Premarket Testing of Industrial Products: A Means of Controlling Unrecognized Environmental Hazards

Martin A. Mattes

Published with the Assistance of the Fund for Environmental Studies (FUST)

International Union
for Conservation of Nature and Natural Resources
Morges, Switzerland
1977
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Every year if not every day we have to wager our salvation upon some prophecy based upon imperfect knowledge.

Justice Oliver Wendell Holmes, Jr.
Populations of the California brown pelican dwindle in numbers. Research results show that reproduction has seriously decreased due to contamination of the pelican's food by residues of DDT.

Workers in plants manufacturing vinyl chloride, a major product of the petrochemical industry, are stricken with a rare form of liver cancer. The disease is traced to inhalation of vinyl chloride particles.

Chemists studying the earth's outer atmosphere recognize the crucial importance of a delicate ozone layer shielding the earth's surface from harmful ultraviolet radiation. Some suggest that current massive emissions into the atmosphere of flourocarbons, widely used as propellents in aerosol sprays, could be diminishing the ozone layer, with catastrophic results.

These are but a few examples of the many commonly used products of modern industry which in recent years have been found to have produced tragic and unexpected side effects or which have been suspected of leading to such results. The common thread of tragedy in these several cases has been the lateness of the warning that all was not well. In most cases it was only the occurrence of injuries which led to an understanding of the danger involved. Even when awareness of a risk was gained independently of actual casualties, many years of possibly hazardous exposure had already been permitted to occur.

Hazardous products and legal measures for their control are the subject of the present study. The focus of attention is the extent to which existing laws and legal principles can cope with the problem of unrecognized environmental hazards. The body of German and American law is surveyed, to ascertain how effective current regulations may be in ensuring that hazardous products are recognized at an early stage and then adequately controlled.

The key to effective regulation is seen to be the requirement that products be tested prior to initial marketing. In certain areas of especially serious risk, as in the field of chemical substances, a comprehensive system of testing under close governmental supervision is considered to be warranted, and the US Toxic Substances Control Act of 1976 is examined and judged an excellent model of such a system. For more general application, a less stringent statute is proposed, which would call for product testing by the manufacturer and provide for confidential filing of testing records with the government subject to later publication if claims of injury are reported.
As this study makes clear, the problem of products which pose unrecognized environmental hazards has gained increased attention from governments in recent years. It is hoped that this survey of laws and regulations, existing and proposed, will offer a useful range of choice to persons seeking appropriate legal tools for the control of the new and as yet unsuspected environmental hazards which the future holds in store.
THE AUTHOR

A native of San Francisco, California, Martin A. Mattes received a B.A. degree in 1968 from Stanford University, and a J.D. degree from the School of Law (Boalt Hall) of the University of California at Berkeley in 1974. He served as Assistant Legal Officer at the IUCN Environmental Law Centre in Bonn, Federal Republic of Germany, from 1974 until 1976, and during that time was the first Editor of the journal Environmental Policy and Law. Since 1976 he has been a member of the legal staff of the Public Utilities Commission of the State of California, in San Francisco, working primarily in the fields of energy and aviation law. He is a member of the State Bar of California, the International Council of Environmental Law, the Bar Association of San Francisco, and Friends of the Earth.

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INTRODUCTION

In this era of economic difficulties in virtually all western industrialized societies, environmental regulation is frequently indicted as an unnecessary encumbrance or even as antithetical to economic growth. This perspective tends to ignore the fact that the widespread awakening of environmental consciousness in the past decade has come at the climax of an almost unprecedented period of industrial growth throughout much of the world. Deterioration of the natural environment, and of the more artificial environments of towns and cities as well, has been largely a side effect of man's productive activity, a by-product of his industry. Efforts to protect the environment often require changes in methods of production. These changes sometimes impose economic burdens; on other occasions or from other perspectives they are a boon to economic activity. The intimate relationship, however, between productive activity and problems of the environment is beyond dispute.

The environmental problems which result from productive activity may be simple or complex, easy to remedy or intractable, clear to the eye or unsuspected. In seeking to assess the range of environmental impacts, it is helpful to consider the process of production in terms of three stages: (1) the gathering of resources; (2) fabrication or production proper; and (3) the use and ultimate disposal of products.

Harm to the environment may arise at the initial stage of gathering or adapting raw materials for the production process. Here the effect may vary from extinction of a species of wildlife to displacement of a local environment - a forest destroyed by clear-cutting or a town swallowed up by an open-pit mine - to disfigurement of a landscape or pollution of the surrounding environment, as by the leaching of poisonous substances into streams and water supplies.

Other environmental harms occur in the production process itself, especially by the dispersal of pollutive substances into the air and, via liquid and solid wastes, into streams, groundwaters and eventually water supplies. Further harmful effects of production processes include the emission of excessive noise, radiation or heat. In all these cases two distinct environments may be affected - the surrounding environment within which the productive installation is located, and the much more acutely affected environment of the workplace itself. The relevant surrounding environment, moreover, varies with the type of activity. For example, the environment affected by an auto repair shop may be one city block; that affected by a steel mill may be an entire region.
Once the production process is completed, the product created may itself pose a risk to the environment. The product may be dangerous for its intended use, threatening the health or safety of its user or bystanders, or its use may have undesirable side effects upon the environment, as by the emission of chemical substances which disturb some element of the food chain or of the atmosphere. Finally, disposal of the product may be difficult or hazardous, giving rise to problems of waste management.

It should be noted that these three major stages of the production process frequently appear to overlap. For instance, in the clearing of a forest to create agricultural land, a herbicide may be employed which harms the surrounding environment. Or in the fabrication of industrial products, a toxic chemical, used as a lubricant for cutting tools, enters into the waste products of production and creates a pollution problem. In both these cases the hazardous substance is in fact the output of a prior production process, and the essential question for the regulator is that of the third stage of industrial production: is the product being put to a proper use and in an acceptable manner?

The law's traditional orientation has been one of hindsight, looking to past conduct and legal relationships to determine the proper allocation of benefits and responsibilities in a matter currently being adjudicated or newly legislated. The law has tended to look forward, to settle conflicts before they arise. Rather, judges and legislators have tended to assume, in accordance with a principle of judicial and legislative restraint, that it is best, or at least more politic, for the law to deal with problems and injuries only once they have become manifest. The accepted wisdom has dictated that to try to forestall and manage risks is too complex a task for legal institutions, and perhaps an unnecessary one, since a "mere" risk of harm may never materialize into the pain and deprivation which would demand a legal judgment or a legislative reform(1).

Science and technology, however, perhaps aided by a free market economic system, have forced the law to face a world in flux, a world of ever new and multiplying production processes, machines and substances. By its dynamic nature industrial society continually produces new benefits and new problems. Lawmakers of past generations had some idea of what hazards the future held in store. Bad sanitation might bring disease and untended forges might start fires, but these dangers were known and could be reckoned with. Today we find ourselves another step removed from certainty, fearing unknown hazards and trying to predict effects upon our environments of substances with which those environments have never before had to interact.
Traditional approaches to commercial and industrial regulation are ill fitted to cope with problems of this sort. Increasingly, in recent years, the need for new approaches has been recognized, as by one commentator on the problems associated with chemicals in our food supply:

"For the first time in his evolutionary history, man is being exposed in an exponential fashion to a large number of synthetic chemicals whose long-term effect is still largely conjecture... The record suggests that our governmental institutions are not now capable of ensuring that benefits and costs are kept in some reasonable balance. In short, we are not masters of this technology. Our technological reach has exceeded our institutional grasp and the gap is widening all the time"(2).

Considering again the three stages of the production process, it is evident that the forms of regulation necessary for environmental protection at the first stage, raw materials exploitation, can be relatively straightforward. The immediate, substantial and localized nature of environmental effects at this stage makes the needs of the environment fairly evident. Whether the will exists to satisfy those needs, possibly at considerable economic costs, is another question. It is possible, however, to impose requirements of prior official authorization at this stage of production at relatively low administrative expense. Such prior authorization requirements are to be seen particularly in systems of land use control, nature protection and resources management.

At the later stages of production and use, environmental harms may be much more difficult to recognize, measure and predict. This is, of course, not always the case. A plume of black smoke from a factory chimney is clear to the eye; the neighbors of a rendering plant cannot ignore its stench; and the unsightly impact upon our roadsides of non-returnable bottles and cans is evident to any motorist or pedestrian. But not all harmful effects of products or production are so unmistakeable. The factory's emissions may contain a substance which is undetected or thought to be harmless, but which turns out to produce cancer or other disease in workers or neighbors after a latency period of ten or twenty years - as has sadly been the case with asbestos fibers, kepone and vinyl chloride particles. The finished product may itself create risk of catastrophic environmental alterations, as is now suspected of fluorocarbon-propelled aerosols, which may be depleting the ozone layer of the Earth's atmosphere, thereby subjecting humanity to sharply increased exposure to dangerous solar radiation(3).
Even where the environmental harm is known and calculable, economic and political considerations may prevent or complicate control efforts. But where the harm itself is an uncertain one, the weighing of burdens and benefits becomes very much more difficult, if the need to consider the potential environmental problem is evident at all. It is this subject area of uncertain and unknown environmental hazards which is the topic of the present study. The focus of our attention will be upon those legal requirements which encourage the study and investigation of possible hazards to health and the environment, particularly those hazards which might be associated with the products of industry.

This discussion will concern laws, legal principles and proposals for legislation in the United States and the Federal Republic of Germany. For both countries our enquiry will largely be restricted to legislation at the Federal level, although certain legal principles not specifically of Federal origin will be discussed as well. It may be noted that these two countries are among the world's most heavily industrialized and also are among those with the most highly developed systems of environmental protection legislation. The combination of these two factors makes the legal situations in these countries an appropriate context for study of the regulation of uncertain environmental hazards, a subject still at the frontier of adequate legal control.

Efforts to control uncertain hazards almost always involve an increase in governmental restriction of private conduct. Some degree of personal freedom, usually of an economic nature, must be sacrificed for the sake of protecting the community at large. It therefore is highly important that the restrictions imposed be no broader and no more rigorous than necessary to achieve the desired degree of protection.

One purpose of this survey of legislation and other legal controls is to explore the variety of approaches which may be taken in seeking such protection. Consideration will first be given to the effectiveness of traditional private law principles, as they have developed in recent years, in coping with uncertain hazards. Then attention will focus upon laws directed to particular substances which are considered hazardous, passing next to the type of law which regulates a category, more or less extensive, of products considered hazardous as a group. Then statutes still broader in scope, establishing a protective regime with respect to some general aspect of the environment, will be studied for their contributions to the control of hazardous products. We shall next consider recent legislation regulating chemical substances, a broad category of products comprehending many sources of environmental risk. Finally, a
different statutory approach, to the control of hazardous products will be proposed, comprehensive in application but calling for a form of compliance which would be relatively simple and inexpensive.

Contrasting the various approaches to the regulation of products which may pose environmental hazards may suggest where the scope and degree of regulation in Germany and the United States have been insufficient, and where they have perhaps been more extensive than necessary. For persons concerned with legal systems less comprehensively developed in the control of product hazards, it is hoped that this study will help to clarify the legislative options available and the factors which may influence a choice among those options.
PRIVATE LAW CONTROLS

In a somewhat simpler age, risks of future harm were matters for private calculation, with the state and its law intervening only when risk had become fact and an answer was needed to the question of who was to suffer on account of the harm which had been done. The mechanism of this intervention was the law of torts and of contracts, and the primary guides for distribution of losses were the rules of liability for negligence and of contractual liability, respectively.

Rights of contract generally provide little protection from product-related injury. The purchaser, user or consumer of a manufactured product most likely will have no direct contractual relationship with the manufacturer. Manufacturers' warranties which do extend to the purchaser are generally limited to the value of the product sold. The bystander and the general public which may be threatened with injury from a product almost certainly would lack any contractual claim to compensation. Even where a person who might be injured does contract directly with the manufacturer, the former is unlikely either to be in a position to dictate or negotiate the terms of contract or even to be aware of the problem of obtaining compensation for such injuries as might occur.

In case of injury attributable to a manufactured product, an injured party is more likely to look for a remedy to the law of torts than to that of contracts. Over the centuries the law of torts has gradually developed to provide a system for the allocation of losses due to injuries in accordance with prevailing social theories and values. Whatever system of compensation is in force, however, looks to events of the past rather than of the future; its major concern is to make financial adjustments for past injuries rather than to prevent future ones.

Indeed, the threat of future liability for damages is not a very effective means of preventing injury. Particularly in business activities, the income to be earned today is a much more powerful influence than the possibility of a debt to be owed tomorrow. The widespread use of liability insurance further lessens the influence of such risks. Even where hazards are obvious and extreme, someone will produce and sell almost any product if the price is right. This is an important reason why governments have not been satisfied with private law controls over product liability and have instituted an array of coercive prohibitions and requirements concerning hazardous products which will be discussed in later sections of this report. With respect to environmental hazards, the utility of private law controls is further limited by the problem of standing - the necessity that a complainant prove his personal interest in the matter at issue.
Despite these limitations, the rules of tort liability for product-related injury are an important element of the context within which legislation for the control of hazardous products must be considered. For that reason this section provides a summary of the requirements and limitations of the law of products liability in the United States and Germany.

Products Liability in the United States

In the common law countries compensation of purchasers and the public for injuries caused by dangerous products was for many years stymied by a confusion of matters of contract and tort law. An English case brought in 1843 by a passenger injured by a defective coach was decided against the plaintiff on the grounds that he had no rights related to the contract of sale of the coach to its owner (5). This case came to stand for the rule that product liability required the contractual "privity" of a direct buyer-seller relationship. Exceptions gradually developed covering articles treated as "inherently dangerous". Finally, in 1916, the decision of Judge Cardozo in the case of McPherson v. Buick Motor Co. (6) established the liability in tort of a manufacturer for placing on the market a product negligently made.

The complexity of manufacturing processes, however, often makes proof of negligence very difficult. This problem is exacerbated by the injured party's frequent lack of access to information in the manufacturer's control. This, among other reasons, resulted in pressure to make compensation simpler to obtain (7).

In recent years products liability has expanded well beyond those cases in which negligence could be proved, at first by inferring an implied warranty of safety on the part of the seller (8). The warranty of safety arose from the traditional common law warranties of merchantable quality and fitness for prospective use. This theory, drawn from the law of contracts, was subject to many limitations and uncertainties, including the fact that it might be rendered inapplicable by simply including a disclaimer of warranty in the contract.

Most scholars and many judges eventually arrived at a doctrine of strict liability and tort. The American Law Institute, an influential body of scholars and practitioners, adopted the rule that one who is engaged in the business of selling a product, and who sells such a product in a defective condition unreasonably dangerous to the user or consumer or his property, is subject to liability for harm thereby caused (9). This rule was further broadened by a decision of the Supreme Court of California, which declared the following doctrine:
A manufacturer is strictly liable in tort when
an article he places on the market, knowing that
it is to be used without inspection for defects,
proves to have a defect that causes injury to a
human being (10).

This case was brought by the purchaser of a defective power
tool, but the implications of the holding were confirmed by a
subsequent decision of the same court that an automobile manu-
facturer's strict liability extends not only to purchasers and
users of a defective product, but to injured bystanders -
members of the general public - as well (11). The courts of at
least two-thirds of American states have followed California's
lead (12).

In products liability cases the requirement of a defect has come
to fill the spotlight formerly taken by the requirement of negli-
gence. The manufacturer still is not held absolutely liable
for any injury associated with his product. The product must
be proven to have been defective and such defect must be shown
to have caused injury to the plaintiff. Broadly speaking, the
prevailing interpretation of "defective" is that the product
does not meet the reasonable expectations of the ordinary con-
sumer as to its safety. The main distinction between the
showing required to prove a defect and that required to prove
negligence is that the defendant's knowledge of the existence
of the defect is irrelevant in the former case, whereas it may
be essential for proof of negligence (13).

With respect to our subject, products posing uncertain hazards,
the distinction referred to can be a crucial one. A product
which unreasonably endangers the user, the bystander or, we
might infer, the environment in general, is a defective pro-
duct. The manufacturer is liable for damage which such a
product causes, whether he is aware of the defect or not. His
prospective liability should encourage him to test and screen
his products more carefully to avoid marketing defective
ones (14). Where the negligence standard applies, however, the
less known the better. The manufacturer's worry that he might
not be taking adequate safety precautions is liable to be out-
weighed by a fear that, if he discovers a hazard, continued
production of a profitable commodity would become clearly
negligent.

The distinction between negligence and strict liability be-
comes even more important in view of the problems of proof
which commonly arise in products liability cases. Proof of
negligence on the part of a manufacturer often requires dis-
covery of the procedures followed in product design, manufacture
and marketing. The existence of testing results on record in
company files would be more likely to harm the defense than help it. If such records revealed no danger, the focus of the plaintiff's case would be elsewhere; but if they did suggest a hazard, the manufacturer's failure to heed such indications would be strong evidence of negligence. Where the rule of strict liability applies, however, discovery of the defendant's production methods and testing procedures will generally be irrelevant. The manufacturer will not have to worry that his safety precautions will be used against him in court.

Of course, proof of a defect will not always be easy. A plaintiff must also prove physical injury, the crucial chain of causation between the defect and the injury, and the fact that the defect was present or potential in the product when it left the defendant's control (15).

Moreover, not all hazardous products are defective. A knife or a gun - or a poisonous substance - is not defective by nature. It is defective only if its material, its manufacture or perhaps its labelling or advertising cause it to be unreasonably dangerous for a predictable use - "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it" (16). The essential issue in this sort of case again becomes one of negligence rather than of strict liability: whether due care has been taken to inform the consumer and the public as to a product's dangerous characteristics.

In addition, the requirement of unreasonable dangerousness has provided grounds for balancing the magnitude of danger against a product's utility (17). Products which, in the present state of human skill and knowledge, are unavoidably dangerous have been held not defective where their social utility outweighs their risk. In effect, courts have refused to apply strict liability to the manufacture of such products. Drugs such as penicillin and cortisone are examples, as is the transfusion of blood, which may produce hepatitis despite the taking of all normal precautions (18). Of course, for the manufacturer to be secure against liability an adequate warning to the "purchaser" of these unavoidably dangerous substances must be provided.

Unfortunately, this exception from strict liability for unavoidably dangerous products has been extended to products which are unforeseeably dangerous (19). The test of liability again becomes one of negligence, judged in the light of knowledge available at the time of sale. The manufacturer's incentive to discover defects in his products disappears, and ignorance is encouraged. The less known, the safer, for the manufacturer although not for the consumer and the environment (20).
The confusion over unavoidable, unforeseeable and unknowable defects derives from confusion over the relationship between defect and danger in products liability cases. American courts have not settled upon a consistent rule establishing the point in time from which a product's dangerousness is to be calculated. One scholar has proposed the following rule:

A product is defective if it is unreasonably dangerous as marketed. It is unreasonably dangerous if a reasonable person would conclude that the magnitude of the scientifically perceivable danger as it is proved to be at the time of trial outweighed the benefits of the way the product was so designed and marketed(21).

Under this rule danger is still balanced against a product's utility, but the manufacturer's actual or potential awareness of that danger at the time of production is no longer relevant. Whether the product is defective depends upon an objective assessment of whether it would have been reasonable to place the product on the market knowing of such dangers as may be proven at the time of trial. This rule does not encourage the manufacturer to remain ignorant of his product's potential defects, nor to conceal such knowledge as is developed. On the contrary the rule's reference to the product "as marketed" allows a manufacturer to shield himself from liability by adequately warning customers of the dangers associated with unavoidably hazardous products.

In summary, the traditional rule of American tort law, requiring: proof of negligence as a condition for the recovery of damages, gives a manufacturer little if any incentive to study the hazards which might be associated with his products. Where the manufacturer is held strictly liable for injuries attributable to defects in his products, he will be encouraged to take precautions to assure that such defects are minimized. For this effect to obtain, however, proof of a defect must not depend upon the state of knowledge at the time a product is marketed, for this might discourage a close evaluation of a new product's potential risks. Rather, any indications of danger proven at trial should be recognized as relevant to the issue of defect in a suit for recovery of damages resulting from a hazardous product.

Products Liability in Germany

In Germany problems of products liability are dealt with under the rubric of Schadensersatzpflicht, the duty to compensate for injury. The basic principles defining this duty are stated in sections 823 and 831 of the Civil Code(22). Section 823(1) sets
forth, the basic standard for tort liability, a negligence standard:

"Whoever intentionally or negligently offends against the life, body, health, freedom, property or other right of another contrary to law is obliged to compensate the latter for injury resulting thereby."

Section 823 (2) declares the same liability to ensue upon violation of a statute designed for the protection of others, where injury is done to interests coming within the scope of that protection (23).

