ENVIRONMENTAL PRODUCT CONTROL

A Comparative Study of the United States and Norway

Per A. Gulden

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Per A. Gulden

PREFACE

This review of environmental product control in Norway and the United States was prepared by Per A. Gulden during a ten months assignment to the U.S. Environmental Protection Agency.

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Office of International Activities
U.S. Environmental Protection Agency
Washington, D.C. 20460

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1.1 Summary

For protection of environmental quality, well-planned land use, and control of pollution from stationary sources will continue to be of great importance. However, it has become increasingly evident that this is not enough. Gradually, but markedly accelerating over the past decade, threats to health and the environment from a great number of the products we produce, use and discard have become strongly apparent.

It can be assumed that the greatest hazards are associated with chemical products, from which long-term effects loom darker than ever before. Closely related in terms of environmental impact are hazardous wastes, resulting both from the production and disposal of products. In modern urban society, noise has become a significant factor in spoiling the quality of life and causing mental and physical illness. Most of the noise is caused by products. Some products have a great potential for littering, which causes visual and sanitary degradation of urban and natural localities. Modern technology has brought into use a great many products that produce various types of radiation, the effects of which are not entirely clear. In the U.S. and in Norway, as in other western countries, protection from products with direct health effects has a relatively long tradition for such products as drugs, food components and pesticides. The new situation has brought about a rapidly increasing government involvement in the last few years.

The term environmental product control as used in this study concerns mainly governmental initiatives or actions taken to study or reduce detrimental effects to human health or the environment.

Many governments have enacted new legislation and taken action to control especially products with chemical effects. Norway has just enacted a law concerning the control of products hazardous to health or the environment (June 1976), which will be used to prevent any of the mentioned effects. Being an enabling law, practical action will depend on development of regulations. In the U.S., a number of laws are used to limit product hazards in for several types of products, and further development is anticipated.

The purpose of this report is to provide some information in view of the increasing general interest in this field of environmental protection, and in particular consideration of the present interest in this area in Norway. The study broadly describes the status of product control in the two countries, with emphasis on U.S. legislation and approaches.

Chapter 1 draws up the scope and purpose of this study, and contains very brief outlines of the status of environmental protection in the two countries and some of the attitudes that exist concerning such matters.

Chapter 2 contains definitions of some of the major terms used in the subsequent text. This is followed by a discussion of some of the basic issues in this field.

Product risk assessment, control of hazards, and coverage of the accompanying costs should ideally be the responsibility of the proponent of a product. This is in keeping with the Polluter Pays Principle, to which OECD member countries subscribe. The role of the government should accordingly be limited, preferably to that of a coordinator and supervisor.

The environmental acceptability of products must be evaluated and secured in the stages prior to marketing, and the assessment of benefits and hazards should be wide enough to reasonably include all effects at any stage from production to final disposal. As a ground rule, the proponent of a product should be charged with proving that the benefits of a product outweigh its associated risks.

While public information about the effects of a product will be a positive and necessary factor in product control, its value is largely supplemental to more concrete regulatory actions. Voluntary controls by agreements between government and manufacturers or importers seem attractive because of their voluntary nature, but in most cases such arrangements are impractical and inadequate for protection. Court rulings establishing liability on the part of the marketer for damages incurred by his product are becoming more common, and will instill increased prudence concerning marketing of hazardous products. The threat of liability is an inadequate deterrent against damage, for example where the effects of a product are delayed or very difficult to discern, or in cases where the primary damage is inflicted on the environment rather than on individual health. This has been recognized in Swedish and Norwegian legislation by specific statements as to the responsibility of anyone who handles a product, and explicitly that the marketer of a product must obtain sufficient information about a product to understand its effects. It is expected that such provisions will inspire the inclusion of criteria related to health and environmental safety at the product development stage. Economic incentives and disincentives have been used to a limited extent to reduce or alter the deleterious effects of products. To make such tools truly useful, new techniques and more experience is needed.

To limit governmental control activities and costs, the marketer of products must be required to provide relevant information for official use. Chapter 2 also contains a listing of various regulatory options, and some views on the need for simplification of relations between marketers and government regulatory agencies.

Costs to government for control activities are difficult to assess, but some cost figures are presented. It is even more difficult to predict costs for marketers of products. Some examples from the U.S. are included. Costs to industry have become a big issue in political debate, sometimes obscuring the fact that the purpose of environmental product control is to produce a net gain to society by preventing damage.

Chapter 3 concerns products with chemical effects. After a brief presentation of the types of problems involved, follows a listing of U.S. laws in this area. Consumer products, and the areas of pesticides, occupational health, and food, drugs and cosmetics are covered by new and viable laws. Consumer legislation, in particular, is quite advanced by international comparison. Conspicuously lacking is legislation to control toxic substances. Norwegian laws were inadequate in areas of hazardous chemicals and consumer products until June 1976, when the new product control law was passed.

Chapter 3 also gives a brief description of the product control situation in the two countries. In the U.S., control of chemicals generally, and in the occupational environment particularly, is not well developed, but the latter is steadily improving. Consumer products, motor vehicle pollution control, and pesticides are areas of considerable activity. In Norway, increased activity is expected in general control of chemicals, in workplace chemicals, and in consumer products.

EPA activity concerning toxic substances is presently limited, but considerable development of policies and approaches has taken place. Some of the most important issues are reviewed. Chapter 3 also includes a brief description of EPA's pesticides program. More detail is spent on EPA's motor vehicle emission control program, which well illustrates the complexity of technical and regulatory problems of product control. EPA's programs for control of fuels, fuel additives, drinking water and oil dispersion agents are also briefly described.

The Occupational Safety and Health Administration's (OSHA) program on hazardous chemicals is being developed, and the body of standards is presently imcomplete. There will be significant problems of compliance monitoring and enforcement.

The Consumer Products Safety Commission (CPSC) reacts to hazards reported in an extensive injury reporting system, and employs a number of powerful and uncommon control options.

Both countries have chosen regulatory restrictions as the primary approach to control of products. Control efforts in the U.S. take place in a very polarized atmosphere, where various actions by industry seem to obstruct prudent and sensible actions by agencies. Agencies are often in the position where they have to prove that a product is hazardous before action can be taken, in spite of express legal requirements concerning industry's obligation to provide test data. This is especially pronounced in the pesticides and food additives area, and reflects an ambiguous situation concerning the "burden of proof."

Chapter 4 deals with noise associated with products, and starts with a brief introduction to the problems of noisy products. The U.S. has advanced legislation concerning control of noise from products. Performance standards will considerably improve noise conditions. However, certain use restrictions may be required, and authority for use control rest with the individual states. The new Norwegian law will provide an adequate basis for regulating noise from products.

In the U.S. it is still too early to assess the effects of regulations, but substantial improvement must be expected as noisy products are replaced by quieter ones.

The EPA noise program has produced valuable information on the nature of noise hazard and control technology, and a number of regulatory techniques have been developed. Because of its many interesting aspects, the program is described in some detail. CPSC's noise program is largely incidental to the concern for safety, and is only briefly mentioned.

The information and techniques developed is the U.S. noise programs will undoubtedly be useful to other governments, and cooperation possibilities should be studied.

Following a brief discussion of some of the environmental aspects of waste and litter, Chapter 5 continues with a presentation of relevant legislation. Provisions for product control to reduce problems in this area are virtually non-existent in the U.S. federal laws, although several bills have been proposed over the years. Norway had limited legislation amenable to reduction of waste and litter from products before the new product control law was passed, and activity in this area has been low.

Generally, problems with hazardous wastes, and with the quantities of waste and litter tend to be greater in the U.S. than in Norway, but there are, of course, local deviations from this.

It is expected that initial U.S. regulatory actions will be more directed to handling, disposal and recycling rather than product control measures to influence quantity, or design or composition of products to reduce environmental impact. In Norway, efforts to enhance waste separation and biodegradability, and to reduce waste by use of return systems and standardization are likely to be undertaken. These are fields where the use of fees may be meritorious.

Other products which give rise to hazards such as radiation, inaudible sound, light, heat, etc., or may be dangerous by virtue of their electrical, explosive, flammable or mechanical properties are treated in Chapter 6. Some of such hazards have environmental significance, some products may exhibit such hazardous properties in combination with those dealt with in the previous chapters. The chapter describes some of the problems in these fields. Control of many such hazards has been established in the U.S., and particularly advanced systems have been developed for consumer products. While flammable textiles have been inadequately dealt with in Norway, quality and safety control of electrical products is good. The new product control law will presumably cover all of the mentioned types of hazards.

Much of methods development and regulatory work done in the U.S. concerning consumer and other products will be of great value to other governments.

1.2 Purpose and Scope of the Study

This study concerns the ways in which society, largely through actions by the federal or national government, protects the individual and the environment from adverse effects of products.

In the U.S. and Norway, as in other western countries, protection from products with direct health -- and safety related effects has a relatively long tradition, as for example drugs, food components and pesticides. But in the later years, with the advent of new environmentally significant chemicals, the proliferation of noisy products, products responsible for high-volume littering and other waste problems, an enormous variety of consumer products and sophisticated electronic products, it has become important to develop prudent protection mechanisms to cope with this new situation.

In recognition of these circumstances, a Norwegian law on product control was passed by Parliament in May 1976. During preparation of the bill it became clear that more than ever before, a comprehensive approach is needed -- an approach to assess the total societal benefits and costs at any or all stages in the "life cycle" of a product, the multiple effects of a product, and its combination effects with other products. The bill was designed to enable the government to act according to such principles, and regulate where needed on the basis of broad enabling powers.

The development of such regulatory capabilities requires inputs of information and experience from related activities elsewhere.

It is the purpose of this study to contribute to such preparations by providing a closer look at some current laws and activities in the U.S., where certain areas of product control are well developed.

A brief presentation of Norwegian legislation and activities will provide a wider frame of reference for some of the specific topics in the study. Also, such information on Norway will show some of the background for the government's initiative in product control, and may be useful in conveying some of the principal ideas to other countries which may be in a similar situation.

The scope of the topic of product control is very wide, and certain areas have been selected for discussion in this report. Those areas where western countries have a developed tradition such as drugs, and food are not covered; pesticides and issues relating to the occupational environment only briefly.

There is a general emphasis on product types with environmental significance and those which represent current issues in Norway. However, these lines are deviated from in cases where certain principles or strategies deserve special attention in relation to the product control concepts which are discussed. Most detail is devoted to descriptions of certain advanced U.S. programs, because this will be particularly useful as background information for planning new product control programs.

The study will also shed light on some of the important current product control issues for the benefit of general interest.

1.3 A Brief Look at Environmental Protection in the Two Countries

The U.S.A.

The abundance of natural resources has brought the U.S. to a level of use of energy, materials and environmental resources which is unparallelled. Growing environmental concern and protective action have not kept up with material development, and considerable environmental deterioration has taken place over the last 20-30 years. Over a relatively short time span, from the mid-sixties until the present, the momentum of environmental responsibility has increased to make it a considerable political force.

In the latest years good progress has been made with the enactment of new legislation in the areas of pesticides, air and water protection, occupational health and consumer protection. There is strong activity in enforcing the legislation.

At present, there seems to be a temporary culmination of the efforts. This is indicated by events such as the failure of Congress to legislate land use planning, strip mining, waste control, and toxic substances, after prolonged political battles. Congress almost decided to ease controls on pesticides by returning certain authorities to the Department of Agriculture in 1975. The delay in fulfilling the ambitious, but necessary, goals for vehicle emission reductions seems to be largely politically motivated.

These cases may be repercussions of acute energy shortages, economic recession and unemployment. If so, activity could be expected to recover as some of these problems now show some sign of improvement. However, the increasing hunger for greater energy consumption will be a most important factor and possible obstacle in the climb towards environmental improvement.

There are also a number of other factors that tend to obstruct environmental improvement in the U.S. One hinges upon the relationship between the states and the Federal government, wherein the states' individual interests tend to make a federal consensus difficult to achieve. The essence of this problem lies in such factors as differences in political climate, economic and industrial development, varying conditions of local environments, and a general waryness of federal influence on the local level.

Another problem is that U.S. society has reached such a level of material maturity that deeply entrenched consumers' habits and strong vested economic interests will provide great inertia against change.

Strong industry influence is present at all political levels, and heavy lobbying pressure on members of Congress is one manifestation of this. Industry is also believed by many to have considerable influence on administrative decisions, and also makes frequent use of the courts to refute or defer agency decisions.

On the other hand, public concern and awareness of the environment seem to be increasing. One issue very much on peoples' minds right now is the need to reduce the risk of cancer caused by environmental factors. There are a number of serious and vocal consumer and environmentalist groups which also influence politics and administrative actions through the courts. However, their economic resources in no way match their "opponents."

A most significant milestone for Federal efforts toward environmental improvement was reached by the passage of the National Environmental Policy Act of 1969, which requires Environmental Impact Statements for any project with federal involvement and directs each Federal Agency to incorporate environmental considerations into its decision making process. The Act established the Council of Environmental Quality responsible for studying the condition of the Nation's environment, to develop new environmental programs, to coordinate Federal environmental efforts, and seeing that Federal activities take the environmental considerations into account. The Council recommends national policies to the President. In 1970, the Environmental Protection Agency was created to carry out the national environmental policies. The Occupational Safety and Health Administration and the Consumer Product Safety Commission, as well as the Food and Drug Administration, are powerful factors in the national quest for a safer environment.

As in most other countries, environmental considerations are generally regarded as a necessary add-on to economic and material development rather than a limiting frame within which such development may take place. The emphasis is on growth in materials and energy consumption, tempered by environmental consideration. There are no direct regulatory efforts to conserve energy and material resources.

Development of environmental protection in the U.S. is likely to have significant impact on environmental actions abroad and internationally, both because of direct influence on a great number of factors, and by more passive example.

Norway

Although highly industrialized, environmental deterioration is generally less evident than in some areas of the U.S. However, grave local pollution problems exist due to industrial developments and population concentrations. Many of the environmental problems existing in the U.S. can be identified also in Norway, although the number of chemical pollutants is likely to be less.

The bulk of these problems developed with the rapid industrial expansion after the second World War. The southern part of the country also receives significant air pollution (acid rain and heavy metals) from middle European countries.

Norway has one of the world's highest per capita consumption of energy, but thanks to hydroelectric power this has not significantly affected the environment. Even though the standard of living is high, the material consumption per capita is relatively smaller. The chemical industry producing hazardous chemicals is also relatively smaller, but will become more significant as Norway enters into petrochemical production. Domestic production and products, as well as imported products create problems in the work place and are potential threats to general health and the environment. Many of the environmentally significant products are imported, and this may make adequate protection somewhat easier to achieve since restrictions will have less direct impact on local industry or employment.

There seems to be a general consensus about the importance of environmental protection, and administrative decisions in the area are not made in the type of adversary climate that often prevails in the U.S. in the chemical products area. However, present and imminent problems should not be underestimated. They will continue to grow with increasing production and consumption. Increasing protection from chemical and other products is clearly required.

The Ministry of Environment was instituted in 1972, and has responsibility for land use planning, nature conservation, resource management and pollution control. The State Pollution Agency is a parallel to the Environmental Protection Agency, but its scope is more limited. Control of pollution from industry and municipalities is progressing in a methodical way. Responsibility for control of other pollution problems also rests with the state authorities for health, occupational health and agriculture. Environmental protection authority is rather centralized, but authorities concerning municipal sewage and solid waste have been delegated to the counties.

2. PRODUCT CONTROL. CONCEPTS AND ISSUES

2.1 Product and Environmental Product Control - Definitions

In the Norwegian law on product control, "product" is a wide term which covers any item or substance at any stage as raw material, auxilliary, intermediate or finished goods. In this study, "product" will generally be used in the same way. When used in the context of specific laws, actions or programs, the term will take on a correspondingly limited meaning.

For the purpose of this study, the term "product control" will apply to any action aimed at reducing adverse effects on health or the environment, either directly or indirectly associated with a product. The study deals with governmental initiatives in product control, and therefore industry or citizen efforts will be touched upon only to the extent they compliment government programs. Product control may take on a variety of forms, such as direct regulation by law, economic insentives, information campaigns, and voluntary restriction agreements.

Product control measures can be applied at any stage of a product cycle -- production, distribution, use, waste disposal or recycling. The measures may affect many types of product related activities, such as production methods, handling, trade protection precautions, storage, packaging, labeling, use, testing and assessment of the effects of products.

