

4 MODERNIZING CHEMICAL REGULATIONS AND OTHER CRITICAL REGULATORY ISSUES

Multiple Contributors¹

This chapter examines the Environmental Protection Agency (EPA) regulations that implement several environmental statutes:

- ▶ The Toxic Substances Control Act (TSCA), which regulates the production, importation, use, and disposal of new and existing chemicals.
- ▶ The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which governs pesticide distribution, use, sales, and labeling.
- ▶ The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly known as Superfund, which regulates the cleanup of sites contaminated by releases of hazardous substances; and
- ▶ The Resource Conservation and Recovery Act (RCRA), which regulates the generation, transportation, treatment, storage, and disposal of hazardous and solid waste.

It also discusses a controversial program that has a cross-cutting effect on EPA regulations: the Integrated Risk Information System (IRIS), a program that identifies and characterizes the health hazards of chemicals in the environment.

An entire chapter (or book) could be written on each of those programs. For reasons of space, and because all the programs address health risks associated with chemicals in the environment, we examine them here in a single chapter.

The chapter begins, however, with two methodological orientations that foster regulatory activism in all EPA regulatory programs including the five covered in this chapter. Those orientations are the precautionary principle, which counsels policymakers to err on the side of caution, and the linear no-threshold model, which assumes hazardous substances can pose serious health risks at any level of exposure above zero.

There are some common themes that run throughout the seven key issues that follow, from the need to properly assess risk and utilize sound science, to recognizing the importance of costs and tradeoffs when promulgating regulations. The EPA has long been characterized by unreasonable risk assumptions and counterproductive rules in areas such as pesticides and hazardous waste, but modernized regulations would avoid such problems. The regulations would effectively protect the health and welfare of Americans without hindering the innovation that improve the lives of Americans.

KEY ISSUE

Require the EPA to abandon the precautionary principle

The precautionary principle is a regulatory strategy designed to minimize potential harms to human health and the environment when scientific uncertainty exists.² The principle operates on the assumption that it is better to overestimate risk and err on the side of caution rather than wait for scientific certainty before implementing regulations. The precautionary principle sounds reasonable at first blush, as it conforms with a “better safe than sorry” approach to risk management. However, adhering to the precautionary principle often leads to overly stringent regulations that impose significant economic costs for few if any corresponding benefits. Moreover, the precautionary principle is tailor-made for expanding bureaucracy and regulatory agency power without any scientific basis.

The EPA employs a number of conservative assumptions in its risk assessments that are grounded in precautionary principle logic. These assumptions lead to overestimation of risk, resulting in tougher-than-necessary regulatory standards.

One conservative assumption employed in EPA risk assessments is the concept of the maximally exposed individual (MEI).³ This approach estimates exposures by assuming a hypothetical person who experiences the highest possible exposure to a pollutant or toxin. For instance, in air quality regulations, the EPA might model exposure based on someone who lives and works at the point of maximum pollution concentration and assumes that this individual spends his entire life in that environment. Or the agency might assume a person eats locally grown food that has absorbed the highest level of contamination in an area, or drinks contaminated water directly from a nearby stream, ignoring the availability of clean water sources or bottled water. The MEI typically does not account for factors such as time spent indoors or away from polluted areas, nor does it consider mitigating actions, such as using water filters or switching to cleaner sources of food or water.

Relatedly, the EPA often introduces conservatism in its risk assessments by assuming 95th percentile exposure levels. For example, in estimating dietary exposure to pesticides, the EPA may

assume an upper bound on pesticide residues left on food.⁴ This can make sense when the agency is calculating a range of uncertainty, with upper and lower bounds. It can also make sense when setting a standard if a statute requires a particular margin of safety. But using upper bounds is inappropriate in other instances, such as when attempting to characterize risks objectively or when incorporating risk estimates into a benefit-cost analysis, where the use of upper bounds will tend to exaggerate regulatory benefits.

The linear no-threshold (LNT) dose-response model is another source of conservatism built into EPA risk assessments. This model assumes that any level of exposure to a hazard carries some risk of harm, with no threshold below which exposure is free of risk. However, in cases where there is a threshold exposure level below which risk is undetectable, the LNT model can overestimate the risk of harm. A detailed discussion on LNT is included elsewhere in this chapter.

The EPA also commonly employs safety factors in its risk assessments to account for uncertainties in data, such as when translating findings from animal studies to potential human health risks or from adults to children. These safety factors are often applied in increments of 10, leading to cumulative reductions in allowable exposure levels by orders of magnitude. For example, a 10-fold factor may be applied to account for differences between animals and humans, another for variability among human populations, and further factors if there is uncertainty in the data or incomplete studies.⁵

While these safety factors are intended to provide an extra margin of safety,⁶ they frequently result in exposure limits that are far more conservative than necessary, often by factors of 100 to 3,000 times.⁷ This overly precautionary approach contributes to a culture of fear surrounding any hazard (chemical or radiological), and leads to unnecessarily stringent regulations, thereby preventing the beneficial uses of substances where the actual risk to human health is minimal or negligible. Overly conservative safety factors also push industries toward substitutes that have not been as thoroughly evaluated, potentially posing greater risks to public health or the environment.

Each of these risk assessment practices is consistent with the precautionary principle. In each case, assumptions shape risk

assessments to reflect worst-case scenarios rather than typical human conditions. These conservative strategies are not harmless, as they can introduce additional countervailing risks in the following ways:

Diverting resources from other public health priorities

Billions of dollars are spent on radiation and other cleanup efforts to meet strict regulatory standards, even when the health benefits are undetectable. These are funds that could be better used for more cost-effective health interventions, such as breast cancer screening programs, which have the potential to save thousands of lives.⁸ By diverting limited public and private resources toward activities with little measurable benefit, the opportunity to fund health strategies that can achieve tangible, life-saving outcomes is lost, leading to a net harm to public health. This inefficient allocation of resources ultimately reduces society's ability to address the most pressing health needs and diminishes overall public welfare.

Ignoring substitutes

A problem with conservative risk assessments is that they often fail to account for the risks posed by substitute products or activities. For instance, the EPA's regulation of phthalates,⁹ a group of chemicals used to make plastics more flexible, is grounded in concerns over potential health risks, such as reproductive toxicity, based on high-dose animal studies.¹⁰ However, the risks posed by phthalates to humans, particularly at typical exposure levels, remain highly uncertain.¹¹ Stringent regulations on phthalates can lead to the adoption of substitute chemicals that may not be as thoroughly studied or could pose greater risks. Another common chemical found in plastics is bisphenol A (BPA), which has raised concerns about endocrine disruption. Yet the science surrounding these concerns is hotly debated,¹² and common substitutes for BPA have also raised concerns.¹³

Ignoring beneficial effects

Another problem with the EPA's conservative approach is its failure to consider hormetic effects or other ancillary health benefits stemming from exposure to certain agents. The EPA's long-standing debate

with the FDA over methylmercury in fish is one example. While the EPA has focused on the risks posed by mercury, the Food and Drug Administration (FDA) has emphasized the health benefits of consuming fish, particularly for pregnant women.¹⁴ The EPA's work has likely discouraged fish consumption by those who stand to see significant health benefits from it. This debate highlights the potential for overly cautious regulations to increase rather than decrease risk.

Raising costs for consumers

The economic costs associated with conservative risk assessments translate into higher prices for goods and services. These higher prices reduce disposable income, limiting consumers' ability to mitigate risks privately.¹⁵ For example, stringent regulations on chemicals or pesticides increase the cost of food production, driving up prices for consumers.¹⁶ This, in turn, reduces consumers' ability to allocate their own resources toward health-protective measures, such as safer housing or healthcare.

Finally, the EPA's conservative estimates of risk feed into benefit-cost analysis,¹⁷ and inflated risk estimates will lead to inflated estimates of the benefits of regulations. This can distort the analysis, making it appear that the benefits of regulation outweigh the costs, when the actual benefits may be much lower than estimated. In some cases, such as with a safety analysis that estimates a reference value¹⁸ or identifies a no observed adverse effect level, the outputs of risk assessment are incompatible with benefit-cost analysis.¹⁹

Recommendations for Congress

Review and revise environmental statutes to avoid precautionary logic. Congress should engage in a comprehensive review of environmental statutes and reform language that is based on precautionary principle rationales. The review should focus on ensuring that any identified potential harms are accurately characterized (in the sense that the EPA reports the expected level of risk) and that regulatory standards are not set so low that their benefits cannot be measured. Additionally, Congress should require that EPA

provide data used to estimate risks and should clarify that finding evidence of harm can inform the decision to regulate but should not automatically trigger regulation. This approach will allow the separation of scientific assessments of harm from the policy decision of whether promulgating a rule is reasonable, thus ensuring a more balanced and rational regulatory process.

Require comprehensive and transparent presentation of risk data.

Congress should codify in statute principles for risk analysis developed by the Office of Management and Budget.²⁰ This includes requirements to clearly identify the relevant populations associated with risk estimates, the expected central risk estimates, upper- and lower-bound estimates of risk, and any significant uncertainties associated with the data. The EPA should be required to report risk estimates that are consistent with and can be incorporated into a benefit-cost analysis.

Require consideration of substitutes. Congress should require the EPA to assess the risks posed by substitute products before setting regulatory standards on chemicals, pesticides, and similar products. This would help prevent unintended consequences from bans or restrictions and ensure that regulations promote overall public health.

These reforms would help ensure that the EPA's risk assessments are scientifically grounded, consistent with benefit-cost analysis, and reflective of actual public health risks rather than precautionary assumptions.

KEY ISSUE

Limit the EPA's use of the linear no-threshold model

Risk assessment is a systematic process used by regulatory agencies to evaluate potential hazards to human health and the environment. It typically involves several steps, including identifying hazards, assessing exposure levels to humans, animals or wildlife, and then characterizing risks. Regulatory agencies like the EPA use risk assessments to inform policy decisions and set safety standards.

