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 impacting endangered species or development projects near wetlands, among others. By way of example, in 2018, the EPA’s enforcement and compliance efforts led to cleanups and redevelopment of over 150 Superfund sites, investments of $4 billion to achieve compliance with environmental and pollution laws, and the incarceration of 73 total individual criminal defendants. And that is only the federal level of environmental enforcement.

While environmental compliance is a complex field that can (and does) occupy many volumes within an entire treatise (if not an entire library), this article is designed to serve as a primer and provide a general introduction. Obviously,
when facing environmental legal or regulatory issues, all compliance professionals must work closely with, and rely upon the guidance, advice, and direction of experienced counsel. Indeed, none of this article constitutes legal advice. Rather, the primary goal of this article is to assist non-lawyers with an overview of some of the common statutes, as well as the concepts, terms, and issues that are likely to arise in dealing with various corporate environmental disputes. Importantly, EPA’s website often provides general and detailed information for its regulatory programs that can be very helpful to interested parties.

Organizationally, after this brief introduction, Part I of this article includes a brief discussion of some recent statistics relating to environmental liabilities and enforcement statistics, as well as the interplay between local, state, and federal laws (which are often inter-related in our federally “delegated” regulatory system). Part II 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 is paramount to prevent violations and reduce their likelihood; to reduce clean-up 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 U.S. Environmental Protection Agency (EPA) is the federal agency charged with administering and enforcing federal environmental laws—most of the laws addressed in this chapter. EPA’s national headquarters are in Washington, D.C., 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. The “Substantive” Rules—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.” 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, 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.

Notably, the scope of the fundamental term “waters of the United States” remains a subject of hot contention and has historically been interpreted broadly to include wetlands and streams connected to navigable waters. After a string of Supreme Court cases on the topic, the EPA promulgated a rule in 2015 that defines which types of water bodies are included in, or excluded from, the definition of waters of the United States. That rule has since been qualified in a February 2018 EPA rule postponing the effectiveness of the rule until February 2020 in response to EPA’s reconsideration of the rule under the new administration and anticipated judicial decisions on the validity of the 2015 rule. Further, EPA has issued a proposed rule to recodify the definition of waters of the United States that existed before EPA’s 2015 rulemaking, and EPA is expected to issue a final rule in fall 2020, which will likely face legal challenges. Individuals and organizations that have 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 regulates this type of pollution by imposing best management practices on the activities responsible for these pollutants.

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, etc.), 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.”[11]

Water quality standards are distinct from the technology-based requirements and are governed by CWA Section 303.[12] 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.[13] To develop water quality standards, the water body is first assigned a designated use or uses (e.g., drinking water, recreation, cold water fishery, etc.). 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 anti-
degradation policy, which requires certain water qualities to be maintained and protected. 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), 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. 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. 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” (IUs).

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. 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.

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, 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[21] (CAA or the Act) 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 the acid rain trading program.

Title I

Title I[22] 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 and Prevention of Significant Deterioration 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.”[23] Currently, standards have been established for six criteria pollutants under this program: sulfur dioxide (SO2), nitrogen dioxide (NO2), particulate matter (PM), carbon monoxide (CO), ozone (O3), and lead (Pb). 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.[24] More stringent standards apply in nonattainment areas.

The New Source Review (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 Prevention of Significant Deterioration (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 (LAER), which is typically more stringent than BACT.[25]

Separately, the New Source Performance Standards 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,[26] EPA promulgates regulations establishing emissions standards for Hazardous Air Pollutant (HAP) emissions from new and modified major and “area” sources 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” (MACT). Under the NESHAP program, EPA currently regulates 187 HAPs from “major” and “area” sources.[27]

Title V

Title V[28] 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.[29] 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\[30\] 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\[31\] and during the servicing, repair, or disposal of appliances and industrial process refrigeration.\[32\]

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.\[33\]

Primary Violations and Penalties

Like most other federal environmental statutes, the CAA empowers EPA to seek administrative,\[34\] civil,\[35\] or criminal\[36\] 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. EPA can also seek compliance orders or injunctions. EPA’s Air Enforcement website provides more detailed and specific guidance regarding enforcement priorities and obligations imposed on specific source categories. Further discussion can be found later in Part Two—Process and Enforcement.

**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 startup, shutdown, and maintenance (SSM) and during emergencies, recent case law and regulations have eliminated or severely limited use of this defense. There are additional defenses, common to other statutes, that are discussed in the enforcement section (Part III).

