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Board on Environmental Studies and Toxicology

Commission on Life Sciences

National Research Council

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NOTICE: A program initiative designed to lead to a funded project on this topic also led to the development of this report. The initiative was approved by the National Research Council Funds Committee, whose members are the Presidents of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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FOREWORD

On May 22, 1985, the National Research Council conducted a workshop to identify the central issues in environmental law, regulation, and management for assessments of current scientific understanding are needed. The workshop focussed on the extent of environmental contamination by potentially hazardous chemicals, whether introduced into the environment deliberately, such as pesticides, or accidentally, as with leachates from hazardous waste disposal sites. A number of topics were identified by the workshop participants for which the National Research Council could provide valuable and unique contributions to the development of public policy on environmental affairs.

One of the conclusions emerging from the workshop was that there is much to be learned by examining the various roles that scientific information has played in regulatory programs dealing with hazardous chemicals in different countries. It was recommended that the Research Council undertake a study to catalog the means by which scientific information is acquired and integrated into decision making for managing environmental risks, to examine the factors that affect the efficacy and acceptance of these procedures both here and abroad, and to assess the mechanisms in terms of their potential for improving the process of risk assessment and risk management in the United States.

In response, the Research Council allocated program initiation funds for a cross-national comparison of approaches to and regulation of chemical hazards which was conducted by Rob Coppock during his tenure as a National Research Council Fellow. Dr. Coppock spent the previous eight years in West Germany at the Science Center Berlin conducting research on regulatory programs in various countries, and brought considerable experience and expertise to the project. The comparison of

approaches in different countries is of considerable interest, not only to the Board on Environmental Studies and Toxicology, but also to other units of the Research Council, as well as governmental agencies and private organizations.

This report is unusual in that it was authored by an individual not by an official study committee whose members were selected by the Research Council for their expertise in various fields. While the views expressed here do not necessarily reflect those of the Research Council or any of its units, the report does reflect Dr. Coppock's scholarly research and draws its conclusions and recommendations from it.

Donald Hornig, Chairman
Board on Environmental
Studies and Toxicology

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In conducting this examination of approaches to chemical regulations in several countries and the European Community, I have benefited from the support and advice of many individuals and organizations. The report is based on interviews conducted and materials collected during my tenure as a National Research Council Fellow, working with the Board on Environmental Studies and Toxicology. Special thanks go to Susan W. Sherman, coordinator of that fellowship program, and to Devra Lee Davis, Acting Director of the Board on Environmental Studies and Toxicology, for the opportunity to pursue this topic. Financial support was provided by the Andrew W. Mellon Foundation, which funded the fellowship program, and by the National Research Council's program initiation funds, without whose combined support this project would not have been undertaken.

The report benefited greatly from comments provided by several reviewers. Chris McShane performed the invaluable service of editing the report. Finally, I would also like to thank my colleagues, especially John Schultz and Mike McGeary, for their time and comments throughout the process.

Rob Coppock

INTRODUCTION

The 1984 tragedy in Bhopal, India, in which more than 2,000 people died as a result of an accidental release of industrial chemicals into the atmosphere, and the subsequent releases in the Kanawha Valley in West Virginia have given a sense of urgency to the effort to examine the adequacy of controls on hazards associated with chemical production in this country. But even before these events occurred, many have been concerned that some of our regulations of toxic chemicals are ineffective in that they do not achieve the degree of safety they are intended to bring about, at the same time that they unnecessarily interfere with commercial activity.

Interest in improving the regulation of chemicals is not limited to this country. In West Germany, a major new administrative ordinance has been proposed that combines under one statutory instrument many aspects of the control of dangerous chemicals. In addition, a new bill has been proposed covering pesticide and herbicide use that would mandate more extensive consideration of human health and environmental impact in the authorization of new agricultural products. In the United Kingdom, major revisions are being made in the way exposure levels to workplace chemicals are determined, and the existing voluntary scheme for pesticide registration is being replaced by legislation.

The growth of governmental involvement in the regulation of hazardous chemicals in most industrialized countries can be traced to three factors. First, tens of thousands of chemicals are now in use and have become indispensable components of modern manufacturing, agriculture, and commerce, and hundreds of new chemical

products are being added to commerce each year. Second, matching this rapid expansion of chemical technology, especially since World War II, have been improvements in the ability to detect chemicals at lower and lower concentrations. These improvements in detection capability have been accompanied by the development of new methods to evaluate the potential consequences for human health of exposure to chemicals. Third, there has been an increase in public concern about what is often called the quality of life, especially (but not limited to) health hazards and environmental quality. The public appears to exhibit something like a lower tolerance for such hazards than in the past. The confluence of these developments has resulted in tremendous expansion in government regulation of chemical hazards in most industrialized countries.

Faced with common problems involving the identification and assessment of potential chemical hazards, governments in industrialized countries have developed control programs that draw on the procedural and regulatory tools available to them. Without doubt, there has been a certain amount of interaction among countries: those formulating laws and regulations look abroad to see what problems others are confronting and how other countries are dealing with those problems. For example, the so-called Sixth Amendment, which established testing procedures for chemicals prior to marketing within the European Community, was clearly formulated in response to the U.S. Toxic Substances Control Act.[1] The selection of a different, step-wise approach to the same problem by the European Community, however, is an example of the many differences found in various regulatory programs and suggests that each country's choices are conditioned by preexisting political institutions, administrative practices, legal traditions, relationships between science and government, interest group politics, and other factors.

Both similarities and differences can be observed in chemical regulatory programs among countries. For example, one study found that, despite pronounced differences in the strength of business and labor in the United States and Sweden, agency regulatory decisions about labor safety in the two countries were quite similar.[2]

A study of the regulation of carcinogens in the United States, West Germany, France, and the United Kingdom found that all four countries had regulated virtually the same chemicals, and that there was no consistent pattern of variation in the stringency of the regulatory actions taken.[3] An earlier study describes how in the United States two pesticides, aldrin and dieldrin, were judged to be carcinogenic and banned, but in Britain were evaluated differently and allowed continued commercial use.[4]

Even though there is an obvious transfer of knowledge and concern among countries, it is clearly naive to expect the laws and regulations of one country to be of direct applicability to the political system of another. Another way of saying this is that the approaches and mechanisms of regulation are neither dictated by the nature of the regulatory task nor randomly determined. Even though given regulatory programs are conditioned by preexisting political, administrative, legal, and other relationships, it is possible to suggest insights about a given system by comparing and contrasting it with the approaches and methods used in other political and administrative systems. The principal working hypothesis of this report is that the political and administrative traditions of a country are important in the approach taken to the control of chemical hazard.

This report examines the varying approaches of selected countries to the regulation of chemical hazards. However, the material presented includes neither a systematic characterization of relevant procedures nor sufficient detail to enable conclusions to be drawn concerning the value of any particular approach for policy concerns in this country. This is principally because information about program definition, implementation, and enforcement were beyond the scope of this report.

A broad range of approaches to the control of chemical hazards are described. Although the principal focus is on governmental regulatory programs, voluntary industry programs are included where appropriate. It describes the approaches used by each country, in part so as to explicitly reveal the coverage of particular

classes of hazards by the various programs. The focus of the examination is complex and best described in terms of three separate but interactive elements: functional coverage, regulatory instruments, and historical context.

The first element is called the "functional coverage" of the program. It is reflected in the program categories described for each country: framework legislation, industrial plant, emissions and discharges, worker protection, industrial substances, poisons, agricultural chemicals, food additives and contaminants, consumer products, transport, chemical wastes, and victim compensation.[5] Although any such categorization will exhibit certain weaknesses, this list is based on previous work by the European Office of the World Health Organization. It is intended to include any regulation dealing with chemical hazards during production, transport, use, or disposal.

The second element is called the "regulatory instruments." This refers to the specification of the purposes and aims of the program, the procedures for data collection and analysis, and the selection, execution, and enforcement of intervention or other mechanisms of control. In some countries, the regulatory instruments are usually specified in laws or other statutory instruments; in other countries, they are specified in administrative ordinances or orders. Although it is beyond the scope of this report to spell out the regulatory instruments in every instance, the relevant regulatory instruments are identified with respect to each category of functional coverage. Taken together, then, functional coverage of the various regulatory programs and the respective regulatory instruments determine the administrative jurisdiction over chemical hazards that are found in each country.

The third element, called the "historical context," which helps establish the constraints within which regulatory programs operate. Another way of thinking of this element is in terms of the political and administrative traditions that influence expectations about responsibility to respond to particular kinds of situations, the jurisdictional strengths and weaknesses of

various parts of government and related institutions, and the power relationships among government, business, labor unions, and other relevant groups.

The literature directly addressing approaches to the regulation of chemical hazards in various countries is suprisingly sparse. Several studies have examined regulatory policies with respect to chemical control of specific industrial sectors or certain classes of chemical use; however, they have usually either compared the policies of only two countries[6] or have examined a limited set of hazards.[7] A few studies have examined chemical laws and regulations in several countries, but they address different questions in a way that is inappropriate for exploring the applicability of given approaches across countries.[8] The Chemical Products Division of the Organization for Economic Cooperation and Development (OECD) in Paris has prepared several reports on various aspects of the regulation of chemicals;[9] however, they tend to examine specific regulatory instruments, rather than the full range of chemical hazards addressed in this report. In short, although there is some literature relevant to various aspects of the question, no study directly addresses the value of examining cross-national studies to illuminate domestic issues with respect to the full range of regulations about chemical hazards. Accordingly, this report addresses the question on the basis of a review of relevant literature and discussions with government officials and other experts in Japan, West Germany, France, the United Kingdom, and the European Community.

These countries were selected because, taken together, they illustrate a variety of relevant cultural and political contexts within which chemical hazards are regulated. For example, the British doctrine of the sovereignty of Parliament contrasts with the French doctrine that democracy implies a national assembly expressing the will of the people; and both contrast with the German constitutional state, which limits the sovereignty of all institutions in the name of human rights. At the same time, these countries also represent considerable diversity in their administration of laws and regulations. For example, the Japanese practice of "administrative guidance" (gyōsei shidō), in

which informal but effective pressure is exerted on the private sector to comply with government directives, has received considerable attention in recent years. Another interesting but less well-known administrative practice is the West German Ministry of Labor's adoption without alteration of workplace exposure limits developed by an independent commission of scientists, and the resulting ease with which acceptable exposure limits can be adjusted as new information becomes available. The governments of these four countries, together with the Commission of the European Communities (which establishes regulations that must be incorporated into the laws of its member states), present sufficient variety in context and in implementation to enable the value of studying the various approaches to regulation and their meaning for this country to be adequately assessed.

The chapters that follow address each country separately. Each chapter begins with a characterization of relevant political and administrative traditions of the country (the historical context). This is followed by a compilation of the major laws and regulations (regulatory instruments) according to the following categories (functional coverage): framework laws, industrial plant, emissions and discharges, worker protection, industrial substances, poisons, agricultural chemicals, food additives and contaminants, consumer products, transport, chemical wastes, and victim compensation. The final section of each chapter reviews current developments with respect to the regulation of chemical hazards.

On the basis of this descriptive material, a framework for further investigation is presented in Chapter 7. It identifies four lines of potentially fruitful research involving comparative analysis of programs for the control of chemical hazards and encourages research in these areas.

NOTES

1. George B. Wilkinson, "The Sixth Amendment: Toxic Substance Control in the EEC," Law & Policy in International Business 12/46 (1980) 461-501.

2. Steven Kelman, Regulating America, Regulating Sweden: A Comparative Study of Occupational Safety and Health Policy (Cambridge, MA: MIT Press, 1981).

3. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83-206771, 1984).

4. Brendan Gillespie, Dave Eva, and Ron Johnston, "Carcinogenic Risk Assessment in the United States and Great Britain: The Case of Aldrin/Dieldrin," Social Studies of Science 9 (1979) 265-301.

5. These categories have been adapted from work performed by the European Office of the World Health Organization. See World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen, World Health Organization Regional Office for Europe, 1984).

6. See, for example, Lennart J. Lundqvist, The Hare and the Tortoise: Clean Air Policies in the United States and Sweden (Ann Arbor: University of Michigan Press, 1980); Steven Kelman, Regulating America, Regulating Sweden: A Comparative Study of Occupational Safety and Health Policy (Cambridge, MA: MIT Press, 1981); Brendan Gillespie, Dave Eva, and Ron Johnston, "Carcinogenic Risk Assessment in the United States and Great Britain: The Case of Aldrin/Dieldrin," Social Studies of Science 9 (1979) 265-301; and Rob Coppock, "Interactions Between Scientists and Public Officials: A Comparison of the Use of Science in Regulatory Programs in the United States and West Germany" Policy Sciences 18 (1985) (371-390).

7. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83-206771, 1982); William M. Wardell (ed.), Controlling the Use of Therapeutic Drugs: An International Comparison

(Washington, D.C.: American Enterprise Institute, 1978); Jerome E. Schnee, "International Shifts in Innovative Activity: The Case of Pharmaceuticals," Columbia Journal of World Business 13 (1978) 112-122.

8. See, for example, Sam Gussman, Conrad von Moltke, and Cynthia Whitehead, Public Policy for Chemicals: National and International Issues (Washington, D.C., The Conservation Foundation, 1980).

9. See, for example, Environment Directorate, Selected Approaches to Data Integration in Assessments of Chemicals (ENV/CHEM/CM/84.14) (Paris: Organization for Economic Cooperation and Development, 1984); Environment Directorate, Administrative and Legislative Aspects of Chemicals Control: Comparative Analysis of Selected Issues (Paris: Organization for Economic Cooperation and Development, 1985); and Environment Directorate, A Review of the Implementation of Two Council Acts on Chemicals (ENV/CHEM/CM/85.13) (Paris: Organization for Economic Cooperation and Development, 1985).

2

JAPAN

POLITICAL AND ADMINISTRATIVE TRADITIONS

To understand the strengths and weaknesses of controls on chemical hazards in Japan, it is necessary to be aware of the historically dominant influence of the bureaucracy in Japanese society.[1] During the nineteenth century, the bureaucracy served as the representative and protector of the imperial rule. Between the promulgation of the Meiji Constitution of 1890 and World War II, the bureaucracy possessed independent legislative powers in the name of the Emperor that were equivalent to parliamentary powers. Until 1918, all members of the cabinet were drawn from the bureaucracy rather than from political parties.[2]

The bureaucracy accordingly possessed the status of an elite class. Government service often enabled high-ranking officials to become wealthy. Virtually all were trained in the prestigious imperial universities, especially Tokyo University. Bureaucrats enjoyed considerable career mobility and respect. They viewed the rest of society with considerable disdain; the maxim, "Officials honored, the people despised" (kanson minpi), epitomized the prevailing attitude.[3]

Following World War II, the authorities of the Supreme Commander of the Allied Powers attempted to eliminate what were considered to be the more undesirable attributes of the prewar bureaucratic system. Key wartime officials were removed, and the bureaucracy as a whole was stripped of many of its symbolic perquisites, such as special decorations and higher pay. Despite these efforts, however, the basic prewar pattern persisted, in part due to the fact that, while the authorities of the occupation removed the apex of the bureau-

cratic hierarchy, the base and the middle were left undisturbed. Perhaps more important, patterns of recruitment, promotion, and retirement still correspond to those of the prewar period. The importance of the bureaucracy is illustrated by former Prime Minister Tanaka's observation that to accomplish something in Japan, you must direct 20 percent of your energies at the legislature and 80 percent at the ministry officials.

Two aspects of the dominant position of the bureaucracy have important consequences for programs controlling chemical hazards. First is the virtual monopoly of the bureaucracy over the legislative process. The success rates of government-sponsored and individual member bills, the declining rate of amendments, and the lack of success of opposition-sponsored bills support this thesis.[4] Second is the importance of ministerial jurisdiction. Historically, broad statutory mandates stimulated loyalty, pride, and solidarity within the ministries--but it also led to bureaucratic territorialism that impeded interministerial collaboration. The strong influence exercised by the bureaucracy and its protection of its jurisdictions have strongly influenced the approaches taken by Japan to the control of chemical hazards.

Conflicts over jurisdiction are usually resolved through development of consensus, and the number of people involved generally indicates the importance of the issue. Consensus can be built in many ways, including informal (often protracted) consultation, formal meetings, and the ringi system, in which documents drafted at lower levels of an organization are circulated to various superior units for approval before formal submission.

All administrative actions must of course have some statutory basis. Japanese legal scholars generally divide administrative actions into two types: official actions that must correspond strictly to the law, with nothing left to discretion; and discretionary forms of administrative action. The greater part of decisions are based on negotiation, discussion, and consultation. This informal, nonauthoritative process of inducing industry cooperation and compliance is commonly called administrative guidance. It may take the form of direc-

tions, requests, warnings, suggestions, or simply encouragement. Although these actions often resemble legally sanctioned directives, administrative guidance ultimately has no legal force.

The real force of administrative guidance lies in the traditional relationship between government and industry. It was government, not the private sector, that developed the railways, ports, roads, and urban services. The rapid industrialization of Japan during the last 100 years was accomplished through the cooperation of the government and the large commercial combines (zaibatsu). Bureaucratic conduct toward small and medium enterprises, however, was considerably more domineering than in the process of administrative guidance directed toward larger entities.

Despite the emphasis on consensus, there can be considerable differences of opinion concerning controls on chemical hazards. Although consensus on the overall aims of control programs may be achieved, there is often disagreement about the best way to achieve those aims. The reliance on consensus combines with jealously guarded administrative jurisdictions to create a situation in which ministries are both constrained by other ministries and given the opportunity to exert influence over them. For example, the powerful Ministry for International Trade and Industry (MITI) and the Ministry for Health and Welfare (MHW) have both been wary of giving up their areas of jurisdiction to the relatively weak Environment Agency, which is a relative newcomer. Thus, it is a committee within MITI, whose principal responsibility is for industrial structure and development, that determines whether a particular substance will be restricted in terms of production or use. At the same time, the Environment Agency has been able to influence other ministries because it is consulted by those ministries during thier consensus-building. Thus, its influence is greater than the size and prestige of the Environment Agency alone would suggest.

The jurisdiction for control of chemical hazards in Japan can be most easily understood in terms of these political and administrative traditions. Although Japan is the only country studied with a general framework

legislation providing a basis for overall environmental regulations, the actual statutory responsibilities reflect the traditional patterns of jurisdiction among the ministries existing at the time of the creation of the Environment Agency. The implementation of health and environmental controls thus requires careful consultation and negotiation among numerous governmental organizations as well as the major actors in the private sector.

