significant and substantial violations that a mine has collected in the previous year) it uses for making a pattern of violations determination. This process would still provide mines with notice to allow them to improve their health and safety records quickly, without having to resort to the complicated and often inconsistent two-step process that is mandated by the current pattern of violations regulations. (Under this existing process, before MSHA can place a mine under a pattern of violations status, it must first issue to that mine a “potential pattern of violations notification” indicating that it has a troubling history of health and safety violations, and then provide the mine with an opportunity to reduce its violations rate.) Critically, the proposed rule would also explicitly allow MSHA to consider all of

the violations for which a mine has been cited, including those still under appeal. MSHA predicts that implementation of this rule will compel mines to greatly reduce their significant and substantial violations, preventing at least 150 nonfatal injuries to miners every year.

Current Status of the Regulatory Solution. MSHA issued its proposed pattern of violations rule in February of 2011, and is accepting comment on the rule until April of 2011. The agency appears to be running a little behind schedule on the rule, since MSHA projected in its fall 2011 Regulatory Agenda that it would issue the propose rule in January of 2011.²⁵

Regulatory Action. MSHA has not yet specified a deadline for issuing a final rule. Once the comment period has ended, the agency must work quickly to develop a draft final rule, so that it has enough time to get the rule through centralized review at the Office of Information and Regulatory Affairs and publish it in the *Federal Register* before June of 2012.

FDA Infant Formula Good Manufacturing Practices Rule

The Problem. In the United States, infant formula provides a critical source of nutrition for millions of babies, with infant formula playing a role in the diet of nearly 90 percent of all babies under 6 months of age. The nutritional needs of infants are complex but essential. During the first year of life, a baby must consume an adequate amount of several nutrients to support proper physical and mental development. The absence or an inadequate amount of these nutrients can result in immediate health problems and impair long-term growth and development. To ensure that babies receive the proper amount and mixture of these nutrients, manufacturers generally try to produce infant formula that approximates the composition of breast milk. In the past, however, some manufacturers have reformulated their products in ways that eliminated some of these key nutrients, causing outbreaks of illness in babies. A baby's fragile physiology also leaves it extremely vulnerable to potential allergens or contaminants that might be found in infant formula. Powdered infant formula is especially susceptible to contamination by *Salmonella enterica* and *Enterobacter sakazakii*, two microorganisms that can cause infection and severe illness, such as meningitis and enteritis (inflammation of the small intestine). For many babies, particularly those that are pre-term or that have compromised immune systems, these diseases can be fatal, while those that survive may be afflicted with long-term physical or neurological disorders.

In 1986, Congress adopted legislation directing the Food and Drug Administration (FDA) to tighten up its existing safeguards for the formulation and manufacture of infant formula. A generation later, the FDA still has not issued all of the rules needed to implement Congress' clear requirements. The reason for this delay is not clear, but the implementation of proper safeguards will help to better ensure that babies in the United States receive proper nutrition and are properly protected against harmful contaminants in their infant formula.

The Regulatory Solution. In 1996, the FDA proposed a rule that would establish updated current good manufacturing practices (CGMP) and quality control procedures for the production of infant formula. The CGMP defines various production processes and procedures for ensuring that infant formula contains the appropriate amounts of all of the required nutrients and is free of any harmful contaminants. The quality control procedures define the required testing procedures that manufacturers must use to ensure that their products contain all of the required nutrients at appropriate levels and are contaminant-free from the moment they leave factory until they are ultimately consumed. The 1996 rule also establishes "quality factors"—that is, requirements designed to ensure that the nutrients contained in infant formula are present in a useable form. In addition, the rule establishes the procedures that a manufacturer must follow in order to notify the FDA of a new infant formula or any changes to an existing infant formula. Finally, the rule updates the reporting and recordkeeping requirements that manufacturers of infant formulas must follow.

Current Status of the Regulatory Solution. The FDA appears to be working toward a final version of its Infant Formula rule.²⁶ Since being issued in July of 1996, the proposed version of the rule has gone through no less than three separate notice-and-comment periods, with the most recent one ending in September of 2006. According to the FDA's fall 2010 regulatory agenda, the agency expects to issue a final rule by June of 2011—almost five years after the last notice-and-comment period ended.

Required Action. The FDA must issue the final Infant Formula as soon as possible. The agency has had more than enough time (5 years) to consider and address all of the comments it has received.

The EPA regulates a few hundred chemicals when they are emitted to the air or water, or when they are dumped in industrial waste sites, but thousands of others are largely unregulated.