**Resource Conservation and Recovery Act (RCRA)—Hazardous Waste Management**
RCRA was enacted by Congress to promote the proper management of solid and hazardous wastes. The primary goals of RCRA are to protect the environment and human health 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. 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:

any 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 402 of the Federal Water Pollution Control Act, as amended, or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended.

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. There are a number of items that are excluded from the EPA’s definition of solid waste. Additionally, the Universal Waste Rules apply to management of batteries, pesticides, mercury-containing equipment, and lamps.
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.\[45]\n
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);\[46\] or (2) are specifically listed in EPA’s List of Hazardous Wastes.\[47\]

Note that EPA has explicitly excluded a number of solid wastes from the “hazardous waste” classification.\[48\]

**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 non-specific sources.\[49\] The second list relates to hazardous wastes from specific sources.\[50\] The third and fourth lists describe discarded commercial chemical products.\[51\] 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.\[52\] 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.\[53\]

**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:\[54\]

- Ignitability;\[55\]
- Corrosivity;\[56\]
• Reactivity.\textsuperscript{[57]}

• Toxicity.\textsuperscript{[58]}

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.\textsuperscript{[59]} 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 4 hazardous characteristics.\textsuperscript{[60]}

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.] part 261 . . . or whose act first causes a hazardous waste to become subject to regulation.”\textsuperscript{[61]} A generator is charged with initially determining, based on the criteria discussed above, whether the waste that is generated is a hazardous waste.\textsuperscript{[62]}

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.\textsuperscript{[63]}

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.”\textsuperscript{[64]} 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.\textsuperscript{[65]} 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.\textsuperscript{[66]} In limited circumstances, transporters carrying wastes from small-scale generators are exempt from these regulations, but still have to follow certain requirements.\textsuperscript{[67]}
Requirements for Treatment, Storage and Disposal (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.\footnote{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.”\footnote{69} 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.”\footnote{70} A number of different TSD facilities are exempted from compliance with the regulations.\footnote{71}

TSD facility operations are governed by regulations that address waste manifesting, recordkeeping, 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.\footnote{72} 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.\footnote{73} 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).\footnote{74} RCRA permittees generally have a continuing obligation to report...
all known releases of hazardous waste or constituents from SWMUs at their facilities.\footnote{75} The three major stages of RCRA corrective action are:\footnote{76}

1. **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.

2. **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.

3. **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.\footnote{77}

Notably, the RCRA corrective action program was designed to mirror the CERCLA\footnote{78} remediation scheme promulgated in the national contingency plan (NCP).\footnote{79} 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 RCRA Subtitle C; however, the facility must also comply with certain other provisions as applicable. [80]

• Under RCRA’s non-duplication provision, RCRA shall not apply to any activity or substance subject to the Clean Water Act, the Safe Drinking Water Act, the Marine Protection, Research and Sanctuaries Act, and the Atomic Energy Act, except to the extent application of RCRA is “not inconsistent” with the requirements of such acts. [81] This provision has been used to bar application of RCRA to activities already governed by the Clean Water Act 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. [82] 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. [83] 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.[84]

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 non-
hazardous, and “other” wastes, as well as lists of hazardous constituents,
streams, and characteristics.[85] 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 Part 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.[86] 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.

Comprehensive Environmental Response, Compensation, and
Liability Act (CERCLA) or “Superfund”

Overview

History. CERCLA[87] 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.[88] 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.\[89\] 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 re-authorized 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 (PRPs)**

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. [90]

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. [91] 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),[92] divide all response costs into two categories: removal actions and remedial actions. Removal actions are generally short-term responses to mitigate the effects of pollution that requires immediate action; they also include all investigation costs.[93] 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.[94] 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),[95] 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 non-compliance (i.e., an objectively reasonable basis to believe that the party was not liable or that the response action was arbitrary and capricious).[96] Failure to comply with a Section 106 order, however, may result in penalties of up to $37,500 per day,[97] as well as treble damages for the amount EPA spends as a result of the party’s non-compliance.[98]

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 cleanup a site to recover costs from other PRPs.[99] 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. Notably, parties that have settled with EPA are protected from contribution claims by other PRPs.[100]

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;
- that a “release” [101] of hazardous substances has occurred;
- the release occurred at a “facility”; [102] and
- the release resulted in response costs (i.e., the costs of investigating and/or remediating a site) that were consistent with the NCP. [103]

