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The Complete Compliance and Ethics Manual 2023
Environmental Law and Compliance

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I. Introduction and Overview

Unique Aspects and Challenges of Environmental Liabilities and Risks

Over the past 40 years, the scope of environmental law has continued to expand to reach almost every company and regulated industry. In this unique field, liabilities abound, as do opportunities for dedicated compliance professionals who are willing to keep up with the evolving changes. Depending on the company and its operations, environmental compliance can encompass the well-known and traditional challenges of regulating industrial wastewater discharges, controlling toxic air emissions, or managing hazardous wastes—as well as the lesser-known liability risks arising from adversely affecting endangered species or development projects near wetlands, among others. By way of example, from 2017 to 2020, United States Environmental Protection Agency (EPA) enforcement and compliance efforts led to advancement of cleanups and redevelopment of more than 415 Superfund sites, investments of more than $32.27 billion to achieve compliance with environmental and pollution laws, and the charging of 486 criminal defendants.[2] And that is only the federal level of environmental enforcement.

While environmental compliance is a complex field, this article is designed to serve as a primer and provide a general introduction. When facing environmental legal or regulatory issues, all compliance professionals should work closely with, and rely upon, the guidance, advice, and direction of experienced counsel. This article does not constitute legal advice but will assist non-lawyers with an overview of some of the common statutes, concepts, terms, and issues that are likely to arise in corporate environmental disputes. EPA's website often provides general and detailed information for its regulatory programs that can be very helpful to interested parties.

After this introduction, **Part II** of this article provides an overview of the most common statutory and regulatory programs. **Part III** then shifts from the substantive rules to the "process" by discussing the different venues where environmental disputes can arise and the different parties who may bring claims. Finally, **Part IV** discusses what every company should have in place: An environmental compliance plan. Part IV explains the core components of environmental compliance plans and other tools professionals in this field can use to prevent, detect, and respond to the most common corporate environmental risks. It also discusses EPA's Audit Policy and the benefits of discovering and voluntarily disclosing regulatory violations to EPA in terms of reduced penalties and goodwill in the event of civil or criminal investigations into significant violations.

In an era of enhanced environmental enforcement and high-stakes civil liabilities, the value and importance of corporate environmental programs are paramount to prevent violations and reduce their likelihood; to reduce cleanup costs or fines and penalties, as well as to influence the broad enforcement discretion of the regulators and prosecutors; and of course to protect the environment and a corporation's business reputation. In short, effective environmental compliance can help greatly reduce risks while also adding value to a corporation.

Federal and State Interplay Through Delegated Programs

Because compliance officers with environmental responsibilities will interact with local, state, and federal agencies, it is important to understand the interplay and interconnections between the federal and state laws and regulations.

The EPA is the federal agency charged with administering and enforcing federal environmental laws. EPA's national headquarters are in Washington, DC, but it has regional offices (split up into 10 regions) throughout the country that oversee various regulatory and enforcement activities.

Each state has its own environmental regulatory agency. These agencies also play an important role in environmental law because EPA delegates (or transfers) the administration of many of the most important federal environmental laws to the states. Many of the federal statutes governing air, water, and solid and hazardous wastes allow for some amount of state implementation while others, such as the Federal Insecticide, Fungicide, and Rodenticide Act, (the law governing the use of pesticides) only authorize EPA to implement and enforce them. For the former statutes, states can seek "primacy"—or program "delegation"—which means that the state will have the lead role in running the program. However, to obtain such delegation, the states must meet certain minimum requirements. In particular, states must convince EPA that they have adopted adequate laws and regulations to meet minimum federal standards, and that they have sufficient funding and other resources to administer and enforce the laws properly.

EPA has an ongoing obligation to monitor the delegated programs to ensure that the state programs continue to meet federal standards. In some cases, EPA may not approve certain elements of the states' programs, and in such cases, EPA itself will administer those components of the state programs rather than fully withdrawing the state's delegated authority. Regardless of whether EPA or the state has the authority to issue environmental permits and approvals for a particular program, both EPA and the state have legal authority to bring enforcement actions.

II. Major Statutory and Regulatory Programs (Overview, Elements, Common Violations, and Defenses)

Clean Water Act

Overview

The Clean Water Act (CWA) was enacted in 1972 to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[3] As the primary federal statute regulating the protection of the "waters of the United States," the CWA established national programs for prevention, reduction, and elimination of pollution in water, including a water quality standards program, a permit program for discharge and treatment of wastewater and storm water, a permitting program for discharge of dredge and fill materials, and an oil pollution prevention program.

Under Section 301 of the CWA,[4] the discharge of any pollutant into the waters of the United States is unlawful unless authorized by a permit. Thus, the heart of the CWA is its two permitting programs. First, the National Pollution Discharge Elimination System (NPDES) permit program and pretreatment programs, implemented by the EPA and/or the states, regulate wastewater discharges, depending on whether the discharge is direct or indirect. Second, the Section 404 permitting program, implemented by the U.S. Army Corps of Engineers, separately regulates discharges (i.e., disposal) of dredged or fill material into waters of the United States.

The scope of the fundamental term "waters of the United States" (WOTUS) remains a contentious subject. The term has historically been interpreted broadly to include wetlands and streams connected to navigable waters.

After a string of U.S. Supreme Court cases on the topic,[5] EPA promulgated a new rule in 2015 redefining the term (2015 WOTUS Rule).[6] In 2018, EPA issued a new rule (2018 WOTUS Rule) delaying the effective date of the 2015 WOTUS Rule,[7] and in January 2020, the EPA and the U.S. Army Corps of Engineers finalized a new rule redefining the term again (2020 WOTUS Rule).[8] The new definition took effect in June 2020, subject to a variety of challenges by states and non-governmental organizations in multiple state and federal courts.[9] Furthermore, in June 2021, EPA and the Department of the Army announced their intention to initiate a new rulemaking process that would revert to the pre-2015 regulatory status.[10] Depending on the outcome of these challenges and rulemaking process, this will continue to be an area in significant flux. Companies with a stake in the definition should stay abreast of new legal developments in this area.

Wastewater Discharges

The NPDES permit program requires all parties to have a permit for all discharges of pollutants into jurisdictional waters from "point sources," which are defined as any "discernible, confined and discrete conveyance." Pollutants that enter surface waters without passing through a "point source" are considered "non-point source" pollution. EPA's Nonpoint Source Management Program leaves nonpoint source pollution to states, with EPA playing a supporting role.

Courts have at times wrestled with the distinction between point and nonpoint source pollution, particularly with regard to whether pollution conveyed to surface waters through groundwater is subject to the CWA's permitting requirements. In April 2020, the U.S. Supreme Court provided greater clarity on this issue, ruling in *County of Maui v. Hawai'i Wildlife Fund*[11] that the CWA's NPDES permit requirement can apply to certain releases of pollutants that reach surface water through groundwater. The Court established a new "functional equivalence" test, holding that the CWA requires NPDES permits "when there is a direct discharge from a point source into navigable waters or when there is the functional equivalent of a direct discharge."[12] Given the novelty of this test, which was not proposed by either of the parties, regulated entities should anticipate continued uncertainty in this area, as further EPA guidance, rulemaking, and litigation will determine what releases are the "functional equivalent" of a direct discharge, and therefore require a permit.

NPDES permits are issued by the EPA, or by individual states where the state has developed and received EPA approval of a permitting program equivalent to that established under the federal statute. The CWA defines the term "pollutant" very broadly when used in the NPDES program to include dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, and agricultural waste discharged into water. There is no *de minimis* level below which the discharge of a pollutant is not subject to the permitting requirement.

An NPDES permit requires compliance with the more stringent of technology-based and water quality-based requirements for each pollutant addressed. For many industries, the EPA has promulgated effluent limitation guidelines that establish technology-based requirements applicable to the industrial category (e.g., paper making, metal finishing), and these are written into NPDES permits. For industries and activities not yet covered by effluent limitation guidelines, NPDES permit writers establish technology-based effluent limits based upon their "best professional judgment."[13]

Water quality standards are distinct from the technology-based requirements and are governed by CWA Section 303.[14] Water quality standards are specific to particular bodies of water and are determined by the state, or if the state fails to act, by the EPA. EPA also publishes its own water quality criteria, which are recommended water

quality values for states and tribes to adopt as water quality standards. To develop water quality standards, the water body is first assigned a designated use or uses (e.g., drinking water, recreation, cold water fishery). Then, numeric ambient concentrations of pollutants sufficient to protect and sustain those uses are established. These numeric values are known as water quality criteria. The water quality standards also may be expressed in narrative form. These standards will additionally reflect a state's antidegradation policy, which requires certain water qualities to be maintained and protected.[15] Regardless of whether they are numeric or narrative, all water quality standards applicable to a given water body must be satisfied by all permits issued for discharges into those waters.

Under Section 303(d),[16] authorized states are required to produce a list of the water bodies in the state that are not expected to meet their water quality standards after the implementation of applicable technology-based standards. These are termed "impaired waters," and the state must produce Total Maximum Daily Loads (TMDLs) for all water bodies designated as such.[17] TMDLs are a numerical expression of the maximum level of a pollutant loading that a water body can absorb and still meet water quality standards. TMDLs are not directly enforceable against dischargers, but are the basis for "waste load allocations" to individual dischargers that must be included and are enforceable through the dischargers' NPDES permits.

Pretreatment Standards

In addition to being subject to the NPDES permit program, publicly owned treatment works (POTWs) are also regulated by national and local pretreatment standards.[18] The general pretreatment standards establish responsibilities for federal, state, and local government; industry; and the public to implement pretreatment standards to control pollutants that pass through or interfere with POTW treatment processes or that can contaminate sewage sludge. The general pretreatment standards apply to all nondomestic sources that introduce pollutants into a POTW. These sources of indirect discharges are more commonly referred to as "industrial users."

POTWs establish local pretreatment programs to control discharges from nondomestic sources. If a POTW accepted prohibited pollutants, it could result in (i) killing the POTW's microbial treatment system, (ii) discharge of untreated wastewater because of a failure to react to the microbial system in place, or (iii) discharge of biosolids instead of proper disposal. Applicable pretreatment standards and general/specific prohibitions are nominally self-implementing, requiring a POTW to comply even without permit. Local limits, however, are only applicable if incorporated into the permit.

Section 404 Dredge and Fill Permits

The CWA dictates that the discharge of dredge or fill material into waters of the United States requires a permit from the Army Corps of Engineers.[19] Though the Corps has primary authority over the Section 404 program, EPA has authority to review and object to permits. The Section 404 permitting program has been extremely contentious in recent years given the controversy regarding the standards for defining "waters of the United States" and, thus, what dredge and fill activities require a Section 404 permit.[20]

Common CWA Violations

The following are some of the most common CWA violations:

- Discharge without a permit

- Discharge in violation of permit terms, including:
    - Numeric effluent limitations
    - Narrative effluent limitations
    - Failure to develop or implement required pollution prevention measures, especially with respect to NPDES storm water permits
- Submission of false reports or certifications

Defenses to CWA Liability

Under the act's "permit shield" defense,[21] a permitted facility that discharges pollutants into jurisdictional waters in compliance with the terms and conditions of its permit is shielded from enforcement actions and citizen suits. This defense is subject to certain qualifications, however; so one should seek advice from qualified counsel to understand the specifics of any given situation. There are additional defenses, common to other statutes, that are discussed in the enforcement section (Part III).

Clean Air Act

Overview

The Clean Air Act[22] (CAA) is a federal pollution control statute designed to protect and restore the quality of the nation's air to promote public health and the environment. Congress first enacted the act in its modern form in 1970 as amendments to prior air pollution statutes and further amended the act in 1990. Generally, the act regulates air emissions from both stationary and mobile sources. The CAA is composed of five main sections (commonly known as Titles). This section will focus on Titles I, V, and VI, which are the most likely to impose substantive requirements on industrial facilities, and will provide generally applicable information on administration and enforcement of the act. Titles II, III, and IV, which we do not discuss here, address—respectively—mobile sources, CAA general provisions, and noise pollution and the acid rain trading program.

Title I

Title I[23] covers stationary sources, and includes the national ambient air quality standards (NAAQS), new source performance standards (NSPS), and National Emissions Standards for Hazardous Air Pollutants (NESHAP) programs. The NAAQS establish overall air pollution standards for the ambient air, while the NSPS and NESHAP rules apply to individual sources. Title I also includes the New Source Review (NSR) and Prevention of Significant Deterioration (PSD) preconstruction permitting program, which is distinct from the Title V operating permit program discussed below.

