Appendixes

Appendix A
Statutory Authority for Regulating Carcinogens

Introduction

By one accounting, 21 different laws may be used to regulate carcinogens (table A-l). However, this appendix describes only the major statutes providing for regulation of human exposure to carcinogens, and the significant judicial decisions affecting this regulation.

Most of the statutes do not single out carcinogens for specific consideration, but merely regulate them as a species of toxic substances. A few, however, have provisions aimed directly at carcinogens; one, the Food, Drug, and Cosmetic Act (FDCA), has special statutory provisions for regulating carcinogens as distinguished from other toxic substances, while several others—the Clean Water Act (CWA), the Toxic Substances Control Act (TSCA), and the Resource Conservation and Recovery Act (RCRA)—mention carcinogens specifically.

Some statutes require premarket review or approval of a substance before it can enter into commerce. This requirement is set in parts of FDCA and TSCA, and in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Even for these three laws, however, the requirement for premarket review applies only to new pesticides or "new" chemicals being proposed for manufacture, although FDCA requires premarket approval of new uses for existing chemicals.

A much larger number of statutes, including parts of FIFRA and TSCA and the other statutes described in this chapter, provide for postmarked regulation of substances-after they have been in commerce and people have been exposed to them. Such laws might require an agency to find that there is a health problem and then propose a regulation based on that-finding,

Table A-1.—Statutes Authorizing Regulation of Carcinogens

Legislation	Agency	Area of concern
● Food, Drug, and Cosmetic Act (1906, 1938, amended 1958, 1960, 1962, 1968)	FDA	Foods, drugs, cosmetics, and medical devices
● Federal Insecticide, Fungicide and Rodenticide Act (1948, amended 1972, 1975, 1978)	EPA	Pesticides
Dangerous Cargo Act (1952)	DOT, USCG	Water shipment of toxic materials
Atomic Energy Act (1952)	NRC	Radioactive substances
● Federal Hazardous Substances Act (1960, amended 1961)	CPSC	Toxic household products
Federal Meat Inspection Act (1967)	USDA	Food, feed, color additives, pesticide residues
Poultry Products Inspection Act (1970)		
Egg Products Inspection Act		
● Occupational Safety and Health Act (1970)	OSHA	Workplace toxic chemicals
Poison Prevention Packaging Act (1970, amended 1977)	CPSC	Packaging of hazardous household products
● Clean Air Act (1970, amended 1974, 1977)	EPA	Air pollutants
Hazardous Materials, Transportation Act (1972)	DOT	Transport of hazardous materials
● Clean Water Act (formerly Federal Water Control Act) (1972, amended 1977, 1978)	EPA	Water pollutants
Marine Protection, Research and Sanctuaries Act (1972)	EPA	Ocean dumping
● Consumer Product Safety Act (1972, amended 1981)	CPSC	Hazardous consumer products
Lead-based Paint Poison Prevention Act (1973, amended 1976	CPSC, HHS, HUD	Use of lead paint in federal assisted housing
● Safe Drinking Water Act (1976)	EPA	Drinking water contaminants
● Resource Conservation and Recovery Act (1976)	EPA	Solid waste
● Toxic Substances Control Act (1976)	EPA	Hazardous chemicals not covered by other acts
● Federal Mine Safety and Health Act (1977)	DOL, NIOSH	Toxic substances in coal and other mines
● Comprehensive Environmental Response, Compensation, and Liability Act (1981)	EPA	Hazardous waste cleanup

"Discussed in this appendix.

SOURCE Office of Sciency and Technology Policy, 1985.

as in the Clean Air Act (CAA), the Clean Water Act, the Safe Drinking Water Act (SDWA), and the Occupational Safety and Health Act. Still other laws might require an agency to find that there is a health problem, establish this fact in court, and seek some judicial remedy on that basis. Some sections of FDCA require this for foods contaminated by naturally occurring environmental carcinogens.

Except for the few parts of statutes that require court-ordered remedies, most agencies authorized to regulate toxic substances causing health problems must follow procedures mandated by the Administrative Procedure Act, or similar procedures. In regulating substances an agency must follow these procedures for agency "rulemaking" in order to "issue a rule. " Such rules may be issued according to rulemaking procedures that range from the relatively informal to the formal, resembling proceedings in a court of law. In general, the agency must announce in the ***Federal Register*** that it is proposing to regulate a substance (or group of substances), and describe the nature of the proposed regulation ***(5*** U.S.C. 553(b)). The agency must also give interested parties "an opportunity to participate in the rulemaking through submission of written data, views, or arguments . . ." (5 U.S. C. 553(c)). Following the comment period, the agency usually holds hearings during which interested parties may have their comments heard. After considering both written and oral comments, the agency issues a final rule.

Apart from these common features, informal and formal rulemaking are distinguished by the nature of evidence presented during the notice and comment period and at the hearings, the procedures followed at the hearing itself, and the standard of judicial review of agency action. Generally, under formal rulemaking an agency must conduct quasi-judicial proceedings with the opportunity to cross-examine witnesses, and agency decisions following such proceedings are in theory more closely scrutinized by the courts if the regulatory decisions are appealed***(103).*** Under most of the statutes considered here, the agencies act under the requirements for informal rulemaking.

At least some of the statutes also provide for immediate emergency action, such as immediate suspension under FIFRA or the establishment of Emergency Temporary Standards under the Occupational Safety and Health Act.

Finally, in considering the statutes, the reader should be aware of some differences between the substantive requirements of the statutes. Different laws reveal different attitudes toward risk. Some statutes reflect attitudes quite averse to human health risks posed by chemical substances. The most extreme example is the Delaney clause of FDCA. According to that provision, if a food additive causes cancer in humans or in animal tests, it is declared "unsafe" and is not allowed as a food additive. The risk to human health is the only factor taken into account. This is a "no-risk" statute.

Other risk-based statutes use different statutory language. CAA makes risks to human health the primary factor by setting the goal of regulating with an "ample margin of safety" ***(42*** U.S.C. 7412(a)(2)). Another approach is risk-risk balancing: weighing the risk to human health from exposure to a regulated substance against the risk to human health from not having the substance in commerce. The FDCA appears to permit this kind of risk-risk balancing for food additives approved by the Food and Drug Administration (FDA) prior to 1958 (127). For human drugs, FDA uses a "risk-benefit" approach, although again, the primary factor involves the benefits and risks to patient health.

Some statutes are "technology based" laws. These may require, for example, the agency to reduce emissions from a particular source to the extent this may be achieved by technological devices placed on the emitting source. Some such statutes require the "best practical technology" (BPT) or the "best available technology" (BAT). "Such regulations do not force new technology, but bring all control efforts up to standards established by existing control technologies" (217). Other technology-based statutes might be "technology forcing" because "new techniques may be required to achieve" some predetermined level of pollutant concentration (217).

Still other statutes permit agencies to balance the risks to human health from carcinogens against benefits to be obtained by consumers, manufacturers, and others by permitting the substance to be in commerce. This is a risk-benefit balancing statute. Congress used the term "unreasonable risk" in TSCA to refer to this kind of balancing.

Occupational Safety and Health Administration

The Occupational Safety and Health Act of ***1970*** established the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH). OSHA sets and enforces regulations to control occupational health and safety hazards, including exposure to carcinogens. NIOSH is a research agency that has contributed to the regulation of carcinogens by supporting epidemiologic research and recommending to OSHA changes in health standards.

The Occupational Safety and Health Act provides three statutory mechanisms for setting standards to protect employees from hazardous substances such as

carcinogens. Section 6(a) authorized OSHA to adopt the health and safety standards already established by Federal agencies or adopted as national consensus standards. This authority was limited to the first 2 years after the act went into effect (April 1971 to April 1973). An unspecified number of carcinogens were regulated on the basis of their noncarcinogenic effects by these start-up standards.

Section 6(c) authorizes OSHA to issue emergency temporary standards (ETS) that require employers to take immediate steps to reduce workplace hazards. An ETS may be issued after OSHA determines that employees are exposed to a "grave danger" and that an emergency standard is "necessary to protect employees from such danger." An ETS, issued without opportunity for comments or for a public hearing, goes into effect immediately. The issuance of an ETS also initiates the process of setting a standard under section 6(b), with the published ETS ordinarily serving as the proposed standard. The act mandates that a final standard be issued within ***6*** months of publication of the emergency standard.

Finally, section 6(b) authorizes OSHA to issue new permanent exposure standards and modify or revoke existing ones by informal rulemaking. However, as a result of congressional compromise, OSHA's informal rulemaking is reviewed by the courts under the "substantial evidence test" normally reserved for formal rulemaking on the record (190).

OSHA's rulemaking can result in requirements for monitoring and medical surveillance, workplace procedures and practices, personal protective equipment, engineering controls, training, recordkeeping, and new or modified permissible exposure limits (PELs). Permissible exposure limits are the maximum concentrations of toxic substances permitted in the workplace air.

From 1971-1986 OSHA issued 23 separate health standards in 9 regulatory actions after rulemaking. Eight of OSHA's final actions on individual health standards established new PELs and other requirements on carcinogens (asbestos (1972), vinyl chloride, coke oven emissions, benzene, 1,2-dibromo-3-chloropropane (DBCP), arsenic, acrylonitrile, ethylene oxide, and asbestos (1986)). One OSHA action regulating a group of "14 carcinogens" did not establish a PEL, but created new requirements for work practices and medical surveillance for employees exposed to this group of carcinogens.

Significant Judicial Decisions

OSHA's regulation of carcinogens has been controversial. Of eight final actions on individual carcinogens, six have resulted in court challenges (asbestos (1972), vinyl chloride, coke oven emissions, benzene, arsenic, and ethylene oxide). Only the DBCP and acrylonitrile regulations were not challenged as final standards. In addition, there were 3 court challenges to the group regulation of 14 carcinogens: ***Dry Color Manufacturing Association v. Department of Labor (46)*** vacated temporary standards for ethyleneimine and DCB; ***Synthetic Organic Chemical Manufacturers Association v. Brennan (191)*** upheld the permanent standard for ethyleneimine; and ***Synthetic Organic Chemical Manufacturers Association v. Brennan*** II (192) vacated the standard for 4,4-methylenebil(2-chloraniline) MBOCA. OSHA's rules were upheld for asbestos (1972), for vinyl chloride, for coke oven emissions, and for arsenic. The courts vacated the temporary asbestos standard in ***1984*** and the permanent benzene standard in 1980.

The decisions resolving these disputes have focused on several major issues. Courts have had to provide interpretations of 1) the role of the courts in scrutinizing agency actions, and 2) the nature of OSHA's burden in demonstrating the merits of its standards. In setting standards the crucial section of the act states:

> [OSHA]. . . shall set the standard which most adequately assures, to the extent feasible, . . . that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life (U. S.C. 655 (b)(5)).

Early decisions by the Courts of Appeal clarified the courts' role in reviewing OSHA standards under the substantial evidence test and the standards of economic and technological feasibility. OSHA may impose regulations even if doing so means raising standards above those that exist in the status quo or above those achievable by present technology (186). In this sense, OSHA can force the development of new technology. Similarly, courts have held that although Congress did not intend to put whole industries out of business to protect their employees' health, it did foresee that health regulations would entail costs and that some businesses might close (5,98).

