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EPA

Chemicals and the Regulatory Facts of Life

EPA is charged by Congress to protect the Nation's land, air and water systems. Under a mandate of national environmental laws focussed on air and water quality, solid waste management and the control of toxic substances, pesticides, noise and radiation, the Agency strives to formulate and implement actions which lead to a compatible balance between human activities and the ability of natural systems to support and nurture life.

Chemicals and the Regulatory Facts of Life

Remarks by

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The title I've chosen for my remarks this evening is "Chemicals and the regulatory facts of life." If I accomplish nothing else, I hope to leave you with a better appreciation of the challenges posed by chemical regulation and with the certain knowledge that EPA is moving vigorously ahead to meet those challenges.

The Toxic Substances Control Act of 1976—or TSCA, as it is known—gives EPA a mandate to protect public health and the environment from the unreasonable risks of chemical substances.

TSCA, of course, is not the first Federal law to address the serious health and environmental problems associated with toxic chemicals in our society. Fourteen other major Federal laws also have such provisions; six of these are administered by EPA—the remainder by the Food and Drug Administration, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the Department of Transportation.

With all of these other laws, you might ask, doesn't TSCA seem a bit redundant?

Much of the 5-year debate in Congress that preceded TSCA's final enactment in October 1976 focused on various aspects of that very question. In the end, Congress and the President concluded—with the support of an extraordinarily broad-based coalition of industry, labor, environmental, consumer, and other groups—that enactment of TSCA was necessary to fill a number of significant gaps that exist in the other Federal toxics-related laws.

One of the major concepts—and one of the major distinctions—underlying TSCA is that the public interest requires EPA to have the capacity to act before harmful substances threaten human health or the environment. The other laws, Congress found, largely enable the government to take action only after widespread exposure and possibly serious harm has occurred.

And this gets to the very heart of TSCA's purpose—and distinctiveness—as perhaps our most far-reaching public-health law yet.

TSCA provides EPA with comprehensive and flexible authority to gather certain kinds of basic information on chemicals, to identify harmful substances, and to control those toxic chemicals whose risks of injury to public health and the environment outweigh their benefits to society and the economy. The reach of the law is extremely broad. It encompasses the estimated 70,000 chemical substances manufactured for commercial purposes and several million research and development chemicals.

It makes the entire chemical industry subject to comprehensive Federal regulation for the first time. EPA's authority under TSCA is extended into virtually every facet of industry—product development, testing, manufacturing, processing, distribution, use, and disposal. And because the Act treats importers of chemical substances as if they were domestic manufacturers, it also

expands EPA's responsibilities into certain aspects of the multibillion-dollar international chemical trade.

Most of TSCA's authorities, however, are discretionary—that means Congress has given EPA the necessary flexibility to apply a variety of non-regulatory and regulatory options in controlling the problems posed by toxic-chemical hazards in our society.

Our actions can range from jawboning to non-mandatory guidelines, limited regulation of handling, use, and labeling, or outright bans on manufacturing and processing.

With all of TSCA's flexibility and discretion, given limited resources, and in light of the enormous number of potential targets for attention, EPA's efforts to implement this law must be well-focused and deliberate.

In this regard, EPA has already set a number of policy and program priorities:

From the standpoint of policy:

• We will give highest priority to substances that pose the greatest risk as a function of both toxicity and exposure.

• Chemical substances that may produce chronic and irreversible health effects such as cancer, birth defects, and gene mutations will take higher priority than those that produce acute effects such as eye and skin irritations.

• Substances that are widely dispersed in the environment and that may significantly disrupt ecosystems will take a higher priority than those that threaten individual species other than man.

Programmatically, in our initial efforts under TSCA:

• We will give highest priority to testing and information-gathering and to establishing the pre-manufacture notification program. This will help to build a firm basis for fulfilling TSCA's preventive health promise and for controlling potentially hazardous substances about which we currently know little or nothing.

• At the same time, we will focus a significant proportion of our resources on assessing the risks of known high-toxicity, high-exposure substances and on taking early regulatory action where those risks outweigh the chemicals' benefits.

• We will use actions under TSCA to promote effective control of toxic substances under other laws.

I believe that these are sound priorities. They represent a responsible approach to the mammoth task we face in carrying out Congress's intent.

Yet I am also aware of—and quite concerned about—an attitude of some within the chemical industry these days: that government is on some kind

of a chemical "witch hunt"—that we view all chemica as inherently "bad" until proven "good," and that we make our regulatory decisions largely on the basis of fear, emotion, and hidden bias against chemicals.

Those who embrace this point of view often portray government regulators as naive, unscientific types who casually arrive at regulatory decisions using a dart board that's one big bull's eye and labeled "industry."