The NAAQS program, often considered the centerpiece of CAA regulation, directs EPA to establish primary and secondary air pollution standards for "criteria pollutants."[24] Currently, standards have been established for six criteria pollutants under this program: sulfur dioxide, nitrogen dioxide, particulate matter, carbon monoxide, ozone, and lead. Under the NAAQS program, EPA sets standards based on the best available science, and states develop implementation plans designed to achieve compliance with federal standards. The state implementation plans (SIPs) become federally enforceable obligations after EPA approval. States are divided into areas designated as attainment, nonattainment, and unclassifiable based on their compliance with the NAAQS.[25] More stringent standards apply in nonattainment areas.

The NSR program requires preconstruction permits for new or modified stationary sources (both "major" and "minor") in order to protect air quality and maintain or achieve NAAQS. In attainment or unclassifiable areas, major sources must also obtain a permit under the PSD program. The PSD program is designed to prevent the deterioration of air quality by setting emissions limits according to the "best available control technology" (BACT), which is determined on a case-by-case basis and requires consideration of energy, environmental, and economic factors. In nonattainment areas, the nonattainment NSR program is designed to achieve NAAQS by setting emissions limits for major sources according to "lowest achievable emission rate" technology, which is typically more stringent than BACT.[26] On November 24, 2020, EPA published a final rule that changes how facilities can calculate their emissions when assessing permitting requirements under the NSR program.[27] Under the rule, facilities are able to include emissions decreases as well as increases when assessing NSR applicability for a particular project. This "netting" of emissions will help some facilities avoid triggering NSR requirements.

Separately, the NSPS are source categories identified by EPA that contribute significantly to air pollution, and the program sets minimum standards to serve as the floor for any new or modified source in that category. EPA has currently identified and set standards for more than 60 source categories of stationary sources, primarily large industrial sources of air pollutants.

Under the NESHAP program,[28] EPA promulgates regulations establishing emissions standards for hazardous air pollutant (HAP) emissions from new and modified "major" and "area" sources (meaning, any nonmajor source) in specific categories. NESHAP also sets standards for existing sources, requiring such sources to achieve the average emissions of the top-performing 12% of sources in the same source category. In setting these standards, EPA determines the maximum degree of emissions reductions achievable for each category and subcategory based on the most stringent level achieved in practice by the best-controlled sources for each of the categories, i.e., the "maximum achievable control technology." Under the NESHAP program, EPA currently regulates 187 HAPs from major and area sources. The original list of HAPs included 189 pollutants, but EPA has modified the list through rulemaking to include 187 pollutants.[29]

Title V

Title V[30] contains the act's comprehensive operating permit program, which consolidates all applicable regulations into one document specific to each source regulated under the act. Sources required to obtain a Title V permit include all major sources, affected sources, sources subject to Section 111, major or area sources subject to regulation under Section 112 for HAPs, sources required to obtain a new source or modification permit, and other sources designated by the EPA under the act.[31] The Title V permit program is an independent requirement in addition to preconstruction permit requirements and other requirements already in place under the PSD program or NSR. Title V also includes monitoring provisions, which allow EPA to require that permits include periodic monitoring sufficient to ensure compliance. Sources are required to certify compliance at the end of the year and submit semiannual deviation reporting.

Title VI

Title VI[32] implements various programs to protect the stratospheric ozone layer. It provides for the phasing out of certain ozone-depleting substances (ODS), imposes labeling requirements for some products containing ODS, bans the import of certain products containing ODS, and implements various regulatory requirements for bulk imports of ODS. Title VI also establishes requirements regarding the use and disposal of ODS during the servicing of motor vehicle air conditioners[33] and during the servicing, repair, or disposal of appliances and industrial

process refrigeration.[34]

Administration

Though the CAA is a federal statute primarily enforced by the EPA, the act relies on a structure of delegated federalism that allows states to administer all of the CAA's major air quality programs. In addition to crafting SIPs to ensure state compliance with NAAQS, states also implement PSD preconstruction and Title V permitting programs after EPA determines that each state's program meets federal standards.

Submitting PSD and Title V permit applications is often a time-consuming and complex process requiring extensive engagement with state regulatory agencies. For Title V permits, each regulated source must submit a timely permit application in accordance with EPA regulations within 12 months of becoming subject to a permit program.[35]

Primary Violations and Penalties

Like most other federal environmental statutes, the CAA empowers EPA to seek administrative,[36] civil,[37] or criminal[38] penalties from regulated entities for violations of the act, and allows citizens to supplement EPA enforcement by initiating private citizen suits against regulated entities seeking penalties or injunctions for noncompliance with the act.[39] EPA can also seek compliance orders or injunctions. EPA's Air Enforcement website[40] provides more detailed and specific guidance regarding enforcement priorities and obligations imposed on specific source categories. Further discussion can be found later in Part III: The Process—Enforcement Actions & Litigation.

Common CAA Violations

The following are some of the most common CAA violations:

- Emissions without a permit
- Violating CAA permit terms, including:
    - Emissions above limits
    - Installing new equipment without permit modifications
    - Not properly operating emission control equipment
- Failure to accurately track emissions
- Violating a NSPS or NESHAP
- Submission of false reports or certifications

Defenses to CAA Liability

Under the Title V permit shield defense, a permitted facility in compliance with the terms and conditions of its permit is automatically deemed in compliance with all of the statutory and regulatory provisions pursuant to which the permit was issued. Although regulated facilities historically could take advantage of affirmative defenses for "upsets" during start-up, shutdown, and maintenance (SSM) and during emergencies, recent case

law and regulations have eliminated or severely limited use of this defense.[41] There are additional defenses, common to other statutes, that are discussed in the enforcement section (Part III).

Resource Conservation and Recovery Act—Hazardous Waste Management

Overview

The Resource Conservation and Recovery Act (RCRA) was enacted by Congress to promote the proper management of solid and hazardous wastes. The primary goals of RCRA are to protect human health and the environment from the potential hazards of waste disposal, to promote environmentally sound recycling that conserves energy and natural resources, and to reduce the amount of waste generated in the first instance. Subtitle C of the act, which is the focus of this section, covers all phases of hazardous waste management, including generation, transport, and treatment, storage, and disposal (TSD). However, it is important to check for relevant state statutes and regulations, because virtually all states are authorized to implement their own hazardous waste programs in lieu of substantial portions of the federal RCRA program.[42] In some instances, the state programs are broader in scope and/or more stringent.

Solid Waste

In order for material to be classified and regulated as hazardous waste, it must first qualify as solid waste. Under RCRA, "solid waste" is defined as:

> garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 1342 of title 33, or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended.[43]

For purposes of the hazardous waste regulatory program, EPA has promulgated a somewhat narrower definition of solid waste, which covers any discarded material—including recycled material in some instances—that is not specifically excluded by another regulation.[44] There are a number of items that are excluded from the EPA's definition of solid waste.[45] Additionally, the universal waste regulations apply to management of batteries, pesticides, mercury-containing equipment, and lamps.[46]

Hazardous Waste

RCRA defines "hazardous waste" as:

> a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may (A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.[47]

The RCRA hazardous waste regulatory program applies only to hazardous wastes that either (1) meet one or more of four characteristics (ignitability, corrosivity, reactivity, toxicity)[48] or (2) are specifically listed in EPA's list of hazardous wastes.[49]

Note that EPA has explicitly excluded a number of solid wastes from the "hazardous waste" classification.[50]

Hazardous Waste Lists. EPA has created four lists of hazardous wastes, and any waste included on one of these lists is automatically deemed hazardous and subject to regulation. The first list describes hazardous wastes from nonspecific sources.[51] The second list relates to hazardous wastes from specific sources.[52] The third and fourth lists describe discarded commercial chemical products.[53] Regulation can be triggered under the third list when, for example, a company decides to discard a listed chemical product in its natural form, or when there is a spill of one of the listed chemicals. A company should compare its waste with the ones listed to determine whether it is handling a hazardous waste.[54] Notably, generators have the ability to prepare a petition to exclude or "delist" a particular facility's waste from hazardous waste regulations if the waste does not possess dangerous properties.[55]

Hazardous Waste Characteristics. If a waste is not included on one of the hazardous waste lists, it can still be considered a hazardous waste if a "representative sample" has any of the following characteristics:[56]

- Ignitability[57]
- Corrosivity[58]
- Reactivity[59]
- Toxicity[60]

Mixing Hazardous and Solid Wastes. If a hazardous waste that is included on one of the four lists is mixed with a solid waste, the resulting mixture is considered a hazardous waste, unless it qualifies for an exemption. However, if a characteristic hazardous waste is mixed with a solid waste, the resulting mixture will only be deemed hazardous if the mixture exhibits any of the four hazardous characteristics.[61]

Requirements for Generators of Hazardous Waste

A "generator" is defined as "any person, by site, whose act or process produces hazardous waste identified or listed in [40 C.F.R. § 261] … or whose act first causes a hazardous waste to become subject to regulation."[62] A generator is charged with initially determining, based on the criteria discussed above, whether the waste that is generated is a hazardous waste.[63]

The amount of hazardous waste and status of the generator (namely, large- vs. small-quantity generators) determines the amount of time that generators may store hazardous waste on-site without a separate permit.[64]

Requirements for Transporters of Hazardous Waste

A "transporter" is any person "engaged in the offsite transportation of hazardous waste by air, rail, highway, or water."[65] Any person who moves hazardous waste off the site where it is generated or the treatment, storage,

and disposal site must comply with the requirements for transporters, which are found at 40 C.F.R. § 263. The regulations promulgated by EPA regarding transporters of hazardous waste largely mirror those issued by the DOT under the Hazardous Materials Transportation Act.

The bulk of the regulations governing transporters concerns manifesting the waste and maintaining proper records, as well as the responsibility of the transporters to clean up spills.[66] In limited circumstances, transporters carrying wastes from small-scale generators are exempt from these regulations but still have to follow certain requirements.[67]

Requirements for TSD Facilities

A "treatment" facility is one that uses:

any method, technique, or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste, or so as to recover energy or material resources from the waste, or so as to render such waste non-hazardous, or less hazardous; safer to transport, store, or dispose of; or amenable for recovery, amenable for storage, or reduced in volume.[68]

A "storage" facility is one that engages in "the holding of hazardous waste for a temporary period, at the end of which the hazardous waste is treated, disposed of, or stored elsewhere." A "disposal" facility is "a facility or a part of a facility at which hazardous waste is intentionally placed into or on any land or water, and at which waste will remain after closure." A number of different TSD facilities are exempted from compliance with the regulations.[69]

TSD facility operations are governed by regulations that address waste manifesting, record keeping, security measures, personnel training, safety, emergency planning, financial assurance for proper closure and post-closure measures, and operations of a variety of treatment and disposal facilities, including incinerators, surface impoundments, landfills, etc.[70] Consult the regulations to see whether one of your facilities has specific regulations that must be followed.

Additionally, certain hazardous wastes are restricted from land disposal or are required to meet certain treatment standards before being placed on land, so consultation of regulations to determine whether your facility handles those wastes is important.[71] These restrictions could impose several other important requirements, such as a dilution prohibition and more paperwork requirements.

Corrective Action (i.e., Remediation of RCRA Facilities)

In 1984, Congress amended RCRA to require all RCRA-permitted facilities to identify and perform corrective action for all releases of hazardous waste or hazardous constituents from all current or past solid waste management units (SWMUs).[72] RCRA permittees generally have a continuing obligation to report all known releases of hazardous waste or constituents from SWMUs at their facilities.[73] The three major stages of RCRA corrective action are:[74]

RCRA Facility Assessment (RFA). RFAs are preliminary reviews of existing documentation and, if necessary, an on-site inspection of a facility. They are designed to identify all SWMUs and all potential releases of hazardous waste or hazardous constituents from SWMUs.

RCRA Facility Investigation (RFI). RFIs are comprehensive on-site investigations and evaluations of the nature

and extent of all potential releases of hazardous waste and constituents at a facility. The data and analysis generated by RFIs inform the Corrective Measures Study.

Corrective Measure Study (CMS) and Implementation. CMSs evaluate the need for corrective measures, describe and analyze alternative corrective measures, and then recommend final corrective measures, which may include remediation, containment, institutional controls, or monitoring.[75]

Notably, the RCRA corrective action program was designed to mirror the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remediation scheme promulgated in the national contingency plan (NCP).[76] CERCLA is a federal statute designed to identify, investigate, and respond to all releases of hazardous substances that threaten human health or the environment. CERCLA is discussed later in Part II. The three stages in CERCLA remedial actions that correspond to the three stages in RCRA corrective action are:

1. Site evaluation,
2. Remedial investigation and feasibility study (RI/FS), and
3. Remedial design and remedial action (RD/RA).