In a major decision, the Supreme Court invalidated OSHA's 1978 benzene exposure standard. The Court ruled that the 1 part per million (ppm) exposure limit was not supported by appropriate findings. A plurality of the Court said that the new standard did not rest on a finding that exposure to 10 ppm would cause leukemia while exposure to 1 ppm would not, and that OSHA acted on assumptions in claiming: a) that exposure to 10 ppm of benzene might cause leukemia and b) that the number of such cases might be reduced by lowering the permissible exposure level to 1 ppm (96).

According to the plurality opinion, section 3(8) defines occupational health and safety standards as requirements ''reasonably necessary or appropriate to provide safe or healthful employment,'' and requires OSHA to make a threshold finding that a workplace is "unsafe" before issuing a standard (96). According to the plurality, "safe" does not mean risk free, and a workplace is not "unsafe" unless it it poses a "significant risk of harm" to the worker (96). In addition, the Court said that "the burden [is] on the Agency to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to [a toxic substance] . . . presents a significant risk of material health impairment" (96).

This review and interpretation of OSHA's benzene standard changed the way OSHA regulates. Prior to this decision, OSHA had refused to prepare quantitative risk assessments concerning substances it regulated. In proposing subsequent standards, the agency has had to demonstrate that exposure at the current permissible levels presents a "significant risk" to workers before it is justified in proposing lower exposure standards. OSHA now uses a four-step process for making decisions about health standards:

> First, the agency determines that the hazard in question poses a "significant risk . . ." [as required by the benzene decision]. Second, OSHA determines that regulatory action can reduce this risk. Third, it sets the regulatory goal (for health standards, this is the permissible exposure limit) based on reducing this risk "to the extent feasible." Finally, OSHA conducts a cost-effectiveness analysis of various options to determine which will achieve this chosen goal in the least costly manner (219).

In 1981, a second Supreme Court ruling provided a partial interpretation of "feasibility. " In opposing new lower standards on exposure to cotton dust, industry had argued that the Occupational Safety and Health Act required cost-benefit analysis before OSHA could issue new standards. The Supreme Court, with a five-member majority comprised of the four dissenters from the benzene case and the author of the benzene plurality opinion, Justice Stevens, strongly rejected this claim, arguing that:

> Congress itself defined the basic relationship between costs and benefits, by placing the "benefit" of worker health above all other considerations save those making attainment of this "benefit" unachievable. Any standard based on a balancing of costs and benefits by the Secretary that strikes a different balance than that struck by Congress would be inconsistent with the command set forth in section 6(b)(5). Thus, cost-benefit analysis by OSHA is not required by the statute because feasibility analysis is (6).

The agency regards this decision as neither requiring nor permitting the use of quantified cost-benefit analysis for the purposes of setting standards (100,118). (See (219) for a more detailed discussion of these issues.)

Recently, a different kind of case has been litigated. Because of health concerns about employee exposure to ethylene oxide, the Public Citizen Health Research Group sued OSHA to issue an ETS. A district court ruled in favor of Public Citizen and ordered OSHA to issue such a regulation. On appeal, the District of Columbia Court of Appeals overruled the district court judge's decision on the grounds that he had impermissible substituted his evaluation for that of OSHA. However, because OSHA had "unreasonably delayed" acting on ethylene oxide, the court ordered OSHA to issue a notice of proposed rulemaking within 30 days of the Court's decision and a final rule within 1 year's time (165).

The Mine Safety and Health Administration

The Mine Safety and Health Administration (MSHA) regulates the exposure of miners to carcinogens. The Federal Mine Safety and Health Act Amendments of 1977 consolidated the regulation of mine health and safety under one statute, and transferred responsibilit, from the Department of the Interior to the Department of Labor. Safety and health in coal mines had previously been regulated under the Federal Coal Mine Health and Safety Act of 1969 by the Department of the Interior's Mining Enforcement and Safety Administration (MESA). Safety and health in metal and nonmetallic mineral mines had been regulated by MESA under the Federal Metal and Nonmetallic Mine Safety Act (1966) (150).

As described in Chapter 3, much of MSHA's regulation of toxic exposures involves incorporating by reference the lists of standards of a private organization, the American Conference of Governmental Industrial Hygienists (ACGIH). The original intention was to update these standards automatically whenever ACGIH issued changes. However, this has not happened. The administration fears violating the Administrative Procedure Act because automatic updates would not provide an opportunist y for public comment (190).

How much of a legal difficulty this situation presents is difficult to know. For example, OSHA's Hazard Communication (Labeling) Standard requires that employers provide information to employees on substances to which they are exposed and on the concentrations that are regarded as "not harmful." According to OSHA's regulations employees must be informed about the most recent ACGIH list of toxic substances (190).

Food and Drug Administration

The Food and Drug Administration regulates foods, drugs, and cosmetics under FDCA. FDCA is the result of several laws passed by Congress since the first Federal statute regulating food safety, the Food and Drug Act of ***1906 (127).*** The Federal Food, Drug, and Cosmetic Act of 1938 established the general outlines of current FDA authority. Congress has amended it with the Pesticides Residue Amendment of 1954, the Food Additives Amendment of 1958, the Color Additive Amendments of 1960, the Drug Amendment of 1962, and the Animal Drug Amendments of 1968.

Main Statutory Provisions for Regulating Carcinogens in Foods and Cosmetics

Carcinogens in foods and cosmetics may be and have been regulated under many different provisions of FDCA, depending on whether they are considered food additives, food contaminants, naturally occurring parts of the food, or color additives in foods, drugs, and cosmetics. In addition, parts of the law have premarket approval provisions, while others have postmarked enforcement provisions.

Under FDCA a food is considered to be adulterated, and thus illegal to sell in interstate commerce, if it contains a food or color additive that is unsafe. An additive is regarded as unsafe if it "may be injurious to health" or is "ordinarily injurious to health" according to section 402(a)(l) (21 U.S. C. 342(a)(2)(c)); if it contains any added poisonous or deleterious substance that is unsafe according to section 406 (21 U.S, C. 342(e); 21 U.S. C. 346); if it contains a food additive which is carcinogenic according to the Delaney clause (sec. 409) (21 U.S.C. 348(a)); or if it contains a color additive that is carcinogenic according to the Delaney clause for color additives (21 U.S.C. 376(a)).

The Delaney Clause for Foods, Section 409.-In the Food Additives Amendment of 1958, Congress established a ***premarket approval procedure*** for food additives (127). This amendment contains the well-known "Delaney clause, " named after Rep. James Delaney of New York, whose hearings led to the amendment (127).

According to FDCA, foods may not contain any intentional additive unless FDA has established conditions under which the additive may be safely used (the general safety provision of section 409) or has issued an exemption from this requirement, The Delaney clause applies to this process of approving the safe use of food additives and provides:

> . . . 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 the safety of food additives, to induce cancer in man or animal . . . (21 U.S.C. ***348(c)(3)(a)).***

Thus, if appropriate evidence indicates that a food additive is carcinogenic, FDA may not consider it safe and must prohibit its use in food. [1] The manufacturer has the burden of proving that food additives are safe before they receive approval to enter the market.

Food additives that are carcinogenic but that have previously been approved by FDA or the U.S. Department of Agriculture, or that are generally recognized as safe (GRAS) (because they were commonly used in food at the time the Delaney clause was passed or are generally recognized by experts as safe on the basis of toxicological tests), are not regulated under section ***409.*** They are instead subject to section 402(a)(l) ***(127).***

Provisions for color additives (21 U.S. C. 376) are similar to section 409 provisions for food additives, i.e., carcinogenic color additives are to be prohibited by FDA.

Although section 409 condemns food additives that are carcinogens, the agency, in an advance notice of proposed rulemaking (ANPR), has indicated an intention to rely on the general safety provision of section ***409*** rather than the Delaney clause for additives that contain carcinogens. In its 1982 ANPR, following the ***Kennedy v. Monsanto*** decision in 1979 (described below), the agency proposed that food and color additives that, taken as a whole, do not cause cancer in animals, but do contain small amounts of carcinogenic impurities should fall under the general safety clause, not the Delaney Clause. If the additive itself is not found to be harmful as shown by quantitative risk asessment procedures, then it is considered safe even though it contains carcinogenic impurities. The FDA impurities policy was upheld in the Scott v. ***FDA*** decision. Previously FDA had used the policy on a case-by-case basis for a number of food and color additives, including some color additives that are not ingested (245).

General Provision Concerning Food Adulteration (Section 402(a) (l)).—Section 402(a)(l) declares that a food is adulterated if it contains added substances that "may render it injurious to health, " or if it contains any substance, added or not, that would "ordinarily render it injurious to health" (21 U.S. C. 342(a)(l)) (1982), The latter standard includes substances that are naturally occuring food constituents (127). The difference between the two is that the first is more stringent, permitting FDA to establish its case with a lower prob-

[1] There are three different **versions of the** Delaney clause, the one described above for food additives, one enacted at the same time for drugs **fed to animals, and one enacted in the Color Additives Amendments of 1960. While they differ in detail, they all prohibit animal and human carcinogens,**

ability of risk. The first allows consideration of sensitive populations, while the second does not (128).

If FDA determines a food to be adulterated under either of these two clauses, it must go to court to remove the food from the market (127). In such a case FDA, not the manufacturer, has the burden of locating the contaminated food, analyzing its chemical makeup, and proving that the substance is harmful (127).

Unavoidable/Necessary Contaminants (Sections 406 and 402(a) (2)(A)).—Under sections 406 and 402(a) (2)(A), FDA is permitted to set tolerance limits for "unavoidable contaminants and other poisonous or deleterious substances that may be necessary aspects of food production" (127). These sections are used primarily for unavoidable contaminants of food such as aflatoxins in peanuts, mercury in fish, and PCBs in milk and fish (127). Together, sections 402(a)(2)(A) and 406 declare a food adulterated if it contains any added poisonous or deleterious substances except where they cannot be avoided or are required in the production of food. In this case, FDA may set tolerance levels for the protection of public health, and the food will be considered safe unless the tolerances for the added substances are exceeded (21 U.S.C. 348). Tolerances must be established by means of the most extreme version of formal rule making procedures (127). Foods that have levels of contaminants exceeding such tolerances are subject to postmarked judicial seizure under section 402(a)(2)(A).

Several considerations enter into the FDA's tolerance setting:

- the level of a contaminant not posing a risk to health,
- the ability of good manufacturing practices to reduce concentrations,
- analytical capabilities for detecting the contaminant, and
- Ž the value of the food (127).

This section was not used until the mid 1970s, but since has been used to establish tolerances for some unavoidable environmental food contaminants(127). Even the tolerance setting provisions have not been widely used because they involve formal rulemaking. Thus, for most foods which might fall under sections 406 and 402(a)(2)(A), the agency has instead merely set "action levels" for contaminants: levels that, if exceeded, would lead the agency to bring court action to seize the food.

Section 408 provided FDA with authority to regulate pesticide residues on raw agricultural products, but this authority was transferred to EPA in 1970. The regulation of pesticide residues will be discussed under the regulation of pesticides.

The several categories of food constituents and color additives that are regulated under the authority of FDCA are summarized in table A-2.

The Regulation of Animal Drug Residues

Animal drug residues and animal feed additives that leave residues in human foodstuffs are subject to the Delaney clause, but with a qualification. Originally, animal drug residues were subject to the Food Additives Amendment of 1958, with its Delaney clause. In 1962, however, Congress amended FDCA to permit carcinogenic residues in animal tissues as long as the residues are in lower concentrations than those that it has set as safe and detectable by FDA-approved analytic techniques. If carcinogenic residues exceed FDA-specified levels, they are subject to the Delaney clause.