EPA TSCA Section 5(b)(4) Chemicals of Concern List

The Problem. Industrial chemicals pervade our lives. Estimates vary, but it is safe to say at least 40,000 unique chemicals exist, and many of those create risks to human health and the environment. The EPA regulates a few hundred chemicals when they are emitted to the air or water, or when they are dumped in industrial waste sites, but thousands of others are largely unregulated. Flame retardants in furniture, chemicals that keep our clothing wrinkle-free, the mystery formulations that scrub the grime off of our floors and countertops—most of our modern conveniences come from chemicals that the EPA has the power to regulate through the Toxic Substances Control Act (TSCA). Thanks to programs like the European Union’s REACH regulation and the EPA’s ToxCast program, we are learning a lot about industrial chemicals’ potential adverse health and environmental effects. Because of various shortcomings in TSCA, however, the EPA has little ability to limit or place restrictions on chemicals that are discovered to be harmful.

Nonetheless, Congress did include a provision in TSCA that at least allows the EPA to warn the public about the dangers posed by toxic chemicals. Section 5(b)(4) of TSCA gives the EPA the authority to publish a list of chemicals that the agency has determined “may present an unreasonable risk of injury to health or the environment,” based on “all relevant factors” including hazard and exposure data specific to both humans and the environment. In essence, the Section 5(b)(4) list (also known as a “Chemicals of Concern list”) is a way for the EPA to communicate a precautionary warning to consumers, retailers, and product manufacturers.

The Regulatory Solution. The EPA has drafted a proposed rule that would add a category of eight phthalates, a category of polybrominated diphenyl ethers (PBDEs), and bisphenol A (BPA) to the TSCA Chemicals of Concern list.²⁷ Critically, the EPA did not pick the chemicals on a whim. Instead, in accordance with TSCA, the agency first undertook a formalized risk assessment. This proposed rule is a key component to the chemical action plans that the EPA has developed for each of these chemicals, which seek to evaluate the chemicals and determine an appropriate course of action for managing the risks. Once finalized, these new entries to the TSCA Chemicals of Concern list will help to provide early warning to the public about the health and environmental problems these chemicals may cause, and give notice to manufacturers that additional regulation of these chemicals may be on the horizon.

Current Status of the Regulatory Solution. The EPA completed a draft proposed rule for the Chemicals of Concern list and sent it to the Office of Information and Regulatory Affairs (OIRA) on May 21, 2010, for centralized review. The draft proposed rule has been stuck there ever since, well beyond the maximum time limit that Executive Order 12866 places on centralized review. It is not clear when this review will be completed.

Required Action. The EPA must not allow OIRA's centralized review to delay publication of the proposed rule for the Chemicals of Concern list any longer. Executive Order 12866 authorizes agencies to publish a proposed rule once the time limit for centralized review has expired, as it has in this case. The EPA should exercise this authority so that it can begin working toward completing a final rule as soon as possible.