Common RCRA Violations

The following are some common RCRA violations involving hazardous wastes:

- Failure to make a proper determination of whether wastes are hazardous;
- Storage of hazardous wastes by generators for longer than 90 days (or the longer limits for small-scale generators);
- Treating, storing, or disposing of hazardous wastes without a required TSD permit;
- Failure to comply with the applicable design and operating standards for the units used to manage hazardous wastes;
- Improper consolidation or mixing of hazardous wastes;
- Record keeping and reporting violations, including failure to comply with the requirements for hazardous waste manifests; and
- Submitting false reports or certifications.

Defenses to RCRA Liability

- Under RCRA's permit shield defense, a permitted facility in compliance with the terms and conditions of its permit is deemed in compliance with RCRA Subtitle C; however, the facility must also comply with certain other provisions as applicable.[77]
- Under RCRA's nonduplication provision, RCRA shall not apply to any activity or substance subject to the CWA; the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act; and the Atomic Energy Act, except to the extent the application of RCRA is "not inconsistent" with the requirements of such acts.[78] This provision has been used to bar application of RCRA to activities already governed by the

CWA and the Safe Drinking Water Act.

- Finally, there are additional defenses, common to other statutes, that are discussed in the enforcement section (Part III).

Basel Convention (International Regulation of Hazardous Waste)

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (Basel Convention) was adopted by the Parties to the Convention in March 1989 and entered into force in 1992 in response to the toxic wastes from abroad being imported to and dumped in various developing countries.[79] The purpose of the Basel Convention is to reduce the transport of hazardous wastes and "other wastes" as defined by the convention (hazardous and other wastes) between nations, especially where waste is transported to developing countries or without the consent of the receiving nation.[80] The Basel Convention seeks to reduce the amount and toxicity of hazardous wastes produced while also encouraging waste disposal in the nation of generation using environmentally sound and efficient management, reducing health and environmental risks.[81]

The Basel Convention establishes restrictions and prohibitions on certain shipments of hazardous and other wastes. The Convention's annexes provide lists of wastes that are presumptively hazardous, presumptively nonhazardous, and "other" wastes, as well as lists of hazardous constituents, streams, and characteristics.[82] Hazardous wastes generally include certain electronic waste, persistent organic pollutants, and other hazardous wastes that are considered explosive, flammable, toxic, or corrosive. Shipments of hazardous and other wastes require prior notice and consent and are prohibited if they are between a party and a non-party, unless the countries have a separate agreement. The Basel Convention does not prevent a party from imposing additional requirements consistent with the convention and international law such that looking at additional national laws may be important depending on the geographic context.[83] Parties to the Basel Convention have a number of treaty obligations, including reporting obligations, national action obligations, and obligations to other parties. Corporations that sell, transport, distribute, or receive hazardous waste abroad must consider the implications of the Basel Convention in their practice.

CERCLA or 'Superfund'

Overview

History. CERCLA[84] was enacted in 1980 to address abandoned sites contaminated by releases of hazardous substances. CERCLA imposes a broad liability scheme that applies retroactively. Therefore, the government may compel the investigation and cleanup of hazardous substances released before 1980, even if the hazardous substances were disposed of legally at the time. In addition, CERCLA's "strict liability" standard means that a party may be held liable even if not found to be negligent.

CERCLA case law imposes "joint and several" liability, pursuant to which a party that contributed only a small percent of the contamination may still be held liable for the full cost of cleanup.[85] In addition to liability for investigation and cleanup costs, CERCLA also imposes liability for natural resource damages (NRD), with which trustee agencies at the state or federal level implement projects to restore damaged natural areas.[86] The purpose of the NRD program is to compensate the public for damages to ecological and recreational services, both past and future.

CERCLA is frequently referred to as Superfund because it originally established a trust fund called the Superfund.

The fund allowed the EPA to respond to serious threats to human health and the environment at contaminated sites or in emergencies, after which EPA would seek reimbursement for the fund from liable parties. Congress has not reauthorized the taxes used to maintain the Superfund. As a result, it is generally EPA's policy to have potentially responsible parties (PRPs) perform or pay for response actions.

Potentially Responsible Parties

The strict liability scheme under CERCLA names four classes of PRPs that are generally liable for "response costs" (i.e., investigation and cleanup costs) and NRD:

1. The current owner or operator of a facility,
2. The owner or operator of a facility at the time of the disposal of any hazardous substance,
3. Any person who arranged for disposal or treatment of hazardous substances at a facility, and
4. Any person who transports hazardous substances to a facility selected by that person.[87]

Under common law principles of corporate law, a party may be held liable for the actions of its subsidiary, parent, or sister corporation if either the corporate veil can be pierced or the party exercised direct control over its corporate affiliate's hazardous waste management operations.[88] Additionally, in certain circumstances, successor companies can be held liable for the actions of their predecessors. Defenses to liability are discussed below.

Removal Actions and Remedial Actions

CERCLA and its regulatory scheme governing cleanups, the National Contingency Plan (NCP),[89] divide all response costs into two categories: removal actions and remedial actions. The NCP has been described as the government's "toxic waste playbook," detailing the steps that must be taken "to identify, evaluate, and respond to hazardous substances in the environment." Any party wishing to recover costs under Section 107(a) must substantially comply with this NCP playbook. Removal actions are generally short-term responses to mitigate the effects of pollution that requires immediate action; they also include all investigation costs.[90] On the other hand, remedial actions are generally long-term responses that aim to permanently remediate or contain contamination at its source across an entire facility.[91] The distinction between the two is significant because different NCP procedures and standards apply to each category of response action and because different statutes of limitations apply to each.

Superfund Enforcement

EPA generally has two enforcement tools: It may order PRPs to investigate and clean up a facility pursuant to a Section 106 unilateral administrative order (UAO),[92] or it may investigate and clean up a site and then seek reimbursement from PRPs for all response costs. Unless there is an emergency requiring immediate action, EPA generally identifies PRPs, issues liability notices to them, and attempts to negotiate a cleanup by those PRPs before resorting to a UAO.

If a party is issued a UAO, the party has three general options. It may enter a consent decree with EPA and then seek contribution from other PRPs, including the United States if appropriate. It may simply comply with the UAO and then sue all PRPs for reimbursement during or after the cleanup. Or it may choose not to comply with the UAO. If EPA seeks penalties in court, the party may defend itself by arguing there was "sufficient cause" for

noncompliance (i.e., an objectively reasonable basis to believe that the party was not liable or that the response action was arbitrary and capricious).[93] Failure to comply with a Section 106 order, however, may result in penalties of up to $59,017 per day, as well as treble damages for the amount EPA spends as a result of the party's noncompliance.[94]

Cost Recovery and Contribution Claims by Private Parties

Private parties may not sue other parties to compel cleanup under CERCLA. However, Section 107(a)(4) allows private parties that voluntarily investigate and clean up a site to recover costs from other PRPs.[95] In addition, a private PRP may bring a contribution claim against other PRPs under Section 113(f)(1) if the PRP has resolved its liability in an administrative or judicially approved settlement, or if it is sued under Section 106 or Section 107. As clarified in the May 2021 U.S. Supreme Court case, *Guam v. United States*, a settlement must by its terms resolve CERCLA liability to trigger a contribution claim under Section 113(f)(3)(B).[96] Notably, parties that have settled with EPA are protected from contribution claims by other PRPs.[97]

Whether brought by a private party or the government, the general elements of a cost recovery claim are roughly the same. The plaintiff must demonstrate that:

- The defendant falls into one of the four categories of PRPs listed above;
- A "release"[98] of hazardous substances has occurred;
- The release occurred at a "facility";[99] and
- The release resulted in response costs (i.e., the costs of investigating and/or remediating a site) that were consistent with the NCP.[100]

The main difference between a cost recovery claim by the government and that by a private party is that the private party has the additional burden of proving that its response costs were necessary.[101] Also, the burden of proof for NCP consistency depends on whether the plaintiff is the government or a private party. For a government response, such costs must be "not inconsistent with" the NCP. For a private party, response costs must be "consistent with" the NCP to be recoverable.[102]

If a court finds a party liable, that party is joint and severally liable with all other PRPs, and all liable parties must either negotiate who pays what or have a court resolve their individual liability through the equitable allocation triggered by contribution actions.[103] Furthermore, a court must issue a declaratory judgment against all parties found liable for cost recovery under Section 107(a),[104] and courts generally grant declaratory judgments against all parties found liable for contribution.

Defenses to CERCLA Liability

CERCLA Section 107 contains the only defenses available against CERCLA liability. Commonly raised defenses include:

- **Third-party defense.** A PRP has a defense to liability if the release of hazardous substances at a facility was caused solely by the actions of a third party. To make use of this defense as to third-party actions, a party must establish that: (1) it had no contractual relationship, direct or indirect, with the third party; (2) the PRP exercised due care with respect to the hazardous substance; and (3) it took precautions against

foreseeable acts or omissions of the third party and the foreseeable consequences.[105]

- **Innocent landowner defenses.** The innocent purchaser defense operates by exempting parties from the contractual element under the third-party defense if they did not know, and had no reason to know, of contamination present on the property at the time the property was acquired.[106] Separately, the bona fide prospective purchaser (BFPP) defense protects non-polluting parties who knowingly acquire contaminated property after January 11, 2002, and if they satisfy eight elements.[107] Lastly, the contiguous landowner defense may be used when property has become contaminated due to a neighbor's actions and the landowner satisfies all nine elements of the defense.[108] Although each defense has distinct elements, they all share the central requirements that the landowner did not pollute the property and also conducted "all appropriate inquiries" into the previous ownership and uses of the facility, in accordance with accepted standards, prior to purchasing the property. The regulations contained in 40 C.F.R. § 312 further describe the "all appropriate inquiries" requirement.
- **Federally permitted releases.** A party is not liable under CERCLA for chemical releases authorized by other environmental statutes, such as discharges in compliance with a NPDES permit under the CWA.[109]

Other defenses include the "*de micromis* exemption" for parties that have contributed a very small amount of hazardous substances to a release at a facility via arrangement or transportation[110] and the "municipal solid waste exemption" for parties that arranged for disposal of only municipal solid waste and are small businesses, small nonprofits, or owners of residential property.[111]

Statute of Limitations

CERCLA also contains a statute of limitations provision for cost recovery and contribution actions. All cost recovery actions for remedial actions must be filed within six years after "initiation of physical on-site construction of the remedial action," and all cost recovery actions for removal actions must be filed either within three years after completion of the removal action (or within six years after initiation of the remedial action if the latter was initiated within three years after completion of the removal action).[112]

All contribution actions must be commenced within three years after either a judgment in a cost recovery action or an administrative or judicially approved settlement.[113]

Emerging Contaminants: Per- and Polyfluoroalkyl Substances

The development of scientific knowledge (e.g., new detection methods, developments in toxicology) leaves open the possibility that new or additional remediation requirements could be imposed at Superfund sites. Currently, per- and polyfluoroalkyl substances (PFAS) are receiving increased attention across the US, especially perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), which have been used in many products for their resistance to heat, chemicals, and corrosion. Specific to Superfund, on December 20, 2019, EPA released interim guidance on remediation of PFOA and PFOS in groundwater at Superfund sites.[114]

The regulation of PFAS remains an evolving issue that will continue to develop in the years to come. EPA has published and continues to develop a PFAS Action Plan that is available on its website.[115] Relatedly, some states have taken steps to establish groundwater standards for various PFAS.

Toxic Substances Control Act

Overview

Congress enacted the Toxic Substances Control Act (TSCA) as the primary federal chemicals law in 1976, giving EPA authority to regulate chemical substances in the United States and impose reporting, record keeping, and testing obligations.[116] TSCA applies to most chemicals in commerce with certain exclusions, such as for pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (see section on FIFRA) and food, drugs, and cosmetics regulated under the Federal Food, Drug, and Cosmetic Act, among others.[117] All chemicals in commerce must be notified to EPA, evaluated, and listed on the TSCA Inventory. TSCA grants EPA the authority to regulate the full life-cycle of chemicals, from manufacturing, processing, and distribution to use and end-of-life.

TSCA remained unchanged for 40 years until it was overhauled in 2016 by the Lautenberg Act, which took effect immediately upon passage on June 22, 2016.[118] The revised statute grants EPA increased authority to evaluate and regulate new and existing chemicals.