In this study, "health effects" means any weakening of physical or mental health. Mental health is regarded only in relation to pollution, noise, visual pollution and odor, and not such things as subversive information media products. "Environmental effects" refer to problems caused by pollution, wastes, noise, radiation, etc.

Product control concepts may be used to protect or manage natural resources. While this study does concern the care of environmental resources, it does not address the problems of protecting non-renewable or contingently renewable resources. However, when product control measures are applied to protect against hazard to health or the environment, improved resource economy is sometimes an accompanying benefit.

2.2 The Need for Control

Environmental problems may be countered in basically three ways: First, we can reduce the negative effects of local pollution or noise by separating the associated activities from other activities which we wish to protect. In other words, we can remove ourselves from the most severe nuisance. This can be accomplished by land use planning. Although available space limits this type of solution, it must still be used where other solutions alone are insufficient, such as with airport and road noise.

Secondly, pollution is controlled by reducing discharges and emissions from stationary sources such as factories, power plants, and urban areas.

However, problems arising from products (or other activities related to them) are constantly taking on more significance. Health problems caused by products have long been under some form of control in many countries (pesticides, drugs, explosives), and product control in this sense is therefore not a new concept. The environmental significance of products, and the environmentally mediated health effects, has become a matter of concern over the last few decades. Control of products to reduce such problems are presently inadequately established. Product control to reduce environmental and health hazards represents the third important thrust in environmental protection.

It is common to apply isolated corrective measures to reduce adverse effects related to products where they are most evident -- emission control, worker protection, consumer protection. But it is very rare that all the hazards and societal costs are viewed together to give a true picture of the impacts attributable to a particular product. The concept of product control, when applied to full advantage, will enable society to raise the entire question of the net societal value of the product and related activities. Instead of the traditional piece-meal corrective approach, it should be possible to list all risks and societal costs related to a product from genesis to final disposal, and all corresponding benefits, and select the appropriate controls on this basis. (Or, the comprehensive assessment may lead to the conclusion that, all factors considered, society can do better without the particular product).

Product control authority completes the basis needed for society to set optimal environmental protection priorities and choose the best means for fulfillment.

The need for control of products will be further discussed in the following section, and in the sections referring to the general problems caused by products.

2.3 Who Should Control?

Ideally, the proponent for the use of a product should make sure that it does not directly or indirectly cause harm to any person or our environment. Since not many products are entirely safe or cannot be made entirely safe, accomodations of this principle must be made. However, it remains a reasonable and equitable principle to observe whenever practicable.

It may be argued that in a free enterprise system where the user has the free choice, the market will automatically discard hazardous products and support the safe ones. Also, the fact that a particular product can be sold, proves that the benefits are higher than the risks. And in order to operate in such a market, the marketer must always have a first hand knowledge of his raw materials, be aware of intended or unintended components in the product, and fully understand any health or environmental effects in order to be able to offer a competitive product. The argument is partly valid, but often there is little incentive to carry the assessment any further than to those properties of the product which are readily understood by the buyer. Therefore, the marketer will often not sustain the capability to assess the effects of a product on the environment or more subtle long-term effects on human health. There is reason to believe that this incentive is becoming stronger as more court rulings point to the liability of the marketer, but past experience does not guarantee that market self-regulation is satisfactory.

Even if the attitudes of society and the individual user were to become more strongly critical, there are several reasons why self-imposed control on the part of the marketer may not be sufficient. For one, there are the delinquents who do not disclose subtle hazards and thus go undetected without any kind of control. Further, even thorough testing may sometimes not reveal certain long-term effects. In such cases broad epidemiological reveiw may be the only possible method of detection.* Due to the volume and confidentiality of health data, such surveys may not even reasonably be expected of the marketer. There is also the fact that although some large companies will develop considerable expertise in assessing the effects of products, some of the smaller producers may never attain a

*Epidemiologic findings imply that certain effects may have been suffered. Such retrospective fault-finding should hopefully become less necessary when adequate pre-market control is established.

satisfactory competence. And since there may be a vast number of sources of environmental contamination, no one marketer has the possibility of evaluating the incremental environmental impact of his particular product. For these and similar reasons, several countries have concluded that some government control must take place.

However, virtually millions of different products are traded in the market today, and a great number of new products are introduced every year. It will be impossible for any government to act as overseer of the hazardous effects of all these products. This points clearly to the need for industrial involvement in the assessment and curtailment of hazardous effects. Such actions will add to the burden of demands and contraints on industry, and may at first hand seem to be undesirable for that reason. Nevertheless, this is the only practical solution, because otherwise an enormous bureaucracy would have to be supported from public funds. Such a solution would also mean that a large number of tax payers would have to contribute to the control of products from some of which they gain no advantage.

The basic idea that the person who benefits from the marketing of a product should also pay the costs of minimizing risks, is also embedded in the polluter pays principle which is formally adopted by the OECD member countries. This means that necessary control actions should be carried out by the industry. With few exceptions, these costs will be passed on to the user, who in turn is the right person to pay since he benefits from the product in question.

A final reason why industry should do as much as the work involved in product control as possible, is the fact that industry by necessity accrues a considerable amount of information before marketing of the product takes place. The party in possession of this information is clearly at an advantage to make assessments.

In conclusion, the largest efforts in assessing and reducing the risks from products should be made by the marketer. Government control, although necessary, must be kept to a minimum. The government should primarily take the role of overseeing measures taken by the marketers and supplement these where the marketer does not have the competence or cannot reasonably be expected to perform the complex tasks needed for adequate control. But even such a minimal government role may amount to a considerable effort.

2.4 How Can Products be Controlled?

Pre-market Control

Experience gives ample evidence of unwanted effects of products caused by lack of knowledge, neglect, or basic conflicts of interest. In many cases, corrective action is taken only when the damage is done and the effects are evident, with little relief to those who already suffered. Many of the problems could have been avoided had the effects been adequately assessed before the product was marketed.

The need for pre-market assessment has long been evident in pesticides, where effects can be so obviously horrible. Because of the sinister, long-term effects of a great number of chemical products, many governments now see the need for pre-market assessment and strong restrictions. The general concept of pre-market control does not only apply to chemical products, it must be effectively used on products that create waste, noise, radiation and other hazards.

Adequate assessment and control of products before marketing to avoid hazard to health and the environment, loss of investment or jobs, is a most important principle to be adopted in product control policy.

Public Information

Government's role in product control can take many forms. The mildest form would be to restrict activity to public information. It is sometimes argued that most problems stem from improper use of products, and that good information could eliminate problems to a significant degree. A government body can review the assessment made by the marketer and require appropriate warnings and directions for use and disposal. It is clear that this role is inadequate for many product types, and it will be more so as effects and use patterns become more complex. However, information is an important tool in product control where stronger measures are not required, or it may supplement other measures.

Voluntary Controls

It is also argued that adequate protection could be ensured by voluntary agreements between marketers and the government, while achieving minimal interference with market processes. This may be a solution in some cases. But just as the marketer would be free to enter into an agreement, he would be equally free not to do so. In very many cases it will to totally impracticable to establish agreements with all parties which have responsibility in producing or marketing a product. Similar difficulties will arise in cases where it is necessary to control the uses of products.

Liability and Responsibility

In many countries, the marketer has certain responsibilities towards the user for malfunctioning or for damage caused by a product. However, to collect damages or to punish a marketer for alleged lack of responsible precaution on his part is a lengthy and uncertain undertaking. This is partly due to the difficulty of establishing an evidential relationship between the product and ill effects, and partly due to lack of clear cut liability rules. More often than not, responsibility does not extend to cases of environmental damage and subsequent damage to human health. While increased liability in relation to products will increase general awareness, it will not per se become adequate as a protection mechanism. However, it may be a valuable component in a larger product control system.

In observance of the need to obtain maximum participation by marketers in the total product control effort, the Swedish and Norwegian product control laws expressly establish marketer responsibility to acquire sufficient information about a product to judge health and environmental effects. For products which have been in use for some time, and whose effects are thought to be understood, a marketer should at least acquire generally available information, and be alert for indicators which should initiate further investigation. In the case of new products, the marketer should have a more active obligation to assess the risks. The assessment should not only include his own handling of the product, but must to a satisfactory degree take into account effects caused by intended uses, and as far as possible also unintended uses.

An obligation to acquire a certain amount of knowledge should be extended to those who handle a product professionally.

Under certain circumstances where considerable analysis is required, a procedure modeled after U.S. Environmental Impact Statement* procedures should be considered.

In practice, information requirements will lead to increased effort on the part of the marketer or those who handle the product professionally to take the necessary steps to minimize risks. The producer will increasingly add to such present product product development criteria as efficacy, reliability, durability, safety and aesthetics, criteria intended to reduce adverse health and environmental effects, other safety hazards, or potential to create litter or excessive or undesirable wastes. Since it will be impossible for government agencies to look at every product, a clear obligation for the marketer to acquare knowledge will be very important. If sufficient guidance and proper enforcement are provided, such requirements will be very useful in a product control program.

*According to the National Environmental Policy Act, see section 1.3.

Economic Incentives

The use of economic incentives or disincentives in product control has been the topic of much discussion. Taxation could be useful when the objective is to reduce the quantity of a product used without having to resort to outright restrictions. Taxation does not directly restrict the choice of products (although the economic situation of the buyer is of importance). Taxation will also tend to inspire the producer to develop substitution products which have less undesired effects. Taxation may also have an advantage over legislative regulation in that it involves less administrative work, particularly with regard to enforcement. It is also argued that taxation may lead to quick results, and that it is a flexible tool that can be easily adjusted to suit the intended purpose.

However, there are few examples of taxation for environmental product control purposes. Norway has a tax on non-returnable beverage and beer containers sufficiently high to significantly reduce sales. There is also a tax on the sulphur content of fuel oil used in industry. In the U.S., an energy policy bill contains interesting provisions for a penalty on a sliding scale on cars that do not meet energy efficiency standards, and a corresponding credit for cars that perform better than the standard.

One of the problems of using taxation for environmental product control is that it is apparently difficult to determine the optimal rate at which the desired effects are achieved. Tax rates can be adjusted according to feed-back information on environmental quality but rate changes create new situations for marketers, whose patience may be understandably strained by repeated adjustments. Because taxation leaves the marketer with several options, it may be difficult to predict not only how much effect a tax rate may have, but also what kind of effects. Indeed, some unexpected effects may turn out to be less desirable than those which the taxation was intended to alleviate.

Thus, taxation may well be a flexible tool, but also a slippery one.

Taxation will not be useful in controlling very toxic products, or for example cancer-causing products. In political terms, taxation seems to become increasingly unpopular. Nevertheless, as experience with economic incentives develops, they may become increasingly important.

Regulatory Control Options

Regulatory control of products may be very complex and requires a broad set of flexible regulatory tools. These tools must be adequate to handle both acute problems and suitable for a systematic long-term effort. The degree of regulation must reflect the severity of the problem to be abated, and this calls for a graduated scale of regulatory options. Some products must be treated as individual cases with specifically tailored restrictions. In general, however, generic approaches to groups of products will be preferable.

There will be cases where regulations will apply to certain geographic areas or limit the number or categories of persons trading or handling a certain product.

Among the more common regulations will be requirements for labeling to inform or warn the user, or labeling and packaging requirements for safer handling, use or disposal.

To reduce hazard or environmental disturbance from products, regulations may be applied to change the composition or design or to set limits for emissions of pollution, noise, radiation, etc. Similar regulations may be designed to reduce waste and litter, and deposit and return requirements may be set for the same purposes.

In-use requirements for products are important in product control. Rules may be issued as to how, how much, where, when and by whom a product may be used. A manufacturer may be required to take responsibility for product compliance over the lifetime of the product, and the user may be prohibited from modifying the product in ways which would violate regulations.

For particularly hazardous or otherwise important products, registration and permit systems may be set up. As condition for granting permits, any of the mentioned requirements could be applied, or amounts produced or sold could be limited.

In some cases where the risks greatly outweigh the benefits, and where no other restrictions are satisfactory to prevent unreasonable hazard, it is necessary to prohibit marketing or use.

Other product control-related actions are: inspections to obtain information or to enforce rules, temporary bans on products where imminent serious hazard is suspected, seizure of products not in compliance, requirements on the marketer to inform the regulatory agency or his customers of suspected hazards with his product and to recall products or compensate buyers for the value of the product.

Several types of legal sanctions are in use in relation to existing product control schemes.

Primary concerns in promulgation of regulations are to make them self-enforcing to the highest possible degree. This may be achieved by such methods as self-reporting, information and record-keeping requirements.

An overriding concern with regulations is to make them simple to promulgate, simple to comply with, and simple to enforce. It is now common to attempt this by setting performance standards on products -- advising what a product should or should not do -- rather than dictating how desired properties or functions can be achieved.

Comprehensive Approach

The question of comprehensive assessment and subsequent selection of optimal corrective measures was introduced in section 2.2. Traditionally, the impacts of products and related activities at various stages have been assessed and regulated by completely separate authorities. Coordinated action has been obstructed by missing, or narrowly specialized legislation. To permit comprehensive assessment and optimal control actions, it is important that product control legislation be made sufficiently wide, and that administrative mechanisms are set up to ensure adequate coordination.

Burden of Proof

How to make good assessments of risks and benefit is a very real problem. The negative effects are sometimes very difficult to predict due to severe limitations in the present state of the art. Also, it may be difficult to know how, and to what extent a new product will be used -- both important factors for estimating risk.

To assess the risks is difficult, to assess the benefits is often no less difficult. An example could be the pesticide DDT. At the time of its introduction, little systematic assessment had been done, the effects have become evident over time. It is said that today, a large portion of the world's population indirectly relies on DDT for food supply and for protection against certain tropical diseases, to an extent probably not conceived of when the product was marketed. Had an assessment been made at that time, it is possible that DDT would have been severly restricted or held off the market.*

*While the merits of DDT are still being argued, the example does indicate problems of predicting both benefits and risks.

Because we are not equipped to make predictions of effects with complete certainty, there will always be doubts. In legal thinking, and according to administrative practices in the past, the benefit of the doubt should go to the proponent of a product. In other words, if the product cannot be proven to be hazardous, it would be unreasonable to interfere with the producer's right to market it. In the present situation of scientific uncertainty concerning the effects of products, it will be necessary to depart from this interpretation of the principle. In the interest of societal protection the burden of proof in relation to certain products must be laid on the shoulders of the marketer. He must prove that the product provides a net benefit, and if it cannot sufficiently be proven, society must have the powers to restrict or ban that product.**

Information Requirements

In order to take an active part in product control, governmental agencies depend on large amounts of information. The information developed by producers will often constitute the bulk of information required for government assessment and regulatory action. In order to avoid duplication of efforts and reduce the costs of government product control, it is reasonable that industry be required to submit information, either on a case by case basis or according to some predetermined format. Mandatory disclosure to government bodies is required in several countries, especially concerning economic poisons and drugs. Requirements on industry to produce information and disclose it to regulatory authorities is most important in environmental product control.

Problems of Over-Regulation and Over-Administration

Marketers of products are facing increasing restrictions and controls -- some of which have become accepted as necessary evils. Environmental protection measures are among the latest additions to the list, and are still often regarded as obstacles to industrial activity rather than considerations which should be naturally included in the course of activities. While perhaps no one would disregard the need for protection of health or the environment from effects of products, increased product control for such purposes will be met with a fair amount of resistance. A common complaint against environmental regulations is that they are often too complex and restrictive. There is

**This principle is applied to pesticides, drugs and food additives.

no doubt about the general need for regulatory action, nor about the complexity of the issues. (As an example, the U.S. Environmental Protection Agency (EPA) anticipates that it will require about 90 persons and several million dollars in contracts to put out necessary regulations for three chemicals in the average year). There is no easy solution to the problem of complexity of regulations, but a consciencious effort must be made to simplify as far as possible.

Another factor of concern to the industry is the need to deal with sometimes large numbers of government bodies for various types of permits or information. In some countries, a manufacturer may have to clear separate environmental permits for discharges to air, water, for waste disposal, for noise, for occupational hygiene, and land use zoning regulations. Depending on the product to be produced, it may become necessary to obtain permits from different authorities regarding for example human health, the environment, and consumer affairs. It must be a primary concern to minimize such administrative problems. Existing legislation is often not conducive to simplification efforts, because laws address limited number of products or effect types, and the agencies responsible are similarly limited in scope. Solutions must be found so as not to unduly limit the creativeness of industry, and to avoid overlapping or contradictory decisions by government. In some cases, the revisions of laws and subsequent consolidation of agencies may be the answer, in other cases inter-agency cooperation is the best answer.

