

# Regulations:

**A Vital Tool for Protecting Public Health and the Environment**



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# Regulations:

## A Vital Tool for Protecting Public Health and the Environment

**W**hat does it take to protect the world around us? Everyone doing their share. Look around your community and you will find volunteers starting recycling programs, cleaning up streams, and planting trees. This same spirit of environmental stewardship can also be seen in the private sector, where companies are adopting green business practices that are good for the environment and the bottom line.



The U.S. Environmental Protection Agency (EPA) encourages voluntary efforts for protecting the environment, but we also have the authority to write mandatory requirements called *regulations*. EPA regulations cover a range of environmental and public health protection issues, from setting standards for clean water to specifying cleanup levels for toxic waste sites to controlling air pollution from industry and other sources.

Businesses, state and local governments, even individuals can be fined if they do not abide by our regulations, and that is one reason why we invite the public to share in their development—we want our rules to be practical and fair for the American people. Continue reading to learn more about how EPA writes regulations, and how your voice can influence the policies that shape our environmental future.

# The Origin of Regulations: Environmental Laws

**T**ypically, Congress learns about an environmental or public health protection issue before EPA writes the regulations to address it. Public interest groups, citizens, businesses, or other government agencies contact Congress with an issue of concern. Congress may then decide to hold hearings and prepare a bill. If the bill gains approval in Congress, it then goes to the President for signature. If signed, the bill becomes a law.

However, most laws do not have enough detail to be put into practice right away. EPA is called a *regulatory agency* because Congress authorizes EPA to write regulations that explain the critical technical, operational, and legal details. For example, the Resource Conservation and Recovery Act requires EPA to write standards for managing hazardous waste. Its central mandate requires EPA to develop standards to “protect human health and the environment” but does not say precisely what those standards should be. As in many other laws, Congress entrusts EPA to develop most of the details for regulations based on our technical and policy expertise.

The box to the right lists the laws that give EPA most of its authority to write regulations. These laws are designed specifically to achieve the nation’s environmental and public health protection goals.

In a single year, EPA publishes about 1,000 regulations in either proposed or final form. Of these regulations, only about 5 to 10 are considered major, meaning they have the potential to impose cumulative costs of more than \$100 million a year.



# MAJOR ENVIRONMENTAL LAWS IN THE UNITED STATES

Congress passed the following laws specifically to protect human health and the environment. Many of these laws have been *amended* since the dates of their enactment to reflect new scientific knowledge or to correct ambiguities.

- 1938** Federal Food, Drug, and Cosmetic Act
- 1947** Federal Insecticide, Fungicide, and Rodenticide Act
- 1948** Federal Water Pollution Control Act (also known as the Clean Water Act)
- 1955** Clean Air Act
- 1965** Shoreline Protection Act
- 1965** Solid Waste Disposal Act
- 1970** National Environmental Policy Act
- 1970** Pollution Prevention Packaging Act
- 1971** Lead-Based Paint Poisoning Prevention Act
- 1972** Coastal Zone Management Act
- 1972** Marine Protection, Research, and Sanctuaries Act
- 1972** Ocean Dumping Act
- 1973** Endangered Species Act
- 1974** Safe Drinking Water Act
- 1975** Hazardous Materials Transportation Act
- 1976** Resource Conservation and Recovery Act
- 1976** Toxic Substances Control Act
- 1977** Surface Mining Control and Reclamation Act
- 1978** Uranium Mill-Tailings Radiation Control Act
- 1980** Asbestos School Hazard Detection and Control Act
- 1980** Comprehensive Environmental Response, Compensation and Liability Act
- 1982** Nuclear Waste Policy Act
- 1984** Asbestos School Hazard Abatement Act
- 1986** Asbestos Hazard Emergency Response Act
- 1986** Emergency Planning and Community Right to Know Act
- 1988** Indoor Radon Abatement Act
- 1988** Lead Contamination Control Act
- 1988** Medical Waste Tracking Act
- 1990** National Environmental Education Act
- 1990** Pollution Prevention Act
- 1996** Food Quality Protection Act
- 1999** Chemical Safety Information, Site Security and Fuels Regulatory Relief Act