THE PATTERN OF ADMINISTRATIVE JURISDICTION

The first efforts to introduce regulatory legislation occurred in the early 1950s at the initiative of bureaucrats within the Ministry of Health and Welfare. It was blocked by various interests, however. In 1958 a comparatively weak national law to control water pollution was enacted. The first major legislation, the Basic Law for Environmental Pollution Control, was passed by the legislature in 1967. In 1969 the Law to Compensate Pollution-Related Health Damage was enacted, and then, in November and December 1970 during the 64th Extraordinary Diet Session, 14 bills related to environmental pollution were passed.[5]

The apparent comprehensiveness of this legislation can be misleading. For example, the Chemical Substances Control Law, often compared with the Toxic Substances Control Act in the United States, applies only to chronic effects resulting from environmental exposures (and, although not explicitly so, effectively only exposures involving the food chain). Similarly, the Industrial Safety and Health Law excludes from coverage all chemicals that are not carcinogens. Direct exposures and acute effects are covered under the Poisonous and Deleterious Substances Control Law and the Pharmaceuticals Affairs Law. One explanation for this diffusion of responsibility among several ministries is that the latter laws existed long before the environmental laws were formulated and were administered by the relatively powerful Ministry of Health and Welfare, which successfully defended its bureaucratic territory as new regulatory responsibilities were defined.

The following review of the major laws governing the control of chemical hazards in Japan thus attempts to describe the most important areas of substantive responsibility and the corresponding organizational jurisdiction.

Framework Laws. In 1965 the Pollution Control Council was established in the Ministry of Health and Welfare as a first step toward solving environmental problems.[6] After two years of study, the Basic Law for Environmental Pollution Control was enacted.[7] The law aimed at clarifying basic principles and objectives, provided for coordination among relevant parts of government, and set out many of the specific topics to be dealt with.[8] It provided for the establishment of Environmental Pollution Control Councils in each prefecture and a central Conference on Environmental Pollution Control in the office of the prime minister. One result has been that local government administrators have been very active in the response to environmental pollution.

The Industrial Plant. Since 1965, MITI has been conducting comprehensive preliminary surveys into industrial air and water pollution from designated intensive development areas and proposed large-scale industrial complexes under the Factory Location Law.[9] For newly proposed industrial areas, the surveys are based on the development plans of the local authority. Results of the preliminary surveys are used by local authorities to guide development of industrial land, the type and scale of industries to be introduced, and the location of factory sites.

Emissions and Discharges. The importance of the Basic Law for Environmental Pollution Control has already been described. Other important laws include the Air Pollution Control Law, the Water Pollution Control Law, the Noise Regulation Law, the Vibration Regulation Law, the Offensive Odor Control Law, the Law on Prevention of Marine Pollution and Maritime Disaster, the Industrial Water Law, and the Wastes Disposal and Public Cleansing Law. These are all administered by the Environment Agency. One older statute, the Sewage Law, is administered by the Ministry of Construction.

The Air Pollution Control Law deals with emissions of smoke, soot, etc., from factories and business establishments, establishes permissible limits for automobile exhaust gases, and provides for liability without compensation companies in the private sector that have caused damage by air pollution.[10] Article 3 authorizes the development of emission standards for sulfur oxides, soot and dust, and toxic substances. Article 5 authorizes development of a standard for total mass emission control.

The Water Pollution Control Law provides for the establishment of effluent standards (article 3), for plans at the level of the prefecture to reduce the total pollution load (article 4), for monitoring pollution levels (article 16), and for compensation for damages (article 19).[11] Of the 186,770 samples examined in 1982, 0.03 percent were found not to meet the standards for environmental quality, a substantial improvement compared with 1972.[12]

Noise and odors are two types of sensory pollution that are perhaps of greater concern in the densely populated urban areas of Japan. Odors constitute about one-quarter of all complaints about pollution.[13] The Noise Regulation Law includes provisions for factories, construction work, and motor vehicles.[14] The Offensive Odor Control Law provides for the development of appropriate standards.[15]

Worker Protection. The principal provisions for the protection of workers are found in the Industrial Safety and Health Law, the Pharmaceuticals Affairs Law, and the Poisonous and Deleterious Substances Control Law.

The Industrial Safety and Health Law stipulates that, before bringing a substance into production, the producer should investigate whether the substance is toxic or presents other potential dangers for workers and that all necessary protective measures be taken.[16] However, substances can be exempted from notification if annual production is to be less than 100 kg per factory; the substance is for testing or research or is a reagent; or an imported substance is sold directly to consumers without repackaging. Furthermore, and most

important, the ordinance implementing the law stipulates that the "investigation of toxicity shall consist of a carcinogenicity test, or other test sufficient to educe information of a level at least equal to a mutagenicity test with special reference to carcinogenicity, or a mutagenicity test."[17] This effectively restricts the applicability of the law to carcinogens, and whenever a substance is determined to be carcinogenetic, regulatory measures are invoked under the law, which is administered by the Ministry of Labor.

The Ministry of Health and Welfare is responsible for both the Poisonous and Deleterious Substances Control Law and the Pharmaceuticals Affairs Law. The former assumes a larger role than might be expected due to the definition of "deleterious" to include most toxic substances. It is described below under the section on poisons. Many substances are regulated as drugs and quasi-drugs under the Pharmaceuticals Affairs Law. Although the apparatus for this is usually not associated with the regulation of worker safety, its applicability extends to substances in these situations as well.

Industrial Substances. The Chemical Substances Control Law is the principal statute for the regulation of industrial chemicals in Japan. It applies to all manufactured or imported substances except those covered by the Foodstuffs Sanitation Law, the Agricultural Chemicals Control Law, the Fertilizers Control Law, the Pharmaceuticals Affairs Law, and the Law Concerning Safety Assurance and Quality Improvement of Feed.[18] Prior to the commencement of business, the Ministry of Health and Welfare and the Ministry of International Trade and Industry must be notified. If the substance is determined to be safe on the basis of available information concerning biodegradability, bioaccumulation, or toxicity test results, it can be freely manufactured or imported.[19] Thus, it may be seen to apply only to environmental exposures and, more particularly, to those that occur through the food chain. Test results for both new and existing commercial substances are reviewed on a case-by-case basis by the chemicals testing and judgment committee, an advisory committee under the Ministry of International Trade and Industry.

Poisons. The Ministry of Health and Welfare is responsible for the Poisonous and Deleterious Substances Control Law. It stipulates that all poisonous or deleterious substances must be registered with the relevant metropolitan, prefectural or other local government pharmaceuticals bureau, as well as the Ministry of Health and Welfare. Containers and packages must be properly labelled.[20] This law assumes a larger role than might be expected due to the definition of "deleterious" to include most toxic substances.[21]

Agricultural Chemicals. Chemicals used as herbicides, insecticides, and fungicides are regulated under the Agricultural Chemicals Control Law.[22] Products must be registered with the Ministry of Agriculture, Forestry, and Fisheries. The efficacy of the product, as well as the results of tests on its toxic or residual properties must be stated.

The Fertilizers Control Law distinguishes between common fertilizers and special fertilizers with different regulations for each category. Although licensing is not required, the manufacturer or importer must register with the Ministry of Agriculture, Forestry, and Fisheries. Fertilizers using new ingredients are required to show efficacy, the absence of toxicity, and the efficacy of additives.[23]

Chemicals intended for home use as opposed to agricultural purposes are regulated under the Pharmaceuticals Affairs Law. For example, pesticides for home use are evaluated as medicines or quasi-drugs depending on the strength of their components.[24]

Food Additives and Contaminants. Under the Food Sanitation Law, the manufacture or sale of chemical compounds for use as food additives is prohibited except when approved by the Minister of Health and Welfare.[25]

Consumer Products. The Household Products (Harmful Substances) Law provides standards for household products containing nine harmful substances.[26] Many products, such as pesticides or insecticides, are also regulated under the Pharmaceuticals Affairs Law as quasi-drugs.[27]

Transport. Packaging and handling regulations of the various laws apply to chemical products. The transport of industrial wastes is regulated under the Wastes Disposal and Public Cleansing Law (see below).

Chemical Wastes. Domestic and industrial wastes are regulated under the Wastes Disposal and Public Cleansing Law and the Law on the Prevention of Marine Pollution and Maritime Disaster. Transportation or disposal of industrial wastes by a firm must be in accordance with standards established by the Ministry of Health and Welfare and industrial waste disposal plans developed by the prefectural or municipal government.[28] For industrial wastes specified to be disposable in the sea, standards on the place and method of disposal are stipulated in the Law on the Prevention of Marine Pollution and Maritime Disaster, which is administered by the Ministry of Transportation.[29]

Victim Compensation. A unique feature of the regulatory scene in Japan is the Pollution-Related Health Damage Compensation Law, which provides for compensation for health damage due to severe air or water pollution as a result of business activity or other human activities.[30] In order to qualify, a victim must be certified by a prefectoral committee as a long-time resident of a designated pollution area and must exhibit certain medical symptoms. The exact medical criteria, which remain unpublished, have been established by a special committee advising the Environment Agency that reviews applications on a case-by-case basis.[31]

CURRENT DEVELOPMENTS

Based on the examination of the situation in several countries, the regulation of chemical hazards in Japan is judged to be surprisingly uncontroversial. Elsewhere there is considerably more dissatisfaction with existing regulatory instruments as well as active efforts to replace or improve them.

The lack of concern about chemical hazards is perhaps doubly surprising given the role that public opinion has played in the past. It was popular pressure

rather than government or business interest that led to the enactment of the environmental regulations in the late 1960s and early 1970s. This pressure mounted in response to the terrible suffering of the victims of minamata disease (attributable to methylated mercury pollution), and chronic cadmium poisoning, victims of air pollution around Yokkaichi.[32] In each case, it was finally necessary for the victims to file suit for damages, and these court cases became a cause célèbre that contributed to the public attention that brought about the legislation.

Today equal public attention and involvement is not accorded issues related to the control of hazardous chemicals, for two principal reasons. First, pollution control programs have quite successfully eliminated, or at least noticably reduced, the most noxious problems. Second, the overall regulatory strategy has been one of decentralization, with considerable powers of implementation delegated to the local level. As a result, any dissatisfaction with pollution control measures is locally constrained, and there is little incentive to develop nationwide coalitions.

The government is directed by the Basic Law to conduct surveys of the environmental conditions in Japan and to disseminate this knowledge and information to the nation.[33] The annual report on quality of the environment report of the Environment Agency reveals substantial improvements in most ambient air quality conditions.[34] The ratio of samples of water-borne pollutants exceeding the permissible standards has been reduced drastically between 1971 and 1982. For example, the ratio of samples exceeding the standard to the total number of samples taken for cadmium was 0.72 percent in 1971 and 0.07 percent in 1982, that for total mercury was 0.25 percent in 1971 and 0.06 percent in 1982.[35] In addition, the trend for the number of days on which smog alerts are issued shows a reduction of at least half between 1974 and 1984 (for the period between 1979 and 1982 this was cut even further to one-third due to favorable meteorological conditions, mostly longer than usual rainy seasons).[36]

Although such indicators are only suggestive of overall environmental pollution, they are probably especially relevant for public opinion because they describe conditions that people are able to confirm with their own senses.[37] They are aware that the incidence and severity of reports of chronic pollution victims in the news media has decreased markedly, and the decrease in photochemical smog can be perceived with their own eyes and noses. Thus, it is altogether reasonable to expect the majority of Japanese to feel that considerable progress has been made in the area of pollution control. Although the most dramatic aspects of pollution have been ameliorated, there remain considerable problems. Water pollution, for example, is still a serious problem in most of Japan's closed water bodies, such as lakes and marshes.[38] The record of progress for each of the five other officially defined areas of pollution--soil, noise, vibration, offensive odors, and ground substances--is mixed. It is of course extremely difficult to determine why such problems are not accorded the kind of public attention that they receive in other countries. It is claimed here that the difference is due, at least in part, to the decentralized implementation of pollution regulations in Japan.

Not all observers agree with the claim that the basic approach in Japan has emphasized decentralization, and that this has resulted in less controversy with respect to pollution and environmental concerns in general. It is true that instances of chemical contamination, pollution, and waste problems are reported in newspapers and elsewhere. Nevertheless, it seems that these issues have been less important in the overall public discussion and debate in Japan than in the other countries included in this report. There are some indications that this may be changing, and an interest in reformulating some aspects of the regulatory framework may emerge over the next few years.

The beginning of this chapter emphasized the importance of local government officials in the implementation of regulatory controls in different areas in Japan. Considerable powers, including improvement orders, spot inspection, and even suspension orders, are in the hands of local government.[39] The tradition of administrative

guidance allows local officials to respond flexibly to local conditions and to avoid the contradictions that would arise if laws were enforced with strict formality. The control of pollution has been effectively decentralized, thereby removing the basis for a national interest group addressing such issues. Neither pollution nor hazardous chemicals are currently the focus of public attention.

NOTES

1. This section draws heavily on: Julian Gresser, Koichiro Fujikura, and Akio Morishima, Environmental Law in Japan (Cambridge, MA: MIT Press, 1981) Chapter 5, "Formulation and Implementation of Environmental Policy: A Comparative Assessment of the Regulatory Process," 229-283.

2. Ardath W. Burks, Japan: Profile of a Postindustrial Power (Boulder, CO: Westview Press, 1981).

3. Julian Gresser, Koichiro Fujikura, and Akio Morishima, Environmental Law in Japan (Cambridge, MA: The MIT Press, 1981) 230.

4. T.J. Pempel, "The Bureaucratization of Policy-Making in Post-War Japan," American Journal of Political Science 18 (November 1974) 647.

5. Michael R. Reich, "Mobilizing for Environmental Policy in Italy and Japan," Comparative Politics (July 1984) 383.

6. For a history of environmental pollution control administration in Japan, see Environmental Control in Japan (Tokyo: Japan External Trade Organization, undated).

7. An unofficial English translation may be found in Environmental Laws and Regulations in Japan - General (Tokyo: Environment Agency Japan, 1984) 1-8.

8. For example, article 7: publication of annual report; article 9: establishment of environmental quality standards; article 10: emissions control;

article 11: control of land use and installation of facilities; article 12: projects for prevention of pollution; article 13: surveillance and monitoring systems; article 14: surveys and investigations; article, 15: development of technologies; Article 15: dissemination of knowledge and information. Environmental Laws and Regulations in Japan - General (Tokyo: Environment Agency Japan, 1984) 1-8.

9. Environmental Control in Japan (Tokyo: Japan External Trade Organization, undated) 18.

10. "Air Pollution Control Law," Environmental Laws and Regulations in Japan (II) Air (Tokyo: Environment Agency Japan, 1984) 5-25.

11. "Water Pollution Control Law," Environmental Laws and Regulations in Japan (III) Water (1) (Tokyo: Environment Agency Japan, 1984) 1-18.

12. Quality of the Environment in Japan 1984 (Tokyo: Environment Agency Japan, 1985) 9.

13. Environmental Control in Japan (Tokyo: Japan External Trade Organization, undated) 34.

14. "Noise Regulation Law," Environmental Laws and Regulations in Japan (II) Air (Tokyo: Environment Agency Japan, 1984) 89-99.

15. "Offensive Odor Control Law," Environmental Laws and Regulations in Japan (II) Air (Tokyo: Environment Agency Japan, 1984) 125-131.

16. K. Hayashida, "Japan's Requirement," (mimeographed), Tokyo: Japan Synthetic Rubber Company, p. 22.

17. Quoted in Toshio Sumida, "Regulation on Chemicals in Japan," (mimeographed), Tokyo: Sumitomo Chemical Co., p. 5.

18. The Chemical Substances Control Law in Japan (Tokyo: Ministry of International Trade and Industry, 1977) 5-6.

19. The "MITI-scheme" requires biodegradability to be tested first, measuring biological oxygen demand in a closed system with standard sewage sludge. If the substance degrades sufficiently completely and rapidly, it is given commercial clearance. Bioaccumulation is measured in fish during an 8-week test. If bioaccumulation is low, it is given clearance. If a substance does not degrade and does accumulate, in fish it is submitted to mammalian toxicity tests.

20. K. Hayashida, "Japan's Requirement," (mimeographed), Tokyo: Japan Synthetic Rubber Company, p. 5.

21. The criteria to determine toxicity used by the Central Pharmaceutical Advisory Committee of the Ministry of Health and Welfare are not published but are said to include acute toxicity from animal experiments:

	LD_{50}
Oral:	
poisonous	Not exceeding 30 mg/kg
deleterious	Above 30 mg/kg but less than 300 mg/kg
Dermal:	
poisonous	Not exceeding 100 mg/kg
deleterious	Above 100 mg/kg but less than 1,000 mg/kg
Inhalation:	
poisonous	Not exceed 200 ppm (1 hr.)
deleterious	Above 200 ppm but not exceeding 2,000 ppm (1 hr.)

22. K. Hayashida, "Japan's Requirement," (mimeographed), Tokyo: Japan Synthetic Rubber Company, p. 6.

23. K. Hayashida, "Japan's Requirement," (mimeographed), Tokyo: Japan Synthetic Rubber Company, p. 6.

24. Interview with Mr. Toru Watanabe, Pharmaceuticals and Chemicals Safety Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Tokyo, June 5, 1985.

25. K. Hayashida, "Japan's Requirement," (mimeographed), Tokyo: Japan Synthetic Rubber Company, p. 7.

26. The nine are: hydrogen chloride, vinyl chloride, formaldehyde, tris (1-aziridine) phosphine oxide, tri (2,3-dibromopropyl) phosphate, triphenyl tin compounds, dieldrin, organic mercury compounds, and sulfuric acid. K. Hayashida, "Japan's Requirement," (mimeographed), Tokyo: Japan Synthetic Rubber Company, p. 9.

27. Interview with Toru Watanabe, Pharmaceuticals and Chemicals Safety Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Tokyo, June 5, 1985.

28. "Wastes Disposal and Public Cleansing Law," Environmental Laws and Regulations in Japan (III) Water (2) (Tokyo: Environment Agency Japan, 1984) 7-9.

29. "Law on the Prevention of Marine Pollution and Maritime Disaster," Environmental Laws and Regulations in Japan (III) Water (2) (Tokyo: Environment Agency Japan, 1984) 47-106.

30. "Pollution-Related Health Damage Compensation Law," Environmental Laws and Regulations in Japan - General (Tokyo: Environment Agency Japan, 1984) 13-54.

31. Interview with Toru Ebihara, Office of Health Studies, Department of Environmental Health, Environment Agency, Tokyo, June 3, 1985.

32. Julian Gresser, Koichiro Fujikura, and Akio Morishima, Environmental Law in Japan (Cambridge, MA: MIT Press, 1981) 29-30.

33. Articles 14 and 16, "Basic Law for Environmental Pollution and Control," Environmental Laws and Regulations in Japan - General (Tokyo: Environment Agency Japan, 1984) 1-8.

34. The principal exception appears to be slight increases in the annual average concentrations of NO_2 at automobile exhaust monitoring stations in continuous

operation (see p. 155 of following reference). For more details, see Part Two, Chapter 2, of Quality of the Environment in Japan 1984 (Tokyo: Environment Agency Japan, 1985) 152-167.