An individual's liability under section 823 may arise from sources not directly related to his personal conduct. Thus a manufacturer may be held liable under section 823 (1) for inadequate organization of the production process under his ultimate control even if the more immediate cause of injury is the inattention of an employee. Section 831 explicitly renders a principal, such as an employer, liable for damage to the interests of third parties where such damage is inflicted by his agent in the course of the latter's performance of his duties. The principal is, however, protected from such liability for the acts of his agents where he has taken reasonable care in the selection of those agents and, to the extent relevant, in their supervision and the provision of equipment for their use.

In a commercial context, the duties described are summed up in the concept of Verkehrssicherungspflicht, the duty to assure the safety of commerce. This principle requires every producer to conduct himself, within the scope of reasonableness, so as not to allow causes of injury to others to arise within the area of his control (24).

As the theory of products liability has developed in German law, those defects which may give rise to liability have been categorized according to their cause or origin. Liability either to a user or a bystander injured by a product may result from (1) mistake or oversight in a product's design or composition (Konstruktionsfehler); (2) defective fabrication of the particular product which caused the injury (Fabrikationsfehler); (3) failure to provide adequate notice or warning of risks posed by the product (Instruktionsfehler); or (4) failure to monitor the product's safety subsequent to marketing (Produktbeobachtungsfehler) (25).

As this categorization suggests, the manufacturer bears a continuing responsibility with respect to his products, from the stage of invention and design, through that of production and
marketing, to the overseeing of the product in public use. Injuries attributable to defects of any of the above-described types may result in the manufacturer being held liable, with one important exception. This exception is the Fabrikationsfehler, the defect due to faulty fabrication of a specific manufactured item. Where the defect is caused by an employee or by faulty equipment, but the manufacturer has taken reasonable care in the selection, direction and supervision of that employee, the manufacturer himself may be shielded from personal liability by BGB section 831. In such a case, however, the manufacturer still may be held liable for a faulty organization of the production process (Herstellungs- or Organisationsfehler). This fifth source of liability under BGB section 823(1) may, in effect, render the manufacturer liable for the Fabrikationsfehler attributable to his employee or to the technical malfunction of his plant (26).

Premarket testing of products is particularly relevant to two of the responsibilities discussed above: the responsibility for product design and for the organization of the production process. Adequate testing may protect a manufacturer against liability for a Konstruktionsfehler, a defect in composition or design which renders a product inappropriate for its projected use. With respect to potentially hazardous products, premarket testing might also be necessary to avoid liability for an Organisationsfehler, a defect arising from faulty organization of production - possibly a failure to carry out adequate quality control of individual manufactured items. Occasional defects in individual items will not be likely to do great environmental harm. For protection against products hazardous to the environment, the primary concern is to assure acceptable product design and composition. Therefore the focus of this discussion will be upon liability for Konstruktionsfehler (27).

In order to avoid liability for faulty composition or design of products, the manufacturer may need to engage in a programme of testing and experimentation before entering upon mass production. The extent of testing required will be determined by the current state of the technical art, as well as by the uses to which the product may likely be put and by the character of the prospective users. The producer's efforts must demonstrate reasonable care to assure that his product is so constructed as to present no unreasonable source of danger to the average user in regard to any foreseeable use of the product. The producer is obliged to consider all realistically foreseeable uses, even those which are not specifically intended. One commentator offers the simple example of a chair, the manufacturer of which ought to anticipate its possible use in the household as a substitute for a ladder (28). Similarly, a pesticide manufacturer should foresee that an insecticide designed for garden use might be
used indoors. To avert liability for resultant injuries he should either assure the product's safety for indoor as well as outdoor use or he should provide adequate warning to the consumer of the danger involved (29).

As noted above, the basic standard in German law for assessing liability for injuries resulting from the sorts of mistakes described is a negligence standard. However, in Germany as in the United States the conditioning of products liability upon proof of negligence has led to unsatisfactory results. The steadily increasing risk of injury due to manufactured products and the ever greater difficulty of ascertaining who might have been at fault in a particular case have created pressure to ease the conditions precedent to recovery of compensation. In Germany, however, the negligence standard has not been superseded; rather, upon certain conditions being met, the burden has been shifted to the defendant manufacturer to prove that he has not been negligent.

The present distribution of the burden of proof in products liability cases is well illustrated by two fairly recent decisions of the Federal Supreme Court: the Hühnerpest Fall (Chicken Pest Case) of 26 November 1968 (30), and the Mercedes Fall (Mercedes Case) of 28 September 1970 (31). The former case involved a chicken vaccine the use of which resulted in the death of a large proportion of the inoculated fowl; the latter concerned an automobile accident apparently resulting from a defective brake system which caused the plaintiff's car to skid across a highway divider into oncoming traffic.

According to the rule of these decisions, the plaintiff in a products liability suit need offer only a prima facie case (Beweis des ersten Anscheins) indicating that a defect in the defendant's product has caused him injury. For such a prima facie case to suffice, the facts offered must, according to normal life experience, indicate a definite course of events pointing toward the defendant as responsible for the injury in question.

The Hühnerpest decision established that, upon proof that the plaintiff's injury resulted from an objective defect within the organizational domain of the producer, the burden then rests upon the producer to prove that he was not responsible for that defect, i.e. that he was not at fault. The court observed in its decision as follows:

"Where the source of uncertainty lies in the domain of the producer, so it adheres also to his sphere of risk. It is thus appropriate and reasonable that the risk of being unable to prove the lack of fault be his concern" (32).
The shift of the burden of proof in the Hühnerpest Fall occurred only upon the plaintiff having proven that a defect "in the domain of the producer" had caused the injury. These elements of proof may, however, be unattainable, particularly in circumstances where the plaintiff lacks access to vital evidence.

In the Mercedes Fall no more than a prima facie showing was required on the issues of defect and causation, because a more complete proof had been obstructed by the defendant's destruction of the relevant evidence - the allegedly defective brake parts had been replaced and disposed of. Once that prima facie showing had been made, the burden rested with the producer to respond with a showing of concrete facts from which the serious possibility could be inferred that no defect existed or that another cause had produced the injury. Abstract suspicions or mere suggestions of other conceivable chains of causation will not suffice to protect the defendant. Thus, in the Mercedes Fall, careless driving could as well have caused the accident as defective brakes, but the defendant offered no positive evidence to support such a theory and so could not overcome the plaintiff's Anscheinsbeweis (33).

Apparently a prima facie showing of this kind will shift to the defendant the burden of making substantiated factual allegations with respect to the proof of a defect and the proof of a causal relationship between that defect and injury to the plaintiff. Given an unrefuted Anscheinsbeweis on these issues, the rule of the Hühnerpest Fall will shift the burden of proof on the issues of fault and liability to the defendant (34).

The range of defendants to which the above-described rules easing the requirements of proof will apply is not yet certain. The easing of probative requirements was a response to the near-impossibility of definitely ascertaining responsibility for a defective product of a large-scale manufacturing operation. A shift in the burden of proof is less appropriate where the defendant's establishment is a small one, for which an outside party's oversight of its procedures would be more practical. It has been observed that strict theory might limit the rules of the Hühnerpest and Mercedes cases to actions against large-scale manufacturers, but that in practice any such limitation would be an arbitrary one, so that for the sake of judicial certainty the reversal of the burden of proof should apply with respect to all manufacturing enterprises (35).

Although easing the plaintiff's duties of offering evidence and sustaining the burden of proof facilitated the conclusion that plaintiff's injury resulted from faulty conduct within the sphere of the manufacturer's control, the legal rationale for holding the manufacturer liable remained unclear. In a
case of Konstruktionsfehler, faulty product design or construction, was the manufacturer to be held vicariously liable for the mistakes of his employees, or was the fault his own failure to oversee the product development process adequately? In a recent case, known as the Feuerwerkskörper Fall (Fireworks Case) of 19 June 1973 (36), the Federal Supreme Court elucidated the distinctions between these theories of liability, recognizing both as tenable grounds for holding the manufacturer responsible for faults occurring within his enterprise.

In the Fireworks Case the Supreme Court made clear that liability based upon either theory depends upon at least a prima facie showing that plaintiff's injury was caused by a defect arising within the organizational realm of the manufacturer. Upon such a showing the shifting burden of proof requires the manufacturer to demonstrate that he was not at fault. In this case the defendant's offer of proof was aimed solely to defend against a claim of Organisationsfehler, contending that a continual, strict supervisory regime underlay the production process and that the technical facilities guaranteed proper construction.

The court observed that under BGB section 831 the manufacturer also stands accountable for his employees' blunders, but noted that the plaintiff normally must prove that his injury resulted from the blunder of a particular employee. In product liability cases, however, the injured party frequently lacks power to oversee the extent to which particular human failures may produce defective products. The court therefore found it appropriate to shift the burden of proof with respect to section 831 liability, as had already been done with respect to section 823. The defendant was required either to prove specifically that his production method excluded all possibility of accidents due to employee blunders - that it was fully automated - or that each and every employee had been adequately selected and supervised. Having failed to offer such an affirmative defense, the manufacturer was held liable under BGB section 831(37).

In general, then, it has become the producer's concern to explain the factual causes of product-related injuries. The language of the Mercedes decision suggests, moreover, that the producer must arrange to be informed promptly of performance and safety test results and of possible mishaps in the production process. If evidence as to the adequacy of his precautions is lacking, the producer will pay the price. And the more serious the risks created by his products, the stricter will be the demands upon the producer to be well informed about their safety, both before and after initial marketing (38).
In contrast to the legal situation in the United States, the German manufacturer still may avoid liability by proving that he was not negligent — neither in the design or construction of his product nor in the giving of instructions nor in the surveillance of its use by purchasers. Practically speaking, however, it has been said that only "perfectly organized enterprises" can attain the high measure of proof required to contravene the presumption of fault which the injured party's prima facie showing creates(39). A thorough system of pre-market testing is advisable for the manufacturer who seeks to be prepared to provide the level of proof required. Failure to have engaged in such testing may be viewed as equivalent to the destruction of evidence by the defendant in the Mercedes Fall. Testing might have demonstrated whether or not a defect existed; not having conducted such tests may impose upon the producer the burden of proving by other means that his product was not defective and that his conduct was not negligent.
SINGLE HAZARD REGULATION

Although developments, in the law of products liability have increased the responsibility of manufacturers and made it more worth their while to be sure of the safety of their products, private law remedies have never been considered to provide adequate protection against all product hazards. Where specific hazards have become known, the state has often been willing to provide legislative solutions. The simplest example is the type of law designed to control a particular harmful substance, perhaps only with respect to particular uses. Such laws may be of long standing, enacted in cases of special danger despite the prevailing doctrine of laissez-faire. Examples are the German Act of 25 June 1887 relating to the Trade in Objects Containing Lead and Zinc (40), which prohibits certain uses of lead or zinc in eating, cooking, or food storage utensils, and the Regulation of 17 July 1934 for Implementing the Regulation on Pest Control with Highly Poisonous Substances (41), which limits the use of arsenic in pesticides.

In recent times statutes or regulations for the control of particular environmental hazards have generally been adopted in reaction to sudden discovery of the toxic nature of a substance or of a particular use of a substance which is not subject to adequate control under existing law. Examples in both Germany and the United States are the controls imposed in recent years over the use of DDT in pesticides and of lead in automotive fuel. In Germany these problems required the enactment of new statutes (42); in the United States it was possible to take administrative action under existing statutory authority for the control of hazardous insecticides and air pollutants respectively (43).

Again, such laws or regulations are designed to control the production and use of specific products or substances recognized as harmful. The problem of regulation is fairly straightforward, its steps following logically from the premise that the substance concerned is known to constitute a hazard. By scientific investigation, a tolerance level for the hazardous substance may often be established (44). Although the extent of the hazard posed may be uncertain, this uncertainty simply requires that the controls imposed provide a greater margin of safety than might otherwise be necessary. Restrictions may be imposed upon the presence of the substance in particular products, in particular exposed portions of products (45), or in products used for particular purposes. The restrictions can be made to apply prior to marketing, and can be enforced effectively by occasional random sampling by authorities, perhaps in combination with special labelling, packaging or other requirements. By these means, a set of
restrictions can be tailored to provide the degree of protection of the public and the environment needed in a particular case.

In some cases it may be possible, or politically necessary, to control a specific hazardous substance by informal means, without instituting mandatory legislation. An illustrative example is the reaction of authorities to the recently discovered hazards posed by the group of chemicals known as polychlorinated biphenyls (PCBs), which have been described as "one of the most widely dispersed and abundant environmental contaminants" (46). The chemical stability of PCBs causes them to accumulate in the food chain and in human tissue and therefore multiplies their hazard to health.

The same properties of stability, however, make PCBs a very useful substance for industry. Their applications range from food-wrapping materials to pesticides, photocopying papers, industrial lubricants and electrical insulating materials. The various uses differ greatly in the extent to which they produce loss of PCBs to the environment (47). The use of PCBs in electrical transformers and capacitors, for example, is a relatively non-contaminative use, at least where the product has a long expected life and, the likelihood of recycling rather than waste disposal is great (48).

A number of governments, including those of Germany and the United States, have therefore negotiated with the original producers of PCBs, which tend to be few, to limit their production to relatively safe uses. The US government gained the agreement of Monsanto Corporation, at present the only major US producer of PCBs, to distribute its products only for uses in what are agreed to be more or less "closed systems", unlikely to add significant wastes to the environment (49).

Such voluntary, economically "practicable" measures to combat environmental hazards can be hoped to succeed only where producers are few and alternative "safe" uses are available. They may also be useful as temporary measures to deal with newly appearing hazards, while enactment of compulsory legislation is under consideration. Recent experience in the case of PCBs, however, indicates that voluntary controls are not likely to offer a satisfactory long-term solution.

Since institution of voluntary controls, some measurements of PCBs in the environment have shown improvement, but others indicate a still worsening situation (50). In consequence of this continuing uncertainty, the US Congress included in the recently adopted Toxic Substances Control Act a provision outlawing the manufacture, distribution or use of PCBs in other than "a totally enclosed manner" after one year and outlawing
all manufacture, distribution or use after two and one-half years, except where the Administrator of the Environmental Pro-
tection Agency CEPA) expressly finds "that no unreasonable risk
of injury to health or the environment is presented" (5L). In
early 1977 the EPA Administrator acted under other statutory
authority to prohibit industrial discharge of effluent contain-
ing significant quantities of PCBs (52). Further regulations
have since been proposed under the Toxic Substances Control Act,
prescribing disposal and labelling requirements for PCBs and
equipment which contains PCBs, whether newly manufactured or
already in use (53).

The development of PCB regulation illustrates the utility of
voluntary agreement as a stopgap means of controlling a specific
product suddenly learned to be hazardous, where no more general
regulatory structure is in effect. This development also sug-
gests, however, the advantage which a more comprehensive system
of monitoring and testing has to offer.
HAZARDOUS CATEGORY REGULATION

Just as some statutes result from awareness that a particular substance is hazardous, so there is another type of statute that regulates a broad category of substances or products, which simply by belonging to that category are thought to require special care. This may be because all substances within the category are likely to pose a hazard, or because any hazard which does exist would likely be of great magnitude. A leading example of such a hazardous category or products for which a special statutory system of control has been created is that of pesticides (54). In this field both reasons for caution noted above are present, since the use of poisonous substances clearly creates hazards, and their use in association with food production suggests that danger to human health may be considerable.

Pesticides Legislation

Where an entire class of substances, such as pesticides, is subject to uniform regulation, the control system must necessarily be much more complicated than for a single substance. Some products within the class may be extremely hazardous, so as to justify forbidding their being marketed at all; others will be safe for use only under particular conditions in limited concentrations; still others will be harmless enough not to require regulatory controls. The system for regulating such a diverse class of substances must have a capacity for ascertaining the extent of regulation required in a particular case and for adjusting its controls accordingly. An important element of such a system is some kind of mechanism for premarket screening of potentially hazardous products.

The United States: FIFRA and FEPCA

In the United States, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (55), controls the marketing and use of "economic poisons" by means of a registration system. This statute was largely replaced by the Federal Environmental Pesticide Control Act of 1972 (FEPCA)(56), but many of the procedures developed under FIFRA will probably carry over to the enforcement of FEPCA. Moreover, a comparison of the different regulation approaches of the two Acts is instructive.

FIFRA was primarily directed toward ensuring that the agricultural consumer would receive an effective product which he could use safely. Thus, major concerns of the Act were to prevent adulteration and "misbranding" of pesticides and to protect against poisoning by a labelling requirement. The Act prohibited
trade in non-registered, misbranded or adulterated products (57), and authorized the competent government official (58) — now the Administrator of the Environmental Protection Agency (EPA) — (1) to require submission of "the complete formula" of a product and (2) to refuse to register products which appeared to violate labelling or other provisions of the Act or which appeared not to live up to claims made for them. The Administrator might also suspend or cancel the registration of an "economic poison" which appeared not to comply with the Act (59). Upon petition by the applicant for registration, cancellation or refusal to register would result in formation of an expert advisory committee and an often lengthy process of administrative hearings, thereafter subject to judicial review. The 1973 Federal appeals court decision in Dow Chemical Co. v. Ruckelshaus (60) established that an order for cancellation remained in effect until the registrant could satisfy the Administrator that registration was warranted, with the burden of proof resting upon the registrant. The cancellation would not actually take effect, however, until the Administrator issued his final order at the conclusion of the hearing procedure.

A further provision permitted immediate suspension of registration when "necessary to prevent an imminent hazard to the public" (61). The suspension power was reserved "for cases in which serious irreparable harm to the public health is likely to occur before the conclusion of the ordinary cancellation process" (62), and was rarely employed. Judicial efforts to create standards to guide the exercise of agency powers of cancellation and suspension proved less than satisfactory (63).

The effect of FIFRA was, then, to give the government the means to prevent hazardous pesticides from being placed on the market or to remove them from commerce, but it was a clumsy instrument for the purpose, designed more for quality and labelling control than for hazard prevention. The registration procedure under the Act served as a mechanism to make EPA aware of products to be placed on the market, but the initial submission of information under FIFRA provided EPA with almost no guidance as to whether the produce might pose an environmental hazard. In order for EPA to develop thorough information concerning a product's potential hazards, it was necessary to refuse or cancel registration of the product, whereupon the registrant could demand that the lengthy administrative proceeding described above be undertaken (64). In case the EPA's initial position was upheld, it was possible to shift much of the costs of this procedure to the registrant (65).

The Federal Environmental Pesticide Control Act of 1972 (FEPCA) (66) was, as its title suggests, formulated with environmental protection in mind. The basic system of FEPCA remains one of
product registration, forbidding commerce in pesticides not registered with the EPA Administrator (67). Before deciding whether to register a product, EPA may, in addition to the labelling and formulary information required under FIFRA, call for a description of tests and results thereof upon which claims for the pesticide are based. The applicant also must specify whether he wishes the pesticide to be classified for general use, restricted use, or both. Information in support of an application for registration must conform to guidelines set by EPA (68).

Registration under FEPCA is to be granted only upon EPA determination that a pesticide "will perform its intended function without unreasonable adverse effects upon the environment" and "when used in accordance with widespread and commonly recognized practice... will not generally cause unreasonable adverse effects upon the environment" (69). Registration for restricted use is an intermediate classification for substances tolerable if applied by a "certified applicator", but excessively hazardous to the applicator, other persons or the environment if made available for unrestricted use. Standards for the certification of professional applicators are to be set by the States, under EPA supervision (70). EPA is also empowered to grant "experimental use permits", for strictly controlled use of a pesticide to enable the applicant to develop information necessary to determine whether normal registration is to be granted (71).

Provisions regarding cancellation or suspension of registration for pesticides already in use provide a system similar to that under FIFRA, but they are more detailed and permit rapid action in emergency cases (72). The power of suspension remains confined to cases of "imminent hazard", but the Act now defines such a hazard to exist "when the continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened... pursuant to the Endangered Species Act of 1973" (73).

Protracted litigation concerning EPA's suspension of certain uses of the agricultural chemicals Heptachlor and chlordane has helped to clarify the evidentiary basis required for a finding that an imminent hazard is presented. A US Court of Appeals determined in Environmental Defense Fund v. Environmental Protection Agency (74) that the appropriate rule is a substantial evidence standard. In such cases, where each party tends to throw into the fray the conflicting prognostications of its own scientific experts, presentation of "respectable scientific authority" for the conclusion that a pesticide is carcinogenic
in laboratory animals is sufficient justification to suspend its use, despite equivalent evidence for the opposite conclusion. Upon such a showing, the burden of proof shifts to the manufacturer (75).

FEPCA also requires registration of all establishments producing pesticides registered under the Act, with information to be filed with EPA periodically concerning types and amounts of pesticides produced (76). The Act empowers EPA to undertake research and monitoring activities as necessary to carry out the purpose of the Act (77).

The Federal Environmental Pesticide Control Act thus gives the government more effective means of controlling environmental hazards from pesticides than did the former law. An important addition in the new law is that EPA's authority to control the uses to which a pesticide is put, by the device of restricted use registration. This more effective control, however, requires broad governmental involvement in research and monitoring as well as in a complex and prolonged procedure for product registration. Substantial expense also may be incurred by the producer in complying with EPA guidelines as to information to accompany applications for registration. It is likely that much such information will, however, be developed by the economically efficient, and even profitable, means of marketing under experimental use permits.