Although I'm sure that this kind of paranoia about EPA is not widely shared by representatives of industry it is indicative of much of the current national concern about over-regulation. In my experience, over-regulation simply is not one of the regulatory facts of life.

On the contrary, the regulatory facts of life tend to temper the process of administering TSCA. They make it very unlikely that EPA would be able to foist sloppy or poorly developed decisions on an unsuspecting industry. Let me give you a few examples:

First, under the law EPA is bound to implement TSCA in a "reasonable and prudent manner," and we must "consider the environmental, economic, and social impact of any action" we take under the Act.

Second, the law provides ample opportunity for public and judicial review of EPA actions or non-actions, including the following:

- TSCA and the Administrative Procedures Act require that all rules under TSCA be subject at least to comments from the public in writing, and in many cases public hearings are required that may involve cross-examination.

- Further, all actions under TSCA are subject to judicial review. Actions to remove imminent hazards can only be taken through U.S. District Courts. And EPA is subject to lawsuit on each and every regulation it promulgates under TSCA.

- Also, citizens may bring actions to compel EPA to perform non-discretionary duties under TSCA, and to compel violators to comply with TSCA if EPA does not do so.

- And finally, citizens may petition EPA to initiate rulemaking proceedings; if EPA does not do so, they may go to court to try and force EPA to do so.

Third, in order to minimize the chance that we will be sued—and to maximize the chance that we will win if we are sued—EPA has to do its homework. We must be well-prepared. Our decisions have to be documented and defensible. For example, the regulations for the chemical inventory reporting took literally thousands of hours to develop. And we estimate that it will take a

similar investment in resources to complete the regulatory process on any given chemical in a way that is scientifically respectable and legally sufficient.

Fourth, beyond the requirements of the Administrative Procedures Act, EPA is committed to involving the public—including the chemical industry and other interested groups—in our decision-making process. The inventory regulations are again instructive. EPA held eighteen public meetings on them between December 1976 and October 1977. On these occasions representatives of industry, labor, environment and other groups met with EPA staff to work out differences on how the inventory procedures should be carried out. All parties agreed that the regulations were improved by that process.

Fifth, at each step of the way toward a regulation EPA's decision makers are subject to careful scrutiny by interested parties inside government as well as by our outside constituencies. EPA's own internal decision and rulemaking procedures require extensive coordination with other offices. Our colleagues in the Council of Economic Advisors, the Council on Wage and Price Stability, and the Department of Commerce keep close tabs on our activities. The Office of Management and Budget takes a special interest in our resource requirements and monitors the record-keeping and reporting we may require of industry. And five separate Congressional Committees exercise the Constitutional prerogatives of guidance, oversight, and appropriations.

Sixth, the system subjects EPA to a number of other constraints that I doubt are shared by our counterparts in industry. Our staffing levels—though growing—are limited by the need to keep overall Federal employment down. We now have about 150 people on board and hope to add 200 more to the TSCA-related staff of the Office of Toxic Substances by the end of next year.

Once we've been authorized to hire a person, it takes an average of 6-9 months to fill the vacancy on our staff—from the time the position becomes available to the time the person actually reports for duty. That kind of delay is formidable when you consider the fact that we are competing in the open job market for highly sought-after scientific talent.

The seventh regulatory fact of life concerns the need to make decisions in the face of uncertainty. I briefly mentioned earlier the many unknowns we must deal with every day. Let me elaborate. We don't even know yet how many chemical substances are in commerce. For most substances we know little if anything about how they are used, what health or environmental effects they may cause, who gets exposed to them and how, and what is the result of such exposure. Although we will use TSCA's powerful testing and information tools to narrow the gaps in our knowledge, we will never be able to answer every question to everyone's satisfaction.

In order to fulfill our public trust we must often act c the basis of partial or incomplete evidence.

The regulation of carcinogens provides a perfect cas in point. Some things are certain about cancer:

- It is the second leading cause of death in the U.S. t day.

- Its symptoms do not show for many years after exposure.

- Some chemicals cause cancer in laboratory animals.

- With one or two exceptions, every chemical that causes cancer in humans also causes it in laboratory animals.

Other things about cancer are still the subject of experiment and investigation. For example:

- whether any given benign tumor will transform into malignancy;

- whether there is a threshold below which exposure t a chemical does not cause cancer;

- whether every chemical that causes cancer in animals also causes it in man.

Science cannot prove beyond doubt the connection between cancer in humans and cancer in the animals used in toxicological studies. Yet we are responsible fo protecting the public from exposure to carcinogens. W can't wait for proof-positive in the form of dead bodies.