35. Quality of the Environment in Japan 1984 (Tokyo: Environment Agency Japan, 1985) 190; Author's calculations.

36. Quality of the Environment in Japan 1984 (Tokyo: Environment Agency Japan, 1985) 8.

37. Credence for the notion that people believe strongly what they perceive with their own sense can be derived from the long history of research on human attitudes, especially as found in the model developed by Fishbein and Ajzen [Martin Fishbein and Icek Ajzen, Belief, Attitude, Intention and Behavior: An Introduction to Theory and Research (Reading, MA: Addison-Wesley, 1975)]. According to this model, an attitude may be defined as an evaluative judgment of the degree to which one likes or dislikes some person, object, concept, or symbol. Attitudes are built on beliefs held about a subject, which are learned relationships between the object and its attributes or characteristics. One gradually builds up a view of the world and the way it works. Since the validity of one's own senses is rarely questioned, descriptive beliefs based on personal sensory experience are held with maximum certainty and generally are more important in the formation of beliefs and attitudes than information received from other sources.

38. Michael R. Reich, "Environmental Policy and Japanese Society: Part I. Successes and Failures," International Journal of Environmental Studies 20 (1983) 195.

39. Environmental Control in Japan (Tokyo: Japan External Trade Organization, undated) 4-5.

3

WEST GERMANY

POLITICAL AND ADMINISTRATIVE TRADITIONS

The approach to the control of hazardous chemicals in West Germany is strongly influenced by the traditional interactions between business and government. West Germany is a federation of states that have their own national status but are integrated into the Federal Republic of Germany as a whole. The German constitutional state is based on the Basic Law (Grundgesetz), which establishes the legal rights of individuals over the sovereignty of institutions. It reflects a degree of distrust of exaggerated nationalism, such as that which emerged under the National Socialists, and establishes a structure that protects the rights of participating states, provides adequate central authority, and guarantees individual rights and freedoms.[1]

West Germany is a social market economy, with a large public sector, which is based on a social partnership involving extensive interaction among representatives of business, trades unions, and government.[2] Within this system of cooperation and consultation, a large part of the public policy process involves not only determining the proper response to a problem at hand, but also deciding which of the affected parties should respond and in what way. Thus, the most common approach to policy decisions involves negotiation and consensus building based on the interdependence of public obligations and private responsibilities. Extensive provisions are made for discussion of relevant issues in advisory committees and various kinds of collective decision processes; however, participation is usually limited to formally constituted groups and organizations.[3] Participants are usually members of professional and industrial associations, and the intro-

duction of public interests is the responsibility of government officials. There is a very limited role for environmentalists, consumer protection groups, or other citizen groups.

This approach to consensus building with respect to public policy issues has been called "neocorporatist" because it is the modern form of the approach taken by Bismarck after the Franco-Prussian war in 1870 in his attempt to stimulate industrialization in Germany. The central problem of Chancellor Bismarck's government in catching up with the stronger economic powers of Europe was to industrialize the country without disturbing the existing political order. In the economic upheaval of industrialization, political and economic conflict were contained by corporative organizations.[4]

Corporatism, in this sense, has two key attributes. First, the intermediary between the citizen and the government is a compulsory membership organization (or set of organizations) based primarily on occupational status. Second, these organizations are granted statutory authority to control work-related aspects of their members' behavior and to administer government programs related to their members. Historically, this approach drew on the traditional guilds, which were cooperative trade associations with authority to regulate all practices associated with particular trades. Within each guild, occupational relationships were clearly defined, and exact requirements for the training of apprentices and the certification of masters were specified and administered. Bismarck's approach transformed the concept of occupationally based authoritative organizations into the economic structures of the industrial revolution. The notion that political interests can best be represented by a set of stable, occupationally based groups has a long tradition in German political thinking and profoundly influenced the response to industrialization.

Bismarck's strategy was to simultaneously protect established social elites and guarantee new economic development.[5] Agricultural tariffs protected the landed aristocracy and allowed established political relationships in the countryside to remain intact.

Interest-free loans were provided to nascent industries, and tariffs protected their markets. But Bismarck also installed a social policy that provided protection for labor as well. In 1883, 1884, and 1889, the government initiated social insurance programs for illness, accident, and old age, respectively.

The accident insurance scheme was administered by employee' associations, but a number of corporative organizations were created to administer the national health insurance program. These "sickness funds" (Krankenkassen) were jointly managed by workers and their employers, who were given exclusive authority to administer them.

Several aspects of the health insurance program are worth noting, because they are typical of the general approach in Germany. First, there was compulsory membership according to occupational position. Second, the system was administered through numerous small, independent sickness funds with statutory authority to manage the program with respect to particular occupations. Third, the principal characteristics of the scheme (the population covered, the levels of contributions, the cash and service benefits) were defined by the legislature. Fourth, the system was financed by contributions from both employers and employees. Fifth, the system included provisions for self-management; employers and employees were granted representation on the governing bodies of individual funds.

The emergence of the social insurance programs, and especially the pattern of interactions among government, employers, and workers embodied in the programs, set a pattern for many other government programs in Germany. The contemporary German system of administrative government relies on many representative advisory groups. Some of these are fixed in statutes. For example, the Concerted Action Committee on Hospital Costs, which establishes guidelines for costs in medical care, dental care, and drugs, was created by the 1976 Medicines Act. The committee has 60 members and consists of representatives of the main associations concerned: the sickness funds, private health insurance, doctors, dentists, hospitals, pharmacists, the pharmaceutical industry, unions, and

employers.[6] Other representative advisory groups have been established by administrative order. For example, new drugs must be approved by an expert commission composed of nine members selected by the minister from names submitted by the governing bodies of the health professions. Six of these are fixed (a toxicologist/pharmacologist, a clinical pharmacologist, a physician, an expert in general medicine, a medical statistician, and a pharmacist) with the remaining members selected from a pool of 21 specialities depending on the type of drug.[7] Innumerable ad hoc committees provide advice to various ministries and other government organizations. Two examples are the Expert Group of the Committee on Phosphate and Water end the Nitrilotriacetate Coordination Group of the Committee on Nitrate and Water, both of which published reports under the authority of the Federal Ministry of the Interior.[8]

The approach to questions of public policy in West Germany has been called a "search for a rationalist consensus."[9] Two overriding characteristics of this search are Sachlichkeit (attention to objectivity and utility, eschewing embellishment and emotion) and Sozialpflichtigkeit (preeminence of social obligation over private interest).[10] The first step in the process focuses on determining not only what action should be taken, but also on which of the parties to the social partnership should take that action. This sense of simultaneous attention to the factual situation and how to respond to it, and to the social obligations of those able to affect it, permeates the entire public policy process.

THE PATTERN OF ADMINISTRATIVE JURISDICTION

Against this background of a social market economy in which there is considerable consultation and cooperation among the parties to the "social partnership," it is not surprising to find that most federal statutes take the form of enabling legislation. That is, most statutes are stated in general terms and contain few provisions explicitly designed to structure or limit the discretion of the agencies to which implementation is

delegated.[11] Specification of the regulatory instrument, or the approach and procedures to be used, is usually left to administrative orders. Two forms are of greatest importance: ordinances, which require Cabinet-level approval, and technical instructions, which implement ordinances and contain guidelines for implementation by the states. In considering the control of chemical hazards in West Germany it is therefore necessary to examine relevant administrative ordinances and technical instructions as well as the federal statutes. In each case, the regulations are implemented by the states.

Framework Laws. There are no statutory measures in West Germany corresponding to this category.

The Industrial Plant. The states are obliged to prepare land-use plans, usually including areas in which industrial installations are prohibited. In addition, the Federal Immission Control Law of 1974 includes provisions for considering potential industrial accidents in the process of licensing construction of industrial facilities.

Emissions and Discharges. The major laws covering emissions and discharges are the Federal Immission Control Law, the Federal Water Act, and the Waste Water Charges Act.

The Federal Immission Control Act is implemented through 12 ordinances.[12] Facilities that are likely to produce significant amounts of emissions or discharges are subject to licensing. Requirements to be met by such installations and maximum permissible emissions levels for a large number of substances have been established. The Federal Ministry of the Interior is responsible, but implementation lies with the responsible state authority, which may order plant closings in cases of noncompliance.

The Federal Water Act was first passed in 1957, and amended in 1976.[13] Effluent discharge levels are prescribed for surface, coastal, and ground water, and the states are directed to establish water management plans with provisions for protected areas. Applications must be made for the use of water, either for withdrawal

or discharge, separately from applications under the Federal Immission Control Law. Federal responsibility lies with the Federal Ministry of the Interior.

The Waste Water Charges Act of 1976, also under the Federal Ministry of the Interior, provides for a system whereby the producers of noxious waste water are charged a fee by state authorities.[14]

Worker Protection. The Federal Immission Control Law also contains provisions for the protection of workers in that the final authorization for the industrial installation is granted only when adequate measures have been included for worker safety. Regulations for worker safety are contained in the Ordinance for Substances Handled in the Workplace, which includes provisions for the prevention of accidents and maximum exposure levels.[15]

Maximum exposure levels are recommended by the Commission on Maximum Workplace Exposures (known in Germany as the MAK Commission) of the German Research Society (Deutsche Forschungsgemeinschaft), which is an independent, nongovernmental scientific body.[16] The MAK Commission produces three lists: substances assigned maximum levels of workplace exposure, carcinogenic substances, and dusts. The list of carcinogens is subdivided into: (A1) substances that are demonstrated to be human carcinogens, (A2) substances that have been proven carcinogenic in animals, and (B) substances presenting positive indications of carcinogenicity. The MAK Commission takes the position that there is no safe level of exposure for (A1) substances. For (A2) substances, stringent monitoring of exposure levels and biological monitoring of workers are recommended. For (B) substances, the commission prescribes maximum allowable levels of exposure (MAK-values) that are considered "safe."

Another committee, the Special Committee for Hazardous Substances in the Workplace, is attached to the Federal Ministry of Labor and Social Affairs. This committee includes roughly equal numbers of members from unions, government, and the chemical industry and has the responsibility of establishing "technical guiding concentrations" (biological tolerance values for working

materials) that take into account economic and technical considerations.[17]

Industrial Substances. The Chemicals Act of 1980 establishes a system of testing and notification of new substances except those covered explicitly by other acts.[18] The lead agency for implementation of the act is the Federal Ministry for Youth, Family Affairs and Health, but technical support is provided by the Federal Health Office (Federal Ministry for Youth, Family Affairs and Health), the Federal Environment Agency (Federal Ministry of the Interior), the Federal Office for Workplace Safety (Federal Ministry of Labor and Social Affairs), the Federal Office for Biological Research (Federal Ministry of Food, Agriculture, and Forestry), and the Federal Office for Materials Testing (Federal Ministry for Economy). Applications are submitted to the Federal Office for Materials Testing.[19]

Testing and notification requirements are in accordance with the 6th Amendment to the European Community directive of 1967 on the classification, packaging, and labeling of dangerous substances. A step-wise testing scheme is employed, with a basic test package required of substances with production volumes of up to 1 ton per year, and respectively more intensive testing required of substances with production volumes of 100 tons per year (or cumulative 500 tons produced) and 1,000 tons (or cumulative 5,000 tons produced). The testing package evaluates health effects, animal and plant toxicity, environmental consequences, physical properties, and industrial health aspects of the substance.

If regulations concerning classification, packaging, and labeling are not sufficient to eliminate unreasonable risk of damage to human health or the environment, the federal government may prohibit its manufacture and use. In cases of imminent hazard, the Federal government may issue ordinances with 6-month validity. State governments may order restrictions in similar situations with a validity of 3 months.

Poisons. Poisons have been regulated by the states, but these provisions are being replaced by the Chemicals Act of 1980 (see above).

Agricultural Chemicals. Pesticides must be approved before marketing and use by the Federal Office for Biological Research (Federal Ministry of Food, Agriculture and Forestry).[20] Applications must include test data on efficacy, human and animal health effects, degradation, and residues.[21] The Federal Ministry of Food, Agriculture and Forestry, in cooperation with the Federal Ministry for Youth, Family Affairs and Health, is empowered to prohibit or restrict the use of pesticides on certain food crops. Tolerances have been established for both food and animal feed.[22]

The production, importation, and export of the chemical DDT are prohibited, with the exception of specific circumstances in public health and forest protection.[23] Approval and registration are required,[24] and the type and quantity of additives and contaminants in animal feed may be regulated.[25]

Food Additives and Contaminants. Food additives, including all substances added to food or that come in contact with food during its treatment, must be approved before use.[26] Applications are reviewed by the Federal Health Office and, if approved, are entered on the appropriate list by the Federal Ministry for Youth, Family Affairs and Health. Additives may be approved for general use or for use in specified foods.

Special ordinances regulate the amount of chemicals that may reach food through migration from packaging materials and utensils, and maximum permitted residual levels have been established for some contaminants (such as mercury in fish, aflatoxin in cereals and nuts, and trace contaminants in drinking water).[27]

Consumer Products. Cosmetics are regulated by an ordinance falling under the Law on Foodstuffs and Commodities. Chemicals prohibited for use in cosmetics are listed, as are chemicals permitted for limited use in cosmetics and coloring agents.[28] Notification of detergents is mandatory, and their formulas must be disclosed together with data on degradability.[29] The Federal Ministry of the Interior is permitted to regulate or restrict the use of chemicals in detergents. Certain detergents have been required to be at least 80

percent biodegradable, and the use of phosphates has been limited.[30] Under the Law on Technical Appliances, the Federal Health Office has issued guidelines concerning the use of hazardous substances.[31]

The concentration of lead in motor fuel has been regulated under the Law to Reduce Air Pollution Caused by Lead Compounds in Carburetor Fuels for Motor Vehicles.[32] Current regulations draw on the Ordinance Concerning the Labeling of Gasoline Quality and the Announcement of Requirements for Gasoline,[33] which specifies standards for previously existing gasoline as well as adding specifications for unleaded normal (regular) and unleaded super gasolines.

Transport. The basis for the transport regulations are the international transport codes for road (ADR), rail (RID), inland waterways (ADNR), and air (IATA-ICAO) transport.[34] The regulations for road and rail have been made more stringent than required under the ADR and RID regulations.[35]

Chemical Wastes. The disposal of waste is the responsibility of the states, but under the Waste Disposal Act they are required to prepare regional waste disposal plans.[36] Transport, storage, treatment, and disposal of waste require approval and can be undertaken only by licensed facilities. The disposal of waste oil is regulated under a separate law.[37]

Victim Compensation. There are no statutory measures in West Germany corresponding to this category.

CURRENT DEVELOPMENTS

A major new development in West Germany is the formulation of a draft dangerous substances ordinance, which is to replace 36 existing regulatory instruments as well as implement 13 guidelines of the European Community guidelines.[38] The ordinance would reinforce and extend the role of scientific and technical committees. The German Research Society's commission on maximum acceptable levels of workplace exposure levels would continue to have a central function. A new panel on dangerous

substances would deal with issues other than workplace exposures. Specific controls on several substances (e.g., blue asbestos, formaldehyde, mixtures containing dioxins) are included. The draft ordinance has been approved at the cabinet level and is awaiting comment from the Commission of the European Community and the other member states; it will probably come into effect late in 1986.[39]

A new bill on the protection of plant crops has also been drafted.[40] It would extend coverage under the law to include damage to the ecosystem in addition to human health effects, as well as introduce new controls on application equipment. The bill has been under review by cabinet advisory committees at the federal level and should be submitted to Parliament during the 1985-1986 session.[41]

Both of these measures may be interpreted as contributing further to the centralization of the regulation of chemicals in Germany. The recommendations of expert committees constituted under professional associations such as the German Association of Engineers and the Association of Sewage Treatment Technology or of the German Committee on Standards are no longer automatically accepted as providing full consideration of all relevant factors.[42] The advisory committees replacing them are established under the authority of the respective federal ministries, and the actual decisions are increasingly made in the ministries themselves. The growing visibility of these decisions to all interested parties appears to make them more political than were similar decisions in the past. There may therefore be an increase in controversy associated with the regulation of hazardous chemicals in Germany in the future, even though they continue to be based principally on the recommendations of scientific and technical advisory groups.

Revision of the 1980 Chemicals Act, which addresses industrial chemicals and implements the European Community's step-wise testing plan for new chemicals, does not appear likely, despite considerable dissatisfaction with the treatment of existing chemicals under its provisions. Every few weeks a new case of environmental contamina-

tion from chemical waste dumps or storage facilities is reported in the news. Such reports are believed to create increasing pressure to improve the capability to deal with existing chemicals.[43] Until now, virtually the only effort to regulate an existing commercial substance under these provisions was directed toward formaldehyde.[44] That effort resulted in an exceptional joint publication by the agencies charged with providing advice on such questions, the Federal Health Office, the Federal Environment Agency, and the Federal Office for Workplace Protection.[45] The report demonstrated the extreme difficulty of responding under current provisions: each regulatory decision concerning existing substances requires action by the federal cabinet, which severely limits the usefulness of the provision.[46] There appears to be some interest in moving toward a fund, perhaps similar to the "Superfund" in the United States, to cover the testing of existing chemicals.[47] However, a statutory basis for such an approach would have to be created.

NOTES

1. Joseph H. Kaiser, "Administration in Germany in 1983: An Outline of Its Orientations and Some Examples of Its Problems," International Review of Administrative Sciences 2 (1983) 137-140.

2. Kenneth Dyson, "West Germany: The Search for a Rationalist Consensus," in Jeremy Richardson, Policy Styles in Western Europe (London: George Allen & Unwin, 1982) 17-46; Kenneth Dyson, "The Politics of Corporate Crisis in West Germany," West European Politics 7/1 (January 1984) 24-46.

3. Peter Knöpfel and Helmut Weidner, "Implementing Air Quality Control Programs in Europe: Some Results of a Comparative Study," Policy Studies Journal 11/1 (September 1982) 103-115.

4. Theodore S. Hamerow, The Social Foundations of German Unification 1858-1871: Ideas and Institutions (Princeton, NJ: Princeton University Press, 1969).

5. The discussion of the emergence of the social insurance programs in Germany is based on Deborah A. Stone, The Limits of Professional Power: National Health Care in the Federal Republic of Germany (Chicago: University of Chicago Press, 1980) 21.

6. Pam Barnacal (ed.), The Pharmaceutical Market in West Germany: A Scrip Special Report (Richmond, Surrey: PJB Publications, Ltd., 1983) 75.

7. G. Assman et al., Institut für Arzneimittel des Bundesgesundheitsamtes (Pharmaceuticals Institute of the Federal Health Office). (mimeographed), Berlin: Institut für Arzneimittel, undated.