Germany: The Plant Protection Act

The Plant Protection Act (Pflanzenschutzgesetz)(78) of the Federal Republic of Germany resembles the United States pesticide legislation in its mixed character, its intent being to assure that plant protection products - pesticides - are both effective and reasonably non-hazardous. Thus the purposes of the Act are:

"(1) the protection of plants against harmful organisms and disease...;

"(2) the protection of plant products against harmful organisms...;

"(3) the prevention of damage which may result from the use of plant protection substances...; in particular where the health of man and animals is concerned."

The third purpose listed is, of course, the only one addressing the environmental hazards of pesticide products themselves.
The plant Protection Act also resembles the US legislation in its system of control - a system of prior authorization combined with ongoing supervision of the use of already authorized substances. The German authorization procedure is, however, more simply organized, at least in theory. Plant protection substances (Pflanzenschutzmittel) may be imported or distributed commercially only if they have been authorized by the Federal Biological Institute for Agriculture and Forestry(80). The application for authorization must include a variety of information describing the substance, its packaging and field of use, as well as "documentary evidence necessary for the decision to be made regarding the application" (81). The types of documentary evidence which are required are set forth in an Ordinance Concerning the Testing and Authorization of Plant Protection Substances (82). These include:

1. test reports as to effectiveness in plant protection;
2. description of effects on health;
3. description of reactions in plants and plant products, especially with respect to decomposition and residues;
4. similar descriptions regarding reactions in the soil and water; and
5. description of analytical methods used(83).

The ordinance also lists aspects of a substance which must be examined by the Federal Institute, including product composition; intended effects; harmful side-effects on plants, products and health; and residues in plants, soil and water(84).

The standards for granting authorization under the Plant Protection Act are quite vague, probably leaving even more room for administrative discretion than FEPCA's provision for a socio-economic environmental balancing test (85). Under the German law, authorization is to be granted if (1) the product is "sufficiently effective...", (2) "precautions necessary for the protection of human and animal health in trade in dangerous materials do not require otherwise", and (3) the product when used as intended "does not produce harmful effects on human or animal health or other harmful effects which are not justifiable in the light of the present state of scientific knowledge"(86). The Federal Biological Institute is required to decide the latter two questions in consultation with the Federal Health Office (Bundesgesundheitsamt), with the advice of a standing committee of experts (87).
Product authorization may be made subject to specific conditions (88), but the relevant clause seems more concerned with product labelling than with establishing the sort of general versus restricted use authorization system existing under FEPCA(89). Still, the German law does provide for control over who may apply pesticides, with supervisory authority delegated to the Lander(90). Also the Act provides Federal authority to restrict or prohibit the use of previously authorized substances, without the involved hearing procedure for cancellation or suspension under the US statutes (91). Under this authority three lists of prohibitions and limitations upon particular substances have been created: (1) total prohibition, (2) prohibition of use except by stated means and for stated purposes, and (3) prohibition of use by stated means and/or for stated purposes (92).

The government also may permit use of an unauthorized substance, “for the purposes of research, analysis and trial” (93). Like the provision for experimental use permits under US law(94), this allows assessment of possible hazards to be carried out at private expense. It is to be hoped, however, that such experimental use be conditional upon adequate warning to agricultural consumers of the substance being tested. Like the EPA under FEPCA, the Federal Biological Institute is empowered by the Plant Protection Act “to carry out scientific research in the field of plant protection...”. In cases where hazards are suspected these agencies ought to weigh carefully whether it would not better protect the public health and the environment for such hazards to be explored through governmental research capabilities rather than through experimental private use.

In general, the pesticide control laws of both the United States and the Federal Republic of Germany present examples, in structure if not always in practice, of detailed and comprehensive systems of governmental control over a range of products. With their provisions for premarket authorization, post-marketing controls and on-going research, these laws demand substantial public and private expenditure(95). It is questionable whether so comprehensive a system of authorization, covering every substance to be marketed within an industrial sector, is appropriate except in fields where every new product ought to be viewed as a potential hazard—as is certainly the case in the field of pesticides.

Consumer Products Legislation

Another type of product for which broad regulatory systems for hazard control have been developed is what may be called consumer
products, products which are designed to be consumed by or to come into close and continuing contact with the ultimate purchaser or other members of the public. Such regulations often apply as well to products used for treating or packaging consumer products proper. The basic reason for stringent regulation of such products is that any hazard which such a product presents is likely to have serious results upon consumers' health. Such legislation thus tends to be directed primarily toward protecting the health or safety of individuals, rather than the "public health" or the environment in general. Still, actions which serve the narrower purpose often serve the broader one as well, and laws designed to protect consumers may often be applied for environmental causes. The means by which such consumer protection laws deal with possibly hazardous new products may, however, vary widely.

The German Foodstuffs and Consumer Goods Act

In the Federal Republic of Germany a recently reformed law controls the production and marketing of foodstuffs, tobacco and cosmetic products and other consumer goods. This Lebensmittel-und Bedarfsgegenständegesetz (96) prohibits the production, handling or bringing into trade of foodstuffs, cosmetics or consumer goods which by their consumption or use according to directions are able to damage health (97). The Federal Minister of Youth, Family and Health is empowered to enact further regulations as required to protect against hazards to health. This competence to protect against hazards, a clause added with the recent reform of the Act, has been seen as an important concretization of the authority to take preventative action against possible (not necessarily probable) dangers to health (98). Among other powers such regulations may prohibit or restrict the use of specific substances, objects or procedures in food production or handling, and may prohibit or make subject to licensing the production, handling or trade in specific foodstuffs (99). The Act also authorizes regulations to prohibit, restrict, or, in contrast, prescribe the use of specific substances, mixtures or procedures in the production or handling of specific consumer goods (100).

Solely with respect to foodstuffs, regulations are authorized to control the marketing of products which have been exposed to radiation or to air, water or soil pollution. This clause provides authority to set tolerances for environmental contaminants (101). Trade in foodstuffs or consumer goods not conforming to such regulations is prohibited (102).

Penalties for violation of these provisions may be strict: up to one year imprisonment for negligent violations, two years if
intentional, and as much as five years "in especially grave cases" such as acts posing danger to the health of "a large number" of persons or posing danger of death or severe injury (103). Other provisions, added with the Act's recent reform, permit many violations to be treated as administrative offenses subject only to fine, making practical enforcement easier (104). The Foodstuffs Act may thus be expected to supply a significant and practicable deterrent to productive or marketing activity careless of consumer health. It places the onus of vigilance upon the producer, a strong supplement to the traditional risk of civil liability.

The framers of the Foodstuffs Law, however, were not satisfied with simply imposing a threat upon careless producers. They also provided for continual surveillance through regular inspections and sample testing by the competent authorities of the Länder, with the use of professionally qualified personnel (105). The Federal Health Office is responsible for publishing an official set of procedures for testing and inspecting products under the Act, the procedures to be kept up to date with the cooperation of scientific and technical experts (106). In addition, the Federal Minister of Health is empowered to establish by regulation uniform procedures for testing and inspection of products, which may make the marketability of an identical lot dependent upon the testing of a sample thereof (107). It should be noted, however, that these are not provisions for premarket testing, whether voluntary or compulsory, but rather for testing of products currently on the market, to establish whether violations have occurred.

Even so, the requirement of an official compilation of testing procedures may have significant effect upon premarketing precautions taken by private parties. The formulators of that provision saw it as serving the interests of all parties to develop uniform investigative procedures to produce reliable analytical data in accord with the progress of investigative techniques. This official compilation of procedures was expected to be drawn upon by producers as well as by government, and so might have an informal influence upon premarket testing by industry (108).

In one area where the likelihood of health hazards is great, that of food additives, the Foodstuffs Act gives the Minister broader and, in effect, earlier control. Generally speaking, unless explicitly authorized by Health Ministry regulation, food additives may not be applied to or produced in foodstuffs intended to be placed in commerce nor may foodstuffs including unauthorized additives be marketed (109). The Minister is empowered to authorize the use of a food additive which, "taking account of the requirements of technology, nutritional
physiology and dietetics, is compatible with the protection of the consumer" (110). This "positive list" system has been implemented by a regulation setting forth two lists of substances: 1) those permitted to be used as food additives without restrictions; and 2) those permitted to be used only subject to stated restrictions. No other substances may be used as food additives (111). The effect of this system is a regime of pre-market research and testing, either by government or by private industry for submission to government, of those substances which may be used as additives.

American Consumer Protection Laws

In the United States Federal regulatory authorities like those provided in Germany by the Foodstuffs and Consumer Goods Act are dispersed among several different laws. Controls over foods and cosmetics are based upon the Federal Food, Drug and Cosmetic Act (112). The types of products which qualify as "consumer goods" under the German Act are regulated in the United States primarily by the Flammable Fabrics Act (113), the Federal Hazardous Substances Act (114), and the Consumer Products Safety Act (115).

The Food, Drug and Cosmetic Act

Foods and medicines were the first consumer products to be made subject to a thorough system of regulation in the United States (116). The Federal Food, Drug and Cosmetic Act (117), enacted in 1906, prohibits manufacture or placing in commerce of any "adulterated or misbranded" food, drug, medical device, or cosmetic (118). Violations are subject to injunction by federal courts (119), are punishable by imprisonment or fine (120) and may result in seizure of the offending products (121). A food is deemed adulterated, among other circumstances, "if it bears or contains any poisonous or deleterious substance which may render it injurious to health", except that if such substance is not an "added substance", the food will not be deemed adulterated if the quantity of such substance does not ordinarily render such food injurious (122). A food also is deemed adulterated "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health" (123).

The Act empowers the Secretary of Health, Education and Welfare to promulgate regulations setting tolerances for poisonous or deleterious added substances when such substances are required or "cannot be avoided by good manufacturing practice". Where
quantities of such substances do not exceed tolerance levels, food will not be deemed adulterated (124).

For our purposes, the heart of the Food, Drug and Cosmetic Act is section 348, which deals with food additives. A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food", including substances used in packaging, transporting or processing food (125). Food additives, thus broadly defined, are to be deemed unsafe unless either an exemption or a regulation pursuant to section 348 is in effect (126).

Exemptions may be granted for food additives "intended solely for investigational use by qualified experts", when consistent with the public health (127). For general use of a food additive, however, positive determination of its safety by regulation is required. The system for regulating food additives under US law thus resembles the "positive list" approach under the German Foodstuffs Act (128).

The American Act, however, is much more explicit than its German equivalent about the procedures to be followed in considering approval of a food additive. The burden is upon interested persons to petition the Secretary for issuance of a regulation. Such petition must describe the food additive, its intended use and proposed labelling, its intended effect, and the means of measuring its presence. Most importantly, the petition must contain "full reports of investigations made with respect to the safety for use of such additive..." (129).

The Secretary then is required to issue an order either denying the petition or establishing a regulation for the food additive in question. Such regulation need not accord with that proposed by the petitioner, but must prescribe conditions for safe use of the additive, including specification of maximum permissible quantities and permissible applications (130). No such regulation shall issue "if a fair evaluation of the data before the Secretary... fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe" (131). The Secretary also is required to set tolerance limitations where necessary to assure that a permitted use of an additive will be safe (132).

Any order issued in accordance with these provisions must be published and "any person adversely affected" may file objections and request a public hearing. Where reasonable grounds are stated, such a hearing must be held, and the record developed
shall form the basis for the Secretary's subsequent action, which will then be subject to judicial review (133).

The standard for the Secretary's issuance of a regulation, quoted above, is subject to an important proviso, which is relevant to our discussion. The proviso, known as the Delaney Clause in reference to its original Congressional proponent, states that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of food additives, to induce cancer in man or animal, except..." for certain instances respecting ingredients of animal feed (134). The clause became law as part of the 1958 Food Additives Amendment to the Food, Drug and Cosmetic Act. This change in the law resulted from scientific recognition of a distinction between reversible and irreversible adverse effects of chemicals, it being doubted that meaningful threshold levels for harm could be set for the latter, particularly in the case of carcinogens. With respect to carcinogens, moreover, testing of an adequate sample of laboratory animals is thought to be enormously expensive, with the results not consistently extrapolable to the health of human beings (135).

Several applications of the Delaney Clause have given rise to controversy. The discovery in 1969 that cyclamates administered to rodents in massive doses could cause cancer led to a ban on these substances, which had been widely used as artificial sweeteners. As a result of similar discoveries, the Food and Drug Administration (FDA) in 1972 prohibited the use of diethylstilbestrol (DES) in cattle feed and the next year prohibited its use altogether in connection with meat production. It was estimated that this would lead to an increase in the cost of meat of 15 cents per pound (136). Perhaps the most intense controversy arose in 1977, with the FDA decision to ban the sale of saccharine, the only readily available low-calorie sweetener, in light of Canadian experiments which had shown carcinogenic effects in laboratory animals. This issue presented a conflict between competing medical concerns, and for many persons the interest in limiting sugar consumption overrode the more distant risk of carcinogenicity (137).

It may seem only reasonable that substances found to be carcinogenic be prohibited from being added to food products. The Delaney Clause, however, has been the object of much debate. The controversy arises from the fact that this total prohibition prevents the Secretary from exercising his reasonable discretion to designate an additive as safe, if it has been found to induce cancer under any circumstances whatsoever. Such an absolute standard has been seen as "outstripped by current scientific knowledge" (138).
The theoretical argument against the Delaney Clause rests upon two main points: (1) the complexity and ambiguity of causation; and (2) the inappropriateness of zero-tolerance in the context of ever more sensitive techniques of analysis. On the first point, it has been argued that the Delaney Clause results from a common sense view of causation which sees removal of "the cause" as a sure means of preventing "the effect" - in this case cancer. But for a scientist, a causal relationship simply means that, under otherwise constant conditions, change in one factor was followed by change in another (139). Opponents of the Delaney Clause fear that such indications of cancer induction under unrealistic laboratory conditions may be relied upon to bar use of food additives which are perfectly safe for human consumption. This fear is compounded by the fact that the Delaney Clause imposes a zero-tolerance level for carcinogenic additives. Opponents argue that actual carcinogenicity is always a function of the potency and concentration of the substance in question, and that use of potentially valuable substances should not be precluded merely because of a possibility which may in fact be extremely improbable (140). Defenders of the clause retort that in the case of irreversible and delayed toxicity, often experimentally unmeasurable, no level of exposure can be verified as safe (141).

That the Delaney Clause was adopted and retains broad support among scientists as well as laymen despite these criticisms testifies to the magnitude of public concern over carcinogenic substances. The clause illustrates one extreme among legislative alternatives for dealing with uncertain hazards: the total prohibition of any substance which has been associated with the evil sought to be prevented. Although such a blanket prohibition prevents judicious administrative weighing of risks and benefits, by the same token it simplifies the administrative decision, a fact of particular importance where decisions may have to rest upon very incomplete factual and scientific knowledge - as is currently the case concerning the means of preventing cancer (142).

The Food, Drug and Cosmetic Act also includes general provisions empowering the Secretary to promulgate regulations "for the efficient enforcement" of the Act (143), to conduct examinations and investigations for the purposes of the Act (144), and, in cases of "imminent danger to health or gross deception of the consumer" to disseminate information regarding questionable products to the public (145). This last power may be used to help effect the recall of goods already distributed in commerce; it may also be used as a threat to gain voluntary compliance from producers, for such adverse publicity can have very detrimental effects upon the producer's commercial position. For example, in 1959 the government warned the public of contamination
of that year's cranberry crop. Although the danger was alleged to be limited to certain portions of the crop, the resultant "cranberry scare" ruined the entire market and led to Congress authorizing compensation payments to the industrial interests affected (146). The merits of particular exercises of this authority to warn the public may be debatable, but such authority provides a very useful instrument in the area of uncertain hazards. Where government may not yet be prepared to take enforcement action against a questionable product, making public what information is at hand may prevent harm in the meantime, while the taking of more forceful action is being considered (147).

The Flammable Fabrics Act

As its name implies, the Flammable Fabrics Act (148) was designed to cope with a particular type of hazard commonly associated with a particular type of product. Fabrics, especially as used in the manufacture of clothing, blankets and curtains, have often presented dangers of injury due to flammability. This statute, enacted in 1953 and amended in 1967, thus represents a way-station between the type of statute designed to protect against a single hazard, and that aimed to control hazards connected with a broad category of products.

The Act prohibits the manufacture or sale of any fabric or products made from fabric not conforming to any standard or regulation issued under section 1193 of the Act (149). Section 1193 defines procedures for the Federal Trade Commission to develop flammability standards, based on a finding of necessity to protect the public against an unreasonable risk of harm (150). Section 1195 empowers that agency to sue to enjoin violation of such standards and to confiscate offending products. Wilful violation is punishable as a misdemeanor by fine up to $5,000 and imprisonment for as much as one year (151). Dealers, however, as distinguished from manufacturers, may rely upon a guarantee received in good faith from the supplier or manufacturer of a fabric attesting that "reasonable and representative tests" show the fabric to conform to applicable standards (152).

The threat of prosecution together with the availability of immunity under a guarantee should exert a pressure upon the dealer to become an advocate of adequate testing. The dealer's market pressure may be thought to compound the direct threat of enforcement action, encouraging fabric manufacturers to test their products adequately for fire hazards. Still, the Flammable Fabrics Act does not require product testing; it only requires actual compliance with standards. Thus the Act is a rather weak tool for encouraging early discovery of unknown hazards.
The Federal Hazardous Substances Act

The Federal Hazardous Substances Act(153), adopted in 1960 and significantly amended in 1966 and 1969, deals with both a broader category of products and a broader range of risks than does the Flammable Fabrics Act. Still, the Act is narrower in scope than its title might suggest, being intended primarily to regulate children's toys and household goods.

The heart of the Act is to be found in its definition of the terms "hazardous substance", "misbranded hazardous substances", and "banned hazardous substance"(154), and its prohibition of interstate commerce in objects meeting either of the latter two descriptions(155). The Act defines a "hazardous substance" as any substance or mixture of substances which is toxic, corrosive, flammable, or possesses any of certain other dangerous characteristics (156). Each of these qualities is defined in turn with some precision, either in the Act or in related regulations (157). Any hazardous substance (or article containing a hazardous substance susceptible of access by a child) which is "intended, or packaged in a form suitable, for use in the household or by children" must comply with detailed labelling requirements; otherwise it will be a "misbranded hazardous substance".

Regardless of labelling requirements, the definition of "banned hazardous substance" includes:

"any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child..."(158).

In addition to this absolute prohibition respecting hazardous toys, the same definition includes "any hazardous substance intended, or packaged in a form suitable, for use in the household", if the public health and safety are found by Federal regulation to require that such substance be kept "out of the channels of interstate commerce"(159). Regulatory proceedings to declare a household product a "banned hazardous substance" must be governed by the formal rule-making procedures of the Food, Drug and Cosmetic Act(160), except that an immediate ban may be imposed pending normal proceedings if the government finds an "imminent hazard to the public health"(161).

Interstate commerce in misbranded or banned hazardous substances and certain similar offenses are misdemeanors punishable by mild fines, but also by imprisonment for as long as one year in case...
of repeated violations or intent to defraud or mislead (162). Banned or misbranded substances are subject to seizure by the government, unless intended and suitable for export (163). Violations may also be restrained by judicial injunction (164). Manufacturers and distributors can be required to repurchase a banned hazardous substance and refund its purchase price (165).

Current Federal regulations declare several potential household goods to be banned hazardous substances, including carbon tetrachloride, certain liquid drain cleaners, products containing cyanide salts, paints with more than a slight percentage of lead, garments containing asbestos, and a wide variety of fireworks (166). Detailed regulations define what characteristics of toys and other children's goods constitute electrical, thermal and mechanical hazards bringing the Act's prohibitions into effect (167).

The regulations also specify a few testing procedures for determining whether a substance is toxic, irritative or flammable (168). However, such tests are not required by the Act, either before or after marketing of a substance. The tests are applicable as standards for determining whether a substance is a "banned hazardous substance", but nowhere does the Act call upon either producers or regulators to conduct any such tests at any point in product development, manufacture or marketing.

In contrast, regulations setting requirements for electrically operated toys (169) and for bicycles (170), include detailed testing requirements. The specified tests must be conducted in order to avoid designation of a product as a banned hazardous substance (171).

It is not clear from the regulations, however, whether the described tests must be conducted upon every article produced or only upon representative samples. In any case, within the scheme of the Act such regulations are appropriate only with respect to products particularly likely to pose a hazard.

The Federal Hazardous Substances Act was designed to control known hazards, and provides very limited protection against uncertain or unknown dangers. The labelling requirements applicable to hazardous substances might also be observed by manufacturers with respect to borderline substances which could be hazardous, and so slightly lessen the dangers posed by such products. With respect to the composition of products designed for use by children, since any hazardous substance is by definition banned, the Act's sanctions may encourage manufacturers to be more careful in testing the toxicity and other potential hazards of their products prior to marketing. Still, the decision whether to conduct such tests remains purely
voluntary, guided mostly by economic considerations, except where regulations make testing mandatory. With respect to products intended for household use, the hazardous substance ban comes into effect only upon enactment of a specific Federal regulation. In this situation the Act provides no added motivation to the manufacturer to test his products for possible hazards.

