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Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives

July 1990

TOXIC SUBSTANCES

Effectiveness of Unreasonable Risk Standards Unclear

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Resources, Community, and
Economic Development Division

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July 20, 1990

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

Your February 21, 1990, letter noted that legislation to amend the Clean Air Act proposed the control of health risks from certain toxic air pollutants by means of an unreasonable risk standard similar to that used in section 6 of the Toxic Substances Control Act (TSCA) to control toxic substances. In essence, the legislation would have required installing maximum available emissions control technology to reduce toxic air pollution and, similar to the standard in section 6, would have mandated additional controls when the remaining emissions are found to pose an unreasonable risk to public health and the environment. You requested that we determine (1) the number of substances that have been controlled or proposed for control under the TSCA unreasonable risk standard and (2) the effectiveness of this standard in controlling toxic air pollutants.

Subsequently, the Clean Air Act legislation which passed the House of Representatives deleted the unreasonable risk standard in favor of a different approach for controlling air toxics. As agreed with your office, we have discontinued our work on this issue, but we are summarizing the information we obtained for your use during conference on the Clean Air Act reauthorization.

Results in Brief

Since TSCA's passage in 1976, the Environmental Protection Agency (EPA) has completed 22 regulatory actions to control five different substances under the unreasonable risk standard contained in section 6 of the act. The substances controlled under the regulations are polychlorinated biphenyls (PCBs), asbestos, chlorofluorocarbons, dioxin, and chromium. The number of other substances EPA has considered for regulation under this standard is unknown because it has not maintained records detailing such information.

The effectiveness of the unreasonable risk standard is difficult to assess because (1) the slow progress in regulating toxic substances under TSCA

may be attributable to reasons besides the unreasonable risk standard and (2) EPA has other mechanisms available to mitigate the risk from toxic substances. Further, views on the effectiveness of the unreasonable risk standard vary—industry groups believe an unreasonable risk standard could be effective in controlling residual toxic air pollution risks, but environmental organizations believe the standard is inherently unworkable. Consequently, it is not clear whether an unreasonable risk standard would be effective or ineffective in controlling toxic air pollutants.

Actions Taken Under Section 6 of TSCA

Section 6 of TSCA requires EPA to impose the least burdensome of a number of specific regulatory requirements concerning a substance or mixture if the agency finds that the manufacturing, processing, distribution in commerce, use, or disposal of the substance or mixture presents or will present an unreasonable risk of injury to health or the environment. When regulating a chemical under section 6, EPA is required to consider any potential benefits from using the chemical and the economic consequences its regulation will have on the national economy, small businesses, and technological innovation.

EPA has completed 22 final regulations for controlling five toxic substances under the section 6 unreasonable risk authority. Of these, 15 regulations were for controlling one substance—PCBs. EPA was specifically directed by TSCA to regulate PCBs under section 6. The other seven regulatory actions were initiated by EPA after a finding of unreasonable risk. Four of these seven actions place controls on asbestos while the remaining three actions control chlorofluorocarbons, dioxin, and chromium.

The completed regulatory actions vary significantly in their scope and financial impact on affected industries and consumers. For example, the scope of EPA's May 1980 dioxin regulation was very limited. This regulation precluded a chemical company from disposing of wastes, located at one facility, that contained a specific type of dioxin and required any other persons planning to dispose of similar dioxin waste to notify EPA 60 days prior to its disposal. EPA estimated that the financial impact of this regulation would be $250,000 annually (the cost to the company to continue storaging the wastes) and did not estimate any reduction in adverse health effects. In contrast, the scope of EPA's July 12, 1989, asbestos regulation was significantly broader. It imposed a three-stage ban, beginning in late 1990, on the manufacture, importation, processing, and distribution in commerce of various asbestos-containing

products. In its analysis supporting the action, EPA estimated the ban on asbestos-containing products would cost consumers and producers from $459 million to $807 million over a 13-year period and prevent a total of 120 to 202 cancer cases.

Other chemicals or substances may have been considered for regulatory action under section 6; however, EPA has not maintained the program data necessary to determine what other regulatory actions it has considered. Officials in EPA's Office of Toxic Substances told us they have not had a system for tracking the progress of chemicals considered for control under the unreasonable risk standard since this standard has been in effect. Consequently, they cannot provide data on the number of regulatory actions the agency formally considered under the unreasonable risk standard, the number of actions initiated, how many were completed, and how long the actions took. We did not attempt to independently develop such data.