The Regulation of Drugs With Carcinogenic Potential

FDA evaluates both new and previously approved drugs. New drugs require premarketing approval, subject to risk-benefit considerations:

> A drug is approved only if the benefits are judged to exceed the risks (real and potential) under intended conditions of use. For drugs, vaccines, medical devices, and diagnostic aids, the term "safety" is never treated as an absolute but is thought of as inherently involving a weighing of benefit and risk (233).

In the approval process an applicant must submit two kinds of application: an Investigative New Drug (IND) application (an application to conduct an investigation into a new drug), and then a New Drug Application (NDA) (an application to conduct a more detailed investigation into a new drug). (For a more detailed discussion of this approval process see (218).)

An applicant first submits an IND application. FDA has 30 days to consider whether the preclinical investigations suggest an undue risk to research subjects that would preclude initiation of human studies. At any time during the research period FDA can terminate the research. In 1983, the Agency received approximately 2,000 IND applications (233). An initial IND application normally would include "chemical, manufacturing, and control information; pharmacologic and toxicologic information from animals and in vitro systems; a plan of clinical study . . ." (233). Animal carcinogenicity tests are required for marketing approval of drugs that would be administered chronically or intermittently in a large population (see discussion in ch. 2).

After the research period an applicant submits an NDA (data developed during the IND-NDA process). An NDA must include full reports of toxicological

Table A-2.—Foods and Drugs Regulated Under the Food, Drug, and Cosmetic Act

Category	Description	Applicable statutory scheme
A. Direct food additives		
1. Ordinary food additives	Substances intentionally added to processed foods	Section 409
2. Substances generally recognized as safe (GRAS)	Substances used in foods prior to 1958 or substances recognized by experts as safe based upon toxicological tests	Section 402(a)(l)
3. Substances previously sanctioned by FDA or USDA	Intentionally added food constituents previously sanctioned by either FDA or USDA	Section 402(a)(l)
B. Color additives	Substances used to color foods, drugs, and cosmetics	Section 706(b)(5) for foods, drugs and cosmetics
C. Indirect constituents of food		
1. Indirect food additives	Substances used in proximity with food in ways that may permit small amounts to migrate and to become part of the food, e.g., substances used in packaging or in equipment used to process or store food	Section 409, subject to qualifications of ***Monsanto v. Kennedy*** (described in text)
2. Animal drug residues	Compounds administered to food-producing animals as drugs or feed supplements	Section 409, but DES proviso allows this only if the amount of residue exceeds the detection limit set by FDA
3. Pesticide residues	Residues of pesticides on raw agricultural products or in processed agricultural products	Sections 408 and 409 (discussed under FIFRA)
D. Natural food constituents	Naturally occurring food constituents, e.g., oyster shell fragments, mushrooms, and mussels (not known as carcinogens)	Section 402(a)(l) (covering substances that would "ordinarily render [food] injurious to health")
E. Unavoidable "added" constituents of food	Substances not inherent in agricultural commodities which may unintentionally contaminate foods such as milk, grain, or fish during production or harvesting, e.g., aflatoxins in peanuts, polychlorinated biphenyls (PCBS) in milk and fish, and mercury in fish	Section 402(a)(l) ["May render injurious to health"] or sections 402(a)(2)(a) and 406 (which authorize the setting of tolerances); FDA has tended to set "action levels" which guide initiation of court action and seizure of such substances under section 402(a)(l) (see ref. 127)

SOURCE: Office of Technology Assessment, 1987.

studies and clinical investigations to show that the drug is safe and effective, a complete list of the drug composition, samples of the drug, information that may be required for subsequent FDA monitoring activity, and specimens of proposed labels (233), Any potential risks of inactive ingredients are also evaluated.

The agency shall not approve an application for a new drug if it is not shown to be safe, if the available information is not adequate to make that determination, or if the labeling is false or misleading. Otherwise, it "shall issue an order approving the application" (2 I U.S.C. 355(d)).

Some drugs are not in chronic or widespread use, and have less potential for carcinogenicity. If a drug is chronically used, FDA requires long term carcinogenicity studies in rodents ***(233).*** For oral contraceptives, carcinogenicity tests in monkeys and dogs are required as well (68). In addition, since the agency uses a risk-benefit balancing test to evaluate the safety of drugs, "a drug . . . [that] has a significant effect on a fatal disease with no alternative therapy could be regarded as adequately safe despite major, even life threatening, side effects" (233). Thus, the agency would approve drugs taken chronically that have possible carcinogenic side effects only if "the benefits [were] judged to exceed the risks (real and potential) under intended conditions of use" (233).

Significant Judicial Decisions

One recent judicial decision is of note, for it may influence developments in the future. In 1977, FDA proposed an extreme procedure for regulating tiny amounts of carcinogenic substances that may migrate from packaging material into foods. The agency had found that under certain laboratory conditions acrylonitrile monomers migrated from beverage containers into the liquids contained inside, FDA argued that even if improved manufacturing methods would decrease the amount of acrylonitrile migrating into beverages, packaging material with acrylonitrile in it could be presumed "to become a component of food, " even though

present analytic methods could not detect it (237). The agency argued that the burden is on the manufacturer to prove that diffusion does not occur when packaging contains "lower residual levels of the material" (237). The Court of Appeals for the District of Columbia in Monsanto v. ***Kennedy*** rejected this argument (129). The Court was concerned

> . . . that the Commissioner may have reached his determination [concerning small amounts of acrylonitrile in beverages] in the belief that he was constrained to apply the strictly literal terms of the statute irrespective of the public health and safety considerations . . . [but] there is latitude inherent in the statutory scheme to avoid literal application of the statutory definition of "food additive" in those de minimis situations that, in the informed judgment of the Commissioner, clearly present no public health or safety concerns (129).

In particular, the Commissioner

> . . . has latitude . . . to find migration "insignificant" even giving full weight to the public health and welfare concerns that must inform his decision . . . [and] he would have latitude to consider whether acrylonitrile is generally recognized as safe at concentrations below a certain threshold, even though he has determined for higher concentrations that . . . acrylonitrile is not generally recognized as safe (129).

This case is important, not only because of its application to indirect food addtives, but because it introduces the idea of de minimis levels of risk into FDA regulation and into the regulatory community more generally. As discussed in chapter 3, it is generally believed that there are no "safe" threshold levels for carcinogens or that these levels have not been demonstrated, Under the Delaney clause, this belief would seem to require that any concentration of a carcinogen as a food additive would have to be banned, for there is no safe level. FDA, however, distinguishes legal arguments from scientific arguments and contends that the Delaney clause is a policy statement and that there are safe levels for carcinogens under the Delaney clause. Since ***Monsanto v. Kennedy,*** some in FDA support the idea that there may be de minimis levels of risk even with carcinogens.

A number of developments since ***Monsanto v. Kennedy*** indicate that FDA is adopting the idea of de minimis risks for carcinogens. The agency permitted lead acetate to remain in hair dye, even though it had been found to be carcinogenic in animal feeding studies, and even though some of it penetrated the scalp and was detectable in the blood stream when the dye was applied to hair (35). In addition, in 1982 the agency approved D&C Green No. 6, "a color additive for use in drugs and cosmetics that was not itself found to be carcinogenic, but contained a carcinogenic constituent" (35), on grounds that ***Monsanto*** allowed the agency some discretion in deciding how to deal with color additives (39). A circuit court of appeals has upheld such an approval since that time (35). In 1982 and 1983 FDA considered six color additives, all of which had been found to be carcinogenic not merely to have carcinogenic components. Rather than banning them outright, as the Delaney clause would seem to require, the agency referred them to a panel of scientists at the U.S. Department of Health and Human Services. "The clear, but unstated, implication of this action is that the agency is now prepared to apply the de minimis principle to direct food and color additives that cause cancer in animals" (35). The agency may also be trying to build a broad base of scientific support for its approach. In a related development on December 18, 1985, "FDA proposed to ban the use of methylene chloride in cosmetics because it causes cancer in lab animals, but declined to lower the maximum residue of it permitted in decaffeinated coffee because that amount is considered safe" (35).

Monsanto v. Kennedy and subsequent developments contrast with an earlier case concerning the FDA's termination of provisional approval of Red No. 2 dye. In that instance, the agency had evidence that Red No. 2 caused cancer in rats at low doses and caused only a slight increase in cancer tumors (compared with those at low doses) at high doses. On this basis, FDA proposed terminating provisional approval of the dye and the industry sued. The court of appeals upheld the agency's action, (1) because the statistical relationships in the initial animal studies, while not providing "conclusive proof that Red No. 2 was a carcinogen, . . . [were] at least suggestive of it . . ." and (2) because these statistical relationships were later confirmed at low doses. More important from the Court's point of view the study "could ***not*** be used to ***establish*** safety . . ." Thus the color's safety was sufficiently questionable to justify FDA terminating its provisional listing ***(27).***

The Consumer Product Safety Commission

Created in ***1970*** by the Consumer Product Safety Act, the Consumer Product Safety Commission (CPSC) is an independent regulatory agency headed by five commissioners appointed by the President for staggered seven-year terms. Its authority to regulate carcinogens is established by both the Consumer Product Safety Act (CPSA) and the Federal Hazardous Substances Act (FHSA).

The Consumer Product Safety Act

CPSA gives the Commission power to regulate consumer products that pose "unreasonable risks" of in-

jury or illness (15 U.S.C. 2051) (1984). CPSC regulates all consumer products except foods and drugs, pesticides, tobacco and tobacco products, motor vehicles, aircraft and aircraft equipment, and boats and boat accessories (15 U.S.C. 2052(a)) (1984). The statute also precludes CPSC from regulating risks of injuries associated with substances that are, or are contained by, a consumer product "if such risk could be eliminated or reduced to a sufficient extent by actions taken under the Occupational Safety and Health Act of 1970, the Atomic Energy Act of 1954, or the Clean Air Act" (15 U.S. C. Sec. 2052(a)) (1984), and it may not regulate "electronic product radiation emitted from an electronic product" (15 U.S. C. 2080) (1984).

Whenever a product poses an "unreasonable risk" of injury or illness, section 7(a) of CPSA authorizes CPSC to promulgate a consumer product safety standard (15 U.S. C. 2056(a)(l)) (1984). The safety standard may specify requirements for product performance or design, requirements for consumer instructions or warnings, or both (15 U.S.C. 2056(a)(l)) (1984). If "no feasible consumer product safety standard . . . would adequately protect the public from the unreasonable risk of injury" presented by a product, section 8 authorizes the Commission to ban the product from commerce (15 U.S. C. 2052(a)(3)) (1984).

Mere risk of injury, death, or serious illness does not by itself make a risk "unreasonable," and the Commission has considered both risks and offsetting benefits in regulating products. Over time, the courts have required that CPSC provide more extensive information to support its decisions concerning consumer product hazards. Prior to 1978, while the Commission indicated the benefits from a regulation in its regulatory rationales, it did not always provide a full description of the costs incurred by manufacturers and consumers because of regulation. In ***Aqua Slide 'n' Dive v. the Consumer Product Safety Commission*** the Court of Appeals for the Fifth Circuit invalidated a requirement that warning signs be attached to home swimming pools offered for sale. The court explained "[t]he Commission does not have to conduct an elaborate cost-benefit analysis . . . It does, however, have to shoulder the burden of examining the relevant factors and producing substantial evidence to support its conclusion that they weigh in favor of the standard" (10). Going on, the court said that "[t]he necessity for the standard depends upon the nature of the risk, and the reasonableness of the risk is a function of the burden a standard would impose on a user of the product. " That burden can be measured by the "increases in price, decreased availability of a product, and also reductions in product usefulness . . . " Moreover, the Court suggested that CPSC had to show that consumers were unaware of the risks before a product regulation would be warranted (10).