# Developing

# Regulations:

## From Start to Finish

**W**hen EPA identifies the potential need for a regulation, staff meet to form a *workgroup*. The workgroup is led by the EPA office that will be writing the regulation and includes members from other parts of the Agency with related interests or responsibilities. This process can take months before an appropriate course of action is carefully and methodically decided. It generally goes like this:

- **Analyze the Problem.** The workgroup studies the origin, magnitude, and impacts of the problem. It may draw information from EPA's own research, scientific literature, or from other researchers in the United States and abroad.
- **Identify Options.** The workgroup then considers the available options for addressing the problem. This may require evaluating environmental technologies, changes in environmental management practices, and incentives that can motivate better environmental performance. As later sections explain, the workgroup also takes related issues into account at this stage, such as the impact of various options on small businesses, on children's health, or on state and local governments. Sometimes the workgroup might find there is no need for regulation.
- **Publish Proposal.** Once the preliminary analysis is complete and the need for regulation is determined, the workgroup drafts a proposed regulation for publication in the *Federal Register*. A law called the Administrative Procedure Act generally requires EPA



(and other federal regulatory agencies) to request comments from the public before finalizing the regulation. The public comment period typically lasts 60 to 90 days.

- **Review Public Comments.** Next, the workgroup reviews and evaluates all the comments received. Depending on the regulation, these comments may range from minimal to extensive. In any case, the workgroup carefully weighs and evaluates the comments before developing a draft final regulation for review and approval by EPA senior management.
- **Issue Regulation.** After approval by senior management, the EPA Administrator reviews the draft regulation and decides whether it should be issued. If the Administrator decides to issue the regulation, it is published in the *Federal Register* and goes into effect soon afterwards. In accordance with the Congressional Review Act, Congress may overturn a regulation even after the Administrator has issued it, however, this is an extremely rare occurrence.

## Sharing the Game Plan: EPA's Regulatory Agenda

Like all federal regulatory agencies, EPA publishes a list of the important regulations that will be completed within the next year. This "Semi-Annual Regulatory Agenda" appears in the *Federal Register* in the spring and fall, serving as an official notice for all interested parties. The Agenda also includes information about important regulations completed within the past year.

Occasionally there are interim steps in this process. For instance, if the workgroup receives new data from the public during a comment period, the workgroup might publish in the *Federal Register* a “Notice of Data Availability” so interested parties can learn more and submit additional comments. Sometimes the workgroup might decide to take a new direction after receiving new data, which can result in a “Supplemental Notice of Proposed Rulemaking.” Finally, the workgroup might decide to draft a notice seeking public comment and information before the proposal is even developed. This pre-proposal is called an “Advanced Notice of Proposed Rulemaking” and is also published in the *Federal Register*.

EPA maintains a central staff within the Administrator’s office to track all the regulations under development. The Regulatory Management Staff monitors the status of workgroups, helps with *Federal Register* publication, and ensures that EPA is following the various laws and mandates that govern regulation writing.

Because EPA is part of the Executive Branch, the White House’s Office of Management and Budget (OMB) reviews some EPA regulations before they are published in the *Federal Register*. Generally, OMB reviews regulations that could potentially impose more than \$100 million in annual costs on society or present controversial legal or policy issues. OMB also ensures rules are consistent with the Administration’s environmental priorities and policies, and coordinates review by other federal agencies that might have an interest in the issue.

## Making It Official—Where To Look for Regulations

EPA publishes its proposed regulations, final regulations, and notices in the *Federal Register*. Final regulations are also published in the *Code of Federal Regulations*. Known as the *CFR*, this compilation of government regulations is divided into 50 titles that represent topics of federal authority, such as education, transportation, and agriculture. The *CFR* contains environmental regulations mainly in Title 40 Chapter I (Parts 1 – 799), Chapter V (Parts 1500 – 1517), and Chapter VI (Part 1700).



# Important Considerations

## That Guide Decision-Making

A quick glance at the steps just outlined may lead some to believe that regulation development is a straight-forward process. But our job is to produce quality regulations that are scientifically sound, cost-effective, fair, and effective in achieving environmental goals. And so we routinely take diverse and often complex issues into account before making final decisions. Some of the most influential factors on our decision-making are discussed below.