The linear no-threshold (LNT) model is a key concept in human health risk assessment. It assumes that any level of exposure results in risk increasing in a linear fashion. Regulatory agencies have traditionally used the LNT model as a default assumption when setting radiation protection standards, considering it a conservative approach to ensure public safety.²¹ However, the model has spread beyond radiation to chemical carcinogens, as well as to some non-carcinogens. Yet the scientific basis and appropriateness of the LNT model, especially for low-dose exposure, has been debated for years,²² and has become particularly controversial as new evidence has emerged about cellular repair mechanisms (which are the body's natural ways of fixing damaged DNA and removing potentially harmful cells).

The LNT concept is fundamentally at odds with the traditional toxicological principle that “the dose makes the poison,” which is a principle that has guided society's understanding of toxicity for centuries. According to this historical view, a substance is only poisonous at a certain dose, suggesting that low levels of exposure could be harmless. In contrast, the LNT model asserts that there is no level of exposure that is free of risk, no matter how minute. This approach serves the interests of regulatory agencies by providing an enduring rationale for their oversight and intervention. By adopting the LNT model, the EPA can justify the need for continuous monitoring, regulation, and control of substances, effectively ensuring that its programs remain necessary indefinitely.

The use of the LNT model across government agencies has had practical implications that affect the lives of all Americans. In the field of medical imaging, the LNT model has led to concerns about

radiation exposure, particularly in diagnostic procedures such as X-rays, CT scans, and mammography.²³ In some cases, physicians avoid ordering potentially lifesaving imaging scans due to fears of radiation exposure, even though the actual risks at low doses are minimal, zero, or perhaps even modestly beneficial. Likewise, the application of the LNT model to radiation regulation has led to extremely stringent safety standards that increase the costs of nuclear power plant construction.²⁴ This has undoubtedly hindered investment in advanced nuclear technologies, such as small modular reactors, which are seen as providing reliable energy while reducing greenhouse gas emissions.

EPA's reliance on the LNT model has had a profound effect on regulatory practices in areas such as radiation exposure, chemical regulation, hazardous waste management under the Superfund program, and air pollution. The extensive application of LNT leads to analysts reporting worst-case scenarios that are unlikely to play out in reality. The result is overly conservative policies that impose substantial costs on industry, delay development, and create unintended social and economic harms.

Formaldehyde

One application of the LNT model in chemical regulation can be seen in the EPA's handling of formaldehyde, a common chemical found in building materials and household products. The EPA considers formaldehyde a carcinogen. Relying on the LNT framework, the agency imposes strict regulations limiting formaldehyde in products such as plywood, particleboard, and insulation materials.

According to EPA estimates, annual compliance with its formaldehyde standards imposes compliance costs of about \$121 million annually.²⁵ The residential construction sector in the U.S. is especially affected by the costs of compliance with EPA formaldehyde regulations. Industry costs are passed on to consumers, contributing to higher prices for housing materials and construction, which exacerbates housing affordability challenges.

Even as the EPA doubles down on its standards, recent studies question the application of the LNT model to formaldehyde.²⁶ Research published by the National Academy of Sciences has shown that

the body can detoxify small amounts of formaldehyde,²⁷ possibly rendering low-level exposures harmless. Indeed, formaldehyde is a naturally occurring substance in the human body that is rapidly metabolized and detoxified through normal physiological processes. Yet in spite of those findings, the EPA continues to regulate formaldehyde using the LNT model,²⁸ reflecting a case where regulatory frameworks may lag behind current scientific understanding.

Radon

The regulation of radon also highlights the challenges and shortcomings of the LNT model. Radon is a naturally occurring radioactive gas. The EPA, using the LNT model, has established an action level of 4 picocuries per liter (pCi/L),²⁹ below which mitigation is still recommended.³⁰ This has led to stringent mitigation measures for homes and commercial buildings, costing millions annually in testing and remediation, even though emerging evidence questions the appropriateness of this action level. Some studies suggest a higher threshold may exist than the EPA's action level suggests, potentially between 8 and 27 pCi/L.³¹ Other research has found that lung cancer mortality rates may actually decrease with low-level radon exposure,³² suggesting that current regulations might not be aligned with beneficial health outcomes. The application of the LNT model to radon regulation thus results in policies that impose significant economic burdens, potentially for little to no public health benefit.

Superfund

The EPA's use of the LNT model also affects Superfund cleanups, where the agency oversees the remediation of contaminated land and water. Superfund sites, which number over 1,300 in the United States,³³ often involve contaminants like heavy metals, chemicals, and radioactive materials. The EPA applies the LNT model to assess a number of the risks posed by this contamination,³⁴ leading to stringent cleanup standards.

One notable problem with this approach is the excessive costs and delays that result from using the LNT model to regulate low-level

contamination. In Fiscal Year 2022, committed cleanup costs were estimated at \$1.1 billion, with a total of \$50 billion since the inception of the Superfund program.³⁵ Cleanup efforts at sites like the Hudson River have dragged on for more than two decades and cost more than a billion dollars.³⁶ The EPA's assumption that even small amounts of residual contamination could increase cancer risks means that cleanup efforts like this often stretch out over years, causing delays in redevelopment and contributing to economic stagnation in affected areas. Former Supreme Court Justice Stephen Breyer referred to this as "the problem of the last 10%,"³⁷ namely that even when a clear environmental harm is present, the marginal benefits of addressing the final residual elements of the harm after substantial cleanup efforts have been undertaken are often dwarfed by the marginal costs.

If the EPA reconsidered its reliance on the LNT model and adopted a more biology-based approach to risk assessment, Superfund cleanups could be completed more quickly and cost-effectively and regulations could be relaxed, freeing up resources for other environmental programs or other priorities.

Particulate matter

The EPA's use of LNT also extends to the regulation of particulate matter. Particulate matter, specifically fine particles known as PM_{2.5} (particles with a diameter of 2.5 micrometers or smaller), has been a central focus of the EPA's air quality standards for years, often forming the largest share of regulatory benefits in EPA economic analysis.³⁸ The agency has applied the LNT model in the context of PM_{2.5} since the inception of the PM_{2.5} standards in 1997; however, it ceased doing so in 2006.³⁹ That change came in response to a statement in support of a threshold from the agency's Clean Air Science Advisory Committee,⁴⁰ along with a corresponding staff report that offered mixed, inconclusive evidence with regard to both linear and threshold concentration-response functions for PM_{2.5} and associated health effects.⁴¹

Then, in 2009, the EPA made a significant and formal shift back to embracing the LNT model in its Integrated Science Assessment for PM_{2.5}.⁴² Returning to past practices was a convenient change for the agency, as it allows the EPA to set PM_{2.5} standards to levels at

which the epidemiological evidence is highly uncertain, due to the diversity of findings across a body of research that spans multiple health endpoints and employs a variety of statistical methods.⁴³ The EPA acknowledges uncertainty surrounding the shape of the concentration-response function for PM2.5,⁴⁴ and this issue continues to be studied.

There have been substantial successes in U.S. air quality since the Clean Air Act was passed.⁴⁵ However, as air quality continues to improve and PM2.5 concentrations fall, the incremental health benefits of further reductions may diminish or be eliminated entirely, even while the costs of achieving stricter standards will continue to rise. The debate surrounding PM2.5 pollution will continue and highlights the ongoing challenge involved with balancing a precautionary public health framework with cost-effective and efficient regulatory policy.

Recommendations for Congress

Require a comprehensive review of the scientific evidence supporting the LNT model. Congress should mandate that the EPA conduct a comprehensive review of the scientific evidence underpinning the LNT model, particularly focusing on recent advances in molecular biology, radiation biology, and cellular repair mechanisms. Since the EPA has historically resisted such reviews,⁴⁶ Congressional action is necessary to ensure that this review occurs.

Shift the burden of proof to the agency to demonstrate significant health risks from low-dose exposures. Congress should require that the burden of proof be placed on the EPA to demonstrate that a particular hazard or stressor poses significant threats to human health. By setting a null hypothesis as the standard, the default assumption would be that low doses of exposure are not harmful unless the body of scientific evidence convincingly shows otherwise. One way to advance this requirement is to mandate that studies finding a null result are not ignored by the EPA when it reviews relevant literature or commissions studies. This approach would promote a more balanced

regulatory framework, ensuring that regulations are based on clear evidence of harm rather than precautionary assumptions.

Establish a “de minimis” dose below which regulation and safety measures can stop. *De minimis non curat lex* is Latin for “the law does not concern itself with trifles.” In cases where health benefits of regulatory standards are either trivial in nature or too uncertain to be distinguished from zero, Congress should require regulators to establish stopping points, or a “de minimis” dose, below which further regulation and safety measures are no longer necessary. Such standards should be tailored to specific hazards and should be updated as scientific understanding advances. By setting clear finish lines for policy programs, regulatory efforts can avoid some of the problem of the “last 10%,” where increasingly burdensome costs are imposed to achieve ever-more trivial health improvements.

Adopt a mixed dose-response model for more tailored risk assessments or use alternatives to LNT to reflect the state of scientific uncertainty. Congress should require that the EPA rely on more than one dose-response model in cases where this is scientifically supported. For example, different ranges of exposure levels might be represented with different models, or different models might be weighted based on their biological plausibility.⁴⁷ This approach would allow for more tailored analysis that does not conflict with known scientific facts, such as superior or indistinguishable health outcomes in countries where pollution levels are high relative to the US, or in areas with relatively high background radiation.⁴⁸ Even when biological plausibility is not established,⁴⁹ say because the mechanism underlying a relationship is not fully understood, alternatives to LNT may still be useful for characterizing model uncertainty.⁵⁰

Taken together, these reforms would go a long way toward grounding US environmental policy in science and evidence rather than fear.

KEY ISSUE

Eliminate the EPA's IRIS program

The Integrated Risk Information System (IRIS) program at the EPA has long been a focus of debates over scientific standards within environmental risk assessment.⁵¹ Established in 1985,⁵² IRIS was intended as a repository for hazard identification and dose-response information on chemicals.⁵³ Having been created administratively, IRIS has never been authorized by Congress.⁵⁴ Nevertheless, its analyses serve as critical inputs supporting EPA's decision-making under numerous environmental statutes, including the Clean Air Act, the Safe Drinking Water Act, and the Superfund program. IRIS analyses and values are also used by regional EPA offices, states, other agencies, and by international organizations and governmental bodies.