The Consumer Product Safety Act

The Consumer Product Safety Act was adopted in October 1972, based upon explicit findings that "an unacceptable number of consumer products which present unreasonable risks of injury" were being placed in commerce and that consumers were frequently unable to anticipate such risks and to safeguard themselves adequately(172). The Act's purposes therefore included protection of the public "against unreasonable risks of injury associated with consumer products", assistance to consumers in evaluating the safety of products, development of uniform consumer product safety standards, and promotion of "research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries"(173).

The last-stated purpose indicates that the orientation of the Consumer Product Safety Act would likely be a reflective one, reacting to hazards as they become known rather than screening products initially to determine whether they might be hazardous. This is in fact the case. It has been noted that the Consumer Product Safety Act creates a supervisory authority endowed with a synthesis of more limited powers previously existing in specialized fields: authority to set product safety standards; to require cautionary labelling; to ban products known to be dangerous; but not to require premarket testing as required for food and color additives under the Food, Drug and Cosmetic Act(174).

This less comprehensive form of regulation is not surprising, in view of the very broad definition of "consumer products" subject to the 1972 Act:

"any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but ..."
with the exception of certain categories of products, most of which — e.g. motor vehicles, pesticides, foods and drugs — are regulated by other Acts. Consumer products under the 1972 US law thus include a much broader range of items than consumer goods (Bedarfsgegenstände) under the German Foodstuffs and Consumer Goods Act (175). Whereas the latter category is restricted mostly to products calculated to come into close personal proximity to the consumer, the US definition seems, by virtue of the phrase "or otherwise", to be almost unlimited except by the definition of the class of "consumers" for whom the product is produced. The Act itself does not define this term; nor have court decisions yet clarified its scope.

The Act creates a Consumer Product Safety Commission, which is required:

"to collect, investigate, analyze and disseminate injury data, and information, relating to the causes and prevention of death, injury, and illness associated with consumer products",

as well as to conduct continuing studies of injuries resulting from consumer product accidents (176). In addition, the Commission is authorized, but not required, to

"(1) conduct research... on the safety of consumer products...;
(2) test consumer products and develop product safety test methods and testing devices; and
(3) offer training... and assist public and private organizations... in the development of safety standards and test methods" (177).

Thus the Commission appears to have the power to engage in testing of consumer products, but use of that power is not required, neither explicitly nor by such a "positive listing" regime as governs additives under the Food, Drug and Cosmetic Act.

The Commission also has the power to:

"prescribe procedures for the purpose of insuring that the manufacturer of any new consumer product furnish notice and a description of such product to the Commission before its distribution in commerce" (178).

This provision provides very significant authority enabling the Commission to oversee the sort of products coming upon the market. It is not, however, sufficient to inform the Commission...
prior to marketing of a new product as to whether that product poses a hazard. Neither does it authorize the Commission to postpone the marketing of products which might be hazardous. It simply enables the Commission to keep informed as to what products might warrant its action under the authority of other sections of the Act.

Where a consumer product poses an "imminent hazard" - i.e. an "imminent and unreasonable risk of death, serious illness, or severe personal injury" - the Commission may take action against the product or its manufacturers or dealers in Federal court. The court may order seizure of products, notification to purchasers, recall, repairs, replacement or refunds (179). The manufacturer's mere description of the product as required by section 2062(a), however, is not likely to provide the grounds to prove an "imminent hazard". The factual basis for taking action against an imminently hazardous product probably will most often be developed through the procedure, described below, for creating product safety standards.

The manner envisaged for the Commission normally to respond to potential hazards is by the promulgation of "consumer product safety standards", as to performance, composition, contents, design, construction, finish or packaging, or as to warnings or instructions to accompany the product. These standards must be "reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such produce"(180). The process for developing such standards, however, is complex and time-consuming, and leaves most investigative work in the hands of vaguely defined private parties.

Generally, product safety standards are to be developed at the Commission’s initiative, commencing with notice published in the Federal Register identifying the product and the risk of injury associated with it, stating the Commission's finding that a standard is necessary, and inviting "any person" either (a) to submit an existing standard as the proposed standard, or (b) to offer to develop the proposed standard(181). Unless the Commission finds an existing standard adequate, it must accept one or more offers to develop a standard, if the offeror appears technically competent and reliable(182). In the process of developing standards, testing data is to be recorded and interested persons are to be allowed to participate(183). With certain exceptions, the Commission may not itself develop product safety standards unless a suitable offeror does not appear or is not making satisfactory progress toward a standard(184).

Within 210 days after the initial notice, the Commission must either withdraw such notice or publish a proposed rule. Such a rule will either propose a product safety standard or will
declare the relevant product a "banned hazardous consumer product". The latter result requires a finding that the consumer product in question presents an unreasonable risk of injury and no feasible safety standard would protect the public adequately (185). A proposed consumer product safety rule can become final only after interested parties have been given opportunity to present their views at an oral hearing. Relevant research and testing data must be considered and findings must be made as to the degree and nature of the hazard and as to the need for the products concerned (186). A special provision prohibits "stock-piling" - the accelerated manufacture or importation of a product for which a rule has been proposed but not yet promulgated (187).

Products placed upon the market for which a consumer product safety standard is in effect, must be accompanied by a certificate affirming that the product conforms to applicable standards. Any such certificate is to be "based on a test of each product or upon a reasonable testing program", which may be prescribed by the Commission (188).

Manufacturers of, or dealers in consumer products are required to inform the Commission if they learn that such products fail to comply with applicable consumer product safety standards or otherwise contain defects which could create a substantial product hazard (189). Where the Commission determines that such a hazard exists, it may require the manufacturer or dealer to notify the public and the specific persons affected, and to repair or replace the product or refund the purchase price (190).

Manufacturing, importing or dealing in products not conforming to applicable standards or which have been declared to be banned hazardous products, or failure to comply with requirements of the previous paragraph, subject violators to civil and, in case of knowing and wilful violations, criminal penalties. Violations with respect to separate products may constitute separate offenses, up to a maximum civil penalty of $500,000. Corporate officers, directors, and agents may be held criminally liable (191). Enforcement by injunction or product seizure is also possible (192).

There are several provisions for public participation in implementing and enforcing the Act. Any "interested person" may petition the Commission to issue, amend or revoke a product safety rule; the Commission may then commence a hearing procedure which can lead to judicial intervention. Rules themselves are subject to timely judicial review (193). Individuals may also be able to take action against violators of the Act, with a rule of strict liability applying to injuries flowing from knowing or wilful violations, and with any "interested person"
entitled to bring judicial action to enforce a consumer product safety rule (194). Compliance with a consumer product safety rule, or failure of the Commission to take action with respect to the safety of a consumer product, however, does not relieve any person from normal civil liability (195).

The Consumer Product Safety Act has been in force for only a few years and the extent to which its possibilities will be exploited remains uncertain. Potentially, the Act provides the structure for careful supervision of the safety of consumer products which are already on the market. The Act's predominant concern is with preventing personal injuries as distinguished from societal calamities. As to whether the Act might be a prototype for legislation to protect against uncertain environmental hazards, however, this orientation is an unimportant factor, correctable by changing a few words here and there which describe interests to be protected. More of a problem is the fact the Consumer Product Safety Act may authorize, but in no way requires, research or testing concerning product hazards prior to marketing; most importantly, marketability is not made dependent upon any such prior testing procedure.

Still, this Act offers a very interesting example of how a premarket testing requirement might be formulated to operate (1) through research by private interests; (2) at governmental initiative; and (3) subject to citizen pressure. The idea of a government agency requesting private offers to develop mandatory standards is one which may be worthy of adaptation to other purposes.

In sum, the current consumer protection legislation, both of Germany and the United States, could make significant contributions toward the control of hazardous products and their elimination from the marketplace. Generally, these laws are designed to cope with already known hazards. Still, the research, product testing and standard setting provided for and encouraged under these laws, even though not always mandatory, should contribute toward the discovery of many product hazards in time to prevent widespread suffering and injury.
RELATED LEGISLATION

The laws surveyed above represent the principal existing Federal legislation in Germany and the United States designed for the explicit purpose of controlling hazardous products, with the exception of the US Toxic Substances Control Act, to be discussed subsequently. Manufacturers are subject to further pressures to investigate and control the hazardous effects of their products as a result of statutes designed for broader purposes. These statutes are of two principal types: (1) those directed toward the safety of the workplace and the welfare of the worker; and (2) those directed toward maintaining environmental quality with respect to particular "media", such as air, water or solid waste. Legislation relating to the working environment includes the US Occupational Safety and Health Act (196), as well as the Trade Regulations for the German State (Gewerboordnung für das Deutsche Reich) (197), and the related Decree Concerning Dangerous Working Substances (Verordnung über gefährliche Arbeitsstoffe) (198). Examples of media-oriented environmental legislation relevant to the control of hazardous products are the American Clean Air Act (199), and the German Federal Immission Control Act (Bundesimmissionschutzgesetz) (200). Both countries' laws for the control of water pollution and the disposal of solid and liquid wastes are of similar breadth and would provide equally instructive examples.

The Occupational Safety and Health Act

The purpose and policy of the Occupational Safety and Health Act of 1970 (OSHA) is to assure "safe and healthful working conditions". The Act seeks to attain this purpose by, inter alia, encouraging employers and employees to reduce the number of occupational safety and health hazards at places of employment by authorizing the Secretary of Labor to set mandatory occupational safety and health standards, and by providing for research in the field of occupational health and safety (201).

OSHA requires the employer to furnish a place of employment "free from recognized hazards likely to cause death or serious physical harm to his employees" (202). Both employers and employees must comply with standards and regulations issued in accordance with the Act (203).

The development and enforcement of occupational safety and health standards is the core of OSHA. A National Institute of Occupational Safety and Health (NIOSH) is established to conduct research necessary to determine appropriate standards, including the development of criteria for safe exposure levels in dealing with toxic materials (204). A detailed, highly formalized
procedure is provided for the Secretary of Labor to promulgate these mandatory standards, including requirements of notice and hearing with respect to interested parties (205). In cases of emergency this procedure may be bypassed and temporary standards put into effect immediately, upon official determination that such standards are necessary to protect employees from current exposure to a grave danger. Here too, however, the formal procedure for promulgation of standards must be initiated and brought for completion, since emergency standards may remain in effect no longer than six months (206). The occupational safety and health standards which have been brought into force in the past five years occupy 6645 pages of small type in the Code of Federal Regulations (207). Most concern the prevention of mechanical accidents, the requirement of safety equipment, and so on, but a sub-part on "toxic and hazardous substances" sets standards for maximum permissible exposure of employees to more than 500 air contaminants, from acetic acid to zinc oxide fumes (208). Separate standards specify permitted exposure levels and also mandatory control measure with respect to certain other substances, including asbestos (209) and vinyl chloride (210).

As the language of the Act makes clear, OSHA's focus is upon the control of "recognized hazards" rather than the discovery of unknown or uncertain ones. Neither employers nor the government are expected to pass upon the safety of all substances, equipment and operations involved in the production process. However, the work of NIOSH has helped to bring attention to several suspected hazards, including vinyl chloride, which has been held responsible for numerous fatal cases of a rare cancer of the liver among plastics workers (211). Moreover, the purposes of the Act encourage workers to demand the alleviation of hazardous conditions (212). Another aid to the recognition of possible hazards is the Secretary of Labor's power to require that employers maintain records useful to develop information regarding causes and prevention of occupational accidents and illnesses. Such records may be required to include accurate data concerning employee exposure to potentially toxic materials (213). This provision could be instrumental in tracing the causes of employee illnesses and so bringing about recognition of unknown hazards.

German Regulation of the Working Environment

The basic German legislation regulating the conduct of commercial and industrial activities is the Trade Regulations for the German State (Gewerbeordnung für das Deutsche Reich) (214), first adopted by the North German Federation in 1869. For the protection of workers and third parties, the trade regulations impose strict mandatory controls upon a category of "facilities
which require special supervision on account of their dangerousness" (215). These "facilities requiring supervision" include steam boilers; facilities for bottling liquified or pressurized gases; pressurized pipelines for flammable, caustic or poisonous gases, vapors or liquids; and facilities for storing, bottling or shipping flammable liquids. The construction and operation of such facilities are subject to reporting, permit and inspection requirements and must satisfy conditions set by specific regulations (216). Such regulations are formulated with the guidance of technical committees composed of governmental, scientific and business representatives (217). Considering these "facilities requiring supervision" as in themselves constituting products, we can see that these provisions of the Trade Regulations constitute a special kind of hazardous category legislation, imposing a strict system of prior supervision and control over this category of products hazardous to the working environment.

Another provision of the Trade Regulations imposes upon all operators of businesses the duty so to arrange working areas, machines and equipment "that the worker is protected against dangers to life and health insofar as the nature of the enterprise permits" (218). Special care is to be taken to provide sufficient light, air space and circulation, and to remove dust, fumes, gases and other wastes. Further regulations are authorized to implement these requirements (220), and this authority provides a basis for the Decree Concerning Dangerous Working Substances (Verordnung über gefährliche Arbeitsstoffe) (221).

The Decree defines dangerous working substances as chemical substances and preparations used in the production of goods or the performance of services, and having one or more of a list of dangerous properties (e.g. explosive, flammable, poisonous, caustic) (222). The competent authorities may require anyone selling or utilizing such substances to provide complete information regarding their composition. This requirement is in effect for numerous substances and preparations listed in appendices to the decree (223). Special packaging, labelling and warning requirements also apply to such substances (224). Most importantly, any employer whose activity involves dangerous working substances must comply with a set of technical and hygienic requirements prescribed in another lengthy appendix, as well as with "the generally recognized rules of technique" (225). The development of these requirements is the duty of an official agency, operating with the cooperation of industry and other experts.

The German Decree resembles OSHA in establishing a system for controlling the presence and effects in the workplace of substances which have been recognized as hazardous. Although the Decree does not impose any general testing requirement, it does
facilitate monitoring of suspected hazards by its provision for mandatory reporting of formulary information to the authority. Unlike OSHA, however, the German system does not require that employers maintain special records of employee accidents, illnesses and exposure to hazardous substances.

The US Clean Air Act

The US Clean Air Act (226), enacted in 1955 and considerably expanded in 1970, is the basis for a comprehensive national regulatory system to combat air pollution. The magnitude and stringency of this system of control have led to recurring political controversies in recent years. The Act calls upon the Administrator of the Environmental Protection Agency (EPA) to maintain a list of air pollutants which adversely affect public health or welfare and the presence of which in the ambient air results from a variety of sources. EPA is required to issue "air quality criteria" respecting such pollutants, reflecting the latest scientific knowledge as to their effects on health and welfare (227). For each of these substances national ambient air quality standards must be promulgated (228). In addition, EPA is responsible for developing standards of performance for both stationary and mobile pollution sources (229).

EPA also has authority to impose mandatory national emission standards for substances designated as hazardous air pollutants (230). Such standards have been issued with respect to several substances, including asbestos, beryllium, mercury and vinyl chloride, specifying mandatory control procedures including a requirement of regular emission sampling in each case (231). In order to achieve settlement of a law suit brought by an environmental group, EPA recently proposed to make its vinyl chloride standard more stringent, setting a theoretical goal of zero emissions but recognizing that its achievement would require closing down a sizeable industry, an unacceptable trade-off (232). EPA also has listed benzene as a hazardous air pollutant, "based on scientific reports which strongly suggest an increased incidence of leukemia in humans exposed to benzene" thereby committing itself to propose emission standards for that substance within six months (233).

For these various responsibilities to be carried out effectively, a research capacity was required, and so section 1857b provides for a research and development program to include investigation of the "causes, effects, extent, prevention and control of air pollution". EPA's mandate here is broad enough to allow study of suspected environmental hazards. The Clean Air Act's emphasis, however, is upon controlling recognized pollutants, with research aimed primarily to assess the extent of control necessary and feasible in such cases.
Even so, the Clean Air Act fulfils a screening function with respect to certain types of products. The most common "mobile source" of air pollution is the automobile, and EPA's standards of performance for automotive emissions have the effect of requiring thorough testing of new automobiles with respect to those particular environmental hazards to which the standards refer. A more direct and more comprehensive screening process applies to another class of products — fuels and fuel additives.

Section 1857f-6c(a) of the Clean Air Act gives the EPA Administrator responsibility for registration of fuels and fuel additives. Sale or introduction into commerce of unregistered fuels or additives is prohibited. For registration purposes, manufacturers are required to notify EPA of certain data concerning fuel additives (234). In addition, EPA may call upon a manufacturer:

"to conduct tests to determine potential public health effects of such fuel or additive (including, but not limited to carcinogenic, teratogenic, or mutagenic effects)" (235).

The manufacturer also may be required to describe techniques to detect and measure additives in fuel and to explain their intended function. Upon compliance with such requirements, registration of the fuel or additive follows. However, when testing results so indicate, EPA may control or prohibit manufacture or sale of any fuel or additive for use in a motor vehicle if any emission will endanger the public health or welfare (236). Violations are subject to a civil penalty up to $10,000 per day of continuance of the violation (237).

It should be evident that this system for regulating fuel additives is not a typical registration requirement. Unlike the registration systems under the American pesticide law or the German foodstuffs law (respecting food additives), the Clean Air Act does not create a positive list of substances approved for use. Registration of a fuel additive indicates only that certain procedural formalities have been observed. To control marketing of a fuel product, EPA must act affirmatively (1) to require testing concerning potential hazards; and (2) to impose restrictions based upon the results of testing. Thus, despite the registration requirement, the control mechanism here is actually that of a negative list — a list of products prohibited on the basis of specific determination that a hazard exists. Such a system, of course, offers greater freedom to industry, but at a sacrifice of regulatory effectiveness.

Another interesting feature of this scheme is that the government has authority to order that testing be conducted in any given case, but such testing is actually carried out by the
manufacturer. Public expense thereby is kept to a minimum, while testing costs to the manufacturer also are limited to cases where cause for concern exists. Still, the preliminary procedure by which EPA decides whether testing ought to be required probably calls for a significant administrative effort in the case of each fuel or fuel additive. Once again, as we saw with respect to pesticides and consumer goods, a system of strict hazard control is imposed only for a limited class of products which are considered especially likely to pose risks to health or the environment.

The Clean Air Act's provision authorizing control of fuels or additives which endanger the public health was at the core of a very significant dispute resolved in the 1976 case of Ethyl Corp. v. Environmental Protection Agency (238). That case involved a challenge to an EPA regulation calling for annual reductions in the lead content of gasoline, even though the extent of the hazard posed by lead in gasoline has yet to be determined. The opinion of the Circuit Court, written by Judge Wright, established that the concept of endangerment as used in section 1857f-6c of the Clean Air Act includes a precautionary element, so that proof of potential harm can establish endangerment, it being unnecessary to prove that actual harm already has occurred. The court summarized its conclusions as to the requisite degree of proof as follows:

"Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect... The (EPA) Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data not yet certifiable as 'fact', and the like. We believe that a conclusion so drawn - a risk assessment - may, if rational, form the basis for health-related regulations under the 'will endanger' language section (1857f-6c)." (239)

The effect of the decision in Ethyl Corp. has been to encourage governmental efforts to control uncertain product hazards (240). However, judicial efforts to restrict industrial operations on the basis of merely suspected risks and uncertain statutory language face a future which is cloudy at best (241). A legislative approach to the problem, mandating or at least encouraging
a process of testing to facilitate evaluation of risks prior to product marketing, provides a more secure basis for the control of potential hazards.

The German Immission Control Act

The Federal Immission Control Act (242) performs for West Germany a function closely resembling that of the Clean Air Act in the United States - providing a complex, many-faceted system to regulate air pollution. The German statute, enacted in 1970, is intended to provide protection against "harmful environmental effects", which are defined as:

"immissions which, due to their kind amount and duration, are apt (geeignet) to bring about dangers, serious disadvantages or serious burdens for the general public or the neighboring population"(243).

Immissions, in turn, are defined as "air pollution, noise, vibrations, light, heat, radiation and similar environmental influences affecting persons as well as animals, plants and other objects" (244). For our purposes, the most significant provisions of the Immission Control Act are sections 32 and 35, regarding the characteristics of operating facilities and of substances and products, respectively.

Section 32 authorizes regulations to prohibit commerce in or importation of mass-produced components of manufacturing plants and other production equipment, unless they satisfy specific requirements for protection against air pollution, noise and vibrations. In particular, such regulations may prescribe that emissions from operating facilities or their components may not exceed specific levels, and that such facilities or their components must comply with specific technical requirements for the limitation of emissions (245). Labelling as to emission levels may be required for such facilities or components to be placed in commerce(246).