As noted above in the Superfund discussion, PFAS are currently receiving substantial attention from legislators and regulators across the US. Under TSCA, EPA has promulgated or proposed several new regulations over the past five years. EPA's website currently provides an overview of these regulations governing the manufacture and importation of products containing PFAS.[119] On July 27, 2020, EPA published a final rule amending its PFAS Significant New Use Rule "giving the agency the authority to review an expansive list of products containing PFAS before they [are] manufactured, sold, or imported in the United States."[120][121] On January 19, 2021, EPA issued a final guidance document providing additional clarification for importers of articles that may contain long-chain PFAS as part of a surface coating.[122] In addition to outlining the imported articles are covered by the July 2020 final rule, the guidance also provides clarity on what is meant by a "surface coating," identifies which entities are regulated, describes the activities that are required or prohibited, and summarizes the notification requirements of the July 2020 final rule.

Key TSCA Provisions

Section 5: New chemical substances. Companies must ensure that the chemicals they manufacture, import, and process are listed on the TSCA Inventory. TSCA requires companies to submit a premanufacture notice (PMN) to EPA if they intend to manufacture or import a new chemical (i.e., a chemical that is not already in commerce and listed on the TSCA Inventory), prior to manufacturing or importing such chemical.[123] The revised statute maintained the basic structure of the PMN review process, requiring EPA to review PMNs within 90 days.[124] However, the revised statute now requires EPA to make an affirmative determination regarding whether a chemical substance presents an unreasonable risk.[125] In making this determination, EPA cannot consider costs or other nonrisk factors and must consider any risk to potentially exposed or susceptible subpopulations. The revised statute requires EPA to make one of the following findings for each PMN reviewed by the agency: (1) the new chemical presents an unreasonable risk, (2) the new chemical may present an unreasonable risk, (3) the new chemical will be manufactured or imported in substantial quantities, (4) there is insufficient information to evaluate the new chemical, or (5) the new chemical is not likely to present an unreasonable risk.[126] Depending on the outcome of this determination, EPA can impose restrictions on the new chemical, promulgate regulations, require further testing, or allow the PMN submitter to commence manufacture or import of the new chemical, or some combination thereof. TSCA reform has resulted in greater scrutiny of new chemicals, delays in the new chemicals review process, and increased restrictions on new chemicals. On January 8, 2021, EPA and OSHA signed a Memorandum of Understanding that advances collaboration and communication between the

agencies on the new chemical review process under TSCA Section 5 and minimizes workplace exposures.[127]

Companies must also comply with significant new use rules (SNURs), if applicable, for chemicals they manufacture, import, process, or use.[128] EPA can use SNURs to regulate the volume and use (e.g., industrial versus consumer use) of individual chemicals and impose worker health and safety, water release, and disposal requirements on the use of such chemicals. SNURs require manufacturers, importers, and processors to notify EPA at least 90 days before starting or resuming new uses of chemicals subject to a SNUR that do not comply with applicable restrictions.[129] On March 29, 2021, EPA announced that it is evaluating its policies, guidance, templates, and regulations under the new chemicals program to ensure adherence to statutory requirements, the Biden-Harris administration's executive orders, and other directives.[130] Specifically, the EPA will stop issuing determinations of "not likely to present an unreasonable risk" based on the existence of proposed SNURs, which was a practice used during the Trump administration.[131]

Section 6: Prioritization, risk evaluation, and risk management for existing chemicals. Section 6 of TSCA governs prioritization, risk evaluation, and regulation of existing chemicals (i.e., chemicals that are already in commerce and listed on the TSCA Inventory).[132] Previously, EPA was required to restrict existing chemicals using the "least burdensome" requirements. In the 2016 updates, Congress removed the "least burdensome" standard, giving EPA more authority to regulate existing chemicals. The revised statute also established a new framework for regulating existing chemicals that involves prioritization, risk evaluation, and risk management. EPA is charged with prioritizing existing chemicals as high- or low-priority substances by considering whether a chemical "may present an unreasonable risk" without considering cost implications.[133] If a chemical is designated as a high-priority substance, EPA must conduct a risk evaluation on the chemical to determine if the chemical presents an unreasonable risk.[134] If EPA determines that the chemical presents an unreasonable risk, EPA must promulgate risk management regulations to ensure that the chemical no longer presents an unreasonable risk.[135]

In December 2019, EPA designated 20 chemicals as high-priority substances for risk evaluations.[136] Companies that manufactured any of those substances in the preceding five years must comply with the TSCA Fees Rule, which required them to self-identify as a manufacturer and will require them to contribute to the costs of the risk evaluations.[137] However, following controversy regarding the definition of "manufacturer" for these purposes, EPA issued a no-action assurance for certain manufacturers subject to the Fees Rule: those that import the chemical substance in an article, those that produce the substance as a by-product, and those that produce or import the substance as an impurity.[138] On December 21, 2020, EPA announced proposed revisions to the TSCA Fees Rule, which would cover fiscal years 2022–2024. The proposed revisions included a number of exemptions for importers of articles containing a chemical substance, companies that produce a chemical as a byproduct or manufacture or import as an impurity, companies that use chemicals solely for research and development purposes, companies that produce a chemical in de minimus amounts, and companies that manufacture a chemical that is produced as a non-isolated intermediate from fees.[139] After considering public comments, the EPA will issue a final rule in 2021.[140]

EPA issued five final rules on January 6, 2021, to reduce exposures to certain chemicals that are persistent, bioaccumulative and toxic (PBT) under TSCA Section 6(h): Decabromodiphenyl ether (DecaBDE); Phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP); Hexachlorobutadiene (HCBD); and Pentachlorothiophenol (PCTP). The public comment period, which collected additional input on these final rules, ended on May 17, 2021. Additionally, EPA issued a temporary 180-day "No Action Assurance" indicating that it will exercise its enforcement discretion regarding the prohibitions on processing and

distribution of PIP (3:1) for use in articles, and the articles to which PIP (3:1) has been added.[141]

Section 8(a): Chemical Data Reporting. The Chemical Data Reporting (CDR) rules according to TSCA section 8(a) require manufacturers and importers of chemicals to report information regarding the production, import, and use of chemical at US facilities, if such activity exceeds certain thresholds, to EPA every four years. In December 2020, a federal district court issued a ruling directing EPA to amend its CDR reporting rule under Section 8(a) of TSCA.[142] EPA finalized amendments to the CDR rules in April 2020, which implemented a number of changes as compared to the 2016 rules.[143] EPA extended the deadline for the latest round of CDR reporting to January 2021.[144]

Section 8(e): Substantial risk reporting. Manufacturers, importers, processers, and distributors are required to immediately notify EPA when they become aware of information indicating that a chemical presents a substantial risk of injury to health or the environment, per TSCA section 8(e).[145] Companies must submit a Substantial Risk Notification to EPA within 30 calendar days of obtaining substantial risk information.[146] It is important for companies to establish internal procedures to evaluate information regarding chemicals for purposes of substantial risk reporting.[147] Persons responsible at a company for management of section 8(e) reporting retain potential civil and/or criminal liability, if required Substantial Risk Notifications are not submitted to EPA.[148]

Other National and International Chemical Regulations

Companies that manufacture, import, and use chemicals in other jurisdictions outside the United States should keep in mind that many other countries and regions have chemicals management schemes in place that regulate the manufacture and use of chemicals. For example, the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation establishes a comprehensive framework that governs the production, import, and use of chemicals placed on the European Union market.[149] Many other countries also have their own chemicals management frameworks.[150] At the international level, the Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals.[151] The Stockholm Convention requires parties to the convention to take measures to eliminate or reduce the release of certain chemicals into the environment, and can trigger the adoption of restrictions or prohibitions on listed chemicals in nearly all jurisdictions across the globe.

Federal Insecticide, Fungicide, And Rodenticide Act

Overview

FIFRA provides for comprehensive regulation of pesticide distribution, sale, and use. All pesticides used in the United States must be registered or licensed by EPA under the statute. Registration assures that pesticides will be properly labeled and that, if used in accordance with specifications, they will not cause unreasonable harm to the environment. EPA conducts periodic reviews and inspections to ensure compliance with the registration-related requirements. Moreover, the use of each registered pesticide must be consistent with use directions contained on the label or labeling.

FIFRA often interacts with the Federal Food, Drug, and Cosmetic Act and the TSCA. Readers should examine these other statutes for a better view of the entire regulatory framework and consult with an attorney when specific cross-cutting legal concerns arise.

FIFRA Programs

Registration requirements.[152] FIFRA prohibits the distribution or sale of a pesticide without registration unless one of a limited number of exceptions applies.[153] The registration requirement is "the heart of EPA's regulation of pesticides."[154] A registration application must include basic information, a confidential statement of formula (CSF), a draft label including detailed information on how the pesticide may be handled and used, and supporting data.[155] Depending on the amount of information already existing on the pesticide's chemical substances, it may not necessarily be voluminous.

The CSF must provide EPA the chemical formula and chemical properties for the pesticide as well as detail the purpose and supplier of each component.[156] The pesticide label must provide detailed information regarding how to safely handle and apply the pesticide product. Unlike many product labels, pesticide labels are enforceable, and all of them carry the statement: "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."[157] Finally, an applicant may either submit data supporting its application (which is required for new active ingredients), or the applicant may cite data that previously had been submitted to EPA or that appear in the public literature.[158]

The statute classifies all pesticides into four categories and provides registration fee schedules for each category.[159] To register a new pesticide, EPA must find the following as supported by the application materials:[160]

- Its composition is such as to warrant the proposed claims for it.
- Its labeling and other material required to be submitted comply with the requirements of the act.
- It will perform its intended function without "unreasonable adverse effects on the environment."
- When used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

"Unreasonable adverse effects on the environment" are defined under the statute as "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," and "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 346a of title 21 [the Federal Food, Drug, and Cosmetic Act]."[161] Thus, in evaluating pesticides under this standard, unless there is a human dietary risk, EPA considers the costs and benefits of using the pesticide in making its registration determination.

As discussed later under "Pesticide Use Classification and Administration," EPA may register a pesticide for general or restricted use. EPA may also deny the registration entirely. The applicant or other interested person is entitled to a hearing on EPA's decision.[162]

Similar to the pesticide registration requirement, FIFRA prohibits production of pesticides or active ingredients in an establishment without prior registration.[163] It also authorizes EPA to promulgate book- and recording-keeping and registration rules.[164]

Compliance review and inspection. Under FIFRA, EPA conducts periodic reviews to ensure that regulated parties comply with the registration requirements on pesticides, establishments, books and records.

EPA may review the records and nullify an existing registration by cancellation,[165] suspension,[166] or emergency order,[167] if it determines that a pesticide no longer complies with the requirements associated with the registration. EPA can also inspect establishments for production and other purposes to check compliance with the standards in the establishment registration.[168] Finally, EPA may access and copy information related to the "delivery, movement, or holding" of pesticides or devices to ensure that there is no violation of the book- and record-keeping rules.[169]

For more information see EPA's Office of Compliance and Enforcement Assurance.[170]

Pesticide use classification and administration. FIFRA also regulates the improper use of pesticides. In the pesticide registration process, the applicant has to register the product based on its uses. EPA will then decide which use is appropriate and whether to approve the registration. Three scenarios are possible for these two questions:

1. EPA permits a general use and approves the registration if following the registered directions or common practice for the pesticide can generally avoid "unreasonable adverse effects on the environment."[171]
2. EPA permits a restricted use and approves the registration if following the registered directions or common practice for the pesticide is not sufficient to generally avoid "unreasonable adverse effects on the environment," but extra regulatory restrictions may cure such defects.[172]
3. EPA permits no use and denies the registration if it is impossible to generally avoid "unreasonable adverse effects on the environment."[173]

Pesticides often have multiple uses. In such situations, EPA will first decide on each use and then classify the entire pesticide for general uses, restricted uses, or both (when some uses are general and the others are restricted).[174] General uses may be later changed into restricted uses, and vice versa, with certain procedures.[175]

A restricted use has to be conducted by or "under the direct supervision of" a certified applicator.[176] Therefore, FIFRA provides a scheme of applicator certification for the restricted use of a pesticide. A person who seeks certification as an applicator has to go through either a state or federal certification process.[177] Depending on the purpose and place of pesticide use, applicators can be either private or commercial.[178] The licensing and certification standards for those two groups are separate under FIFRA.[179] Consequently, EPA applies heightened use standards from general use, to restricted use with a certified private applicator, to restricted use with a certified commercial applicator.