The dilemmas of an increasing governmental role as overseer may best be pictured by such current terms in U.S. debate as: accountability, predictability, credibility, objectivity, and self-perpetuation of government agencies. Who is really accountable for decisions, and are individual interests sufficiently protected? How can agency actions be predicted, so that industry may have time to adjust? And is the scientific basis for decision adequate and used without prejudice? There are no easy answers. Unnumbered actions and changes in attitude must together contribute to acceptable solutions.

2.5 Economic and International Trade Issues

In economic terms, the purpose of environmental product control is to produce a net gain to society by preventing damage to health and environment. This net gain is the difference between the benefits and the costs. (The costs include damage caused by a product, as well as direct costs.) The magnitude of these items depend on what the specific problems will be, the level of activity undertaken to counteract them, and the influence of foreign trade relations, among other things. Therefore, at this point, it is only possible to make general statements relating to some of the important economic factors. The costs may be divided into two categories, (1) concerning direct costs of government and private involvement and (2) the micro-economic effects.

An order-of-magnitude of governmental expenditures may be indicated by looking at figures for largely new efforts as planned by the Norwegian government. Excluding pesticides control and supportive research, and expected to increase substantially over a few years, the estimate is about U.S. $0.15 per capita per year. Costs in Sweden are of the same order of magnitude. In the U.S., the EPA Office of Toxic Substances' funding under future legislation may be around $0.15 per capita per year. Corresponding figure for the EPA pesticides program is about $0.23.

Major cost items for producers will be for gathering information, testing and assessment. Large companies already do considerable work in these areas, and the average additional expenditures can generally be expected not to be disruptive. Some large companies, and in particular a greater number of smaller companies not presently equipped for these tasks will in some cases experience significant costs impacts.

In the U.S., attempts have been made to calculate direct costs to industry following adoption of the Toxic Substances Control Act (TSCA). The Manufacturing Chemists Association (MCA) sites figures ranging from U.S. $360 million to 1,300 mill. per year, EPA figures range from $80 million to $140 million. The wide range of each set of figures and the overall difference of almost a fact of 10 reflects uncertainties and different presumptions. On a national per capita basis, these figures vary from $.40 to $6.50. In the latter figure, almost one half is attributable to assumed loss of profit as a result of control-initiated decrease in industry new product innovation, and the rest seems somewhat inflated on the presumption that government actions will be concluded on a sweeping unselective basis.

In some cases, production or marketing may be postponed while further tests or assessments are carried out, and this may mean loss of return on capital invested in production or marketing. Such costs will again tend to have stronger effects on small marketers with a limited number of product categories. While such costs can not be avoided in some cases, close cooperation between industry and control agency will help.

When government product control actions reduce or halt the sale of product or require changes in processes of products, invested money may be partly or wholly lost. In cases where changes can only be made at high cost, reasonably extended periods of transition may ease the economic effects. More and more, it will be important for marketers to make early and thorough assessments to avoid such effects, and for the government to signal indications of potential problems as early as possible.

A general cost-benefit analysis must expressly or implicitly be made in connection with product control decisions. The problems are well known: economic costs must somehow be weighed against values which often can not be expressed in economic terms. Since this may be exceedingly difficult to do in compatible unit terms, a reasoned judgement must be made. Here, costs of health care, loss of productivity, environmental cleanup and waste handling costs must be considered. Imperfect as cost-benefit analysis techniques may be, they are nevertheless useful for indicating relative merits of control actions. It must also be remembered that trade-offs between economic and other values are implicit in almost any political decisions in any other area. Such trade-offs are in other words not peculiar to environmental politics.

The costs of control measures to be born by manufacturers are normally included in the price of the products and passed on to the consumer. As compared to the sum of all fixed and variable costs items that make up the price of a product, it is generally assumed that the additional cost increment caused by control measures is relatively small on the average, but there may be notable exceptions. Normally, such factors as fluctuations in costs of raw materials, energy and labor will be more significant than product control costs. Ideally, such cost should be directly reflected in the price of the product concerned, for reasons mentioned in connection with taxation as a product control tool. In practice, the marketer will have the option of distributing some of the costs of control to some of his other products.

Estimates by EPA and MCA conclude that the inflationary impact of the Toxic Substances Control Act (TSCA) will be very small.

Increased product control measures may present more problems to small marketers with limited assessment capability than to larger broad-based companies, and this may increase the tendency for small firms to merge. This tendency could to some degree be counteracted by cooperative efforts between small marketers by way of improved information and common testing facilities. Employment dislocations resulting from product control measures are extremely difficult to estimate because there are several more significant factors that determine the employment situation. Again using the above mentioned studies as examples, the EPA estimates that the TSCA will not cause a net increase in unemployment, whereas the MCA estimate is between 20,000 and 80,000 jobs lost in the U.S. over a 10 year period.

Dislocations in international trade is an aspect that must be considered as a result of product control actions. If the price of a product is significantly increased by product control requirements in one country, the product will be less competitive in international markets. It is important that such effects be minimized by international cooperation. Organizations such as the OECD and the EEC are working towards this end. EPA estimates that the balance of trade will not be seriously effected, whereas MCA predicts a reduction in the trade balance of up to 25% caused by declining sales of chemicals alone.

In some cases, different requirements for products for domestic and foreign use could be considered. For example, there may be cases where it is justifiable to use a certain product in one country and not in another. The question of unequal product requirements in countries also becomes a problem when a country with lax requirements tries to sell products to a country with stricter requirements. A refusal to import a product on such grounds may in some cases violate trade agreements. Generally, EEC, EFTA and GATT rules expressly permit import restrictions resulting from measures taken to protect health or the environment.

3. PRODUCTS WITH CHEMICAL EFFECTS

3.1 The Problem in General

Products with chemical effects are likely to be the most important category in terms of hazard to health and the environment. And possibly the most difficult to understand and control.

The number of chemicals, and the volumes used, have increased at an accelerating rate mainly within the last 80-100 years. It has been estimated that today some 2 million different chemical substances exist, most of which are of synthetic origin, and that this figure is increasing by some 20,000 new substances every year. The number of chemicals in the market is assumed to be about 200,000 and 200 to 500 new chemicals are introduced each year, mostly without systematic assessment. These substances are used in a far greater number of commercial products.

Most of these substances will be reasonably safe as they are presently used, but many have known hazardous qualities, and others are suspected. Also there are examples of substances previously believed to be safe, which have turned out to be harmful after closer investigation.

Although some organisms have shown ability to adapt and thus protect themselves against chemicals (such as certain insects against certain pesticides), it is obvious that we cannot count on such protection even against minute quantities of the great number of chemicals we are exposed to. While knowledge remains incomplete, it is suspected that maybe 70% - 80% of cancer cases are caused by some kind of environmental factors, a great portion of which are assumed to be linked with chemicals.

The potential for harm depends on chemical and physical properties of the substance, concentration, the magnitude, type and duration of exposure, and may vary from individual to individual. The damaging potential of a chemical may increase to a surprising degree in the presence of another substance.

Acute poisoning, evidenced by ill effects after a short period of time, is relatively well understood. Many such cases are results of careless or unqualified handling of a product, and such accidents may to some extent be avoided by better packaging or labelling, restricted use, and other means. But there are

also many examples of cases of acute poisoning where a product has been put to its intended use, such as when cadmium has been used in soft drink machines and contaminated the beverage, or when heavy metals have been released from crockery glazing into acidic foods.

Long term effects may arise from low exposures either long after the exposure has terminated or after extended periods of exposure. The symptoms may be loss of vitality, psychological disturbance, organ damage, mutation, damage to fetuses, and cancer. One well known example is the ability of vinyl chloride to induce liver cancer after a latency period of 15-20 years.

The problem of relating illness to the effect of some chemical is often evasive, and even suspected relationships may be hard to prove because there may have been other factors simultaneously influencing the health situation of the individual in devious ways. In some cases, the only method of value in discerning such a relationship is by statistical epidemiological study. Although a very useful method, it can only demonstrate after-the-fact damage, and will not warn of hazard before harm is done.

Most commonly, prediction of hazards must rely on toxicological tests carried out on some type of organism. Although substantial gains have been made in perfecting methods, the validity of results from other organisms as related to effects in man is constantly debated, and much knowledge has yet to be developed.

Some substances may be retained and accumulated in certain organs, their effects becoming manifest after certain concentrations have been reached. This, for example may be the case of cadmium, to which humans are exposed by way of many products like ceramic glazes, solder, rubber, plastics, paints, textiles, etc. Also well known examples of substances accumulating in tissues are certain synthetic stable hydrocarbons such as PCBs.

Chronic effects may also result from long term exposure to chemicals which do not accumulate in the body, such as sulphur dioxide. This compound resulting from combustion of oil products is a significant cause of respiratory ailments.

Danger of damaging contact with a chemical product is naturally greater for individuals exposed to relatively larger doses, such as workers, or housekeepers daily using a product. Products used in the closed environments are very important causes of damage to health. Chemicals purposely or inadvertently introduced into food are also important.

Chemicals dispersed in the natural environment will have effects on man, as well as other organisms and ecosystems. The distribution of chemicals in the natural environment may be regarded in four steps: discharge, transport, deposition, and possible uptake by organisms. Once discharge has taken place, it becomes almost impossible to limit dispersion and subsequent damage. In general, damage should, therefore, be prevented by limiting discharges. This is being done partly by restrictions on discharges to water and emissions to air from stationary sources such as factories and power plants.

In the overall pollution situation, the diffuse, non-point sources are charged with increasing significance. A vast number of different products constitute such sources such as transportation vehicles, pesticides and fertilizers, detergents, paints, solvents, etc. The only remotely practical way of limiting environmental contamination from such sources is to carry out some form of product control.

Chemical products dispersed in the environment will not only affect man's health through contact with air, water and soil and through food, but they will also have a variety of effects on the environment.

These effects are in some cases even more difficult to predict than direct effects on man, owing to variations in types and levels of exposure, and to the large number of different organisms, sometimes interdependent, that exist under a variety of environmantal conditions.

Because of the complexity of natural conditions, laboratory tests which shed true light on environmental effects are difficult to set up. Apart from acutely toxic substances, persistent substances such as the halogenated hydrocarbons and heavy metals have particular environmental significance. Metals, and to some degree hydrocarbons, may even be converted to compounds more poisonous than the original substance by biosynthesis (as mercury may be transformed into methyl mercury). Persistent substances may bioaccumulate in individual organisms and through the food chains, resulting in thousand-fold higher levels than those of the ambient environment.

Some chemicals may have more serious effects on the environment than on man directly, of which acid precipitation over Scandinavia may be an example. The acid is formed in the air by sulphuric pollutants emitted in large quantities in the middle European countries and from some local sources, and is shown to have devastating effects on fish and other limnic life over large

areas in Norway. Ecosystems may also be disturbed by chemical substances not particularly poisonous. Phosphates from fertilizers, detergents and other sources will under certain conditions give rise to abnormal algal growth in inland waters, causing oxygen depletions and subsequent death of fish and other organisms.

Some products having relatively insignificant direct effect on organisms may turn out to have the most profound impact on environmental conditions, leading to various forms of damage to life. One such product may be fluorocarbons used in spray cans in great quantities. As the substances find their way into the stratospheric ozone layer they may react with the ozone, and reduce the amount of free ozone. It is feared that this may lead to an increase in ultraviolet radiation, resulting in increased incidence of cancer and other ecological damage.

A chemical product may give rise to a large number of effects associated with all stages from production to final disposal. A full assessment of the impacts of a chemical on society and the environment may cover any number of problems related to production, distribution, use and disposal, and questions of direct exposure, entry routes to the environment, environmental exposure levels, uptake in organisms and toxicological and ecological effects.

Such comprehensive analyses have been made for a fair number of chemicals. There is also a very large litterature on specific effects of chemicals, particularly in animal toxicology. The problem here is that information is not increasing in pace with a growing number of chemical products used.

There is presently great need for more knowledge concerning the effects of chemicals and how to limit them. It is clearly essential to prevent damage to the individual, to populations and the environment, instead of the present tendency to try to correct damage once it has been done.

3.2 U.S.A.

3.2.1 Major Legislation

There are over 20 different acts that have provisions concerning chemicals inimical to man or the environment. The emphasis here is on environmental chemicals and on products for which there is no long-standing tradition of control. Therefore, laws pertaining to foods, drugs, cosmetics, explosives, pesticides, and other less related laws will only briefly be commented upon.

The Consumer Product Safety Act of 1972, which established the Consumer Product Safety Commission (CPSC), is a relatively strong legal tool that provides a number of options for product control regulation. While tobacco, motor vehicles, pesticides, aircraft, boats, food and drugs are excluded, it covers must other consumer products that represent unreasonable risks of injury.

When necessary, the Commission may formulate product safety standards with emphasis on performance requirements. Standards may also contain requirements pertaining to composition, contents, design, construction, packaging, or labeling with warnings or instructions. To insure openess and public participation, the Commission has to file public notice identifying the product and risk involved. Each notice must also include an invitation for any person to offer to develop the proposed product standard.

When a product presents an unreasonable risk of injury, and no feasible consumer safety standard will adequately protect the public, the Commission may ban the product.

The law provides that any interested person may petition the Commission to develop a new product safety standard or to amend or revoke existing standards.

When the Commission decides that a product presents imminent and unreasonable risks of death, serious illness, or severe personal injury, the product may be seized, or the marketer may be required to give public notice concerning risks, or to recall, repair, replace or give refund for such a product.

The Commission may also require pre-market notification for products which incorporate such design, material or form of energy exchange which has not previously been used substantially in consumer products or for which there is insufficient information to determine safety of the product.

The manufacturer is responsible for insuring that the product conforms to standards, and the Commission may prescribe a testing program when necessary.

A marketer has to notify the Commission immediately whenever a product fails to comply with product safety standards, or contains a defect which could create a substantial product hazard. When necessary, the Commission may order the marketer either to give public notice, direct individual notice, or to change, replace, or give a refund for the product.

The Commission may specifically require records and reports on products from marketers, and has the right to inspect the premises and documents of manufacturers and distributors to check compliance with the Act.

Imported products may be stopped by Customs if they fail to comply with safety standards or lack appropriate labeling or warning. Products that are exclusively exported are not covered by the Act.

The Act states the right of any person to sue for damages any person who knowingly has violated a product safety rule, and that remedies so provided shall be in addition to other remedies provided by other liability laws.

While the Commission has primary responsibility for enforcement, any interested person may also bring court action to enforce a consumer product safety rule. The Act also require CPSC to cooperate with states and other federal agencies, and states the right of CPSC to acquire information from other agencies.

The Federal Hazardous Substances Act of 1960 provides authority to monitor and regulate: (1) any substance which is toxic, corrosive, and irritant, flammable or combustible, or which generates pressure through decomposition, heat or other means, if such substance may cause substantial personal injury or illness as a result of any reasonably foreseeable use; (2) any radioactive substance determined to be hazardous and (3) any toy or other article intended for use by children which is determined to present an electrical, mechanical or thermal hazard.

The Consumer Product Safety Commission (CPSC) is directed to establish reasonable variations or additional label requirements for those substances found to present a special hazard to public

health and safety. The law prohibits the delivery or receipt in interstate commerce of any banned or misbranded hazardous substance, and authorizes CPSC to conduct inspections and investigations in the enforcement of these regulations, and to seize products not in conformance.

The Poison Prevention Packaging Act of 1970 contains authority to regulate packaging of household substances including hazardous substances as defined under the previously mentioned Act, pesticides, food, drugs, cosmetics and fuels. CPSC may set standards for safety packaging to protect children from serious personal injury or illness, and may forbid packaging that is unnecessarily attractive to children.

The Federal Insecticide, Fungicide and Rodenticide Act of 1947 as Amended by the Federal Environmental Pesticide Control Act of 1972 provides that all pesticides products be registered with EPA and reviewed for effectiveness and safety to man and the environment. All pesticide products must be classified for general use (available to the general public), or for restricted uses (only by certified applicators). All products previously registered under the Act of 1947 must be re-registered and classified in accordance with the 1972 Amendment. The registration of a pesticide product may be canceled if new evidence indicates that the product generally causes an unreasonable adverse affect on the environment. If action is necessary to prevent an imminent hazard during the time required for cancellation, the Administrator may suspend the registration of pesticide immediately. Hearing processes may be initiated whenever a pesticide product is canceled or suspended. The establishment in which a pesticide is produced must be registered and producers must be registered and must maintain such records as are required by regulation. A pesticide must be used in accordance with its labeling.