However, beginning in late 1988, EPA began tracking commercial chemical risk management projects it is currently conducting that may potentially result in findings of unreasonable risk under section 6. According to an Office of Toxic Substances' March 8, 1990, status report on commercial chemical projects, 19 projects are being conducted that examine the risks involved in commercial uses of various substances. Included among the substances under review are acrylamide (used in grouting), chlorofluorocarbon substitutes, chlorinated solvents, lead-containing solder, and formaldehyde emissions from pressed wood.

Effectiveness of the Unreasonable Risk Standard

Although only limited progress has been made in regulating the commercial use of chemicals under section 6, it is difficult to determine whether the unreasonable risk standard was the primary reason why few regulatory actions were taken. A number of steps have to be taken to review the health effects of a substance, assess the human and nonhuman exposure to it, and ascertain the economic impact that would result from regulating the substance before it is determined to be an unreasonable risk. However, few chemicals have progressed through the process to be considered for unreasonable risk.

For example, EPA must determine the health effect of specific substances as input to its unreasonable risk analysis. Section 4 of TSCA authorizes EPA to require chemical manufacturers to test potentially harmful chemicals for developing data on their health and environmental effects. As

discussed in our April 1990 report on EPA's chemical testing program,[1] EPA has made little progress in obtaining test data. Approximately 60,000 commercial chemicals in commerce have been identified by EPA and listed in the TSCA inventory. However, due in large part to insufficient production and exposure data, an interagency testing committee[2] has recommended only 386 for testing to determine if they present a health risk. Further, EPA has been slow to issue final rules requiring manufacturers to test these substances; as a result, it had received complete test data for only six chemicals by the end of fiscal year 1989 and had not finished assessing any of them for possible further action.

In addition, EPA has taken other actions to control toxic substances under its TSCA authority that did not involve the use of the section 6 unreasonable risk standard. According to data provided by the Office of Toxic Substances, nine actions have been taken to control new substances and chemicals under the authority of section 5 of TSCA, and over 300 orders have been issued that set conditions on the manufacture of new chemicals. Further, information and reports on seven substances have been referred to the Occupational Safety and Health Administration for its consideration in reducing risks to worker health, and nine chemical advisories have been issued warning various workers, manufacturers, and others of potential hazards from substances such as used motor oil and nitropropane.

We discussed the effectiveness of the unreasonable risk standard with representatives of environmental organizations and the chemical industry. All were concerned that the unreasonable risk standard under TSCA has not been effective, but for different reasons. Representatives of the Natural Resources Defense Council and the Environmental Defense Fund said that the unreasonable risk concept is inherently unworkable because it places a tremendous burden on EPA to demonstrate that any impact from toxic substances is unreasonable when it must also consider the economic impact that any required control may have on business and the national economy. They said that EPA's track record under TSCA is poor and that the unreasonable risk standard is "a recipe for doing nothing."

[1]Toxic Substances: EPA's Chemical Testing Program Has Made Little Progress (GAO/RCED-90-112, Apr. 25, 1990).

[2]Section 4 of TSCA established an interagency testing committee composed of members from eight federal entities and authorized it to recommend to EPA chemicals that should be given priority consideration for testing.

Representatives of the Chemical Manufacturers Association (CMA) said the unreasonable risk standard has not been as effective as it could have been, in large part, because EPA has been overly cautious about developing "perfect" rules and as a result has devoted a significant portion of its limited resources to one rule—the control of asbestos—which affected the progress of other section 6 activities. However, the CMA representatives and the staff director of the American Institute of Chemical Engineers believe the unreasonable risk approach for controlling air toxics is preferable to other approaches because it takes the cost to consumers and industry into consideration and prevents industry from devoting disproportionate resources to removing a limited risk.

Regulatory officials also had differing viewpoints on the validity of the unreasonable risk standard for controlling air toxics. Environmental officials from Maryland and North Carolina and the executive director of the State and Territorial Air Pollution Program Administrators/Association of Local Air Pollution Control Officials had concerns with using an unreasonable risk standard. They said that enough information is known about the health effects of air toxics to establish a specific numerical standard—such as a 1 in 1 million risk of cancer—for controlling these emissions. They believe that emission sources exceeding a numerical standard should be required to employ additional measures to reduce emissions.