Two other sections of the act might be used to regulate carcinogens (126). Section 12 permits the agency to bring suit in Federal district court seeking the seizure of "an imminently hazardous consumer product" or injunctive relief against a distributor (15 U.S. C. 2061(a)) (1976). This section apparently has not been invoked against a product containing a carcinogen (126). Section 15 authorizes the Commission to order a variety of remedial actions with regard to any product that presents a "substantial product hazard, " resulting from a product's defect. (15 U.S. C. 2064) (1984). The Commission intended to use this section to order the recall of hairdryers containing asbestos and had issued a preliminary conclusion that these hairdryers presented a "substantial product hazard, " but the manufacturers voluntarily recalled their hairdryers (126). CPSA requires "informal rulemaking" to establish a product safety standard or to ban a product (126).

In 1981 Congress amended CPSA by requiring that CPSC convene a "Chronic Hazard Advisory Panel" (CHAP) before issuing any proposed rule designed to reduce exposures to a product presenting a risk of cancer, mutations, or adverse reproductive effects (15 U.S.C. 2081(b)(l)) (1984). Such a panel is appointed by the Commission, consists of seven members from a list of nominees submitted by the President of the National Academy of Sciences. The nominees cannot be Federal employees and must not have any "substantial financial interest in any manufacturer, distributor, or retailer of a consumer product" ***(15*** U.S. C. 2077(b)(1)) ***(1984).*** The members must, in addition, be experts capable of critically assessing "chronic hazards and risks to human health" (15 U.S.C. 2077(b)(2)) ***(1984).*** CPSC cannot take action until it receives a report from such a panel. CPSC has convened CHAP's since 1981.

The Federal Hazardous Substances Act

FHSA was enacted in 1960 as a labeling statute intended to fill gaps in other statutes. The act was later amended to permit more drastic action to control hazards and expanded "to cover hazardous substances in general use in the home, and particularly to protect children from hazardous toys and products" (Poison Prevention Packaging Act of 1970, Public Law 91-601, 84 Stat. 1670 (1970); Child Protection and Toy Safety Act of 1969, Public Law 91-113, 83 Stat. 187 (1969); ChiLd protection Act of 1966, Public Law 89-756, ***8*** Stat. 1303 (1966)) (126). FHSA was administered by the Food and Drug Administration until the creation of CPSC, at which time the new agency took responsibility for the act.

Section 2(f)(l)(a) of FHSA defines "hazardous substance" as a substance or mixture which ". . . may cause substantial personal injury or substantial illness . . . as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children" (15 U.S.C. Sec. 1261(f)(l)(a)) (1984). The act excludes, among other things, pesticides, foods, drugs and cosmetics, certain radioactive materials, and tobacco and tobacco products. Under FHSA, CPSC may require a hazardous substance to bear a hazard label or, if CPSC determines that this step would be insufficient, to ban the product from commerce. CPSC has authority to seize banned substances and to require businesses to repurchase banned hazardous substances ***(15*** U.S. C. 1264) (1984).

In contrast to CPSA, FHSA has slower and more complex rulemaking requirements. The agency issues a proposed rule, entertains comments, and publishes a "final order" (126). If parties adversely affected by the order file "legally sufficient" objections, the Commission is obligated to conduct an evidentiary hearing before an administrative law judge ***(126).*** In effect, this procedure is much like formal rulemaking on top of informal rulemaking. Any party whose products have been banned as hazardous under FHSA may petition a court of appeals within ***60*** days for review (126). A reviewing court must affirm the Commission's order if the order is "based on a fair evaluation of the hearing record" (126).

The Commission has preferred to rely on CPSA because of FHSA'S more complex rulemaking and because it believes the informal procedures of the CPSA would better facilitate participation by diverse interests (229). This preference has recently been overruled for some kinds of cases, however. In the recent formaldehyde decision heard by the 5th Circuit Court of Appeals, the court noted that "[r]ulemaking under the Consumer Product Safety Act is to be the exception, not the rule . . ."(76).

Major Court Decisions

Four major legal decisions have affected CPSC regulation of carcinogens. Three cases concerned procedural matters: ***Pactra Industries v. CPSC (153), Springs Mills v. CPSC (190),*** and Dow ***Chemical v. CPSC*** (45). The major lesson from the cases is that the Commission must scrupulously follow due process requirements in issuing regulations (110).

In Dow ***Chemical v. CPSC,*** the Commission attempted to use its cancer policy, which had been issued as part of a proposed rulemaking, to classify substances according to evidence of their carcinogenicity. Using the policy, the Commission provisionally classified perchloroethylene as a suspect carcinogen. The Dow Chemical Company sued because it believed even such a provisional classification harmed Dow. The court held that CPSC could not rely on the cancer policy in this manner until it was adopted in rulemaking procedures ***(45).*** Subsequent to this decision CPSC formally withdrew its cancer policy from the rulemaking process and decided to use the guidelines adopted by the Interagency Regulatory Liaison Group (IRLG), and more recently the guidelines issued by the President's Office of Science and Technology Policy (OSTP). (Both are discussed more fully in ch. ***2.)*** CPSC had intended to issue a legally binding cancer policy, hoping to foreclose some legal debates in issuing carcinogen regulations. The Dow ***Chemical*** court blocked the attempt. At present the Commission's position is that it may refer to guidelines such as the old IRLG or present OSTP cancer guidelines, but cannot use them to foreclose legal debates until they have been formally adopted as legal documents in rulemaking procedures. In addition, there are some legal issues that cannot be foreclosed by publishing a cancer policy, e.g., whether a particular animal bioassay is a valid scientific experiment or not.

A fourth case concerning CPSC's regulation of carcinogens could have more far-reaching impact. In 1982, after a 6-year investigation and rulemaking regarding urea-formaldehyde foam insulation (UFFI), the Commission issued a final rule banning UFFI in residences and schools ***(76).*** Four industry petitioners objected to the ban and convinced the 5th Circuit in ***Gulf South Insulation v. Consumer Product Safety Commission*** to overturn the ban on UFFI ***(76).*** In particular, the court objected to the Commission's "exclusive reliance" on a single animal study to support its risk assessment ***(76).*** About a large animal bioassay involving 300 animals, the court noted that

> . . . in a study as small as this one, the margin of error is inherently large. For example, had 20 fewer rats or 20 more developed carcinomas, the risk predicted by [the] Global 79 [risk assessment model] would be altered drastically (76).

This is very close to saying that if the victim of the gunshot wound had not died, the defendant wouldn't be guilty of murder.

The court went onto conclude that even if the study were valid for some purposes, it did not constitute substantial evidence to support CPSC's "precise" estimate of risk, without which CPSC could not validly conclude that UFFI posed an unreasonable risk of cancer.

The court believed that formaldehyde "should be presumed to pose a cancer risk to man, " but regarded as "questionable" two assumptions the Commission relied upon: that at identical exposure levels the "effective dose for rats is the same as that for humans,"

and that the "risk of cancer from formaldehyde is linear at low dose—in other words that there is no threshold below which formaldehyde poses no risk of cancer" (76). Finally, as indicated above, the court held that CPSC had not properly justified its rulemaking under CPSA rather than FHSA, concluding that the Commission should have regulated UFFI under the Federal Hazardous Substances Act (76).

The Environmental Protection Agency

In 1970 by executive order, President Richard Nixon created the Environmental Protection Agency, merging 15 existing programs "managed by 5 different departments or councils . , . into . . . an organization headed by a single administrator . . . charged with regulating virtually all sources of pollution rather than a single industry" (114).

EPA is headed by an administrator, with assistant administrators in charge of its major divisions. (Table A-3 lists EPA units responsible for administrating the various environmental statutes.)

Table A-3.—EPA Administration of Statutes

EPA office	Statute administered
Assistant Administrator for Air and Radiation	Clean Air Act
Assistant Administrator for Pesticides and Toxic Substances	
Office of Pesticide Programs	Federal Insecticide, Fungicide, and Rodenticide Act
Office of Toxic Substances	Toxic Substances Control Act
Assistant Administrator for Solid Waste and Emergency Response	Resource Conservation and Recovery Act, Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
Assistant Administrator for Water	Clean Water Act, Safe Drinking Water Act

SOURCE: Office of Technology Assessment, 1987.

The Clean Air Act

One of the first major environmental statutes enacted in the early 1970s was the Clean Air Act Amendments of 1970. The statute provides an elaborate Federal-State scheme for controlling conventional pollutants, such as sulfur dioxide and carbon monoxide. Because of the emphasis on controlling conventional air pollutants, toxic pollutants were almost ignored. The House version of the bill did not contain a provision for hazardous air pollutants (although the Senate version did) and during the House-Senate Conference negotiations, the administration recommended deletion of the hazardous pollutants section (71). Despite this opposition, Congress approved a hazardous air pollution provision–section 112.

While sections 108-109 and 111 have been considered by EPA as possible statutory authority for regulating carcinogens, the agency has not relied on these and has used section ***112*** as its primary authority. However, in 1977 Congress amended CAA by adding, among other things, a section on the regulation of radioactive pollutants, cadmium, arsenic, and polycylic organic matter. The agency was ordered to review within one year all "available relevant information" on these substances to decide whether or not they "may reasonably be anticipated to endanger public health" (42 U.S, C. ***7422(a)). If any did, it*** was to be considered for regulation under sections 108-109, 111 or 112, or a combination of them. The agency subsequently regulated two of these substances. (See ch. 4.)

Section 112 authorizes EPA to set emission standards for "hazardous" air pollutants, which include any air pollutant

> . . . to which no ambient air quality standard is applicable and which in the judgment of the Administrator causes or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapaciting reversible, illness (42 U.S. C. 7412(a)(2)).

The administrator must establish standards for each pollutant

> . . . which in his judgment provides an ample margin of safety to protect the public health from such hazardous air pollutant. (42 U.S.C. 7412(b)(l)(b)).

Under this section EPA was required within 90 days of December 31, 1970, to publish, and from time to time revise, a list of hazardous air pollutants that EPA intends to regulate (42 U.S.C. 7412(b)(l)(a)). The idea is that a pollutant is first listed as hazardous based on pertinent scientific data, then national standards are established for each source category of such pollutants (71).

A substance can become a candidate for listing by agency nomination or by citizen petition (71). A substance is not listed until the EPA staff prepares a comprehensive health assessment document, the agency's Scientific Advisory Board (SAB) gives written comment, and the EPA administrator determines to list it (71).

Once a substance is listed, the administrator is to propose emission standards within 180 days, hold a public hearing within 30 more days, and publish final emission rules within 180 days of the proposal (42 U.S.C. 7412(b)(l)(b)). The pollutant must be regulated

"unless [the agency] finds, on the basis of information presented at such hearings, that such pollutant clearly is not a hazardous air pollutant" (42 U.S.C. 7412(b)(l)(b))(1982). Once a substance is listed as a hazardous pollutant, the administrator has a duty within the deadlines to propose and issue national emission standards, and citizens may sue in Federal courts to force compliance with these procedures (42 U.S. C. 7604 (a)(2)).