8. H. Bernhardt et al., NTA: Studie Über die aquatische Umwelt- verträglichkeit von Nitriloacetat (NTA) (NTA: Study of the Impact of Nitriloacetate on Aquatic Environments) (Sankt Augustin: Verlag Hans Richarz, 1984); H. Bernhardt et.al., Phosphor: Wege und Verbleibin der Bundesrepublik Deutschland (Phosphorus: Pathways and Sinks in the Federal Republic of Germany), (Weinheim: Verlag Chemie, 1978).

9. Kenneth Dyson, "West Germany: The Search for a Rationalist Consensus," in Jeremy Richardson (ed.), Policy Styles in Western Europe (London: George Allen & Unwin, 1982) 17-46.

10. In a more detailed treatment, I include Gemeinwohl (general well-being or welfare) and öffentliche Ordnung (fitting into a predefined pattern of public responsibility) as additional, if somewhat less central, influences on the conceptualization of public policy decisions in West Germany. See Rob Coppock, "Interactions Between Scientists and Public Officials: A Comparison of the Use of Science in Regulatory Programs in the United States and West Germany" Policy Sciences 18 (1985) (371-390).

11. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83-206771, 1982) 49.

12. Law for the Protection from Harmful Effects of Air Pollution, Noise, Vibration and Similar Processes (Federal Immission Control Law of 15 March 1974, with 12 Ordinances), Federal Ministry of the Interior.

13. Act on the Regulation of Matters Relating to Water (Federal Water Act of 27 July 1957, as amended on 26 April 1976), Federal Ministry of the Interior.

14. Act Pertaining to Charges Levied for Discharging Waste Water Into Waters (Waste Water Act of 13 September 1976), Federal Ministry of the Interior.

15. Verordnung über gefährliche Arbeitsstoffe in der Fassung der Bekanntmachung vom 11 Februar 1982 (Bundesgesetzblatt I. 144) (Ordinance on Dangerous Chemicals in the Workplace) Federal Ministry for Labor and Social Affairs.

16. Deutsche Forschungsgemeinschaft, Maximum Concentrations at the Workplace and Biological Tolerance Values for Working Materials 1984 - Report No. XX of the Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (Weinheim: Verlag Chemie, 1984).

17. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83-206771, 1982) 444.

18. Act on Protection Against Dangerous Substances (Gesetz zum Schutz vor gefährlichen Stoffen - Chemicals) Act of 16 September 1980 (Bundesgesetzblatt I.S. 1718) Federal Ministry for Youth, Family Affairs and Health.

19. Chemikaliengesetz - Prüfung und Bewertung der Umweltgefährlichkeit von Stoffen (Chemicals Law--Testing and Evaluation of Environmental Hazards from Substances), (Berlin: Umweltbundesamt, 1984).

20. Plant Protection Law (Pflanzenschutzgesetz) of 10 May 1968 (Bundesgesetzblatt I.S. 2591), as last amended 16 June 1978 (Bundesgesetzblatt I.S. 749) Federal Ministry of Food, Agriculture and Forestry.

21. Elisabeth Wolf, Die Prüfung und Zulassung von Pflanzenschutzmitteln (Berlin: Biologische Bundesanstalt für Land- und Forstwirtschaft, 1983).

22. Verordnung über Höchstmengen an Pflanzenschutz- und sonstige Mitteln sowie anderen Schädlingsbekämpfungsmitteln in oder auf Lebensmitteln und Tabakerzeugnissen (Pflanzenschutz-Höchstmengenverordnung - PHmV) from 24 June 1982 (Bundesgesetzblatt Z. 745) (Ordinance on Limits of Plant Protection and Other Substances Used to Prevent Damage to Food and Tobacco Products).

23. Gesetz über den Verkehr mit DDT (DDT-Gesetz) vom 7 August 1972 (Bundesgesetsblatt I.S. 1385) (Law on DDT Commerce).

24. Law on Fertilizers (15 November 1977) Federal Ministry of Food, Agriculture and Forestry.

25. Animal Feed Law (2 July 1975) Federal Ministry of Food, Agriculture and Forestry.

26. Law on Foodstuffs and Commodities (15 August 1974) Federal Ministry for Youth, Family Affairs and Health.

27. Legislative and Administrative Procedures for the Control of Chemicals (Copenhagen: World Health Organization Regional Office for Europe, 1984) 93.

28. Legislative and Administrative Procedures for the Control of Chemicals (Copenhagen: World Health Organization Regional Office for Europe, 1984) 93.

29. Act on Environmental Compatibility of Washing and Cleansing Agents (Detergents Act of 20 August 1975) Federal Ministry of the Interior.

30. Ordinance on Degradability of Anionic and Nonionic Surface Active Agents in Detergents (30 January 1977); Ordinance on Maximum Amounts of Phosphates in Washing and Cleansing Agents (4 June 1980) Federal Ministry of the Interior.

31. Law on Technical Appliances (24 June 1968) Federal Ministry of Labor and Social Affairs.

32. Gesetz zur Verminderung von Luftverunreinigung durch Bleiverbindungen in Ottokraftstoffen für Kraftfahrzeugmotoren (Benzinbleigesetz - BzBlG) von 5 August 1971 (Bundesgesetzblatt I. 1234) Federal Ministry of the Interior.

33. Benzinqualitätsangaberverordnung (BzAngabV) von 1 August 1984 (Bundesgesetzblatt I. 1069) (Ordinance on Labeling of Gasoline Content, Federal Ministry for Economy).

34. RID: International Regulations Concerning the Carriage of Dangerous Goods (1978 edition); ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road (30 September 1957); ADR: Draft European Agreement Concerning the International Carriage of Dangerous Goods by Inland Water Way (1976) International Maritime Goods Code; IATA-ICAO: Restricted Articles Regulations of the Air Transport Association (23rd edition, 1980).

35. Act on Transport of Dangerous Goods (6 August 1975) Federal Ministry of Traffic.

36. Waste Disposal Act of 7 June 1972, as amended on 5 January 1977; Federal Ministry of the Interior.

37. Law Concerning Measures to Assure the Disposal of Waste Oil, 23 December 1968, Federal Ministry for Economy.

38. Verordnung über gefährliche Stoffe (Gefahrstofverordung - GefStoffV), Entwurf April 1985 (Dangerous Substances Ordinance, draft from April 1985), Federal Ministry of Labor and Social Affairs.

39. Interviews with Prof. Dr. D. Henschler, chairman of the DFG Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, University of Würzberg, June 10, 1985, and with Bernard Warnat, Federal Ministry for Youth, Family Affairs and Health, Bonn, June 11, 1985.

40. Entwurf eines Gesetzes zum Schutz der Kulturpflanzen (Planzenschutzgesetz - PflSchG), Deutscher Bundestag 10. Wahlperiode 10: 1262.

41. Interview with Dr. Hansgeorg Pag and Dr. Ralf Petzold, Federal Ministry of Food, Agriculture, and Forestry, Bonn, June 11, 1985.

42. Interview with Prof. Dr. Martin Uppenbrink, Federal Environment Agency, Berlin, June 13, 1985.

43. Interview with Dr. Ekkhard Offhaus, Federal Environment Agency, Berlin, June 13, 1985.

44. For a detailed discussion of West German treatment of formaldehyde, see Rob Coppock, "Interactions between Scientists and Public Officials: A Comparison of the Use of Science in the Regulatory Programs in the United States and West Germany, Policy Sciences 18 (1985) (371-390).

45. Der Bundesminister für Jugend, Familie und Gesundheit, Formaldehyd: Gemeinsamer Bericht des Bundesgesundheitsamtes, der Bundesanstalt für Arbeitsschutz und des Umweltbundesamtes (Fromaldehyde: A Joint Report of the Federal Health Office, the Federal Workplace Safety Office, and the Federal Environment Agency) (Stuttgart: W. Kohlhammer GmbH, 1984).

46. Interviews with Dr. Ekkhard Offhaus (see note 43) and with Dr. Spielmann, Federal Health Office, Berlin, June 13, 1985.

47. Interview with Dr. D. Kaiser, Federal Health Office, Berlin, June 14, 1985.

4

FRANCE

POLITICAL AND ADMINISTRATIVE TRADITIONS

The national government plays a more dominant role in the management of the economy in France than in most other Western industrialized countries. This state-led development, and the institutions and patterns of interaction that sustain it, are important factors influencing the control of hazardous chemicals in France.

There are three principal levels of government in France: the national government, the departements, and the communes.[1] Only at the local level are government executive powers exercised by individuals who are not the agents of the central government. Not surprisingly, many political issues may be seen in terms of the conflict between the central government and the municipalities. The functions of government at the national level are extremely centralized under the President, who is selected by direct election for a period of seven years. The power of the President in foreign affairs and defense policy and in domestic affairs is so extensive that the office is often referred to as an elected sovreign, a republican monarch.[2]

Three aspects of the political and administrative traditions in France affect the regulation of chemical hazards there: 1) the dominance of the central government, 2) the functioning of the technical services within the government, and 3) the predominant attitudes of business.

The dominance of the central government may be seen clearly in its control of industrial finance, land use plans, and construction permits. The state uses the financial system as its principal instrument of national

industrial policy.[3] The Treasury, a part of the Ministry of Finance, rations and established timetables for major bond issues on capital markets, channels funds to particular sectors, and disposes of the Funds for Economic and Social Development. Together with the Bank of France, it is responsible for monetary policy, the national budget, and the flow of funds for public and private investment.

The national economic investment and regional development plan adopted by Parliament serves as a basis for land use planning at the municipal level.[5] Major industrial projects, either new construction or modification and extension of existing facilities, must obtain two different licenses. The construction license, which essentially establishes conformity to existing land use plans, is granted by the mayor of the locality, usually only after authorization for operation of a classified installation has been obtained from the prefect.[6] In the French system, it would be unwise for a firm to apply for such authorization without prior consultation with the Service des Mines, which advises not only on the completeness but also on the substance of the required dossier.

National technical services such as the Treasure or the Services des Mines ensure the dominance of the central government in controlling the construction and operation of industrial facilities in France.

The second major attribute of political and administrative traditions in France, the functioning of the national technical services in the French bureaucracy, is even more important than the control of licensing procedures would suggest. Two aspects are especially salient: the elite education and recruitment of members of the technical services, and the tension between centralization and fragmentation exhibited by the system.

The members of the technical services traditionally constitute an elite established and maintained through a relationship between specialist schools (grandes ecoles) and the governmental technical services (grand corps). The top graduates of the leading specialist schools all

go into particular services[8] and most of the members of these services are drawn from these schools.[9]

This relationship dates from the rule of Napolean Bonaparte, who came to power in a period of economic disorder and widespread discontent following the revolution.[10] His greatest concern was to reestablish the authority of the government: he not only abolished local elections, but also named the members of the General Councils of the deparments from lists of notables provided by his agents, the prefects. He established a series of specialist schools to provide a highly trained elite to serve the state in various activities. Since the time of Napolean, the French state has relied, in the way that a battle commander relies on the troops, on a cadre at once expert and loyal.

This system of elite technical services, however, exhibits a tension between centralization and fragmentation. Like the education system in France, the administrative organizations of the central government tend to be vertically organized and to exhibit clear delineation of responsibility. This is partly due to what has been called the desire to avoid direct face-to-face authority relationships and to organize interactions so that open conflicts occur only between groups that do not directly confront each other.[11] Thus, the bureaucracy in France tends to be formally organized, so that authority at any particular level can function relatively free of conflict. Should disagreement emerge with other units, especially with units in the parallel hierarchies of other ministries, they must be dealt with not directly but in high-level committees. In fact, the control of hazardous chemicals in France has been characterized as involving extensive interministerial consultation.[12]

This tendency to organize the bureaucracy so that authority can function independently at each level also contributes to a dual character: at lower levels there is a predominantly reactive, short-term, and piecemeal approach to problems, but at the apex of the bureaucracy there is an ability to challenge routine norms and impose an active, longer-term, and comprehensive style of policy making and implementation.[13] The nature of the response to various problems, and the flexibility and

vision exhibited, thus depend in large measure on the level of the bureaucracy involved.

The last aspect of the political and administrative traditions in France discussed here is the structure of French business combined with the relevant attitudes commonly found in the business community. At the end of World War II, French industry was composed primarily of small- to medium-sized companies that had been insulated from foreign competition for decades.[14] As a signatory nation of the General Agreement on Trade and Tariffs, one of the prime movers in the creation of the European Community, and a founding member of the Western political alliance, France has been forced into a modernization of its industrial life over the past 40 years. Despite considerable efforts directed by the relevant parts of the government to concentrate key industries in (often nationalized) firms of sufficient size to compete in international markets, relations between business and government have retained many of the attributes of interactions with family firms.

Many French businesses continue to envisage the firm as an enlarged family circle in which property rights confer undisputed authority. Expansion is generally felt to be a necessary evil to be undertaken when all other means to ensure the firm's survival have been exhausted. Since property rights have not been readily surrendered in the form of equity, funds for investment outlays can be secured only from retained earnings or debt.[15] The extent to which business is viewed as a family affair is reinforced by debt responsibilities. Courts may pursue a lender for partial payment of loans owed by the company to which money has been lent. The idea is that if money is lent during a period of losses, suppliers are misled as to the financial health of the company. If the firm goes bankrupt, the lender, like a member of the immediate family in a personal bankruptcy, bears part of the blame. This also applies to managers and directors of companies (limited liability or not) who can find their personal fortunes forfeited to pay part of their company's debts.[16]

In the past it could be claimed that the French government managed the national patrimony; the head of a firm managed it as a part of the family patrimony. These

attitudes are consistent with the strength of the central government in financial matters and the overall structure of industry. During the 1970s, about 44 percent of the capital market and bank lending were based on selective credits extended on preferential terms. In France, 59 percent of shares held are not quoted and, according to the 1975 census, 98.2 percent of all firms employ fewer than 49 people.[17] The reliance on personal, preferential interactions by large numbers of very small firms may constitute a context that helps explain why industry representatives remain relatively unconcerned about the threats posed by regulation.[18] Industrialists know that central government officials will consider the effects of their decisions on industry. Furthermore, they know that they can raise issues that concern them in informal personal contacts.

THE PATTERN OF ADMINISTRATIVE JURISDICTION

Most laws in France may be called framework legislation in the sense that they establish the objective to be accomplished. Government decrees or ministerial orders are issued for their implementation, and a law is not enforceable until the applicable decrees are published. Texts relating to particular topics may be collected into codes (e.g., the Public Health Code, the Labor Code), and all laws and regulations are published in the Journal officiel de la république francaise. Advisory mechanisms are flexible, and responsible ministries may seek advice from any appropriate body, in addition to those established for the purpose of assisting the implementation of certain laws.

Framework Laws. There are no statutory measures in France that establish the basic approach to environmental regulations in all areas of concern.

The Industrial Plant. The Decree on Town Planning[19] and the Decree on Land Usage[20] require all communes with more than 10,000 inhabitants to have a development plan that must be listed by the departement prefect. Industrial facilities are restricted in areas designated as residential.

The Law on Installations Classified for Purposes of Environmental Protection provides for the control of all factories, workshops, or other installations that may cause danger or nuisance to health, safety, amenities, agriculture, environment, and historic sites or monuments.[21] Under the decree of 20 May 1953, installations are subject to either authorization or declaration. For authorization, applications are submitted to the prefect and must include information on the site, the nature and volume of activity, manufacturing processes, materials to be used or manufactured, and maps and plans of the surroundings. A study must be included of details of the treatment of emissions and discharges and the removal of wastes, conditions of the transport of materials and products, emergency plans, and a notice concerning the conformity of the installation to regulations for worker protection. The Service for Registered Installations can propose, in consultation with the health council of the *département*, that supplementary regulations be imposed or that original regulations eased when the initial requirements are no longer justified. Overall responsibility lies with the Ministry of the Environment.

Emissions and Discharges. The Ministry of the Environment and the Ministry of Health share responsibility for administering the Law on the Control of Air Pollution and Odors.[22] Limits may be imposed on emissions into the air from classified installations in areas of special protection. Treatment technologies are usually not prescribed. In 1980 the Agency for Air Quality was established, which undertakes monitoring, preventive measures, and dissemination of information concerning atmospheric pollution.

The Act on Administration and Classification of Waters and Control of Water Pollution (included in the Public Health Code) prohibits the discharge of certain chemicals in drinking water catchment areas.[23] River basin financial agencies (there are six) impose a tax on both water usage and discharges of waste water. Discharge taxes may be avoided by the construction of a purification system.[24] As indicated in the section on the industrial plant, registered installations must receive authorization from the prefect for the discharge

of liquid waste into inland waters that do not fall under the Public Health Code. Exact conditions are determined separately for each case.

The Law on Energy Use governs the use of energy by large thermal units and institutes a consultative committee on energy use.[25] The order of 20 June 1975 regulates the equipment for such installations and is aimed at reducing air pollution and conserving energy resources. The decree of 13 May 1974 regulates the content of emissions into the atmosphere and foresees the creation of specially protected zones.

Worker Protection. The safety of workers exposed to chemical hazards is regulated under the Law on the Organization of the Labor Medical Service,[26] and the Work Code[27] (the Law on the Control of Chemicals, described below in the section on industrial chemicals, also restricts workers' use of chemicals in the workplace). Under the labor medical service law, the company doctor is responsible for the surveillance and examination of workers. A number of chemicals have been listed that necessitate special medical surveillance. Although the doctor determines the methods to be used, details can be prescribed by decree. Enabling authority in the Work Code (prior to 1976) gave rise to a series of regulations on the labeling, packaging, and use of various substances. Certain substances, such as benzene, asbestos, and lead, are subject to special regulations. The 1976 revision of the Work Code provided not only for prohibiting the use of, but also for the banning or restriction of any stage of the manufacture, import, or transport of dangerous substances or mixtures.[28] The Ministry of Labor is responsible for implementation of the code.

Industrial Substances. The Law on the Control of Chemicals[29] implements the requirements of the so-called Sixth Amendment of the European Communities (described in Chapter 6). It ensures investigation of the hazards of each chemical substance before it enters the market and incorporates environmental concerns into the hazard evaluation. It excludes chemicals for research, pharmaceuticals, food additives, and other chemicals in contact with food, cosmetics, agricultural pesti-

cides and fertilizers, explosives, and radioactive substances. The manufacturer or importer is responsible to determine if a substance is new to the French market and, if so, for submitting the necessary dossiers to the Ministry of the Environment (copies are forwarded to the Ministry of Industry and the Ministry of Health).

Poisons. The Public Health Code[30] includes classification of chemical products used in agriculture, industry, and medicine and prescribes labeling and packaging requirements. A "negative list" (specifications of substances and preparations that may not be used) is employed. The code is complemented by the Law on the Control of Chemicals (described under the section on industrial substances).