Endnotes

- ¹ At the same time, the EPA also proposed two other closely related rules. The first establishes standards for limiting toxic air pollution from industrial and commercial incinerators, which large industrial and commercial facilities use to dispose of solid waste, and the second proposes a new definition for nonhazardous solid waste under the Resource Conservation and Recovery Act (RCRA), which the EPA will use to determine whether a particular facility is a boiler or an incinerator, and thus what Clean Air Act standard to apply.
- ² At this time, the EPA also issued the final rules establishing emission standards for industrial and commercial incinerators and the regulatory definition of nonhazardous solid waste. In addition, the agency also released another closely related final rule, which establishes emission standards for sewage sludge incinerators. Press Release, Env'tl. Protection Agency, EPA Establishes Clean Air Act Standards for Boilers and Incinerators (Feb. 23, 2011), <http://yosemite.epa.gov/opa/admpress.nsf/1e5ab1124055f3b28525781f0042ed40/06ddf3abfb133d585257840005e6406!OpenDocument> (last visited Mar. 28, 2011).
- ³ These numbers include the total regulatory benefits of the final Boiler MACT rule and the three other final rules that the EPA issued along with the final Boiler MACT rule.
- ⁴ National Emission Standards for Hazardous Air Pollutants; Notice of Reconsideration, 76 Fed. Reg. 15266 (Mar. 21, 2011) (to be codified at 40 CFR pts. 60 and 63), available at <http://www.epa.gov/ttn/atw/boiler/fr21mr11p.pdf>.
- ⁵ Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: Review of the National Ambient Air Quality Standards for Particulate Matter*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2060-AO47> (last visited Mar. 28, 2011).
- ⁶ Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: Reconsideration of the 2008 Ozone Primary and Secondary National Ambient Air Quality Standards*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2060-AP98> (last visited Mar. 28, 2011).
- ⁷ Env'tl. Protection Agency, *Rulemaking Gateway: Reconsideration of the 2008 Ozone Primary and Secondary National Ambient Air Quality Standards*, <http://yosemite.epa.gov/opei/RuleGate.nsf/byRIN/2060-AP98> (last visited Mar. 28, 2011).
- ⁸ Press Release, Env'tl. Protection Agency, EPA to Set Modest Pace for Greenhouse Gas Standards (Dec. 23, 2011), <http://yosemite.epa.gov/opa/admpress.nsf/6424ac1caa800aab85257359003f5337/d2f038e9daed78de8525780200568bec!OpenDocument> (last visited Mar. 28, 2011).
- ⁹ Env'tl. Protection Agency, *Air Quality Planning & Standards: Listening Sessions on Greenhouse Gas Standards for Fossil Fuel Fired Power Plants and Petroleum Refineries*, <http://www.epa.gov/airquality/listen.html> (last visited Mar. 28, 2011).
- ¹⁰ INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, CLIMATE CHANGE 2007: SYNTHESIS REPORT 3.3.1 (2007), available at http://www.ipcc.ch/publications_and_data/ar4/syr/en/spms3.html.
- ¹¹ Nat'l Highway Traffic Safety Admin., *Fact Sheet: NHTSA and EPA Establish New National Program to Improve Fuel Economy and Reduce Greenhouse Gas Emissions for Passenger Cars and Light Trucks* (2010), available at http://www.nhtsa.gov/staticfiles/rulemaking/pdf/cafe/CAFE-GHG_Fact_Sheet.pdf.
- ¹² Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: Passenger Car and Light Truck Corporate Average Fuel Economy Standards MYs 2017 and Beyond*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2127-AK79> (last visited Mar. 28, 2011).
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- ¹⁴ Memorandum from the Majority Staffs of the Committee on Oversight and Government Reform and Committee on Transportation and Infrastructure to Rep. Henry A. Waxman, regarding The Decline of the Clean Water Act Enforcement Program (Dec. 16, 2008).
- ¹⁵ Office of Mgmt. & Budget, Exec. Office of the President, *Meeting Record: Meeting Record Regarding: Waters of the US Guidance; Date: 1 / 11 / 2011*, http://www.whitehouse.gov/omb/2040_meeting_01112011 (last visited Mar. 28, 2011); Office of Mgmt. & Budget, Exec. Office of the President, *Meeting Record: Meeting Record Regarding: CWA Guidance; Date: 3 / 1 / 2011*, http://www.whitehouse.gov/omb/2040_meeting_03012011 (last visited Mar. 28, 2011).
- ¹⁶ NAT'L ACADEMIES, REPORT IN BRIEF: URBAN STORMWATER MANAGEMENT IN THE UNITED STATES (2008), available at http://www.nctog.dst.tx.us/envir/SEEClean/stormwater/nrc_stormwaterreport_fs.pdf.
- ¹⁷ *Id.*

- ¹⁸ The EPA's regulation of stormwater from MS4s occurred in two phases, depending on the size of the municipality. Passed in 1990, the Phase I regulations required large MS4s to develop a stormwater management program (SWMP), oversee industrial facilities, conduct monitoring, and submit periodic reports. A decade later, the Phase II regulations went into effect for smaller MS4s, which require a SWMP that includes six minimum control measures: public education and outreach, public participation and involvement, illicit discharge detection and elimination, construction site runoff control, post construction runoff control, and pollution prevention and good housekeeping.
- ¹⁹ NAT'L RESEARCH COUNCIL, URBAN STORMWATER MANAGEMENT IN THE UNITED STATES (2008), available at http://www.epa.gov/npdes/pubs/nrc_stormwaterreport.pdf.
- ²⁰ Specifically, the request for public input highlighted the following issues that the EPA would be considering in the new rulemaking: (1) expanding the area subject to stormwater regulations; (2) establishing specific requirements to control stormwater discharges from new development and redevelopment; (3) developing a single set of consistent requirements for Phase I and Phase II MS4s; (4) requiring MS4s to address stormwater discharges in areas with existing development; and (5) including any additional changes to the stormwater regulations.
- ²¹ Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: Stormwater Regulations Revision To Address Discharges From Developed Sites*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2040-AF13> (last visited Mar. 28, 2011).
- ²² Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: Stream Protection Rule*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=1029-AC63> (last visited Mar. 28, 2011).
- ²³ Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: Standards for the Management of Coal Combustion Residuals Generated by Commercial Electric Power Producers*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2050-AE81> (last visited Mar. 28, 2011).
- ²⁴ This rule was designed to safeguard workers against musculoskeletal injuries that can arise as result of the stress of making repetitive motions. The rule was finalized during the last days of the Clinton Administration, but was struck down under the Congressional Review Act soon thereafter following the election of George W. Bush.
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- ²⁷ Office of Info. & Reg. Affairs, Office of Mgmt. & Budget, Exec. Office of the President, *Reginfo.gov: TSCA Chemicals of Concern List Under Section 5(b)(4) of the Toxic Substances Control Act*, <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2070-AJ70> (last visited Mar. 28, 2011).

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