States may issue their own standards for hazardous air pollutants "as long as they are at least as stringent as those required by EPA. If States submit adequate control programs to EPA, the administrator is authorized to delegate his implementation and enforcement authority to the States" (76).

However, Congress provided no explicit guidance for regulating carcinogens as compared with other hazardous substances under this section. This failure to address carcinogens explicitly has led to considerable controversy in the interpretation of the statute for application to carcinogens. For a substance with a toxic threshold, i.e., a level below which there are no harmful health effects to a group of people, setting a standard would involve determining a "no effects" threshold and providing for a margin of safety. However, for carcinogens there is no known safe threshold. Thus, providing an ample margin of safety as required by the statute would imply elimination of all exposures by setting an emissions standard of zero, or, possibly, a standard of no detectable concentrations. Faced with economically beneficial activities which produce such pollutants and with control equipment incapable of reducing emissions to zero, EPA's strategy has been to require

> . . . emission reduction to the lowest level achievable by use of the best available control technology in cases involving apparent nonthreshold pollutants, [where] complete emission prohibition would result in widespread industry closure and EPA has determined that the cost of such closure would be grossly disproportionate to the benefits of removing the risk that would remain after imposition of the best available control technology (325),

The definition of "best available technology" (BAT) differs for new and existing sources. For existing sources EPA considers "economic feasibility" and sets the requirements at "the most advanced level of technology that at least most members of an industry [can] afford without plant closures" (325). For new sources, BAT will be the "technology which in the judgment of the administrator, is the most advanced level of control adequately demonstrated, considering economic, energy, and environmental impacts" (324). In addition to requiring BAT, for new sources, if EPA finds that there is an "unreasonable residual risk, a more stringent alternative would be required" (324). The administrator will base his judgment of "unreasonable residual risk" on:

- the range of additional cancer incidence;
- the range of health risks to the most exposed individuals;
- readily identifiable benefits of the substance or the activity;
- economic impacts of requiring additional control measures;
- the distributions of benefits of the activity versus the risks it causes; and
- other possible health and environmental risks (324).

Although this overall strategy was articulated in a proposed rule adopting a policy for airborne carcinogens (324) which has never been finalized by the agency, EPA staff say that the agency continues to follow the broad outlines of the policy (103). EPA has acknowledged that the BAT approach was not explicitly recognized by the statute and, at the time it regulated asbestos and vinyl chloride, the approach had not been tested in the courts.

The court test arose over the 1976 vinyl chloride standards (55). That case ended with a consent decree in which EPA agreed to issue proposed amendments to the standard for vinyl chloride with "the ultimate goal of zero vinyl chloride emissions." In addition, EPA agreed to lower the 10 ppm emission standard to 5 ppm as soon as "technology can achieve the lower standard" as a means of working toward the zero emission standard (55), EPA's interpretation of the "ample margin of safety" requirement of section 112 has been controversial. The General Accounting Office as well as others have disagreed with the agency's position (183,198). Nevertheless, it received tacit endorsement by the courts when the District of Columbia Court of Appeals approved the consent decree.

Subsequent to the consent decree in ***EDF v. Train,*** there has been further litigation concerning regulation of vinyl chloride and EPA's interpretation of "ample margin of safety. " On January 9, 1985, EPA announced that it would not continue to pursue the goal of zero emissions for vinyl chloride and would not require a standard of 5 ppm (compared with the present 10 ppm). It supported its position on several grounds:

- EPA continues to hold that section 112 does not "express an intent to eliminate totally all risks from emissions of airborne carcinogens" (325),
- 10 ppm represents "the lowest level of control which has been consistently achieved" (325), and
- the proposed 5 ppm emission "was not based on data from a control technology different from that analyzed for the current standard" (325).

The Natural Resources Defense Council (NRDC), alleging that EPA had "reneged" on provisions of the 1977 consent decree, sued EPA on June 17, 1985, concerning its interpretation and procedure for setting standards under the "ample margin of safety" phrase (142). NRDC argued that the language of the statute does not specifically provide for cost-benefit analysis, and, additionally, section 112 does not permit EPA to impose cost-benefit or technological feasibility tests on proposed standards for toxic pollutants. NRDC argues that the Supreme Court has held that the agency cannot use cost-benefit analysis when setting health standards unless the statute provides for it (140). A panel of the D.C. Circuit ruled in 1986 that, since the statute provides EPA with some discretion in setting regulations under section 112 and since it does not specify precisely how this discretion is to be exercised, the court will permit the agency to exercise reasonable discretion in implementing the statute. However, the panel decision was subsequently vacated by a grant of rehearing for certain source categories by the entire court. Oral argument was held on April 29, 1987, and a decision is pending.

In addition, the Agency has been sued over its failure to issue benzene standards. NRDC argues that the statute requires that hazardous air pollutant regulations be based exclusively on public health considerations, not technology and cost tests which may compromise the protection of health. It also argues that EPA is prohibited by statute from dismissing as insignificant an increase in mortality that may be caused by benzene exposure, because the agency is required to issue regulations with an ample margin of safety, not simply to prevent "significant" health risks (145).

The agency responds that section 112 of the Clean Air Act permits "EPA not to regulate source categories of benzene that present an insignificant risk" (146). The contention is that Congress, in its 1977 amendments, "intended to codify an approach . . . [taken in an earlier legal case] . . . which plainly held that a finding of 'significant risk' is an appropriate test for regulating and stressed that the administrator may 'weigh risks and make reasonable projections of future trends' . . . " (146).

The outcome of this case will be important for the development of hazardous air pollutant regulations, and it may also indicate the extent to which the courts are willing to permit agencies not to regulate toxic substances because the agency has determined that the risk is "insignificant" or "de minimus. "

The Clean Water Act

Since the Federal Water Pollution Control Act was first enacted in 1948, it has been amended nine times, and is now generally referred to as the Clean Water Act. The most important of the amendments were made in 1972, 1977, and 1987. In 1972, Congress set the goal of achieving "fishable, swimmable" waters by 1983 and prohibiting the "discharge of toxic pollutants in toxic amounts . . ." by 1985 (33 U.S.C. 1251(a)) (1982). In the 1977 amendments, Congress endorsed a new method for regulating toxic pollutants that had been developed to settle a lawsuit between environmental organizations and EPA. In 1987, Congress continued its emphasis on control of toxic pollutants.

The CWA protections are less directly related to human health than are the protections of some other laws such as the Safe Drinking Water Act, which aims at securing the safety of drinking water supplies. Nonetheless, CWA has a number of sections aimed at regulating human exposure to carcinogens and other toxics.

Central to controlling all water pollutants under CWA are the National Pollution Discharge Elimination System (NPDES) permits for "direct" dischargers. It is lawful to discharge a pollutant only if the discharge is in compliance with an NPDES permit. Such permits can be issued by EPA or by States whose permit programs are approved by EPA. At present 37 of a possible 54 jurisdictions have been approved to administer their own NPDES programs; EPA administers the remainder (31).

An NPDES permit is written for a facility which may have a number of discharge pipes (typical facilities have from 1 to 3 such pipes, but large facilities like steel mills may have as many as 100) (74). For each discharge pipe a permit will contain the following:

- a list of pollutants that must be regulated according to Federal or State law, together with specified permissible amounts of each pollutant that may be discharged per unit of time;
- monitoring requirements and schedules for implementing the pollution concentration requirements; and
- special conditions regarding pollutants the permit writer thinks should be imposed on the permit holder, for example, additional testing and procedures for spills of pollutants into the water.

NPDES permits are written both for conventional pollutants (e.g. biological waste material) and for toxic substances.

In writing a permit for toxic substances such as carcinogens, the responsible State agency or EPA will consider the following:

- Federal toxic effluent standards and toxic effluent limitations,
- Federal water quality criteria for toxics,
- State water quality standards or effluent stand-

ards for toxics, and
- special conditions.

Sections 301, 304, and 307 of CWA are the centerpiece, containing substantive conditions on NPDES permits for regulating toxic pollutants. Under it, EPA may issue binding regulations known as effluent limitations and effluent standards. These are legally binding Federal regulations limiting the concentrations of pollutants in point source discharges and they must be on NPDES permits.

An "effluent limitation" uses a technology-based approach to limit the amount of a toxic substance that can be discharged from a point source, such as a pipe. Toxic substances regulated in this manner have been regulated on an industry by industry basis. [z] An "effluent based standard, " by contrast, is a control requirement based on the relationship between the discharge of a pollutant and the resulting water quality in a receiving body of water (62), but has not been used since 1977. Water quality-based effluent limitations which specify certain concentrations of a chemical in a point source of effluent, are typically more stringent than technology-based effluent limitations (62), and must be established "with an ample margin of safety" (33 U.S.C. 1317(a)(4)) (1982). Finally, CWA requires informal rulemaking (79).

Because only six pollutants had been regulated with effluent standards, EPA was sued by NRDC.The subsequent consent decree (discussed below) provided that EPA could instead set effluent limitations to regulate toxic pollutants. In 1977, Congress added a reference to a specific list of toxic substances that had been agreed to for the consent decree. (See table 1 of the House committee on Public Works and Transportation Committee Print 95-30.) An account of how this list of toxic pollutants was developed is provided in chapter 3. This list may be revised from time to time as the administrator deems appropriate (loll; 1317(a)) (1982).

For each listed toxic chemical the administrator must establish effluent limitations or standards. Substances controlled by either of these mechanisms have been regulated on a pollutant-by-pollutant basis. Effluent limitations are issued industry-by-industry, however, with specific requirements for each relevant pollutant. Effluent standards, when used, have been issued pollutant-by-pollutant, regardless of which industries might be affected.

Section 307(b) also requires pretreatment standards for toxic substances discharged from private pollution sources into publicly owned water treatment facilities. Pretreatment standards together with discharge limitations on publicly owned treatment facilities must produce as great a reduction of toxic pollutants as the use of effluent limitations would on a private polluting point source (33 U.S. C. 1317(b)).

Section 306 requires technology regulations on new facilities similar to effluent limitations on existing facilities (so-called new performance standards). New facilities must provide the best available demonstrated technology and, where it is practicable, there must be no discharge of pollutants (33 U.S.C. 1316).

Section 304 authorizes EPA to develop ambient water quality criteria for all pollutants, including toxics. These criteria are not legally binding on EPA or the States, but may be used as pollutant goals to be pursued in improving the quality of water courses. The production of the water quality criteria documents was a major risk assessment activity at EPA in the late 1970s (see ch. 4). NPDES permit writers, under the narrative criteria of the permits, may impose more stringent limitations on toxic pollutants than BAT effluent limitations would require. The extent to which permit writers have used this section of NPDES permits is unknown, but some in EPA believe that EPA regional offices do use the ambient water quality criteria in writing permits for facilities in States where there are not State-approved programs (15).

State water quality standards are to be developed for the amount of a pollutant permitted in a given course (sec. 303). The limitations established here must protect the public health or welfare, enhance the quality of water, and serve the purposes of the act. CWA requires that the States develop State water quality standards. The extent of this standards-setting activity, however, has been very limited (see ch. 3).

Water quality-based effluent limitations, adopted under section 302, might be used to impose "limitations more stringent than BAT for sources on a particular stream segment, " such as the prohibiting of all discharges of toxic pollutants, "if the water quality in a stream will not attain the national goal of "fishable/swimmable' waters . . ." (62). To date this section has not been used, but EPA has announced its intention to begin to develop such standards (282). However, the agency will first develop limitations for fish and aquatic life and acknowledges that the human health limitations "lag behind" (15).