The Occupational Safety and Health Act of 1970 authorizes the Secretary of the Department of Labor to provide for the general welfare by assuring, as far as possible, every working man and woman in the nation a safe and healthful working condition. The law authorizes mandatory occupational safety and health standards, requirements of record keeping of employee exposure to hazardous materials, inspections and investigations of places of employment, and in the case of a violation of any standard or rule, citations or proposed assessments of penalty to the employer. The Secretary may also take immediate action to restrain any conditions or practices in any place of employment if imminent danger exists.

The Act also authorizes the Secretary of Health, Education and Welfare (HEW) in consultation with the Secretary of Labor, to conduct research relating to occupational safety and health. In addition, the Secretary of HEW is to publish annually a list of all known toxic substances, and to develop criteria and recommended occupational safety and health standards for handling these substances.

The Federal Food, Drugs, and Cosmetic Act, as amended 1972, authorizes the Secretary of the Department of Health, Education, and Welfare (HEW) to monitor and regulate the manufacture and distribution of any food, drug, device or cosmetic. Consideration is to be given to the safety, efficacy, and toxicity of ingredients of drugs (human and veterinary), food and food additives, and cosmetics. The Environmental Protection Agency is to set levels for maximum residues of pesticide in food and feed crops, while the Food and Drug Administration (of HEW) is authorized to enforce the levels. In establishing pesticide tolerances, the manufacturer must submit data on safety (toxicity to lab animals), the amount, frequency and time of application, and methods for identifying and removing excessive residues.

The Clean Air Act of 1970, as amended, directs the Administrator of the Environmental Protection Agency (EPA) to set national ambient air quality standards for various pollutants -- both primary standards, at a level which will protect the public health, and more stringent secondary standards, at a level to prevent the many other undesirable effects of pollution. The primary standards are to be achieved within five years (subject to a possible two-year extension) and the secondary standards are to be achieved within a longer time which each State can set, subject to EPA approval. Each State is required to adopt sufficient emission standards for individual pollution sources to achieve the ambient standards. If the measures adopted by a State are insufficient, EPA is required to adopt additional or more stringent measures. Cost is not a factor in achieving the primary (health-based) standards. Emission standards need not be limited to levels achievable by current technology, but instead can be used to force the development of new technology by private industry, with a "safety valve" extension procedure available to those who can show that they made maximum efforts to meet the standards, but failed.

The Clean Air Act also directs EPA to establish nationwide emission standards for various categories of industrial plants, which new or modified sources of pollution must meet. These "new source performance standards" must be equal to what is achievable by the "best available" technology. They are allowed to push the development of technology to some extent, but cost factors must be considered.

EPA is directed to establish nationwide emission standards for pollutants which are exceptionally hazardous to human health. These standards are to be set at a level which provides an "ample margin of safety" rather than a level based on cost or available technology. The Administrator is empowered to grant extensions of up to two years for compliance by existing sources, but not for new sources.

For motor vehicles, the U.S. Congress itself established standards requiring a 90% reduction in pollutants within five years, with a one-year extension being available from EPA if the automobile manufacturers can show both that technology is not available and that they made maximum efforts to develop the technology.

The Act allows EPA to establish regulations pertaining to the manufacture or sale of fuel or fuel additives which endanger public health or interfere with the performance of pollution control devices on vehicles, and to establish emission standards for aircraft.

Citizens are given the right to bring lawsuits against pollution sources for not meeting applicable standards and aganist EPA for not carrying out the law.

The Federal Water Pollution Control Act Amendments of 1972 mandated a comprehensive program to restore and maintain the chemical, physical and biological integrity of the Nation's waters. The stated goals of this Act are (1) to obtain, by 1983, an interim level of water quality that provides for the protection of fish, shellfish and wildlife and recreation, and (2) to achieve the elimination of the discharge of all pollutants into the waters of the United States by 1985.

The Act requires the individual States to adopt ambient standards protecting the uses of all waters and develop detailed plans for maintaining the desired quality. The Act directs EPA to set effluent limitations for most of the major industries in the country. These standards, are to be based on the "best practicable" technology -- to be achieved by 1977 -- and the "best achievable" technology by 1983.

Compliance with the water quality standards is achieved by a nationwide system of permits. Permits must be obtained from EPA (or from States with approved permit programs) prior to discharge into waterways. Permits contain conditions limiting the volume of waste water and the amount and type of pollutants which may be discharged.

Other provisions of the Act direct EPA to develop limits of toxic pollutants, pretreatment standards for industries discharging into a municipal treatment plant, and provisions regulating spills of oil and hazardous substances.

The Safe Drinking Water Act of 1974 requires EPA to set national health standards for public water systems, including primary standards which establish limits for contaminants to safeguard the public health, and secondary standards which apply to the odor, taste, and appearance of the water. It directs EPA to conduct research and studies regarding health, economic, and technological problems of drinking water supplies, and specifically concerning viruses and contamination by cancer-causing chemicals. The Act further provides for the protection of underground sources of drinking water by means of a regulatory program similar to that governing public water systems. Although EPA has the primary responsibility for establishing the national standards, the States are responsible for enforcement and supervision of public water supply systems and sources of drinking water.

The Marine Protection, Research and Sanctuaries Act of 1972 regulates the dumping of all types of materials into ocean waters, and allows for prevention or limitation of the dumping into ocean waters of any material which would adversely affect human health, welfare or amenities, or the marine environment, ecological systems or economic potentialities. The law prohibits the dumping or radiological, chemical or biological warfare agents and high-level

radioactive wastes, and regulates, through a permit system, the ocean disposal of other materials. The Secretary of the Army may issue permits for dumping dredge material, while EPA has the responsibility of issuing permits for all other materials.

The law further charges the Secretary of Commerce with responsibility for a comprehensive and continuing research program involving the long-range effects of pollution, overfishing or man-induced changes in ocean ecosystems. The Secretary of Commerce is also authorized to designate as marine sanctuaries those areas that should be preserved or restored for their conservation, recreational, ecological, or esthetic values.

The Solid Waste Disposal Act of 1965 provides for assistance to state and local governments, and others involved in managing solid wastes, by financial grants to demonstrate new technology, technical assistance through research and training, and encouragement of proper planning for state and local solid waste management programs. Under the Act, collection and disposal is left to the local governments.

The Resource Recovery Act of 1970 amended the legislation to provide a new focus on recycling and recovery of valuable waste materials. The Act directs EPA to publish guidelines for solid waste recovery, collection, separation and disposal systems, and to supervise the construction, demonstration and application of waste management and resource recovery systems for the preservation of air, water and land resources. EPA was also authorized to conduct a comprehensive research and development program to develop and test methods of dealing with collection, separation, recovery, recycling, and safe disposal of non-recoverable waste. Training grants are to be given in occupations involving design, operation, and mantenance of solid waste disposal systems so as to develop the needed highly skilled engineers and technicians.

The Transportation Safety Act of 1974 consolidates under the Secretary of Transportation the regulatory and enforcement authority to protect against the risks to life and property which are inherent in the transportation of hazardous materials in all modes of commerce. Under this law, the Secretary may issue rules governing any safety aspect of transporting these materials, including packaging, labeling, routing and handling. The law allows the Secretary to establish a program of registration for people who transport or manufacture certain designated hazardous materials.

One section of the Act deals specifically with regulation of aerial transport of radioactive materials to prohibit any transportation of radioactive materials on any passenger-carrying aircraft unless the radioactive materials are intended for use in research, medical diagnosis or treatment and the materials as prepared do not pose an unreasonable hazard to health and safety during transportation.

3.2.2 Proposed Legislation

Legislation has been proposed in two areas important to environmental product control. One concerns toxic substances, the other hazardous waste.

Toxic substances is a term covering industrial chemicals which are not covered by existing legislation. The first bill on toxic substances control was introduced in 1971, and since then, several versions have been considered. As of May 1976, Congress is working on new bills, and passage could be anticipated this year, or next.

Bills on toxic substances control presently under consideration, propose that EPA be granted the authority to require information on i.a. chemical identity, proposed uses, estimates of amounts, description of by-products, and number of workers exposed to both new and existing chemicals, to require tests to be performed by producer or marketer on health and environmental effects, and to regulate those substances which present or are likely to present an unreasonable risk. Specifically, EPA could establish test protocols for such chemical substances where there may be substantial exposure, or if there is insufficient data to conclude that a risk does or does not exist, and where testing would assist in making such a determination.

EPA would also institute a system for the premarket screening of new chemical substances. Manufacturers and processors of new chemicals, or existing chemicals for significant new uses must give information as mentioned above, including test data, 90 days prior to marketing. If the chemical is on an EPA list of chemicals which may contribute to unreasonable risks, the marketer must provide test data which show that there is no such risks. EPA may prohibit or limit manufacture if data are insufficient basis for risk assessment.

EPA will also have authority to prohibit or limit manufacturing, processing, or distribution of a chemical, or require labeling, and EPA can take prompt action in the event of an imminent hazard.

If risk presented by a chemical may be sufficiently reduced by a federal law administered by another agency, EPA shall request that agency to determine the risk. If that agency finds no risk, or conversely, takes action, EPA may not take regulatory action.

The aim of the act is to provide adequate testing by manufacturers or processors with respect to effects on health and the environment. It provides comprehensive authority to regulate any chemical substance at any stage from production to final disposal.

In order to reduce hazards connected with waste, it will be possible to regulate composition or contamination of products and probably also by-products from the production process. The Act will also give authority to regulate the disposal of waste both from manufacturer, handler or user. Authority concerning wastes in this Act overlaps to some extent with provisions under the Solid Waste Utilization Bill described in section 5.2.2.

3.2 U.S.A.

3.2.3 The Product Control Situation

The U.S. has a very large chemical industry, both in absolute terms and per capita. The industry's production volume has almost doubled over the past decade, with synthetic organics, paints, dyes, inks, plastics and elastomers expanding most rapidly.

The chemical manufacturers maintain that present voluntary pre-market testing and assessment generally is adequate for protection. Yet the industry vehemently opposes new legislation on grounds that testing requirements will unduly raise costs. This apparent contradiction seems to indicate that present testing activity is held back to cut costs. The Environmental Protection Agency (EPA) has estimated that testing requirements under the proposed Toxic Substances Control Act would cost industry from $80 to $140 million (sales are estimated at about $72 billion, profits at more than $5.5 billion, and research and development costs about $2 billion in 1974).

In the present situation, the government cannot require testing or disclosure of industry information needed to assess effects, and has no authority to control production, distribution or use or disposal of "toxic substances" not addressed by specific laws (as pesticides, drugs, food, etc.). Meanwhile, a great number of synthetic chemicals turn up in air, drinking water, meat, fish and plant based foods.

According to the EPA Administrator there is now a need to move from limited curative action to preventive action. This can only take place on the basis of new toxic substances legislation. EPA is preparing for regulatory action in anticipation of new legislation.

Control of chemical products in the workplace is the responsibility of the Occupational Safety and Health Administration (OSHA). It is probably not unfair to say that occupational health protection in the U.S. is presently insufficient, and that substantial improvement is necessary. The recent Kepone (pesticide) incident in Hopewell, Virginia, illustrates the inadequacy of enforcement (and lack of employer responsibility). In the plant, where

conditions later have been described as "incredible", a large portion of the work force were on sick leave or had to find other employment, many with permanent damage. While average conditions certainly are not that bad, the Council on Environmental Quality (CEQ) sees improvement of occupational health protection as a very important issue.

At present, only a few occupational health standards have been promulgated, and enforcement has been difficult because of lack of resources. Although Congress has enacted a relatively strong piece of legislation, many people are of the opinion that institutions charged with administering the law are inadequately equipped. The occupational health sector appears to have been particularly sensitive to industry's warnings of adverse economic and employment effects, and there has been heavy pressure to limit agency operations.

New health standards, as other environmental standards, are often contested in court (as for example the vinyl chloride standard, which was unanimously upheld in 1975). OSHA is undertaking a massive effort to produce health standards which address specific substances. Within the next few years, several hundred standards may be completed. Subsequently, compliance enforcement must be significantly boosted.

For the protection of farm workers, minimum reentry times from 24 to 48 hours have been established for some highly toxic pesticides as a national minimum requirement. Some States, notably California, have much stricter requirements. However, it is believed that many incidents of poisoning go unreported, and enforcement and reporting may have to be further intensified.

More and more studies indicate that the indoor environment, where perhaps most people spend most of their total time, is an environment where significant exposure to chemical agents takes place. So far, little work has been done to assess the total and combined impact of such things as toxic gases from gas ranges and oil heaters, indoor pesticides and disinfectants, detergents, paints, solvents, aerosol sprays, plastics leaking hydrocarbons and other synthetic material into air and food, new glues, and other products. EPA is taking some interest in studies of air quality, the Consumer Safety Protection Commission (CPSC) looks at products with mostly short term effects, and FDA has responsibility for example for food wrappings (as well as foods, drugs and cosmetics). An intensified and more comprehensive approach will probably develop over some years, as more studies throw light on the situation.

The consumer, using a variety of chemical products in household and leisure situations, is exposed to both acute and long-term hazards. Actions by CPSC are primarily aimed at acute hazards by requirements of labeling and safe packaging, little emphasis has been placed on long term hazards. Certain products have been regulated as to content (such as lead in paint), and a few have been banned (such as vinyl chloride in spray cans). Apart from labeling and packaging regulations, sale of products with chemical effects is rather unrestricted. While it is maybe too early to judge the impact of the agency's work, significant progress has been made to reduce child poisoning from drugs.

Control of chemical contamination of food is under the Food and Drug Administration (FDA), and the prolonged legal battles fought against food additives illustrate the technical and legal difficulties involved in its efforts to protect the public. While a lot of good work obviously is done by FDA, many share the feeling that FDA's position is too weak in the control of food additives. Work in the field of cosmetics has not been substantial.

The management of pesticides is well established. All products must be registered with EPA, which assesses test results submitted by the applicant. Pesticides are classified into two classes, one for restricted and one for general use. Establishments producing pesticides are being registered. Products are not yet subject to packaging regulations, but work on child safety packaging is being started. A factor which greatly increases administrative work, and which makes treatment of acute poisoning cases more difficult, is the fact that the U.S. has a very large number of registered products, in all some 40,000. While critics hold that EPA was largely rubber-stamping these chemicals up to about 1975, more decisive action has subsequently taken place as manifested by the banning of DDT, aldrin and dieldrin, and suspension of heptachlor/chlordane.

Hazardous wastes resulting from products or from activities related to products is a problem not satisfactorily addressed. Adequate technology for waste disposal exists for most substances, but there is no legislation to control and enforce adequate practices. CEQ has repeatedly underlined needs for regulation in this area, as contamination from wastes increases.

In many urban areas, emissions from motor vehicles present serious health hazards. As a result of restrictions, substantial reductions in emissions per vehicle mile traveled have been achieved, but because of the increasing number of automobiles, total nationwide emissions have increased by about 3.4% per year between 1960 and 1970. With the present goals for reduction of emissions, it is believed that there will be substantial

air quality improvement concerning hydrocarbons and carbon monoxide, but that there will be an actual increase in nitrogen oxide because of anticipated strong increase in such emissions from stationary sources. The ambitious motor vehicle control program is under heavy pressure from industry, and has been deferred on two occasions. Problems with unintended pollution by platinum and sulphuric acid mist (from the catalytic converter) also hamper the program.

No regulations pertain to sulphur content in oil or coal products to reduce pollution by sulphur oxides.

Additives to motor vehicle fuels may have significant effects on public health, as well as on emission control systems, and are required to be registered with EPA. Proposed limitations on the content of lead in gasoline have narrowly been upheld in the courts,the goals to be achieved by 1979.

Products to be used to disperse oil spills on water must be registered with EPA. No such products intended for marketing have been registered yet.

In the 1974 National Water Quality Inventory Report to Congress made by EPA in 1974, nitrate and phosphate levels in water contributed to byproducts such as detergents and fertilizers were significant. These pollutants increased by 54% and 74%, respectively, in 1968-72 over the previous years. There are no regulations pertaining to these products.