Disinfectants for Use Against Coronavirus. Many surface, air, and water disinfectants (including sprays, wipes, and liquids intended for use against viruses, bacteria, and other microbial pests) are regulated under FIFRA. EPA has compiled a list of disinfectant products that meet the criteria for use against the coronavirus in List N, "Products with Emerging Viral Pathogens AND Human Coronavirus claims for use against SARS-CoV-2."[180] In 2020, EPA announced a series of regulatory changes designed to ease production of such regulated disinfectant products approved for use against the coronavirus. Manufacturers were permitted to obtain certain "commodity" active ingredients from different suppliers without first obtaining a registration amendment. Registrants were also permitted to substitute registered sources of noncommodity active ingredients by "notification," even if the ingredients have different purity levels.[181] EPA, in conjunction with the Centers for Disease Control and Prevention, also issued an unprecedented recommendation to use unregistered commodity substances for

disinfection when EPA-approved products are not available.[182] However, as of April 2021, the EPA has ended priority review for surface disinfectant products, returning registration requests for new surface disinfectants for SARS-CoV-2 back to standard FIFRA registration process and associated deadlines.[183] Additionally, EPA issued an updated Compliance Advisory to prevent the sale of unregistered sanitizing products that claim to be effective against the SARS-CoV-2 virus.[184] The EPA reiterated that making false or misleading labeling claims about the safety or efficacy of a pesticidal device is prohibited and that it has the authority to take enforcement actions under FIFRA.[185]

Typical Violations Under FIFRA – Section 12(a)

Unlawful Distribution or Sale. Section 12(a)(1) concerns the unlawful distribution or sale of pesticides or devices. The rule for devices is simple: It is unlawful to distribute or sell a misbranded device.[186] As for pesticides, FIFRA forbids distribution or sale if the pesticide:

- Is not registered or its registration is cancelled or suspended;[187]
- Has claims, in the distribution or sale, that "substantially differ" from claims in the registration statement;[188]
- Has composition, in the distribution or sale, that differs from the description in the registration statement;[189]
- Violates the coloring or discoloring requirements in Section 25(c)(5);[190]
- Is adulterated or misbranded;[191] or
- Is classified for restricted use, but the distribution or sale of such pesticide is for purposes other than the restricted use conditions.[192]

Other Violations. Section 12(a)(2) imposes a much broader scope of prohibitions in seven general categories:

1. Alteration of labeling or substance of a pesticide;[193]
2. Refusal or failure to keep, provide, or give access to information as required;[194]
3. Breach of confidentiality requirements in the statute;[195]
4. Advertising of a registered product without giving the Section 3(d) classification;[196]
5. Unauthorized or improper use of a pesticide;[197]
6. Violation of orders,[198] laws, or regulations;[199] and
7. Falsification or providing false information.[200]

Depending on the violation and the responsible party, a person may be subject to orders of stop sale and use, seizure, or disposal of products,[201] as well as civil and criminal penalties with monetary fines and imprisonment.[202]

Common Defenses to FIFRA Liability

Substance Outside the Scope of FIFRA. FIFRA covers a finite range of pesticides and devices. It exempts many substances or devices, either fully or partially, from regulatory control. First, FIFRA completely excludes or exempts some items, including:

- Certain nitrogen stabilizers, vitamin hormone products, and products intended to aid the growth of desirable plants (conditions apply);[203]
- Fertilizer products with no pesticide and products intended to force bees from hives for the collection of honey crops;[204]
- (Without pesticidal intent) Deodorizers, bleaches, and cleaning agents, nontoxic products intended only to attract pests for survey or detection purposes, and nontoxic products intended to exclude pests only by providing a physical barrier against pest access (e.g., certain tree-pruning paints);[205]
- Treated articles or substances, pheromones and pheromone traps, preservatives for biological specimens, foods, natural cedar, and listed minimum risk pesticides.[206]

Activities Not Covered. Certain transfer, distribution, or sale activities trigger the product registration exemption. Although other FIFRA requirements may still apply (such as establishment registration, books and records maintenance, and access for authorized inspection):

- For pesticides, no registration is required for (1) any transfer between establishments, solely for export, or for disposal;[207] or (2) any distribution or sale under experimental use permits, under emergency exemptions, or of the existing stocks of a product whose registration is cancelled or suspended.[208]
- For pest control devices, no registration is required for any transfer, distribution, or sale activities as long as the device works only by physical means without any chemical substances or mixtures.[209]

Regulated by Other Statutes. FIFRA exempts some other substances that will nevertheless be subject to other statutes:

- Certain biological control agents and nonliquid chemical sterilants (other than ethylene oxide);[210]
- Liquid chemical sterilants, human and animal drugs, and animal feeds.[211]

Defenses to 12(a)(1). Specific defenses from Section 12 challenges are also available. Section 12(b) exempts Section 12(a)(1) liabilities from five categories of responsible parties:[212]

- Guaranty recipients;
- Carriers who permit inspection;
- Public officials in their official capacity;
- Users or possessors who comply with experimental use permits; and
- Shippers of pesticides for some specific testing purposes from which users do not expect benefit from their use.

Defenses to 12(a)(2). For 12(a)(2) liabilities, the primary defense is in (a)(2)(F): While it is unlawful to sell a restricted use pesticide for purposes other than prescribed under Section 3(d) (the restricted use requirements), it is lawful to sell a restricted use pesticide to a noncertified applicator if a certified applicator will apply the pesticide.[213]

Follow-On Registration Issues[214]

Another common issue under FIFRA is the use of prior applicant environmental, health, and safety data by later applicants of the same or similar product. As a general matter, a 10-year exclusive-use period applies for those data that are submitted to support the initial registration of a product containing a new active ingredient. No other applicants may rely on the supplied data during that time. Under certain scenarios, the exclusive-use period may be extended. After the expiration of the exclusive-use period, there is an additional 15-year period where the data submitter is entitled to compensation rights for data. The "follow-on" or "me-to" applicant is allowed to use prior data under the law if they provide the data submitter with an offer to pay compensation.[215] FIFRA provides that the terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant or, failing such agreement, by binding arbitration. An arbitration decision regarding compensation is final and is only reviewable in court for fraud, misrepresentation, or misconduct. The burden is on the claimant, or party claiming compensation is due, to establish the "amount of compensation that respondent should pay," by a preponderance of the evidence.[216]

Emergency Planning and Community Right-To-Know Act (EPCRA)

Overview

In 1984, an extremely toxic gas, methyl isocyanate, escaped from a chemical plant in Bhopal, India, killing thousands of people. In 1986, the U.S. Congress responded by passing the Emergency Planning and Community Right-to-Know Act (EPCRA).[217] The law was designed to improve local preparedness for chemical emergencies and increase the availability of information on toxic and hazardous chemicals.

EPCRA imposes obligations on state governments, local officials, and facility owners and operators. These obligations span emergency planning, emergency notification of certain releases, and reporting of hazardous and toxic chemical inventories.[218]

Emergency Planning (Sections 301–03)

States are required to develop State Emergency Response Commissions (SERCs), which oversee Local Emergency Planning Committees (LEPCs).[219] LEPCs prepare and regularly review chemical emergency response plans.[220] Local facilities are required to have their facility emergency coordinators participate in the planning process if they are subject to Subchapter I of EPCRA, which is triggered by the presence of extremely hazardous substances (EHSs) on-site in quantities that exceed the threshold planning quantities (TPQs).[221] Facilities must notify the SERC within 60 days of becoming subject to Subchapter I, and they must appoint an emergency response coordinator and notify the LEPC of that person's identity.[222] If a facility undergoes any changes that may affect emergency response planning, the owner or operator must notify the LEPC. The following definitions apply under EPCRA:

- **Facilities.** EPCRA defines "facility" broadly to cover "all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned

or operated by the same person."[223] Facilities are subject to Subchapter I if an EHS is present at the facility in excess of the TPQ for that substance. Additional facilities can be designated by the governor or SERC.

- **Extremely Hazardous Substances.** EHSs are listed at 40 C.F.R. § 355 app. A. The EPA administrator may revise the list, taking into account "toxicity, reactivity, volatility, dispersability, combustability, or flammability of a substance."[224]
- **Hazardous Chemical.** Defined under EPCRA § 111 (discussed later).
- **Toxic Chemical.** Defined under EPCRA § 113 (discussed later).
- **Threshold Planning Quantities.** TPQs may be based on classes of chemicals or categories of facilities, and the administrator has discretion to revise the TPQs.[225]
- **Timing.** A facility must notify the SERC and the LEPC within 60 days of an EHS becoming present at the facility in excess of the TPQ or if the EHS list was revised to include new substances that are present at the facility. [226]
- **Penalties.** If a facility does not appropriately or timely notify the SERC and LEPC, EPA may order compliance, and the U.S. district court where the facility is located can enforce the order and assess civil penalties of up to $25,000 against a party for each day of the violation or failure to comply.[227] A state or local government may also bring a civil action against a facility owner or operator for violations.[228]

Emergency Notification (Section § 304)

If there is a release of an EHS from a facility that produces, uses, or stores a hazardous chemical, EPCRA may require the owner or operator of the facility to provide immediate notice to the LEPCs and the SERCs with jurisdiction over the facility. Immediate notice is required under EPCRA if the release requires a notification under CERCLA Section 103(a)[229] or if the release exceeds the reportable quantities under EPCRA, and CERCLA has separate reporting requirements that facilities may have to meet. EPCRA further requires the facility to follow up as soon as practicable in writing regarding the release response and any health effects.[230]

- **Release.** Release is defined broadly to include "any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles) of any hazardous chemical, extremely hazardous substance, or toxic chemical."[231]
- **Reportable quantities.** Reportable quantities are established by the administrator and available at 40 C.F.R. § 355 app. A.
- **Content of the notification.** The immediate emergency notification must include: the chemical name; whether the chemical is an EHS; an estimate of how much of the chemical was released; the time and duration of the release; the medium/media (land, air, and/or water) into which the chemical was released; known or anticipated acute or chronic health risks linked to the release (and advice regarding appropriate medical attention for people who are exposed); proper precautions (e.g., evacuation); and the contact information (name and telephone number) for whoever should be contacted for further information.[232]
- **Exemptions.** Facilities are exempted from these reporting requirements if the release only results in

exposure to people on-site where the facility is located or the release is federally permitted under CERCLA Section 101(10).[233] CERCLA Section 103 may provide other relevant exemptions.

- **Penalties.** A Class I administrative civil penalty up to $25,000 may be assessed by the administrator (after notice and opportunity for a hearing) for each violation.[234] The administrator may also impose a Class II civil administrative penalty of not more than $25,000 for each day that the violation continues. This Class II limit increases to $75,000 per day for a second or subsequent violation. The administrator can also bring an action in a U.S. district court to assess and collect the penalties. Finally, a criminal penalty can be imposed on any person who knowingly and willfully violates the emergency notification requirements. The criminal penalty can take the form of a fine of not more than $25,000, not more than two years of imprisonment, or both. For a second or subsequent conviction, these limits rise to $50,000 and five years of imprisonment.[235] Citizens may also bring a civil action against the facility owner or operator for failure to follow up after the release.[236]

MSDS and Inventory Reports (Sections 311–12)

Each facility required to prepare and have available a Material Safety Data Sheet (MSDS) for any hazardous chemical under the Occupational Safety and Health Act of 1970 (OSHA) must submit a MSDS and an inventory form for each such chemical in excess of the threshold planning quantity.[237] Facilities must at least submit a Tier I inventory form (requiring general estimates of categories of chemicals present at the facility), but may be required to or elect to instead submit a Tier II inventory form (requiring more specific information about the presence of individual chemicals).[238] A facility must submit these forms to the appropriate LEPC, SERC, and fire department that has jurisdiction over the facility.[239]

- **Affected facilities.** Facilities are subject to these requirements if they are required by OSHA to prepare and maintain a MSDS for a hazardous chemical and have such a chemical in amounts above the threshold levels at the facility.[240]
- **Thresholds.** The administrator has established thresholds under which these reports are unnecessary. The thresholds depend on whether the chemical is an EHS or hazardous chemical.
- **Hazardous chemicals.** Facility owners or operators must submit a report for hazardous chemicals that are present at a facility at or in excess of 10,000 pounds at any point in time.[241] EPCRA adopts the definition of "hazardous chemical" from 29 C.F.R. § 1910.1200(c), but excludes several categories like food regulated by the Food and Drug Administration, substances used for household and research purposes, etc.[242]
- **Extremely Hazardous Substances.** Facility owners or operators are subject to these requirements if an EHS is present at any one point in time at or in excess of 500 pounds or the chemical's TPQ, whichever is lower.[243]
- **MSDS alternative.** The facility can submit a list of hazardous chemicals instead of submitting a MSDS for each such chemical.[244] The list must include: the hazardous chemicals for which the facility is required to have a MSDS, the chemical or common name of each chemical, and the hazardous components of each chemical.
- **Inventory form options.** Facilities may submit either Tier I or Tier II information forms.
    - **Tier I.** Tier I forms provide information grouped by categories of health and physical hazards. The

information should include the maximum and average daily amount of hazardous chemicals in each category present at the facility over the preceding year and their general locations.[245]

- **Tier II.** The SERC, LEPC, or fire department may request a facility to submit a Tier II form. Tier II forms require more detail: each chemical or common name provided on the MSDS sheet, maximum and daily average amounts of each hazardous chemical at the facility any time during the preceding calendar year, information about the manner of storage and location of each hazardous chemical, and an indication of whether the facility owner wishes to withhold location information for specific hazardous chemicals from public disclosure.[246]

- **Timing.** Facilities need only submit and revise MSDS sheets (or lists) once in response to new information.
  - **One-time MSDS sheet.** The initial MSDS sheet or list must be submitted within three months of when the owner or operator is required to prepare the MSDS for OSHA.[247] Facilities must submit a revised MSDS sheet within three months of when the owner or operator discovers new information relating to a hazardous chemical for which a MSDS was already submitted to the LEPC.[248]
  - **Annual inventory form.** A Tier I form is due by March 1 each year with the preceding calendar year's information (unless the facility is submitting a Tier II form by the same deadline).[249]
- **Penalties.** The EPA administrator may assess a civil penalty against anyone violating these reporting requirements by bringing an action in a U.S. district court.[250] Citizens, state governments, or local governments may bring a civil action against a facility owner or operator for these violations.[251]
  - **MSDS sheet violations.** Anyone violating the MSDS sheet requirements is liable for not more than $10,000 per violation. Each day of continued violation counts as a new violation.
  - **Inventory form violations.** Anyone violating inventory form requirements may be assessed a civil penalty of not more than $25,000 per violation. Each day of continued violation counts as a new violation.