Agricultural Chemicals. The Law on Agricultural Pesticides and Related Substances[31] requires approval for pesticides before marketing and specifies restrictions concerning labeling. Responsibility for approval is shared by three groups: the Commission on Agricultural Pesticides sets the criteria for approval; the Commission for Examination of the Toxicity of Agricultural Pesticides examines the toxicity data and classifies the pesticide as to toxicity; and the Committee for the Study of Agricultural Pesticides examines the efficacy of the product and decides on registration or provisional authorization.[32] The order of June 1971 introduces tolerance limits in food and prescribes precautions in the application of pesticides for purposes of environmental protection.[33]

The Law on the Control of Fertilizers[34] provides for registration of fertilizers, including all products intended to improve plant nutrition or soil properties. Studies of efficacy are conducted and safety to humans, animals, and the environment must be demonstrated. Both the pesticide and fertilizer regulations are under the authority of the Ministry of Agriculture.

Food Additives and Contaminants. The Law on Prevention of Fraud,[35] which dates from 1905, includes provisions for the regulation of materials and objects in contact with food and drink. The decree of 12 February 1973 stipulates that these items must not give off

elements that may alter the quality of the food or damage the health of the consumer. All chemicals that are intended to be in contact with food must be approved. The regulations are the responsibility of the Ministry of Consumer Affairs, although some actions are taken jointly with the Ministries of Agriculture and Health.

Consumer Products. The Law on Cosmetics[36] provides for a "positive list" (specification of substances allowed in cosmetic preparations), for the notification of all formulations, and for authorization prior to manufacture. It is administered by the Ministry of Health. The decree of 14 March 1973, under the Law on Prevention of Fraud (see above), regulates the biodegradability of detergents, and the decree of 28 December 1977 prohibits the discharge of detergents into surface waters, ground waters, and the sea if they are less than 90 percent biodegradable.[37] Both are under the authority of the Ministry of the Environment. The Law on the Use of Dangerous Toys and Substances for Toys[38] is intended to protect children against the ingestion of harmful substances; it is administered by the Ministry of Health.

Transport. French regulations are not in line with the international conventions on the transport of hazardous substances. Additional measures are being developed for the control of transport companies, including vehicles, routes of transport, and parking.[39]

Chemical Wastes. The Law on Waste Disposal and Recovery of Materials[40] introduced the principle that anyone producing or holding waste in such a way as to produce harmful effects is required to ensure that it is disposed of under proper conditions to avoid such effects. Certain categories of waste, specified by decree, may be transported, treated, and disposed of only by approved operators. The law is administered by the Ministry of the Environment.

Victim Compensation. There are no statutory measures in France corresponding to this category.

CURRENT DEVELOPMENTS

There appears to be general satisfaction in France with the procedures that have been devised for dealing with chemical hazards. Most current effort is devoted to improving the functioning of existing mechanisms.

For example, the procedures for obtaining construction and operating permits under the Law on Installations Classified for Purposes of Environmental Protection provides for adequate consideration of relevant problems. However, there is some concern with the quality of the dossiers prepared.[41] Two dossiers must be developed to obtain the permits, an analysis of environmental impact and an analysis of possible dangers involved. The law also provides for the control of emissions and waste disposal, with dangerous wastes treated at duly authorized installations. Furthermore, dossiers on environmental impact and dangers are to be prepared for all existing industrial facilities by 1989; dossiers must therefore be prepared for about 330 factories, some with multiple facilities. In all, about 600 full-risk analyses are to be performed.

The principal concern about control of chemical products in France lies in the implementation of testing.[42] The French regulatory units are obliged to follow the test guidelines and procedures developed by the Organization for Economic Cooperation and Development. It has proved difficult to evaluate individual studies (for chronic effects, not physical properties), and a system of private associations providing inspection and certification of testing laboratories is being developed. There will probably be separate associations covering laboratory and environmental studies. In the field of pharmaceuticals, there are currently bilateral agreements concerning good laboratory practice with the United States and Japan. Although it is felt that a common system would be preferred, further bilateral agreements are expected with other countries in the next few years.

NOTES

1. There are now 100 *départements*, each governed by a General Council elected every 6 years, with one councilor from each *canton* (there are between 13 and 79 *cantons* per *département*). The central government is represented in the *département* by the prefect (*préfet*), who is also the executive agent of the General Council. The prefect is assisted by a subprefect (*sous-préfet*) within each of the subdivisions (*arrondissements*) of the department (there are 324 *arrondissements* throughout France). At the local level are the municipalities (*communes*). Each has a municipal council with a minimum of nine members who are elected for six years. Because over 22,000 *communes* have fewer than 500 residents, many have been grouped into municipal unions. Another adaptation is the federal organizations of larger towns and cities such as Bordeaux, Lille, Lyon, and Strasbourg. The mayor is the chief executive of the *commune* as well as representative of the central government.

2. Jonathan Story, "Capital in France: The Changing Pattern of Patrimony?" *West European Politics* 6/2 (April 1983) 92; Maurice Duverger, *La monarchie républicaine* (Paris: R. Laffont, 1974).

3. John Zysman, *Governments, Markets and Growth: Financial Systems and the Politics of Industrial Change* (Ithaca, NY: Cornell University Press, 1983) 99-169.

4. Jonathan Story, "Capital in France: The Changing Pattern of Patrimony?" *West European Politics* 6/2 (April 1983) 92.

5. Michael Pollak, "Industrial Siting and Environmental Protection: The French Approach," *Zeitschrift für Umweltpolitik* 81/3 (1981).

6. Law on Installations Classified for Purposes of Environmental Protection (19 July 1976, with decree 21 September 1977).

7. Michael Pollak, "Industrial Siting and Environmental Protection: The French Approach," *Zeitschrift für Umweltpolitik* 81/3 (1981).

8. The two schools with greatest status are the Ecole National d'Administration (ENA) and the Ecole Polytechnique. The most important services which are most often chosen by graduates of the ENA are the Inspection des Finances (the elite of the elite bureaucracies, the Inspection operates the levers of the financial markets) and the Conseil d'Etat (which combines the function of the final judicial review with that of the government's principal advisor concerning formulation and wording of laws). Other services drawing on ENA graduates include the Cour des Comptes, Administrateurs civils, Diplomatic corps, and Prefectoral corps. These are for the most part the services dealing with the general administration of government, as opposed to the more technically oriented services, which draw students from the Polytechnique, the most important of which include the Corps des Mines (responsible for technical and engineering expertise related not only to extraction industries but also to manufacturing), Ponts et Chaussées (responsible for transportation infrastructure), Telecommunications, and Armaments. See Ezra N. Suleiman, Elites in French Society: The Politics of Survival (Princeton, NJ: Princeton University Press, 1978) Table 4.1, 98.

9. In 1974, for example, the Inspection des Finances admitted three non-ENA graduates; the Ponts et Chaussées and the Conseil d'Etat drew only about one-third of their cadre from outside the Ecole Polytechnique. Ezra N. Suleiman, Elites in French Society: The Politics of Survival (Princeton, NJ: Princeton University Press, 1978) 99, note 8.

10. Ezra N. Suleiman, Elites in French Society: The Politics of Survival (Princeton, NJ: Princeton University Press, 1978) 17-24.

11. Michael Crozier, The Bureaucratic Phenomenon (Chicago: University of Chicago Press, 1964) 221.

12. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service #PB 83-206771, 1982).

13. Jack Hayward, "Mobilising Private Interests in the Service of Public Ambitions: The Salient Element in the Dual French Polity Style?" in Jeremy Richardson (ed.), Policy Styles in Western Europe (London: George Allen & Unwin, 1982) 116.

14. John Zysman, Governments, Markets and Growth: Financial Systems and the Politics of Industrial Change (Ithaca, NY: Cornell University Press, 1983) 100.

15. Jonathan Story, "Capital in France: The Changing Pattern of Patrimony?" West European Politics 6/2 (April 1983) 94.

16. John Willis "Threading a Path Through the French Way of Doing Business," International Management (November 1984) 51.

17. Jonathan Story, "Capital in France: The Changing Pattern of Patrimony?" West European Politics 6/2 (April 1983) 94.

18. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB 83-206771, 1982) 267.

19. Decree on Town Planning: Décret No. 58-1463, Plans d'urbanisme, J.O.R.F., No. 3, 91ème an. (4 janvier 1959) 265.

20. Decree on Land Usage: Décret No. 70-1016, Plans d'occupation des sols, J.O.R.F., No. 258, 102ème an. (5 novembre, 1970) 18238.

21. Law on Installations Classified for Purposes of Environmental Protection: Loi No. 76-663, Installations classées pour la protection de l'environnement, J.O.R.F., No. 167, 108ème an. (9 juillet 1976) 4320; with decree: Decret No. 77-1134, Installations classées pour la protection de l'environnement, Tableau, J.O.R.F., No. 234, 109ème an. (8 octobre 1977) 4901; see also World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of

the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 73-74.

22. Law on the Control of Air Pollution and Odors: Loi No. 61-842, Lutte contre les pollutions atmosphériques et les odeurs, J.O.R.F., No. 181, 93ème an. (3 aout 1961) 7195.

23. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 75.

24. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 75.

25. Law on Energy Use: Loi No. 48-400, Utilisation de l'énergie, J.O.R.F., No. 62, 80ème an. (11 mars 1948) 2474; with administrative order: Arrêté, Equipement et exploitation des installations thermiques en vue de reduire la pollution atmosphérique et d'économiser l'énergie, J.O.R.F., No. 176, 107ème an. (31 juillet 1975) 7778; and decree: Décret No. 74-415, Contrôle des émissions polluantes dans l'atmosphére et certaines utilisations de l'énergie thermique, J.O.R.F., No. 115, 106ème an. (15 mai 1974) 5178.

26. Law on the Organization of the Labor Medical Service: Loi No. 46-2194, Organisation des services medicaux du travail, J.O.R.F., No. 239, 78ème an. (12 octobre 1946) 8638; with decree: Decret No. 69-623, Organisation des services medicaux du travail, J.O.R.F., No. 141, 101ème ans. (18 juin 1969) 6092 (rectificatif 26 juin 1969, 6517).

27. The Prevention of Accidents in the Workplace Act of 1976: Loi No. 76-1106, Developpement de la prévention des accidents du travail, J.O.R.F., No. 285, 108ème an. (6 decembre 1976) 7028.

28. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB 83-206771, 1982) 420.

29. Law on the Control of Chemicals: Loi No 77-771, Contrôle des produits chimiques, J.O.R.F., No. 161, 109ème an. (13 juillet 1977) 3701; with decree: Décret No. 79-35, Contrôle des produits chimiques, J.O.R.F., no. 13, 111ème an. (17 janvier 1979) 148.

30. Public Health Code; see the ministerial decree: Arreté, 2 octobre 1972, Utilisation des substances dangereuses en agriculture, J.O.R.F., No. 250, 104ème an. (25 octobre 1972) 11177.

31. Law on Agricultural Pesticides and Related Products: Loi No. 72-1139, Organisation du contrôle des produits antiparisitaires à usage agricole, J.O.R.F., No. 299, 104ème an. (23 decembre 1972) 13349; with several decrees.

33. The commission on toxicity consists of representatives of various ministries and of industry and other private interests. The criteria commission and the authorization committee are both made up of representatives from ministries and the different technical services. See Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83-206771, 1982) 417-420.

33. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 79.

34. Law on the Control of Fertilizers: Loi No. 79-595, Organisation du contrôle des matières fertilisantes et des supports de culture, J.O.R.F., No. 151, 112ème an. (14 juillet 1979) 1834; with decree: Décret No. 80-478, Contrôle des matières fertilisantes et des

support de culture, J.O.R.F., No. 151, 112ème an. (29 juin 1980) 1617 (Annexes 5623).

35. Law on Prevention of Fraud: Loi No. 46-197, Répression des fraudes dans la vente des marchandises et des falsifications des denrées alimentaires et des produits agricoles, J.O.R.F., an. 1905, B. 2641, 811; with decree: Décret No. 73-138, Répression concernant les produits chimiques dans l'alimentation humaine et les matériaux et objets au contact des denrées, produits, boissons destinées à l'alimentation de l'homme et des animaux ainsi que les procédés et les produits utilisés pour le nettoyage de ces matériaux et objets, J.O.R.F., No. 39, 105ème an. (15 février 1973) 1728; and joint circular: Circulaire, 12 septembre 1963, J.O.R.F., No. 226, 95ème an. (26 septembre 1963) 8661 (Rectificatif, 3 octobre 1963, 8878).

36. Law on Cosmetics (28 December 1977), see: Décret No. 77-1558, Produits cosmétiques et produits d'hygiène corporelle, J.O.R.F., No. 21, 110ème an. (25 janvier 1978) 497.

37. Décret No. 73-336: Répression concernant la vente des détergents et celle des produits de lavage ou de nettoyage qui les contiennent, J.O.R.F., No. 71, 105ème an. (24 mars 1973) 3222; Decree No. 77-1554: Déversement de certains produits détergents dans les eaux superficielles, souterraines et de la mer, J.O.R.F., No. 15, 110eme an. (18 janvier 1978) 405.

38. Law on the Use of Dangerous Substances for Toys: Ordonnance No. 45-402, Interdiction de jouets ou d'amusettes dangereux contenant des substances vénéneuses, J.O.R.F., No. 63, 77ème an. (15 mars, 1945) 1364.

39. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 80.

40. Law on Waste Disposal and Recovery of Materials: Loi No. 75-633, Elimination des déchets et récupération des matèriaux, J.O.R.F., No. 163, 107ème an. (16 juillet 1975) 7279.

41. The discussion of developments with respect to industrial facilities in this paragraph are based on a telephone conversation with M. Demarc, Ministry of the Environment, December 2, 1985.

42. The discussion of testing and inspection of laboratories is based on an interview with M. Deschamps, Ministry of the Environment, Paris, June 28, 1985.

5

THE UNITED KINGDOM

POLITICAL AND ADMINISTRATIVE TRADITIONS

The control of chemical hazards in the United Kingdom is strongly influenced by a system of government that has developed gradually over a long period of time with very few pronounced breaks. Many of its important institutions and processes have origins in the nineteenth century, and some even earlier.[1] In addition, laws and statutory instruments have been added as needs were recognized. For example, a summary and interpretation of laws and regulations applicable to the manufacture and transport of dangerous substances in 1984 included 30 laws (the earliest being the 1774 Fire Prevention (Metropolis) Act; four were enacted prior to 1920) and 88 statutory instruments providing specific regulations (38 of which were promulgated prior to 1970).[2] The evolutionary character of regulation contributes to what has been called the labrynthine complexity of regulations in the United Kingdom. Two factors, the institutions of public administration and the evolutionary development of regulations, are the important influences on the approach to chemical hazards throughout the United Kingdom today.

An important tradition of civil administration in the United Kingdom is that ministers are responsible to Parliament for all the actions of their departments. This tradition originally developed in the mid-nineteenth century, prior to the emergence of a disciplined party system and before the growth in the scale of government. There has been some modification of the tradition, so that a minister is no longer expected to resign for any departmental mistake that is uncovered. But the tradition has by no means been superseded; in 1978 it was officially endorsed by the government.[3]

The convention of the personal responsibility of ministers for the actions of their departments contributes to the reluctance of civil servants to take public positions. Since all official action is taken in the name of the minister, civil servants remain largely anonymous. Within departments, great care is generally taken to ensure that the minister is not exposed to parliamentary criticism. This concern has decided impact on the way decisions are made. In addition, since no minister can issue directions to another, disagreements among departments must be resolved by compromise. Below the Cabinet, there is an elaborate machinery of interdepartmental committees founded on the principle of securing agreement among all interested governmental parties.

The predilection for negotiation and consultation, taking place in private and without public exposure, is also reflected in regulatory interactions with commercial enterprises. Historically there has been a heavy reliance on factory inspectors, an approach originally developed during the Industrial Revolution.[4] Even today, the overall approach to regulation in the United Kingdom relies on and reinforces the role of inspectors who have intimate acquaintance with plant operations and problems of compliance. For example, an important step in the regulation of chemical substances already in commercial production and use is the preparation of a detailed report on current industrial practice by the factory inspectorate.[5] The United Kingdom relies on much more intrusive inspection programs than do most other countries.

This approach emphasizes the particulars of plant operations and compliance difficulties and reinforces the use of the "best practicable technology" as a control instrument, the avoidance of strict, obligatory standards in favor of flexible guidelines that can be negotiated with individual firms, and a predilection for the phased implementation of standards." The dominant style of policy processes in the United Kingdom has been called "bureaucratic accommodation."[6] Policy initiatives are discussed both with other departments and with client groups outside the government. Client groups coordinate their own responses and are aware of each other's posi-

tions. In general, the approach has five attributes: sectorization, "clientelism," the institutionalization of compromise, negotiation, and the development of exchange relationships.[7]

The sectorization of activities among departments places them in competition with each other. One result is that departments treat pressure groups and industry organizations as clients. Not only do departments welcome external "pressure," but also on occasion they attempt to mobilize activity by such groups. Underlying such interaction and the forms it takes--consultation and negotiation--is a broad cultural norm that government should rule by consent. The participation of those affected is thus viewed as enhancing the legitimacy of a policy. Arrangements for consultation are often formalized into permanent advisory committees and other standing bodies; these sometimes evolve into structures in which more or less standard exchanges are negotiated.

There are two important results of this approach. First, the strong sectorization, clientelism, and formalization of consultation and negotiation contribute to a relatively closed system. There is a tendency to consult only with those with whom interaction has already been conducted successfully in the past and to ignore others. Those privy to negotiations will be fully informed, but anyone not included will receive no information at all. The privileged character of consultation is mandated by the Official Secrets Act, which makes virtually all information in the possession of departments a state secret.[8]

The second result of the United Kingdom's approach to the policy process is legitimization through participation, and it constitutes an apparent--but only apparent--contradiction to this pattern of exclusive consultation. The extent of participation is based on the need to obtain the consent of those affected rather than on a need to be responsive to the population in general. Thus, there are strong incentives to legitimize administrative action by inviting the participation of those most clearly affected--the departmental "clients"--and very weak incentives to extend participation to an ill-defined public whose involvement is indirect and diffuse.

THE PATTERN OF ADMINISTRATIVE JURISDICTION

The United Kingdom Parliament exercises overall powers of legislation in England, Northern Ireland, Wales, and Scotland. There are certain administrative differences between Wales and England, but with respect to Scotland the Parliament may include special provisions in the legislation or pass separate legislation. At present, Northern Ireland is administered by regulation from the United Kingdom government following the suspension of the Northern Ireland government in 1972. The secretaries of state for Northern Ireland, Wales and Scotland issue regulations, through their offices, on matters of environmental and public health concern in their jurisdictions.

The central government passes the framework legislation within which executive action is exercised. Some implementation is at the local level, by local authorities or water authorities, albeit under guidance and advice from the central government, which also exercises certain financial controls.

Given the tradition of negotiation and consultation, it is not surprising that the control of chemical hazards in the United Kingdom avoids obligatory, legally enforceable controls (with the exception of food additives and a few other instances).[9]

Framework Laws. There are no statutory measures in the United Kingdom corresponding to this category.