Over the years, criticisms of IRIS have abounded, with voices as varied as the Government Accountability Office (GAO), the National Academy of Sciences (NAS), Congress, and industry groups all questioning the program's scientific rigor and transparency. While a recent 2022 IRIS Handbook⁵⁵ shows modest improvements, the program remains deeply flawed and appears incapable of meeting the evolving demands of chemical safety assessment.

Checked history

Chief among the criticisms of IRIS has been the tendency of its assessments to employ overly conservative assumptions,⁵⁶ leading to hazard assessments that exaggerate health threats. For example, IRIS's 2010 draft assessment value for formaldehyde was set lower than the amount humans naturally exhale with each breath.⁵⁷ The draft assessment faced widespread criticism, including from the NAS, for its lack of transparency and "recurring methodologic problems."⁵⁸

NAS, in its 2011 review of the IRIS assessment for formaldehyde, criticized the program's lack of standardized criteria for data selection and evidence integration.⁵⁹ NAS found that IRIS's practices were not transparent and lacked a clear underlying conceptual framework. In the 2011 report, as well as a follow-up review of the IRIS process in

2014, NAS recommended that IRIS adopt systematic review methods to improve transparency and reproducibility across its assessments.⁶⁰

In spite of these criticisms, the formaldehyde value was finalized in 2024,⁶¹ highlighting how a myopic focus on hazards, absent any context related to real-world exposure data, can result in an absurdly low health value.⁶² Similarly, the EPA's IRIS program established a risk value of 100 parts per quadrillion for the sterilizing agent ethylene oxide (EtO), a level that is 19,000 times lower than naturally occurring levels in the human body.⁶³ IRIS's EtO value came under scrutiny when it contributed to sterilization plant closures and worsened critical shortages of medical equipment during the COVID-19 pandemic.⁶⁴

GAO has been an especially vocal critic, placing IRIS on its High-Risk List since 2009.⁶⁵ The purpose of this list is to identify federal “programs and operations that are particularly vulnerable to waste, fraud, abuse, or mismanagement, or in need of transformation.”⁶⁶ GAO reports highlight IRIS's chronic delays and recurring methodological problems.⁶⁷ These reports find that, as a result of failing to implement recommendations from NAS and other parties, the IRIS program struggles to produce accurate, scientifically sound toxicity values, undermining its role in public health protection and creating regulatory uncertainty for industry. A 2023 GAO report recommends that the EPA establish clear and predictable timeframes for completing assessments to reduce stakeholder uncertainty, and to align IRIS's resources with strategic goals to effectively balance workload demands with available resources.⁶⁸

Failed modernization

The IRIS program has responded to these criticisms with a series of reforms, the most notable being the creation of the IRIS Handbook in 2022.⁶⁹ This handbook introduces systematic review methods intended to standardize the program's approach to issues related to literature review, evidence synthesis, and risk modeling, among others. A central feature is the attempt to ensure consistent application of principles across evaluations. The Handbook also includes more rigorous protocols for study evaluation and evidence integration,

establishing risk of bias frameworks that aim to address NAS's call for transparency and reliability in scientific evaluation.

The IRIS Handbook represents a significant procedural update, but this document on its own is unlikely to be sufficient given the longstanding nature of IRIS's problems. For one thing, the NAS has questioned the reasonableness of some of its contents.⁷⁰ Additionally, the IRIS Handbook's support of the LNT model, especially in cancer assessments, remains a contentious issue.⁷¹ The handbook's endorsement of uncertainty factors will encourage agency policy decisions to be hidden behind a veneer of science.⁷² In short, EPA continues to default to conservative methods without sufficiently considering alternative approaches. As a result, we can expect IRIS will continue to produce risk assessments that remain out of step with current scientific understanding.

IRIS's final formaldehyde assessment also provides reason to doubt the program's ability to make meaningful improvements. One industry group argued the assessment ignored peer review feedback, failed to use the best available science, and deviated from international standards.⁷³ Others argued the EPA failed to establish the biological mechanism linking formaldehyde with cancer.⁷⁴ In other words, in spite of having years to finalize the formaldehyde report, IRIS failed to adequately respond to the concerns surrounding its earlier, much criticized, drafts.

The path forward

IRIS hazard values are developed without considering real-world exposure scenarios. As a result, these values often include extremely conservative assumptions that make them impractical to implement. The problems with these overly cautious values typically only become apparent once the EPA attempts to use them in actual regulations and stakeholders see their practical implications.

Despite the procedural improvements in the IRIS Handbook, the program's continued reliance on a hazard-only framework for many chemicals remains a critical weakness. This limitation not only leads to inflated risk estimates but also misleads regulatory decisions by leaving out critical information related to context. The result is

too often undue economic burdens on industries without any clear public health benefits. Moreover, the redundancy between IRIS and the Toxics Substances Control Act's (TSCA) chemical risk evaluation process has become more apparent as TSCA's program has evolved in recent years.⁷⁵ Unlike IRIS, the TSCA program operates under statutory authority and has clear guidelines to use the "best available science." This has allowed that program to develop assessments with greater authority and practical relevance for regulatory decision-making.⁷⁶

Disbanding IRIS and moving assessors into respective program offices, such as EPA's Office of Chemical Safety and Pollution Prevention tasked with managing programs under TSCA,⁷⁷ would provide EPA risk assessments with the legal mandate and established procedures necessary for more effective chemical risk assessment. By consolidating these responsibilities, the EPA could eliminate the redundancies that contribute to IRIS's low scientific standards. Once disbanded, IRIS's overly conservative values should not be used by EPA regulatory programs without re-evaluation.

Recommendations to Congress

Wind down the IRIS Program. The IRIS program has demonstrated an inability to consistently produce timely, scientifically robust assessments. Congress should initiate a phased wind-down of IRIS, transferring resources, including human capital, to the Office of Chemical Safety and Pollution Prevention and other regulatory program offices, which should develop their own hazard assessments in line with statutory requirements. By leveraging TSCA's legislative requirements for science-based evaluations, the EPA can improve the reliability and credibility of its hazard evaluations.

Prohibit the use of legacy IRIS values. Congress should mandate that EPA regulations may not use existing IRIS values after the IRIS program is wound down, unless those values have been re-evaluated using updated scientific methods that incorporate real-world exposure data and avoid overly conservative assumptions. This will prevent outdated and overly conservative IRIS values from continuing to

influence regulatory decisions through citation in future rulemakings or risk assessments.

Mandate that evaluations consider real-world context. Congress should require that all EPA chemical assessments integrate real-world exposure data that consider naturally occurring levels of chemicals in the human body and environment. Moving away from hazard-only frameworks would help address critiques of IRIS's reliance on conservative models that ignore these baseline exposure contexts. This adjustment could help prevent assessments from overestimating risk, producing regulatory standards that reflect actual health impacts rather than theoretical worst-case scenarios.

Make hazard assessments legally accountable. IRIS's history of disregarding peer review feedback demonstrates the weakness of the current peer review process. Congress should make the Information Quality Act judicially reviewable to enable stakeholders to challenge flawed hazard assessments in court.⁷⁸ Enabling judicial review would create accountability and ensure the EPA properly addresses scientific criticisms of its hazard assessments.

Prioritize central risk estimates while accounting for uncertainty. Congress should mandate that EPA assessments present a range of values based on uncertainty but prioritize central estimates of risk rather than defaulting to overly conservative assumptions or relying on concepts such as reference values. By focusing on central estimates—those representing the most probable risk level—the EPA can provide a more balanced and realistic portrayal of chemical risks. Meanwhile, a range allows analysts to select alternative values when appropriate based on the unique circumstances of the situation they are assessing (e.g. exposure to children). Publishing the point of departure value before uncertainty factors are applied should also be required.⁷⁹

KEY ISSUE

Reform the TSCA

The Toxic Substances Control Act (TSCA), originally enacted in 1976, provides the EPA with the authority to regulate all production, importation, use, and disposal of new and existing chemicals. Under TSCA, the EPA must review and approve all new chemicals before they can be manufactured domestically or imported from abroad. TSCA also authorizes the EPA to place use restrictions, including bans, on existing chemicals currently utilized in commerce. Companies regulated under TSCA are subject to extensive reporting, record keeping, and testing requirements.⁸⁰

2016 Lautenberg Amendments

In 2016, with bipartisan support, including support from industrial and environmental stakeholders, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Amendments) amended TSCA.⁸¹ The Lautenberg Amendments did not change the EPA's obligation to regulate chemical substances or mixtures that present an unreasonable risk of injury to health or the environment, and consider the environmental, economic, and social impact of any action proposed or taken under the statute.

However, the Lautenberg Amendments did significantly change the EPA's authority to ensure the safety of chemicals. The amendments included:

- ▶ Mandatory requirements for the EPA to evaluate existing chemicals with clear and enforceable deadlines.
- ▶ A new requirement that the EPA make an affirmative finding on the safety of new chemicals or significant new uses of chemicals before they are allowed to enter the marketplace.
- ▶ New and more frequent substantiation requirements for certain confidentiality claims.
- ▶ A provision that allows EPA to collect up to \$25 million annually in user fees from chemical manufacturers and processors.⁸²

Importantly, the Lautenberg Amendments also added new scientific quality standards that must be met when EPA evaluates chemicals. The new standards include requiring the EPA to rely on the best available science and the weight of scientific evidence.⁸³

To carry out the Lautenberg Amendments' numerous requirements, the EPA adopted four important framework rules:

1. The July 2017 Risk Prioritization Process Rule,⁸⁴ which established a framework and criteria for identifying high-priority chemicals for EPA risk evaluations.
2. The July 2017 Risk Evaluation Procedures Rule,⁸⁵ updated in May 2024,⁸⁶ which established a framework for evaluating high priority chemicals to determine whether they present an unreasonable risk to health and/or the environment.
3. The August 2017 Inventory Update Rule,⁸⁷ which required industry reporting of chemicals manufactured, imported, or processed in the US over the past 10 years to identify which chemical substances on the TSCA Inventory are active in US commerce.
4. The October 2018 Fees Rule,⁸⁸ updated in February 2024,⁸⁹ that established the structure and approach the EPA will follow to collect user fees to defray the cost of TSCA implementation.