Toxic Release Inventory (Section 313)

Each year, EPCRA requires owners or operators of a facility to submit a toxic chemical release form for each listed toxic chemical that was manufactured, processed, or otherwise used in excess of the threshold levels.[252] The information from these reports makes up the Toxic Release Inventory (TRI).[253]

- **Covered facilities.** These requirements apply to owners or operators who have 10 or more full-time employees; are in certain Standard Industrial Classification (SIC) codes; and manufactured, processed, or otherwise used listed toxic chemicals in excess of the threshold levels. "Manufacture" is defined as "to produce, prepare, import, or compound a toxic chemical."[254] "Process" is defined as "the preparation of a toxic chemical, after its manufacture for distribution in commerce."[255] The EPA administrator also has discretion to apply the requirements of Section 313 to any facility with on-site toxic chemicals.
- **Listed toxic chemicals.** A list of regulated chemicals is available at 40 C.F.R. § 372.65. The administrator has discretion to add or remove chemicals.[256]
  - In June 2020, EPA released a final rule to add 172 per- and polyfluoroalkyl substances (PFAS) to the

list of toxic chemicals, pursuant to the National Defense Authorization Act (NDAA) for Fiscal Year 2020.[257] Reporting forms are due by July 1, 2021.[258]

- **Thresholds.** For a toxic chemical used at a facility, the threshold for reporting is 10,000 pounds per year.[259] For a toxic chemical manufactured or processed at a facility, the threshold is 25,000 pounds per year. The administrator may revise these thresholds.[260]
- **Timing.** These reports must be made online using the EPA's TRI-MEweb interface (except for trade secret submissions).[261] The reports must be submitted by July 1 each year, but the Administrator can change the reporting frequency and deadlines. [262]
- **Penalties.** Anyone violating these reporting requirements may be assessed a civil penalty of not more than $25,000 per violation.[263] Each day of continued violation counts as a new violation. The EPA administrator may assess these penalties or bring an action in a U.S. district court. Citizens may also bring a civil action against a facility owner or operator for a violation of these provisions.[264]

Common EPCRA Violations

The following are some common EPCRA violations:

- Failure to timely report chemical releases into the environment.
- Failure to report information on chemicals stored on-site above certain thresholds.
- Unique state and local requirements. Facilities should be aware that states and local governments have requirements for reporting releases that may provide additional requirements.
- Batteries. Batteries are subject to the emergency planning requirements of EPCRA Section 302, so their contents should be included in calculating whether the quantity of an EHS exceeds the TPQ. Facilities often overlook the sulfuric acid contained in batteries used for emergency power backup.
- Off-site impact. Under EPCRA, a release must have a potential or actual off-site impact in order to require emergency notification. There is an exemption for releases that only affect people on-site.
- Notifying all parties of EPCRA release. When a release requiring immediate notification has occurred, the facility owner or operator must notify the appropriate SERC and LEPC, in addition to any necessary notification of the National Response Center under CERCLA.
- Follow-up reports. When a release requiring immediate notification has occurred, the facility owner or operator must also make a follow-up report as soon as practicable.
- MSDS sheet revisions. Although MSDS sheets need not be submitted annually, they must be revised and resubmitted if they require a revision based on increased chemical quantities at the facility or new chemicals becoming subject to MSDS requirements.
- Nonchemical industries. Nonchemical industries are still subject to many of the requirements of EPCRA. The application of EPCRA generally depends on the presence of certain chemicals at a facility and not the industry associated with the facility (except with toxic release inventory reporting, which relies on SIC codes).

Common Defenses

The easiest way to defend EPCRA violations is by voluntarily reporting them under EPA's Audit Policy, which allows entities to make voluntary disclosures of violations in exchange for penalty reductions.[265] The Audit Policy is discussed in more detail in the Environmental Compliance Plans & EPA's Audit Policy section. Under EPA's eDisclosure system,[266] EPA's response to disclosures will differ depending on whether a violation falls into Tier 1 or Tier 2 (unrelated to the Tier I and Tier II inventory information discussed above). Tier 1 disclosures cover most EPCRA violations that meet all nine criteria of the Audit Policy, but do not include EPCRA violations with significant economic benefit or CERCLA Section 103/EPCRA Section 304 emergency release notification violations. If the violation qualifies as Tier 1, the eDisclosure system will automatically issue an electronic notice of determination, confirming the resolution of the violations without a civil penalty (as long as the disclosure submission is complete and accurate). If a disclosure does not qualify as Tier 1, it will be treated as a Tier 2 disclosure, and EPA will issue an electronic acknowledgement letter to confirm receipt of the submission. EPA will determine penalty mitigation eligibility if and when it considers taking an enforcement action for the disclosed violations.

Other common defenses are discussed in the enforcement section (Part III).

Occupational Safety and Health Act

Overview

The Occupational Safety and Health Act of 1970 created OSHA,[267] a subdivision of the United States Department of Labor. OSHA is designed to "[t]o assure safe and healthful working conditions for working men and women . . . by providing for research, information, education, and training in the field of occupational safety and health . . . ."[268] While OSHA regulates a wide array of industries and activities, this section will focus on environmental hazards and related employer requirements.

OSHA imposes a "general duty" on employers to maintain a safe working environment and requires certain industries to comply with specific regulations. Violations are discovered through routine inspections, whistleblowers, and news events. Notably, whistleblowers who have been fired or otherwise disciplined for reporting unsafe work conditions may file a complaint with OSHA.[269]

OSHA applies to all employers and their employees in the U.S. However, federal and state government employers, and workplaces protected by other federal agencies (e.g., Atomic Energy Commission, Mine Safety Health Administration), are excluded.[270] Workplaces employing 10 or fewer workers are partially exempt from certain requirements, but may still be subject to accident and worker complaint investigations, and they are still required to follow hazard communication requirements.[271]

Even workplaces that are not covered by a specific set of regulations are subject to OSHA regulation under the "general duty" clause. Under this clause, OSHA places a general duty on employers in situations where no standard currently exists to provide a work environment free of "recognized hazards that are causing or are likely to cause death or serious physical harm."[272] Courts broadly construe this duty because it is specifically triggered by a lack of regulation and is therefore often invoked in novel situations. As a corollary to the general duty clause, employees have the right to refuse to work in the face of serious injury or death.[273]

Twenty-eight states have OSHA-approved State Plans in place. These State Plans must have standards and enforcement programs that are at least as effective as those of OSHA and may contain additional state-specific

requirements.

The most common OSHA violations include fall protection, scaffolding, and ladders (construction); hazard communications (general); respiratory protection (general), eye and face protection (general); and machinery lockout/tagout procedures (general).[274]

Environmental Issues Under OSHA

Several specific OSHA standards apply to environmentally related issues.[275] For example, employers using hazardous wastes are subject to specific standards and reporting requirements. Employers who engage in corrective actions at RCRA sites and other operations involving hazardous substances are subject to OSHA's Hazardous Waste Operations and Emergency Response (HAZWOPER) standards.[276]

At HAZWOPER sites, a minimum of four people must be working at all times: two inside the dangerous atmosphere and two outside for assistance and rescue.[277] A site safety and health plan must address safety and health risks, employee training, personal protective equipment for employees, medical surveillance, monitoring frequency and type, site control measures, decontamination procedures, emergency response procedures, confined space entry procedures, spill containment procedures, pre-entry briefings before initiation of work, and a plan for inspections.[278] Employers must also provide respirators to employees exposed to hazard by breathing oxygen-depleted or contaminated air.[279] Employers should ensure that they have provided the appropriate respirator for the working conditions at hand.[280]

OSHA's hazard communication standard (HCS) requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import and to provide information about those hazards to downstream distributors and employers that use those chemicals.[281] In turn, those employers must provide that information to their employees. In February 2021, OSHA published a proposed rule to update its requirements, revising its criteria for classification of certain health and physical hazards.[282] A final rule would likely require most labels and safety data sheets to be revised.[283]

In addition, OSHA has promulgated specific regulations applicable to the use of and exposure to a variety of chemicals and substances. For instance, the air contaminant regulations apply exposure limitations to more than 400 different air contaminants (including specific chemicals like acetaldehyde, chemical classes like chromium compounds, and general categories like coal tar pitch volatiles). The contaminants are divided into three groups, each with specific exposure limits. Lead and asbestos have specific, independent regulations.[284]

Toxic industrial chemicals are regulated by OSHA for emergency preparedness purposes. These are presented in a "guide," which provides the requirements for chemicals that are either produced in large quantities or may be used in terrorist threats. The guide addresses 21 "high risk" chemicals, 38 "medium risk" chemicals, and 39 "low risk" chemicals. Facilities that handle these chemicals may be subject to specific precautions and additional reporting standards.[285]

OSHA also establishes guidelines for Indoor Air Quality (IAQ). OSHA guidance tasks commercial and institutional building owners with proactively addressing IAQ issues. Buildings suffering from a number of inadequate IAQ factors are such a large problem that the EPA listed IAQ as one of the "top five most urgent environmental risks to public health." The guidelines include a general duty clause and address specific air contaminants and ventilation systems.[286]

Coronavirus (Coronavirus SARS-CoV-2) & OSHA

In 2020, the coronavirus pandemic presented a new challenge to maintaining safe work environments.[287] In January 2021, OSHA released new COVID-19 guidance in accordance with President Biden's Executive Order on Protecting Worker Health and Safety.[288] The guidance emphasized how employers should implement COVID-19 prevention programs in the workplace.[289] It also included key information regarding COVID-19 protections in the workplace, such as identifying opportunities to get vaccinated, properly wearing a face covering, physical distancing, participating in any training offered by building managers to learn how rooms are ventilated effectively, practicing good personal hygiene, and frequent handwashing.[290] The guidance also included ways for employers to engage with workers and their representatives to determine how to implement multilayered interventions to protect unvaccinated or otherwise at-risk workers and mitigate the spread of COVID-19, such as:

- Paid time off for employees to get vaccinated;
- Instructing any workers who are infected, unvaccinated workers who have had close contact with someone who tested positive for SARS-CoV-2, and all workers with COVID-19 symptoms to stay home from work;
- Implementing physical distancing for unvaccinated and otherwise at-risk workers in all communal work areas;
- Providing unvaccinated and otherwise at-risk workers with face coverings or surgical masks, unless their work task requires a respirator or other PPE;
- Educating and training workers on COVID-19 policies and procedures using accessible formats and in language they understand;
- Suggesting that unvaccinated customers, visitors, or guests wear face coverings;
- Maintaining ventilation systems;
- Performing routine cleaning and disinfection;
- Recording and reporting COVID-19 infections and deaths;
- Implementing protections from retaliation and setting up an anonymous process for workers to voice concerns about COVID-19-related hazards;
- Following other applicable mandatory OSHA standards, including requirements for PPE (29 C.F.R. § 1910, Subpart I (e.g., 1910.132 and 133)), respiratory protection (29 C.F.R. § 1910.134), sanitation (29 C.F.R. § 1910.141), protection from bloodborne pathogens, (29 C.F.R. § 1910.1030), and OSHA's requirements for employee access to medical and exposure records (29 C.F.R. § 1910.1020). Many healthcare workplaces will be covered by the mandatory OSHA COVID-19 Emergency Temporary Standard.[291]

In addition, OSHA issued an Updated Interim Enforcement Response Plan for Coronavirus Disease 2019 (COVID-19), which provides new instructions and guidance to area offices and compliance safety and health officers (CSHOs) for handling COVID-19-related complaints, referrals, and severe illness reports.[292]

As the pandemic situation and regulatory response continues to evolve, OSHA guidance and industry best practices will likely continue to shift rapidly.[293]

Record Keeping and Reporting

Regulated parties must report all accidents on the job.[294] Any workplace accident requiring treatment or resulting in lost work time must be recorded within seven working days.[295] Employers must alert OSHA within eight hours of a fatality or within 24 hours for an in-patient hospitalization, amputation, or loss of an eye.[296] Knowingly made false representations are subject to criminal penalties.[297]

OSHA requires employers to maintain monitoring and medical records for particular hazards. Affected employers must maintain these records for 30 years.[298] Work posing a hazard to hearing requires baseline and periodic hearing tests, and work involving lead exposure requires blood-lead level testing. Elevated blood-lead levels may serve as a basis for removing employees from work until their levels return below the accepted threshold. Finally, OSHA's ionizing radiation regulation requires monitoring of radiation exposure and absorption.[299]

Inspections

OSHA inspects workplaces in the following descending order of priority: imminent danger situations, severe injuries and illnesses, worker complaints, referrals, targeted inspections, and follow-up inspections. For low-level complaints, OSHA may engage in a phone/fax investigation. OSHA telephones the employer and describes the violation. The employer must respond in writing within five working days noting problems found and solutions implemented.