Regulations authorized by section 32 of the Immission Control Act perform a similar function to the standards of performance for stationary and mobile pollution sources mandated by the US Clean Air Act(247). An important difference is that the German Act imposes control before the stage at which the offending facilities are placed into use, regulating instead the prior trade in those facilities and components which would be used for production activities(248). Regulation is imposed upon production equipment at the stage when it is itself a product. The government's authority to prescribe emission levels and technical requirements should cause manufacturers of such equipment to
engage in extensive premarket testing to verify compliance with such requirements.

Section 35 of the Immission Control Act authorizes regulation of the composition and production methods related to substances and products which when used as directed or when incinerated for disposal or recycling purposes, are apt to give rise to air pollution having harmful environmental effects. Like section 32 this provision prohibits commerce in and importation of items not complying with regulations; it also prohibits the production of non-complying substances and products (249). Again, labelling of such substances and products may be required to indicate the possibility of harmful environmental effects (250).

Regulations issued under the authority of section 35 could mandate testing procedures prior to marketing of products to determine whether the products or substances contained therein are apt to give rise to air pollution. Requirements may be framed to come into force at a later date, as technological development permits (251).
HAZARDOUS CHEMICALS REGULATION

The preceding survey of statutes and legal doctrines indicates the variety of approaches which have been and are being taken for the control of product hazards, known and unknown. Almost all the legislative remedies reviewed were motivated by a recognition of the existence of a specific hazard, whether it was a particular substance, or a category of substances related by composition or by prospective use. To discover protective measures of a truly general application it is necessary to look back to the private law rules of products liability. More than any of the specialized hazard control legislation, these court-developed rules encourage the manufacturer to monitor and investigate products of whatever description and thereby to discover hazardous characteristics which might otherwise have gone unsuspected. Proper application of strict liability and the shift of the burden of proof, as practised in the United States and Germany, respectively, helps prevent the dissemination of products posing unrecognized environmental risks.

Even so, as has been noted, the rules of tort law generally are not a sufficiently strong influence upon behaviour to protect against uncertain hazards. These rules do not require prudent conduct; they merely encourage it, and their sanction is a delayed and uncertain one. It is therefore appropriate to look for a legislative remedy which would more effectively facilitate the discovery of product-related hazards.

As the examples used in this discussion may have suggested, those products which have gained notoriety as environmental hazards, generally have been portrayed in terms of their chemical composition: DDT-based pesticides; paints and motor fuels containing lead; lubricants and electrical equipment composed of PCBs; plastics made up of vinyl chloride; etc. This is certainly logical, because it is only by analysis of chemical and biochemical interactions with the environment that the environmental impact of such products can be understood. Of course, chemical analysis alone cannot provide adequate environmental protection with respect to some products. Careful analysis of product design and mechanical testing may be required, as in efforts to produce low-pollutive automobile engines and oil tankers reasonably secure against oil spills. The fact remains, however, that to assess environmental hazards associated with a great many products, the most important procedure would be an analysis of the product's chemical composition and of the impact of those chemicals upon the environment over the course of product manufacture, use and disposal.

The regulation of chemicals production may be considered a broad species of hazardous category regulation, akin to the examples
of pesticide and consumer products legislation discussed above. A difference, however, is that chemical substances are basic products which may be employed in a wide variety of uses, either directly or as ingredients or components of other products. Subjecting chemicals to thorough testing with respect to potential health or environmental impacts may eventually affect the composition and design of a large proportion of all manufactured goods. It is not surprising, therefore, that efforts to assert broad environmental control over manufactured products have focused upon chemical substances. The most prominent of such efforts has been the five-year legislative struggle in the United States to enact a Toxic Substances Control Act.

The first effort in the United States to legislate comprehensive controls over chemical products was a bill introduced in Congress in 1970 by Representative Charles A. Vanik, motivated by the recently recognized hazard of phosphate detergents (255). A report published in 1971 by the President's Council on Environmental Quality outlined the environmental hazards posed by toxic substances and called for emphasis on preventive rather than reactive approaches to such problems (256). In the course of the next five years and the next three Congresses, a variety of bills was introduced to create a system of Federal regulation in this field. Always the crucial and nearly irresoluble issue was the extent and nature of the premarket testing requirement which was to be imposed. Some bills would have called for testing, but without regulatory review; others would have required testing only of such products as the Environmental Protection Agency found likely to be hazardous; still other bills would have mandated testing of virtually all chemical products, subject to exceptions granted by the EPA (257).

Advocates of a rigorous requirement of premarket testing argued that there was:

"a compelling need to broaden and standardize the test procedures and to provide for a regulatory review of test results prior to the entry of substances suspected of being dangerous into the stream of commerce and into the marketplace" (258).

Opponents feared that unnecessary testing of new chemical substances would be required and that the expense of such testing would be unreasonable. The President of the Manufacturing Chemists Association (MCA), a spokesperson for the industry, declared as recently as February 1976 that:

"this legislation will impose serious and unnecessary economic penalties on the public..., will restrict the development of new products and will add to unemployment" (259).
Re expressed fear that "blanket requirements for testing and screening of chemical substances" would handicap efforts to protect against the most serious potential risks, because scarce monitoring resources would be diverted to perform unnecessary tasks (260).

The basis for much criticism of the proposed Toxic Substances Control Act (TSCA) was a study prepared by consultants to the MCA (261). This study estimated that approximately 14,000 new products annually would potentially be covered by the proposed Act, with some 340,000 products covered if "minor developments" were included. Testing costs were estimated as averaging anywhere from $15,000 to $800,000 per product, with total direct costs of compliance within a range of $360 million to $1.3 billion per year (262). The study warned that comprehensive premarket testing would drive small chemical producers into bankruptcy, channel production into high volume products, divert research and initial marketing to other countries, and result in the loss of up to 80,000 jobs (263). Industry representatives also argued that the combination of broad regulation at the product development stage together with the polarization and advocacy orientation of regulators and regulated alike would prove incompatible with the maintenance of scientific and technological innovations (264).

Other studies have indicated that environmental and safety regulation actually encourage rather than stifle innovation (265). On the financial issue, the Environmental Protection Agency estimated the costs of product testing as far lower than had the Snell study - approximately $3,000 for each chemical substance the hazards of which could not otherwise be predicted, with some substances not requiring testing at all (266). EPA calculated the costs of compliance with the TSCA as within a range of $78.5 to $141.5 million per year (267). It has been suggested, moreover, that in many cases these costs would represent little or no added burden to the manufacturer, in that such product testing is already routinely conducted in response to potential liability under other laws (268).

The tremendous discrepancies among estimates of regulatory costs illustrate the dearth of definite information in this field, which has itself been pointed out as a justification for more stringent regulation. A report prepared under the auspices of the US National Academy of Sciences argued that:

"society suffers large and unnecessary expense because of inadequate investment in determining the hazards of chemicals. The less precise the determination of hazard, the larger must be the necessary margin of safety incorporated in the regulatory standard to protect society" (269).
The Academy of Sciences report strongly advocated adherence to a comprehensive cost-benefit analysis, "broadened to cover all significant advantages and disadvantages", as the most appropriate basis for organizing information and translating value judgements into regulatory decisions (270). The report recommended adoption of the Toxic Substances Control Act as a means of creating the broad regulatory authority envisioned (271).

The debate over the cost of implementing a Toxic Substances Control Act was translated into a prolonged conflict between the two houses of the US Congress, with the Senate favoring a strict requirement of premarket testing and the House preferring a less comprehensive provision. The General Accounting Office, a research arm of the Congress, studied the Snell and the EPA cost projections, as well as those made by Dow Chemical, and concluded generally in favor of the EPA figures, subject to some adjustments. On the most crucial factor, the number of chemicals to require testing, the GAO accepted the EPA's estimate of 150 new substances to be thoroughly tested annually, rejecting Dow's projection of 900 and Snell's of 1230 to 7900 per year. The GAO also disallowed as unsubstantiated Snell's claim that the maintenance of innovation in product development in the face of the Act would cost a further $600 million per year. The GAO concluded that the annual cost to the chemical industry of the proposed act would approximate $100 to $200 million (272). Whether in response to the GAO report or to the pressures of an election year, the two houses of Congress were finally able to resolve their differences and adopt a bill enacting a Toxic Substances Control Act, which was signed into law by President Ford in October 1976 (273).

The Senate report on the bill which became the Toxic Substances Control Act drew attention to several gaps in regulation which the Act was designed to fill (274). It was noted that premarket review was previously required only with respect to pesticides, drugs and food additives, and that with the exception of the Clean Air Act's provision on fuel additives (275), no Federal statute applied direct controls over industrial chemicals. The report also noted that no regulatory agency had the authority to look comprehensively at all the risks posed by a chemical substance, and that no other statutes made the manufacturer responsible for providing the information upon which regulation would be based (276). It was stated that a primary motive for the Act was the conviction that the most effective and efficient time to prevent unreasonable risks is prior to the initial manufacture of a product (277).
The Toxic Substances Control Act

The Toxic Substances Control Act establishes a system for the regulation of chemical substances, with the following central elements: (1) a selective requirement that manufacturers of chemicals conduct tests with respect to those new or pre-existing products which the Environmental Protection Agency designates; and (2) a blanket requirement that manufacturers notify EPA of certain data regarding any new product prior to initial marketing; (3) limited authority for EPA to prohibit or regulate such manufacture pending sufficient testing; (4) broader authority for EPA to prohibit or regulate manufacture upon a finding of unreasonable risk; and (5) authority for EPA to seek injunctive judicial relief against new or pre-existing substances likely to pose imminent hazards. In addition, the Act creates further reporting requirements; authorizes EPA to conduct research, collect data, and carry out inspections; provides for the imposition of substantial civil and criminal penalties; and authorizes "citizens' suits" and citizen petitions to help enforce the Act. Each of these features will be briefly discussed below.

Requirement of Testing

The Toxic Substances Control Act empowers the Administrator of EPA to adopt rules requiring that testing be conducted to develop data on the health and environmental effects of certain chemical substances, where the Administrator finds that such testing is necessary to remedy an insufficiency of data for predicting the substance's effects upon health or the environment. This testing requirement applies to those chemical substances which the Administrator finds "may present an unreasonable risk of injury to health or the environment" or, alternatively, "will be produced in substantial quantities, and (i) ... may reasonably be anticipated to enter the environment in substantial quantities, or (ii) ... may (involve) significant or substantial human exposure..." (279).

An immediate problem is to decide which among the many thousands of products developed each year merit consideration even as candidates for testing. The Act establishes a committee of experts to recommend which existing or newly developed chemical substances should be given priority consideration by the Administrator (280). In requiring testing, the Administrator must identify the substance and specify standards for the development of test data, taking into consideration "the relative costs of the various test protocols and methodologies which may be required under the rule and the reasonably foreseeable availability of the facilities and personnel needed..." (281).
The duty to conduct such tests applies to those who manufacture or process the relevant substance or intend to do so, but provision is made to avoid duplicative testing (282). Those who are thereby freed from the necessity to perform tests are obliged to provide "fair and equitable reimbursement" to those who have submitted test data or previously contributed with respect thereto (283). The Administrator must publish notice of the receipt of test data (284). If any such data, or other information available, indicate that there may be a reasonable basis to conclude that a substance presents "a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects", then the Administrator must within 180 days either find that no unreasonable risk is presented or take controlling action as described below (285).

Manufacturing and Processing Notices

In contrast to the testing requirement, which is to be selectively imposed at the initiative of EPA, a requirement of premarket notification applies to all chemical substances newly brought upon the market (286). A person proposing to manufacture or process such a substance must notify the Administrator of his intention, after which at least 90 days must pass before manufacture commences. Notification to EPA must include, in addition to certain data describing the substance, any relevant test data in the proponent's possession and a description of all known data concerning environmental and health effects of the substance (287). If testing of the new substance has been required, submission of the data developed by that testing must accompany or precede notification. If testing has not been required, the manufacturer must submit data which he believes to show that the chemical substance will not present an unreasonable risk of injury to health or the environment (288). The Administrator must promptly publish notice describing such notifications and the data submitted which shall be available for examination by interested persons (289).

The 90-day waiting period prior to manufacture may for good cause be extended by the Administrator for one further 90-day period (290).

Where testing has been insufficient to allow evaluation of a substance's effects, and upon a finding that the substance may present an unreasonable risk or may result in extensive exposure, the Administrator may, up to 45 days before the notification period expires, issue a proposed order prohibiting or restricting manufacture, distribution, use or disposal until such testing has been completed (291).
A related provision authorizes the Administrator to issue a proposed rule, to regulate a substance subject to notification effective more or less immediately. Such a proposed rule may be adopted upon a finding "that there is a reasonable basis to conclude that the manufacturing (etc.) ... will present an unreasonable risk of injury to health or environment before a (permanent) rule ... can protect against such risk" (292). With respect to either a proposed order or a proposed rule, objection by a manufacturer or processor will prevent the proposed order from taking effect. The Administrator, however, may apply to a Federal court for an injunction against manufacture, etc., which the court shall grant upon making the same findings as are required of the Administrator (293). Where he does not issue such a proposed order or take other restrictive action, the Administrator must, within the 90-day waiting period, publish a statement of his reasons for not doing so (294).

Regulation of Chemical Substances

Issuance of a proposed order prohibiting or restricting production of a chemical substance is a stopgap measure pending adequate testing, requiring only a suspicion of risk. Where the risk is more substantial, or where a proposed order is temporarily in effect, the EPA Administrator may, following a rulemaking procedure, impose a variety of permanent restrictions and/or prohibitions upon the chemical substance. The exercise of such controls is conditioned upon a finding:

"that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture... presents or will present an unreasonable risk of injury to health or the environment" (295).

The controls which may be applied include the following: (1) prohibition or quantitative limitation of the manufacture, processing or distribution of the substance; (2) such prohibition or limitation with respect to a particular use, or with respect to use in excess of a specified concentration; (3) regulation of the manner of use or disposal; (4) labelling or instructional requirements; (5) requirement that manufacturers notify distributors and the public of the risks and either replace or repurchase the products concerned; and (6) requirement of recordkeeping, monitoring and testing as necessary (296).

In promulgating a rule imposing such controls as described above, the Administrator must make findings with respect to the health and environmental risks presented, the magnitude of
human and environmental exposure to the chemical substance, the benefits of the substance, the availability of substitutes, and "the reasonably ascertainable economic consequences of the rule" [297]. Detailed procedural requirements for the development of such rules are set forth, including provision for informal hearings and submission of views by interested persons [298].

**Imminent Hazards**

The Administrator's authority to impose permanent restrictions on chemical substances is limited by the necessity to follow the steps of a detailed rulemaking procedure. His more summary authority to impose restrictions by proposed order has already been discussed as it applies to new substances not yet subjected to premarket testing. Similar authority is provided to facilitate prompt regulatory action in ease a chemical substance already on the market is discovered to constitute a serious hazard. Under the Toxic Substances Control Act, summary regulation in such cases may be imposed either by the EPA's promulgation of a proposed rule or by action through the courts. However, a proposed rule may not go so far as to prohibit manufacture, processing or distribution of a chemical substance unless a Federal court has already granted relief with respect to the risk at issue [299].

The EPA Administrator apparently may impose less drastic forms of regulation, such as quantitative limitation of production, labelling or monitoring requirements, or regulation of use or disposal, by declaring a proposed rule before the time-consuming rulemaking procedures have been completed. To do so he must find that "unreasonable risk of serious or widespread injury to health or the environment" is likely to result prior to the effective date of the final rule, and that the public interest requires such a proposed rule [300].

This required finding is virtually identical to the Act's definition of an "imminently hazardous chemical substance or mixture" [301]. The EPA Administrator is authorized to file an action in Federal court for the seizure of an imminently hazardous chemical substance or against its manufacturer or other persons involved in its sale or use [302]. The court may grant such temporary or permanent relief as may be necessary to protect against the risks posed by the substance at issue. The manufacturer, but not the distributor, may be ordered to notify purchasers and the general public of the risk, as well as to recall and either replace or repurchase the chemical product [303]. Such relief may be granted notwithstanding the pendency of an administrative or judicial proceeding or the existence of a rule or order under any other provision of the Act [304].
It may be noted that the protection of the manufacturer is greater with respect to a product which may pose an imminent hazard than in the special case of a product which has not been sufficiently tested. To prohibit an imminent hazard, the EPA Administrator must seek a court order, whereas in the latter case the mere possibility of an unreasonable risk justifies an administrative prohibition of manufacture, subject only to subsequent judicial approval (305).

Reporting and Research

The Act requires the Administrator to promulgate rules to assure that manufacturers maintain such records and submit such reports—as are reasonably necessary, including a listing of health and safety studies conducted by or for the manufacturer (306). The Administrator is to maintain an inventory, compiled on the basis of manufacturers' reports, of chemical substances manufactured or processed in the United States, to be published initially no later than November 1977 (307). Each manufacturer must maintain records of adverse reactions to health or the environment alleged to have been caused by his products, including consumer allegations of injury and any complaints of environmental damage (308). If a manufacturer of a chemical substance obtains information supporting the conclusion that the substance contributes to an unreasonable risk of injury to health or the environment, he must see that the Administrator is adequately informed without delay (309).

EPA is also authorized to conduct such research and monitoring as are necessary to carry out the purposes of the Act. The Administrator is to be responsible for an interagency committee to coordinate the collection, dissemination, and use of data submitted in accordance with the Act (310). The Administrator is also empowered to inspect manufacturing plants and storage facilities and to obtain testimony or documents by subpoena (311). The protection of trade secrets or other proprietary information is questionable, inasmuch as disclosure of submitted data is permitted not only to Congress and to employees of and contractors with the government, but also "if the Administrator determines it necessary to protect health or the environment against an unreasonable risk of injury" (312). This may, however, be the ideal solution, lodging with a hopefully disinterested public official the authority to decide when the maintenance of secrecy must give way to the public's need to know.
Enforcement

Failure to comply with requirements of the Act or rules promulgated thereunder is subject to substantial civil and criminal sanctions. The EPA Administrator may impose civil penalties of up to $25,000 per day of violation, with factors to be considered including ability to pay and the history of prior violations (313). Knowing or willing violations are subject to criminal penalties in addition to or in lieu of any civil penalty, up to an additional $25,000 per day of violation, imprisonment for not more than one year, or both (314). Upon application by the Administrator or the Attorney General, Federal courts are authorized to issue restraining orders and mandatory injunctions, and may order the seizure of substances manufactured or distributed in violation of the Act (315).

The Toxic Substances Control Act includes several provisions designed to encourage citizen enforcement. "Any person" may commence a civil action against any person, including the government, alleged to be in violation of the Act. At least 60 days prior to taking such action, however, the plaintiff must have conveyed notice of the violation to the EPA Administrator and the alleged violator (316). The court may award the costs of suit and attorneys fees as deemed appropriate (317). A further provision establishes procedures for citizens' petitions to the Administrator seeking action to fulfill the purposes of the Act. The petitioner may be entitled to undertake a court action to compel the Administrator to initiate the action requested (318).

Summary

The sharp and persistent controversy engendered by efforts to regulate chemical substances is reflected in the Act which was adopted. The Toxic Substances Control Act is a carefully balanced compromise with which both the Manufacturing Chemists Association and consumer groups will find it possible to live. A fairly broad discretion is allowed to the EPA Administrator, but the threshold tests for his intervention vary with the nature of the intervention and in several important instances the sanction of a court of law will be required.

To justify adoption of a rule requiring testing, EPA need only determine that a chemical substance "may present an unreasonable risk" or even that, where production will be substantial, it may result in substantial human or environmental exposure. Similar threshold findings justify temporary controls over new substances subject to notification requirements. Thus, where testing has been insufficient, a proposed order restricting production pending the outcome of tests may be imposed if manufacture "may
present an unreasonable risk". The threshold is somewhat higher to impose a proposed rule based solely on a need for haste – there must be "a reasonable basis to conclude" that manufacture will present an unreasonable risk" before the normal rulemaking process is completed. In both these cases of proposed orders or rules a manufacturer's objection will require EPA to seek judicial confirmation of its action.

Summary action with respect to a product already on the market depends upon meeting a still higher threshold test – that the substance "is likely to result in an unreasonable risk of serious or widespread injury" before rulemaking can be accomplished. To prohibit a substance in this summary fashion, moreover, a prior court order must be obtained. And, finally, to justify adoption of a permanent rule restricting or prohibiting production, EPA must itself find "a reasonable basis to conclude" that an unreasonable risk will be presented.

The differences among these threshold formulas are not accidental, although they may be more convoluted than ideal legislative draftmanship might recommend. Their precise meanings probably will have to await judicial or administrative clarification as the Act is implemented.

A common feature of all these threshold tests is that each one, even that for the adoption of a permanent rule restricting manufacture, shifts the burden of proof away from the regulator and imposes it, to a greater or lesser extent, upon the producer. The extent of these shifts is unclear; in no case need the producer expressly demonstrate that his product is safe, as is required with respect to pesticides under FEPCA(319). Rather, the consistent inclusion of a consideration of reasonability suggests that a balancing of interests will be part of every enforcement decision.