Importance of chemicals

Chemicals are the backbone of so many elements of modern life. Without chemical manufacturing and processing, many important products and technologies such as computers, batteries, cell phones, solar panels, and motor vehicles would not be possible.⁹⁰ In addition to supporting innovative technologies, chemicals are also indispensable to the manufacture of, among other things:

- ▶ Cleaning and disinfection products that enable us to quickly and effectively remove bacteria and dirt from our clothing, homes, and workspaces.
- ▶ Pharmaceuticals such as vaccines, antibiotics, and painkillers that prevent and cure disease and avoid or reduce suffering from illness, injury, or surgery.

- ▶ Fertilizers that enhance agricultural yields and thereby enable farmers to feed a planet of eight billion people without further encroaching on wildlife habitat.⁹¹
- ▶ Construction materials essential for building homes and critical infrastructure, such as bridges, roads, and tunnels.

Although some chemicals may pose risks under certain exposure scenarios, it is important to assess chemicals in a thoughtful manner that does not discount the myriad benefits they provide to modern life. Indeed, in a world without industrial chemistry, human life would be poor, brutal, and short.

Overly burdensome and untargeted regulations, even if well meaning, can undermine progress and make it much more difficult for American companies to produce the chemicals that Americans rely on in everyday life. This can make products more expensive, lower quality, or make them unavailable entirely. Ensuring that regulations are prudent and protect public health while still allowing access to goods Americans rely upon is essential.

Recommendations for Congress

There are numerous issues that Congress needs to address to improve TSCA, from improper consideration of risk, failure to consider costs and tradeoffs, to unreasonable delays in the review of new chemicals. Specifically, Congress should:

Ensure that TSCA is implemented consistent with a risk-based approach. TSCA provides for a robust risk-based approach for the evaluation and management of chemicals. Congress must ensure that the EPA is evaluating and regulating based on risk, not hazard. Even if a chemical poses a hazard, this is a woefully incomplete picture of whether it could pose harm to people or the environment. In a formula, $\text{risk} = \text{exposure} \times \text{hazard}$. For example, chemicals that may be harmful at high exposure levels can carry little risk if workers using them wear proper personal protective equipment, and if downstream users and consumers are only exposed at low levels below which the

chemical may cause harm.⁹² Precautionary hazard-based decisions, which do not consider exposure, should be avoided.

Consistent with this approach, Congress should clarify that determinations of unreasonable risk should be made on a use-by-use basis rather than for the chemical as such. Determinations of risk based on the chemical, independent of specific uses, take exposure out of the risk equation and are not consistent with the intent of TSCA. Currently, if the EPA finds that even one condition of use presents an unreasonable risk, the agency determines that the entire chemical presents an unreasonable risk, even if there are conditions of use that present no risk at all. Determinations of whether a chemical presents an unreasonable risk should be tied to specific uses.

Clarify the conditions for mitigating unreasonable risk. The EPA's risk evaluation procedures rule mentions several considerations likely to inform unreasonable risk determinations. Currently, the EPA does not consider any costs or non-risk factors when evaluating whether a chemical, under a condition of use, presents an unreasonable risk. When evaluating restrictions to mitigate unreasonable risks, Congress should ensure that the EPA considers the harm any regulation would place on society, including through lost benefits or the creation of indirect or additional risks to health, the environment, and the economy.

Improve the new chemicals evaluation process. TSCA requires that the EPA review and approve chemicals within a 90-day window. However, the EPA's current practices, such as reviewing all reasonably foreseen uses of a chemical rather than just the chemical's intended use, are stifling the innovation pipeline. The EPA routinely misses the 90-day deadline,⁹³ and a recent survey shows that the agency is taking more than 365 days to review 81 percent of individual chemical applications.⁹⁴ This is harming the competitiveness of the US manufacturing sector. Congress should ensure that the EPA puts in place the policies and procedures needed to meet its statutory mandate of completing reviews of new chemicals in 90 days. Congress should:

- ▶ Clarify that for new chemical reviews, the term “under the conditions of use” means the circumstances under which a

chemical is known or intended to be used.⁹⁵ New chemicals should not be reviewed for uses that are neither intended nor expected by the manufacturer.

- ▶ Ensure that the EPA's assessment is based on the actual conditions of use, including personal protective equipment and engineering controls, that the manufacturer has in place and intends to put in place. This would allow the EPA's evaluation to be based on real-world exposure scenarios.
- ▶ Ensure that the EPA is conducting risk-based reviews, rather than precautionary hazard-based reviews for new chemicals.
- ▶ Ensure that the EPA is relying on the best available science, including information provided by manufacturers, sometimes at the EPA's request.

Improve the existing chemicals risk evaluation process. Through the Lautenberg Amendments, Congress gave the EPA three years to conduct risk evaluations for existing chemicals.⁹⁶ Due to the EPA's ever-expanding scope of risk evaluations, the EPA has been unable to meet this deadline. Congress should ensure the timely review of existing chemicals while ensuring that the agency focuses on the most significant potential risk, not chasing miniscule risks. Congress should also ensure that the EPA is relying on the best available science, the weight of the scientific evidence, and all reasonably available information when conducting risk evaluations.⁹⁷ In addition, Congress should:

- ▶ Ensure that the EPA's risk evaluations are focused on pathways of exposure that are expected to lead to significant risks and are not covered by other EPA program offices or other statutes. Congress should clarify that TSCA is a gap filler. For example, there is no reason for TSCA to look at chemicals in drinking water. Eliminating TSCA scope creep in risk evaluations will make EPA's workload more manageable.
- ▶ Ensure that the EPA is focusing on the potential risks of greatest concern, and not seeking to evaluate risks that are due to *de minimis* exposures and unintentional minor uses. If the EPA were to evaluate all conditions of use of a chemical, the agency

would not be able to complete risk evaluations consistent with the congressionally mandated timeline.

- ▶ Ensure that TSCA risk evaluations focus on chemicals currently in commerce, not on chemicals that have already been phased out or discontinued uses.
- ▶ Prohibit the EPA from regulating chemical risk exposures in the workplace. After the EPA completes a risk evaluation, it may then refer the results to the Occupational Safety and Health Administration (OSHA). However, Congress should clarify that OSHA is the agency that sets workplace health and safety standards.
- ▶ If the EPA is to retain authority to regulate workers, the EPA should not set existing chemical exposure limits (ECELs) unless it determines that current practices, including current occupational exposure limits and current personal protective equipment (PPE) requirements and practices are not sufficiently health protective. Congress should ensure that ECELs are reasonable and achievable, and that if an ECEL is set, compliance with the ECEL is performance-based.
- ▶ Ensure that when establishing a baseline for existing exposures to chemicals, EPA risk evaluations take account of existing regulatory requirements, including requirements from other EPA program offices and other agencies, such as OSHA. In particular, the EPA should assume that facilities regulated by OSHA comply with all OSHA requirements, including the requirements to use PPE.
- ▶ Clarify that conditions of use include all practices that impact an evaluation of risk, including existing regulations and actual practices. For instance, OSHA general industry standards, including requirements for PPE and existing workplace practices regarding use of PPE, should be considered as ‘reasonably available information’ that impacts the risk of a chemical under a particular condition of use.
- ▶ Ensure that TSCA’s scientific standards for best available science, weight of the scientific evidence, and reasonably available

information are clearly defined by the EPA within each risk evaluation. Approaches to risk that do not meet TSCA standards for best available science, such as the use of Integrated Risk Information System (IRIS) hazard values and developing methods for cumulative and aggregate assessment, may not be used.⁹⁸ If a TSCA risk evaluation does rely on an IRIS value, Congress must ensure that the IRIS value is subject to peer review by the Science Advisory Committee on Chemicals.

- ▶ Congress should also require the EPA to base its decisions on the weight of scientific evidence. That means the agency must not only assess the strengths, limitations, and relevance of multiple lines of evidence, but also give the most weight to the highest quality and most relevant information.
- ▶ Due to their importance, all risk evaluations and risk management rules should be subject to Executive Order 12866 review, at the proposed and final stages, as is done for rulemakings.

Eliminate non-mandated EPA programs that take resources away from TSCA implementation. There are two programs that should be eliminated:

- ▶ **Safer Choice program.** The Safer Choice program is a voluntary program implemented by the EPA. Under Safer Choice, the EPA certifies products that are considered to be “safer” for people and the environment.⁹⁹ There is no statutory authority for this program and in fact the program’s designation of chemicals as “safer” is not consistent with TSCA.¹⁰⁰ Congress should mandate the EPA stop certifying chemicals under Safer Choice and current resources for this program should be used to implement TSCA instead. If the public deems such information to be valuable, then the private sector is more than capable of meeting this need.
- ▶ **EPA’s Environmentally Preferable Purchasing Program and Procurement Recommendations.** The EPA provides recommendations to other federal agencies with respect to how they can comply with purchasing under their own statutory mandates. It recommends purchasers look for various ecolabels, standards, and seals.¹⁰¹ Congress should eliminate this non-

authorized program, which meddles in the procurement policies of other agencies that have their own priorities, picks winners and losers, and diverts resources from statutory priorities.

Require implementation guidance for risk management. While the EPA developed framework rules for the fees program, chemical prioritization, and risk evaluation, the EPA has not provided any frameworks for the risk management of chemicals under TSCA Section 6 (15 U.S.C. § 2605).¹⁰² Congress should require that the EPA develop a framework rule for risk management. Congress should also require the EPA to ensure that its restrictions on chemicals are technically and economically feasible, cost-effective, and do not result in the creation of greater risks for health or the environment.

Strengthen the Section 21 petition process. Congress should ensure that Section 21 petitions and other TSCA provisions (Section 20, Section 4(f), Section 7) that address chemical risks flagged by citizens or the EPA on a case-by-case basis¹⁰³ do not undermine the design and function of the TSCA Section 6, comprehensive, multi-year risk evaluation and risk management process. For example, Congress should prohibit the EPA from making a determination of unreasonable risk on a Section 21 petition that would bypass performing a section 6 risk evaluation. Congress should also clarify that any unreasonable risk determination by the agency should be subject to notice and comment.

Improve the approach to test orders. Congress should ensure that the EPA follows TSCA's tiered approach to data gathering¹⁰⁴ and does not order new testing until it has demonstrated the necessity for the information. All testing requirements must be narrow, reasonable, technically feasible, and not imposed on companies manufacturing chemicals for uses and purposes for which the chemistries are not intended.