EPA officials told us that, in their opinion, the unreasonable risk approach is a valid approach to protecting public health and the environment. They acknowledged that the implementation of the unreasonable risk provisions of section 6 could have been more effective. The officials pointed out that one of the major problems with the section 6 authority is that it contains no deadlines for completing regulatory actions. As a result, analyses and decisions have become more complex, drawn out, and difficult to issue. Further, they added that other provisions of TSCA require EPA to exhaust other regulatory avenues with other federal agencies and programs before issuing rules under unreasonable risk, which can add further delays.

The EPA officials believe that using the unreasonable risk standard for controlling air toxics, or some similar flexible approach, could be effective if given proper priority and resources. In this regard, they said that under the provisions of the proposed legislation, a deadline would be imposed for making regulatory decisions on unreasonable risk and this would likely increase the priority, and reduce the time frame, for making unreasonable risk determinations. The officials also believe that

such a standard, in contrast to a rigid numerical standard such as a 1 in 1 million risk of cancer, would provide the agency with more flexibility to exercise professional judgment in balancing residual health risks and costs after maximum achievable control technology is installed.

Observations

EPA's past efforts in implementing the unreasonable risk standard in section 6 of TSCA appear to be limited, but various factors other than the standard itself—such as the little progress in obtaining test data on potentially harmful chemicals—may have contributed to this situation. Consequently, it is not clear whether a similar unreasonable risk standard would be effective or ineffective in controlling emissions of toxic air pollutants, particularly if regulatory deadlines are mandated as part of the authorizing legislation. With such regulatory deadlines, the major problem with unreasonable risk under TSCA—low priority and long time periods for issuing regulations—could potentially be overcome. However, the other factors involved in determining unreasonable risk—the overall health risk to the public, the benefits of the activities/substance in question, and the economic cost of regulation—are subject to analysis and interpretation and could result in substantial delays and difficulties in using this standard to control air toxics.

Objectives, Scope, and Methodology

As requested in your letter, our objectives were to gather information on EPA's efforts to control toxic substances under the unreasonable risk standard in TSCA and to determine if this approach has been effective in controlling toxic substances. Further, we determined if the standard could be effective in controlling toxic air pollutants.

To gather information on the efforts to control toxic substances under the unreasonable risk standard, we obtained pertinent documents from EPA's Office of Toxic Substances on the regulations it had issued under its TSCA section 6 authority. We discussed with officials from that office (1) other substances that have been considered for regulation under the section 6 standard, (2) the past and current procedures for recording and tracking the progress of substances in its review process leading up to a finding of unreasonable risk, and (3) their perspectives on the implementation of the unreasonable risk standard. We also obtained and reviewed records of the October 3, 1988, hearing on TSCA of the Subcommittee on Environment, Energy, and Natural Resources, House Committee on Government Operations.

To determine if the unreasonable risk standard would be effective for controlling toxic air emissions, we discussed EPA's implementation of the unreasonable risk standard with representatives of the Natural Resources Defense Council, Environmental Defense Fund, the Chemical Manufacturers Association, and the American Institute of Chemical Engineers. We selected these organizations because (1) they are knowledgeable of both the TSCA section 6 unreasonable risk standard and the currently proposed controls over toxic air emissions and (2) these organizations represent differing perspectives on environmental issues. We also conducted discussions with officials in EPA's Office of Toxic Substances, Office of Air and Radiation, and Office of Air Quality Planning and Standards on the potential effectiveness of an unreasonable risk standard for controlling toxic air pollution. Further, to obtain additional regulatory perspective, we discussed toxic air pollution risks and controls with the executive director of the State and Territorial Air Pollution Program Administrators/Association of Local Air Pollution Control Officials and with representatives of the Maryland Department of the Environment and the North Carolina Department of Environment, Health, and Natural Resources.

We discussed information contained in this report with EPA officials, who generally agreed with the factual information in the report, and we have included their comments where appropriate. As requested. we did not obtain official agency comments on this report. We conducted our review in March and April 1990 in accordance with generally accepted government auditing standards.

Major contributors to this report are listed in appendix I. You may contact me at (202) 275-6111 should you or your staff have any questions.

Sincerely yours,

Richard L. Hembra
Director, Environmental Protection
Issues

Major Contributors to This Report

Resources, Community, and Economic Development Division, Washington, D.C.	Peter F. Guerrero, Associate Director William F. McGee, Assistant Director John R. Schulze, Assignment Manager
San Francisco Regional Office	Dennis W. Day, Evaluator-in-Charge
Norfolk Regional Office	Philip L. Bartholomew, Evaluator

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