

Foreign and Domestic Regulations

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U.S. Regulation



- While many federal and state environmental laws exist today, five key federal laws largely govern and drive environmentally sound business practices today. These are the:
 - Clean Air Act
 - Clean Water Act
 - Resource Conservation and Recovery Act
 - Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
 - Toxic Substances Control Act
- It's important to note that most of these federal regulations have state-based counterparts, so make sure to check your state and local laws to ensure full regulatory compliance.
- For more on how these laws relate to specific manufacturing practices, please see the set of corresponding slides in Section V. (Example: see Air Quality for Clean Air Act)



Clean Air Act



- The Clean Air Act (CAA), originally passed in 1963 and revised most recently in 1990, is designed to protect and improve air quality in the U.S. as well as the ozone layer.¹
- The law charges EPA with developing and enforcing regulations to:
 - Reduce outdoor, or ambient, concentrations of air pollutants that that cause smog, haze, acid rain, and other problems;
 - Reduce emissions of toxic air pollutants that are known to, or are suspected of, causing cancer or other serious health effects; and
 - Phase out production and use of chemicals that destroy stratospheric ozone.²
- Under the CAA, EPA sets limits on specific air pollutants as well as pollutants coming from specific sources (e.g. chemical plants, utilities, steel mills, etc.). It also establishes auto gasoline formulation and emissions control standards.

¹ EPA. 'Clean Air Act'

² EPA. 'The Plain English Guide to the Clean Air Act'



Clean Air Act (Cont.)

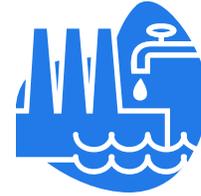


- CAA regulates Six Criteria Air Pollutants (as described in the Air Quality Section in the previous lesson), but also allows the EPA to regulate other pollutants that could harm the environment or human health.
- States play an integral role in carrying out CAA by working with facilities to reduce air pollution and reviewing and approving permit applications for industries or chemical processes.
- For more information on the Clean Air Act, check out the [EPA's CAA website](#) as well as ['The Plain English Guide To The Clean Air Act'](#).

¹ EPA. 'Clean Air Act'



Clean Water Act

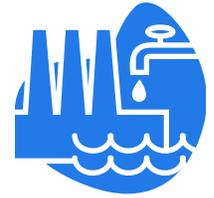


- The Clean Water Act (CWA) governs discharges of pollutants into the waters of the United States as well as quality standards for surface waters (not including groundwater, which is covered by other federal legislation).¹
- Under CWA, the EPA has implemented pollution control programs (such as setting wastewater standards for industry) and set water quality standards for all contaminants in surface waters.¹
- The CWA makes it unlawful to discharge any pollutant from a “point source” (e.g. industrial facility, military base) into navigable waters without a permit. EPA's National Pollutant Discharge Elimination System (NPDES) permits program controls discharges.
- For the most part, EPA relies on states to issue permits directly to discharging facilities.

¹ EPA. 'Summary of the Clean Water Act'



Clean Water Act (Cont.)



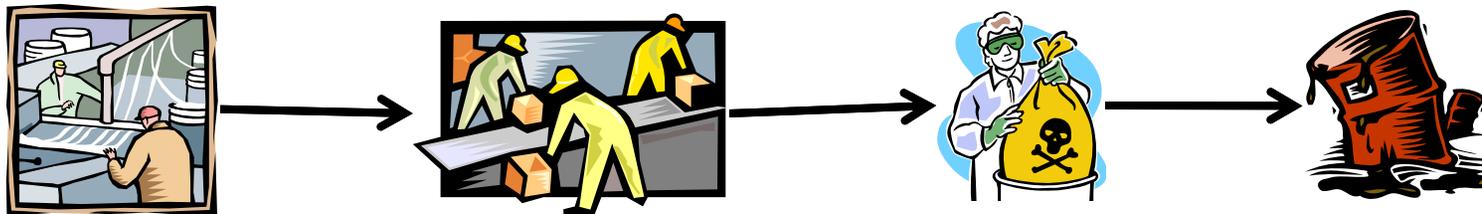
- Under CWA, EPA develops national “best available technology” standards for categories of dischargers. This is to ensure a basic national discharge standard for all facilities within a category.¹
- Where these standards are insufficient for a specific location, water quality standards may be employed. Water quality standards are designed based on expected end use (e.g. drinking water, supporting aquatic life, industrial use, etc.) and setting local standards is a task typically taken on by the states.
- For a more comprehensive overview of CWA and your obligations as a company, please see the [EPA's Introduction to the Clean Water Act](#) learning module.

¹ EPA. 'Introduction to the Clean Water Act'



Resource Conservation Recovery Act

- The Resource Conservation and Recovery Act (RCRA) is the U.S.'s primary law governing the disposal of solid and hazardous waste.
- RCRA gives the EPA the authority to control hazardous waste from “cradle-to-grave” (including generation, transportation, treatment, storage, and disposal) and provides a framework for the management of non-hazardous solid wastes.
- To meet its goals, RCRA established three distinct, yet interrelated, programs:
 1. *RCRA's Solid Waste Program (RCRA Subtitle D)* bans all open dumping of waste, encourages states to develop plans to manage nonhazardous industrial solid waste and municipal solid waste, and sets criteria for municipal solid waste landfills and other solid waste disposal facilities.