3.2.4 The United States Environmental Protection Agency (EPA)

EPA began operations in December 1970 to protect the health and welfare of the American people by controlling pollution hazards. In pursuit of this the Agency sets and enforces air and water pollution standards, monitors pollution, controls pesticides, set standards for noise and general ambient standards for radiation, works on solid waste management, conducts research and demonstration projects and supports state and local environmental efforts. The Agency has an extensive field organization with regional offices in ten major cities, and national environmental research centers in four locations, as well as a number of smaller laboratories throughout the country.

Toxic Substances

Almost every EPA office with program, research or legal responsibilities is involved in some way with efforts to control toxic substances. Such activities in the offices are integrated into the office programs, and the strategy of the Office of Toxic Substances (OTS) can be considered as a core strategy of the Agency's overall efforts to control toxic substances.

While OTS has no part of EPA authority to administer directly, it carries out important support functions for other EPA programs. Since toxic substances control actions by EPA seem to be impending (see section 3.2.2 on proposed legislation), and because it will develop into a program of great importance, a presentation of some of the main aspects of a possible control strategy will be made here. The degree to which the following principles will be carried out obviously depends upon powers vested in the law, and must be regarded as <u>indicative only</u>.

An approach to the control of environmentally significant chemicals will be directed primarily to those substances which exhibit adverse effects at relatively low concentrations, and concerns toxic effects resulting from sustained chemical or biological activity. Other hazardous effects such as fire, explosions, and radioactivity will not be in the primary plane of focus. EPA's concern with toxic substances is two-fold. The basic issue is to identify and assess the risks associated with the manufacture, distribution, use and disposal of chemicals and weigh these against the benefits. The other is to take practical steps to mititgate or prevent unwarranted risks posed by chemicals, by voluntary or mandatory actions as appropriate.

The toxic substances control activity may be structured on three main functions:

-Coordination and support of agency-wide efforts, with particular attention to pollutants deriving from multiple sources or which are significant in several of the environmental media, and corrdinate EPA activities with other agencies.

-Line function, such as assessment of risks and control options for products, development of regulations, monitoring strategies, and research needs assessment.

-Crisis function, including mobilization of agency resources to clarify a problem, and develop an implement control measures.

A list of program elements can be based on these functions:

-Restrictions
-Testing
-Industrial Reporting
-Early Warning
-Monitoring
-Crisis Response
-Research Needs
-Strategy and Coordination

These elements will be elaborated upon in the following.

Restrictions

A major problem is to select the substances of greatest concern and subsequently assess the risks and benefits associated with them. Given the diversity of effects, production and use patterns, economic, trade and labor issues, a good assessment is formidable task. Given the size of sector of industry involved in commercial chemicals not currently subject to regulatory authorities, it seems totally unrealistic to expect direct governmental intervention to regulate a large fraction of these products, each of which is to some extent a unique case. Much effort will, therefore, probably be directed at heightening industrial concern over the necessity to clarify the risks and to take action to reduce the risks, in other words make industry regulate itself as far as possible. To this end, EPA could give explicit public recognition of positive action taken by industry, and could take general regulatory action to force a re-orientation of industrial decision

making processes. Efforts will also be directed towards encouraging trade associations and professional societies towards greater responsibility.

Wherever necessary, direct restrictions will be imposed to mitigate severe environmental problems or to prevent future problems. The need for restrictions, what form they should take, and the impact of such restrictions must be clarified by defining governmental decision making criteria. In general terms these criteria are health effects, environmental effects, economic considerations, alternative materials, etc.

The basis for regulatory action is a thorough assessment to determine the appropriateness of regulatory actions. Such analysis will include factors such as risks, benefit costs, market trends, available and projected control technologies, extent and effectiveness of current regulations, and a study of available regulatory options.

Testing

Although the testing programs of some of the larger companies are acknowledged, current testing activities are generally inadequate, as reflected by the lack of effects data, the periodic occurrence of adverse environmental incidents and a conspicuous absence of information for identifying potentially harmful substances. Capabilities to interpret data are also limited. Industry tends on the whole not to release much of its test data, a practice that limits government's capability to participate in assessment of chemicals. A great total testing effort is undertaken by government laboratories and universities, but testing is predominantly science oriented and thus not always directly applicable in regulatory situations. Finally, the state of the art of testing needs to improve to meet present needs.

To tackle the problems of testing, EPA sees a need to improve approaches by government, industry, and the scientific community. EPA hopes to draw on industrial experience in developing testing procedures. The two key tasks are the determination of the chemicals which are to be tested, and the actual test requirements. To select those chemicals, methodologies for ranking priorities must be developed, based on multiple criteria such as similarity to known problem substances, production levels, inadequacy of available test data, presence of the chemical in the environment etc. Formulation of test requirements for all types of chemical products is beyond reach, and the agency will seek to provide guidelines concerning the types of test data needed. However, for some selected chemicals test protocols will be made up in detail.

Industrial Reporting and Processing of Data

Adequate control of chemical products requires not only effects data, but industry information on levels of production, use, geographical distribution of such activities, by-products, etc. Information is these areas available from government sources are inadequate, and EPA must set up a system whereby industry gives annual reports and pre-market notifications. Given the number of substances produced and the number of producers, it is essential to limit reporting requirements to data that will be directly usable for pre-market screening, regulatory or early warning purposes.

For existing chemicals, EPA will have to set priorities based largely on best judgement to require reporting on predetermined classes of particularly troublesome chemicals.

For new chemical products, and for new uses of existing products, data will be required from industry to determine potential adverse effects prior to marketing. Systematic files of such information will constitute a most important tool in efforts to prevent adverse effects. The data system must be able to point out chemicals that belong to chemical classes that have caused past problems, or processes with certain properties that should trigger further investigation. It is also important that the system point out products that are produced in large quantities and are used in a way which results in large human or environmental exposure. The system must be designed to perform a rapid screening process which should help pinpoint chemicals of concern.

Early Warning

Essential to warnings of incipient crisis is a viable data system as mentioned above. Review of all data on all chemicals or even limited data on all chemicals, is not practical. Criteria must, therefore, be developed for how to select chemicals that show potential for causing adverse effects. These criteria could be based on relationships between properties of a substance and its possible environmental effect. Past cases will be studied, and formal ranking schemes or mathematical models will be developed.

Early warning capability will also be enhanced by establishing a panel of experts knowledgeable in various areas of industrial processes, environmental problems, and chemically induced health effects. Another important reinforcement of early warning activities will be the search for indicators in information from monitoring, trend assessment, industrial reporting and the open literature.

Monitoring

Monitoring of the environment is of prime importance for assessment of the risk posed by substances in the environment and by new substances entering the environment. Monitoring data are required to determine the need for regulatory action, and to review the effects of regulatory actions. At present, monitoring programs for water and air are directed towards major, well known pollutants and pesticides. There is a need to single out useful information from existing monitoring systems and initiate new monitoring efforts. Monitoring is costly and complicated, both regarding methods and interpretation of data, and comprehensive monitoring for a large number of substances in all media is impractical. Target substances for monitoring must be carefully selected in limited geographical areas, and monitoring strategies should be tailored to each substance. Since such activity will be substance-specific, EPA must devise monitoring methods to discover previously unsuspected chemicals in the environment. EPA will attempt to use field information from its regional offices and teams of monitoring and assessment specialist who can respond to alarm signals. Further, attempts at a system of biota indicators will be made, and some scheme of selecting geographical areas.

Crisis Response

The increasing frequency of incidents of environmental contamination from toxic substances makes an effective crisis response capability necessary. It is felt that regional offices with their considerable experience in dealing with air pollution alerts, spills of oil and hazardous materials in waterways, and misuse accidents with pesticides, will be capable of the most direct response. EPA headquarters will aid local efforts by making available a range of specialists who can analyze technical aspects of the problem, by facilitating rapid access to relevant reports and scientific data, by keeping abreast of monitoring and data analysis capability to determine the distribution and levels of the product substance, and by preparing coordinated action with other federal agencies.

If a crisis incident points to the need for actions to reduce the probability of similar incidents, EPA will write guidelines for identifying and sampling potential hot spots around the country, make available adequate laboratory capability to analyze monitoring samples and review the need for research to clarify the properties of the substance. Where the situation may call for regulatory action, EPA will maintain a readiness to develop and implement regulatory steps.

Research

There is a need for research in new areas as well as to orient the current research efforts more specifically to actual program requirements. Improved test methods that are more responsive to regulatory needs are urgently needed, as are techniques for estimating human and environmental exposure levels and techniques for assessing economic, technological and market trends which may give forewarnings of future problems with chemicals. Further work will be done to develop rapid and low cost testing methods for predicting chronic effects in screening procedures, and methods for predicting environmental effects are needed.

Enforcement

Enforcement of regulations pertaining to production, import, use and waste disposal may become an activity of considerable magnitude. Enforcement will probably be carried out primarily by the EPA regional offices, supported by a team of technical experts at headquarters.

EPA's Office of Toxic Substances is currently working actively with some of these program elements and is preparing methodologies in those areas which depend on new legislative authority. Substantial efforts are made in monitoring, test methods, early warning techniques, and both preliminary and in-depth studies of specific chemicals, groups of chemicals and industry categories. A major portion of the work is done by contracts. The number of professionals in OTS is presently around 40, anticipated to increase to about 90 if legislation is enacted. The budget is expected to increase correspondingly from around $7 million to $20 million/yr. Activities in control of chemical products require very large resources. At the future funding level as indicated, some 15 chemicals (or groups of chemicals) may be under study at any time, and about 2-4 regulations promulgated per year.

Pesticides

There are four major parts to the U.S. pesticides program: supply control, use control, hazard evaluation and research and special studies. The major thrust of supply control is the classification of pesticides for either general or restricted use. Registration is required to insure that products are reasonably safe and effective, and to allow EPA to restrict the use of products which may cause unreasonable adverse effects, including injury to the applicator. The Act does not allow limitation of the number of pesticides in use. The present number of registered products is very high, around 40,000, based on around 1,000 chemical compounds.

About 55% of pesticides are used by agriculture, 30% by industrial, institutional and government users, and 15% by home and garden users. About 100-200 human deaths are reported from misuse of pesticides each year, and there is a much larger number of cases of poisoning. Pesticides are not yet subject to special packaging regulations, but EPA will formulate such regulations for child safety packaging. All packages are presently labeled with instructions for use and appropriate warnings. The main thrust in the use control sector are (a) certification of a great number of applicators of restricted use pesticides, (b) better packaging and labeling, (c) more extensive and timely enforcement, (d) extensive applicator training, and (3) dissemination of information to the consumer and public. Applicator training is carried out by the states under federal supervision.

In the hazard evaluation sector, extensive testing and a monitoring and surveying program have been in operation for a number of years. These efforts are made to identify possible problems and to provide supporting data for decisions to remove registered products which cause unreasonable adverse effects from the market. The monitoring system supplies information on levels and distribution of pesticides residues in the environment, and on acute and long term exposure levels. EPA sets pesticide residue tolerances for food and feed, and the standards are enforced by the Food and Drug Administration. Some major uses of important pesticides have now been discontinued and it is estimated that levels of dietary intake will decline fairly rapidly.

A substantial research and development program is aimed at providing scientific data on the health and ecological effects of pesticides, and methodologies for monitoring, analysis, and quality control to determine pesticide residue. Possible chemical and biological replacements for particularly hazardous pesticides are being studied. The budget figures for the entire pesticides program for 1976 is $44 million dollars, and the program has around 1,000 permanent positions.

Product Control under the Air Program

Motor Vehicle Emission Control

Mobile sources of air pollution are significant contributors to urban air pollution. In American cities, almost all of the carbon monoxide, more than half of the hydrocarbons and slightly less half of the nitrogen oxide come from mobile sources. In order to achieve the national ambient air quality standards for these major pollutants, Congress decided that emissions from mobile sources should be controlled by the incorporation of solutions into new motor vehicles at the point of manufacture, this being the most effective point for such action. The manu-

facturers were charged with the responsibility for developing the technologies needed. The Clean Air Act places the burden of producing vehicles that meet emission performance specifications on the manufacturer, and provides enforcement authority. Congress in effect established numerical emission standards, and did not define any solutions. While this gave little guidance to manufacturers, it allowed for flexibility and industrial innovation. It was probably also a wise decision, as the government, which obviously cannot match the expertise of the auto makers, might otherwise become responsible for a possibly inadequate solution. The solution chosen by manufacturers has been one of add-on technology (an emission control device incorporated in the system without changing basic principles), which may yet prove to be less than satisfactory.

Pollution controls mandated in the 1970 Clean Air Act were to be in effect in the 1975 model year, but have been deferred. After the point where the original reducation goals requirements are applied to all new vehicles (about 1982), it will take approximately ten years before almost all vehicles conform, due to a ten year turnover rate.

Successful improvement of air quality cannot be achieved if pollution control systems in new cars were to lose their efficacy over a short time. Vehicle emission control is one rare case where it has been necessary to require a certain durability in a product. EPA requires 50,000 miles of driving distance as a lower limit for emission control equipment efficacy.

This has given rise to interesting legal and practical questions. Manufacturers argue that their responsibility is to make emission control devices that satisfy requirements at the time of sale. At that moment the product moves out of their control, and it would therefore be unreasonable to demand their continued responsibility. Nevertheless, requirements have been based on what must be expected performance over time when the vehicle is operated by an average prudent user who observes proper care and maintenance needs. Periodic testing and maintenance will be required to ensure satisfactory operation. However, such testing authority rests with the states. So far very little state actions have been taken, and failure to institute state programs may seriously reduce the overall effects of the federal emission control efforts. If a vehicle which has been properly operated and maintained fails emission tests, the manufacturer must cover the costs of necessary repair. The user is subject to anti-tampering rules which make it illegal to make changes in the vehicle that result in reduced pollution control efficacy.

The Act allows EPA to require the recall and repair (at no cost to vehicle owners) of entire classes or catagories of vehicles which do not satisfy emission regulations. This is in effect a rather strong tool to ensure product compliance. So far, more than 1.5 million vehicles have been recalled for alterations in the emission control system. (Recall of vehicles has been practiced for many years for vehicles which have not had satisfactory safety characteristics).

The program also highlights such product control issues as compliance and enforcement of regulations. In this complicated field, it was recognized that enforcement activities could overload agency capacity, and regulations have consequently been made self-enforcing to a large measure. The manufacturer must demonstrate that the design of his vehicles will meet emission tests and must keep records, subject to EPA inspection. EPA formulates testing procedures, supervises testing, reviews and certifies applications on new designs, and performs a number of production and vehicle in-use spot checks.

Although it is very difficult to relate reductions in auto emissions to improvement in ambient air quality, analyses have shown that the vehicle emission reduction goals probably will not give acceptable air quality in some of the major cities. Where product performance requirements are by themselves not enough, it may become necessary to regulate product use. Congress has indeed made allowance for in-use controls in the law -- however, it has not set any specific guidelines. According to this authority, EPA has endeavored to impose other cures in some cities, such as parking restrictions, vehicle free zones and improvement of public transportation. This has been interpreted as federal intervention in local affairs, and has resulted in a very heated squabble. Most such measures proposed by EPA have been either obstructed by Congress or turned down by the courts. However, EPA still has certain options which may be developed, and the States have authority to impose regulations to control the use of vehicles.

It is a common trait in most recent environmental legislation that studies of technological feasibility and cost are required. In this case, as Congress itself set the standards, this requirement was not included. However, Congress will at intervals review EPA's decisions and the need for, and achievability of, proposed standards.

Two side effects of the vehicles emission control program are interesting to note. One that is environmentally beneficial, is that the chosen method involving catalytic converters requires unleaded gasoline. Since gasoline is the major source

of lead in the environment, this pollution will also be cut back as emission controls increase. A negative side effect, which led EPA to a one year suspension of standards applicable to the 1977 model year, is a previously unrecognized problem of sulfuric acid emissions from catalyst equipped vehicles. The effect of this pollutant and means of control are presently being studied. (One way to do it is to remove sulfur from gasoline at a cost of approximately six dollars per ton of gasoline).

Imported vehicles constitute a substantial portion of the United States market. The same requirements apply to imports. EPA also plans emission regulations on motorcycles, light duty and heavy duty trucks. Certain emission standards have been set for aircraft, and significant emission reductions are expected in 1979 and 1981.

The large and complex emission control program exhibits many of the concepts and issues discussed in chapter 2. It also illustrates technical, political and economic problems, and inertia to change in a well-established technology. It is an example of a case where an environmentally significant product has been based on an environmentally unacceptable principle (the internal combustion engine). While it is doubtful that another principle could have been chosen at the beginning in this case, the experiences point out that it is also important to reassess environmental impacts of products and bring about technology changes before problems get out of hand.