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.[104] 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.[105]

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.[106] Furthermore, a court must issue a declaratory judgment against all parties found liable for cost recovery under Section 107(a),[107] 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. [108]

• **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. [109] 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. [110] 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. [111] 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. Part 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 National Pollutant Discharge Elimination System permit under the Clean Water Act. [112]

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; [113] 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. [114]

**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 6 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 3 years after completion of the removal action (or within 6 years after initiation of the remedial action if the latter was initiated within 3 years after completion of the removal action).\[115\]

All contribution actions must be commenced within 3 years after either a judgment in a cost recovery action or an administrative or judicially approved settlement.\[116\]

**Toxic Substances Control Act (TSCA)**

**Overview**

Congress enacted 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.\[117\] 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 below) and food, drugs, and cosmetics regulated under the Federal Food, Drug, and Cosmetic Act, among others.\[118\] 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.\[119\] The revised statute grants EPA increased authority to evaluate and regulate new and existing chemicals.

**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.[120] The revised statute maintained the basic structure of the PMN review process, requiring EPA to review PMNs within 90 days.[121] However, the revised statute now requires EPA to make an affirmative determination regarding whether a chemical substance presents an unreasonable risk.[122] In making this determination, EPA cannot consider costs or other non-risk 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.[123] 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.

Companies must also comply with Significant New Use Rules (SNURs), if applicable, for chemicals they manufacture, import, process, or use.[124] 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.[125]

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).[126] 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.[127] 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.[128] 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.[129]

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 U.S. facilities, if such activity exceeds certain thresholds, to EPA every four years. The next round of CDR reporting is due in 2020, so companies will need to evaluate their chemical use during calendar years 2016–2019.[130] EPA is planning to amend the CDR rules, but at the publication time of this manual, a final regulation had not been issued.[131]

Section 8(e): Substantial risk reporting. Manufacturers, importers, processors, 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).[132] Companies must submit a Substantial Risk Notification to EPA within 30 calendar days of obtaining substantial risk information.[133] It is important for companies to establish internal procedures to evaluate information regarding chemicals for purposes of substantial risk reporting.[134] 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.[135]

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. Many other countries also have their own chemicals management frameworks. At the international level, the Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals. 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 (FIFRA)**

**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 Cosmetics Act (FFDCA) and the Toxic Control Substances Act (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.** FIFRA prohibits the distribution or sale of a pesticide without registration unless one of a limited number of exceptions applies. The registration requirement is “the heart of EPA’s regulation of pesticides.” 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. 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.\[143\] 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.”\[144\] 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.\[145\]

The statute classifies all pesticides into four categories and provides registration fee schedules for each category.\[146\] To register a new pesticide, EPA must find the following as supported by the application materials:\[147\]

- 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”; and
- 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 FFDCA].”\[148\] 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 further below 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.[149]

Similar to the pesticide registration requirement, FIFRA prohibits production of pesticides or active ingredients in an establishment without prior registration.[150] It also authorizes EPA to promulgate book- and recording-keeping and registration rules.[151]

**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,[152] suspension,[153] or emergency order,[154] 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.[155] 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.[156]

For more information see EPA’s Office of Compliance and Enforcement Assurance.[157]

**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:

- EPA permits a general use and approves the registration, if following the registered directions or common practice for a pesticide use alone can generally avoid “unreasonable adverse effects on the environment”;[158]

- EPA permits a restricted use and approves the registration, if following the registered directions or common practice for a pesticide use alone is not sufficient to generally avoid “unreasonable adverse effects on the environment,” but extra regulatory restrictions may cure such defects;[159]
EPA permits no use and denies the registration, if it is impossible to generally avoid “unreasonable adverse effects on the environment.”[160]

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).[161] General uses may be later changed into restricted uses, and vice versa, with certain procedures.[162]

A restricted use has to be conducted by or “under the direct supervision of” a certified applicator.[163] 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.[164] Depending on the purpose and place of pesticide use, applicators can be either private or commercial.[165] The licensing and certification standards for those two groups are separate under FIFRA.[166] 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.