On-site inspection follows a more involved process. Inspectors research the work site inspection history and gather proper testing and protective equipment. The inspector goes to the site and presents his/her compliance officer credentials (containing a photograph and serial number).[300] The Supreme Court has held that facilities may deny access to inspectors on fourth amendment (unconstitutional search) grounds. However, there is a low threshold for OSHA to obtain a warrant.[301] Next, the inspector explains why the site was chosen. After the employer chooses a representative to join the inspector, the inspector performs a walk-around to inspect the workplace. After the walk-around, the inspector will explain any violations found, citations made, and options for the employer to contest or resolve citations. OSHA must issue citations within six months of the occurrence. OSHA may reduce citation penalties based on the employer's good faith, inspection history, business size, and the gravity of violations. "Willful" violations may not be mitigated by good faith.[302]

The value of OSHA penalties is capped by violation category, regardless of circumstance. The maximum penalty for "serious," "other-than-serious," posting requirement, and failure-to-abate violations is $13,653 per violation; the maximum penalty for repeated or willful violations is $136,532 per violation. These penalties took effect on January 15, 2021.[303]

Appeals and Defenses

Employers facing OSHA citations may respond by seeking an informal conference with OSHA, by formally contesting the citation, or by accepting the citation. An employer may seek an informal conference with the OSHA area director to discuss citations, penalties, abatement, or other inspection issues. Settlements are possible. Alternatively, employers may, within 15 working days, formally dispute a citation by writing to the OSHA area director. The Occupational Safety and Health Review Commission reviews all disputed citations.[304] Uncontested or unsettled citations become a final order of the Occupational Safety and Health Review Commission.[305]

Before a citation is issued, an employer may seek a variance from the relevant regulation. Variances may be temporary, lasting less than one year with up to two six-month renewals, and are provided when the employer is unable to meet the standard in time, is taking all steps to protect employees from the regulated hazard, and has a method for coming into compliance. Permanent variances are also available when an employer proves by a preponderance of the evidence that the alternative practice either in place or proposed as an alternative to the regulation will provide a safe workplace.[306]

Employers may use various defenses when before the review commission. Employers may allege a Section 4(b)(1) defense, arguing that OSHA does not have jurisdiction because the relevant working conditions are under the purview of another federal agency or state agency. OSHA avoids preemption and workplace regulation duplication through this provision but, in so doing, also limits its power. Employers must show that the other agency possesses statutory authority to regulate the workplace working condition cited by OSHA in its citation and that the other agency has exercised this authority.[307] Employers may also argue that the hazard was caused by isolated, independent employee conduct. The employer must show that the rule regarding the unsafe condition existed, had been communicated to the employee, and that compliance was routinely checked and enforced.[308]

Courts have recognized other defenses as well. Employers may argue, where multiple employers are on-site, that the cited employer did not create, expose the employee to, or have a responsibility to remove the hazard cited.[309] Employers may also argue reasonable reliance on the expertise of another if they can show that they reasonably relied on an expert/specialist to safely perform the job, and there was no way to reasonably foresee the work being done unsafely.[310] Employers may also argue that compliance with a regulation is infeasible, although courts very rarely grant such a defense.[311] Courts have also recognized a "greater hazard" defense. To successfully use this defense, employers must show that (1) compliance poses a greater threat to employees than noncompliance, (2) alternative protections were either nonexistent or used, (3) and a variance would be appropriate.[312]

Endangered Species Act

Overview

The Endangered Species Act (ESA) was enacted in 1973 to provide a program for the conservation and recovery of species at risk of extinction and the protection of ecosystems upon which they depend.[313] The ESA's strict substantive prohibitions against "take" of listed species on both public and private lands, the federal government's recent broad regulatory interpretations of key ESA terms, and recent judicial developments have all combined to make the ESA a significant compliance hurdle for many types of projects.

In August 2019, the Department of the Interior issued a final rule (2019 ESA Rule) imposing significant changes to the implementing regulations for the act. The rule rescinds automatic protections for threatened species and revises the process for listing and delisting species, the process of designating critical habitat, and the procedures for interagency cooperation under the act.[314]

Seventeen states and a number of environmental groups challenged the 2019 ESA Rule in the U.S. District Court for the Northern District of California. The suits remain pending as of May 2021.[315]

Listing

Species listed as "endangered" or "threatened" receive legal protections under the ESA. An "endangered listing"

means that the species is at risk for extinction, and a "threatened listing" means that an animal is likely to become endangered in the foreseeable future, which the 2019 ESA Rule describes as "extend[ing] only so far into the future as the Services can reasonably determine that both the future threats and the species' responses to those threats are likely."[316]

The listing process can be initiated through either of two ways: (1) the candidate assessment program implemented by the Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS) (collectively, FWS), or (2) petitions by concerned individuals or organizations. The classification of the particular species of concern dictates which of these two agencies implements the ESA with respect to that species. Most, but not all, marine species fall under NMFS jurisdiction. The agencies consider five listing factors:

- The present or threatened destruction, modification, or curtailment of [the species'] habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; or
- Other natural or manmade factors affecting [the species'] continued existence.[317]

The FWS listing decision must be based solely on "the best scientific and commercial data available," rather than cost.[318] In response to a petition, FWS first makes a "90-day finding" as to whether there is "substantial" scientific information presented to warrant further consideration for listing. Then, FWS makes a "12-month finding" on whether to propose the species for listing. FWS may determine that listing is not warranted, ending the process. A positive 12-month finding to propose listing the species triggers a lengthy rulemaking process.[319] Alternately, FWS may find that a listing is warranted but precluded by other agency priorities, placing the species on the "candidate" list. For a warranted species listing, FWS also must consider designating critical habitat for that species to the extent prudent and determinable.[320] Critical habitat consists of the specific areas within a species' geographical range that are considered essential to the conservation of the species and which may require special management considerations or protection.[321]

FWS implementation of Section 4 continues to evolve and change. In 2011, FWS settled with environmental groups to expeditiously resolve a backlog of hundreds of candidate species. In 2020, FWS and the National Oceanic and Atmospheric Administration's National Marine Fisheries Service jointly defined "habitat" within the context of critical habitat designations as "the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one of more life processes of a species."[322] In addition, FWS outlined the process for excluding areas of critical habitat following a discretionary exclusion analysis.[323] FWS is currently considering expansions of critical habitat determinations as well as improvements to its listing process, including whether it will continue to consider multispecies petitions and whether states' input should be solicited before a petition is filed.

Section 7—Consultation

Under Section 7 of the ESA, federal agencies are prohibited from taking any action that is "likely to jeopardize the continued existence" of an endangered or threatened species or result in the destruction or adverse modification of critical habitat.[324] To ensure implementation of this prohibition, the ESA requires that any federal agency taking an action that "may affect" a listed species to consult with FWS. The first step in the consultation is the

biological assessment, in which the action agency analyzes any effects that its proposed action may have on a listed species. If the consulting agency and the action agency conclude that the action will likely adversely affect a listed species, then formal consultation begins.[325] The keystone to formal consultation is the biological opinion. The biological opinion is a scientific, final FWS opinion on whether the proposed action will result in jeopardy or an adverse modification of critical habitat. If either of these is found, the biological opinion sets out reasonable and prudent alternatives that the action agency must take to avoid jeopardy or adverse modification. Absent such findings, the action agency still must comply with reasonable and prudent measures to minimize the impacts of "incidental take" of listed species during the course of the project. These measures are memorialized in an Incidental Take Statement, which shields parties to the project from ESA liability[326] as long as any harm to the species is within stipulated limits, the reasonable and prudent measures are complied with, and the harm is truly incidental.

Section 9—Take Prohibition

No person (including a federal agency) may "take" a listed species pursuant to Section 9 of the ESA and its implementing regulations unless otherwise authorized under Section 7 (for federal agencies) or Section 10 (for private parties) of the ESA. "Take" is broadly defined under Section 3(18) of the ESA, including:

- Harass
- Harm
- Pursue
- Hunt
- Shoot, wound, kill, capture, collect
- Attempt to do any of the above

Section 10—Take Exceptions

For private parties, a "take" of an endangered or threatened species is only authorized if the party committing the take obtains an incidental take permit. To obtain an incidental take permit, an applicant must prepare and submit a habitat conservation plan (HCP). The HCP should demonstrate how the proposed project will minimize, to the greatest extent possible, the take of listed species and the destruction of habitat. The FWS must issue the incidental take permit if it finds all of the following in its evaluation of the HCP:

- The taking will be incidental;
- The taking will be minimized and mitigated to the greatest extent possible;
- The applicant has ensured that funding will be available to implement the HCP;
- The taking will not appreciably reduce the likelihood of survival and recovery of the species; and
- The applicant will comply with any measures the agency has deemed necessary and appropriate for the purposes of the HCP.

As noted above under Section 7, if a project is federally funded or federally implemented, an incidental take statement in the biological opinion shields private parties involved in the project from Section 9 liability, as long

as the taking is within specified limits (in the biological opinion) and the reasonable and prudent measures are complied with.

Exemptions and Defenses

If the consulting agency (under Section 7 consultation) finds that the proposed project jeopardizes a listed species, then a cabinet-level ESA committee, commonly termed "the God Squad," can exempt a particular project from a jeopardy finding. Though this exemption is a theoretical option to avoid the consequences of take, an exemption has only been granted a handful of times since the inception of the God Squad in 1978.

To shield itself against a potential FWS or citizen suit enforcement action under the ESA, a project proponent can take one or more steps. The party should first determine whether impacts to the species can be avoided altogether through alterations to the project or by adoption of certain protocols to benefit the species in the project area. As described above, a party can obtain incidental take coverage for one or more species under an incidental take permit (if there is a federal nexus) or an incidental take permit/habitat conservation plan, though these are time-consuming and expensive processes. To economize efforts, one or more parties may pursue a programmatic habitat conservation plan for one or more species, under which future site-specific projects may seek eligibility.

In the face of a potential future listing, parties may proactively engage the FWS to approve a Candidate Conservation Agreement or Candidate Conservation Agreement with Assurances (CCAA) to afford upfront take coverage on more favorable terms in the event of a future listing of a candidate species, or to obviate the listing altogether.[327] The facts of each case may support certain defense arguments about the absence of any take, or the lack of proximate cause for the take.[328] Eligibility for a CCAA covering a candidate species under an habitat conservation plan requires that there also be a currently listed species affected by the project.[329] An example of a candidate species covered under a CCAA is the greater sage grouse in Harney County, Oregon.[330] The FWS and the Harney County Soil and Water Conservation District entered into an agreement to protect ranch and land management practices preventing habitat loss of the sage grouse while also allowing for incidental take in the case that the species becomes listed. This particular example also showcases how the ESA and CCAAs identify opportunities to provide further benefit to a species through removing existing or future threats.