The federal auto emission control program currently requires $2 million and 53 positions for standards and guidelines $6.1 million and 162 positions for certification and testing.

Fuel and Fuel Additives

To provide availability of lead-free gasoline for catalyst-equipped vehicles, regulations were formulated in 1973. Also, for the general purpose of reducing airborne lead in the environment (of which lead in gasoline accounts for 90%) a schedule for general reduction of lead in gasoline to about 0.12g per liter has been set. This average limit is to be attained by 1979.

For reasons of possible effects on public health, and reduced efficacy of catalytic converters, regulations for the registration of fuel and other fuel additives have been proposed by EPA. Fuels and additives must be registered before marketing. This is one of few cases where a group of products has been singled out for control for environmental protection reasons.

Product Control Under the Water Program

Water Supply

An 80 city survey of water supplies in 1974 confirmed widespread low level contamination of water supplies by toxic substances. Interim drinking water standards were proposed in 1975, and will be supplemented and finalized on the basis of more research and monitoring data. The drinking water program will not be described here, since drinking water as such is perhaps not a typical "product." It is, however, interesting to make note of a rather unusual enforcement tool favored by EPA. It is based on a self enforcement mechanism, requiring suppliers of drinking water to notify consumers of contaminants in the water. If the water fails to meet health standards, the supplier may be obligated to notify of such failure and of the possible resulting health effects. Such notification, coupled with the possibility of a citizens' suit, is believed to provide a strong incentive to maintain compliance with the standards.

Water Quality

One group of products is directly addressed under the national oil and hazardous substances pollution contingency plan. For this group of chemical dispersing agents to be used on oil spills on water, rules call for submission of data on physical, chemical and toxicity characteristics prior to their use. In the year since this rule was made effective, no such data have been submitted. This means that there are presently no chemical dispersants authorized for general use. (Other agents may be used where necessary to prevent hazard to human life or limb or to substantially reduce explosion or fire hazard.)

3.2.5 The Occupational Safety and Health Administration (OSHA)

The decisive step in protective regulation of chemicals in the occupational environment was taken with the passage of the Occupational Safety and Health Act in 1970. Up to the present, the greatest part of workplace improvement efforts have been directed to safety, but strong action is now taken to improve control of health-threatening chemicals. A substantial program of research, rulemaking, education and enforcement training has been started, although many hold the opinion that capacity is still inadequate to catch up with developing problems.

Identification of hazard substances, assessment of their potential health effects, and study of control options is largely done by the National Institute of Occupational Health (NIOSH). The Institute also contributes to development of standards, the promulgation of which is the responsibility of OSHA.

The lack of standards is presently seen as the main problem. Where standards are not established, the employer has only a general duty to maintain a safe workplace. This in effect gives inadequate protection to the worker (courts have construed this responsibility to go only as far as to those hazards which may be recognized as clearly evident to the senses, i.e. smell, eye irritation, etc.), and the employer is not required to monitor, report conditions, or inform workers of established threshold values. (Recommended Threshold Limit Values exist for a number of chemicals).

So far, about ten standards have been promulgated for chemicals, and a major effort is underway to complete standards for around 400 substances. Certain monitoring and reporting requirements will be included. Fourteen standards have been established for carcinogenic chemicals. The standards are largely directed to proper practices to be followed in a plant. No permits or monitoring is required. As part of its standards promulgation activity, OSHA must consider economic and inflationary impacts of proposed actions.

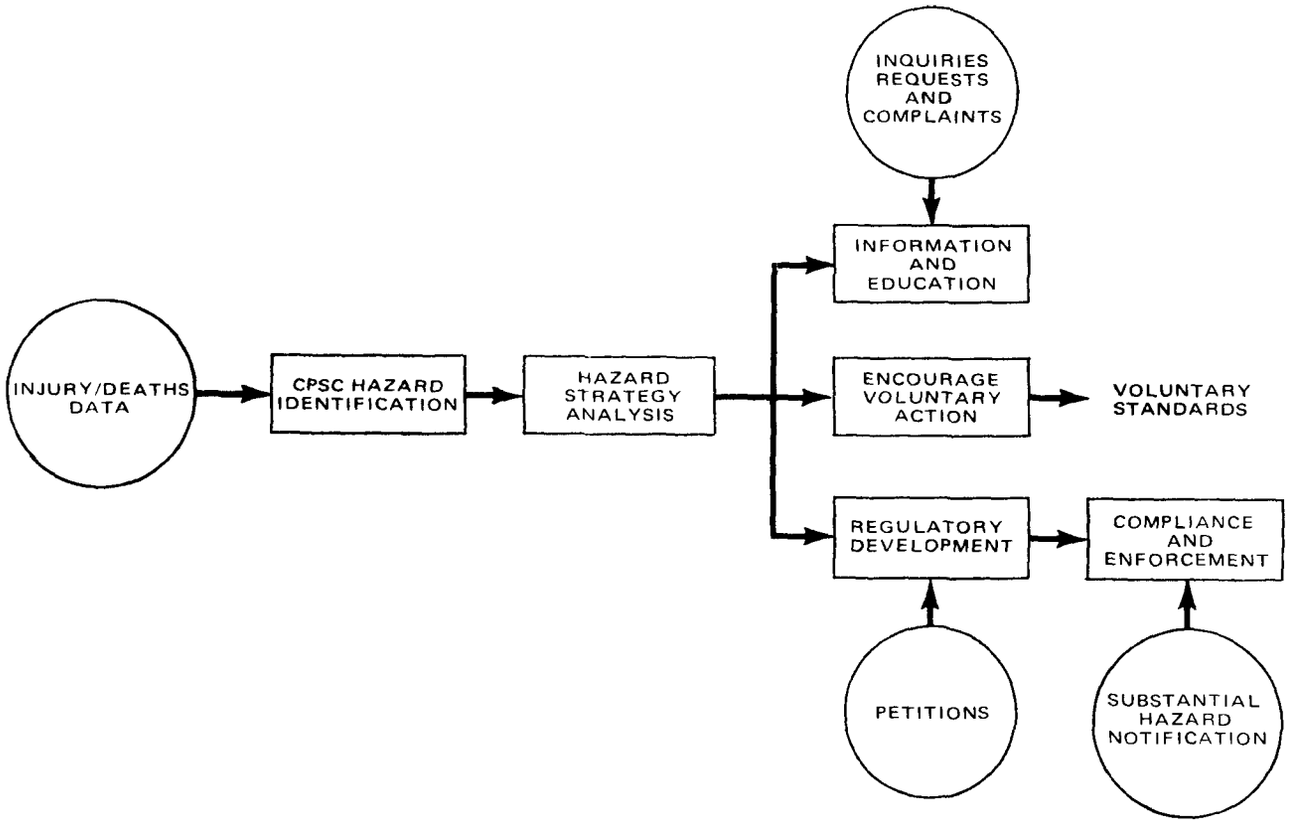
As standards are completed, an increase in plant inspections for exposure to chemicals must follow. OSHA plans to step up this activity substantially. An often-heard criticism of current regulations is that they are not sufficiently self-regulating, but require too much inspection effort. Education and consultation programs for employers and employees in states without approved health programs are considered very important. Such programs will i.a. provide local guidance to employers, especially smaller employers.

OSHA's current appropriations for standards development are about $5.2 million (about 140 positions), about $96.5 million (about 1.700 positions) for enforcement equally divided between state and federal activity (10% of this may be ascribed to chemical-related inspections), and additional funds for training, information and health statistics.

3.2.6 Consumer Product Safety Commission

The Consumer Product Safety Act established the Consumer Product Safety Commission, which was activated in 1973. Its primary mission is to protect the public against unreasonable risks of injury associated with consumer products. According to this, the Commission will assist consumers in evaluating the comparative safety of consumer products, develop uniform safety standards for products, and promote research and investigation into the causes and prevention of product related hazards. The Agency's authorities relating to chemicals are vested in the Consumer Product Safety Act, the Hazardous Substances Act and the Poison Prevention Packaging Act. These authorities are both unique and powerful. In recognition of the complexity of the assessments and trade-offs involved in its decisions, the Agency has adopted a cooperative, open approach. Maximum participation from interested groups is sought, as reflected in a broad representation in three Advisory Committees. Also, the Agency maintains an active information program and strives to open its internal and external actions to interested parties.

The Agency's operation involves many of the principles and mechanisms of product control that are discussed in chapter 2, and closer look will provide some interesting practical examples. The following sketch shows a simple program structure which identifies the major action components:



It is clear that the system is set up to act in a reactive way, in that action is initiated only on the basis of after-the-fact information on injury and death. While this may seem to be a some what static policy more aimed at cure than prevention, it nevertheless seems to be a practical way to start. With regard to chemicals, the approach has lead to an emphasis on acute hazards rather than long term effects.

To meet its statutory responsibilities, the Agency must collect information on injuries associated with consumer products. This information constitutes the major input to the planning process and gives a rational basis for the development of appropriate strategies for hazards and injury reduction. It has been found that about 1/3 of accidents related to products are treated by private physicians, and about 1/3 by hospital emergency rooms. The information systems gathers data from emergency rooms of 119 hospitals daily. This large body of information is related to 990 different product codes, and a ranking system is applied to help the Agency focus on those products against which action should be taken to reduce hazards. While chemical products are not at the top of the ranking list, the system tells of about 100,000 estimated injuries related to such products in homes per year. Data are also gathered from other sources such as the National Center for Health Statistics and the National Household Interview Survey, and the Agency is planning to expand its data base through a physician's office survey. The gathered information is also used as input in predictive models. For example, one such model predicted that 20% of poisoning injuries from antifreeze could be prevented by a poison prevention packaging regulation.

Child resistant packaging has been required for a number of drugs, resulting in a substantial drop in accident rates. However, the Agency assumes that safety packaging can only reduce risk by about 20%, and that risk will be somewhat further reduced by labeling and other means of information. Apart from packaging and labeling regulations, the sale of hazardous chemical consumer products is relatively unrestricted. The Agency has applied stricter measures in some cases, for example by limiting the amount of lead in paint, or banning vinyl chloride as aerosol propellant because of possible carcinogenic effects.

For selecting appropriate regulatory measures, the Agency develops a predictive impact analysis in which effects of various restrictive actions are analysed. The Agency is also examining the feasibility of regulating product hazards by issuing generic standards as an alternative to the product by product approach.

The Agency's regulatory activity is partly conducted in response to the Agency's gathered information, and partly on the basis of petitions received from organizations or individuals. Such petitions, while allowing a necessary and valuable opportunity for providing public participation, seem to divert a substantial part of the Agency's resources from a systematic approach to a case by case approach.

One interesting feature of the Consumer Product Safety Act is the institution of the "offeror" process. It is intended to promote development of safety standards by making the maximum use of the expertise of consumers and industry by providing opportunities for all interested parties to participate in the standards development process. (Most of such work is otherwise usually done by the agencies or by contracts with specialized firms or institutions.) The approach has apparently been quite successful.

The Commission believes that the development of creditable voluntary standards in an open forum is in the public interest and can result in more effective utilization of commission resources, and there is considerable activity in this field. Most voluntary standards being developed will apply to non-chemical products.

Education of the consumer is considered to be a very important factor in reducing hazards from product. About 1/6 of the Agency's budget is spent on information programs through radio and television and in schools.

The Agency's field force makes numerous inspections of various hazardous household substances, and a large number of products are being analyzed every year for chemical composition by private laboratories. The Agency has also instituted "consumer deputy" programs, in which trained volunteers have taken part in retail surveillance for child resistant packaging and labeling requirements for a number of chemical household products. An interesting self-regulatory feature of the Agency's compliance program is the "substantial hazard notification." The law expressly places responsibility on the manufacturer, importer, distributor or retailer for immediately notifying the Agency of any hazard related to a product which does not comply with regulations or which poses an unreasonable hazard. One hundred twenty-four such notifications were received from manufacturers in 1975. The Agency also advises producers that their products may involve defects that constitute substantial hazards if the Agency has received such indication by its own investigation or from consumers. There have been numerous examples of crimminal prosecutions and seizures of chemical products.

The Agency's budget is about 37 million dollars, and the number of full time positions is about 900.

3.3 NORWAY

3.3.1 Major Legislation

The Drugs and Poisons Act of 1964 requires applications for pre-market approval of any drug. The law also regulates pricing and advertising of drugs. For other poisons and hazardous chemicals, certain regulations apply. For poisons (as defined by official listing), permits are required for production, sale, import and export, and purchase of poisons is restricted. There are also provisions for packaging and labeling. Other less hazardous materials are subject to milder restrictions such as labeling and minimum age of the purchaser. There are regulations concerning responsibility in connection with handling and storage. The law is used for reducing health hazards, and has no provisions for controlling environmental effects.

The Pesticides Act of 1963 requires permits prior to marketing. The marketer must provide information sufficient to show that the benefits of the products outweigh its risks. Workplaces which handle pesticides are subject to inspection for safety. There are regulations concerning approval, packaging, labeling, use, storage, sale and transportation, production, import and trade, advertising, fees, etc.

Law on Worker Protection of 1956 gives the government authority to act against any product used in a work place. The main responsibility for safety remains with the employer, who is expected to exercise a large measure of self-control concerning use and handling of chemicals. There are provisions for government inspections, and the employer may be required to undertake investigations where a chemical substance is believed to be hazardous to health. The Law has not in practice provided adequate protection against hazardous chemicals, and is presently under revision.

The Water Pollution Act of 1970 and the Neighbors' Act of 1961 (used in connection with air pollution and noise) can be used to restrict introduction of chemical substances into the environment from stationary sources, and are thus valuable components in the overall control of chemicals.

The Act to permit limitations in the use of heating oil of 1970 allows regulation of sulfur content in the oil. There is also an act governing the use of lead in paint, and regulations concerning lead in gasoline.

Several laws govern control of food and feedstuffs and apply to their quality as well as to additives and chemical residues.

Most of these laws are designed to protect health against direct exposure to hazardous chemical products. A few aim at preventing damage to the environment. These are either directed towards narrow groups of products (as pesticides) or towards emissions or discharges to air and water.

The Law concerning product control of June 11, 1976

The purpose of the Law is to prevent damage to health or disturbance of the environment by pollution, waste, or noise etc. from any product. Product is widely defined as raw material, auxiliary substances and intermediate and finished products of any kind, and measures may be directed towards production, importation, use and other handling of a product.

The law imposes a degree of responsibility on anyone who handles a product, over and beyond existing general rules, by requiring that the handler shall exercise care and take reasonable precautions to prevent and limit hazards. Moreover, manufacturers and importers are specifically required to obtain such information that may be necessary to determine whether the produce may pose hazards to health or the environment.

The act authorizes the use of a wide range of regulatory measures. Regulations may apply to any aspect of production, importation, distribution, sale, labeling, use or other handling of a product. Schemes for return of products, deposit, recycling or waste handling may be mandated, and the composition or design of a product may be regulated. Limitations on emission of pollutants or noise may be set. Products may be subject to application for approval before marketing, production or importation, or total prohibition of these activities may be applied.

Anyone may be required to provide information necessary for enactment of the law. The importer or producer may also be required to provide samples of products, or to undertake such investigations as are necessary to determine the nature or effects of products, and to cover the attendant costs. The authorities may themselves decide to conduct investigations or tests, and may recover the costs from manufacturer or importer when this is reasonable.

When it is considered necessary, temporary bans may be imposed on production, importation, sale, use or any handling until sufficient information concerning properties or effects of a product has been submitted. The same applies when there is reason to doubt the validity of previously submitted information. After sufficient information has been produced, authorities must terminate any ban within six months, except in special cases where the period may be extended to 12 months.

Products subject to registration requirements may be approved on certain conditions, and approval may be voided if new information or new interpretations of this information warrants withdrawal. Permits may also be withdrawn in cases of willful or negligent violations.

The law also contains provisions for inspection of facilities and sampling of products, and general rules concerning observation of confidentiality. Confidentiality shall not restrain dissemination of information concerning the effects of a product. Provisions for punishment include fine and imprisonment, and under certain conditions a business entity may partly or wholly lose its operating privileges.

A Product Control Council shall keep itself informed about products which may cause problems, and propose official action. The Council shall also give a certain amount of guidance to industry, and act partly in a decision-making and partly in an advisory capacity. The Council shall prepare an annual report to Parliament, which reviews past actions and decides on programs.