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.[167] As for pesticides, FIFRA forbids distribution or sale if the pesticide:

- Is not registered or its registration is cancelled or suspended;[168]
- Has claims, in the distribution or sale, that “substantially differ” from claims in the registration statement;[169]
- Has composition, in the distribution or sale, that differs from the description in the registration statement;[170]
- Violates the coloring or discoloring requirements in Section 25(c)(5);[171]
- Is adulterated or misbranded;[172] or
• Is classified for restricted use, but the distribution or sale of such pesticide is for purposes other than the restricted use conditions. [173]

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

• Alteration of labeling or substance of a pesticide; [174]

• Refusal or failure to keep, provide, or give access to information as required; [175]

• Breach of confidentiality requirements in the statute; [176]

• Advertising of a registered product without giving the Section 3(d) classification; [177]

• Unauthorized or improper use of a pesticide; [178]

• Violation of orders, [179] laws or regulations; [180] and

• Falsification or providing false information. [181]

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, [182] as well as civil and criminal penalties with monetary fines and imprisonment. [183]

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); [184]

• Fertilizer products with no pesticide, and products intended to force bees from hives for the collection of honey crops; [185]

• (Without pesticidal intent) Deodorizers, bleaches, and cleaning agents,
non-toxic products intended only to attract pests for survey or detection purposes, and non-toxic products intended to exclude pests only by providing a physical barrier against pest access (e.g., certain tree pruning paints); \[186\]

- Treated articles or substances, pheromones and pheromone traps, preservatives for biological specimens, foods, natural cedar, and listed minimum risk pesticides. \[187\]

**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; \[188\] 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. \[189\]

- 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. \[190\]

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

- Certain biological control agents and non-liquid chemical sterilants (other than ethylene oxide); \[191\]

- Liquid chemical sterilants, human and animal drugs, and animal feeds. \[192\]

**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: \[193\]

- 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 one 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 non-certified applicator if a certified applicator will apply the pesticide.^[194]

Follow-On Registration Issues^[195]^ 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 ten-year exclusive-use period applies for those data that are submitted to support the initial registration of a product containing a new active ingredient.^[196]^ No other applicants may rely on the supplied data during that time.^[197]^ 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.^[198]^ 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.^[199]^ 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.^[200]^ An arbitration decision regarding compensation is final and is only reviewable in court for fraud, misrepresentation, or misconduct.^[201]^ 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.^[202]^
In 1984, an extremely toxic gas, methyl isocyanate (MIC), 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). 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, and reporting of hazardous and toxic chemicals.

Emergency Planning (Sections 301–03)

States are required to develop State Emergency Response Commissions (SERCs), which oversee Local Emergency Planning Committees (LEPCs). LEPCs prepare and regularly review chemical emergency response plans. 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) onsite in quantities that exceed the threshold planning quantities (TPQs). 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. 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.” 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.”

- **Threshold planning quantities.** TPQs may be based on classes of chemicals...
or categories of facilities, and the Administrator has discretion to revise the TPQs. [211]

- **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. [212]

- **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. [213] A state or local government may also bring a civil action against a facility owner or operator for violations. [214]

**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 the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Section 103(a) [215] or if the release exceeds the reportable quantities under EPCRA. (Note: 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. [216]

- **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.” [217]

- **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. [218]

- **Exemptions.** Facilities are exempted from these reporting requirements if the release only results in exposure to people onsite where the facility is located or the release is federally permitted under CERCLA Section 101(10). [219] 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. [220] 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 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. [221] 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. [222] For a second or subsequent conviction, these limits rise to $50,000 and five years of imprisonment. [223] Citizens may also bring a civil action against the facility owner or operator for failure to follow up after the release. [224]

**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. [225] 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). [226] A facility must submit these forms to
the appropriate LEPC, SERC, and fire department that has jurisdiction over the facility. [227]

- **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. [228]

- **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. [229] EPCRA adopts the definition of “hazardous chemical” from 29 C.F.R. § 1910.1200(c), but excludes several categories like food regulated by the FDA, substances used for household and research purposes, etc. [230]

- **EHSs.** 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. [231]

- **MSDS alternative.** The facility can submit a list of hazardous chemicals instead of submitting a MSDS for each such chemical. [232] 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. [233]
  - **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. [234]

- **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 3 months of when the owner or operator is required to prepare the MSDS for OSHA. [235] Facilities must submit a revised MSDS sheet within 3 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. [236]
  - **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). [237]

- **Penalties.** The EPA Administrator may assess a civil penalty against anyone violating these reporting requirements by bringing an action in U.S. District Court. [238] Citizens, state governments, or local governments may bring a civil action against a facility owner or operator for these violations. [239]
  - **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. The information from these reports makes up the Toxic Release Inventory (TRI).