Programmatic Habitat Conservation Programs Allowing for Incidental Take

Programmatic or master permits are sought "to address a group of actions as a whole, rather than one at a time" through separate permits.[331] Programmatic Habitat Conservation Plans may address a single action occurring in a number of different places or a group of various actions taking place in the same location. In the master permittee structure, there is a single master permittee who administers the conservation plan and is fully responsible for answering to the agency. The master permittee enrolls property owners into contractual agreements called "certificates of participation" or "certificates of inclusion."[332] The property owners thereby obtain incidental take authorization through the master permittee.

ESA Updates

In August 2019, the Department of the Interior issued a final rule (2019 ESA Rule) imposing significant changes to the implementing regulations for the act. The rule rescinds automatic protections for threatened species and revises the process for listing and delisting species, the process of designating critical habitat, and the procedures for interagency cooperation under the act.[333]

Seventeen states and a number of environmental groups challenged the 2019 ESA Rule in the U.S. District Court for the Northern District of California. The suits remain pending as of June 2021.[334]

In June 2021, FWS announced plans to revise ESA regulations. The planned revisions are directed at aligning the ESA regulations with Bidden-Harris administration policies and priorities. The revisions will require notice and comment rulemaking and a satisfactory administrative record to justify the changes.[335] The planned revisions include:

- Rescinding regulations governing exclusions from critical habitat designations;
- Rescinding the regulatory definition of "habitat" for purposes of critical habitat designations;
- Revising regulations for listing species and designating critical habitat;
- Revising regulations for interagency cooperation; and
- Reinstating protections for species listed as threatened under ESA.[336]

Responsible Sourcing

While the trend in corporate responsible sourcing surrounds voluntary sourcing policies and reporting, a number of federal and international laws require corporate compliance with responsible sourcing for industries like conflict minerals, timber, and wildlife.

Conflict Minerals

Conflict minerals generally include tantalum, tin, gold, and tungsten. In 2010, the U.S. Congress passed Section 1502 of the Dodd-Frank Act, which required U.S. public companies to address the issue of exploitation leading to the humanitarian crisis in the Democratic Republic of the Congo (DRC) financed through the trade of conflict minerals.[337] Section 1502 did not prevent sourcing from the DRC; rather, it required companies to disclose use of conflict minerals if those minerals are "necessary to the functionality or production of a product" manufactured by those companies.[338] In 2015, the U.S. Court of Appeals for the District of Columbia Circuit held that Section 1502 "violate[s] the First Amendment to the extent the statute and rule require regulated entities to report to the Commission and to state on their website that any of their products have 'not been found to be "DRC conflict free."'"[339] Although part of Section 1502 was held unconstitutional, the rule is still in place.

Timber Sourcing

Timber sourcing regulation is covered by a variety of responsible sourcing laws, including the U.S. Lacey Act, the Australia Illegal Logging Prohibition Act, the European Union Timber Regulation, and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).[340]

The Lacey Act

The Lacey Act is the oldest U.S. wildlife protection law. It was originally enacted in 1900 with amendments in 2008 extending the scope of the act to cover a broader range of plant and plant products, including timber and associated wood products.[341] One of the major goals of the Lacey Act is to prevent illegal logging practices and associated trafficking of illegally sourced wood.

The Lacey Act's key component is that it prohibits the trafficking of "fish or wildlife or plant taken, possessed, transported, or sold" in violation of any federal, state, Indian tribal, or foreign law or any U.S. treaties.[342] Regarding timber and other plants, the act also requires that when importing such products, one must identify the scientific name of the plant, the value of imported merchandise, the quantity of plant material, and the country of harvest.

The Lacey Act is implemented by USDA's Animal and Plant Health Inspection Service with support from Customs and Border Protection and enforcement by the Department of Justice (DOJ). There are various criminal and civil penalties for violations of the act, depending on the intent and type of prohibited conduct.[343] There are a number of recent criminal enforcement actions involving violations of the Lacey Act, which often implicate the ESA as well.[344]

Convention on International Trade in Endangered Species of Wild Fauna and Flora

CITES is a voluntary international agreement between 193 parties that entered into force in 1975.[345] CITES governs the international trade in specimens of wild animals and plants to prevent threats to those species' survival. All import, export, and re-export of species covered under CITES must be authorized through a licensing system.[346] Parties to the agreement list species in one of three appendices to CITES where appendixes I and II require a vote of the parties to the convention.[347] Appendix I lists species threated with extinction, Appendix II lists species that require controlled trade to prevent exploitation that may be incompatible with species' survival, and Appendix III contains species of at least one country that has appealed to CITES for help in managing the trade of that species. A number of timber species are listed within the various appendices.[348]

National Environmental Policy Act

The National Environmental Policy Act (NEPA) was signed into law in 1970 for the purpose of establishing a national policy of productive yet protective use of the human environment.[349] NEPA aims to achieve this purpose by injecting environmental considerations into federal agency decision-making before those decisions are made and resources are irrevocably committed to a course of action. As a procedural statute, NEPA compels an agency to follow procedures, rather than prescribe the particular result an agency should achieve. Many states have enacted their own versions of NEPA for nonfederal projects within their jurisdictions, some of which (most notably California) have substantive components.

The NEPA Review Process

EPA's goal of ensuring consideration of environmental factors is achieved primarily by requiring preparation and public circulation of environmental analyses on "proposals for . . . major Federal actions significantly affecting the quality of the human environment."[350] As a practical matter, federal actions encompass any project conducted, authorized, or funded by any federal agency.

Through the NEPA review process, federal agencies evaluate the environmental and related socio-economic impacts expected from their proposed actions. When NEPA is triggered, the federal agency in charge of the proposed action (or "lead agency") must either prepare an Environmental Assessment (EA), prepare a more detailed Environmental Impact Statement (EIS), or, where available, use a more streamlined Categorical Exclusion. When in doubt as to whether the expected impacts will be significant, or where litigation is viewed as unlikely, agencies often begin with an EA.

The EA must contain a brief statement of the action proposal and an analysis of whether or not an EIS is needed. The touchstone of this analysis is whether or not the proposed action significantly affects the quality of the human environment. If the agency concludes in the EA that there would not be significant effects to the environment and an EIS is not needed, then the agency may issue a Finding of No Significant Impact (FONSI). A FONSI states the reasons why a proposed project would have no significant effects on the human environment. A FONSI must additionally include a copy of, or reference to, the EA, which contains data and analysis supporting the agency's conclusions on environmental impacts. An agency also may use an EA/FONSI where it commits to binding mitigation measures to render impacts insignificant—this is called a "mitigated FONSI."

If the EA finds that there would be significant effects from the proposed project, or if it is known from the outset that significant effects are likely to occur, then the agency must produce a comprehensive EIS. An EIS involves more procedural requirements (e.g., public scoping meetings, publication of draft EIS) than an EA. That said, differences between the two have become blurred as agencies frequently apply the EIS process to EAs, and publish EAs that are no shorter than an EIS.

There are two types of EISs—project-specific and programmatic. Project-specific EISs analyze specific individual projects or actions, while programmatic EISs analyze a larger federal program or plan. Programmatic EISs are built upon a larger stage with project-specific reviews (EAs or EISs) for individual actions within the program. This process is generally called "tiering."

The first step in the drafting process of an EIS is a notice of intent published in the *Federal Register*. The notice of intent contains a short description of the proposed action and an announcement of any scheduled meetings to discuss the EIS. Next, there is a scoping process wherein affected parties, including private actors and any other federal agencies, are invited to participate in identifying issues that should be analyzed in the EIS. Increasingly, these other agencies are using this opportunity to coordinate their permitting functions and environmental reviews into a concurrent process with the lead agency's EIS.

Contained in the draft EIS is a statement of the purpose and need of the project, a list of alternatives to the action (including a No Action status quo alternative), a description of baseline environmental conditions, and a description of the environmental impacts associated with each alternative.[351] The alternatives analysis section of the EIS is the "heart" of the document. A federal agency is only required to include a "reasonable range" of alternatives, which all must further the stated purpose and need. In this analysis, the agency must identify the most environmentally protective alternative and any alternatives considered but not carried forward for detailed analysis. The description of environmental effects associated with each alternative must include direct, indirect, and cumulative effects. Additionally, this section might include mitigation measures that make a particular alternative more environmentally protective.

After completing a draft EIS, the agency files it with EPA. EPA will publish a notice in the *Federal Register*, and parties will have 45 days to submit comments on the draft EIS. Once the comment period is complete, the agency files a final EIS with the EPA, which consists of the draft EIS, plus the agency's response to all comments and any revisions the agency is making in response to comments. EPA then publishes a notice in the *Federal Register*, and there is a 30-day period where the public can comment on the final EIS decision on the project and the process it went through in analyzing the alternatives. The drafting agency then files a Record of Decision (ROD) that explains the agency's ultimate decision and mitigation contained in the EIS. The agency's filing of the ROD constitutes a "final agency action" under the Administrative Procedure Act and is thus subject to judicial review.[352]

Along with setting up a procedural framework, NEPA also established the Council on Environmental Quality, a division of the Executive Office of the President that issues guidance to federal agencies on completing a proper

EIS and how agencies should incorporate environmental analyses into their decision-making process. Agencies adopt (and amend) their own NEPA-implementing regulations, which may vary across agencies.

NEPA Challenges

As noted above, NEPA is a procedural statute; it does not provide for any substantive duties or stipulated written penalties. The statute is wholly enforced through judicial challenges under the Administrative Procedure Act,[353] with parties challenging an EIS on its substance, or challenging a FONSI or Categorical Exclusion with the claim that an EIS should have been prepared instead. Because of the procedural framework established by NEPA, challenges principally aim at establishing that a federal agency did not follow required procedures. That said, challenges to the ultimate merits of a project are often cloaked in NEPA challenges. While the mere fact that an agency eventually chose a less environmentally protective alternative is not the proper basis for a claim, courts faced with sketchy administrative records have on occasion been swayed by NEPA plaintiffs to perform more exacting reviews and afford less deference than should normally be expected.

Given that the legal claim in a NEPA case is based in the Administrative Procedure Act, the court analyzes the agency's NEPA review on an arbitrary and capricious standard.[354] A court's review will be limited to the administrative record, which is the collection of all of the agency-produced NEPA documents and the public comments. For this reason, a thorough, well-reasoned administrative record is crucial for the agency to defend a NEPA challenge. In order to rule in favor of the agency, the reviewing court has to determine that the agency took a hard look at environmental impacts. The administrative record must reflect and document the agency's hard-look analysis.

Other NEPA Strategies

Other than defending the NEPA analysis and administrative record for a project, arguments can sometimes be made that the project is not subject to NEPA at all. Proponents can argue that the particular project is not federal enough to require NEPA review, such as a "small handles" scenario where the majority of the project requires only state or private approvals. Alternately, one might argue that the federal action agency does not have any discretion in its decision whether or not to go through with the project, such that the NEPA analysis could not inform the decision. Either argument, if successful, takes the project out of NEPA review. A project may also fit in one of several statutory or regulatory Categorical Exclusions to satisfy NEPA review in the most streamlined manner possible. In such cases, the agency must check for any extraordinary circumstances (e.g., endangered species, protected cultural sites, wetlands, and certain other effects) precluding use of the Categorical Exclusion.[355]

The procedural nature of NEPA claims mean that those wanting to either protect or halt a project requiring NEPA review will want to be strategic about the contents of the administrative record. Challengers to a NEPA review generally waive arguments not specifically made in the comment period, though challengers usually are not required to have authored a particular comment to later make arguments based on it. Therefore, proponents of a particular project might want to argue that plaintiffs have waived particular arguments in order to weaken the challenge to the project. Additionally, through the filing of comments or the production of environmental studies, proponents of a project can aid the agency in thoughtfully and credibly responding to comments and explaining its decision.

NEPA Updates

In July 2020, the Council on Environmental Quality published a final rule that significantly revised the NEPA

implementing regulations for the first time in more than 40 years.[356] Among other changes, the final rule set presumptive time limits for completion of an EIS or an EA, as well as presumptive page limits for the documents. The rule strikes the requirement to consider indirect and cumulative impacts, excludes projects with "minimal" federal funding or involvement, allows applicants to prepare an EIS, and requires joint records of decision where proposals require actions by more than one federal agency. The rule also required federal agencies to revise their own NEPA procedures for consistency with the final rule by September 14, 2021.

Since publication, several lawsuits have been filed challenging the final rule in the U.S. District Court for the Northern District of California, the U.S. District Court for the Southern District of New York, and the U.S. District Court for the Western District of Virginia.[357] The challenges primarily focus on the scope of NEPA applicability and the alleged departure from longstanding policies, particularly with respect to consideration of effects.[358] The suits remain pending as of June 2021.