3.3.2 The Product Control Situation

In the preamble to the bill on product control, the Government states that the control of chemical products is in general inadequate. However, certain chemical products are methodically controlled.

Pesticides are subject to strict control, and the Ministry of Agriculture's Poison Board by policy limits the number of products allowed on the market. The marketer must supply all information necessary to assess a product, and in effect has the burden of proof.

Drugs are also strictly controlled, and the marketer is required to provide all necessary information. While the existing law concerning drugs and poisons allows a certain degree of control of other chemical products, both the law and the existing administrative capacity in this area are inadequate. Special permission is required to produce, import or export substances designated as poisons in the official "Poisons list", and certain regulations apply to purchase, packaging and labeling of poisons. Other less hazardous products are subject to rules concerning packaging, labeling and sale to minors. However, chemicals are not assessed in a wholly methodical way and environmental considerations are rarely taken. The insufficiency of the present state of affairs is cited as one main reason for enactment of the new product control law.

In the occupational environment, several incidences of illness related to chemicals underline the need for strengthening of the law, stricter enforcement, and increased activity in methodical assessment and information to both employers and workers.

Regulations are in force to reduce the sulphur content of fuel oil in industrial applications, and low limits have been set for sulphur in oils for heating in two major cities. The geographical coverage may be extended in the near future.

Lead in gasoline has been set at 0.4 grams per liter, which is less strict than U.S. goals. Auto emission control regulations follow ECE regulations, which are generally more lenient than U.S. requirements.

Drinking water facilities and drinking water quality are under government supervision, and food and feed is subject to government control.

3.4 Discussion

3.4.1 Legislation

In the U.S. numerous laws exist to protect health and the environment from various categories of products with chemical effects. The laws reflect various degrees of authority delegated to administrative agencies, and some of the laws provide the agencies with considerable discretion and flexibility. The range of regulatory power vested in the laws ranges from wide (the Clean Air Act, the Consumer Product Safety Act), to nothing (the Solid Waste Disposal Act).

Periodic review of the laws and their bureaucratic implementation enables Congress to adjust the laws to political and economic changes. This critical review process is probably more far-reaching than in most western countries. Interest groups are admitted to testify before Congressional Committees, ensuring direct democratic participation. However, there is the danger that interests may win influence disproportionate to their number of supporters, more on the strength of their efforts and resources than on the merits of their arguments.

All the mentioned laws reflect a strong concern for human health (consumer product safety, pesticides, occupational health, foods), and some are also aimed at protecting the environment (ex. pesticides, air and water laws). Some laws regulate specific groups of products such as pesticides or motor vehicles. Other laws address products in particular areas of use, such as in the occupational environment, or consumer products. Laws directed at environmental protection (air and water acts) allow regulation of the introduction of specific substances into the environmental media, and the concentration of the substances in those media.

Similar to the legislative situation in most countries, the present set of laws does not meet demands for comprehensive protective control of products. A large number of toxic substances can presently not be regulated, and this is probably considered to be the most important issue in environmental legislation today.

To illustrate the situation, consider the case of Polychlorinated biphenyls (PCBs), which presently are found in water, fish, wildlife and domestic animals, foods, and human tissues. The substance is known to have deleterious effects on organisms, and is even a suspected carcinogen. It has been possible to set limits for PCB contamination in foods, and EPA is investigating possibilities for using air and water acts to limit its continued introduction into the environment. There is no basis for regulating the production, sale, use and disposal of the substance. If toxic substances legislation is passed in 1976, it will probably become effective from late 1977.

The U.S. laws tend to be rather specific and detailed. This helps define closely what the authorities of the agencies are, and may act as a control against unwarranted use of power. It is also interesting to note the frequent inclusion of time limitations set for completion of special tasks or goals. Such specificity has the advantage that it promotes a certain degree of action and promptness on behalf of the agencies. They may be prodded into increased activity or swifter action by public suits, and may similarly be curbed by court actions by industry or other interest groups who feel an agency is going too far too fast. Specificity requires consistency in the law, and there are examples of inconsistencies between different sections within an act. Detailed statutes may also prove inflexible in the face of unforseen problems.

It should be noted that some of the modern laws specifically allow for lawsuits by any person against responsible government agencies, and call for public hearings before certain major decisions are taken. These are probably rather unique features in law anywhere, and they seem to assert the end of the era of passive acceptance of government decisions. Legal challenge and public hearings are conducive to increasing participation in societal affairs and are valuable means of exerting influence on governmental actions. But they may also be used as means for slowing down or postponing decisions which should be made for the benefit of the general public.

An issue much debated in connection with chemical products legislation is the question of which benefits and risks should be considered before a regulatory decision is made, and how these factors should be weighed against each other. Whereas for example the "Delaney clause" (which excludes carcinogens from food) and the Clean Air Act do not call for consideration of the economic and societal effects, many of the laws do require such considerations. But it is not always clear just how benefits and risks should be weighted, and the laws contain varying requirements. The problem is compounded when it is necessary to apply more than one law in a particular situation.

Another important issue is the question of who has the burden of proof when it is necessary to determine the hazards of a chemical substance. At present, this burden of proof largely rests with the regulatory agencies (with the exception of e.g. drugs and pesticides). This means that, unless they can prove beyond doubt that a substance is hazardous, it is very hard to restrict its use even though indications of hazard may be strong. A Toxic Substances Control Act is expected to clarify the question of burden of proof, and impose information requirements on the manufacturers.

It is interesting to note, that no economic incentives or disinsentives are mandated in present or proposed legislation. Given a growing disenchantment with restrictive regulation, and economists' claims for the usefulness of taxation, proposals for tax measures could have been expected.

The U.S. has particularly well developed laws in the consumer product safety area and is probably ahead of most other countries in this field. Also, the vehicle pollution control statutes give the government substantial authority in that area, and again this would rank as probably the most ambitious in the world. On the other hand, general control of toxic substances is deficient, and some countries have much more advanced legislation for chemicals.

The Norwegian legislation before enactment of the new product control law was in some ways similar in coverage to U.S. legislation. The emphasis of Norwegian laws was also on health more than on the environment, applied generally to the same types of products as the U.S. laws, and they were not considered adequate for satisfactory protection from products with chemical effects.

The new law is designed to correct these shortcomings. It provided general authority to regulate any product with chemical effects, and therefore, overlaps much of the previous legislation. The new law is primarily intended for use in those area where previous legislation did not provide coverage, and in situations where broad coordination and comprehensive regulatory action is required. This arrangement generally leaves existing agencies with their jurisdictions and well-established functions unaltered, while ensuring complementation and coordination of their efforts.

The most important laws in the area are generally enabling laws, leaving considerable discretion to the agencies. There is probably no precedence for time limitations or time requirements on agencies in the laws.

Decisions involving risk/benefit assessments are generally made by government agencies or their appointed committees, and are rarely contested on legal grounds. The burden of information and proof lies with the proponent of a product in the drug and pesticides areas, and the proposed product control law establishes the principle for any product.

Direct public participation and industry lobbying influence in the decision processes concerning products with chemical effects are still very limited, but participation by the various interest groups is ensured by preview and comment on proposed laws and regulations.

There is no provision in the new law for taxation as a tool for product control. However, selective taxation can be imposed by parliament.

Special attention is drawn to the product control law's provision concerning general responsibility and specific obligation on the part of a manufacturer or importer to acquire information sufficient to determine for himself whether a product may be hazardous. The provision may become very useful in increasing awareness and critical self-restraint in dealing with products. Since government control cannot be fully effective, and should ideally be very limited, it is important that industry and commerce carry as much of the burden of control as possible. The impact of the provision will depend on the regulations to be developed and how they will be legally enforced.

A product control council with agency and interest group representation has been proposed in the law. In addition to proposing actions and making decisions, the council should facilitate inter-agency coordination and secure a balancing of interests and views.

3.4.2 Actions and Approaches

There are two areas where particularly advanced programs have been developed in the U.S. One is the EPA auto emission control program, which is interesting because it illustrates a great number of the product control principles discussed in Chapter 2, and because of its size, complexity and considerable ramifications for other sectors of society. It is noteworthy that Congress has been able to agree on such a significant program, considering the opposing interests in this area. There have been a series of strong political battles that have obstructed the program, and there may still be some more. Also, there are technological problems with the chosen catalytic converter system such as the sulphuric acid mist, the proliferation of platinum in the environment, and administrative hurdles concerning compliance and enforcement of product in-use standards.

It has been said that time limitations set on the auto industry for compliance with emission standards was too short, and that this has forced the industry to choose a technology that was possible to develop in a short time, but which is inadequate. Given more time, the industry could have based control systems on other and better principles. It seems that the federal action is appropriate, because there are indeed few indications that the industry would have made adequate efforts to develop such a technology when needed. The present devices certainly pose problems, but these are likely to be smaller than the effects of unabated pollution would have been. Meanwhile, the industry has the option to develop better systems.

The other area referred to concerns consumer products safety. The program, as well as the law itself, are rather unique as phenomena, and some very significant concepts and techniques are likely to emerge from the program to benefit efforts in other countries. The information systems, the participation of groups outside the agency in standards development, the manufacturers' hazard notification responsibility, and the relatively strong compliance tools and sanctions, are some of the features that make the program noteworthy.

The standards developed in the U.S. for occupational health will clearly become an important basis for similar development in other countries. Also, information on products and their effects gathered under the program will be very valuable, and should as far as possible be made available to foreign agencies.

But there is still a long way to go from having adequate regulations to the point where compliance with the rules gives satisfactory protection for the worker. To achieve this, some

new concepts will probably have to be introduced to achieve more self-enforcement of rules and more active participation by the employees. Protection from occupational hazard also depends on the development of better equipment for detection and monitoring of chemical pollution.

Information needs in relation to toxic substances may be listed in four categories: industrial data, exposure data, health effects data and environmental effects data. In the present situation, the primary research emphasis is on health effects, followed by environmental effects. Industrial and exposure data are by comparison neglected areas, and more attention must be given to satisfy these needs, both in the U.S. and elsewhere.

The very great efforts in research and assessment of the effects of chemicals in the U.S. will be a major contribution on a world scale. The U.S. probably has more capacity and output in this area than any other country, and it will increase further as industry will be required to perform more adequate testing. However, a number of other countries have considerable activity in these areas, and there is duplication of work. In view of the enormous needs, better sharing of information and international coordination of efforts is desirable.

Although principal authority for control of chemical products is divided among four different agencies, there seems to be a reasonable degree of coordination, partly because this is required by law.

Generally, regulation of products with chemical effects appears to be a much more politicized process in the U.S. than in Norway. In the U.S., agencies are sensitive to political influence directly from Congressmen, the President via the powerful Office of Management and Budget, and from industry lobbying groups and public organizations. In Norway, governmental value judgements of the kind involved in chemicals assessment tend to be far more accepted as bona fide best available societal judgements. There may be many reasons for this difference not to be discussed here, but it is interesting to keep this difference in mind when considering some of the attitudes and approaches to the regulation problems below.

The basic approaches to product control in this area is similar in the two countries, both have primarily chosen regulation as the primary tool. This seems to be the only effective way. (The disadvantages of taxation and voluntary agreements are discussed in Chapter 2). Regulation has many disadvantages, too. The process is slow, complex, and at this stage much effort is required if we are to catch up with the needs. Regulation also implies more government interference. But experience has shown that interference cannot be avoided in any case, and the sooner this can be accepted, the sooner the work can proceed. However, it should be a constant goal to limit the involvement to that which is strictly necessary. To achieve this, mechanisms for engaging industry and commerce in self-control through testing, assessment and participation in promulgation of standards should be further explored.

A very important problem once regulations are adopted, is how to enforce compliance. To enforce all the standards that have to be developed is a very formidable task for any government. The solution must be built on the highest possible degree of self-enforcement by industry. Mechanisms must be developed so that industry can monitor and keep records of products and related activities, subject to government review and strong sanctions in cases of non-compliance.

As discussed in Chapter 2, the burden of proof of safety should rest on the proponent for the use of a product. But even where the principle is applied, it does not solve all problems. For example, recent findings in the U.S. pesticides program indicate that manufacturers have manipulated test data to enable them to "prove" the safety of the products involved. This forces the agency to allocate valuable resources to a strict review activity.

A difficult situation arises when there is no clear and irrefutable proof either for or against the safety of a product. This situation is common, and will be more so as more emphasis is placed on protection from long term effects. Who is to prevail, the proponent of use, or the regulator who feels there is reason for grave concern but cannot disprove the submitted "proof"? The question can be highlighted by such examples as the case of the food additive red dye #2, which it has taken FDA many years to ban, or the EPA lead-in-gasoline balancing act in which the latest court decision upheld EPA 5 to 4. It illustrates the problems of proof, even when most scientists seem to agree that lead is harmful to health, and that auto emissions account for the lion's share of exposure.

It is easy to see that if the same approach were to be used in all future cases where clear proof is evasive, government regulatory and judicial resources may well be exhausted while attempting to protect public health. In the mentioned U.S. cases, the proponent of the use of the chemical products are seen as the defendants in the case, and by long tradition, the defendant has the benefit of the doubt. This good principle is in such cases misdirected. The true defendant is the public whose right to continued good health is at stake, and the public should be given the benefit of the doubt. This inevitably points to the not entirely appetizing concept of increased government authority to take restrictive action to postpone or ban in cases of reasonable doubt. It is not an ideal approach, but it should prevail until the art of effect assessment is sufficiently developed.

4. NOISE ASSOCIATED WITH PRODUCTS

4.1 The Problem In General

Noise may be defined as unwanted sound. This infers that the experience of noise is subjective, modified by mood, attitudes and habits. When noise is related to actions that evoke fear, the noise is perceived as very annoying. If noise is concomitant with a well paid job, the noise is more easily tolerated. Individual susceptibility to noise irritation varies with time, situation and from individual to individual.

The parameters that describe sound are sound pressure level (intensity), pitch (frequency) and duration. Noise is commonly a combination of tones of different frequencies. Sound intensity is measured in decibel, dB. The following figure will indicate how human response is related to sound levels. An increase in sound level of 10dB is percieved by the human ear approximately as a doubling of intensity.

	Noise level	Respon e	Hearing effects	Conversational relationships
Carrier deck jet operation	140		Contribution To Hearing Impairment Begins	
		Painfully loud		
	130	Limit amplified speech		
Jet takeoff (200 feet) Discotheque Auto horn (3 feet)	120	Maximum vocal effort		
Riveting machine	110			
Jet takeoff (2,000 feet) Garbage truck	100			Shouting in ear
N Y subway station		Very annoying		
Heavy truck (50 feet)	90			Shouting at 2 feet
Pneumatic drill (50 feet)				Very loud
Alarm clock	80	Annoying		conversation, 2 feet
Freight train (50 feet)				Loud
Freeway traffic (50 feet)	70	Telephone use difficult		conversation, 2 feet
		Intrusive		Loud
Air conditioning unit (20 feet)	60			conversation, 4 feet
				Normal
Light auto traffic (100 feet)	50	Quiet		conversation, 12 feet
Living room				
Bedroom	40			
Library				
Soft whisper (15 feet)	30	Very quiet		
Broadcasting studio	20			
	10	Just audible		
	0	Threshold of hearing		

Source: Environmental Protection Agency, *Noise Pollution: No More Than This* (Washington, D.C. Government Printing Office, 1974 reprint)

Effects of noise may be divided into two categories, one concerns direct effects on hearing, the other concerns physiological and psychological effects. Direct effects on hearing may take the form of disturbance of desirable communication, or hearing impairment due to very high exposure or protracted high exposure. Physiological effects may include changes in heart rate, blood pressure, metabolism, or depressed respiration, sleep disturbance and tiredness. Psychological effects include depression and irritation.

Apart from the direct physical and psychological effects, noise may be hazardous in other ways. Noise from a device could prevent the user or others in the vicinity from hearing an auditory warning signal. Likewise, a noisy product may prevent the user from detecting a mechanical malfunction. A noisy device might distract the operator and others from the demands of the task which they are performing, or it may increase the level of fatigue or irritability which again may result in accidents.

Knowledge about the effects of noise on animals is presently insufficient, but physiological changes have been observed. There are several reports of cases where animals such as skunks and minks have eaten their offspring when disturbed by airplanes or explosions. Conversely, it seems that some animals have a great ability to adapt to high noise levels.

Among all the noise sources, transportation is probably the most significant in terms of numbers of people affected. Of these, road transportation is likely to be responsible for the greater portion, but also aircraft, railway and to some extent shipping activity are significant noise sources. Noise from transportation sources represents a problem both in the outer environment and for the passengers transported.