- **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.” “Process” is defined as “the preparation of a toxic chemical, after its manufacture for distribution in commerce.” The EPA Administrator also has discretion to apply the requirements of Section 313 to any facility with onsite 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.

- **Thresholds.** For a toxic chemical used at a facility, the threshold for reporting is 10,000 pounds per year. For a toxic chemical manufactured or processed at a facility, the threshold is 25,000 pounds per year. The Administrator may revise (and has revised) these thresholds.

- **Timing.** These reports must be made online using the EPA’s TRI-MEweb interface (except for trade secret submissions). The reports must be submitted by July 1 each year, but the Administrator can change the reporting frequency and deadlines.

- **Penalties.** Anyone violating these reporting 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. The EPA Administrator may assess these penalties or bring an action in U.S. District Court. Citizens may also bring a civil action against a facility owner or operator for a violation of these provisions.

**Common EPCRA Violations**
The following are some common EPCRA violations:

- Failure to timely report accidental 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.
- Offsite impact. Under EPCRA, a release must have a potential or actual offsite impact in order to require emergency notification. There is an exemption for releases that only affect people onsite.
- 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 (NRC) 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 TRI 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.\[251\] The Audit Policy is discussed in more detail in the Environmental Compliance Processes section. Under EPA’s eDisclosure system,\[252\] 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 (NOD), 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 below (Part III).

**Occupational Safety and Health Act**

**Overview**

The Occupational Safety and Health Act of 1970 (the Act) created the Occupational Safety and Health Administration (OSHA),\[253\] 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 . . . .”\[254\] 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.[255] As of 2011, more than half of OSHA’s enforcement actions dealt with construction sites; a quarter are related to manufacturing; the final quarter spans a variety of industries, including oil and gas field services.[256] OSHA mainly regulates manufacturing activities such as plastic production, sheet metal, structural metal fabrication, metal stamping, and shipwright services.

OSHA applies to all employers and their employees in the U.S.[257] However, federal and state government employers, and workplaces protected by other federal agencies (e.g., Atomic Energy Commission or Mine and Safety Health Administration), are excluded.[258] 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.[259]

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.”[260] 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.[261]

Environmental Issues Under OSHA

Several specific OSHA Standards apply to environmentally-related issues.[262] For example, employers using hazardous wastes are subject to specific standards and reporting requirements. Employers who engage in corrective actions at Resource Conservation and Recovery Act (RCRA) sites and other operations involving hazardous substances are subject to OSHA’s Hazardous Waste Operations and Emergency Response Standards (HAZWOPER).[263] 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.[264] 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.[265] Employers must also provide respirators to employees exposed to hazard by breathing oxygen-depleted or contaminated air.[266] Employers should ensure that they have provided the appropriate respirator for the working conditions at hand.[267]

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 over 400 different air contaminants (including specific chemicals like Acetaldehyde, chemical classes like chromium compounds, and general categories like Coal Tar Pith Volatiles). The contaminants are divided into three groups, each with specific exposure limits. Lead and asbestos have specific, independent regulations.[268]

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.[269] 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.[270]

OSHA also establishes guidelines for Indoor Air Quality (IAQ).[271] 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.”[272] The guidelines include a general duty clause and address specific air contaminants and ventilation systems.

Recordkeeping and Reporting

Regulated parties must report all accidents on the job.[273] Any workplace accident requiring treatment or resulting in lost work time must be recorded within seven working days.[274] Employers must alert OSHA within eight hours of a fatality or within twenty-four hours for an in-patient hospitalization,
amputation, or loss of an eye.\textsuperscript{[275]} Knowingly made false representations are subject to criminal penalties.\textsuperscript{[276]}

OSHA requires employers to maintain monitoring and medical records for particular hazards. Affected employers must maintain these records for 30 years and transfer those records to the National Institute of Occupational Safety and Health\textsuperscript{[277]} in the event the employer goes out of business.\textsuperscript{[278]} 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.\textsuperscript{[279]}

Effective August 10, 2016, employers need to inform employees of their rights under OSHA to report work-related incidents, \textsuperscript{[280]} and employers will need to submit electronically OSHA reports and data, which will be available to the public. The new regulations are designed to encourage workplace safety reporting and discourage employer retaliation.