Special conditions imposed by an NPDES permit writer are designed to achieve a generalized goal, or narrative criteria, of the State water laws or CWA, e.g., preventing toxic pollutants in toxic amounts in the nation's waters (sec. 301).

[z] Best available technology provisions for regulating toxic substances were not included in the major revisions of CWA in 1972. Section 307 originally included only the nontechnology-based toxic effluent standards. Congress amended CWA in 1977 to provide for technology-based limitations as agreed to in the 1976 *NRDC v. Train* consent decree.

In addition to regulating toxic substances, CWA declares that there should be no discharges of "oil or hazardous substances" into or on the navigable waters, including shoreline coastal waters. Hazardous substances are those that present an "imminent and substantial danger to the public health or welfare . . ." (33 U.S.C. 1321(b)(2)(a)). EPA was required to list such substances, determine quantities which might be harmful, and issue regulations concerning these (33 U.S. C. 1321(b)(2)(a), 1321(b)(4)). The law also provides for liability in case of discharges of hazardous substances or oil. This provision of CWA anticipates some of the hazardous substances prevention and cleanup provisions of the later Resource Conservation and Recovery Act and the Comprehensive Environmental Response, Compensation, and Liability Act.

Significant Judicial Decisions.—A judicial decision led to the development of toxic effluent limitations under CWA. In 1975a group of lawsuits were filed against EPA challenging its failure to regulate toxic pollutants (55). In 1976 those cases ended in a consent decree, with EPA agreeing to place specific "numerical limits on the quantities of 65 toxic pollutants in 21 industrial categories" (62). EPA was required to complete these regulations by June 30, 1983. The consent decree permitted EPA to regulate toxic substances through those sections of CWA designed to control ordinary nontoxic pollutants, in particular, the technology-based provisions of the statute. The agency has been in the process of issuing BAT effluent limitations for 28 industrial categories which may limit these 65 categories of toxics, including at least 29 carcinogens. Congress, in the 1977 amendments to the CWA, incorporated these changes, in effect creating the new category of toxic effluent limitations.

There have been several judicial developments related to the 1976 consent decree. The National Research and Demonstration Center sued EPA to show the agency in contempt of the agreement (this was settled out of court, extending EPA's original deadline from June 30, 1983, to June 30, 1984) (140). Eight times EPA requested Judge Flannery to modify the agreement to give it more time to complete the regulations. Except for the May 1982 request, which Judge Flannery denied, urging the agency to "work harder, " (144) the requests were granted (144). These guidelines are in various stages of revision and litigation.

Another judicial development of note was Velsicol Corporation's attempt to overturn EPA's first regulations of two toxic substances, toxaphene and endrin, regulated under the Federal Water Pollution Control Act of 1972. Velsicol argued, among other things, that the technology-based effluent limitations added in the 1977 congressional amendments superseded the previous health-based authority of section 307 and that, in addition, EPA was required to consider economic and technological factors in setting its regulations. The court ruled that the 1977 amendments were required to aid, not impede, EPA's health-based authority, and thus denied both pleas (and several others as well) (88).

One final judicial development of note is EPA's use of "fundamentally different factors" (FDF) variances. These have been used to modify, on a case-by-case basis, BAT or pretreatment limitations of pollutants, including toxics (62). However, such variances are not specifically authorized by the statute and have been the subject of some litigation. Although the Court of Appeals for the Third Circuit struck down the use of these variances, the Supreme Court in a 5-4 opinion upheld EPA'a authority to apply FDF variances to toxic pollutants (29).

The Safe Drinking Water Act

A second major statute for regulating carcinogens in water is the Safe Drinking Water Act (SDWA) of 1974. Although the Clean Water Act, discussed above, was designed to control water pollution, it Ṗrovided no authority to regulate polluted water discharged into nonnavigable waters, such as groundwater, which often is a source of drinking water. Thus additional legislation was needed to "assure safe drinking water" (214). SDWA aims primarily to regulate water provided by public water systems, and it contains several provisions that may be used to regulate hazardous substances, including carcinogens in drinking water. In contrast to CWA, SDWA is more directly concerned with protecting human health.

Under SDWA, EPA is to regulate contaminants "which . . . may have an adverse effect on the health of persons . . ." (42 U.S.C. 300f(l)(b)). The act then prescribes the steps which the agency must go through over time to protect drinking water.

First, EPA was required to publish national interim primary drinking water regulations within 90 days of December 16, 1974. These regulations were to "protect health to the extent feasible, using technology, treatment techniques and other means, which the Administrator determines are generally available (taking costs into consideration)" on the date of enactment (42 U.S.C. 300g-l(a)(2)).

Second, Congress required that EPA request a National Academy of Sciences (NAS) study to determine the maximum contaminant levels that should be recommended as national standards, and to identify the "existence of any contaminants the levels of which in drinking water cannot be determined but which may have an adverse effect on the health of persons" (42 U.S.C. 300g-2(e)). In addition, revisions of the NAS study reflecting any new information "shall be reported

to Congress each two years thereafter" (42 U.S.C. 300g-$_2$(d)(2))." In considering whether contaminants have an adverse effect, the NAS study had to consider the impact of contaminants on groups or individuals in the population more susceptible to adverse effects than normal healthy individuals, as well as exposure to contaminants in other media, synergistic effects of contaminants, and body burdens of contaminants in exposed persons (42 U.S.C. 300g-1(3)). In 1977 NAS provided its first list of contaminants (chosen on the basis of its own criteria) that might have an adverse effect on health (36,134).

Third, within 90 days of the publication of the NAS study, EPA was required to establish by rulemaking "recommended maximum contaminant levels (RMCL) for each contaminant which . . . may have any adverse effect on the health of persons" (42 U.S.C. 300g-l(b)(l)(b). Each such RMCL was to be "set at a level at which . . . no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (42 U.S.C. Sec. 300g-l(b)(1)(b)).

The House report on the 1974 SDWA elaborated on the criteria for setting RMCLS:

> . . . the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect, It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at zero level (214).

RMCLS are nonenforceable health goals, which are used as guidelines for establishing enforceable drinking water standards. The agency also had to publish a list of contaminants whose levels cannot be measured accurately enough in drinking water to establish an RMCL, and which may have an adverse effect on the health of persons (42 U.S.C. 300g-l(b) (1)(b)).

Once the agency established RMCLS for each contaminant it was required to publish revised national primary drinking water regulations. These regulations establish the requisite enforceable health standards. The required regulations must specify a maximum contaminant level (MCL) or require the "use of treatment techniques for each contaminant" for which an RMCL is established. The established MCLS were to be as close to the RMCLS as is "feasible" (42 U.S. C. 300g-l(b)(3)), In determining feasibility, the administrator may consider "the use of the best technology, treatment techniques and other means, . . . [that] are generally available (taking cost into consideration)" (42 U.S.C. 3oog-l(b)(3)).

In general, enforcement of MCLS rests with the States. EPA sets MCLS. The agency then has the responsibility of reviewing and approving State programs to achieve the mandated standards, and, once a State program is approved, it gives States the authority to enforce the MCLS. Until a State has an approved program, EPA has authority to regulate levels of contaminants in drinking water.

SDWA was modified by the 1986 Amendments which are discussed in chapter 3.

Significant Judicial Action.—To date only one case has been brought regarding EPA's regulation of carcinogens (concerning the regulation of trihalomethanes) under SDWA, and it was settled after briefs were filed. Since the agency issued a final rule for RMCLS and a proposed rule for MCLS for eight volatile organic compounds in November 1985, it has been sued by both industry and environmental organizations. Environmental organizations are challenging the classification of 1,1-dichloroethylene as category II in EPA's weight-of-the-evidence classification scheme and contend that that there should be zero concentration levels for RMCLS for carcinogens regardless of the weight of the evidence.

The Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act was originally passed by Congress in 1947. This act was replaced by the Federal Environmental Pesticide Control Act (FEPCA) of 1972, although the name FIFRA continues to be used. Central to regulating the sale, shipment, and delivery of pesticides is a registration system: generally, it is unlawful to sell or distribute a pesticide which is not registered with EPA (7 U.S.C. 136j(a)(l)(a)).

Registration of New Pesticides.—An applicant for registration of a pesticide must file certain required information, including a statement of all claims made for the pesticide, directions for its use, a description of tests made upon it, and the test results used to support claims made for the substance with EPA (7 U.S.C. 136a(c) (l)(a-d)). Most important for this report is that an applicant must supply appropriate health and safety data for each pesticide.

In a typical registration procedure a prospective registrant, typically the pesticide manufacturer, submits an application for a registration. If a registration package contains all required material it goes on for an evaluation of toxicity studies, wildlife data, exposure information, etc. At the same time, if appropriate, the agency considers residue data for purposes of setting food-safety tolerances as required under sections 408 and 409 of FDCA (described below).

FIFRA requires that EPA "shall register" a pesticide if its composition warrants the proposed claims for it, and its labeling and other required material comply with the requirements of the Act (meaning "it will per-

form its intended function without unreasonable adverse effects on the environment, " and "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment" (7 U.S.C. 136a(c)(5))). "Unreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" (7 U. S. C.136(bb)). The agency may refuse to register a pesticide after giving the applicant notification of this intention and opportunity to correct the deficiencies in the application (7 U.S. C. 136a(c)(6)).

If EPA finds that a pesticide meets or exceeds any of several criteria for risk specified by EPA which includes carcinogenicity (40 CFR 154.7), it must initiate the special review process. During the special review, the risks and benefits of the pesticide are considered and public comments received. Unless the manufacturer can show EPA is wrong, or that exposures would not be significant, proceedings are initiated to deny, cancel, or modify the registration of the pesticide.

A pesticide may be registered for general use or restricted use. If a chemical will not "generally cause unreasonable adverse effects on the environment, [EPA] will classify" it for general use (7 U.S.C. 136a(d)(l)(b)). If it "may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injuries to the applicator, [EPA] shall classify" it for restricted use (7 U.S.C. 136a(d) (1)(c)). Nearly all pesticides are registered for particular uses, such as for particular crops (328). If a registrant desires to sell a product for a use not permitted by the registration, then he or she must submit it for agency approval and registration for that different use. If the agency classifies a pesticide for restricted use because "the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, " then it shall be applied only by or under the direct supervision of a certified applicator (7 U.S.C. 136a(d)(l)(c)(i)). The States have the authority to certify pesticide applicators (7 U.S.C. 136b(a) (2)).

In registering a pesticide for use, EPA's approval requires the granting of a residue tolerance if pesticide residues are expected to remain on a raw foodstuff, or to issue an exemption from the tolerance requirement if appropriate. The setting of a tolerance is required by section 408 of the Food, Drug, and Cosmetic Act. Sections 408 and 402(a)(2)(b) of FDCA forbid the distribution of raw or processed foods bearing pesticide residues that have not been sanctioned by EPA (21 U.S.C. 342(a)(2), 346a(a)). Unlike the Delaney clause of section 409 of FDCA (concerning food additives), residues of pesticides used on foodstuffs are not precluded even when they induce cancer in laboratory animals (127). However, EPA must determine the quantity of a pesticide that may remain on a raw commodity when it enters commerce and must set an appropriate tolerance for the substance (21 U.S. C. 346a(a)). In setting a tolerance, the agency must take into account the necessity for an "adequate, wholesome, and economical food supply, " other ways consumers may be affected by the same or other chemicals, and the opinion of the Secretary of Agriculture, "submitted with a certification of the usefulness" of the pesticide (21 U.S.C. 346a(a)).