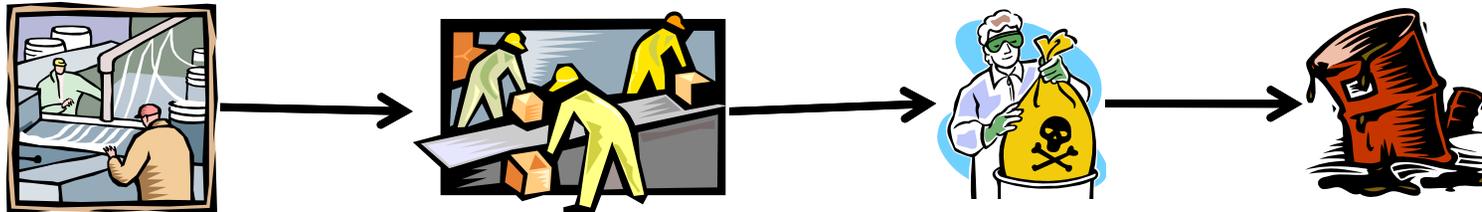
¹ EPA. 'Summary of the RCRA'

² EPA. 'RCRA Online'



Resource Conservation And Recovery Act (Cont.)

2. *RCRA's Hazardous Waste Program (RCRA Subtitle C)* establishes a system for controlling hazardous waste from the time it is generated until its ultimate disposal.
 3. *RCRA's Underground Storage Tank Program (RCRA Subtitle I)* regulates underground storage tanks containing hazardous substances and petroleum products.
- Items 2 and 3 most directly apply to U.S. manufacturers. Subtitle C requires extensive tracking and reporting of hazardous waste beginning at the point of generation all the way through until disposal. Generators of hazardous waste can learn more about their RCRA obligations [here](#).
 - Under RCRA, owners of underground storage tanks (USTs) that store petroleum or hazardous substances need to take precautions against potential leaks that may affect groundwater. Owners of USTs can learn more about their RCRA obligations [here](#).



¹ EPA. 'Summary of the RCRA'

² EPA. 'RCRA Online'





CERCLA/Superfund

- The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), better known as Superfund, was created to remediate sites contaminated by hazardous substances. It allows the EPA to clean up such sites and to compel responsible parties to perform cleanups or reimburse the government for EPA-led cleanups.¹
- The Superfund cleanup process is complex. It begins with an initial site assessment and hazard ranking, and is followed by a public comment period, EPA decision as to whether or not the site is placed on EPA's National Priorities List, a remedial investigation and feasibility study, and finally, the design and implementation of a cleanup plan.¹
- Parties identified as responsible for a contaminated site are obligated to bear the financial burden for the site's cleanup. When a responsible party cannot be identified, the government assumes financial responsibility for the cleanup.²

¹ EPA. 'Superfund: Basic Information'

² EPA, Superfund Enforcement



Toxic Substances Control Act



- The Toxic Substances Control Act provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides.¹
- TSCA addresses the production, importation, use, and disposal of specific chemicals including polychlorinated biphenyls (PCBs), asbestos, radon and lead-based paint.¹
- TSCA requires EPA to maintain and publish a list of each chemical substance that is manufactured or processed in the United States (referred to as the **TSCA Inventory**). The law prohibits the production or importation of chemicals not on this inventory.²

¹ EPA. 'Summary of the Toxic Substance Control Act'

² EPA. 'TSCA Chemical Substance Inventory'



Toxic Substances Control Act (Cont.)



- Under TSCA, manufacturers of “new” chemicals (those not in the TSCA Inventory) must provide pre-manufacture notification to EPA.¹
- These notifications are reviewed by EPA, who may prohibit or restrict use of the chemical if it is deemed to present significant risks to human health or the environment.
- TSCA also permits the EPA to require health and environmental risk assessments of chemicals by manufacturers, processors, importers or distributors.
- For further information on TSCA and manufacturer obligations associated with this law, please visit EPA’s TSCA website. Compliance assistance with TSCA can be found here.

