



new directions

A REPORT ON REGULATORY REINVENTION

Getting Back to Basics

Reinventing Environmental Regulations

Of all the opportunities that exist for reinventing environmental protection, perhaps none is more basic than the task of reinventing environmental regulations. As Congress has passed laws over the years, EPA has responded with regulations to protect people and the environment from a multitude of risks. These regulations have made a tremendous difference in the quality of life here in the United States, and yet, in some cases, they are not always as effective as they might be.

In order to achieve greater results and to reduce unnecessary costs and regulatory burden on communities and the private sector, EPA is working to improve environmental regulations in a number of ways. Basic enhancements include consolidating similar requirements for certain industries; eliminating requirements that are duplicative, obsolete, or unnecessary; and writing in "plain English" to ensure better comprehension of what is required.

At the same time, the Agency is working to develop fundamentally new regulatory approaches as a way of moving environmental protection beyond the command and control regulatory approach of the past. By offering certain features, such as more operational flexibility in exchange for greater public accountability or extended compliance schedules for those willing to invest in innovative new technologies, EPA is helping to redefine the traditional regulatory framework. Over time, these efforts could create a whole new mind-set about environmental regulation. Rather than burdens requiring compliance, the environmental regulations of tomorrow may very well be recognized as a simple, straightforward means to achieving multiple objectives, including recognition for environmental stewardship, long-term sustainability, less waste and liability, and higher profits.

In the summaries that follow, EPA's four national environmental program managers — Mary Nichols (Air), Lynn Goldman (Pesticides), Tim Fields (Solid Waste—Acting) and Robert Perciasepe (Water) — provide an overview of how environmental regulations are being reformed and what those reforms may mean for environmental and public health protection.

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"Protect **people**,
not bureaucracy.
Promote **results**,
not rules.
Get **action**,
not rhetoric."

PRESIDENT CLINTON



Recognizing the challenge that industries face in dealing with multiple air emissions requirements, EPA is working on a proposal that would consolidate 16 different air rules into a single set for the synthetic organic chemical manufacturing industry. Known as the **Consolidated Air Rule**, EPA expects this action will significantly reduce the regulatory burden for industry and for state and local air quality agencies as a result of streamlined monitoring, data handling, reporting and recordkeeping requirements. EPA also expects the rule to help reduce overall emissions by improving understanding of what is required and by allowing the manufacturers to focus on emissions control rather than the administrative intricacies of each individual requirement. This new rule, scheduled for proposal later this year, could serve as a model for consolidating air requirements for other industry sectors.

Flexible, facility-wide air permitting is another reform effort underway. Under Title V of the Clean Air Act, facil-

ities obtain permits that include all applicable Clean Air Act requirements, and any change in operational status can trigger the need for permit modification or review. This permit review process can hamper a facility's ability to quickly meet changing market demands. To address this problem, last year EPA initiated the pollution prevention permitting pilot (P4) to test ways of providing more operational flexibility within the existing regulatory structure and of achieving better environmental protection through improved pollution prevention techniques. Through a series of pilot projects, EPA is working with states and industry to develop innovative permits that include facility-wide emissions caps and pre-approvals of certain control technologies. These permits allow certain operational changes to occur over the 5-year life of a permit, using a streamlined review process, as long as emissions stay below the overall facility cap.

EPA expects the P4 program to produce several important benefits. First, promotion of pollution prevention

the added operational flexibility helped save up to \$1 million per day. Finally, streamlining the review process is expected to lower workload burdens for air emissions sources and permitting authorities, allowing each to focus on higher priority issues.

Recognizing that permit revisions will always be necessary in some circumstances, EPA is working with states and industry to **streamline the Title V permitting revision process**. The purpose is to reduce the cost and delay associated with these revisions as well as the duplication that exists with state air emission permitting programs. EPA expects to issue its final permit revision procedures early next year. When implemented, these provisions will improve compliance and provide public review of environmentally significant permit changes without being unnecessarily burdensome to the affected industry.