EPA also must set tolerances for pesticide residues in processed agricultural products, such as grain flours or processed vegetable or fruit products, under section 409 of the Food, Drug, and Cosmetic Act. A pesticide residue becomes a "food additive" and thus may be subject to the Delaney clause, if the processing increases the residue concentration levels in the processed food above the tolerance established for the raw commodity (21 U.S. C. 342(a)(2)(c)). If the concentration after processing remains below that established for the raw commodity, the Delaney clause does not apply (127). EPA sets the pesticide residue limits, and FDA monitors and enforces the regulations.

When Congress amended FIFRA in 1978, it permitted "conditional registration" of a pesticide, even though some of the test data may not have been submitted to or evaluated by EPA. The Agency may conditionally register pesticides if "insufficient time has elapsed since the imposition of the data requirements for those data to have been developed, use of the pesticide product(s) containing the new active ingredient during the conditional period would not cause any unreasonable adverse effects, and conditional registration of the pesticide product and its uses are in the public interest" (203). Even though Congress intended conditional registrations to be "rarely exercised, " EPA conditionally registered about half the pesticides submitted between 1978 and 1984 (203).

Pesticides contain both "active" and "inert" ingredients. Active ingredients are the components in pesticides that prevent, destroy, repel, or mitigate any pest, or disrupt the normal biological functioning of certain organisms such as insects, fungi, and plants (21 U.S.C. 136(a) (l-4)). An inert ingredient is one that is not active in this sense. Typically inert ingredients are used to dilute or deliver the active ingredients.

In the past most regulatory attention in registration has been focused on active ingredients, for they are typically the ones that damage pests or plants. However, there has been increasing concern about inert ingredients because they may have dangerous health effects (2). Problems with inert ingredients are described

in chapter 3. EPA issued a policy statement for regulating inert ingredients on April 22, 1987 (295). EPA intends to encourage the use of the least toxic inert ingredients, require data to determine the conditions of safe use of particular inerts, require labeling, and hold hearings to determine if the use of certain inerts should continue.

Special Reviews, Cancellation, Suspension of Registered Pesticides.—In addition to the cancellation provisions of FIFRA, section 6, once a substance has been registered, if data indicate that it may present an acute toxicity or a chronic toxicity hazard, including oncogenicity, or if it lacks an emergency procedure in case of exposure, EPA may announce a "special review" ***(40*** CFR ***154.11*** (a)(3)). Until 1983 these had been known as "rebuttable presumptions against registration (RPAR)" (2). Unless the data on which the special review is based are shown to be unreliable or invalid, or the estimated benefits of continued uses (possibly with additional restriction) outweigh the estimated risks, the pesticides are candidates for cancellation or suspension of their registration ***(360).***

Reregistration of Pesticides Registered Prior to 1972.–When FIFRA was amended in 1972, a number of pesticides were in use that had neither been registered under the new statute nor subjected to more stringent data requirements. Congress required a review of all substances then registered, to reassess the safety of those pesticides. The "reregistration" was intially to be completed by 1976, but in ***1975*** Congress extended that deadline to ***1977,*** and in ***1978*** dropped the deadline completely because of the large number of substances outstanding ***(203).*** EPA has identified some ***600*** active ingredients that are used in a large majority of pesticides, but only a small fraction of these have adequate health and safety data for reregistration purposes ***(2).*** Reregistration involves a number of steps described in chapter 3.

Significant Judicial Decisions.—The courts have heard a substantial number of cases concerning EPA's regulation of pesticides under FIFRA. Many of these may be summarized by saying that in general the courts have shown considerable deference to EPA's action, since it has considerable discretion to act under FIFRA (53,54). In particular, several court decisions have held that the burden of proof to establish the safety of a product remains at all times on the applicant and registrant of a product (53,54). Furthermore, a registrant must show that the benefits from a product outweigh risks, once the agency has identified risk to human health or the environment (54). Sometimes the courts have upheld the agency in refusing to suspend a substance (DDT) known to cause cancer in animals and "various injuries in man" (54), and sometimes they have upheld agency action (banning aldrin and dieldrin) on the basis of animal test results showing the substances caused cancer in several strains of mice and rats ***(52).*** In addition, the courts upheld the agency when it ordered suspension of 2,4,5-T and Silvex based upon "inconclusive but suggestive evidence" that the pesticides caused a statistically significant increase in spontaneous abortions in women exposed to them ***(44).*** Finally, the court upheld EPA's reliance on "cancer principles" concerning use of animal tests, extrapolation from animals to humans, the presumption that there is no safe level for carcinogens, and use of both benign and malignant tumors in animal studies in determining cancer hazards to humans. The court noted that industry's scientific disagreement with these principles was not sufficient to rebut them (53).

The Toxic Substances Control Act

TSCA was enacted in ***1976,*** and allows for the regulation of chemicals in commerce as well as before they ***even*** enter commerce. In TSCA, Congress set the policy that:

- chemical manufacturers and processors are responsible for developing data about the health and environmental effects of their chemicals;
- the government regulate chemical substances which pose an unreasonable risk of injury to health or the environment and act promptly on substances that pose imminent hazards; and
- regulatory efforts not unduly impede industrial innovation ***(15*** U.S.C. 2601(b)).

Unlike some other statutes, which are aimed at regulating exposures to toxic substances through specific media, such as water or air, TSCA is directed toward hazardous substances wherever they occur. Section 4 singles out for special concern substances which present or will present significant risks of cancer, genetic mutations, or birth defects. Under TSCA, EPA must review data on "new" chemicals prior to their large-scale manufacture (sec. 5), may restrict or even ban uses of new or existing chemicals (sees. 5, 6, and 7), may require manufacturers to conduct toxicity tests (sees. 4 and 5), and may impose certain record keeping and reporting requirements (sec. 8).

TSCA permits EPA to do two important tasks in regulating new or existing toxic substances:

1. require testing of new or existing chemicals; and
2. restrict production and use of, or even ban, substances posing "unreasonable risks" to health or the environment.

The treatment of new and existing substances is somewhat different (as described below) and generates somewhat different pressures on the Agency.

TSCA is directed at chemical substances. Thus a number of substances are excluded from TSCA regu-

lation, including pesticides when they are used as pesticides; tobacco and tobacco products; nuclear materials; foods, drugs, and cosmetics; and pistols, firearms, revolvers, shells, and cartridges (15 U.S.C. 2602).

Section 8 requires EPA to compile an "inventory of chemical substances" containing all chemicals subject to the provisions of TSCA manufactured or imported into the United States (15 U.S. C. 2607(b)). The initial inventory was published on June ***30, 1979,*** and all chemicals that did not appear on that list and that are not exempted from TSCA are considered "new" chemicals. The treatment of "new" and "existing" chemicals on the inventory is somewhat different, although for both types EPA has broad authority to review available information, require testing, and regulate production and use.

The major criteria for EPA decisions under TSCA is whether use of a substance **1)** presents an unreasonable risk to health or the environment or 2) may present such a risk. In deciding whether a substance poses an unreasonable risk to health or the environment, the agency must take into account:

- "the effects of such substance or mixture on health and the magnitude of the exposure of human beings" to it;
- Ž "the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance of mixture";
- "the benefits of such substance or mixture for various uses and the availability of substitutes for such uses"; and
- "the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health" (15 U.S.C. 2606(c)).

It is not clear that the test of "unreasonable risk," however, is an explicit cost-benefit analysis, for at least one major committee, the House Committee on Interstate and Foreign Commerce, indicated that assessing the reasonableness of the risk does not require a quantitative cost-benefit analysis (212).

New Chemicals.—In general, anyone who intends to manufacture a "new" chemical must notify EPA of his or her intention 90 days before manufacture is to begin. The company must submit a "remanufacture notice" (PMN) which contains information about chemical identity, proposed uses of the chemical, the expected production volumes of the chemical for the various uses, expected byproducts, estimates of the numbers of people likely to be exposed in manufacture of the chemical, and methods for disposal (15 U.S.C. 2604(d) (1)(a), 2807(a)(2)). The PMN must also include information on any toxicity testing that the company has performed, although TSCA does not require that any testing be done prior to submission of a PMN.

EPA has 90 days to review the PMN, although this period may be extended for an additional 90 days. EPA's review can result in any of four actions:

1. the substance maybe manufactured without restriction;
2. the substance maybe manufactured for uses described on the PMN, but the agency can require that it be notified if any significant new use is considered (15 U.S.C. 2604(a)(2));
3. the manufacture, processing, use, distribution, or disposal of the new substance may be regulated pending the development of additional information about it (15 U.S.C. 2604(e)); or
4. the manufacture, etc. of it may be regulated because it presents or will present an unreasonable risk (15 U.S.C. 2604(f)) (222).

In the PMN process, often the mere threat that EPA might require additional testing or some kind of restrictive action is sufficient to cause a manufacturer to remove a substance from consideration or to agree to the proposed restrictions.

In addition, TSCA (sec. 6) gives EPA broad authority (for either new or existing substances) to regulate the manufacture, processing, distribution in commerce, use, or disposal of a toxic chemical. If the agency finds that "there is a reasonable basis to conclude" that any of these activities, alone or in combination, "presents or will present an unreasonable risk of injury to health or the environment" (15 U.S. C. 2605(a)), it may regulate the substance in a number of ways. For any substance the agency may:

- prohibit its manufacture, processing, or distribution in commerce;
- limit its amount;
- limit its uses or amounts;
- require certain labeling
- . require maintenanc, of records and monitoring;
- prohibit or regulate any manner or method of commercial use;
- Ž prohibit or regulate its disposal; or
- require manufacturers or processors to notify EPA of any unreasonable risks posed by it (15 U.S.C. 2605(a)).

Existing Chemicals.—For existing chemicals, EPA can require testing and can restrict production and use. For testing existing chemicals the statute establishes an Interagency Testing Committee to recommend substances to EPA for testing. Priority attention is to be given to substances that cause or contribute to cancer, gene mutations, or birth defects (15 U.S.C. 2603(e) l(a)). TSCA also lists a number of other factors to be considered in making testing recommendations (see ch. 4).

For substances on the list, EPA synthesizes existing exposure and hazard data to determine what data gaps must be filled. (It may also rely on section 8 record keeping and reporting provisions (described below) to get exposure information.) The aim is to try to obtain enough information to determine whether there is an "unreasonable risk" from the substance. If there is not sufficient data to make this decision, the agency can issue a regulation, using informal rulemaking, to require companies to test existing chemicals. EPA staff regard this as an inflexible and slow procedure (343).

Testing may be required when there is insufficient data and experience to determine whether a substance may present an unreasonable risk of harm to health or the environment, when testing is necessary to develop such data, and when one of two other circumstances occur: 1) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture "may present an unreasonable risk of injury to health or the environment" (15 U.S.C. 2603(a)(l)(a)(i)), or 2) the substance is or will be produced in large quantities and it will or may reasonably be anticipated to enter the environment in large quantities or there will or may reasonably be anticipated to be significant or substantial human exposure (15 U.S.C. 2603(a)(l)(b)(i)).