Some critics have argued that the Act's many variations upon the standard of "unreasonable risk" to health or environment indicate an improper bias toward trying to ensure absolute safety of chemical products while ignoring the social and economic benefits which such products offer (320). This is an incorrect reading of the Act. For EPA to conclude that a chemical substance is likely to present an unreasonable risk, thus justifying adoption of a rule restricting production, a detailed set of findings is required, the nature of which makes clear that the threshold determination must involve a balancing of benefits against risks(321). By no means must a chemical substance of substantial social or economic value be proven "absolutely safe".
The Act's legislative history confirms the Congressional intent to provide for a balancing of interests in the regulation of toxic chemicals. The Act itself declares the intent of Congress that the Act be carried out "in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action" taken thereunder.

A further safeguard to assure against overzealous enforcement of the Act is a provision requiring the EPA Administrator to defer to other governmental agencies where he determines that sufficient preventive action to control a toxic substance may be taken under a Federal law administered by a different agency. In such a case the Administrator must submit and make public a report to the relevant agency, describing the risk presented. If the agency either takes regulatory action or finds that no unreasonable risk in fact exists, EPA may not impose restrictions upon the chemical substance, although it still may order that testing be conducted. This provision should help protect against the oft complained of inefficiency of duplicative administrative controls.

In the face of industry fears regarding the costs of testing and subsequent blight upon technical innovation, EPA has consistently emphasized its intention to enforce the Act selectively. The creation of a committee of experts to recommend substances for EPA's priority consideration will help implement this intention. On the other hand, the citizens' suit and petition provisions will draw attention to those administrative oversights which a selective system of regulation will inevitably produce. Similarly, placing the burden on the manufacturer to inform EPA of information suggesting that a product is hazardous will help to close gaps in the regulatory net.

The Toxic Substances Control Act was clearly a compromise. Economic considerations and industry pressure narrowed the scope of the manufacturer's notification duty and complicated the procedures for rulemaking and regulation. Even so, the law's enactment was seen as a victory by advocates of environmental protection, while yet grudgingly acceptable to the chemical industry.

The most essential feature of the Act remains its provision for selective requirement of premarket testing of chemical substances, to be conducted by industry under close governmental supervision. This approach to the control of hazardous products has important advantages: particularly its preventive rather than compensatory character, as well as its creation of a thorough system for supervising an industry which profoundly affects the environment.
There are, however, also serious problems with a regulatory scheme such as the Toxic Substances Control Act. As has been noted above (328), costs of administering the law, both to government and to industry, are uncertain but sure to be substantial. The findings required as conditions to regulation are imprecise and may lead to lengthy litigation. Further problems may arise in interpreting the complicated provisions on confidentiality and disclosure of proprietary information, as well as those for sharing of the costs of compliance and testing. Even with many duties placed upon the industry, the task of regulation remains a difficult one, for which years will be required to develop the necessary administrative expertise. Finally, it should be realized that the intensive regulation of one industrial sector, as by the Toxic Substances Control Act, represents an expenditure of governmental resources which might alternatively have been applied in a less rigorous form to a broader scope of environmental risks.

In summary, the Toxic Substances Control Act creates a reasonable system for the control of unreasonable risks. Its distribution of responsibility establishes a proper balance among a regulatory agency with adequate but limited powers and resources, a set of other agencies with their own regulatory duties to tend, and an industry and a citizenry to which are allocated significant but not disproportionate roles in fulfilling the purposes of the Act. Whether this complex system of regulation will succeed in revealing and controlling potential hazards before they do damage to human health and the environment, only time will tell.

Chemicals Regulation in Germany

Proposals similar to elements of the Toxic Substances Control Act have been made in Germany as well. A study group on environmental chemicals and biocides, contributing to the government's environmental programme, proposed in 1971 that a more stringent law be developed to govern the trade in poisons (329). The proposed Federal poisons law would have made the bringing into commerce of poisonous substances dependant on official authorization. The study group also proposed establishing a central registration and evaluation agency for biocides within the Federal Health Agency, to maintain a register of tests and regulations concerning the environmental impacts of chemicals and to evaluate health hazards (330).

Subsequent amendments to the Plant Protection Act and the Foodstuffs and Consumer Goods Act have implemented these proposals with respect to pesticides and food additives (331). The German government, however, has adopted no law with the broad scope of the US Toxic Substances Control Act.
AN ALTERNATIVE. PROPOSAL FOR LEGISLATION

The analysis which has been presented of a variety of German and American statutes demonstrates that a premarket testing requirement may take many forms. In some special cases the responsibility for testing rests with government, but the most common arrangement is to impose a primary duty to conduct testing upon the manufacturer while enabling a government agency to conduct its own tests and other research to corroborate or call into question the results of Industry testing.

The manufacturer's duty of testing may apply to all his products of a certain character or may be limited to those items specifically designated by the regulatory agency. The testing required may be defined by government regulations in terms of precise test protocols and procedures, or may be set forth in very general terms, as by a requirement of testing "reasonably adequate to inform the manufacturer of any unreasonable risk presented by his product".

Generally, where the primary duty of testing rests with the manufacturer, the results of such testing must be submitted to the supervising agency, which has authority either to approve or disapprove marketing of the product. The requirement of producer testing might be accompanied by a less controlling (and less expensive) role for government. One less restrictive alternative is to empower the regulator solely to certify or refuse to certify the adequacy of testing, without the power and the burden of deciding whether to prohibit commerce in the product. Such a regime, however, might have the undesirable result of shifting civil liability from the manufacturer to the government with respect to products certified as adequately tested. Such a problem could be avoided by requiring that the manufacturer conduct premarket testing but without any direct governmental supervision. Here the only effective pressure to conduct adequate testing would be the threat of civil liability in case the product causes injury to personal or property interests, with all the uncertainty that the proof of such liability involves.

The inadequacy of private law remedies for controlling industrial activities has been discussed above(332). However, these remedies may prove more effective in concert with a carefully formulated obligation to conduct premarket testing, even without direct governmental supervision or control over the testing process. Such a system could operate without contemporaneous disclosure of the data developed by testing with the confidentiality of such data retained unless the manufacturer elects voluntarily to disclose such information in defense against claims of injury attributed to his products.
If it could be so designed as to provide a real impetus for adequate testing, while yet limiting governmental involvement and protecting proprietary information, this approach would be practical for application not only to "hazardous categories" of products, but to the entire range of manufactured and processed goods which are placed upon the market.

Such a universal requirement would be of unique value in assisting discovery of unanticipated, unsuspected hazards. Where other laws require carefully controlled production and use of products or classes of products which have been recognized as hazardous, this less intensive regime would help to protect against gaps in current knowledge. This approach might also be feasible for application in countries where shortage of economic and technical resources makes intensive governmental regulation unfeasible.

A General Requirement of Testing

A basic element of the proposed legislation would be a general requirement of adequate testing of all products to be manufactured for sale. An appropriate standard would be that every manufacturer or processor of a new product, before bringing said product upon the market, must perform or have performed for him such investigation and testing as is reasonably adequate under all the circumstances to inform the manufacturer or processor of any unreasonable risk to human health or the environment which may be presented by the manufacture, processing, distribution in commerce, use or disposal of said product.

Certain terms of this standard will have to be defined. The definition of "bringing a product upon the market" may be limited so as to exclude activities which need not or should not be regulated, such as the manufacture of chemical substances in small quantities for experimental use, or the manufacture of products for use solely by the manufacturer or persons under common ownership or control. If desired, a further exception could be made for the marketing of a product clearly labelled with a notice such as the following: "This product has not been tested for safety and may present a hazard to health or the environment". Following the lead of several American product regulatory statutes, an exception might also be made for products intended solely for export. In such event, however, the least that should be required is a notice to the governments of countries to which export is intended, as is called for by the US Toxic Substances Control Act(333).

What constitutes a new product will also require definition. The term probably should be defined to include any product of a composition or design not substantially identical to a
product previously manufactured or processed by the same manufacturer or processor or by another manufacturer or processor under common ownership or control. To exempt a product identical to products of another manufacturer might improperly allow one manufacturer to shift his liability for his own products to another producer. Where a very similar product previously has been manufactured by others, the testing required of a new product may be supplemented and to a degree supplanted by a survey of experience with the previously marketed product.

The standard of reasonable adequacy under all the circumstances should not be further defined in the statute, except perhaps to provide that adequacy be assessed in consideration of the best available investigative technology.

The purpose of this requirement is no more than to reiterate the manufacturer's duty of due care which already exists under both American and German law(334). The statute's preamble or statement of purpose would include an explicit declaration that the statute is intended for the protection of the public, so that, at least under German legal principles, a violation of the testing requirement will subject a manufacturer to liability for any harm resulting therefrom(335). On the other hand, this general standard of duty will not require a manufacturer to conduct testing of a product if its harmlessness is obvious or already proven by experience.

Even if no monetarily quantifiable damage results from an inadequately tested product, such product might harm the environment in other ways, as by generating excessive air pollutants or by imposing an inordinate burden upon waste disposal facilities. To curb the manufacture of such products the statute should include a provision for imposition of civil fines upon violators of the testing requirement whose products result in non-quantifiable injury to or burden upon health or the environment. This provision would, in effect, resemble a liquidated damages clause, setting a range of damages to be paid where the precise extent of actual damages may not be ascertainable. It would probably not be wise, however, to seek to impose criminal penalties for violation of the testing requirement, because such penalties may not properly be conditioned on so general a standard, which is not, and for the sake of its effectiveness must not be, easily predictable in its application. The same reasoning makes it improper to impose a punitive fine upon the manufacturer, exceeding any reasonable monetary equivalent to the damage resulting from his product.
In most cases the obligation to conduct reasonably adequate testing would impose little if any liability beyond that which would result from the application of general tort law principles. The statutory standard's effect would be mainly to clarify and accentuate the manufacturer's responsibility to exercise due care. For jurisdictions such as the many American states in which a manufacturer may be held strictly liable for injuries resulting from his products, the statute should state that it is not intended under any circumstances to exculpate any person from liability according to other applicable legal standards. Further provisions of the statute, to be described below, would more markedly affect the manufacturer's actual liability, by means of changes in the burden of proof and the admissibility of evidence.

A Supplemental Testing Requirement

The duty to conduct reasonably adequate product testing should not expire when the product is placed upon the market. Rather, as with the German doctrine of Produktbeobachtungshaftung(336), the manufacturer should bear responsibility for monitoring the product's safety subsequent to its initial marketing as well. More specifically, upon receiving any further information, not patently unreliable, which reasonably suggests that prior testing was not reasonably adequate to inform him of risks presented, the manufacturer must resume testing in order to attain such a reasonably adequate assurance of safety. Examples of the types of information which would make renewed testing necessary include the following:-

1. information indicating that a previously unknown hazard may exist;

2. information indicating that a previously known hazard may present a significantly greater risk than prior testing had indicated;

3. information indicating a significant deficiency in a testing method previously relied upon;

4. information indicating that an alternative testing method is available which would probably provide significantly greater assurance as to whether or not a product is hazardous; and

5. information indicating that a product has been the cause of significant injury to any aspect of the environment or to the health of any person.
In effect, the manufacturer would stand under a continuing obligation to reexamine the safety of his product upon receiving information of the types described.

The producer's duty might be extended by placing him on constructive notice of any such information which is reasonably available to him. This would require the manufacturer to monitor in an active fashion the performance of his and related products, as well as to keep abreast of developments in investigative technology. Such a requirement, however, might impose an excessive burden upon the small manufacturer. It would appear preferable to impose responsibility to conduct renewed testing only upon actual notice to the manufacturer of information fitting the above-listed categories. This would provide an incentive for individuals claiming personal injuries or for consumer or environmental protection groups to make sure that manufacturers are fully informed of new developments which might make further product testing advisable.

A Requirement to File Records of Testing

The second basic element of the proposed statute would be a filing requirement, which might call upon every manufacturer or processor of a new product, before bringing said product upon the market, to file with an official depository, designated by the appropriate governmental agency, complete and accurate descriptions of all tests, examinations, studies and assessments, and of the data developed thereby, which may be relevant to the possible effects of said product upon human health or the environment. Alternatively, a procedure for the filing of such descriptions of tests and test results may be provided but made optional at the will of the manufacturer or processor.

Records of supplemental testing might be added to the filing at any time, but the file should indicate the date on which each such record is filed.

Whether filing be mandatory or voluntary, the statute would provide that the record currently on file with the official depository would be the only evidence admissible on behalf of the manufacturer or processor in order to prove what testing had been conducted in defense of a claim of liability for breach of his duty to conduct reasonably adequate testing or for breach of any other duty related to the safety or environmental compatibility of the product at issue. An exception might be made for admission of explanatory evidence, but should be expressly limited to the testimony of persons who participated in the testing and studies which were recorded, and whose names were included in the record itself.
Any test results filed would remain confidential until a bona
fide controversy were to arise. In fact, it would be unneces-
sary for the official depository or any other agent of
government even to examine the data, placed on file, except to
the extent required to record a physical description of the
filing and to mark each document or group of documents with a
notation of the date of filing. Employees of the official
depository and any supervisory agency would be strictly for-
bidden to disclose to any person any information about the data
filed with the depository, until such time as disclosure is
authorized by the filing party or ordered by a court of law of
competent jurisdiction. Violators, whether government officials
or third parties, might be subject to criminal penalties (337).
This system of confidentiality would provide the regulator with
a strong defense to the common objection by manufacturers that
regulation would infringe their right to protect proprietary
information and would jeopardize trade secrets. Moreover, the
largely passive role of the official depository would impose
only a slight burden on governmental resources.

The manufacturer would be free to disclose any records of
testing which he has filed, in order to meet public criticism
of his research efforts or for any other purpose whatsoever.
The more important means of disclosure, however, would be by
court order. Such an order should be mandatory in any case
where a party is able to prove that injury has occurred to
health or the environment and is able to offer a prima facie
showing (Anscheinsbeweis) that such injury resulted from a
defective characteristic of the manufacturer's product (338).

Effects upon Liability

Under a system of strict products liability such as predominates
in the United States, the requirement of filing testing records
here proposed would have little impact upon products liability
cases. Negligence not being an issue, it would be irrelevant
whether or not product testing had been sufficient. At most,
the records might shed some light on the issue of whether a
product was defective, but their evidentiary value might be
suspect due to their being the creation of the defendant
producer.

Under the German rules of products liability for negligence,
with the possibility of very significant shifts in the Burden of
proof, the proposed filing requirement might have a greater in-
fluence. According to the rule of the Mercedes Fall, discussed
aBoye (339), the plaintiff's proof of injury, plus an Anscheins-
beweis, or prima facie showing, that such injury was caused by a
defect in the defendant's product, suffice to shift to the defendant the burden of proof on these issues of causation and defect, and on the issue of negligence as well. In seeking to prove that his conduct has not been negligent and that his products were not defective, the manufacturer will often have to demonstrate that these products have been adequately tested. Under the proposed statute, the only evidence which the manufacturer may offer on this issue is the record of testing on file with the official depository. The record must speak for itself; if it does not indicate that the manufacturer has exercised due care to protect against harm of the sort alleged, the issue of negligence will be concluded in the plaintiff's favor.

The existence of an official filing of tests conducted might on occasion work to the manufacturer's benefit. He will have at hand evidence of the care which he has exercised, filed and documented at an earlier date and which is therefore less suspect than if compiled in the heat of the current controversy. The injured party might find it very difficult, perhaps years after the date of filing, to undermine the credibility of such a record.

It is only proper that the manufacturer should stand to benefit from having conducted and placed on record testing procedures commensurate with the requirements of due care. There is a risk, however, that a manufacturer might file false records of testing which was not in fact conducted, so as to provide himself with a documented defense to later claims of liability. As noted, disproof of the validity of such records may be difficult at a later date. Therefore, it would be appropriate to provide for a severe penalty to deter fraudulent filings. Inasmuch as the principal use of such filings would be as evidence in the courts of law, the filing of records which are known or reasonably should be known to contain false information should be treated as the equivalent of perjury and punished accordingly.

Even where the record of testing indicates a lack of due care, the manufacturer still may escape liability to the injured plaintiff, if the defendant is able to sustain his burden of proving either that the product was not defective or that no defect which existed could have caused plaintiff's injury. The manufacturer, however, will still be likely to suffer certain disadvantageous consequences of his lack of due care. The record of inadequate testing having been disclosed to public scrutiny, the manufacturer will be subject to the civil fine to be imposed upon violators of the testing requirement. Moreover, other persons who might have suffered injury due to the manufacturer's negligence may be encouraged to bring further lawsuits.
Impact of the proposal

The proposed system for mandatory or voluntary filing of product testing data would likely have significant effects upon subsequent product liability litigation, as outlined above, but cannot be expected to induce any sort of revolution in manufacturers' concern for environmental and health impacts of their activity. When a new product is under development, the prospect of civil liability will generally be a contingency of secondary importance. It is to be hoped, however, that the proposed filing system would make manufacturers more conscious at an early stage in product development that they may then be in the process of creating risks of future harm to the environment and of future liability for themselves. As the filing of product testing data - adequate or inadequate, comprehensive or cursory - becomes routine, the process may focus a greater attention upon environmental impacts, an attention which would otherwise have to await the possibly catastrophic effects of a dangerous product being placed upon the market.

The idea that execution of a formal data-filing procedure will focus attention on safety issues at an early stage would seem to fit the small proprietary enterprise better than the large corporate operation. In the latter case, the division of labor may result in the responsibility to comply with a filing requirement being routinely delegated to an organizational unit having no significant impact on production decisions. A means of avoiding such a trivialization of compliance with the filing requirement would be to hold a particular member of the corporation's board of directors directly and personally responsible for the conduct of product testing, at least to the extent of personal liability, jointly with the corporate manufacturer, for the civil fine applicable in case reasonably adequate testing has not been conducted. This person might be given a designation such as Director in Charge of Environmental Compliance. The appointment of at least one such director, and the filing with the official depository of his name and his personal acceptance of responsibility, would be required of every corporation intending to place any product upon the market. This director himself would be adequately motivated to see that the official depository be informed of any transfer of his responsibility to another person. The major effect of such a requirement would be to establish a voice at the highest levels of corporate decision-making with a personal interest in carrying out a fully adequate programme of testing with respect to every new product to be marketed.

The concept of imposing special legal responsibilities upon particular corporate directors is not an altogether new one. Existing examples include the Betriebsbeauftragter, a corporate
director or officer obliged to perform mandatory supervisory functions under German safety and environmental statutes (341), for whose misconduct the corporation may in turn be held liable under the law of corporations (342). Under American law a doctrine has developed which requires that a director possessing a particular expertise, such as that of a lawyer or an accountant, apply that expertise in the conduct of his corporate duties (343).

Whether the manufacturer is an individual proprietor or a multi-national corporation, the proposed requirement of filing data on product testing will not assure that products harmful to health or to the environment will no longer be brought upon the market. With respect to products which can be expected to present environmental risks, or which belong to a class known to present such risks, a much more rigorous form of regulation is appropriate. In such cases a governmental agency with enforcement powers should be given responsibility to oversee and regulate premarket testing or to conduct such testing itself. The varied forms which such testing requirements may assume have been surveyed in this report.

The proposal offered here would not conflict with any of the existing statutory arrangements discussed above, although some statutes impose more extensive duties upon the manufacturer. The requirements of product testing and data filing would have little if any impact in relation to statutory provisions intended to control hazards already known to the authorities, such as the US Hazardous Substances Act or the Toxic Substances Control Act's restrictions on PCB production. Nor would the proposal have much effect where existing statutes require manufacturers to gain positive governmental approval by submitting the results of testing for product safety, as called for by both German and American laws relating to pesticides and food additives, as well as by section 4 of the Toxic Substances Control Act. The same is true with respect to statutes, like the US Consumer Product Safety Act, which rely upon government-initiated testing and standard-setting rather than requiring testing by the manufacturer.

The Consumer Product Safety Act, however, also provides that manufacturers must inform the regulatory agency of known defects giving rise to hazards or violations of standards. The proposal's general requirement of testing and data filing may assist knowledge of such defects and promote reporting, thus facilitating compliance with the CPSA. Where a statute, such as the Flammable Fabrics Act, calls upon manufacturers to guarantee that testing has been adequate the proposal's filing requirement would help to deter false claims. That confidential filing requirement might also help assure the public filing of complete and accurate manufacturing and processing notices, as called for by section 5 of the Toxic Substances Control Act.
Generally speaking, where an existing statute looks primarily to governmental action — whether it be prohibition, the setting of standards, or the review and approval of testing conducted by industry — there the proposal of a universal testing and filing duty borne by the producer will have slight impact. But where the initiative to investigate and acknowledge hazards remains with the industry, the proposal should help to assure good faith compliance by the manufacturer.

The proposal's unique virtue is its universality — it would apply to every new product brought upon the market. The price of this breadth of coverage is the mildness of the proposal's controls — the secrecy of testing data until controversy arises, and the absence of any regulatory authority to restrict marketing of products found to be hazardous.