Finally, EPA is proceeding with reforms to **streamline and simplify New Source Review permitting requirements**. Under the New Source

In one pilot project involving a pharmaceutical plant in Georgia, the company—Searle Corporation—estimated that the added operational flexibility helped save up to \$1 million per day.

opportunities and overall net reductions in emission levels will improve environmental protection. Second, the experience of developing these innovative permits on a pilot basis will help lay the framework for potential broader applications to other sources. Third, operational flexibility may help companies avoid unnecessary financial losses that can occur as a result of regulatory delay. In one pilot project involving a pharmaceutical plant in Georgia, the company — Searle Corporation — estimated that

Review program, large industrial facilities planning to build or expand production capacity are required to obtain a permit. A final rule, expected early next year, will provide industry with greater flexibility, reduce time delays in issuing permits, and create incentives for use of innovative technology. EPA expects this move will reduce the number of permitting actions that would otherwise occur for new sources by one-half.

— Mary Nichols



Pesticide registration is another area of EPA regulatory reform. Before any new pesticide becomes available in the commercial marketplace, it first goes through a thorough EPA review and approval process under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act (FQPA). Every year, EPA receives thousands of applications to register or amend products. Over the past 3 years, EPA has worked to make the registration process faster and easier while still providing strong protection for public health and the environment.

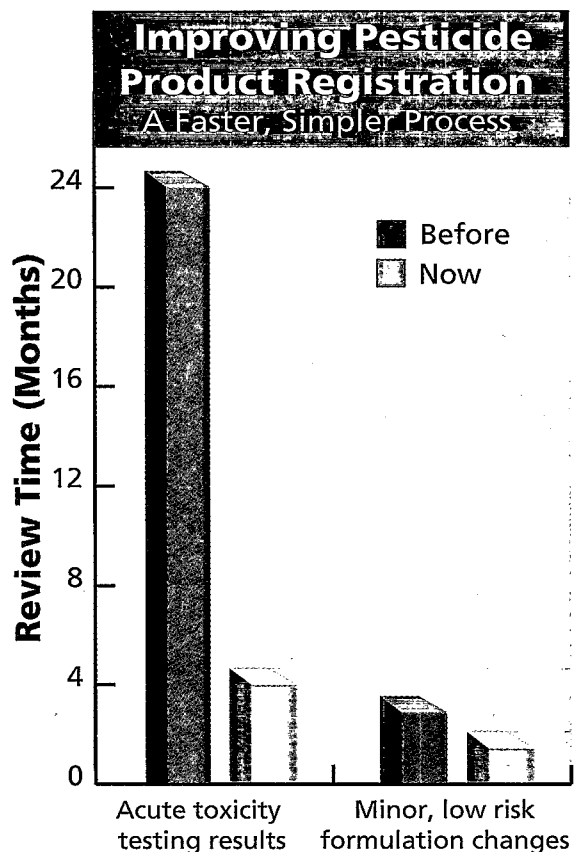
Based on new risk-related information indicating that the ingredients would pose no unreasonable adverse effects, in May 1996, EPA **exempted 31 low-risk pesticide active ingredients from regulation.** This exemption

relieves pesticide manufacturers from unnecessary regulation and helps the Agency direct its resources to higher risk priorities. At present, EPA is considering similar exemptions for other chemicals and chemical uses.

As a result of changes to its internal review process, EPA has cut average review times for pesticide product **acute toxicity studies** by more than 80 percent. The pesticide registration process requires applicants to submit acute toxicity testing results to EPA for

response has dropped from about 24 to 4 months.