After receiving required test data or any other information available if EPA finds that a chemical "presents or will present an unreasonable risk of injury to health or the environment," it shall by rule require one of the actions permitted under section 6 (described above) using the least burdensome requirements consistent with preventing unreasonable risks (15 U.S.C. 2605(a)). In addition, if the agency receives information that indicates there "may be a reasonable basis to conclude" that a substance "presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects," the administrator may initiate appropriate action under sections 5, 6, or 7 of the act. Upon finding such risks from substances EPA has ***180*** days to initiate action to reduce the risks or explain why they are "not unreasonable" (15 U.S.C. 2603(f)).

For one group of substances, polychlorinated biphenyls (PCBs), the statute specifically requires EPA to issue rules to prescribe methods for their labeling and disposal (15 U.S.C. 2605(e)).

Other Provisions of TSCA. —EPA also has authority to regulate "imminent hazards, " chemicals that present an imminent and unreasonable risk of serious or widespread injury to health or the environment, and are likely to occur "before a final rule under" section 6 could protect against it (15 U.S.C. 2606(f)). The statute permits EPA to initiate a civil action in Federal District Court for seizure of such substances or for judicial relief.

The agency is required under section 8 to issue rules requiring manufacturers and processors to keep and maintain certain records, which include information on the chemical, its byproducts, the quantity manufactured, exposures, and reports of adverse effects. In addition, manufacturers must report to EPA any information "which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment" (15 U.S.C. 2607(c)).

Finally, section 9 requires that if EPA finds that an unreasonable risk from a chemical may be better prevented or reduced by another Federal agency, it shall submit to that agency a report describing the risks and activities that lead to the risks, and it shall request the other agency to examine the risks and to prevent or reduce them, if this can be done by that agency's action. The other agency must report back to EPA within ***90*** days regarding its findings concerning the risks from the referred substance (15 U.S.C. 2608).

The Resource Conservation and Recovery Act

The Resource Conservation and Recovery Act of ***1976*** provides for regulating the treatment, transportation, and disposal of hazardous waste. The cornerstone of the hazardous waste management system is the identification and listing of hazardous wastes. Hazardous waste is defined as a solid waste that may cause death ***or*** serious disease, or may present a substantial hazard to human health or the environment if it is improperly treated, stored, transported, or disposed of ***(42*** U.S.C. ***6903(5)).*** The term "solid waste" includes solid, liquid, semisolid, or contained gaseous materials from various industrial and commercial processes. The definition excludes solid or dissolved materials in domestic sewage or in irrigation return flows, industrial discharges subject to the Clean Water Act or the Atomic Energy Act, and in situ mining waste ***(42*** U.S.C. ***6903(27)).***

RCRA required EPA to develop and issue criteria for identifying the characteristics of hazardous waste and for listing hazardous waste within 18 months of the passage of the law.

Any waste which exhibits the characteristics of or which is listed as a hazardous waste is regulated under RCRA[3] ***(221).***

Under RCRA, EPA sets standards concerning recordkeeping and reporting, as well as "proper" handling and management of hazardous wastes for generators,

[3]**Any listed waste may be delisted by rulemaking procedure, upon petition from a particular generator or upon petition for a generic delisting. A waste from a particular generator maybe delisted because under individual circumstances it does not meet criteria that caused it to be listed in the first place, or the generic waste itself may be removed from RCRA lists, if EPA erred in its original listing and the waste does not meet criteria for listing.**

transporters, storers, and disposers of hazardous wastes. Generators must arrange for disposal of their wastes or shipment to a waste disposal site. Transporters must keep manifests. Transfer and disposal must be done under certain procedures. Because regulations take this form, EPA has not set specific ambient air or water standards or effluent concentrations for each hazardous substance, including carcinogens. There appears to be an assumption underlying RCRA and these regulations that once hazardous wastes are at a disposal site they will not escape into the environment—that "proper handling" will prevent escape.

EPA has decided that the defining characteristics of a hazardous waste are that it 1) pose a present or potential hazard to human health and the environment when it is improperly managed and 2) can be measured by a quick, available, standardized test method or reasonably detected by generators of solid waste through their knowledge of their waste (40 CFR 261.10). The idea is to provide a quick test to identify wastes that are capable of presenting a substantial present or potential hazard when improperly managed.

EPA has identified four characteristics of hazardous waste: ignitability, corrosivity, reactivity, and extraction procedure (EP) toxicity. Only the fourth is important for this report. EPA designated "extraction procedure" as a method of chemical analysis to be used to detect the presence of certain toxic materials in wastes (listed at ***40*** CFR 261.24) at levels greater than those indicated in the regulation. This procedure is designed to identify wastes likely to leach hazardous concentrations of toxic substances into the groundwater under improper management (289). Constituents of waste materials are to be extracted in a manner designed to mimic the leaching action that occurs in landfills, and this test is used to determine whether the waste contained any toxic contaminants identified in the National Interim Primary Drinking Water Standards under the Safe Drinking Water Act. If an extract from a representative sample of waste contains any contaminants (listed in table I at 40 CFR 261.23) in concentrations equal to or greater than those indicated in the table, it exhibits EP toxicity. A person with such material must then follow RCRA regulations for handling, transport, disposal, and record keeping. In general, substances on the EP toxicity list are regulated under this procedure only if their EP concentrations are no greater than 100 times the maximum levels set by the National Interim Primary Drinking Water Standards. EPA believes that a variety of mechanisms in the soil and water, including dilution, adsorption, and absorption, will serve to attenuate the toxicity of hazardous wastes before they reach the intakes of underground water supplies, should they be improperly disposed of and escape from a facility (289).

Some properties of solid wastes that pose a threat to health or the environment, such as carcinogenicity, are not included in characteristics for identifying hazardous wastes because EPA does not know of generally available testing protocols for these effects (221).

Substances are also subject to regulation under RCRA if they are listed as hazardous wastes or are a mixture of solid wastes and listed wastes (***42*** U.S. C. 6921(b)). A substance is "listed" if it:

- exhibits ignitability, corrosivity, reactivity, or EP toxicity;
- has been found to be toxic to humans in human or animal studies;
- is otherwise capable of causing or significantly contributing to an increase in serious illness (in which case it is designated an "acute hazardous waste"); or
- contains any toxic constituents listed in Part 261, Appendix VIII which have been shown in scientific studies to have toxic, carcinogenic, mutagenic, or teratogenic effects on human or other life forms (such waste is designated "toxic waste") (221).

In May 1980 EPA published three generic lists of wastes, based on these criteria and available scientific and technical information, which were considered to be hazardous and subject to RCRA subtitle C regulation: "1) hazardous waste from nonspecific sources (40 CFR 261.31); 2) hazardous waste from specific sources (40 CFR 261.32); and 3) discarded commercial chemical products, off-specification species, containers, and spill residues thereof (40 CFR 261.33). The discarded commercial chemical products lists is further divided into wastes designated as ***toxic wastes*** (40 CFR 261.33 (f)) and as *acutely hazardous wastes* (40 CFR 261.33 (e))" (221). These lists contain 361 commercial chemicals and 85 industrial waste processes, with others proposed as additions. Of these substances 152 are suspected carcinogens.

Either the Federal Government, or a State entity if it has a federally approved hazardous waste program, may enforce regulations issued under RCRA. In addition, there is a provision to permit citizen suits against private parties and Federal or State agencies if they are in violation of RCRA permits or regulations.

There have been no significant judicial decisions concerning the regulation of carcinogens under RCRA.

The Comprehensive Environmental Response, Compensation, and Liability Act

While the Resource Conservation and Recovery Act was prospective—designed to prevent problems from hazardous wastes in the future—the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as "Superfund," was

designed to address the problems of cleaning up existing hazardous waste sites.

These problems range from spills requiring immediate responses to hazardous waste dumps leaking into the environment and posing long-term health and environmental hazards. "Hazardous substances" includes substances specified by sections 307 and 311 of CWA, section 3001 of RCRA (42 U.S.C. 6921), section 112 of CAA, section 7 of TSCA (15 U.S. C. 2606) and any substance designated as hazardous under section 9602 of CERCLA (substances which "when released into the environment may present substantial danger to the public health or welfare or the environment . . .").

Through this definition of "hazardous substances," CERCLA establishes a list of substances which, when released in sufficient amounts, must be reported to EPA. CERCLA section 102 sets reportable quantities of hazardous substances at 1 pound, except when different reportable quantities have been set under section 311(b)(4) of the Clean Water Act, and authorizes EPA to adjust these amounts as appropriate (42 U.S.C. 9602).

Anyone in charge of an onshore or offshore facility is required to report immediately a release of more than the relevant' 'reportable quantity" of any hazardous substances to the National Response Center established under the Clean Water Act (33 U.S.C. 1251 et seq.) The National Response Center in turn must convey the information 'expeditiously" to appropriate Federal and State agencies (42 U.S.C. 9603(a)). The site then becomes a candidate for cleanup action.

CERCLA provides EPA with "broad authority for achieving cleanup at hazardous waste sites" (173) and paying for the cleanup out of the Act's "Hazardous Substances Response Fund," financed jointly by industry and the government (Superfund), or forcing others "to do the cleanup by requesting an injunction in court or by itself issuing an administrative order" (14). This report considers only the the provisions affecting Federal regulation of carcinogens, not the many controversies surrounding the funding or administration of Superfund.

CERCLA section 105 requires EPA to establish procedures, standards, and criteria "for both EPA and private parties for responding to releases of hazardous waste and for cleaning up waste sites" (43). The basic design is contained in the EPA-issued "National Contingency Plan." This is based on a 5-step remedial response process:

1. site discovery or notification;
2. preliminary assessment and site inspection;
3. establishment of priorities for remedial action using a scoring process (the Hazard Ranking System (HRS)) for identifying sites to be included in the National Priorities List (NPL);
4. remedial investigation and feasibility study;
5. remedial design and construction (327).

HRS prescribes the method to be used to evaluate the relative potential of uncontrolled hazardous substance facilities to cause health or safety problems, or ecological or environmental damage. HRS is in part used to set cleanup priorities. HRS assigns scores for potential harms from migration of hazardous substances away from the site by means of groundwater, surface water or air, from explosion or fires, and from human contact. All assignments of scores must take into account "waste characteristics, " which include waste quantities, toxicity, and persistence.

Carcinogens are assigned the highest toxicity scores, meaning they are among the most toxic substances according to the ranking system, and many of them tend to be judged quite persistent, thus less likely to biodegrade in the environment, according to the system (40 CFR 300, App, A, pp. 710-712). EPA has developed a quantitative system for deciding the reportable quantities of carcinogens based on the quality of evidence for the carcinogenicity of a substance and its potency. This procedure is described in chapter 4 under "Agency Actions."

Once a site has been identified for cleanup the appropriate agency (a Federal or State governmental entity or private party) must investigate the site and then remedy the problem. In studying the feasibility of cleanup, rather than proposing some target standards to answer the question, "How clean is clean?" EPA recommended that the lead agency consider at least five alternative cleanup strategies:

1. an alternative that considers treatment or disposal at an off-site facility, i.e., removal of the problem wastes;
2. an alternative that attains applicable or relevant Federal or State environmental and health standards;
3. an alternative that exceeds such standards;
4. an alternative that does not attain applicable or relevant standards, but will "reduce the likelihood of present or future threats to public health;" and
5. a no-action alternative (327).

The selection of remedy, however, is being reevaluated in light of the 1986 Superfund Amendments and Reauthorization Act (SARA), section 121, which requires that the degree of cleanup at superfund sites "assures the protection of human health and the environment" and achieves compliance with standards established under other Federal and State environmental laws. Other sections of SARA are discussed in chapter 3.