KEY ISSUE

Reform FIFRA

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) governs pesticide distribution, use, sales, and labeling.¹⁰⁵ As the Environmental Protection Agency (EPA) explains, the agency must register (license) all pesticides distributed or sold in the United States, and before the agency may register a pesticide under FIFRA, “the applicant must show, among other things, that using the pesticide according to specifications ‘will not generally cause unreasonable adverse effects on the environment.’”¹⁰⁶

Overview of requirements

FIFRA requires the EPA to evaluate human health, ecological risks, and safety before any pesticide can be registered. As a part of that evaluation, the EPA undertakes a thorough scientific review, including a review of carcinogenicity and non-cancer effects, including endocrine effects, as well as effects on sensitive subpopulations including children and pregnant women and agricultural workers who may be exposed to pesticides. The EPA may not lawfully approve a pesticide unless the agency confirms the product does not cause unreasonable adverse effects to the environment or humans.¹⁰⁷ The EPA also regularly evaluates all new information to guarantee the safety of existing products.¹⁰⁸

FIFRA defines the term “unreasonable adverse effects on the environment” to mean: “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.”¹⁰⁹

Amendments to FIFRA

In 1996, Congress unanimously passed the Food Quality Protection Act (FQPA) that amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA).¹¹⁰ Most importantly, FQPA requires that the EPA

consider the special susceptibility of children to pesticides by using an additional tenfold (10X) safety factor¹¹¹ when setting and reassessing tolerances¹¹² unless adequate data are available to support a different factor; consider aggregate risk from exposure to a pesticide from multiple sources (food, water, residential and other non-occupational sources) when assessing tolerances; and consider cumulative exposure to pesticides that have common mechanisms of toxicity.

In 2004, FIFRA was amended further by the passage of the Pesticide Registration Improvement Act of 2003 (PRIA).¹¹³ PRIA created a registration service fee system for applications for specific pesticide registration, amended registration, and associated tolerance actions. According to the EPA, the goals of PRIA were to create a more predictable evaluation process for affected pesticide decisions, and to couple the collection of individual fees with specific decision review periods.¹¹⁴ PRIA fees have been reauthorized four times, most recently by PRIA 5 (a fifth update to the legislation) which was passed in December 2022.¹¹⁵ Registration service fees authorized by PRIA fund approximately one third of EPA's pesticide program activities.¹¹⁶

Benefits of pesticides

As a preliminary matter, it is important to understand the importance of pesticides. Pesticides are necessary for the effective protection of our food supply, public health, homes and structures, infrastructure, our natural resources, and environment. Pesticides protect people, pets, companion animals, and wildlife from diseases transmitted by mosquitoes, ticks, and rodents. Our homes, businesses and other structures are protected by pesticides against pests such as cockroaches, bedbugs, mice and rats, termites, flies, and moths. The judicious use of pesticides helps maintain safe, beautiful, and functional outdoor spaces such as home lawns, gardens, public parks, athletic fields, and golf courses. Furthermore, pesticides are vital to our nation's production of food and fiber.

Today, up to 40 percent of global crop production is lost to pests, weeds, and disease.¹¹⁷ Without the use of pesticides, crop yields could decrease by more than 70 percent and additional land would need to be removed from natural habitat and converted for food production.¹¹⁸

Annually, plant diseases cost the global economy over \$220 billion, and invasive pests at least \$70 billion.¹¹⁹ Without pesticides, a greater reduction in yields would mean less food and, as a result, higher prices. All food prices would increase as costs for products, such as animal feed and ingredients in processed food, would be passed on to consumers in some fashion. For instance, without pesticides, the yields of corn, cotton, and soybeans show declines of up to 70 percent,¹²⁰ underscoring the indispensable role of pesticides in agriculture and ensuring food security. And cultivating corn, cotton, and soybeans without pesticides, results in upwards of three times more land, water, energy use, and greenhouse gas emissions.¹²¹ Crucially, pesticides are not only enhancers of productivity but significantly mitigate the environmental impact of agricultural crops.

Problems with FIFRA

Today, the EPA's implementation of FIFRA is broken in many ways. EPA's risk evaluations of pesticides are overly precautionary and not consistent with the agency's own science, leading to unnecessary restrictions on important crop protection tools. And the EPA is implementing Endangered Species Act (ESA) requirements in a manner that will significantly curb growers' abilities to effectively use pesticides. These concerns are further compounded by the EPA's inability to meet the statutory timeframes mandated in PRIA. Approximately 60 percent of all pesticide registration actions are not completed until after their statutory decision review times and many are still incomplete 18 to 24 months later, leaving farmers and ranchers without the up-to-date tools they need.¹²² This is just the tip of the iceberg. Significant reform is necessary as described in the recommendations below.

Further, the EPA, along with other agencies such as the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS), too often undertake efforts to undermine the existing risk- and science-based regulatory frameworks for these tools, making the US more reliant on foreign competitors for food and agricultural goods. Agency pesticide decisions should not be politicized, but rather should be based on sound science and Congress should hold the agencies accountable for such decisions.

Recommendations for Congress

Require the EPA to pay for fee program delays. To incentivize the timely review of pesticide applications and to provide certainty to innovators, Congress should ensure that PRIA fees are refunded to applicants when PRIA deadlines are exceeded. If a deadline is exceeded by more than 10 percent of the time originally allotted, the EPA should refund the fee to the applicant at a level commensurate with EPA's delay. For instance, if the PRIA timeline is 100 days and it takes EPA 151 days to review the action, the EPA should refund 51 percent of the fees to the applicant. Congress may want to consider setting an appropriate cap or additionally considering changes to the collection of maintenance fees to incentivize increased efficiencies.

Improve the oversight of important registration decisions. Individual pesticide registrations are considered adjudications and not reviewed by the Office of Management and Budget (OMB).¹²³ However, when pesticide tolerances and registrations are withdrawn by the EPA (as opposed to being withdrawn voluntarily by registrants), Congress should ensure that these actions undergo coordinated interagency review managed by OMB. In addition, when a pesticide is necessary for a particular crop, if the EPA is proposing modifications to the registration to limit use or make a tolerance more restrictive, Congress should also ensure that there is an interagency review coordinated and managed by OMB. Moreover, that procedure should be followed even if the crop's market share is not economically significant.

Ensure the robustness of evaluations. Before manufacturers can sell pesticides in the United States, the EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. In evaluating a pesticide registration application, the EPA assesses a wide variety of potential human health and environmental effects associated with use of the product.

Potential registrants must generate scientific data pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide. The EPA establishes robust guidelines that provide the necessary predictability and rigor for scientific

decisions. However, during registration review, the EPA considers all available information, including non-guideline-compliant studies. Consequently, although the EPA has a framework for considering epidemiologic studies of health and disease in human populations, the agency does not always rely on high quality data, and sometimes fails to adequately control for confounders and uncertainties.

Using epidemiologic findings simply because they are more recent, and because they rely on human data rather than other scientific information, does not necessarily make the findings sufficiently robust for informing regulatory decision making. Congress should ensure the EPA is appropriately considering the quality of the epidemiologic information. At a minimum, the EPA should evaluate the statistical significance, or lack thereof, of research findings when evaluating causality.

Congress should also ensure that the EPA relies on U.S. Department of Agriculture (USDA) and state usage data that reflect actual pesticide use in registration reviews and ESA analyses. The FWS and NMFS should rely on similar data in their ESA analyses. Such data represent the best available information to describe how pesticides are used.

Finally, the EPA develops guidance documents, frameworks, white papers, strategies, public relations notices and other documents (under many different names) that shape the pesticide programs' approach to individual registrations and reregistration review decisions but are subject to little scrutiny by OMB or Congress. Any document of this type, which informs the EPA's general approach to evaluating human and/or ecological risk, should be treated as an economically significant guidance document. Congress should ensure that these documents go through a robust peer review process which is consistent with the Federal Advisory Committee Act (FACA) and allows for public comment, such as the EPA's Office of Chemical Safety and Pollution Prevention Science Advisory Panel. After peer review and notice and comment, Congress should ensure that each of these documents goes to OMB for coordinated interagency review.

Improve Endangered Species Act (ESA) implementation. Congress mandated, through FIFRA, that the review of pesticides take their benefits into account.¹²⁴ However, the ESA does not allow for risk and

benefit balancing, according to the Supreme Court's ruling in *Tennessee Valley Authority v. Hill* (1978).¹²⁵ Current implementation of the ESA by the EPA essentially ignores the necessary risk benefit balancing required by FIFRA. Congress should enact an exemption to the Supreme Court's ruling to ensure the continued use of pesticides that are important for public health and food security.

Recognizing the important benefits of pesticides to public health protection and food security, Congress must ensure that EPA pesticide decisions (including registrations and reregistration decisions) are exempt from the provisions of the ESA except in cases where an ecological assessment, conducted by the EPA, makes a preliminary determination that the use of the product is likely to adversely affect a species or critical habitat. Only if a "likely to adversely affect" (LAA) determination is made, should the EPA move forward with informal or formal consultation with the U.S. Fish and Wildlife Service and National Marine Fisheries Service.

Congress should additionally ensure that emergency exemptions for unregistered uses of pesticides, including under Section 18 of FIFRA, are fully exempt from ESA requirements and are reviewed within 90 days or are automatically granted by default.

Ensure uniform pesticide labeling. Congress should ensure that pesticide labels are uniform and do not create confusion for users based on their location. This means that individual states and localities should not be able to require additional warnings on labels and packaging. Uniformity is particularly important for labeling related to human health assessments, including carcinogenicity and for pesticide use requirements. Congress must reaffirm that the EPA is the sole authority for making safety findings related to pesticides while retaining the states' ability to further regulate the use of these tools.

Reaffirm the importance of state lead agencies. Congress should reaffirm that state lead agencies charged with implementing EPA regulations under FIFRA are the agencies in that state with the authority to regulate the use of crop protection and pest control tools, providing regulatory certainty for farmers, commercial applicators, and small businesses who rely on these tools. A patchwork of localities dictating the use of these tools makes compliance difficult for the

regulated community, and localities often do not have the budgets and resources necessary to ensure adequate pesticide enforcement.