### Using Sound Science

All of EPA's work is supported by sound science, especially our work on regulations. Whether we are developing a new standard to protect the public from a newly recognized risk or specifying monitoring requirements to gauge how well an environmental control is working, EPA bases its regulations on the most current and credible scientific information available. This information might come from EPA's own research laboratories, or from literature reviews that help pinpoint useful research from other sources.

Under the best circumstances, EPA uses information that has undergone thorough *peer review*. During peer review, leading experts verify the accuracy of data and any resulting conclusions. Sometimes, however, the need for immediate action leads EPA to rely on data that are preliminary or that present conflicting results. In these instances, EPA



uses its expertise to draw reasonable conclusions based on what is already known.

In addition, we often rely on outside expertise to review research results and inform our scientific judgments. Most notable is EPA's Science Advisory Board. Composed of outside experts from various scientific disciplines, representing academia, industry, and environmental organizations, this distinguished group generally serves as a technical review panel, providing EPA with sound advice on important science issues that might affect the development and implementation of a regulation. Outside expertise may also come from the National Research Council, other federal agencies with related responsibilities, or other outside experts.

Because sound scientific data are so critical to quality actions, EPA conducts its own research and provides support to researchers outside the Agency. Many studies examine the effects of pollutants and other environmental stressors on human health and the natural environment, how harmful effects occur in the body, and the health risks they represent. Some of the issues currently under investigation at EPA include the impacts of global climate change on ecosystems, the effects of the chemical dioxin on human reproduction, and the potential vulnerability of the nation's drinking water supply. These studies are part of a broader research agenda that provides critical support for EPA's regulatory work.

## Following Laws and Executive Orders


Besides carrying out directives in environmental laws, EPA must abide by several laws and executive orders (E.O.s) that guide the process for developing regulations at the federal level. These mandates, shown on the next page, direct EPA to consider issues of concern to the President, Congress, and the American public.

### Economic Benefits and Costs

Before drafting a regulation, EPA assesses the expected *benefits and costs*. Consistent with E.O. 12866 on regulatory planning and review, EPA performs economic analyses using a set of principles that make the regulatory system work well for the American people. These analyses call for EPA to assess the benefits and costs of the regulatory alternatives available, including the alternative of *not* regulating. EPA regulation writers use quantitative (numerical) and qualitative (descriptive) measurements to gauge the benefits and costs of imposing a regulation.

But how do you put a dollar value on the benefits of nature? If wetlands are filled in because there is no regulation to protect them, what is the loss to society? How do you fully measure the cost that society incurs from some degree of exposure to a cancer-causing chemical? As difficult as these questions seem, economists have developed methods to make prudent estimates about the benefits and costs of environmental regulations.

We estimate benefits in several ways. Human health benefits might include reduced mortality rates and fewer incidences of cancer or chronic illnesses. Ecological benefits might include restoration of degraded habitat and increases in populations of certain species. Other benefits reflect quality-of-life factors, such as improved taste and odor of drinking water.



## LAWS AND EXECUTIVE ORDERS THAT GOVERN FEDERAL RULEMAKING

- The Administrative Procedure Act
- The Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act)
- The Unfunded Mandates Reform Act
- The Paperwork Reduction Act
- The National Technology Transfer and Advancement Act
- The Congressional Review Act
- E.O. 12866 on regulatory planning and review
- E.O. 12898 on federal actions to address environmental justice in minority populations and low-income populations
- E.O. 13045 on protection of children from environmental health risks and safety risks
- E.O. 13132 on federalism
- E.O. 13175 on consultation and coordination with Indian tribal governments
- E.O. 13211 on regulations that significantly affect energy supply, distribution, or use

We estimate the cost of a regulation by looking at the cost of *compliance*. A new regulation often forces businesses, communities, non-profit organizations, or government agencies to buy new pollution control equipment or adopt new practices. Other costs include social welfare losses, such as higher consumer and product prices, and transitional social costs, such as business closings and unemployment.

EPA's "Guidelines for Preparing Economic Analysis" provides a sound and consistent framework for measuring benefits and costs of regulatory options. Recognizing the need to focus our analytical efforts where they are most useful, EPA applies its most rigorous analyses to the "economically significant" regulations—those that we expect to cost society more than \$100 million a year.