EPA has also offered **self-certification** procedures for certain circumstances which allow pesticide applicants to proceed with registration activities as long as they notify the Agency first. This option, which includes random audits by EPA to ensure the process is working properly, helps applicants avoid unnecessary delays waiting for EPA review. In May 1995, EPA expanded self-certifications for certain **low-risk, minor product labeling changes.** Since that time, the number of labeling changes handled in this manner has doubled, saving time and resources for both EPA and industry. EPA is proceeding with self-certification initiatives to cover other steps as well. In February 1997, this option was proposed as a way to better manage more than 2,000 submissions for **product chemistry testing data** that come to EPA for review every year. Self-certification would be offered for simple straightforward determinations, such as color, odor, or pH results, that do not require stringent oversight. About one-third of product chemistry testing submissions fall into this category. Because each self-certified action would cut EPA review time by about one-fourth, about 15 extra weeks of staff time would be freed up each year to focus on higher priorities. A final decision on this issue is expected later this summer.



review, and on average, the Agency receives about 900 submissions per year. Over time, a backlog of more than 400 studies accumulated, slowing the rate at which new submissions received attention. Without a change in practices or resources, this backlog was projected to grow while the average time a company waited for review stood at about 24 months. As a result of its reinvention efforts, EPA eliminated this backlog — despite a reduction in staff and a 6-week government shutdown that occurred during the latter part of 1996. Perhaps more importantly, the amount of time that applicants spend waiting for an EPA

Another improvement effort focuses on reviewing deficient (or unacceptable) pesticide applications. By conducting an in-depth rejection rate analysis of applications that have not been approved, EPA expects to reveal additional opportunities for improving registration in the future. Applications may be found to be deficient for any number of reasons, such as missing data or incomplete labelling. Newly developed and tested computer software may solve the latter problem by standardizing "precautionary" labelling. This labelling, determined based on results from acute toxicity studies, provides consumers and workers with important safety information. EPA staff hope to make the software available soon for widespread use within the industry.

More recently, EPA has established new divisions to focus specifically on improving registration of biological pesticides, which can provide a safer pest control alternative, and of antimicrobial pesticides, which are critical to public health and controlling human disease. During the last 3 years, EPA has registered over 40 new biological pesticides, including the first pesticides produced by genetically engineered crop plants. As part of an overall effort to speed registration of microbial pesticides, the Agency committed to eliminate a backlog of applications waiting for review. During the past 6 months, the backlog has been slashed by 40 percent, and staff expect it to be completely eliminated by the end of the year.

Last November EPA's efforts to improve pesticide registration were recognized through the Administration's highest award for reinventing government — a "Hammer Award" under the Vice President's National Performance Review. The award ceremony was hosted by NYCO Products, a pesticide man-

ufacturer outside Chicago. Company President Bob Stahurski described some of the benefits that small-and medium-sized microbial manufacturers were realizing as a result of the reinvented registration process, including an ability to get products to market faster. Similar acknowledgments have come from other sources. In a letter offering congratulations on the Hammer Award,

Ciba-Geigy Corporation stated, "You and others who worked on removing the logjam on acute toxicity reviews are to be commended for your dedication to this project and for implementing creative solutions to make the review process more efficient."

— Lynn Goldman



One of the first reinvention efforts undertaken in the hazardous waste area focused on making it easier for consumers and businesses to recycle commonly used items, such as batteries, pesticides, and mercury-containing thermostats. In May 1995, EPA issued a final regulation, known as the **universal hazardous waste rule**, designed to reduce hazardous waste items in the municipal solid waste stream, encourage recycling and proper disposal of certain common hazardous wastes, and reduce the regulatory burden on businesses that generate these wastes. The new rule addresses a number of burdens and deficiencies in the old system. For example, it eliminates manifest require-

ments for universal wastes, allowing businesses to transport these materials using common carriers rather than hazardous waste transporters, and it allows businesses to store universal waste on site for up to one year, eliminating the need for more frequent collection and disposal arrangements. In addition to streamlining a number of administrative requirements, the rule also includes incentives to encourage manufacturers to "take back" certain products. All totalled, EPA estimates the new rule will save \$70 million per year while still ensuring safe collection, recycling, handling, and treatment of low-risk items.

Several other common sense improvements have been made to improve hazardous waste management. For example, in November 1995, EPA

proposed changes that would promote the **environmentally sound recycling of petroleum residuals**. This rule, scheduled for completion by May 1998, would streamline regulatory requirements and increase petroleum

recycling opportunities. In fact, if all oil-bearing sludges currently being generated were recycled, the total volume of petroleum residuals now requiring disposal could be cut by approximately one million metric tons per year.