Remove barriers to biotechnology. Plant-incorporated protectants (PIPs) are pesticidal substances produced by plants and the genetic material necessary for the plants to produce these substances. While some PIPs are achieved through conventional breeding and have not been subject to federal regulation, PIPs created using genetic engineering are still subject to regulation under FIFRA. Congress should remove excessive regulatory burdens for plant breeders by exempting from regulation PIPs that are identical to those found in nature.

Recognize the importance of plant biostimulants. Plant biostimulants are substances that support a plant's natural nutrition processes and can thereby improve the efficiency of a plant. Congress should provide a clear definition for plant biostimulants. Developing this definition is a first step towards creating a pathway to avoid an inefficient patchwork of differing laws and regulations at the state level that make innovation and interstate commerce exceedingly difficult.

Create certainty for registration review. The EPA must review each pesticide at least every 15 years to ensure that the pesticide can carry out its intended function(s) without creating unreasonable adverse effects to human health and the environment.¹²⁶ To ensure certainty for the marketplace and growers, if this review is not completed on time, an automatic 2-year extension should be provided to allow certainty for the marketplace and growers.

Give some more flexibility for state registrations. Under section 24(c) of FIFRA, states may register an additional use of a federally registered pesticide product, or a new end-use product, to meet special local needs.¹²⁷ The EPA has concluded that state registrations that limit or restrict use of pesticides registered by the EPA are beyond the scope of FIFRA section 24(c), and that such registrations should be disapproved.¹²⁸ Congress should revise this section of FIFRA to allow state registrations to be more restrictive, as appropriately determined by the state.

Increase coordination between the EPA and USDA. The USDA often provides feedback to the EPA on pesticide registration and

reregistration decisions during a public comment period. While USDA career scientists frequently submit comments that include recommendations on how these actions can reduce the impact on agriculture, while simultaneously protecting human health and the environment, the EPA frequently ignores these recommendations. As such, Congress should amend FIFRA to require further coordination between the EPA and USDA during the pesticide registration and registration review processes.

Provide advanced notification and account for existing stocks.

Farmers make decisions related to their input costs, including chemicals and seed varieties to use alongside those chemicals, months before the start of the growing season. When the EPA completes registration review decisions prior to or during the growing season that either restrict the use of a pesticide or requires the implementation of costly and burdensome mitigation measures, it causes additional uncertainty for producers. To prevent any restrictive actions being taken prior to or during the growing season, Congress should amend FIFRA to ensure an advance notification of at least 9 months is required prior to implementing these restrictions.

Additionally, some courts frequently vacate pesticide registrations or tolerances, creating uncertainty for growers who rely on these tools to protect their crops from damaging pests, weeds, and diseases. To minimize the economic impacts when courts vacate registrations or tolerances, Congress should amend FIFRA to provide for a mandatory existing stocks order that allows farmers to continue using pesticides already in the chain of commerce for a specified period of time.

Eliminate duplicative permitting. In some instances, the EPA requires a permit under the Clean Water Act's National Pollutant Discharge Elimination System to use a pesticide that has already been approved for use under FIFRA. Since all pesticides undergo both a human health and an ecological risk assessment before being registered under FIFRA to ensure the use of the pesticide does not cause unreasonable adverse effects to the environment or humans, Congress should remove this duplicative step in the regulatory process.

KEY ISSUE

Reform CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund, addresses the cleanup of sites contaminated by releases of hazardous substances.¹²⁹ It was signed into law in 1980¹³⁰ following public outcry over toxic waste contamination of groundwater, soil, and surface water at several residential communities.¹³¹ One of the most notorious toxic waste sites was Love Canal, a former dumping ground for industrial waste at Niagara Falls in New York that eventually became home to a neighborhood and elementary school.¹³²

CERCLA works in combination with another statute, the Resource Conservation and Recovery Act (RCRA), enacted in 1976. Typically, Superfund authority is used to cleanup previously contaminated sites no longer in productive use while RCRA covers the management of contaminants through their lifecycle and regulates releases at currently operating sites.¹³³

In 1986, Congress amended CERCLA through the Superfund Amendments and Reauthorization Act (SARA). SARA gave the EPA wider enforcement authority under CERCLA, increased state involvement in Superfund activities, and increased the size of the Hazardous Substance Superfund Trust Fund.¹³⁴

Superfund is implemented by the 10 EPA regional offices and overseen by the Office of Superfund Remediation and Technology Innovation (OSRTI) within the Office of Land and Emergency Management (OLEM).¹³⁵

Potentially responsible parties

CERCLA is intended to ensure that “potentially responsible parties” (PRPs) are held responsible for the remediation of releases hazardous substances on a site. A PRP can be any owner or operator of a site, both past and present, as well as a party who generated, transported, or arranged the transport of waste.¹³⁶ PRPs are potentially liable for various cleanup costs and natural resource damages associated with

the site. Courts have interpreted Superfund as imposing strict liability that is retroactive, joint and several. In other words, a PRP can be compelled to cleanup sites based on actions that happened before CERCLA was enacted and can be held liable for the whole cleanup even if other parties were involved and even if all the actions taken were legal at the time.¹³⁷

Hazardous Substance Superfund Trust Fund

To fund cleanups when PRPs cannot be located or no longer exist, CERCLA established the Hazardous Substance Superfund Trust Fund. Originally, the Trust Fund obtained its revenues from a Superfund tax on industries using specific chemicals and appropriations from the Treasury's general fund.¹³⁸ The Superfund tax expired in 1995,¹³⁹ but was reinstated in 2022 for many chemicals.¹⁴⁰ Recent EPA estimates indicate that approximately \$1.2 billion will be collected for FY2024—less than half of the agency's original projection.¹⁴¹

National Priorities List

Under the law, the EPA maintains a National Priorities List (NPL) of contaminated sites in need of remediation. These are intended to be the most significantly contaminated sites in the country. New sites are added to the list annually. Many sites remain on the list for a long period of time without action being taken to remediate them.

Recommendations for Congress

Controversies over CERCLA typically concern when and how sites will be cleaned up and then reused, and who will pay for it. Many of the law's provisions cause sites to languish rather than be redeveloped as intended. The transaction costs associated with Superfund sites related to PRP litigation and consulting costs add considerably to the overall time and expense of remediation. While efforts have been made to allow for redevelopment of brownfields¹⁴² (sites that are potentially contaminated or less contaminated than a Superfund site, but for which potential liabilities hinder redevelopment), expeditious redevelopment will require further reforms to the law. The following

are some specific recommendations to modernize CERCLA so that it best achieves the statute's objectives:

Prune the National Priorities List to focus resources on the most important sites. The NPL should be reserved for the sites that are most severely contaminated and would not otherwise be remediated by state or private action. The NPL is meant to prioritize cleanup of the most hazardous sites.¹⁴³ However, the current list does not reflect that objective. As of December 2024, there were 1,340 sites on the NPL.¹⁴⁴ Placing too many sites on the list undermines the NPL by diffusing resources and focus. Additionally, once on the list, a site must go through a rigorous planning process under complex National Contingency Plan regulations¹⁴⁵ before remediation can occur. In numerous cases, many years will pass between listing a site and the actual start of remediation.

In short, the current NPL is too inclusive and as a result too little gets done as resources are spread across too many sites. Better gatekeeping by the EPA and more effort focused on alternative cleanup paths can get contaminated properties back on the tax rolls quicker.

One way to keep the list focused on the worst sites would be to eliminate the requirement that the list be updated annually.¹⁴⁶ The worst sites, those that truly belong on the list, will be immediately apparent. The requirement to update the list only causes lower priority sites to be added to the pile during each cycle.

Alternatively, Congress could direct the EPA to raise the Hazard Ranking System (HRS) score required for a site to be eligible for placement on the NPL.¹⁴⁷ Congress also could ensure that the HRS score be a more meaningful measurement of actual risk.¹⁴⁸ Concentrating Superfund activities on fewer sites will result in the most severely contaminated sites receiving the necessary remediation rather than expending the same money and effort across a broader array of partially completed, lower-priority cleanups.

Allow states to assume the responsibility for long term monitoring of sites. The NPL would be more manageable if states were given access to Superfund money by Congress to address sites before placement on the NPL, typically considered the last option. States should also have

more latitude to manage Superfund sites over the long term once the most severe contamination has been remediated and the site is subject to long term monitoring. This begins with allowing sites to be removed from the list if they are under state management. States should also be able to use Superfund money to conduct and oversee cleanups under state law.

The EPA and states should be given the authority to delegate the long-term stewardship of sites subject to monitoring to land trusts, similarly motivated non-profits, or other organizations qualified to manage the site both for beneficial use of the land and environmental monitoring. Use of such organizations will help stretch Superfund dollars while also putting land back into use, either for recreation, wildlife conservation, or other uses of benefit to the local community.

Currently, taking on this responsibility comes with legal liabilities under CERCLA.¹⁴⁹ Creating an arrangement where those attempting to use or improve the land do not become PRPs and are shielded from future liability is essential to allowing land to be put back into use.

RACER Trust is a great example of how an entity can successfully manage a portfolio of contaminated properties to the benefit of many communities.¹⁵⁰ During the 2008-09 financial crisis, General Motors went through chapter 11 bankruptcy. As part of the GM reorganization plan, RACER Trust was established. Funded at nearly \$500 million, RACER managed a portfolio of 336 tax parcels (closed plant sites and other unwanted real estate), many of which were contaminated (approximately 60 locations). Its mission was to prepare the properties for redevelopment to help the local economies. It has been a great success story.¹⁵¹

One critical key to RACER's success is its ability to manage funds across multiple sites so that cost savings at one site can free up funds for the more difficult sites. That is in contrast to the NPL, where all funds for a site must be used on that site, resulting in delays and limiting the ability to maximize cleanup dollars. Allowing the pooling of monies over a portfolio of sites creates efficiencies in both costs and time. When Congress created Superfund it anticipated sites being cleaned up over a relatively short timeframe. It did not intend the

current situation in which many sites are managed and monitored in virtual perpetuity.