The Industrial Plant. Planning procedures are complicated processes involving local and water authorities, the Health and Safety Executive, the Department of the Environment, and often other entities such as the Ministry of Agriculture, Fisheries and Food in England and Wales or the Department of Agriculture and Fisheries in Scotland. In principle, the local authority may grant permission to prepare planning outlines, but no further development can take place until detailed permission has been granted. Objections to applications may be raised by a range of organizations, including conservation and pressure groups. Planning decisions are made with refer-

ence to organizational plans, taking into consideration water abstraction and effluent discharges, control of air pollutants, waste disposal plans, land drainage, and outfalls into rivers or the sea. In the case of major hazards, the Health and Safety Executive must be consulted.[10]

The principal legislation includes the Local Government, Planning and Land Act of 1980,[11] which simplifies building regulations and abolishes many local government controls; the Town and Country Planning Act of 1971,[12] which provides for statutory general development orders stipulating limits of permitted developments and the governmental offices to be consulted; the Health and Safety at Work Etc. Act of 1974,[13] which provides for the secretary of state for the environment to regulate the design and construction of buildings and the provision of services, fittings, or equipment in or connected to buildings; and the Factories Act of 1961,[14] which chiefly concerns fire hazards and provides for inspections both by local fire brigades and central government inspectors.

The Department of the Environment (or the Scottish Development Department) is responsible for the implementation of the planning laws; the Department of Employment and the Health and Safety Executive are responsible for the Health and Safety at Work Act; and the Health and Safety Home Office is responsible for the Factories Act.

Emissions and Discharges. The principal regulations regarding air pollutants are provided for in the Alkali and Other Works Regulation Act of 1906. Manufacturing processes are scheduled under the act according to industry groups (chemical and allied industries, metal industries, electricity and gas generation etc., and other). Emissions limits are specified for only four processes. For other processes, control of emissions is determined by the Alkali and Clean Air Inspectorate in England and Wales and the Pollution Inspectorate in Scotland, using the "best practicable means" appropriate to the local situation.[15] Overall implementation is under the authority of the Health and Safety Executive.

The Public Health Acts of 1936 and 1961[16] relate to noxious or offensive emissions other than smoke, grit, or dust from such premises as small factories that are not covered by specific legislation and outside the Alkali and Other Works Act. The Clean Air Acts of 1956 and 1958[17] subsumed and extended some of the provisions of the Public Health Acts, especially concerning the control of smoke emitted from industrial combustion processes. Implementation of these laws is the responsibility of local authorities and the Department of the Environment.

The Health and Safety at Work Act[18] provides for the control of emissions into the atmosphere of noxious or offensive substances from premises of any class prescribed under the Act by regulation. When fully implemented, the Act is to subsume the Alkali and Other Works Act.

Existing legislation in the United Kingdom does not directly control the level of substances discharged directly into water, but it does enable regional water authorities to exercise control, which usually limits the levels, volume, etc., of the substances to be discharged. Controls are tailored to meet the present or potential quality objectives of the receiving water and take full account of river use, dilution, and the assimilative capacity of the water.[19] These provisions are provided under several acts.[20]

Worker Protection. Most legislation on worker protection is contained in the Health and Safety at Work Act.[21] Under the act, the Health and Safety Commission was created with representatives from employers and trade unions, local authorities, and other relevant groups. Beginning in 1975, the staffs of the Health and Safety Inspectorates, with responsibilities for factories, mines, explosives, alkali and other chemical works, and pipelines were transfered to the Health and Safety Executive, which is now responsible for implementation of the act together with local authority inspectors.

The act is concerned with the health and safety of all employers and employees (except domestic servants), self-employed workers, and those in charge of premises

used as workplaces. It places obligations on manufacturers of equipment and materials used at work. Inspectors may issue a prohibition notice in situations deemed to constitute a risk to health or safety until specified remedial measures are taken, even if no legal contravention has occurred. If legal contravention of the relevant statutory provisions of the act occurs, an inspector can issue an improvement notice requiring remedial actions within a specified time. Such notices may be served on employers, employees, or suppliers of equipment or materials.

An inpsector may also prosecute anyone contravening a relevant statutory provision of the act or seize, render harmless, or destroy any substance or article deemed to be of potential imminent danger of causing serious personal injury. The Health and Safety Commission may, with the consent of the secretary of state, serve an order requiring any person to furnish information about the matters specified in the notice. Inspectors may give factual information regarding worker health, safety, and welfare to employees but must inform the employer of any such action.

Industrial Substances. The Health and Safety at Work Act also requires any person who designs, manufactures, imports, or supplies any substance or article for use at work to ensure it is safe when properly used and without risk to health. Tests must be performed in order to provide adequate information about the safety of the product, and information must be supplied about its intended use.

In 1978 regulations concerning the packaging and labeling of dangerous substances were amended, adding 121 chemicals to the schedules and introducing risk warnings against possible sensitization effects of handling certain acrylates and anhydrides.[22] In all, more than 900 chemicals are covered by regulations, which also require that containers are properly designed, constructed, and secured to prevent spillage.

A nonstatutory notification scheme is in operation for the selection of chemicals used offshore. Under the authority of the Department of Energy but in consulta-

tion with other departments (in particular, the Ministry of Agriculture, Fisheries and Food and with industry), the scheme is directed primarily at oil field operations. The objective is to avoid the use of chemicals that are highly toxic to marine organisms or that tend to persist in the marine environment and that are likely to be discharged in other than disaster situations.

Poisons. The Poisons Act[23] covers the sale, supply, transport, packaging, and labeling of poisons. Part I of the Poisons List consists of poisons for which retail sales may be made only through registered pharmacies. Part II contains poisons that may be sold through normal retail outlets that are registered by addresses.

Agricultural Chemicals. Under the Health and Safety at Work Act, regulations protect operators from the more dangerous chemicals by the wearing of protective clothing. The Farm and Gardens Chemical Act[24] controls certain aspects of the labeling of farm and garden pesticides. But the most important controls on agricultural chemicals fall under the nonstatutory Pesticide Safety Precautions Scheme (PSPS).[25]

The introduction to the market and the labeling of pesticides are closely controlled through the PSPS, a nonstatutory but formally negotiated agreement between government and industry. The scheme requires manufacturers to notify the Ministry of Agriculture, Fisheries and Food or the Health and Safety Executive prior to marketing a new pesticide or suggesting a new use of an existing one. Manufacturers must provide sufficient data to enable government to decide whether a pesticide can be used without harm to humans, livestock or other domestic animals and with minimal harm to wildlife, provided reasonable safety precautions are taken. Manufacturers are required to include warnings, precautions, and the names of the active ingredients on their product labels.

Food Additives and Contaminants. The Food and Drugs Act[26] prohibits the addition of any substance to food, the use of any substance as an ingredient in the preparation of food, the abstraction of any constituent from food, or the subjection of food to any other process or

treatment that renders the food harmful to health. The act provides for the seizure, examination, and prohibition of the use of harmful substances. Under the authority of the Ministry of Agriculture, Fisheries and Food and the Department of Health and Social Security, the act is enforced by local authorities. Under the act a number of regulations control the labeling of food and the composition of food additives and contaminants.

Consumer Products. In addition to laws dealing with commercial hazards, consumer safety legislation is intended to enable the responsible minister to ensure the protection of people from avoidable hazards presented by goods in and around the home. For example, the Consumer Protection Act[27] and the Consumer Safety Act[28] provide power to regulate the composition, design, or packaging of goods to prevent or reduce the risk of death or personal injury to consumers. The Sale of Goods Act[29] and the Trade Descriptions Act[30] set out the implications for both buyer and seller in any contract for the sale of goods and make it a criminal offense to apply a false description to any trade. The Road Traffic Act[31] requires that motor vehicles be constructed so that no avoidable smoke causes injury to persons or damage to property. The Motor Fuel Regulations, promulgated under the Control of Pollution Act, provide for the statutory reduction of lead in motor fuel.[32]

Transport. The Petroleum Act[33] is concerned with all storage problems, from major facilities down to garages. Under the act, a number of regulations have been promulgated dealing with manufacture, conveyance, and use and apply to petroleum and petroleum mixtures, carbon disulfide, compressed gases, and other substances. A number of regulations concerning the packaging and shipping of explosives have been made under the Explosives Acts.[34] Specific requirements for road tankers (tank trucks) or containers are found in the Packaging and Labelling of Dangerous Substances Regulations[35] under the Health and Safety at Work Etc. Act.

Chemical Wastes. The collection of domestic and industrial waste is the responsibility of district councils in England and Wales and of the regional and island councils in Scotland. Central government advice

to local authorities is provided by the Department of the Environment. The Ministry of Agriculture, Fisheries and Food provides advice concerning farm waste disposal. The Control of Pollution Act[36] includes provisions for the maintenance of a register of certain wastes. The Deposit of Poisonous Waste Act[37] requires those handling hazardous wastes to notify authorities at least three days prior to disposal and to provide complete details about it.

Victim Compensation. There are no statutory measures in the United Kingdom corresponding to this category.

CURRENT DEVELOPMENTS

Major adjustments are currently under way in the determination of exposure limits for hazardous substances under the Health and Safety at Work Etc. Act.[38] Two kinds of limits are now is use. The first, control limits, carry the force of law and are applied when there is good information about a serious problem. The second, recommended limits, are usually flexible and function as guidelines rather than enforceable limits. But the courts have usually required industry to demonstrate that the protection provided in a recommended limit is at least matched, so that the recommended limits carry almost the same force while permitting greater flexibility.

For about three years, new legislation (Control of Substances Hazardous to Health—COSHH) has been discussed. One of the principal effects of this proposed act would be to replace the use of the Tolerance Limit Value list of recommended maximum workplace exposures developed by the American Conference of Governmental Industrial Hygienists with exposure levels developed in the United Kingdom. Toward this aim, a Working Group on the Assessment of Toxic Chemicals was established. Under this working group, two panels have been organized, one on organic substances and one on dusts. Each panel includes three members from the Trades Unions Council and three from the Congress of British Industry, together with additional experts as necessary to deal with specific questions. A consultative document on COSHH has been

circulated,[39] and a bill establishing an appropriate statutory basis is expected to be submitted to parliament in 1987.

New legislation, the Food and Environment Protection Bill, is being prepared to replace the voluntary Pesticides Safety Precautions Scheme (PSPS).[40] The PSPS consists of a formally negotiated agreement between the British Agrochemicals Association, the British Pest Control Association, and the British Wood Preserving Association representing industry; and the government departments and agencies responsible for agriculture and health and safety in the United Kingdom. It provides for all products to be evaluated and cleared prior to introduction into commerce in the United Kingdom. Although the proposed legislation is partly a response to pressure from the European Community (the voluntary negotiation with British industry associations appears to be a nontariff barrier to trade), it also includes provisions to extend control into new areas. For example, the PSPS examines a pesticide purely in terms of safety and does not regulate use of the product. The proposed statute would evaluate not only the safety of the product, but also its efficacy and humaneness. It would also include provisions for the regulation of pesticide use, which until now has not been covered, and would provide the basis for requiring all formulations in commerce to be approved.

Although these developments will provide somewhat greater proscription on regulatory decision processes in the United Kingdom, they will not alter the overall preference for nonstatutory and informal approaches. The control of chemical hazards in the United Kingdom will for the foreseeable future remain opaque to those not involved in the actual decisions.

NOTES

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3. D.R. Steel, "Britain," in F.F. Ridley (ed.) Government and Administration in Western Europe (New York: St. Martin's Press, 1979) 18.

4. For a general history of these institutions, see Gerald Rhodes, Inspectorates in British Government (London: George Allen & Unwin, 1981).

5. Interview with P. Oldershaw, Health and Safety Executive, London, July 2, 1985.

6. Grant Jordan and Jeremy Richardson, "The British Policy Style or the Logic of Negotiation?" in Jeremy Richardson (ed.), Policy Styles in Western Europe (London: George Allen & Unwin, 1982) 80-110.

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8. Official Secrets Act of 1911 (1 and 2 Geo. 5 c. 28).

9. Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83-206771, 1982) 36.

10. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 207.

11. Local Government, Planning and Land Act of 1980 (c. 65).

12. Town and Country Planning Act of 1971 (c. 78), as amended (Town and Country Planning (Amendment) Act of 1977 c. 29). Also, the Town and Country Planning (Scotland) Act of 1977 (c. 10).

13. Health and Safety at Work Etc. Act of 1974 (c. 37).

14. Factories Act of 1961 (9 & 10 Eliz. 2 c. 34).

15. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 211.

16. Public Health Acts of 1936 (26 Geo. 5 & 1 Edw. 8 c. 49) and 1961 (9 & 10 Eliz. 2 c. 64).

17. Clean Air Acts of 1956 (4 & 5 Eliz. 2 c. 52) and 1968 (c. 62).

18. Health and Safety at Work Etc. Act of 1974.

19. World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 212.

20. Rivers (Prevention of Pollution) Acts of 1951 (14 & 15 Geo. 6 c. 64) and 1961 (9 & 10 Eliz. 2 c. 50); Rivers (Prevention of Pollution) (Scotland) Acts of 1951 (14 & 15 Geo. 6 c. 66) and 1965 (c. 13); Clean Rivers (Estuaries and Tidal Waters) Act of 1960 (8 & 9 Eliz. 2 c. 54); Water Resources Act of 1963 (c. 38); Water Acts of 1945 (8 & 9 Geo. 6 c. 42) and 1948 (11 & 12 Geo. 6 c. 22); Water (Scotland) Act of 1946 (9 & 10 Geo. 6 c. 42); Water Act of 1973 (c. 37); Water (Scotland) Act of 1967 (c. 78) and Local Government (Scotland) Act of 1973 (c. 65); Public Health Act of 1936 (Note 16); Public Health (Drainage of Trade Premises) Act of 1937 (1 Edw. 8 & 1 Geo. 6 c. 40); Public Health Act of 1961 (9 & 10 Eliz. 2 c. 64); Salmon and Freshwater Fisheries Act of 1975 (c. 51); Salmon and Freshwater Fisheries (Protection) (Scotland) Act of 1951 (14 & 15 Geo. 6 c. 26).

21. Health and Safety at Work Etc. Act of 1974.

22. Packaging and Labelling of Dangerous Substances (Amendment) Regulations (S.I. 1981 No. 792)

23. The Poisons Act of 1972 (c. 66).

24. The Farm and Gardens Chemical Act of 1967 (c. 50).

25. See United Kingdom, Ministry of Agriculture, Fisheries and Food, Pesticides Branch, United Kingdom Pesticides Safety Precautions Scheme: Agreement Between Government Departments and Industrial Associations (London: Ministry of Agriculture, Fisheries and Foods, 1979).

26. The Food and Drugs Act of 1955 (4 & 5 Eliz. 2 c. 16).

27. The Consumer Protection Act of 1961 (9 & 10 Eliz. 2 c. 40).

28. The Consumer Safety Act of 1978 (c. 38).

29. The Sale of Goods Act of 1979 (c. 54).

30. The Trade Descriptions Act of 1968 (c. 29).

31. The Road Traffic Act of 1972 (c. 20).

32. The Motor Fuel (Lead Content of Petrol) Regulations of 1976.

33. The Petroleum (Consolidated) Act of 1928 (18 & 19 Geo. 5 c. 32).

34. The Explosives Act of 1875 (38 & 39 Vict. c. 17); the Explosives Act of 1923 (13 & 14 Geo. 5 c. 17).

35. Packaging and Labelling of Dangerous Substances Regulations of 1978 (S.I. 1978 209).

36. The Control of Pollution Act of 1974 (c. 40).

37. The Deposit of Poisonous Waste Act of 1972 (c. 21).

38. The discussion of exposure limits and the proposed legislation is based on interviews with P. Oldershaw, Health and Safety Executive, July 2, 1985, with J.P. Hamilton, Trades Union Congress, July 3, 1985, and with P. Lewis, Chemical Industries Association, July 4, 1985.

39. Health and Safety Commission, Consultative Document: Control of Substances Hazardous to Health: Draft Regulations and Draft Approved Codes of Practice (London: Health and Safety Commission, 1984).

40. Interview with B. Holdworth, Pesticides Branch, Ministry of Agriculture, Fisheries and Food, July 5, 1985.

6

EUROPEAN COMMUNITY

POLITICAL AND ADMINISTRATIVE TRADITIONS

The institutions of the European Communities--the Council of Ministers, the Commission, the Parliament, and the Court of Justice--make up an unprecedented mixture of public power constituted under national and international law. The European Community is analogous to a nation-state in that it has authority in certain areas, especially agriculture and commercial and industrial competition, and also it seeks to further the interests of its members as a whole in a general way. It is not a federation to which national parliaments and governments are subordinate in specified areas. The European Community is a unique institutional system unlike any other legislative and regulatory structure in the world.

The European Community came into being through a gradual process of integration.[1] It is based on treaties establishing three separate organizations: the European Coal and Steel Community (ECSC), established in 1952; the European Economic Community (EEC), established in 1958; and the European Atomic Energy Community (Euratom), also established in 1958. Originally the three Communities had separate Councils and executive Commissions (known as the "High Authority" in the ESCS). Since 1967, however, there has been a single Commission, known as the Commission of the European Communities, and a single Council, which together exercise all the powers and responsibilities vested in the three Community treaties. Common European usage is followed in this report by referring to the European Community, rather than to the European Economic Community or the European Communities.

The Council of Ministers is made up of representatives of the governments of the member nation-states. Although a country's foreign minister is regarded as its principal representative in the Council, ministers with other portfolios also sit frequently for specialized Council meetings, and sometimes sit alongside the foreign minister. The presidency of the Council rotates among the member governments every six months. For decisions are made in the Council by majority vote, Germany, France, Italy, and the United Kingdom have 10 votes each; Belgium, Greece, and the Netherlands 5 each, Denmark and Ireland 3 each, and Luxembourg 2. With rare exceptions, the Council of Ministers considers only proposals brought before it by the Commission.

The Commission consists of 14 members appointed by agreement among the member governments. Each member serves a 4-year term of office, during which he or she is independent of the governments and of the Council. The Council makes major decisions, and the Commission makes minor decisions under powers accorded it by the treaties or by guidelines laid down by the Council. The Commission acts as the executive arm of the Community institutions. Acting under the Rome Treaties (EEC and Euratom), the Council and Commission issue regulations, directives, decisions, recommendations, and opinions.[2] Regulations are of general application and are binding in their entirety. Directives are binding on the member nation-states but leave the form and methods for achieving the requirements to the discretion of national authorities. Decisions may be addressed to a government, an enterprise, or an individual and are binding on those to whom they are addressed. Recommendations and opinions are not binding.

In the event of disputes between the Commission and a member state or between the Commission and a commercial enterprise, the Court of Justice decides. The Parliament, which discusses policy and approves the budget, is elected by direct election in each member nation-state.