Although estimates of benefits and costs are ordinarily essential to our work, occasionally some laws prescribe an approach that actually prevents EPA from taking costs into account. For example, the Clean Air Act does not allow EPA to consider the economic costs of implementation when developing National Ambient Air Quality Standards. These standards define the maximum allowable levels of certain pollutants in our atmosphere, and when Congress amended the Clean Air Act in 1970, it intended for EPA to act without considering how much it would cost or even whether it was technologically feasible. Congress understood that this approach might impose unusual burdens on society, for example by forcing the development of new control technologies, but decided to put protection of public health and welfare ahead of economic considerations.

### Small Businesses and Small Communities

EPA routinely looks closely at how rules might affect small businesses and small towns. Compared to larger organizations, these *small entities* often do not have the resources needed to completely manage their environmental responsibilities. Therefore, under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act), Congress directs EPA to take the impacts of its proposed regulations on small entities into account. Specifically, unless the EPA Administrator can certify that a regulation will *not* have a significant economic impact on a substantial number of small entities, EPA generally must:

- **Convene a small business advocacy review panel.** The panel examines the economic impact of the proposed regulation on small entities, reaches out to small entities for comments, and prepares a report summarizing both the comments and the panel's recommendations. The comments become part of the official record, and EPA factors the recommendations into its decision-making.
- **Prepare a regulatory flexibility analysis.** This analysis describes the impact of the proposed regulation on small businesses. It also outlines alternatives that could accomplish the same objective while minimizing the significant economic impacts.



Together these actions ensure that EPA fully considers the impacts of its actions on small entities and ways to minimize those impacts as much as possible. One example of how this affects our regulations is the rule for regulating the injection of certain liquid wastes into underground wells. Some wastes from vehicle repair and maintenance shops receive little or no treatment before injection into the ground, which can lead to groundwater contamination. When EPA issued a regulation halting use of injection wells at these operations, we did so based on input from environmental groups and other affected stakeholders and with the knowledge that it could have a significant economic impact on 4,800 small businesses and 380 small towns. And so to lessen this impact, we used a phased approach whereby well owners have about seven years to comply. The regulation also allows owners and operators to seek a waiver from the ban and get a permit to continue operations as long as certain conditions for environmental and public health protection are met.

### Environmental Justice and Child Safety

Protecting public health means protecting the health of all Americans, including those segments of society that might need more attention than others. In recent years, public concern that some populations were bearing an uneven share of environmental health risks led to E.O. 12898 that requires “federal actions to address environmental justice in minority populations and low-income populations.” This executive order calls for EPA to identify and address impacts on minority and low-income populations when we develop our regulations.

Additionally, EPA considers how regulations might impact children.



In relation to their body size, children breathe more air, drink more water, and eat more food than adults, so their exposure to environmental health risks is greater. In the past, EPA regulations considered health risks to adults almost exclusively. But as new information emerged suggesting that children are more vulnerable to health risks, EPA began altering its approach to risk analyses. E.O. 13045 “on protection of children from environmental health risks and safety risks” strengthened our focus on children, requiring us to analyze whether certain regulations would have disproportionate impacts on their health.

## Providing Flexibility

Often, the biggest complaint about regulations—and not just environmental ones—is that they can be too rigid. In particular, companies sometimes argue that by mandating specific solutions, EPA regulations stifle innovation that could lead to better environmental results. By pursuing innovative approaches and insisting on strong accountability for results, we are finding ways to build more flexibility into regulations.

One way EPA does so is by using *performance-based* approaches that emphasize the end result we want to achieve. For example, an air quality regulation directs heavy-duty diesel trucks and buses to cut sulfur emissions by 95 percent. The regulation does not specify how refiners and engine manufacturers must achieve this goal, but it does give them significant time to decide for themselves. In other instances, EPA has offered companies extra time to comply with a new requirement if those companies were willing to invest in more



advanced technologies than required. This approach means better protection for the environment and more flexibility in making environmental investment decisions.

EPA works with states, businesses, and other organizations with environmental interests to test approaches that can lead to more flexible regulations. The objective is to find more efficient and effective ways of achieving environmental goals and to then apply those approaches on a scale that produces the greatest possible benefits. One innovative approach that has proven effective is the use of facility-wide permits that put a cap on overall emissions rather than specifying limits for every emission source at a site. This approach gives companies more flexibility in managing their operations, and it reduces regulatory burden.