Specify that federal funds are only to be used to meet federal standards. States can use federal funds to meet state cleanup standards that go beyond the federal standards. This should be prohibited. States that want to exceed federal standards are free to do so, however they should use their own funds to meet this objective. Specifying that federal funds are solely for the purpose of attaining federal standards would help ensure that the worst sites are ameliorated first as cleanup standards under CERCLA are already considered protective.¹⁵²

Transfer large river and harbor sites to the Army Corps of Engineers. The Army Corps of Engineers already provides significant assistance on a variety of Superfund programs, but there are some sites, typically large river segments and ports, which would be best served by being transferred fully to the responsibility of the Corps. When control over an issue is divided among several government agencies, progress can often be slowed considerably. Multiple versions of similar paperwork, poor communication between agencies, and the ability to obfuscate ultimate responsibility behind the layers of bureaucracy all come into play.

Harbor sites frequently require significant dredging activities. A prime example is the Portland Harbor site, a 10-mile stretch of the lower Willamette River, added to the NPL in 2000. Nearly a quarter century later, the main in-river remediation remains in the planning stages.¹⁵³ Another example is the New Bedford Harbor cleanup, which the EPA presents as a series of successful milestones. Nonetheless, the project began before 2000 and remains a work in progress in December 2024.¹⁵⁴ This cross-agency model is simply not working. These projects would be best managed by the Corps, which has the more relevant skill set suited to the sites' dredging requirements and scale.

Eliminate the Superfund tax. The Superfund tax, which initially expired in 1995, was reinstated as part of the 2021 Infrastructure, Investment, and Jobs Act, and came back into force on July 1st, 2022.¹⁵⁵ This tax should be eliminated. It is a tax “imposed on any *taxable chemical* sold or used by a manufacturer, producer, or importer.”¹⁵⁶ Companies that still exist and are responsible for historical releases already bear financial responsibility for their contaminated sites—

this is the crux of the “polluter pays” principle.¹⁵⁷ At the same time, those companies as well as new chemical and refining companies are subject to the Superfund tax. The latter are paying a tax for being in the business of making gasoline and chemicals--not for any connection to actual releases that caused a site to be on the NPL. They are paying for cleanups for which they bear no responsibility.

Worse, many companies that contaminated sites neither pay to remediate nor pay the tax because they no longer exist. Under this tax scheme, the best-behaved companies are forced to bear the costs of the worst-behaved companies. That is not a prudent incentive structure, nor a fair one. The Superfund tax also disadvantages US manufacturers compared to their international rivals and worsens supply shortages for needed chemicals.¹⁵⁸

Allow simple Good Samaritan projects without triggering CERCLA liability. As it currently stands, CERCLA punishes “Good Samaritans” for trying to improve conditions at a contaminated site. Once a Good Samaritan “touches” a site, it becomes a PRP. That is particularly problematic for the thousands of abandoned hard rock mining sites across the West. Many nonprofit organizations have approached the EPA with proposals to clean up segments of a contaminated stream. Their desire to clean up abandoned hard rock mining sites they did not create is laudable. But they face legal liability for the entire scope of contamination even if all they did was improve conditions at one portion of the site. Additionally, the work they do will likely not be sufficient to meet all the requirements of a CERCLA cleanup. Consequently, to avoid potential liability to clean up the entire site, some potential “Good Samaritans” decline to proceed with any improvement works at all—a classic example of the “perfect” being the enemy of the “good.”¹⁵⁹

This prevents reasonable improvement efforts, such as moving overburden (waste from surface mining such as slag leftover from mineral extraction) from a stream bed or covering an area to prevent rainwater from leaching metals out of waste rock piles. Organizations that would otherwise like to clean up and make improvements are unwilling to do so in the face of the legal threat. This is the sort of project that would help ameliorate the conditions that CERCLA exists

to improve. Unfortunately, the law often unintentionally deters efforts to improve such sites.

In January 2024, Senator Martin Heinrich (D-NM) introduced legislation to create a permit system for Good Samaritans to remediate mine residue without threat of liability, S.2781 the Good Samaritan Remediation of Abandoned Hardrock Mines Act of 2024.¹⁶⁰ A House version, H.R. 7779, was introduced by Rep. Celeste Maloy (R-UT).¹⁶¹ The bill passed the Senate in August.¹⁶² Similar legislation has been introduced several times.¹⁶³

Create a separate program for uranium mines on tribal lands. During the early days of nuclear weapons development and during the Cold War, miners extracted a large amount of uranium from tribal lands, especially within the Navajo nation. Miners produced almost 30 million tons of ore from Navajo lands over a 32-year period beginning in the 1940s.¹⁶⁴ Uranium mines on tribal lands pose unique challenges under CERCLA. Due to the slow rate of decay for uranium radiation and the stringent CERCLA guidelines established by the National Oil and Hazardous Substances Pollution Contingency Plan, it will take hundreds to thousands of years to achieve near-zero radiation at those sites.

Because of this, it is often difficult for any progress at all to be made. More than a billion dollars is already set aside to clean up these sites.¹⁶⁵ For many sites, the federal government is the responsible party, and the burden from its poor management has fallen on the tribes that own and live on the land. The EPA has been slow to move on those cleanups. A separate program within CERCLA and the NCP to acknowledge the unique nature of this problem would help people living in those areas gain access to quality drinking water.

Allow buyout of “reopeners” for cleaned up sites. Once remediation is complete, a site can be considered closed (although there may still be long-term monitoring in place) meaning that no further cleanup is required. However, CERCLA judicial consent decrees often contain provisions authorizing the EPA to “reopen” a Superfund site and require additional remediation well after cleanup has been completed, leaving PRPs subject to a lingering long-term liability risk that EPA will require more work to be done at a “closed” site at some point in

the future.¹⁶⁶ That may happen, for example, if the EPA obtains new information about the presence or health risks of certain chemicals at the site. Reopeners are not common but occur often enough to create business risk. With the recent designation of Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as CERCLA hazardous substances,¹⁶⁷ reopeners could happen more frequently.¹⁶⁸

Compounding PRPs' financial risk from reopeners, the EPA interprets CERCLA §122(b)(3) to require that any money collected at a site must only be used for the purpose of cleaning up that site.¹⁶⁹ Consequently, the EPA is not allowed to use money left over from one site to clean up another site. That inflexibility creates an additional future contingent liability for PRPs as the threat of a reopener looms that is very difficult to resolve.

One possible solution to this issue, one that would likely require an amendment to CERCLA §122(b), would be to allow the EPA to accept a buy-out of those reopener provisions and allow the money to go into a pool for use at any site that is brought into the buy-out program rather than limiting the use of the money to a specific site. Over the Superfund program history, only a limited number of sites have been reopened, so the pooling of the monies from multiple sites will provide a cushion, or a form of insurance, as cash collected from sites that are not reopened is available for the handful that are reopened and may have additional costs above the amount collected and contributed to the pool.

Forty years of cleanup efforts should be sufficient data to determine a viable buy-out number. These buy-outs could go into a general fund that would function like insurance. Essentially, responsible parties would buy out their reopeners and the few sites that are eventually reopened are remediated using the pooled reopener money.

Eliminate the PFOA and PFOS designation. In May of 2024, the EPA finalized a rule that designated PFOA and PFOS as hazardous substances under CERCLA.¹⁷⁰ The rule was unprecedented—the first time the EPA used CERCLA §102 to designate a substance as hazardous. The rulemaking failed to consider several factors.¹⁷¹ For example, the rule did not properly account for cost or provide

adequate scientific support that the regulations were “appropriate,” which is a requirement under §102(a).¹⁷²

The biggest problem with the rule though is that CERCLA is simply not the right tool to regulate PFOA and PFOS. CERCLA’s liability regime, which is strict, and joint and several, will pull far more PRPs into the mix than necessary or even useful, subjecting multitudes of sites, both new and reopened, to an avalanche of contribution and cost recovery actions.¹⁷³ Moreover, an adequate treatment or destruction method for those substances has not been properly established. Consequently, designation under CERCLA will create an endless legal quagmire without ameliorating this issue.¹⁷⁴ The EPA possesses, and has used, other legal tools, such as the Safe Drinking Water Act, to address PFAS impacts on drinking water aquifers. The EPA should address PFOA and PFOS risks without designating those substances as hazardous under an untested CERCLA provision.

KEY ISSUE

Reform RCRA

The Resource Conservation and Recovery Act (RCRA) enacted in 1976 established the federal program that regulates the management of solid and hazardous waste. It amended the Solid Waste Disposal Act of 1965 to create a much larger and more specific role for the federal government in handling waste.¹⁷⁵ Specifically, RCRA provides the Environmental Protection Agency (EPA) with authority over hazardous waste, “from cradle to grave,” meaning the generation, transportation, treatment, storage, and disposal of waste are all under the purview of the statute. RCRA also established a high-level framework¹⁷⁶ for the regulation of non-hazardous wastes, including municipal solid wastes.¹⁷⁷ Subsequent amendments expanded RCRA’s scope, stringency, and requirements.

Hazardous and Solid Waste Amendments

The Hazardous and Solid Waste Amendments of 1984¹⁷⁸ effectively required the EPA to phase out the disposal of untreated hazardous wastes in impoundments and landfills. The amendments also created a “corrective action” requirement for facilities that initially filed for a RCRA permit and received interim status, and for RCRA permitted facilities. Corrective action requires facilities to investigate and remediate contamination caused by solid and hazardous waste management activity. In addition, the amendments increased the agency’s enforcement authority, imposed more stringent standards for the management of hazardous waste, and created an underground storage tank program.¹⁷⁹

Superfund Amendments and Reauthorization Act

The Superfund Amendments and Reauthorization Act of 1986, also known as SARA, made further changes to the treatment of underground storage tanks to address leaching from underground storage tanks that hold petroleum and other substances classified as hazardous.¹⁸⁰

E-Manifest program

In 2012, the Hazardous Waste Electronic Manifest Establishment Act authorized the establishment of the e-Manifest program to track the shipment of hazardous waste electronically. The program launched in 2018 and was intended to save money and man-hours compared to the previously paper-intensive process while making information available in a central hub.¹⁸¹ Despite the long wait between authorization and rollout and five additional years of implementation, user errors occur so frequently that the EPA issued a compliance advisory in 2023.¹⁸²

Reuse challenges

Presently under RCRA, it is difficult to reuse many waste substances once they have been discarded. This is especially true for coal ash and other substances with reasonable and well documented reuse cases. It is also an issue for pharmaceutical products that may be able to be either reused or reprocessed.