In February 1997, EPA addressed a **hazardous waste transportation** difficulty for generators with several locations separated by public or private rights-of-way, such as universities with buildings scattered across several city blocks. EPA exempted hazardous waste transport between these locations from extensive tracking, packaging, labelling, marking, and placarding requirements. This action would allow hazardous waste generators to consolidate hazardous material from multiple facilities and proceed with appropriate treatment and disposal actions more efficiently. In addition to reducing regulatory burden, allowing consolidation should help prevent potential exposure from multiple small collection sites.

In April 1997, a common sense improvement to EPA's **land disposal restriction** regulations significantly cut paperwork requirements. Under the old system, hazardous waste generators were required to complete

detailed paperwork on each hazardous waste shipment even if the quantity and quality of the material were the same each time. The new rule allows generators to file the necessary records with the land disposal facility, and as long as the shipments do not change, no additional paperwork is required. EPA expects this change will reduce total paperwork burden associated with land disposal by 1.6 million hours — a one-third reduction overall.

Currently, EPA is working on a number of other changes to provide equally protective, but more cost-effective, hazardous waste management alternatives for businesses and communities. Early next year, EPA will propose several new approaches to the **definition of solid waste** that could substantially reduce the number and types of operations subject to hazardous waste regulation. It would also remove regulatory disincentives that currently lead companies to choose incineration or land disposal over safe recycling. For example, under the current system, companies that generate and recycle hazardous waste are subject to full hazardous waste treatment requirements. The new rule would allow some hazardous waste recycling to occur without imposing the burden of hazardous waste regulation.

Another action underway is re-proposing the **hazardous waste identification rule**. Under the current system, once a waste is listed as hazardous, it is always considered hazardous — even if the toxic chemicals have been removed. This approach, while protective of human health and the environment, has the disadvantage of discouraging innovative treatment and pollution prevention — why would a company invest in detoxifying its waste if the detoxified product was still subject to

hazardous waste requirements? In 1995, EPA proposed a rule that would allow companies to test their waste, and if all potentially hazardous chemicals were at or below safe levels, then it would no longer be federally regulated as hazardous waste. Instead it would be managed under alternative, but protective, state programs. This rule will provide relief by allowing low-risk waste, historically considered to be hazardous, to be managed under alternative or less costly means. Because of the extensive comments received by the public and EPA's Science Advisory Board, the Agency requested a multi-year extension to revise the underlying risk assessment used in establishing safe levels. As of April 11, EPA received a new court-ordered deadline to complete a proposal of this rule by October 31, 1999, and a final rule by April 30, 2001.

Finally, EPA is completing a **contaminated media rule** to establish a new regulatory framework for managing remediation wastes generated during hazardous waste cleanups. Now, these wastes are subject to management, treatment, and disposal requirements under Resource Conservation and Recovery Act (RCRA). In April 1996, EPA proposed a rule with options to exempt some remediation wastes and allow for more site-specific management, treatment, and disposal alternatives. The final rule, which would also simplify and streamline RCRA permit requirements, is scheduled for issuance in June 1998. EPA expects the changes will significantly reduce the amount of material subject to hazardous waste treatment requirements. While the actual cost-savings will depend on the particular approach taken in the final rule, EPA estimated total savings ranging from \$1.2 to \$1.5 billion per year.

— Tim Fields

To achieve higher levels of water quality on a broad, national scale,

EPA is promoting greater use of watershed management approaches as a way of better addressing a more diverse range of issues. Building on the water quality improvements of the past, EPA is developing tools — regulatory and nonregulatory — to help communities address water quality issues on a watershed basis. In June 1996, EPA released the *Watershed Protection Framework* document that describes how these more comprehensive, integrated strategies can be developed and outlines actions EPA is taking to encourage use of watershed approaches by states.