Instead, we must assume—in the public interest—tha a benign tumor may be the precursor of a malignant tumor, that any exposure to a carcinogen may pose some risk, and that a chemical shown to be carcinogenic in animals is potentially carcinogenic in humans.

Risk, of course, is only one side of the equation. TSCA explicitly requires us to take the benefits of a chemical substance into account. We can only act against a chemical if we can demonstrate that it poses an unreasonable risk—that is, if the risks to health or the environment outweigh the social and economic benefits of the chemical.

Implicit to this balancing of risks against benefits is the need for us to concentrate on real-life problems—problems whose actual or potential magnitude present the greatest possible opportunities for assessing risks in relation to benefits.

There's one final regulatory fact of life under TSCA that I want to mention this evening. From industry's point of view, it's probably the most important one of all.

Although EPA is responsible for carrying out this law, the industries affected by TSCA must shoulder a tremendous share of the burden for making sure that the law works, and that it works well.

I am not talking about the need to enlist industry in the ranks of those who support the underlying principles upon which TSCA is founded—namely, that the Nation has a right to be protected against unreasonable chemical risks. Most responsible members of industry are already in those ranks, and have been for some time.

Instead, I am talking about some specific forms of cooperation under TSCA that are very much in industry's self-interest. Let me give you a few frank examples:

• First, in submitting chemical data to EPA under TSCA, industry must avoid frivolous claims of confidentiality. We are aware of industry's concerns about confidentiality, and have developed procedures for handling confidential industry data that we believe are second to none, in government or in industry. But in order to work properly, our data security system must not become overburdened with "confidential" information that really isn't confidential at all. Already there have been a few isolated cases where companies have submitted data under TSCA as confidential when we know the same information has been given non-confidentially to other agencies. We consider this to be an abuse of the protection TSCA provides against unauthorized disclosure of confidential business information, and we are not going to tolerate it. A manufacturer making obviously frivolous claims of confidentiality will in the eyes of the Agency cast doubts about the veracity of future claims. Such a practice on a broad scale will force the Agency to tighten its policy as to the circumstances under which claims will be honored.

• Second, industry must make every effort to comply rationally with TSCA's key pre-manufacture notification and review provisions under section 5. Industry should view our recommended guidelines for testing and other kinds of data as minimum requirements, and should exercise its best scientific judgment in assessing the risks of new substances and uses. We view these data as essential to performing our required review of new chemicals and significant new uses of existing chemicals. Where a scientifically responsible decision would be to perform additional tests, we expect industry to do so rather than wait for EPA to intervene. Further, industry should only submit notices for chemicals that it actually intends, in good faith, to introduce into commerce. Otherwise, a central element in TSCA's preventive approach will become paralyzed with unnecessary work—and if this happens, I assure

you that EPA will seek stronger pre-manufacturing review authority to remedy the situation.

• Third, companies that have not yet done so must establish logical internal procedures for deciding wha kinds of information need to be reported to EPA un TSCA's section 8(e) authority to require notices of substantial risk. Non-compliance with this provision the Act, or malicious compliance—that is, submitting notices of non-substantial or obscure risk—will discre industry and force EPA to take strong enforcement measures that industry would not favor. Moreover, in dustry should not stop ongoing or planned testing sir ply in order to avoid the requirements of section 8(e)

• Fourth, industry must insure that data it submits to EPA under TSCA meet the high standards for good laboratory practices. Our recommended standards un section 4 of TSCA should, if followed, go far toward avoiding the kinds of outrageous and fraudulent prac tices that have been the focus of recent national atten tion. And again, we will forced to take tough remedia action if failure to voluntarily adopt such practices compromises our ability to fulfill TSCA's national ma date.

My purpose in laying out this final regulatory fact o life is to encourage industry to protect its own prerog tives under the present version of TSCA. The flexibili and discretion that TSCA provides apply to industry a well as to EPA, and must be exercised with equal restraint, reason, and common sense.

Knowing more now than you might have before abo some of the regulatory facts of life under TSCA, it should be clear to you that many of the toughest deci sions under this law are yet to be made. The course th we take in the coming months and years largely depen on how wisely we chart our way through these early days. As each day passes, our knowledge about toxic substances seems to grow exponentially. Yet we remain humbly aware, as Walter Lippmann once wrote, that "the distance between what we know and what we nee to know appears to be greater than ever."

Closing that gap in an area that bears singnificantly on the Nation's future health and environmental quali is what TSCA is all about.

I reflect the hope of many at EPA and in this Administration that, with the continued advice, support, and cooperation of industry, history will prove TSCA to have been a good idea, well executed. □

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