The proposed requirement of data filing is not offered as a substitute for more rigorous existing regulation. Nor is it seen as an adequate solution to the lack of effective regulation of certain types of products known to pose or suspected of posing serious environmental risks, such as PCBs, asbestos, vinyl, chloride, fluorocarbons, or chemical substances in general. Rather, the proposal is offered as a means of defining a minimal level of regulation appropriate with respect to the development of products of every type and description. By making routine the deposition of testing results in the case of every manufactured product, we may hope to make more likely the recognition at an early stage of those products which may pose an unacceptable risk of harm to man and the environment.
NOTES

1. An interesting example, from a completely different sphere, of an effort to forestall anticipated hazards by means of the law is the now-discredited (though still in force) Smith Act (see especially 18 USCA §2385 (West 1969)), by which the Red Scare of late 1940s' America was translated into a means of ostracizing politically hazardous persons from public life. In the minds of the American public the threat of Communism was then as real (and at least as acutely felt) as is the threat of environmental catastrophe today. It required the brave decisions of a few independent-minded jurists to preserve traditional rights of free speech and free association from being violated in the fervent effort to save America from the hazard of Communism. The analogy may be tenuous, particularly because the "rights" threatened by environmental controls are economic rather than political ones, but its lesson is that the system of law developed to draw conclusions from historical facts comprises a rather blunt instrument for protection against the uncertain hazards of the future, an instrument to be applied with care and circumspection.

2. H. Wellford, Sowing the Wind (New York 1972), at 185. The courts of law have not been unaware of this dilemma. Thus, for example, it has been observed that the US Food, Drug and Cosmetic Act (21 USCA §301 et seq. (West 1972)) was enacted in order "to protect consumers who, in circumstances of modern industrialism, are largely beyond self protection". 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 US 593, 71 S. Ct. 515, 95 L. Ed. 566 (1951).

3. Several agencies of the US government recently have acted to control the marketing of aerosol products containing fluorocarbons. In April 1977, the US Food and Drug Administration (FDA) adopted a regulation requiring warning labels on foods, drugs, cosmetics and medical devices in fluorocarbon-propelled pressurized containers. See Notice of Rule Making, 42 Fed. Reg. 22017 (29 April 1977). The Consumer Product Safety Commission has adopted a similar labelling requirement applicable to "consumer products", as defined by the Consumer Product Safety Act (cf. text accompanying note 175 infra), which use a chlorofluorocarbon propellant. See Notice of Final Rule, 42 Fed. Reg. 42780 (24 Aug. 1977), adopting new 16 CFR part 1401. The FDA also has proposed an outright prohibition of the use of certain fluorocarbons in all such products, with a few specific...

4. Sometimes referred to hereinafter simply as Germany. A useful catalog of various types of regulation all of which encourage the control of product hazards is to be found in Carpenter, Legislative Approaches: Regulation of Chemicals, in Consumer Health and Product Hazards/Chemicals, Electronic Products, Radiation (R. Grundy & S. Epstein eds., Cambridge, Mass. 1974), at 1, 39-40.


7. For a concise statement of arguments supporting strict products liability, see Report of the Secretary-General on Liability for Damage Caused by Products Intended for or Involved in International Trade, UN Doc. A/CN.9/103 (1975), at 30-31 (hereinafter cited as UN Report on Products Liability).


9. See American Law Inst., Restatement (2d) of Torts § 402A (1965). A strong case for this development was argued by Professor William Prosser, who described the warranty of safety as "a freak hybrid born of the illicit intercourse of tort and contract". W. Prosser, The Assault upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, 1126 (1960).

11. Elmore v. American Motors Corp., 70 Cal.2d 578, 451 P.2d 84, 75 Cal. Rptr. 652 (1969). Similarly broad relief is proposed by EEC Doc. XI/332/74-E (first preliminary draft directive concerning the approximation of the laws of member States relating to products liability), Art. I: "The producer of an article manufactured by industrial methods or of an agricultural product shall be liable even without fault to any person who suffers damage as the result of defects in such article". (Emphasis added.)


13. See id. at 659-60 and articles there cited at notes 74-75. See also Draft European Convention on Products Liability, Council of Europe Doc. EXP/Resp. Prod. (75), 24 Jan. 1975, providing for strict products liability. Article 2(c) of the Draft Convention would define a defective product as one which does not provide the safety which a person is entitled to expect, having regard to all the circumstances including the presentation of the product. See UN Report on Products Liability, supra note 7, at 7.

14. See Brody v. Overlook Hospital, 121 N.J. Super. 299, 296 A.2d 688 (1972), where the court applied a theory of strict liability in the expectation that it would encourage more adequate research by manufacturers.

15. The UN Report on Products Liability, supra note 7, at 31, suggests that an injured person ought only to bear the onus of proving the existence of a defect, causation and injury, "leaving it to the producer to prove that he was not responsible for the defect". This would amount to a partial shift in the burden of proof. In German practice the burden of proof has been shifted even more radically. See text accompanying notes 30-39, infra.


19. See Borel v. Fibreboard, supra note 17.

20. The limitation of manufacturers' liability for unknown risks has been defended as a means to make possible "the sufficient user experience indispensable to research". See Byrne, supra note 18, at 673, citing Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969). This theory appears to be based on the premise that guinea pigs - even human ones unaware that they are being so used - ought not to be compensated when the experiment fails.


23. Similarly, the Common Law provides that where injury results from violation of a statute designed to protect against such injuries, the violation creates a conclusive presumption of negligence or amounts to "negligence per se". See W. Prosser, The Law of Torts, at 200-03.


25. See id. at 1433-35.

26. The distinction between the manufacturer's liability under BGB § 831 for his employee's mistakes and his liability under BGB § 823 (1) for faulty organization of his business is clarified in J. Schmidt-Salzer, Produkthaftung (Heidelberg 1972), at 185-87.
27. Adequate premarket testing to assure reasonable safety will sometimes be impossible, as in the case of pharmaceuticals tested primarily on laboratory animals. Here the producer must carefully monitor effects upon users of his product when marketed. Under such circumstances the responsibility for Produktbeobachtung merges into that for Konstruktion. See Schmidt-Salzer, supra note 24, at 1435.

28. Id. The same author has noted elsewhere that the manufacturer is not an insurer for all injuries which may arise from use of his product; it need not be "idiot-safe", but need only be free of defects relative to actually foreseeable uses. Schmidt-Salzer, supra note 26, at 181.

29. Thus the responsibility for providing adequate information to promote safe use has been described as a special case of the responsibility for adequate composition and design. Schmidt-Salzer, supra note 24, at 1434.

30. Judgement of 26 Nov. 1968, 51 BGHZ 91 (Bundesgerichtshof (BGH)), also published in 1969 Der Betriebs-Berater 12.

31. Judgement of 28 Sept. 1970 (BGH), in 1970 Der Betriebs-Berater 1414 (also known as the Bremsen Fall, or Brakes Case).


33. See Schmidt-Salzer, supra note 26, at 168, 176.

34. See id. at 188; see also F. von Westfalen, Neue Gesichtspunkte für die Produzentenhaftung, 1971 Per Betriebs-Berater 152, 153; Prag, supra note 16, at 89. For a strong argument favoring a shift in the burden of proof in environmental cases under American law, see J. Krier, Environmental Litigation and the Burden of Proof, in Law and the Environment (M. Baldwin & J. Page eds. New York 1970), at 105. Krier contends that the normally plaintiff role of the environmental advocate results in an unjustifiable bias in the burden of proof against environmental interests. See id. at 107, 117.

35. The Hühnerpest Fall left this question undecided. See Schmidt-Salzer, supra note 26, at 171-72.

37. *Id.* 1973 NJW at 1603.


43. EPA Order of 14 June 1972 cancelling registration of DDT as an economic poison, under authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC §135b(c) 1970); EPA Regulations on Fuels and Fuel additives, 40 CFR 80, as amended to 29 Aug. 1975, under authority of the Clean Air Act, 43 USCA §1857f-60(c) (1) (West Supp., 1977). Efforts to limit the lead content of automotive fuel, despite the uncertain extent of the risks involved, were upheld in Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 8 Environmental Rptr. Cases (ERC) 1785 (D.C. Cir. 1976) (en bane). This case is discussed more fully at text accompanying notes 238-40 infra.

44. In some instances no level of exposure may be deemed safe; here a zero tolerance is appropriate.

45. See, e.g., The German Act Concerning the Trade in Objects Containing Lead and Zinc, *supra* note 40, §§ 1-3; see also the US Federal Hazardous Substances Act, 15 USCA §1261 et seq. (West, 1974), which in 1261 (g) (1) defines "banned hazardous substance" to include "any toy or other article intended for use by children, which ... bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted". The Hazardous Substances Act is discussed further in text accompanying notes 153-71 infra.

109. PCB contamination of cooking oil and chicken feed in Japan has been blamed for outbreaks of Yusho, a severe skin disease, and for the death in one incident of 400,000 chickens. Id. at 111. The United States Food and Drug Administration has set an informal standard for levels of PCBs in poultry which in several incidents of contamination has led producers more or less voluntarily to slaughter large numbers of birds. Id. at 111-12. See also J. Arbuckle, et al., Environmental Law Handbook (Washington, D.C. 1975), at 204; Interdepartmental Task Force on PCBs, Polychlorinated Biphenyls and the Environment (Washington D.C. 1972). PCBs well illustrate the insidious character of some environmental contaminants. Thus in 1971 high incidence of PCBs in food wrapping paper in the US was attributed to the recycling of photocopying paper - impregnated with PCBs - for the production of wood pulp.

47. See the thorough outline of uses, emission problems and alternative products in OECD Environment Directorate, Polychlorinated Biphenyls: Their Use and Control (Paris 1973), at 25-36.

48. See id. at 25-27.

49. See id. at 41-42; Grundy, supra note 46, at 112-13; see also the parallel recommendation by Der Rat von Sachverständigen für Umweltfragen, in Umweltgutachten 1974 (Stuttgart 1974), at 116.

50. Measurements of PCBs in mothers' milk in Japan have declined since 1972, but 1974 measurements still showed 25 per cent of samples contaminated in excess of tolerance levels. See PCB Pollution of Mothers' Milk, 5 Pollution (no. 12) (Alton-Hampshire, England 1975), at 11. Recent testimony by an Environmental Protection Agency consultant to a US Senate subcommittee, however, indicates that PCB contamination in fish in various parts of the United States has worsened since 1972. This may be a result of the alleged continued importation and open system use of PCBs. See 6 Env. Rptr. - Curr. Dev. 1235 (Washington, D.C. 1975); cf. 4 Ground Water Newsletter (no. 22) (Port Washington, N.Y. 1975), at 3; N. Buder & L. Billings, Tox-ic!: Legislation to Control Toxic Substances, 9 Sierra Club Bull. (no. 9) (San Francisco 1975), at 25, 28; Note, Federal Toxic Controls: The Patchwork Attack on PCBs, 6 Env. L. Rptr. 10056 (Washington, D.C. 1976).
51. Pub. L. No. 94-469, § 6 (e) (2), (3), 90 Stat. 2003, 2025 (11 Oct. 1976). The term "totally enclosed manner" is defined as "any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant..." Id. §6(e) (2) (C). The US Toxic Substances Control Act, a major step toward the prevention and control of hazardous products, is discussed in detail at text accompanying notes 255-328 infra.


57. FIFRA, §135a (a); see also Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, 40 Code of Federal Regulations (CFR)$162.1 et seq. (1976).

58. Formerly the Secretary of Agriculture; since 1970 the Administrator of the Environmental Protection Agency EPA).

59. FIFRA, §135b (b), (c).

60. 477 F.2d 1317, 5 ERC 1254 (8th Cir. 1973).

61. FIFRA, §135b(c).

62. Wellford v. Ruckelshaus, 439 F.2d 598, 2 ERC 1123 (D.C. Cir. 1971). It was decided, however, that a hazard might be "imminent" even if its impact, as with many carcinogens, would not be apparent for many years. Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 2 ERC 1114, 1121 (D.C. Cir. 1971).

64. When preliminary investigations concluded that there was substantial question about the safety of any registered product, the agency was obliged to initiate the cancellation or suspension process. Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584, 2 ERC 1114, 1119 (D.C. Cir. 1971).

65. FIFRA, §135b(c).


67. FEPCA, § 136a(a).

68. Id. § 136a(c) (1), (2).

69. Id. § 136a(c) (5). The phrase "unreasonable adverse effects on the environment" is explicitly defined to take into account the economic, social and environmental costs and benefits of the product's use. Id.§ 136(bb). The EPA and the courts have interpreted this standard as imposing upon the producer the burden of proving his product safe. See Environmental Defense Fund v. Environmental Protection Agency, 510 F.2d 1292 (D.C. Cir. 1976).


71. §136c. EPA may require that studies be conducted of adverse environmental effects of pesticides approved for experimental use. Id.§136c (d), see also Regulations governing the grant of experimental use permits, 40 CFR §172.1 et seq. (1976).

72. Id. §136d(b), (c), (d).

73. Id. §136(1).

74. 548F.2d 998, 9 ERC 1433 (D.C. Cir. 1976).

75. Id. at 1104-10, 9 ERC at 1436-41. Upon rehearing the court affirmed its decision, and made the more general finding "that in a suspension hearing conducted under FIFRA § 6(c)(2) the burden of persuasion rests ultimately on the registrant". F.2d ________, ________, 9 ERC
EPA finally cancelled the registration of heptachlor and chlordane, and prohibited the sale, distribution or use of these substances, by a notice published at 42 Fed. Reg. 45944 (13 Sept. 1977). See also the earlier, but similar, decision sustaining EPA suspension of the pesticides aldrin and dieldrin, Environmental Defense Fund v. Environmental Protection Agency, 510 F.2d 1292, 7 ERC 1689 (D.C. Cir. 1975).

76. FEPCA, §136e.
77. Id. §136r.
79. Plant Protection Act, §1(1). The definition of "plant protection product" (Pflanzenschutzmittel) is considerably narrower than that of pesticide or "economic poison" under the US statute.
80. Id. §7 (1).
81. Id. §7(3).
82. Ordinance of 4 March 1969 (BGB1. I, at 183).
83. Id. §1(2).
84. Id. §4(1).
85. See text accompanying note 69 supra.
86. Plant Protection Act, §8(1).
87. Id. §8 (2), (3).
88. Id. §8(4).
89. See text accompanying note 68 supra.
90. Plant Protection Act, § 14. The Lander are the eleven States which comprise the Federal Republic of Germany.
91. Id. §6.

94. See text accompanying note 71 supra.

95. It may be argued, however, that roughly equivalent private expenditures for researching potential product hazards would be undertaken by responsible producers even without such legislation, so that the economic burden of compliance should not be given great weight. On this question see text accompanying note 268 infra.


97. Id. § 8 (foodstuffs), § 24 (cosmetics), § 30 (consumer goods). Consumer goods are defined in § 5(1) to include articles, such as packaging materials or tableware, which are intended to come into contact with foodstuffs, cosmetics or tobacco products; articles which are intended to come into prolonged contact with the body, such as toothbrushes or clothing; cleaning products for household use; toys; etc. Tobacco products, since they constitute a known hazard, are subjected to explicit premarket controls over their contents. Id. § 20.

98. Id. §§ 9(1), 32(1); see W. Zipfel, Das Neue Lebensmittel und Bedarfsgegenstände-Gesetz, 28 Neue Juristische Wochen-schrift (no. 13) 553, 555 (1975).

99. Foodstuffs Act, supra note 96, § 9(1).

100. Id. § 32(1).

101. Id. § 9(2); see Zipfel, supra note 98, at 555.

102. Foodstuffs Act, §§ 9(2), 32(2).

103. Id. § 51(1), (3), (4).

104. Id. § 53; see Zipfel, supra note 98, at 557.

105. Foodstuffs Act, §§ 40(1); 41(1), (2); 42. In the document proposing the 1974 reform of the Act, it was noted: "The sought for intensification of foodstuffs surveillance can succeed, especially in view of the rapid progress of food technology and the related need for greater sensitivity in surveillance procedures, only if surveillance duties are in future carried out solely by professionally trained personnel". Bundestag Drucksache 7/255, at 39 (1973).
106. Foodstuffs Act, §35.

107. Id. § 44.


109. Foodstuffs Act, § 11(1). "Food additive" is defined in §2 of the Act.

110. Id. § 12(1),


112. 21 USCA § 301 et seq. (West, 1972). As its title indicates this Act also governs the production of drugs and medicines, a subject regulated in Germany by the Pharmaceuticals Act (Arzneimittelgesetz) of 16 May 1961 (BGBl. I, at 533), as last amended by Act of 15 Aug. 1974 (BGBl. I, at 1945). As might be expected, this is a subject of strict governmental regulation. The German Act functions primarily through a system of licensing producers and distributors and requiring that the composition and quality of products conform to precise specifications set by regulation. Id.§§ 5, 12. For our purposes, the most interesting provision of this Act is section 27, which empowers the Federal Minister of Health, in co-operation with several other ministers, to order that certain batches of Pharmaceuticals, which could be especially hazardous due to unavoidable inconsistency of composition or variations in content of active ingredients, may be brought into commerce only after governmental testing (Prüfung) and approval. Under the US Food, Drug and Cosmetic Act no new drugs may be marketed without prior governmental approval. The basic system of regulation is similar to that described below with respect to food additives. See text at notes 125-133 infra; see also Federal Food, Drug and Cosmetic Act, 113. 15 USCA §1191 et seq. (West, 1974).

114. 15 USCA §1261 et seq. (West, 1974).

115. 15 USCA §2051 et seq. (West, 1974).
116. Food products also were the first products to the sale of which an implied warranty of safety was attached. See text accompanying note 8 supra and W. Prosser The Law of Torts (4th ed., St. Paul 1971), at 653-54.

117. 21 USCA §301 et seq. (West, 1972).

118. Id. § 331.

119. Id. § 332.

120. Id. § 333(a), (b).

121. Id. § 334.

122. Id. § 342(a) (1).

123. Id. § 342(a) (6).

124. Id. § 346. See also §346a, providing for the setting of tolerances by the EPA Administrator with respect to unsafe pesticide chemicals to permit their presence in or on agricultural commodities. Such tolerances may be set upon EPA initiative, the request of "any interested person", or petition by registrants under FIFRA (see text at notes 57-65, supra). The burden of persuasion in such cases rests upon those seeking to permit chemical residues to remain. See Environmental Defense Fund, Inc. v. US Dept. of Health, Educ. & Welfare, 428 F.2d 1083 (D.C. Cir. 1970).


126. Id. § 348(a).

127. Id. § 348(i).


129. Federal Food, Drug and Cosmetic Act, § 348 (b) (1), (2).

130. Id. § 348(c) (1).

131. Id. § 348 (c) (3) (A). In making this determination, factors to be considered include the probable consumption of the additive or its byproducts, the cumulative effect of such additive in the diet, and safety factors (margins of error) generally recognized as appropriate in animal experimentation.
132. Id. §348(c)(4).

133. Id. §348(e), (f), (g).

134. Id. §348(c)(3)(A); see also the similar provision respecting color additives, §376(b)(5)(B).


136. See Blank, supra note 135, at 1084; but see Wellford, supra note 2, at 161-63.

137. At the time of publication, it appeared likely that the US Congress would adopt legislation specifically exempting saccharine from the scope of the Delaney Clause, at least for an interim period.

138. C. Edwards, then Commissioner of the US Food and Drug Administration, December 1972, quoted in Epstein, Public Health Hazards, supra note 135, at 81.

139. See Blank, supra note 135, at 1096-99.

140. Id. at 1106, 1108-11. See also Environmental Law Handbook, supra note 46, at 198-99.

141. See Epstein, Public Health Hazards, supra note 135, at 81; Wellford, supra note 2, at 179-81, 207-08.
142. The great difficulty and expense of adequate testing for
carcinogenicity is discussed in Epstein, The Delaney
Amendment, supra note 135, at 425-26. For a good outline
of the complicated issues of public health regulation in
the face of inadequate scientific data, see M. Karstadt,
Protecting Public Health from Hazardous Substances:
Federal Regulation of Environmental Contaminants, 5
Env. L. Rptr. 50165 (1975).


144. Id.§372(a); concerning inspection procedures; see also
§374.

145. Id. § 375(b).

146. See Morey, FDA Publicity Against Consumer Products -
Time for Statutory Revitalization?, 30 Business Lawyer
165 (1974), for a critical view of agency implementation
of this provision.

147. Government generally would be free to make public such
information even without explicit statutory authority.
See Hoxsey Cancer Clinic v. Folsom, 155 F. Supp. 376
(D.D.C. 1957). Still; making such authority explicit
confirms the agency's responsibility to protect the
public.

148. 15 USCA §1191 et seq. (West, 1974).

149. Id.$ 1192.

150. Further procedures are set forth by regulation, published
under the Act has been taken over from the FTC by the
Consumer Product Safety Commission. 16 CFR §1607.3.

151. 15 USCA §1196.