Although the goal of the law is to encourage resource reuse and recycling and thereby reduce waste, the complicated way the law has been implemented and interpreted frequently makes it difficult to achieve Congress' goal of resource reuse. The following recommendations seek to ease and eliminate those unnecessary complexities and complications.

Recommendations for Congress

Clarify the definition of solid waste. RCRA focuses too much on where material comes from rather than focusing on where it is headed. The current definition of solid waste under RCRA as interpreted by the EPA is subjective and reliant upon assessing the state of mind of the disposer. Material qualifies as “solid waste” if it is discarded by being “abandoned” or “inherently waste-like.”¹⁸³ These concepts are nebulous and leave room for different interpretations that depend to some extent on the disposer’s intentions especially as regards to abandonment.¹⁸⁴ Once something is deemed to be a waste, RCRA requirements take hold and seemingly never let go. This in turn makes it unnecessarily complex to productively use material once the RCRA “solid waste” tag has been affixed to it.

“Sham” recycling,¹⁸⁵ where recycled material is ineffective or only marginally effective for its claimed use, is a legitimate concern. However, current restrictions inhibit many legitimate uses, particularly in a world moving towards a “circular economy” where material is constantly reused and regenerated rather than discarded as waste.¹⁸⁶ The “waste” from one process is the feedstock for another manufacturing process.¹⁸⁷ Manufacturers can be discouraged from reusing “waste” instead of a virgin material as a feedstock if that material is subjected to regulatory requirements or designations that do not apply to the virgin feedstock.

Additionally, the law needs to incorporate the ability to “undispose” material. Disposed materials are currently considered to be waste, in perpetuity. RCRA regulations technically do not regulate the actual act of recycling but regulate the material before it is recycled. Designating the material as waste frequently discourages recycling due to the burdensome regulations that follow the material considered a waste.

The law should be based on objective factors about how material is handled and not rely on an evaluation of intention. For example, if the receiver of the material plans to use it as a raw material in its manufacturing process, then the material should now be regulated as a raw material as it is no longer a waste. Factors to look at could include:

- ▶ The material is stored in a manner similar to other raw materials.
- ▶ The material receives the same accounting treatment as other raw materials.
- ▶ The material, like virgin materials of similar kind, is now subject to other environmental regulations.

Flue gas desulfurization (FGD) gypsum provides an example of a product that, although derived from waste, should not be regulated as waste. As part of the effort to control toxic emissions from coal-fired power plants, Clean Air Act (CAA) regulations required the installation of FGD scrubbers to reduce sulfur dioxide emissions. During this process a sludge is created. Utilities quickly found that with some additional oxidation the sludge could be turned into gypsum of a purity superior to that of mined gypsum. However, since the gypsum

came from a treatment process, the EPA considers this material subject to its waste rules for coal ash, or combustible coal residuals (CCR). Consequently, the RCRA rules follow the material all the way through until it becomes wallboard. In contrast, newly mined gypsum, although inferior in purity, moves through the supply chain with no RCRA waste rules attached.¹⁸⁸

Require regulation of air emissions related to waste management to be addressed under the Clean Air Act. Currently, the EPA has CAA rules that govern solid waste incinerators and RCRA rules that establish control requirements for air emissions associated with waste handling.¹⁸⁹ RCRA should be focused on solid waste management exclusively. The CAA is structured to address air-related emissions from all types of processes including waste handling processes. Rather than covering air emissions under both laws, the CAA—without any RCRA strings—should be the vehicle for governing the emissions from waste management units. That would streamline the regulatory process and consolidate it into one authority. Quite simply, there is nothing unique about air emissions from waste management that the CAA could not handle.

Require all regulation of wastewater discharges to be regulated under the Clean Water Act. Just as the CAA should be the sole source of regulatory controls on air emissions from solid waste landfills and incinerators, so the Clean Water Act (CWA) alone should cover wastewater discharges. To classify them under RCRA is both repetitive, unnecessary, and confusing. Transferring this authority to the CWA exclusively would reduce repetition and ease communication burdens between offices while simplifying the regulatory process.

Allow coal ash reuse as an alternative to current regulation and enforcement. The EPA for many years resisted regulating coal ash under RCRA. In Kingston, Tennessee in 2008 the dike of a large surface impoundment filled with coal ash mixed with water failed sending over 5 million cubic yards of ash into the nearby water system and ultimately to the Emory River channel.¹⁹⁰ The Kingston coal ash pond failure in 2008 eventually culminated in the 2015 coal ash rules. In these rules, the EPA determined to not regulate coal ash as a RCRA hazardous waste under subtitle C, but the final regulations are so

stringent that some requirements as implemented by the EPA exceed the hazardous waste handling requirements.

Recognize benefits of coal ash. There are many useful applications for coal ash, as the EPA acknowledges.¹⁹¹ For example, fly ash from coal combustion may be used to strengthen concrete, and FGD gypsum may substitute for mined gypsum to make wallboard (sometimes also referred to as gypsum board). About 12.6 million tons of the concrete and 7.6 million tons of the wallboard products are made in this fashion each year, making up a small, but not insignificant portion of the market for these products.¹⁹²

However, when EPA finalized its RCRA rules in 2015, it placed restrictions on some beneficial reuses of coal ash thus creating a barrier to the potential re-use of coal ash in certain circumstances and casting a cloud of regulatory uncertainty over other reuses. RCRA rules should be limited to regulating wastes not beneficial uses. Were a simpler regulatory regime for coal ash reuse established, those uses could be expanded, and others could be added in a manner that both protects the environment and conserves resources. Without clear statutory protection for all beneficial uses, coal ash will end up in long-term storage in a landfill or closed impoundment rather than in productive use.

Make it easier to reuse coal ash. The challenges with coal ash epitomize the inability of RCRA, as administered by the EPA, to effectively create a regulatory regime for material reuse and recycling. For the most part, under RCRA as implemented, certain reuse and recycling activities are permitted by way of exempting those activities. An alternative approach would be, for example, if the EPA, the Department of Transportation and the Department of Energy could coordinate in rulemaking as they do on other rules to certify coal ash management standards that states could implement for reuse in applications such as road material, building material, and a source of critical minerals. Once a coal ash source is designated for reuse, it can be removed from RCRA regulation, and the regulation can be left to the states. State regulation would still cover failure to reuse the ash as promised and other possible misuse situations. This would both lower

the burden of RCRA enforcement and allow the material to go to a useful purpose.

Remove reverse distribution from RCRA and support the circular economy. Pharmacies use the services of reverse distributors to return unsold or non-saleable pharmaceutical products to the manufacturer, wholesaler, or waste disposal facility.¹⁹³ Some products that are beyond their expiration date and can no longer be sold in the US can still legally be sold in other markets. Since the product still has economic value in another market, it should be treated the same as any other pharmaceutical in international trade rather than as a waste requiring disposal under RCRA rules.

Moreover, the Food and Drug Administration (FDA) also regulates reverse distributors and can handle redistribution to foreign markets, because pharmaceuticals are not industrial process wastes. Allowing such products to move to those markets reduces waste disposal and benefits consumers. If there are no other markets available for the expired products, then pharmacies and other drug sellers would need to discard the material per applicable RCRA rules. But RCRA need not be applied to both situations.

Eliminate land disposal restrictions. Land disposal restrictions impose technology-based, not health-based, standards on the disposal of RCRA hazardous waste, including the residues from the treatment of hazardous waste; they effectively ban the disposal of untreated RCRA wastes on land.¹⁹⁴ Although in theory intended to prevent additional releases of hazardous materials, land disposal restrictions often result in less optimal modes of disposal that can appear to be treatment for the sake of treatment and not for any measurable environmental benefit. Such restrictions implicitly favor incineration as a disposal method, even when wastes already meet health-based exposure limits and toxic air emissions from incineration could cause harm to health or the environment. Disposal restrictions can also impede recycling, making it more difficult to dispose of incinerator wastes, such as ash containing toxic metals.

Another element of the land disposal restriction that often poses problems is the dilution prohibition that forbids waste handlers from diluting wastes to meet treatment standards.¹⁹⁵ That is, simply

adding water or another material to a waste to make it less toxic is not considered to be a treatment under the law. But in many cases, dilution is a cost-effective way to reduce toxicity to below hazardous levels. Forbidding this option in all cases is unwise.

Repeal and replace the e-Manifest law with a real electronic manifest system and not allow the EPA to create it. When Congress passed the Hazardous Waste Electronic Manifest System law in 2012, it surely did not envision years of inefficiency. To comply, users continue to submit paper manifests produced only by EPA-approved printers, and manually enter data on PDFs prior to submitting to the database.

Rather than use a system of their own creation, the EPA should defer to a more well-developed technology to allow speed, accuracy, and ease of use. Many companies in the technology space could create a system that would be both more user-friendly and more secure than the system currently used by the EPA. Many shipping companies including UPS and FedEx use such systems. FedEx in particular uses location tracking chips for its most sensitive packages. The technology, called SenseAware, provides specific information about the package's location, temperature, and other metrics.¹⁹⁶ Utilizing a system of this kind, providing some additional features and security measures, would better fulfill the aims of the eManifest program.

Conclusion

Americans should rightfully expect to live their lives without having to worry about genuine threats to their well-being from chemicals and hazardous substances. The EPA helps to address these threats. However, the agency also has a history of overstating risk and not using the best science to make decisions. Being too risk-averse can itself cause major harm, such as by limiting the use of chemicals that would improve the overall well-being of the public or that would result in industry using alternative products that are more problematic than what they replace.

A modernized EPA would properly assess risk and science. It would recognize that there are costs and tradeoffs that must inform its regulatory decision-making. Americans should expect thoughtful regulation and to be protected from genuine harms. At the same time, they should also expect that the agency will not promulgate regulations that are far broader and sweeping than what is necessary. The latter of which itself can also create genuine harms. The EPA faces a challenge in identifying when regulation is appropriate and the proper scope of regulation for issues like chemicals and hazardous substances. However, by being committed to careful and thoughtful consideration of risk and costs as well as the objective review of the best available science, the EPA will go a long way to meeting this challenge.