**Inspections**

OSHA inspects workplaces in the following descending order of priority: Imminent Danger Situations, Fatalities and Catastrophes, Complaints, Referrals, Follow-Ups, Planned or Programmed Investigations. 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.

Onsite inspection follows a more involved process. Inspectors research the worksite 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).\textsuperscript{[281]} 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.\textsuperscript{[282]} Next, the inspector explains why the site was chosen. After the employer chooses a representative to join the inspector, the inspector performs a “walkaround” to inspect the workplace. After the walkaround, 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.[283]

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 $12,471 per violation; the maximum penalty for repeated or willful violations is $124,709 per violation.[284] These penalties took effect on August 1, 2016.[285]

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.[286] Uncontested or unsettled citations become a final order of the Occupational Safety and Health Review Commission.[287]

Before a citation is issued, an employer may seek a variance from the relevant regulation. Variances may be temporary, lasting less than one (1) year with up to two (2) 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.[288]

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. The Act 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.\footnote{289} 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.\footnote{290}

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.\footnote{291} 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 that there was no way to reasonably foresee the work being done unsafely.\footnote{292} Employers may also argue that compliance with a regulation is infeasible, although courts very rarely grant such a defense.\footnote{293} 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 non-existent or used, (3) and a variance would be appropriate.\footnote{294}

**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.\footnote{295} 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, shortly before publication of this article, the Department of the Interior announced it had finalized significant changes to the implementing regulations for the Act, rescinding automatic protections for threatened species and revising the process of listing and de-listing species, the process of designating critical habitat, and the procedures for interagency cooperation under the Act.\footnote{296} Several Congress members and state attorneys general
indicated their intentions to challenge the final rules.\[297\]

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.

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” herein),\[298\] or (2) petitions by concerned individuals or organizations. 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.\[299\]

The FWS listing decision must be “based solely on the best scientific and commercial data available,” rather than cost.\[300\] 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.\[301\] 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.\[302\] 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.\[303\]

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. FWS also is currently considering expansions of critical habitat determinations, as well as improvements to its listing process, including whether it will continue to consider multi-species 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.\[304\] 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 their proposed action may have on a listed species. If the consulting agency and the action agency come to the conclusion that the action will likely adversely affect a listed species, then formal consultation begins.\[305\] 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 (RPAs) 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 (RPMs) 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\[306\] as long as any harm to the species is within stipulated limits, the RPMs 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, or
- 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 one time since the inception of the God Squad in 1978.[307]

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.[308] 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.[309] 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.[310] An example of a candidate species covered under a CCAA is the greater sage grouse in Harney County, Oregon.[311] 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 permits “to address a group of actions as a whole, rather than one at a time” through separate permits. [312] 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.[313] The master permittee enrolls property owners into contractual agreements called “Certificates of Participation” or “Certificates of Inclusion.”[314] The property owners thereby obtain incidental take authorization through the master permittee.

Responsible Sourcing

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

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.[315] 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.[316] In 2015, the DC Circuit Court of appeals held 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.”[317] The rule is still in place, however the current administration and Congress have hinted on multiple occasions that it will be either amended drastically or repealed in the future.[318]

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 (AILPA), the European Union Timber Regulation (EUTR), and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).[319]

The Lacey Act

The Lacey Act is the oldest U.S. Wildlife protection law 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.[320] One of the major goals of the Lacey Act is to prevent illegal logging practices and associated trafficking of illegally sourced wood. The two major components of the Lacey Act implicating wood products is (1) the prohibition on interstate and foreign trade of illegally sourced plant products and (2) the declaration requirement for imports where 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 (APHIS) with support from Customs and Border Protection and enforcement from the US Department of Justice. There are various criminal and civil penalties for violations of the Act depending on the intent and type of prohibited conduct.[321] There are a number of recent timber cases involving violations of the Lacey Act and often these cases implicate the Endangered Species Act as well.[322]

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

CITES is a voluntary international agreement between 193 parties which entered into force in 1975.[323] CITES governs the international trade in specimens of wild animals and plants to prevent threatening species’ survival. All import, export, and re-export of species covered under the CITES must be authorized through a licensing system.[324] Parties to the agreement list species in one of three Appendices to the CITES where Appendixes I and II require a vote of the Parties to the Convention. Appendix I lists species threatened 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 the CITES for help in managing the trade of that species. A number of timber species are listed within the various Appendices.\[325\]