## Involving the Public

Many individuals outside the government are affected by and interested in environmental regulations. These *stakeholders* often provide valuable comments on EPA's proposed regulations. Stakeholder comments can illuminate issues that EPA has not yet considered, allowing us to benefit from the knowledge and experience of the concerned public. Ultimately, stakeholder comments lead to better regulations.

When EPA proposes a regulation in the *Federal Register*, the Agency includes information about how the public can comment. Options include sending comments via regular mail, e-mail, or fax. We





encourage stakeholders to tell us where they stand on a proposed regulation and to send information and data that support their position.

For most regulations, EPA saves public comments in a *docket*. The docket organizes information related to each regulation, including background reports, *Federal Register* notices, and other supporting documents. Each docket is accessible to the public. Check the final page of this publication to find out how you can visit our online EDOCKET system, which allows users to send comments and access docket materials electronically.

Federal advisory committees also provide EPA with advice and recommendations. Sometimes EPA will establish a federal advisory committee to get advice on a particular issue. However, EPA convenes the following committees on a routine basis to get advice on issues that cut across EPA programs:

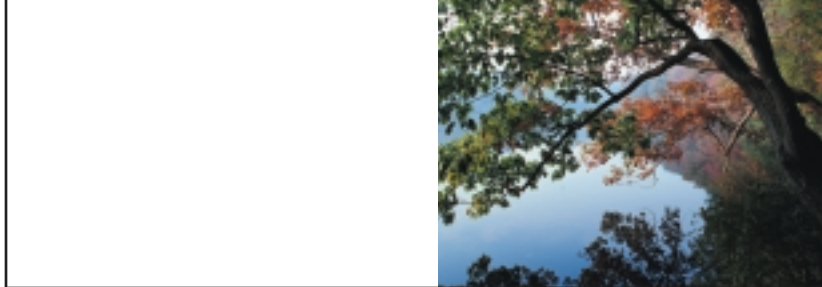
- **The EPA Science Advisory Board** provides EPA with feedback on the scientific underpinning of its decision-making.
- **The National Advisory Council for Environmental Policy and Technology** advises EPA on ways to improve our domestic and international environmental management policies, programs, and technologies.
- **The Environmental Financing Advisory Board** provides EPA with advice on how regulations should be paid for once they go into effect.

# When Regulation Is Not Needed

Sometimes EPA finds that a regulation is not needed after all. While developing a new regulation, we periodically assess the latest information to reaffirm our approach. If the evidence suggests that a proposed regulation is unnecessary or inappropriate, we may abandon the issue or choose an alternative course of action. Such was the case for a proposed wastewater regulation targeting pollution from industrial laundries. After reviewing new information about the toxicity and volume of pollution from the laundries, EPA decided that local wastewater authorities could more effectively address the problem. Consequently, EPA began to work with industry on a voluntary pollution prevention program aimed at reducing pollutants to the air, water, and land.

Although EPA believes that regulations play an irreplaceable role in environmental and public health protection, there are some circumstances where we can achieve superior environmental results using alternatives. Some of these alternatives are described below:

- **Voluntary programs.** Today, EPA has more than 30 voluntary national programs to help companies and other organizations improve specific aspects of environmental management. For example, ENERGY STAR® promotes energy efficient products and practices; Design for the Environment helps companies find more environmentally sound alternatives to existing processes or technologies; and the Commuter Choice<sup>SM</sup> Leadership Initiative works with



employers to reduce greenhouse gas emissions by offering commuter benefits to employees. EPA has many other voluntary programs that address regional priorities.

- **Economic incentives.** Used to link environmental and economic goals, economic incentives can take many different forms. For example, pollution fees charged by volume create an incentive for companies to reduce waste. Market-based trading programs, such as those used successfully to control acid rain, give companies the option to buy or sell pollution credits, depending upon their circumstances. Subsidies offer financial aid for environmental investments that might otherwise prove too expensive. And liability rules, such as those used in the federal Superfund program, create an incentive for businesses and communities to address environmental management issues before they become a problem.
- **Partnerships.** EPA often works with other organizations to share ideas and leverage resources, achieving more environmental protection than we could ever achieve through individual effort—or regulation—alone. These partnerships involve other agencies and levels of government, universities, non-profit and community groups, and private companies. From scientific research to information sharing, environmental partnerships can be a powerful tool for accomplishing specific goals. For example, in 2001, EPA launched a new public education campaign in partnership with the Ad Council and Major League Baseball that alerts parents of asthmatic children about the dangers of second-hand smoke in the home—a problem that would be difficult to regulate and impossible to enforce.