Under the Treaty of Rome, the principal purposes of the European Community are the free movement of goods and services, a customs union, and common agricultural policy.[3] The actions taken by the Council and the

Commission in regulatory matters are all designed to encourage trade within the Community through harmonization of the laws and regulations of the respective member nation-states. This is an important aspect of the Community directives applicable to the control of hazardous chemicals.

The actions that are of greatest concern here are Council directives, which are binding on the member nation-states and require that the provisions included in the directives are implemented through their respective laws. The Council, however, considers only measures proposed by the Commission. To assist the Commission in its work, many committees of government representatives (called management committees in the area of agriculture) are attached to it. Measures the Commission intends to enact are submitted in draft form to the appropriate committees, which give their opinions by qualified majority (45 of 63 votes), votes being weighted as in the Council. Committee opinions are not binding on the Commission, which notes the contents but remains entirely free to decide for itself. However, if the Commission decides to go against a committee, the matter is referred to the Council, which may reverse the Commission's decision within a month. The procedure is used extensively for Commission decisions as well as preparation for Council actions.

THE PATTERN OF ADMINISTRATIVE JURISDICTION

The fourteen members of the Commission are responsible for 20 Directorates-General (DGs).[4] In terms of the control of hazardous chemicals, the most important are: DG XI--Environment, Consumer Protection, and Nuclear Safety; DG V--Employment, Social Affairs, and Education; and DG III--Internal Market and Industrial Affairs. DG XI and DG V have responsibility for health consequences and environmental protection, and DG III is responsible for industrial development and trade, which is the primary concern of the Community.

The Treaty of Rome does not specifically include provisions to protect the life and health of European

citizens.[5] However, Article 235 of the treaty provides that if action of the Community is necessary to attain one of its objectives and the treaty has not provided the necessary powers, then the Council can, acting unanimously on proposals of the Commission, take the appropriate measures. Thus, many environmental measures are based on Article 235, sometimes in conjunction with Article 100, which provides for the harmonization of national measures.[6]

Community efforts to regulate dangerous substances began in 1965, when two directives were proposed.[7] After two years of deliberation, the Council of Ministers adopted Council Directive of 27 June 1967 on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances.[8] As the title indicates, the original 1967 directive applies only to the labeling and packaging of hazardous chemicals. The directive has been amended several times, and two important changes have been introduced.[9] The Fourth Amendment introduced a procedure whereby a formal committee may adopt technical "adaptations to technical progress." This provision for "updating" the technical specifications of the directive are decisions taken at the level of the Commission and therefore subject to the general guidelines laid down by the Council of Ministers. A new committee is named (by the responsible government offices in the member nation-states) for each decision.

The Sixth Amendment, passed in 1979, introduced provisions for information exchange among the member nation-states. It established a step-wise testing scheme for chemicals being introduced to commerce and provided for the dissemination of a summary dossier among the member countries. The step-wise testing scheme closely follows the recommendations of the Organization for Economic Cooperation and Development.[10] The Sixth Amendment is severely restricted to testing and information exchange; any regulatory action would be taken by member nation-states under the guidance of a separate directive.[11]

In 1972, the year of the United Nations Conference on the Human Environment, the Community heads of state

and government called on the Community institutions to work out an action program on the environment.[12] The program submitted by the Commission was adopted by the Council of Ministers in 1973 and was renewed and supplemented in 1977 and 1983.

Framework Laws. Aside from the provisions in Article 235 and Article 100 of the Treaty of Rome mentioned above, the European Community does not have legislation corresponding to this category.

The Industrial Plant. The Council directive of 24 June 1982 on the major-accident hazards of certain industrial activities, commonly called the "Seveso Directive," stipulates that where certain industrial activities are capable of causing major accidents, the manufacturer must make a prior assessment of such hazards.[13]

Emissions and Discharges. Council Directive 80/779/EEC on air quality sets limit values, which cannot be exceeded, and guide values, which establish concentrations over specified periods, for sulfur dioxide and suspended particulates.[14]

Council Directive 76/464/EEC covers pollution caused by certain dangerous substances discharged into the aquatic environment (inland surface waters, territorial waters, internal coastal waters, and ground water).[15] Prior authorization by the competent authority in the member nation-state is required for all discharges of listed substances.

Worker Protection. Council Directive 80/1107/EEC sets out requirements for the protection of workers from chemical, physical, and biological agents.[16] This is a framework directive, which covers: limitation of the use of listed hazardous agents in the workplace; limitation of worker exposure; health engineering; threshold limit values; sampling procedures; collective and personal protection; industrial hygiene; worker information; warning and safety signs; health surveillance; record-keeping; emergency measures for abnormal exposures; and consultation with employers' and workers' associations. The first individual directive under 80/1107/EEC is the directive of 28 July 1982, which specifies limit values

for exposure to metallic lead and its ionic compounds (alkylated lead compounds are not included).[17]

The Seveso Directive, mentioned above under the section on the industrial plant, provides for prior assessment of potential industrial accidents that may also be considered to provide protection to workers.

Council Directive 78/610/EEC deals with exposure to vinyl chloride monomer.[18] It defines measuring methods, mandates the provision of information to workers about the risks to which they are exposed and the measures to be taken, requires the keeping of a register describing the type and duration of work involving exposure, and provides for medical surveillance.

Industrial Substances. Council Directive 67/548/EEC on classification, packaging, and labeling, and the Fourth and Sixth Amendments to the 1967 directive, have already been described. The Sixth Amendment requires that, at least 45 days prior to marketing a new chemical, manufacturers and importers are required to submit to the competent authority of the relevant member nation-state a notification including:[19]

- a technical dossier for evaluating the foreseeable risks to humans and the environment
- a declaration about the unfavorable effects of the substance;
- the proposed classification and labeling system in accordance with the directive; and
- proposals concerning recommended precautions relating to the safe use of the substance.

The notification is forwarded to the Commission for distribution among the member nation-states. Substances marketed in quantities of less than one ton per year per manufacturer need no notification. Notifiers must inform the competent authority of changes in the total or annual quantities marketed, new uses of the substance, or any changes in properties. The competent authority

can request additional studies to be undertaken at two levels: when the notifier markets quantities of 10 tons per year or a total of 50 tons, and 1,000 tons per year or a total of 5,000 tons.

The notification is required of all substances not classified as existing as of 18 September 1981.

Poisons. The European Community has no special legislation concerning poisons.

Agricultural Chemicals. Council Directive 78/631/EEC deals with the classification, packaging, and labeling of pesticides.[20] Pesticides are classified according to acute oral toxicity or percutaneous toxicity expressed as LD_{50} or respiratory toxicity expres- sed in LC_{50} values.[21] Council Directive 79/117/EEC establishes prohibitions on the marketing and use of products for plant protection containing certain active ingredients that, even when properly used, have harmful effects on human or animal health or on the environment.[22] Council Directive 76/895/EEC establishes maximum levels for pesticide residues in and on fruits and vegetables.[23]

Council Directive 76/116/EEC provides for the identification and appropriate packaging and labeling of fertilizers marketed in the Community.[24] Only containers of quantities greater than 100 kg need be identified on the accompanying documents. Council Directive 70/524/EEC lists additives permissible in animal feeds.[25] About 30 additional directives have amended the lists of substances included.[26]

Food Additives and Contaminants. The Council directive concerning coloring agents authorized for use in foodstuffs intended for human consumption has been amended several times.[27] It contains both general and specific criteria and includes labeling requirements. Council Directive 64/54/EEC lists permitted preservatives against deterioration caused by microorganisms;[28] it too has many amendments. Council Directive 74/329/EEC specifies permitted emulsifiers, stabilizers, thickeners, and gelling agents.[29]

Council Directive 76/893/EEC is a framework directive laying down procedures for the drafting of further directives concerning foodstuffs.[30] Specific materials, such as ceramics, plastic materials, paper, and paper board, are listed. Member countries may authorize the use within its territory of substances not included on the list under certain conditions, which include a maximum period of three years.

Consumer Products. Council Directive 76/768/EEC and its amendments cover the marketing of cosmetics and toiletries within the Community.[31] Cosmetics containing listed substances are prohibited. Council Directive 73/404/EEC specifies an average level of 90 percent biodegradability on anionic, cationic, nonionic and ampholytic detergents.[32] If a member country determines by test procedures specified in the directive that a detergent does not comply with its requirements, the country must prohibit the marketing of the detergent and inform the Commission and the member country from which the detergent came. Labeling requirements include product name and the identification of the organization marketing the product.

Council Directive 85/210/EEC directs that member countries are to reduce the content of lead in leaded gasoline to 0.15 gram/liter as soon as they consider it appropriate; that, until 1990, the lead contamination of unleaded gasoline by lead compounds may exceed 0.013 g/l provided it does not exceed 0.020 g/l; and that, from October 1989, the benzine content of leaded and unleaded gasoline may not exceed 5.0 percent by volume.[33]

Transport. Except for control of toxic wastes (see below) the European Community has no special legislation governing the transport of chemicals.

Chemical Wastes. Council Directive 78/319/EEC requires member countries to ensure that disposal of toxic and dangerous wastes is carried out without endangering human health or harming the environment.[34] Only competent authorities are permitted to store, treat, or deposit such waste. Toxic and dangerous wastes are to be kept separate from other matter and packaged and labeled appropriately. When transported, such waste is

to be accompanied by an identification form. Provision is made for monitoring and supervising installations and establishments that produce, hold, or dispose of toxic and dangerous waste and for keeping proper records regarding disposal. A list of toxic or dangerous substances and materials is given, and provision is made for additions to the list.

Victim Compensation. The European Community has no statutory measures corresponding to this category.

CURRENT DEVELOPMENTS

There does not appear to be much interest within the Commission to change the approach to hazardous chemicals or the harmonization mechanisms now in place. Approximately every three months, the competent authorities of the member nation-states meet to discuss the interpretation and implementation of the Sixth Amendment provisions.[35] The principal focus is on developing common interpretations of the toxicological data included in the base-set data required of manufacturers by the Sixth Amendment.

Much more seems to be happening at the Commission, however, with respect to regulation of biotechnology and its products.[36] The governments of the member nation-states appear to be in agreement that the Community should take the lead in formulating regulations in this area. This would be the first case in which the Community has established regulations om am area in which such have not already existed in one or more of the member nation-states.

The Commission appears to be waiting to see the response generated by the United States' Office of Science and Technology Policy bequest for public comment on its proposal for a coordinated framework for the regulation of biotechnology.[37] This interest is not surprising, for one of the motivations for the enactment of the Sixth Amendment was to provide a basis for negotiation with the United States after passage of the Toxic Substances Control Act.[38]

Since the regulation of biotechnology and its products would cut across so many areas of responsibility within the Commission, and since experience with coordination among various Directorates-General has been somewhat difficult in the past, a new type of structure is being considered for dealing with this new area of regulation. One proposal is to create a Biotechnology Management Committee to coordinate relevant interests within the Commission, to which a high-level science advisory body with public visibility would be attached. Detailed scientific advice concerning specific questions would also be sought from existing science advisory committees within the various Directorates-General.

The intention is to develop a mechanism capable of reflecting the interests of the member nation-states, make professional judgments concerning the scientific issues involved, and provide a basis for international coordination given the global nature of the markets involved. The hope is that what is approved in the United States would be accepted in the European Community and vice-versa.

NOTES

1. The description of the institutions of the European Communities is based on Emil Noël, Working Together - The Institutions of the European Community (Luxembourg: Office for Official Publications of the European Communities, 1985).

2. Under the ECSC, however, different meanings are attached to similar terms. Under the ECSC treaty, decisions are binding in their entirety, recommendations are binding as to ends but not as to means, and opinions are not binding. Emil Noël, Working Together - The Institutions of the European Community (Luxembourg: Office for Official Publications of the European Communities, 1985) 5.

3. Ten Years of Community Environment Policy (Brussels: Commission of the European Communities, 1984) 11-12.

4. DG I--External Relations; DG II--Economic and Financial Affairs; DG III--Internal Market and Industrial Affairs; DG IV--Competition; DG V--Employment, Social Affairs, and Education; DG VI--Agriculture; DG VII--Transport; DG VIII--Development; DG IX--Personnel and Administration; DG X--Information; DG XII--Science, Research, and Development; DG XIII--Information Market and Innovation; DG XIV--Fisheries; DG XV--Financial Institutions and Taxation; DG XVI--Regional Policy; DG XVII--Energy; DG XVIII--Credit and Investments; DG XIX--Budgets; DG XX--Financial Control. Directory of the Commission of the European Communities (Brussels: Commission of the European Communities) 1984.

5. George B. Wilkinson, "The Sixth Amendment: Toxic Substance Control in the EEC," Law and Policy in International Business, 12/46 (1980) 462.

6. Ten Years of Community Environment Policy (Brussels: Commission of the European Communities, 1984) 11-12.

7. George B. Wilkinson, "The Sixth Amendment: Toxic Substance Control in the EEC," Law and Policy in International Business, 12/46 (1980) 462.

8. "67/548/EEC: Council Directive on the Approximation of the Laws, Regulations, and Administrative Provisions Relating to the Classification, Packaging, and Labelling of Dangerous Substances," Official Journal of the European Communities, 196 (16 August 1967) 234.

9. The following description of the Fourth and Sixth Amendments is based on an interview with Patricia Brunco in Brussels on June 24, 1985. The more important of the two, the Sixth Amendment, may be found in: "79/831/EEC: Council Directive of 18 September 1979 Amending for the Sixth Time Directive 67/548/EEC on the Approximation of the Laws, Regulations, and Administrative Provisions Relating to the Classification, Packaging, and Labelling of Dangerous Substances," Official Journal of the European Communities, L 259 (15 October 1979) 10.

10. For a description of OECD activities in this field, see Joachim Ernst von Marschall, "OECD Efforts to Harmonize New Chemicals Testing: Variations on a Theme," Environmental Law Reporter 12 (October 1982) 15038-15048.

11. "76/769/EEC: Directive du Conseil relative à la limitation de la mise sur la marche et de l'amploi de certains substances et preparations dangereuses," Official Journal of the European Communities L 262 (22 September 1976) 201.

12. Ten Years of Community Environment Policy (Brussels: Commission of the European Communities, 1984) 11.

13. "82/501/EEC: Council Directive of 24 June 1982 on the Major-Accident Hazards of Certain Industrial Activities," Official Journal of the European Communities L 230 (5 August 1982) 1-7.

14. "80/779/EEC: Council Directive of 15 July 1980 on Air Quality Limit Values and Guide Values for Sulfur Dioxide and Suspended Particulates," Official Journal of the European Communities, 229 (30 August 1980) 30.

15. "76/464/EEC: Council Directive of 4 May 1976 on Pollution Caused by Certain Dangerous Substances Discharged into the Aquatic Environment of the Community," Official Journal of the European Communities, 129 (18 May 1976) 23.

16. "80/1107/EEC: Council Directive of 27 November 1980 on the Protection of Workers from the Risks Related to Exposure to Chemical, Physical and Biological Agents at Work," Official Journal of the European Communities, 327 (3 December 1980) 8.

17. "82/605/EEC: Council Directive of 28 July 1982 on the Protection of Workers from the Risks Related to Exposure to Metallic Lead and its Ionic Compounds at Work (first individual directive within the meaning of Article 8 of Directive 80/1107/EEC)," Official Journal of the European Communities, L 247 (1980) 12.

18. "78/610/EEC: Council Directive of 29 June 1978 on the Approximation of Laws, Regulations and Administrative Provisions of the Member States on the Protection of the Health of Workers Exposed to Vinyl Chloride Monomer," Official Journal of the European Communities, L 197 (22 July 1978) 10.

19. Legislative and Administrative Procedures for the Control of Chemicals (Revised and Expanded): European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 246.

20. "78/631/EEC: Council Directive of 26 June 1978 on the Approximation of Laws of the Member States Relating to the Classification, Packaging and Labelling of Dangerous Preparations (Pesticides)," Official Journal of the European Communities, L 206 (29 July 1978) 13.

21. Legislative and Administrative Procedures for the Control of Chemicals (Revised and Expanded): European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 247.

22. "79/117/EEC: Council Directive of 21 December 1978 Prohibiting the Placing on the Market and the Use of Plant Protection Products Containing Certain Active Substances," Official Journal of the European Communities, L 33 (8 February 1979) 36.

23. "76/895/EEC: Council Directive of 23 November 1976 Relating to the Fixing of Maximum Levels for Pesticide Residues in or on Fruits and Vegetables," Official Journal of the European Communities, L 340 (9 December 1976) 26.

24. "76/116/EEC: Council Directive of 18 December 1975 on the Approximation of the Laws of the Member States Relating to Fertilizers," Official Journal of the European Communities, 19, L 24 (January 30, 1976) 21.

25. "70/526/EEC: Directive du Conseil concernant les additifs dans l'alimentation des animaux," Official Journal of the European Communities L 270 (14 December 1970) 1.

26. Legislative and Administrative Procedures for the Control of Chemicals (Revised and Expanded): European Cooperation on Environmental Health Aspects of the Control of Chemicals - Interim Document 5 (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984) 249.

27. "Council Directive on the Approximation of the Member States Concerning the Colouring Matters Authorized for Use in Foodstuffs Intended for Human Consumption," Official Journal of the European Communities, 2645 (11 November 1962) 62.

28. "64/54/EEC: Council Directive of 5 November 1963 on the Approximation of the Laws of the Member States Concerning the Preservatives Authorized for Use in Foodstuffs Intended for Human Consumption (64/54/EEC)," Official Journal of the European Communities (Special Edition) 1963/1964 (November 1972) 99.

29. "74/329/EEC: Council Directive of 18 June 1974 on the Approximation of the Laws of the Member States Relating to Emulsifiers, Stabilizers, Thickeners and Gelling Agents for Use in Foodstuffs," Official Journal of the European Communities, 189 (12 July 1974) 1.

30. "76/893/EEC: Council Directive of 23 November 1976 on the Approximation of the Laws of the Member States Relating to Materials and Articles Intended to Come into Contact with Foodstuffs," Official Journal of the European Communities L 340 (1 December 1976) 19.

31. "76/768/EEC: Council Directive of 27 July 1968 on the Approximation of the Laws of the Member States Relating to Cosmetic Products," Official Journal of the European Communities, L 262 (27 September 1976) 169.

32. "73/404/EEC: Council Directive of 22 November 1973 on the Approximation of the Laws of the Member States

Relating to Detergents," Official Journal of the European Communities, L 347 (17 December 1973) 51.

33. "85/210/EEC: Council Directive of 20 March 1985 on the Approximation of the Laws of the Member States Concerning the Lead Content of Petrol," Official Journal of the European Communities L 96 (3 April 1985) 25.

34. "78/319/EEC: Council Directive of 20 March 1978 on Toxic and Dangerous waste," Official Journal of the European Communities, L 84 (31 March 1978) 49.