¹ EPA. ‘Summary of the Toxic Substance Control Act’



U.S. Regulation - Takeaways



- For decades now, the U.S. has been passing laws designed to compel U.S. manufacturers to be responsible for their emissions to air and water, solid and hazardous waste streams and, in the case of chemical manufacturers, the environmental and health impacts of their products.
- More importantly, these laws are designed to drive reductions in manufacturer emissions and waste (particularly hazardous wastes).
- Done strategically, such reductions can significantly improve your bottom line. Many manufacturers have found that setting environmental performance goals above and beyond their regulatory requirements have led to not only increased profits, but have substantially reduced regulatory compliance burdens as well.¹

¹ EPA, Performance Track Website





International Regulations



- International regulations, or regulations outside the United States, related to environment and health have become as big a driver (and sometimes a greater driver) of sustainable business practices as domestic regulations, rising natural resource costs or consumer demands.
- While it's impossible to cover all regulations driving sustainability in this module, a few key regulations warrant attention. These include:
 - Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) Regulation
 - Restriction of Hazardous Substances (RoHS) Directive
 - Waste Electrical and Electronic Equipment (WEEE) Directive
- Though each of the above originated in the EU, they represent the basis for or have inspired similar regulations in other countries (e.g. China, Korea, Turkey) as well as U.S states (e.g. California).¹
- Each of these regulations, and others like it, carries significant implications for U.S. producers exporting to or selling in these markets—failure to comply could mean the loss of important markets for a company.

¹ Wikipedia, "Restriction of Hazardous Substances Directive"





REACH (EU)



- Registration, Evaluation, Authorization and Restriction of Chemical Substances (or REACH) is one of the most comprehensive regulations in the world governing the use of chemicals.
- REACH will eventually require all companies manufacturing or importing chemical substances (whether in products or by themselves) into the European Union, in quantities of one ton or more annually, to register these substances with the European Chemicals Agency (ECHA).
- All registrations require an assessment of the chemical's risk to human health and the environment during the product's expected life (including the disposal stage).
- REACH also identifies Substances of Very High Concern (SVHCs), which are banned or whose use is restricted in the EU.¹
- [ECHA's REACH website](#) provides companies with comprehensive guidance and tools to assist them in complying with REACH. The UK's Competent Authority also offers a [two-page leaflet](#) on what REACH means for manufacturers.

¹ TheManufacturer.com, "Impact of REACH on U.S. Exporters of Manufactured Goods to the EU"





RoHS



- The EU's Restriction of Hazardous Substances (or RoHS) Directive restricts the use of six hazardous materials in various types of electronic and electrical equipment (EEE) sold in the EU. These materials include:¹
 - lead
 - cadmium
 - mercury
 - hexavalent chromium
 - polybrominated biphenyl (PBB)
 - polybrominated diphenyl ether (PBDE)
- Though not all EEE is covered by RoHS, the Directive does apply to a large swath of products: large and small household appliances; IT and telecommunications equipment; consumer electronics; lighting; electronic and electrical tools; toys, leisure and sports equipment; medical devices; monitoring and control instruments; automatic dispensers; and semiconductor devices.¹
- Any business that sells these products, sub-assemblies or components directly to EU countries, or sells to resellers, distributors or integrators that in turn sell products to EU countries, is impacted if they utilize any of the restricted materials.³
- The EU has developed a [FAQ guide](#) for companies who are unsure of their status under RoHS and WEEE.

¹ European Commission Environment Website, "Recast of the RoHS Directive"

³ RoHS Guide, RoHS Compliance FAQ





WEEE



- The EU's Waste Electrical and Electronic Equipment Directive (WEEE) sets collection, recycling and recovery targets for the EEE sold in the EU (and covered under RoHS) and is designed to address the problem of toxic e-waste.
- WEEE places financial responsibility for the environmentally-friendly disposal of EEE on the manufacturers of such equipment, mandating that customers be offered a "free of charge" method of returning end-of-life EEE.¹
- Though RoHS and WEEE were designed to complement one another (RoHS aiming to reduce hazardous materials in EEE; WEEE aiming to improve the environmentally responsible handling of such goods), they have not been uniformly implemented in the EU, which can complicate export procedures for U.S. businesses.
- U.S. manufacturers seeking to export EEE to the EU should consult the Department of Commerce's [WEEE/RoHS Country-by-Country Export.Gov page](#) to learn how RoHS/WEEE have been implemented in your export market of interest.

¹ Export.Gov, WEEE and RoHS: an overview



Implications for U.S. Manufacturers

- Though different in their purpose, REACH, RoHS/WEEE , and the proliferation of other “design for the environment” and product stewardship-related regulations around the world carry a host of cross-cutting implications for U.S. manufacturers. These include the increasing necessity for companies to:
 - Allocate adequate staff and establish the needed infrastructure to obtain a thorough understanding of the materials and chemicals in the products you produce, and their impacts to the environment and human health. More often than not, this will involve engaging your supply chain.
 - Identify more environmentally responsible chemical/material alternatives as inputs to your products.
 - Establish effective product take back, recycling or remanufacturing programs in the communities you do business in.



Opportunities for U.S. Manufacturers



- However, approached strategically, the spread of such regulations could present unique opportunities for firms designing and manufacturing with sustainability in mind. These include:
 - Expanding market share in relation to competitors that are less prepared for this new regulatory environment
 - Driving product innovation in a way that reduces production costs AND life cycle impacts
 - Improving brand recognition as a forward-looking company that cares about the environment and society
 - Establishing stronger, more transparent relationships with suppliers