Over the past few years, EPA has focused on reinventing one of the most critical tools for watershed management — the National Pollutant Discharge Elimination System (NPDES). Under this program, industries and municipalities obtain permits before discharging wastewater to rivers, lakes, coastal waters, or the open ocean. At present, more than 61,000 NPDES wastewater discharge permits are in effect to protect water quality throughout the country. In the first of a series of actions aimed at improving the effectiveness and efficiency of the NPDES program, EPA issued guidance in June 1996 to reduce the regulatory burden associated with water quality monitoring and reporting. The guidance allows facilities with excellent performance records to significantly reduce monitoring and reporting activities, and it provides incentives for voluntary pollutant reductions through such means as reuse and recycling. If fully implemented, EPA estimates this performance-based approach would cut the average facility's NPDES monitoring and reporting burden by about 25 percent.

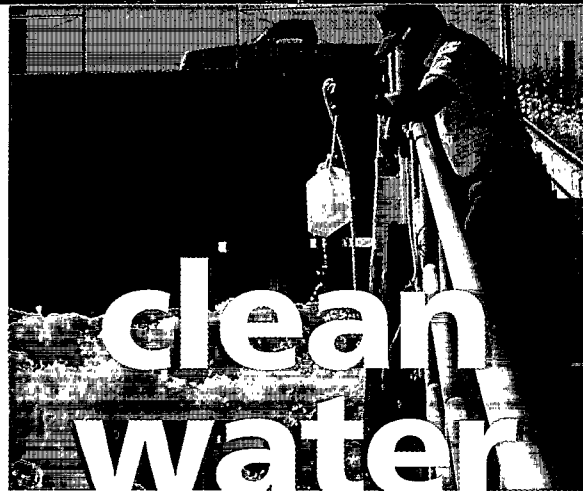


Photo courtesy of Trinity River Authority of Texas

More significantly, it could improve water quality by allowing facilities to direct their attention and resources to higher water quality priorities.

A second round of reforms, proposed in December 1996 and scheduled for completion this July, streamlines the NPDES permitting appeals process. Under the current system, facilities can file for an evidentiary hearing in order to appeal permitting decisions, a process that usually takes about 18 to 21 months to resolve. The proposed reform would eliminate these hearings and allow more timely appeals to EPA's Environmental Appeals Board where decisions are reached in about 9 months. In addition to helping facilities save costs associated with appeals actions, this move could help communities realize water quality improvements more quickly as new permit conditions go into effect.

The second round of reforms would also allow greater use of general permits for certain industries. General permits, which cover multiple facilities and eliminate the need to develop individual permits, would provide a regulatory option for controlling pollution from sources that are not permitted under the current system. EPA is considering proposing a third round of administrative reforms that would include expanding the types of permitting actions that can be considered "minor" and processed by the Agency more quickly.

Other NPDES improvements are aimed at **biosolids management and industrial pretreatment**. At present, only Utah and Oklahoma manage biosolids permitting. As a result, in the remaining 48 states, facilities are required to interact with two levels of government — their state agency and EPA. In March 1997, EPA pro-

posed a rule easing state program adoption. In addition, EPA is working on a final rule that will allow community sewage treatment plants to make certain minor, low-risk changes to industrial pretreatment programs without having to go through public notice procedures.

Another significant reform effort is focused on one of the biggest challenges for protecting water quality: **urban storm water runoff**. Ten years ago, Congress passed amendments to the Clean Water Act that required EPA to issue NPDES permits in two phases to better control stormwater. Phase I addresses large industries and municipalities of more than 100,000 people, while Phase II addresses the remaining smaller municipalities, industries, and commercial establishments. Phase II represents an enormous potential increase in the number of facilities subject to NPDES permitting requirements — millions of new permits could be needed. In an effort to obtain the greatest possible environmental benefit at a reasonable cost to the regulated community, EPA proposed a more targeted, risk-based approach for Phase II that would only require permits for facilities deemed highly likely to cause pollution due to runoff. EPA expects this approach would reduce the number of facilities subject to stormwater regulation by as much as 80 percent while still ensuring water quality protection. The final rule is expected this September.