35. Interview with George Strongylis, DG-XI, Brussels, June 24, 1985 .

36. Interview with Thomas Garvey, DG-III, Brussels, June 25, 1985.

37. Office of Science and Technology Policy, "Proposal for a Coordinated Framework for Regulation of Biotechnology: Notice for Public Comment," Federal Register 49:252 (December 31, 1984) 50856-50907.

38. George B. Wilkinson, "The Sixth Amendment: Toxic Substance Control in the EEC," Law and Policy in International Business, 12/46 (1980) 462.

7

A FRAMEWORK FOR FURTHER INVESTIGATION

The preceding chapters describe political and administrative traditions, patterns of administrative jurisdiction, and current developments with respect to regulating chemical hazards in Japan, West Germany, France, the United Kingdom, and the Commission of the European Communities. As discussed in the introductory chapter, the material presented includes neither a systematic characterization of the procedures and their contexts, nor sufficient detail to enable conclusions to be drawn concerning the value of any particular approach for policy concerns in this country. This is principally because information about program definition, implementation, and enforcement were beyond the scope of this report. Nevertheless, it is important to examine a few of the principal attributes of such comparisons before discussing potential further investigations.

What seems to be the obvious process for reaching a fair and equitable resolution of a conflict in one political system may be awkward and disruptive in another. For example, in the United States, the courts are relied on to resolve many environmental conflicts. This approach gives the respective parties their "day in court," but places them in formal conflict. In contrast the French system is politically rather than legally oriented. It relies on government rulings and encourages public officials at all levels, from minister to prefect, to base their authoritative decisions on positions carefully prepared through informal, private negotiations. What would be highly suspect in the United States because of susceptibility to "undue" influence is viewed in France as the necessary integration of relevant interests in the formulation of mutually acceptable results.

Differences in procedure extend to the use of scientific evidence and expertise in regulatory and other decisions. One study comparing the regulation of formaldehyde in the United States and West Germany concludes that scientific studies serve a different role in the conduct of regulatory programs in the two countries because of fundamentally different understandings of what is required of a governmental decision.[1] In the United States, regulatory decisions are required by law to be justified in writing, and to be supported by the factual situation. One consequence is a great deal of research whose primary purpose is to support regulatory decisions. In West Germany, the essential attribute of regulatory decisions is not the interpretation of the factual situation but the balancing of interests to determine, first, who has the social responsibility to respond, and second, in which manner. Although the factual evidence is clearly a part of such determinations, the central aspect of the process is the balancing of interests. The presentation of evidence is presumed to reflect the interest of the presenter, making it essential to include all relevant interests throughout the process of deliberation. Less policy-driven research is performed, with greater emphasis given to the development of consensus.

Despite the pervasiveness of such differences among countries, an incontrovertible attribute of the modern world is that ideas and inventions cross political and geographical boundries, often with astonishing rapidity. But differences such as those described above mean that borrowing processes or regulations without careful attention to the contextual setting is likely to produce misleading and surprising results. It may be possible to learn valuable insights from other systems, but only by careful study of contextual factors affecting the developments in those countries. Various aspects of the regulatory systems in each of the countries examined in this report could, for example, be adapted to the American system. But it would be necessary to carefully examine the exact procedures and the context within which they are used to understand the function of each step of the respective processes. The counterparts of these functions in the American system could then be

examined to determine how they might be adapted in light of the foreign experience.

As stated in the introductory chapter, it is not the aim of this report to develop such comparative conclusions. Doing so for even one of the areas of regulatory concern examined in this report would require more resources than were available. The intent is rather to demonstrate the potential value of such comparisons. This report should be considered as a resource document for further, more explicitly comparative work. It reviews the regulation of chemical hazards in several countries in such a way that research topics which could inform the decisions of any particular country can be identified.

The examination presented here suggests several potentially fruitful and important lines of further investigation. This chapter describes four areas of possible research: (1) different approaches to problems or issues shared by all countries, (2) applications of similar policy instruments in different countries, (3) the examination of unique approaches or mechanisms developed by some countries and their applicability in other countries, and (4) the further refinement of the character of political and administrative traditions to understand the constraints on and potential alternatives in the implementation of regulatory programs.

APPROACHES TO COMMON ISSUES AND PROBLEMS

A major issue of common concern is the identification of problem chemicals and the subsequent selection of chemicals for testing. A study conducted under the auspices of the Chemical Products Division of the Organization for Economic Cooperation and Development (OECD) identified 62 known priority ranking systems in various countries and international organizations.[2] Despite this considerable effort, discussions with government officials suggest widespread concern in the countries included in this survey that systems currently used inadequately identify chemicals for regulatory attention. Examination of the systems for establishing priorities for further testing among commercial chem-

icals is especially important because of the crucial role played by this step in the implementation of whatever regulatory program is used in any given country. Examination of this step in the overall process of managing chemical hazards would likely reveal valuable insights into the functioning of the respective systems.

It should be extremely useful to examine the priority-setting systems currently used in terms of the following: the issues or questions addressed; the theoretical or conceptual basis of the method; the limitations of the approach, in terms of either applicability or methodology; and the prospects for further development of the system or extension of its application.

The problem of hazardous wastes, and especially what to do about depositions of such wastes in "disposal sites," is another problem confronting virtually all industrialized countries. Although this problem does not have the same degree of public recognition in all the countries included in this report, it is of considerable concern everywhere. Furthermore, the risks associated with hazardous waste sites have been identified through discovery of their negative consequences (Love Canal is a prominent example) rather than through anticipatory analysis (as in the regulation of most commercial chemicals). Thus, the examination of how hazardous wastes have been addressed in different countries should reveal important aspects of the way scientific knowledge and expertise is brought to bear on pressing issues of public policy.

Another issue that may be usefully addressed by comparative analysis is the problem of complex mixtures. The testing methods used to evaluate the toxicity of single compounds may not be appropriate for complex mixtures such as cigarette smoke or gasoline fumes. Some work is currently being undertaken,[3] but a review of relevant work in several countries would clarify and catalogue currently available alternatives. Issues that might be addressed include the classification of such mixtures, the identification of relevant routes of exposure, sampling techniques, appropriate testing protocols (including selection of dosage, duration of observation), and appropriate interpretive models.

A third issue common to the countries discussed here is exposure assessment. There is often much better information available concerning the potential health and environmental effects of a chemical than about the extent to which that it actually impinges on the target human, plant, and animal populations. One promising approach to increasing the sensitivity and preventive health value of studies in environmental health appears to be the identification and development of biologic markers at the biochemical or cellular level. Recent advances developed in basic research laboratories offer potential application to these questions. Some preliminary work has been performed, and a certain amount of international exchange is under way.[4]

A useful way of addressing these issues, and other issues common to these and other countries as well, is to conduct workshops involving investigators from relevant countries. The principal questions are conceptual and procedural, dealing primarily with problems that have not yet been addressed in laws and regulations. Although there are certain difficulties deriving from cross-national differences, for example in the expected roles of scientists in public policy decisions, these generally are not of critical importance to the conceptual and procedural questions on which such meetings would focus.

DIFFERENT APPLICATIONS OF SIMILAR POLICY INSTRUMENTS

Numerous concepts for the control of chemical hazards have been applied in many countries. One is the idea, often advocated by economists, that market incentives be used to make the legality of an action contingent on the receipt of specified returns. The reasoning is that efficiency will be promoted if a price can be placed on activities that would otherwise remain either costless or forbidden. This approach has been used under the Clean Air Act in the United States, which provides for a pollution offset trading and banking system, in which industrial facilities may be located in areas violating national ambient air quality standards only if existing polluters are either cleaned up or bought out

and shut down. This offset policy is designed to allow industrial development while permitting continued progress toward achievement of national standards for ambient air quality.[5]

A similar approach, in which total industrial sewage discharges were fixed at one point in time and subsequently could be bought and sold, may be found in the Effluent Control Law in West Germany.[6] This law must be seen in conjunction with the Federal Water Act, which empowers the federal government in Germany to establish uniform standards for certain major pollutants and the level of technology that must be used by municipalities and industries in processing their effluents.[7] The Effluent Charge Law provides for the issuance of discharge permits by the Länder which establish a discharge right, including specification of waste water quality and quantities, and the data upon which the discharge fee may be calculated.

A comparative examination of actual applications of market incentives such as offset policies or effluent charges might contribute to a better understanding of the relative advantages and disadvantages of this approach under specific conditions.

Another area in which different applications of similar instruments might be compared is the collection of data concerning adverse drug reactions. The approaches used in different countries include voluntary reporting by prescribing doctors and monitoring of prescription practices by professional organizations or other institutions with appropriate oversight responsibilities.[8] Even though these schemes are highly dependent on the specific nature of the overall health care system, they might reveal the conditions under which particular policy instruments are likely to be effective.

Investigation of the similarities and differences of particular policy instruments would require a case-study perspective. It would be necessary to examine exactly what was done, the context in which the approach was used, and the effect or outcome. Since it is usually necessary to have a common framework in order to compare

such case studies, a series of two or more workshops would probably be appropriate. In such a series of meetings, the treatment of several policy instruments in different countries could be considered efficiently.

UNIQUE APPROACHES AND MECHANISMS

The specific approaches taken and mechanisms used in particular countries may offer interesting and important models for other countries. Although the notion of learning from the experience of other countries is intuitively appealing, such analyses must be conducted with extreme care in order to avoid spurious conclusions. It is essential that such studies adequately account for the political and administrative contexts within which such programs are conducted, and that they examine the purposes served by specific procedures in terms of that context.

Japanese administrative procedures which involve considerable informal interaction between government and industry, are the focus of considerable outside interest. Furthermore, in combination with the decentralization of pollution controls, administrative guidance constitutes a flexible way of responding to pollution problems and might be a fruitful topic for investigation. A full examination would include sufficient instances to be representative of such relevant variables as geography and population concentration. It would also be necessary to relate the cases to pollution effects, perhaps through the monitoring program conducted by the Japan Environment Agency.[9]

Another unique mechanism that exhibits certain advantageous properties is the MAK Commission of the West German Research Society. The West German Research Society is an organization with the independent status similar to the U.S. National Academy of Sciences, and a limited funding authority, similar to the National Science Foundation; it sponsors research as well as providing advice to government. The MAK Commission, which is made up of independent scientific experts, annually publishes a list of maximum permissible concentrations in the workplace for selected chemicals. These

values are invariably adopted without modification by the Ministry of Labor for its regulations (guidelines and standards for workplace procedures and equipment are developed by another commission within the Ministry of Labor).[10] Each year the MAK Commission announces the chemicals to be included the following year (there is provision for extraordinary measures should faster action be warranted). The MAK Commission determines its exposure concentration values on the basis of the latest scientific information and alters its recommendations whenever new information provides sufficient justification. The degree of acceptance and lack of controversy surrounding this mechanism for integrating the development of new knowledge into the regulatory process is relevant for regulatory programs elsewhere.

Another such mechanism that has generated interest in other countries is the MITI testing scheme for evaluating chemicals in Japan. The MITI scheme screens chemicals for commercial use in three different tests and is used for both new products and chemicals already in commerce. Chemicals are first tested for biodegradability; if sufficiently degradable, they are cleared for commercial use. Those not sufficiently degradable are submitted to a test of bioaccumulation; if they do not degrade and do accumulate in fish, they are submitted for mammalian toxicity testing.[11] During its first 12 years of operation, more than 750 commercial chemicals were evaluated under this scheme, in addition to those submitted as new products. This is far and away the most extensive testing of "existing" chemical products in any country and has generated interest elsewhere. However, in accordance with Japanese laws, it applies only to environmental exposures. Care would be needed in interpreting this experience in terms of programs of chemical regulation in other countries.

Investigation of these and other specific approaches and mechanisms clearly calls for a case-study approach. It is essential that each case examines not only the attributes that make it of particular interest, but also associated activities and procedures with sufficient detail to reveal their contribution to the relevant components of public policy decision processes. The most direct way of interpreting the meaning or appli-

cability of unique approaches and mechanisms for other countries is in terms of the analogous components of public policy decisions in those countries.

CONSEQUENCES OF POLITICAL AND ADMINISTRATIVE TRADITIONS

The final area for further investigation discussed here is the further development and refinement of the character of political and administrative traditions and their impact on the contemporary conceptualization and implementation of programs regulating chemical hazards. This area is somewhat different from the others because it addresses the general approach to solving social problems in various countries rather than the specific mechanisms for solving particular problems. Several different lines of research are of immediate relevance, including comparative research on policies for controlling chemical hazards,[12] comparative research on policy formation and governmental processes in general,[13] and descriptions of the structure and organization of government across countries or within a single country.[14]

This topic includes potentially valuable contributions to each of the other lines of further investigation discussed above. A working hypothesis of this report has been that the political and administrative traditions of a country are important factors in the approach taken to the control of chemical hazards. The approaches to programs controlling chemical hazards in the various countries described in this report illustrate the importance of these traditions.

An example might be the apparent duplication of effort through replication of particular evaluative procedures in several countries. The American Conference of Government Industrial Hygienists is a private group of experts that has published recommended tolerence level values (TLVs) for exposure to chemicals for years. This function is also performed by the MAK Commission in West Germany and, as reported in Chapter 5, the Control of Substances Hazardous to Health Act in the United Kingdom includes provisions for independently establishing such levels there. The approach in this

report, which emphasizes the political and administrative context within which particular regulatory mechanisms should be seen, would suggest that there may be reasons for separate and independent evaluations in each country. But these evaluations are nevertheless based on scientific evidence and interpretations that are to some extent universal, and there might be ways of improving the coordination and exchange among these groups. However, determination of how this might be accomplished would require consideration of the exact procedures used by them and the nature of the scientific, administrative, and regulatory tasks they perform.

Other important topics in this general area of investigation include the assignment of responsibility among the relevant societal units or groups and the nature and patterns of interactions among those entities, and how to determine the "success" of a program in terms appropriate to that system. One way of addressing these issues would be to conduct workshops involving investigators researching relevant topics. The aim should be to clarify deep-seated assumptions that influence the conceptualization and implementation of regulatory programs. Such comparisons may be the most direct, if not the only, way of identifying these assumptions.

CONCLUSIONS

This report has examined approaches to the regulation of chemical hazards and mechanisms for enhancing the credibility of science-based regulations in Japan, West Germany, France, the United Kingdom, and the Commission of the European Communities. On the basis of its findings it may be concluded that comparative research attempting to draw lessons for domestic policy from foreign experience is not only feasible, but also that a great deal of value can be learned concerning the regulation of chemical hazards and other issues of public concern which may inform conclusions about approaches in any given country. Four areas of potentially fruitful and important further investigation have been proposed: different approaches of problems or issues common to all countries, different applications of similar policy approaches, unique approaches or

mechanisms and their applicability in different countries, and further analysis of the character of political and administrative traditions and their impact on contemporary conceptualization and implementation of regulatory programs.

NOTES

1. Rob Coppock, "Interactions Between Scientists and Public Officials: A Comparison of the Use of Science in Regulatory Programs in the United States and West Germany," Policy Sciences 18 (1985) 371-390.

2. OECD Existing Chemicals Programme, Chemicals on Which Data are Currently Inadequate: Selection Criteria for Health and Environmental Purposes, Final Report of Expert Groups III and IV, Volume I (Paris: Organisation for Economic Cooperation and Development, 1985).

3. The Complex Mixtures Committee of the Board on Toxicology and Environmental Health Hazards, National Research Council, is examining this issue, and the Working Group on Water Management Policy of the OECD Chemicals Product Division is preparing a report on the use of bioassays to identify integrated toxicity exposures.

4. See, for example Committee on Science, Engineering, and Public Policy, "Report of the Research Briefing Panel on Human Health Effects of Hazardous Chemical Exposures" (Pp. 108-121 in New Pathways in Science and Technology, New York: National Academy Press/Random House, 1985); the OECD Chemical Products Division is also planning a 1986 workshop on the topic.

5. Richard A. Liroff, Air Pollution Offsets: Trading, Selling, and Banking (Washington, D.C.: Conservation Foundation, 1980).

6. Gardner M. Brown, Jr. & Ralph W. Johnson, Polution Control by Effluent Charges: It Works in the Federal Republis of Germany, Why Not in the U.S.," Natural Resources Journal 24 (1984) 929-966; Gerd Winter, "Bartering Rationality in Regulation," Law and Society

Review 19/2 (1985) 219-250.

7. Gardner M. Brown, Jr. & Ralph W. Johnson, Polution Control by Effluent Charges: It Works in the Federal Republis of Germany, Why Not in the U.S.," Natural Resources Journal 24 (1984) 929-966.

8. William M. Wardell (ed.), Controlling the Use of Therapeutic Drugs: An International Comparison (Washington, D.C.: American Enterprise Institute, 1978).

9. See Quality of The Environment in Japan 1984 (Tokyo: Environment Agency Japan, 1985).

10. See the discussion in Rob Coppock, "Interactions Between Scientists and Public Officials: A Comparison of the Use of Science in Regulatory Programs in the United States and West Germany," Policy Sciences 18 (1985) 371-390.

11. Katsutoshi Kobayashi, "Safety Examination of Existing Chemicals -- Selection, Testing, Evaluation and Regulation in Japan," in OECD, Proceedings of the Workshop on the Control of Existing Chemicals Under the Patronage of the Organization for Economic Cooperation and Development (Berlin: Umweltbundesamt, 1981) 141-163.

12. Analytical studies of policies concerning the control of chemical hazards in several countries include: Sam Gussman, Conrad von Moltke, and Cynthia Whitehead, Public Policy for Chemicals: National and International Issues (Washington, D.C., The Conservation Foundation, 1980) and Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, Chemical Regulation and Cancer: A Cross-National Study of Policy and Politics (Springfield, VA: National Technical Information Service # PB83 206771, 1982). A compendium of laws and regulations in European countries may be found in World Health Organization, Legislative and Administrative Procedures for the Control of Chemicals: European Cooperation on Environmental Health Aspects of the Control of Chemicals--Interim Documents (Revised Edition) (Copenhagen: World Health Organization Regional Office for Europe, 1984). Examples of studies comparing chemical policies in two countries include:

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13. General comparative work includes: A. Heidenheimer, Hugh Heclo, and Carolyn Adams, Comparative Public Policy: The Politics of Social Change in Europe and America (New York: St. Martin's Press, 1975); Richard Rose (ed.), The Dynamics of Public Policy: A Comparative Analysis (Beverly Hills, CA: Sage, 1975); and Jeremy Richardson (ed.), Policy Styles in Western Europe (London: George Allen & Unwin, 1982).

14. See, for example, F.F. Ridley (ed.), Government and Administration in Western Europe (New York: St. Martin's Press, 1979); Ardath W. Burks, The Government of Japan, Second Edition (Westport, CT: Greenwood Press, 1964).