- **Technical assistance.** EPA believes that businesses and other organizations require tools to improve their environmental performance. We offer assistance on the Internet, during onsite visits, via telephone hotlines, and through training efforts. For example, EPA funds job training programs to clean up brownfields—abandoned or underused industrial and commercial properties that remain undeveloped because of concern about potential contamination. The training allows communities to speed up cleanup and redevelopment efforts and, as a bonus, helps prepare local residents for future employment in the environmental field.

As EPA looks beyond traditional “command and control” regulations and toward creative approaches to environmental problem-solving, we benefit from the diverse skills of our staff. As you would expect, EPA has many employees with science, engineering, and law degrees. But you will also find staff with degrees in business, statistics, sociology, education, and public policy. This diversity of knowledge and experience is useful in our problem-solving, whether it involves regulation—or not.

# Improving the Process:

## Setting the Stage for Future Regulatory Actions

**E**PA began issuing regulations shortly after opening its doors in 1970. Since then, we have learned a great deal about working with stakeholders and running a sound regulatory development process. We have learned the process is dynamic—often requiring continual adjustments in both substance and process. For example, we are learning to harness the power of the Internet—the EDOCKET system mentioned previously allows stakeholders to go online and submit comments on proposed rules. Similarly, new electronic reporting capabilities now under development will provide regulated facilities with a quick, efficient, and paperless option for complying with reporting requirements.

Recognizing the critical role that regulations play in achieving its mission, in April 2001, EPA launched a comprehensive review of the regulatory process. This review—the first in many years—resulted in recommendations that will strengthen our regulatory actions. The recommendations are designed to get EPA managers, scientists, and economists more actively involved in developing quality regulations, to ensure workgroups consider different policy options before making decisions, and to increase public participation.



EPA will continue pursuing improvements that can improve environmental regulations. Because our responsibilities do not end once a rule appears in the *Federal Register*, we continue to work with the businesses and communities that are bound to put them into practice. Technical assistance, monitoring, compliance assurance, and enforcement are all equally important parts of the regulatory process, even though occurring later. And so, while the focus of this brochure is on how regulations are developed, to achieve the intended benefits, EPA works with affected parties long after requirements take effect.

Moreover, in order to move towards a cleaner future, EPA will continue to rely on the American people to do their part—by getting involved with our regulatory actions and by volunteering and promoting environmentally friendly actions in their businesses, communities, and homes.

## FOR MORE INFORMATION

You can learn more about environmental regulations by calling EPA's Regulatory Management Staff at 202 564-5480. You can also visit EPA's Web site at <[www.epa.gov](http://www.epa.gov)> and click on "Laws and Regulations." Additional Web sites relating to specific regulatory issues and resources described in this document are highlighted below:

Children's Health	<a href="http://www.epa.gov/children">www.epa.gov/children</a>
<i>Code of Federal Regulations</i> (Title 40)	<a href="http://www.epa.gov/epahome/cfr40.htm">www.epa.gov/epahome/ cfr40.htm</a>
Environmental Laws	<a href="http://www.epa.gov/epahome/laws.htm">www.epa.gov/epahome/ laws.htm</a>
E-Docket	<a href="http://www.epa.gov/edocket">www.epa.gov/edocket</a>
Environmental Economics	<a href="http://www.epa.gov/economics">www.epa.gov/economics</a>
Environmental Justice	<a href="http://www.epa.gov/compliance/environmentaljustice">www.epa.gov/compliance/ environmentaljustice</a>
Innovative Approaches	<a href="http://www.epa.gov/innovation">www.epa.gov/innovation</a>
<i>Federal Register</i>	<a href="http://www.epa.gov/fedrgstr">www.epa.gov/fedrgstr</a>
Science Advisory Board	<a href="http://www.epa.gov/sab">www.epa.gov/sab</a>
Small Business	<a href="http://www.epa.gov/smallbusiness">www.epa.gov/smallbusiness</a>
Voluntary Programs	<a href="http://www.epa.gov/partners">www.epa.gov/partners</a>



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