— Robert Perciasepe

"Plain English" Regulations

The difficulty in understanding federal regulations has been a longstanding criticism of federal agencies, including EPA. In order to reduce regulatory burden on our stakeholders and improve regulatory compliance, EPA has established a pilot program aimed at improving both the clarity and comprehension of regulatory language. Under the pilot, 13 regulations cutting across all program areas are being written or revised using more concise language. In addition, they are being restructured to allow users to find information more quickly. Results from this effort should become visible this summer when EPA begins issuing the first of these regulations for public comment.

What To Expect...

Sample Language from Hazardous Waste Rulemaking

Current	Plain English
<p>Exemption for listed hazardous waste containing low concentrations of hazardous constituents and managed in landfills and monofills.</p> <p>(a) Any hazardous waste listed under this subpart, any mixture of such a listed waste with a solid waste, or any waste derived from the treatment, storage or disposal of such a listed waste is exempt from regulation as a hazardous waste under parts 262-266 and 270 of this chapter if it meets the requirements in 261.37(b) and (d) (including the requirement that all hazardous constituents present in the waste be at or below the levels listed in appendix XI to this part and that the waste be disposed in a landfill or monofill, but not a land application unit). To maintain the exemption, the waste must satisfy the conditions in 261.37(e). Any such waste which also meets the requirements of 261.37(f) is also exempt from the requirements of part 268 of this chapter.</p>	<p>What waste is eligible for this exemption?</p> <p>(a) Three types of waste are eligible for exemption from the requirements in parts 262-266 and 270 of this chapter.</p> <p>(1) Any hazardous waste listed in this subpart.</p> <p>(2) Any mixture of such a listed waste with a solid waste.</p> <p>(3) Any waste derived from treating, storing or disposing of a listed waste.</p> <p>(b) To be exempt, the waste must meet the requirements in 261.37(b) and (d).</p> <p>(c) To remain exempt, the waste must meet the requirements in 261.37 (e).</p> <p>(d) If the waste also meets the requirements of 261.37(f), it also is exempt from the requirements of part 268 of this chapter.</p>

Reaffirming Reinvention

In an effort to better coordinate and provide a more consistent focus on EPA's reinvention activities, on February 27, Administrator Carol Browner announced that a new Office of Reinvention (OR) would be established within the Agency. She also announced that J. Charles Fox will serve as its new Associate Administrator. Mr. Fox will bring valuable insights from the state perspective as he served, most recently, as the Deputy Secretary for the Maryland Department

of the Environment. Prior to that position, he served in EPA's Office of the Administrator and Office of Water.

In her announcement, the Administrator stated that "the real power of reinvention lies in incorporating reinvention principles into the way we do business — using performance-based approaches, trying new ways of achieving compliance, redefining our relationship with state environmental programs, using incentives and voluntary programs to achieve environmental objectives, adopting community-based approaches to achieve sustainable communities, or new ways to monitor the progress of protecting public health and the

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Reaffirming Reinvention

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environment. These are large tasks, and they merit a prominent place in our organization."

The new office will ensure progress towards EPA's reinvention commitments laid out in the "Reinventing Environmental Protection" agenda issued by President Clinton and Vice President Gore in March 1995. Other responsibilities for the new office will include:

- Managing Agency-wide reinvention initiatives, such as the Common Sense Initiative and Project XL.

- Helping businesses and communities interested in pursuing more flexible and innovative new ways of meeting strong environmental standards.

- Coordinating with the new Center for Environmental Information and Statistics to improve the quality, accessibility, and use of vital environmental data.

A complete description of OR responsibilities will be provided in a future issue, once the details of the new organization have been fully developed and approved. Final clearance on the new organization is expected this summer. In the meantime, EPA's Reinvention Team, now reporting to Mr. Fox, will continue to serve as a

For More Information

Do you have questions about EPA's reinvention activities? Would you like extra copies of this report? If so, contact the Regulatory Reinvention Team at (202) 260-4261 or by e-mail at reinvention@epamail.epa.gov. Also, look for information on the Internet at <http://www.epa.gov/reinvent>. You'll find special reports, remarks from senior Administration and Agency officials, detailed fact sheets, and much more.

point of contact for questions or comments related to reinvention activities.



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