152. Id.$ 1197. Appropriate procedures for testing fabrics
are established by the Standards for the Flammability
of Clothing Textiles and Vinyl Plastic Film, at 16 CFR
part 1610 (1976) and 16 CFR part 1611 (1976), respect-
ively. Each of these standards includes a set of
"reasonable and representative tests" adequate to
guarantee a dealer's immunity from prosecution. See 16
CFR §§1b10.37, 1616.37.

153. 15 USCA §1261 et seq. (West, 1974).
154. Id. § 1261(f), (p), (q).

155. Id. § 1263(a), (c).

156. Id. § 1261(f).


158. Federal Hazardous Substances Act, § 1261(q) (1) (A).

159. Id. § 1261 (q) (1) (B). The power to issue regulations is delineated in section 1262. The reference to interstate commerce is in recognition of the need to establish Federal jurisdiction.

160. 21 USCA §371 (e), (f), (g); see text accompanying note 143 supra.

161. Federal Hazardous Substances Act, § 1261 (g) (2). Such a finding was recently made with respect to the chemical substance TRIS (2,3 dibromopropyl) phosphate, which has commonly been used as a flame-retardant in children's clothing, but now is suspected of being a carcinogen. See Notice of Rule, 42 Fed. Reg. 18850 (8 April 1977), designating TRIS as a "banned hazardous substance". Id. at 18853. A court subsequently stayed this summary determination, ruling it violative of the due process rights of the manufacturers. Interestingly, concern over TRIS was initiated by tests conducted not by manufacturers, or even by government, but rather by the Environmental Defense Fund, a private organization which filed a complaint with the Consumer Product Safety Commission in March 1976, and which also has actively promoted enforcement of federal pesticide laws. See notes 74–75, and accompanying text supra.

162. Federal Hazardous Substances Act, § 1264 (a).

163. Id. § 1265.

164. Id. § 1267.

165. Id. § 1274.


167. Id. § 1500.18.
168. Id. § 1500.40-.46.
169. Id. § 1505.1 et seq.
170. Id. § 1512.1 et seq.
171. Id. §§ 1505.2, 1505.6; §§ 1512.3-.18.
175. See text accompanying notes 96-111 supra.
177. Id. § 2054 (b).
178. Id. § 2062 (a). "New consumer product" is defined to mean a product incorporating "a design, material or form of energy exchange" not previously used substantially in consumer goods and as to which safety information is lacking. Id. § 2062 (b).
179. Id. § 2061(a), (b). See also BNA study, supra note 174, at 69-70.
180. Consumer Product Safety Act, § 2056 (a); see also § 2058(c) (2) (A).
181. Id. § 2056 (b). Procedures for developing and submitting proposed standards are specified in the regulations, 16 CFR §1105.2 to -.8 (1977). Section 1105.9 permits the Commission to contribute toward the cost of developing such standards.
182. Consumer Products Safety Act,$ 2056 (c), (d) (1).
183. Id. § 2056 (d) (3).
184. Id. § 2056 (e) (1), (2).
185. Id. §§ 2056 (f), 2057; see also § 2058 (c) (2) (C). See also the recently adopted 16 CFR part 1303, intended to
reduce the risk of lead poisoning among children. This regulation designates as a banned hazardous substance any paint containing more than a certain percentage of lead or any article intended for use by children, or household furniture, to which such paint has been applied. See Notice of Final Rule, 42 Fed. Reg. 44193 (1 Sept. 1977). Such a finding has recently been made with respect to certain products containing respirable asbestos, based upon a lengthy catalog of diseases induced by asbestos. See Proposal to Ban Certain Patching Compounds and Artificial Emberizing Materials, 42 Fed. Reg. 38763 (29 July 1977).

186. Consumer Products Safety Act, § 2058 (a), (b), (c). The system for developing product safety rules is summarized more completely in BNA study, supra note 174, at 53.57.

187. Consumer Products Safety Act, § 2058(d)(2). Safety standards cannot be given retroactive effect, but this may be possible with respect to declaring a product to be a banned hazardous product. See § 2058(d) (1); BNA study, supra note 174, at 58.

188. Consumer Products Safety Act, § 2063 (a) (1), (3). One certificate may apply to an entire batch of products. See BNA study, supra note 174 at 60.

189. Consumer Products Safety Act, § 2064 (b). "Substantial product hazard" is defined in § 2064 (a) to include failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public. The precise notification required is detailed in regulations concerning substantial product hazard notifications, 16 CFR § 1115.1 et seq. (1977).

190. Consumer Products Safety Act, § 2064 (c), (d).

191. Id. §§ 2068-70.

192. Id. § 2071.

193. Id. §§ 2059-60. Suit may be brought by "any person adversely affected...or any consumer or consumer organization". Id. § 2060(a). The importance of public participation in carrying out the purposes of the Act is recognized in the implementing regulations. See 16 CFR §§ 1105.1(a), (d), (f) 1977.

195. **Id. § 2074.** See also J. Brodsky & M. Cohen, "Uncle Sam", the Product Safety Man: Consumer Product Safety Standards in the Marketplace and in the Courts, 2 Hofstra L. Rev. 619, 640-49 (1974), in which the authors argue that even unknowing failure to comply with the Act should be considered negligence per se in related tort cases, but that compliance with the Act should nonetheless not be sufficient to prove due care.

196. 29 USCA §651 et seq. (West, 1975).


202. OSHA, §654 (a) CD (emphasis added).

203. Id. § 654 (a) (2), (b). Violations may result in citations, and are punishable by fines of up to $1000 or, in the case of willful or repeated violations, of as much as $20,000 and one year's imprisonment. Id. §§ 658, 666.

204. Id. §§ 669, 671.

205. Id. § 655; see also rules of procedure for promulgating, modifying or revoking occupational safety or health standards, 29 CFR § 1911.1 et seq. (1976).

206. OSHA, § 655(c). An emergency temporary standard was recently placed in effect respecting benzene, a petroleum byproduct now established to be a cause of leukemia. The emergency standard sets employee exposure limits at one part per million (ppm) as an eight hour average and 5 ppm for a 15 minute exposure, as well as calling for monitoring, record keeping and use of protective...


208. Id. §1910.1000 et seq.

209. Id. §1910.1001.

210. Id. §1910.1017.

211. In the case of Society of the Plastics Industry, Inc. v. Occupational Safety and Health Adm'n, 509 F.2d 1301 (2d Cir.), cert. denied, 421 U.S. 992, 95 S. Ct. 1998, 44 L. Ed.2d 482 (1975), a Federal appeals court upheld the standard for vinyl chloride despite uncertainty as to whether it was technically attainable and although the very existence of a danger was an issue "on the frontiers of scientific knowledge" Id. at 1308. See also Industrial Union Dep't, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974), in which a similar situation was found to exist with respect to the danger associated with asbestos dust. Id., at 474. Cf. Note at 5 Env. L. Rptr. 10042 (1975).

212. OSHA, §651 (b) (1).

213. Id. § 657(c)(1), (3); see also regulations concerning recording and reporting occupational injuries and illnesses, 29 CFR §1904.1 et seq. (1976).

214. See note 197 supra.

215. Trade Regulations for the German State, §§24(1), 24a.

216. Id. §24(1), (3). Inspections are conducted by official or officially recognized experts organized into technical supervisory organizations. Id. § 24c.

217. Id. §24(4).

218. Id. §120a(1).

219. Id. §120a(2).

220. Id. §120e.

221. See note 198 supra.

222. Decree Concerning Dangerous Working Substances. §1.
223. Id. §§ 2, 3.

224. Id. §§ 4-10, 14.


227. Id. § 1857c-3. This authority is not discretionary; rather the EPA is obliged to establish air quality criteria for any pollutant the presence of which is determined to affect adversely the public health or welfare. Natural Resources Defense Council v. Train, 545 F.2d 320, 9 ERC 1425 (2d Cir. 1976).

228. Clean Air Act, § 1857c-4.

229. Id. §§1857c-6, 1857f-1.

230. Id. §1857c-7.

231. 40 CFR §61.01 et seq. (1976). The asbestos standard was challenged in court on the basis that an emission standard must be confined to a quantitative limitation of emissions and that the specification of a "work procedure" was beyond EPA's authority under the Clean Air Act. The court upheld the EPA standard, noting that existence of a safe dose level of asbestos was uncertain and that a standard work procedure was "perhaps the only practical means of combatting a recognized health hazard". US v. Big Chief, ____ F. Supp. ______, 7 ERC 1840, 1843 (E.D. La. 1975).


234. Clean Air Act, § 1857f-6c (b) (1); see also regulations for registration of fuel additives, 40 CFR §79.1, et seq. (1976).

235. Clean Air Act, § 1857f-6c (b) (2).

236. Id. §1857f-6c(c) (1).

237. Id. §1857f-6c(d).
238. 541 F.2d 1, 8 ERC 1785 (D.C. Cir.), ten bane), cert. denied U.S. 96 S. Ct. 2662, 49 L. Ed. 2d 394 (1976); see Comment, Precautionary Controls: D.C. Circuit Upholds EPA's Phase-Down of Gasoline Lead Additives in the Interest of Public Health, 6 Env. L. Rptr. 10100 (1976).

239. Id. at 28, 8 ERC at 1804. The court later expressed its conclusion more simply: "A supportable and reasonable hypothesis may well form the basis for regulations under Section (1857f-6c(c)(1)(A))". Id. at 44, 8 ERC at 1817. Judge Wilkey, dissenting, warned that the court's opinion would "grant the plainest license for the wildest speculation". He argued that "(it) is precisely a devotion to facts, not hunches, that distinguishes the professionals from the amateurs in assessing risks". 591 F.2d at 96, 8 ERC at 1858 (emphasis in original).


241. A prime example of judicial hesitation to adjudicate important economic interests on the basis of hypothetical risks, as distinguished from ascertainable facts, is the protracted litigation in the case of United States v. Reserve Mining Co., an action brought by federal, state and local authorities to curtail the disposal of massive quantities of taconite fiber (similar to asbestos) in Lake Superior. A federal district court found that the defendant's operations were a public nuisance and violated federal and state pollution control laws. 380 F. Supp. 11, 54-56, 6 ERC 1449, 1657, 1682-83 (D. Minn. 1974). Even though convincing proof of a definite hazard was lacking, the judge found the risk that such a hazard existed so serious as to warrant shifting the burden of proof to the defendant on this issue. In the absence of proof that no imminent hazard to health existed, the court enjoined further disposal operations immediately. Id. at 69-71, 6 ERC at 1692-94. The appellate court, however, refused to accept the lower court's reasoning in justification of a shift of the burden of proof, and consequently stayed the injunction. 498 F.2d 1073, 1084-H5 6 ERC 1609, 1617 (8th Cir. 1974). The US Supreme Court refused to over-turn the appellate court's decision. 420 US 1000, 7 ERC 1113 (1975). The district court's ruling on the substantive merits of the case, however, was sustained by the higher court. 514 F.2d 492, 7 ERC 1618, as modified.
by 7 ERC 1782 (8th Cir. 1975). Thereafter, Reserve Mining was ordered to abate its disposal operations as of July 1977, but has since been granted an extension until the year 1980. 417 F. Supp. 789, 9 ERC 1001 (D. Minn. 1976); 479 F. Supp. 1013, 10 ERC 1113 (D. Minn. 1977). In the meantime, the company has been required to pay the cost of water filtration systems for the City of Duluth and other communities faced with a potential health risk. 408 F. Supp. 1212, 8 ERC 1689, 1978 (D. Minn. 1976).


243. Federal Immission Control Act, § 3(1). The expression for "dangers" (Gefahren) connotes a state of facts which recognizably offers an objective possibility of injury. See Commentary to the Immission Control Act, §3, para. 4.

244. Federal Immission Control Act, § 3(2). Air pollution is defined as a change in the natural composition of the air. Id. §3(4).

245. Id. §32(1).

246. Id. §32(2).

247. See text accompanying note 186.


249. Federal Immission Control Act, § 35(1). As first proposed, this section would have applied only to plastic packages and containers, but was expanded to cover the broader range of synthetic and natural products posing the specified danger. See Commentary to the Immission Control Act, §35, paras. 1, 2.

250. Federal Immission Control Act, § 35(3).

251. Id. §35(2).

252. See text accompanying note 5 et seq., supra.

253. See text accompanying notes 9-21 supra.

254. See text accompanying notes 30-39 supra.


260. Id.


262. Snell study, supra note 261, at 3-4, 57, 123. The cost of "a reliable test for carcinogenicity" has been estimated at $200,000 to $400,000 per chemical. E. Blair & F. Hoerger, Toxic Substances Legislation - Regulators v. Science, 2 Environmental Policy and Law 84, 138 (Bonn, 1976).

263. Snell study, supra note 261, at 4, 12, 94.

264. See Blair & Hoerger, supra note 262, at 87.
265. See N. Ashford & G. Heaton, Environmental & Safety Regulations: Reasons for their Adoption and Possible Effects on Technological Innovation, 1 Environmental Policy & Law 172, 175-76 (Bonn 1976).


268. See Blodgett, supra note 257, at 508; see also Baise letter, supra note 252.


271. Id. at 15. An alternative scheme of regulation, implicitly criticized as over-rigid in the report, is presented as an appendix. The heart of this scheme would be a system of six “marketing categories”, ranging from a minimal requirement that a producer notify the regulator of his intent to market a new product, through registration, certification, premarket clearance, and marketing restrictions, to an extreme of banning distribution of the product. See Working Paper on Market and Private Sector Decision Making, App. J, in id. at 220-28.

272. See Note, 6 Env. Rptr. - Curr. Dev. 1234 (Washington, D.C. 1975); see also Blodgett, supra note 247, at 508.


278. In general, the Act applies the same requirements to chemical "mixtures" as to "substances", and references to the latter in this discussion will include the former unless otherwise indicated. The Act's controls apply to imported chemicals but not to those intended for export, except that provision is made for notice in certain circumstances to the government of a country to which export is intended. See Toxic Substances Control Act, §§ 12, 13.

279. Id. § 4(a). Subsequent references to the "Administrator" are to the Administrator of the Environmental Protection Agency. References to "manufacturers" may include processors and distributors as well, unless indicated otherwise.

280. The total number of substances included on the "priority list" may at no time exceed fifty. Id. § 4 (e).

281. Id. § 4(b) (1).

282. Id. § 4(b) (3), (c) (2).

283. Id. § 4(c)(3), (4); see also § 5 (h).

284. Id. § 4(d). Both a system for sharing the costs of testing and a practice of thorough public disclosure were among the recommendations of the National Academy of Sciences report, supra note 269, at 4, 28, 53.

285. This obligation will not take effect until two years after the Act's effective date. Toxic Substances Control Act, §4(f). This clause is much less strict than the comparable provision of the Food, Drug, and Cosmetic Act, the Delaney Clause, which absolutely prohibits the use of food additives known to induce cancer in man or animals, without regard to the probability of the risk. See discussion of the Delaney Clause at text accompanying notes 134-42 supra.
286. Toxic Substances Control Act, § 5(a) (1). A similar notification requirement applies to the manufacture or processing of a substance for a "significant new use", as determined by the Administrator upon consideration of the anticipated volume of production, human and environmental exposure, and other factors. Id. § 5(a) (2).

287. Id. § 5(d) (1).

288. Id. § 5(b) (1), (2).

289. Id. § 5(d) (2).

290. Id. § 5(c).

291. Id. § 5(e) (1) (A), (B). This provision represents a compromise between the Senate proposal, which would have given force to the Administrator's order directly, and the House version, which would have required that he seek a court injunction from the start. See 7 Env. Rptr. - Curr. Dev. 739 (Washington, D.C. 1976).

292. Toxic Substances Control Act, § 5 (f). See also § 6(d) (2).

293. Id. § 5(e) (1) (C), (2).

294. Id. § 5(g).

295. Id. § 6(a).

296. Id.

297. Id. § 6(c) (1).

298. Id. § 6(c) (2), (3). The government may compensate for costs and attorneys fees incurred by persons participating in such proceedings. Id § 6(c) (4); see also note 317 and accompanying text, infra. Procedures for rulemaking under section 6 have been proposed at Notice of Proposed Rules, 42 Fed. Reg. 20640 (21 April 1977).

299. Toxic Substances Control Act, § 6(d) (2) (A) (ii).

300. Id. § 6(d) (2) (A) (i).

301. Id. § 7(f)

302. Id. § 7(a) (1)
303. Id. § 7(b) (1), (2).

304. Id. § 7(a) (1).

305. See text accompanying note 291 supra.

306. Toxic Substances Control Act, § 8 (a) (1), (d). Other specific information as to which reporting may be required is listed in § 8 (a) (2). Small producers (a category still to be defined by the EPA) are exempt from these reporting duties except as specifically required by the Administrator. Id. § 8(a)(3).

307. Id. §8(b). In March 1977 the EPA published proposed rules to govern inventory reporting by manufacturers to assist compiling the initial inventory of chemical substances required by section 8 (b). Substances not reported will become subject to the premarket notification requirements of section 5(a)(1). See Notice of Proposed Rules, 42 Fed. Reg. 13130 (9 March 1977); cf. Supplementary Notice, 42 Fed. Reg. 19298 (12 April 1977). A further revision of the proposed inventory reporting rules calls not only for the identification of chemical substances being manufactured, but also for a specification of the location and quantity of manufacture. The EPA has recognized that this expansion of the producer's reporting duty will require a delay in the initial inventory reporting. See Supplemental Notice of Proposed Rules, 42 Fed. Reg. 39182 (2 Aug. 1977).

308. Toxic Substances Control Act, § 8 (c). Except where employees are affected, such records need be retained for only five years. This may prove unfortunate in view of the insidious nature of some chemical hazards.

309. Id. § 8 (e); see also Notice of Proposed Guidance, 42 Fed. Reg. 45362 (9 September 1977). The original Senate bill would have imposed the same duty upon the manufacturer's liability insurer.

310. Toxic Substances Control Act, § 10 (a), (b); see also §25.

311. Id. §11 (a), (b).

312. Id. § 14 (a) (3). If the manufacturer has previously designated the data to be disclosed under this authority as "confidential" the EPA must notify the manufacturer at least 15 days prior to releasing the data, except that only 24 hours notice is required if release is
necessary to protect against an imminent hazard. Id. §14(c)(1), (2)(B)(i).

313. Id. §16(a)(1), (2). Appeal of a civil penalty is permitted in Federal court if filed within 30 days and if administrative remedies were exhausted. Id. §16(a)(3).

314. Id. §16(b).

315. Id. §17(a), (b).

316. Id. §20(a), (b).

317. Id. §20(c)(2). An author of the Act has described the attorneys fees provisions as "very important to the proper vindication of rights under this legislation". Remarks of Senator John V. Tunney, 122 Cong. Rec. S4416 (daily ed. 26 March 1976).

318. Toxic Substances Control Act, §21(a), (b).

319. See text accompanying note 69 supra. The National Academy of Sciences report favored such a shift with respect to new uses of chemical substances, but would shift the burden to the producer of an existing product only where the government has made a reasonable case showing excessive risk. National Academy of Sciences report, supra note 269, at 3, 17-18.

320. See Blair & Hoerger, supra note 262, at 84, 138.

321. See text accompanying note 297 supra.

322. See S. Rep. No. 94-698, at 12, 1976 US Code Cong. & Admin. News 4926. See also Toxic Substances Control Act §24, requiring that the EPA "evaluate on a continuing basis the potential effects on employment" of the issuance of rules or orders under the Act.

323. Toxic Substances Control Act, §2(c). See also §2(b)(3), which declares a policy that authority over chemical substances should be so exercised as not to create unnecessary economic barriers to technological innovation.

324. Id. §9(a)(1), (2).

325. See text accompanying notes 259-268 supra.

326. See text accompanying note 280 supra.

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327. See text accompanying note 309 supra.
328. See text accompanying notes 262 and 266-269 supra.
329. See Materialien zum Umweltprogramm der Bundesregierung, supra note 269, at 81.
330. See id. at 84.
331. See text accompanying notes 80, 106 and 109 supra.
332. See text preceding note 5 supra.
333. See note 278 supra.
334. See the discussion of Konstruktionsfehler and Herstellungsfehler at text accompanying note 27 supra.
335. See BGB § 823 (2) and text accompanying note 23 supra.
336. See text accompanying note 25 supra.
337. Official revelation of trade secrets reported in accordance with the German Plant Protection Act is subject to criminal penalties. See Plant Protection Act, supra note 78, §24.
338. The report of a defect should be judged according to the "unreasonably dangerous as marketed" standard, discussed in relation to US law at text accompanying note 21 supra.
339. See text accompanying note 34 supra.
340. It might also be appropriate for the Director in Charge of Environmental Compliance to be held legally responsible for the corporation's compliance with all legal requirements relating to the compatibility of its products with health and environmental needs. Such personal liability would help to counteract the capacity of corporate enterprises to resist compliance with environmental controls, while yet avoiding the economically burdensome shutdown of operations which may be the only effective alternative enforcement otherwise available.
342. BGB §§30, 31.