Noise from road transportation devices has become a significant factor of an urban and rural areas. It is estimated by EPA that more than 50% of the population are adversely effected by road traffic noise. A statistical survey of housing conditions in Norway in 1973 indicate that 18% of the population are adversely affected indoors by various forms of noise from neighbors and from road traffic combined. Road vehicle noise is caused by the motor, the interaction between tires and the roadway, and air friction. Motor noise is prevalent at lower speeds, and the other types of noise are more significant at speeds above 50 to 90 kilometers per hour depending on conditions. Noise can be reduced by shielding motors, muffling exhaust and use of low-noise tires. Aircraft noise severely effects people around the airports, and EPA estimates that 24.5 million neighbors are adversely effected in the U.S. In Norway, severe

conditions are found in certain localities. Significant improvements can be made by sound damping devices on existing aircraft, and by phasing out older noisy aircraft in favor of newer, quieter types. Aircraft noise is much dependent on how and when planes are operated, and much can be improved by changing operational procedures.

Noise from railroads primarily comes from motors of non-electric locomotives and impact between wheels and rails. Significant improvements on noise can be made with present technology.

Over the last years there has been a marked increase in the number and use of various recreational transport devices such as pleasure boats and snow mobiles. These can be sources of major annoyance, both because they may emit much noise and because they tend to be used in areas where people withdraw from everyday life to experience peace and quiet.

Construction activities are major sources of noise from such products as compressors, jack hammers, earth moving equipment, pile drivers, etc. It is estimated that such noise daily effects some 26 millions americans. Also in this area, significant noise sources and by changing use patterns. Around 20 millions workers in the U.S. in construction and other occupations are exposed to noise levels that pose a threat to their health and well being. Of these, around 8 1/2 millions workers are exposed to noise that entails immediate significant risk of hearing impairment. In Norway, a 1973 Trade Union survey disclosed that 27% of workers sited noise as the cause of personal injury or illness. In this area too, much can be done to reduce harmful noise. However, some of the industrial processes are by their nature noisy (grinding, milling, metal stamping), and cost of improvement are considered relatively high. Agricultural machinery may also be a major noise source, for the operator as well as surrondings.

Sundry home appliances and craftsman equipment expose a large part of the population to noise levels which interfere with communication and ability to enjoy domestic quiet. Some of them also have the potential for adversely effecting hearing, and power lawn mowers may present this threat as well as creating environmental noise problems. Again, significant reductions maybe anticipated by design changes.

The noise problem can in most cases best be tackled by controlling the sources of noise; very often the source is a product. Source reduction seems to be the best approach from the view point of setting standards, and lends itself well to cost-benefit analysis. Control of the general noise situation and enforcement is made simpler by source reduction than by other means. There is substantial technology available for control of noise from products, and where this is not sufficient, changes is use patterns maybe imposed.

4.2 U.S.A.

4.2.1 Major Legislation

The Noise Control Act of 1972

The Act represents the first major Federal attempt to eliminate excess noise at the design stage of a wide variety of products.

EPA is directed to develop and publish information on limits of noise required for protecting public health and welfare with an adequate margin of safety, to issue reports identifying products that are major sources of noise, and to give information on the techniques for controlling noise from such products. EPA is given broad authority to obtain from manufacturers the information it needs to implement the Act.

EPA is further required to set noise emission standards for products that have been identified as major sources of noise and for which standards are deemed feasible, taking into account costs and available technology. The law specifically requires noise emission standards for products in the categories of construction equipment, transportation equipment (except aircraft), all motors of engines, and electrical and electronic equipment. It also grants authorities to set standards regarded as feasible and necessary to protect public health and safety for other products.

EPA has authority to require the labeling of domestic or imported consumer products as to their noise generating characteristics or their effectiveness in reducing noise. Fines are levied against those responsible for non-conforming or mislabeled products. Manufacturers must issue warrants that their regulated products comply with standards at the time of sale. They are also required to maintain records and provide information, and samples of products.

In addition to setting product performance requirements, EPA is to prescribe noise emission standards for the operation of the equipment and facilities of interstate railroads, trucks and buses. In-use noise problems from products will generally be controlled by state and local government.

EPA is to submit proposed regulations to control aircraft and airport noise to the Federal Aviation Agency (FAA) which shall consider them prior to prescribing the same regulation, a modified regulation or no regulation. If EPA believes the FAA's action does not protect the public health and welfare it may request the FAA to review its decision, and make public the reason for its action.

The Act gives responsibility to EPA for coordinating and activating the capabilities and noise control policies of other Federal Agencies. EPA's ultimate authority, if it disagrees with an Agency's final action, is to appeal the case to the Council on Environmental Quality (CEQ). Under the Act, EPA's authority is not restricted to environmental noise, but covers also products in the workplace and consumer products.

The Federal Aviation Act of 1968 empowers the Federal Aviation Administration to precribe regulations for the control and abatement of aircraft noise. The legal authority covers aircraft noise emission levels as well as operating rules. Economic and technological considerations must be taken in the formulation of a standard. By amendment in the Noise Control Act of 1972, EPA has certain powers concerning air traffic noise.

The Occupational Safety and Health Act of 1970

Reference is made to the presentation of this law under section 3.2.1. According to the Act, the Occupational Safety and Health Administration (OSHA) has the final authority to set a workplace noise rule (EPA has certain authorities of request for review and appeal, as mentioned above).

Basically, compliance with an occupational noise standard may be attained through the use of personal protective equipment, administrative controls involving rotating workers out of high noise areas, or by shutting down machines for a time, or engineering controls to quiet noise at the source by enclosing a machine or redesigning equipment. The effect of the Act on products used in the workplace is accordingly indirect through engineering controls. Direct regulation of products such as machinery and equipment is under EPA authority.

The Consumer Product Safety Act of 1972

Reference is made to the presentation of this Act under section 3.2.1. The provisions of the Act are applicable to any product which poses an unreasonable risk to safety or health, and will therefore apply to products whose noise characteristics constitute such risks.

Federal Hazardous Substances Act, as Amended by the Toy Safety Act of 1969

Reference is made to the presentation of this Act under section 3.2.1. The Toy Safety Act provides for regulation of products that may cause hearing damage to children.

4.2.2 The Product Control Situation

EPA started regulation of products in 1974, with heavy motor carriers engaged in interstate commerce. Regulations are also being promulgated for locomotives and railroad cars, and for new portable air compressors and new medium and heavy duty trucks. Whereas requirements for railroad performance do not seem to be particularly strong, noise from the other mentioned product groups will be significantly reduced. Officially identified for future regulation are motorcycles, buses, earth moving equipment and special auxilliary equipment on trucks. The full effect of product control measures will only be achieved after a number of years, owing to turnover time for existing products.

Control of noise from consumer products has only just begun. The Consumer Products Safety Commission (CPSC) has issued regulations on play items that create explosion noise impacts such as toy caps, etc. EPA plans to study noise problems related to such consumer products as small engine powered equipment, electrical and electronic equipment, and the general categories of household appliances and industrial eqiupment during 1976. Regulations may be forthcoming in two to three years. CPSC is working on safety regulations for power lawn mowers, and restrictions on noise emission may be included.

While OSHA has authority to regulate noise levels in the occupational environment, EPA will study noise abatement technology and possibly regulate industrial machinery through new product regulations. Such regulations may be forthcoming in two to three years.

The Federal Avaiation Agency (FAA) requires by regulation that all new jet-propelled transport plans not exceed specified noise levels. In 1974, only 10% of existing aircraft met FAA new aircraft standards. However, modification of noisy aircraft is technologically feasible. In 1975, EPA proposed a retrofit regulations that would require all existing airplanes to comply. Later, FAA has proposed more limited retrofit action, and the Air Transport Association of America has made a proposal to modernize part of the existing fleet to reduce noise. In all cases, federal loans or quarantees are implied. The Department of Transportation has not made any official decision (May 1976).

Existing regulations do not prohibit super sonic aircraft (SSTs) from operating at U.S. airports at subsonic speeds, and a 16-month trial operation of SSTs began in May 1976.

4.2.3 The Environmental Protection Agency

EPA embarked on its noise control program by analyzing the noise situation in the country, arriving at information on the number of persons impacted from different sources, and at what levels. A very important corner stone for a balanced and pragmatic approach was laid by the completion of the "levels" document in March 1974, which identifies "Noise levels requisite to protect public health and welfare with an adequate margin of safety."

The general goal of the presently planned noise abatement program of the EPA is to reduce the impact of noise pollution by minimizing the incidence of:

-Noise induced hearing loss
-Sleep loss from noise
-Noise inference with speech communications
-Annoyance from noise

Through a system of weighting of the number of people exposed to noise, and the degree of noise exposure, these quantities are converted into nominal numbers (called impact units) representing the number of people one hundred percent impacted by noise (i.e. up to the levels considered requisite to protect public health and welfare) from different noise source categories. The general goals mentioned above have subsequently been expressed in numerical terms. As an example, EPA assumes 112 million noise impact units in 1992 if no noise reduction measures are taken, and aims at reducing this to 17.5 million noise impact units by 1992). This overall figure is split up in different noise source categories and specific reduction goals are formulated for each one. The goals will be accomplished by regulations on maximum noise emissions from products, labeling, information to the public, cooperation with states and local governments and coordination of federal noise programs, and research. By 1992 it is assumed that all major sources are regulated, that almost all of the old noisy units manufactured before regulation will have been retired, and that noise from products will be at low, long term steady state values. At that time, EPA will put relatively more emphasis on enforcement, leadership in providing technical assistance and support of state and local programs, coordination, research, and improvement in existing regulations.

Before regulations may be published for any product, the product must previously have been formally identified as a major source. To do this, EPA makes a technical analysis of noise impact for the product type in question, and compares this to criteria in the "levels" document. Depending upon the severity of the impact, products are either designated major noise sources, or considered

as candidates for labeling, or not considered for regulatory action. The results of this analysis are weighed along with such factors as available technology, costs, voluntary actions, time requirements, etc. Once a product is publicly identified as a candidate for regulation, EPA must publish reports giving information on techniques for control of noise from that product, including data on the technology, cost and alternative methods of noise control. Further, EPA must publish proposed regulations within 18 months and final regulations within 24 months where regulation is feasible. In cases where regulation is not feasible, EPA may decide on a labeling requirement or on no action.

Formal identification prior to regulation serves two purposes: One is that once a problem has been identified, society is assured that corrective action will be taken within reasonable time (on the other hand, EPA may theoretically choose to ignore a problem and hence not identify it). The other is an effect of positive value to manufacturers, who by the formal identification of products as major noise sources receive warning of impending change. The 18 month period gives opportunity for the manufacturer to study or effectuate changes in his products if he so desires.

Informing the public about the noise emission characteristic of products is expected to become an important element in the EPA noise program. Required labeling with information on noise emission from a number of outdoor and indoor consumer products will give the purchaser opportunity to choose a quieter product, and it will give manufacturers an incentive to reduce noise emissions to avoid adverse sales development. Labeling may also contribute to a keener public awareness of noise, and may contribute to attitutes essential to reducing the noise problem.

The information program will also aim at educating the public about how to avoid discomforting exposure to noise and danger of hearing loss from voluntary exposure to electronic equipment (amplifiers, hi-fi sets, etc.) and other noise sources.

As is the case with pollution emission control from cars, the EPA noise enforcement strategy places a major share of responsibility on the manufacturer for pre-sale testing to determine compliance with noise standards. It is felt that this has both the advantage of letting the manufacturer retain control of many aspects of a compliance program, while reducing government interference to a minimum. The program involves product verification, under which products intended for marketing are tested in order to verify that a manufacturer has the requisite noise attenuation technology in hand and is capable of applying the technology in his manufacturing process. The testing will be done in accordance

with EPA test procedures. EPA reserves the right to be present during testing, and the manufacturer is requires to file a production verification report before any sales of the product. Such reports are also required when a previously verified product is significantly changed. To further secure that products comply to regulations, assembly line vehicle testing is included in the enforcement strategy.

According to the program strategy being planned, a special audit staff will select the manufacturers and products to be tested, prepare the test orders, monitor compliance, and perform such testing as may be required. The staff will also take appropriate actions in the case of nonconformity, and conduct investigations as necessary. EPA will retain free access to all production, testing and storage facilities.

It is essential for the achievement of noise reduction goals that a product not only conform to emission standards when new, but also during its useful life. Similar to what applies to the auto emission control program, the noise program requires the manufacturer to provide a warranty to purchasers, and to recall products for technical changes. Manufacturers will be required to provide purchasers with instructions specifying the maintance, use and repair required to assure conformity with regulations. There will also be provisions against tampering which alters the noise emission properties of the product.

A strong compliance tool is the authority to require the manufacturer to recall products. Recall would be required when a production verification is not submitted and the product is found not to conform with standards. It may also be used when audit tests reveal non-compliance with regulations, and when properly maintained and operated vehicles fail to conform to in-use standards.

On aircraft noise, EPA has assessed the current FAA flight and operational noise controls, noise emission controls, and possibilities for retrofiting or phasing out existing aircraft. EPA has also studied control measures available to airport operators and local governments and the implications of establishing cumulative noise level limits around airports. The studies have resulted in several proposed regulations directly concerning noise emissions from aircraft. While implementation of these aircraft source noise regulations will bring considerable relief to a large sector of the noise impacted population, they alone will not eliminate the problem. EPA has therefore also proposed regulations on take-off and approach procedures, and airport regulations.

The Act requires the Secretary of the Treasurer to issue a regulation that will ensure compliance for imported products, and EPA is to enforce them. As with the Clean Air Act import program, the strategy will be to require labeling of imported products to simplify customs procedures. Products made solely for export will not be covered by U.S. noise standards. Because of the trans-frontier pollution aspects of air and surface transportation, and in view of expanding international trade in noise-emitting products, a part of EPA's noise abatement program will be devoted to harmonization of product noise regulations.

EPA is establishing a long term noise monitoring program to be implemented ultimately within the ten federal regions. The main purpose of this program will be trend monitoring of the noise program's measure of effectiveness, as expressed by the reduction of the national noise impact. The noise levels in 8 categories of noise sources will probably be measured every 3 years from aircraft operations, urban motor vehicle traffic, highway traffic, construction equipment, railroads, industrial noise, home appliances and equipment, and noise within transportation vehicles.

The principal responsibility for enforcement of federal noise standards and labeling requirements lies with EPA. However, state and local governments can assist enforcement through in-use control of regulated products if their laws properly complement federal regulations. State and local governments can also assist the federal government in enforcing warranty and anti-tampering provisions of federal regulations. The Department of Transportation (DOT) has responsibility for enforcement of interstate rail carriers and interstate motor carriers.

Public participation in the development of regulations, both for noise emission and labeling, is required in the EPA program.

The budget for the EPA noise program calls for around 10 million dollars per year in 1976 and 1977, the number of positions around 90.

4.2.4 The Consumer Product Safety Commission (CPSC)

CPSC has authority in noise control according to the Consumer Protection Safety Act and the Federal Hazardous Substances Act. A presentation of CPSC and some of its program aspects is given in section 3.2.6.

Possibly as a consequence of EPA's dominating role in control of product noise according to the Noise Control Act, noise connected with consumer products is not top priority in the Agency. The noise problem has been addressed for such products as toy explosives for children, where permanent hearing damage was considered a serious and unreasonable risk.

The NEISS injury reporting system, which collects a fundamental portion of hazard information for the Agency, does not regularly pick up reports of hearing damage from noisy consumer products. This is partly due to the fact that even severe hearing damage is not regularly referred to hospital emergency rooms, and also due to the fact that hearing loss is often very gradual and, therefore, not perceived by a person as being caused by exposure to noise from products.

The Agency also gives priority to noise from products which also pose a safety hazard, and where the noise may increase this hazard. One such example is power lawn mowers, from which noise may tend to mask warning signals to the operator, and thereby increase the safety hazard. In this example, regulation of noise is incidential to safety considerations, and does not cover the wider environmental aspects of the noise.

4.3 Norway

4.3.1 Major Legislation

The Road Traffic Act of 1965 contains provisions for regulating vehicle noise.

The Building Law of 1965 gives a basis for the incorporation of noise considerations in land use planning, and there are regulations concerning noise insulation of buildings.

The Neighbors' Act of 1961 sets limitations for the individual's activities in consideration of his neighbors. The law is used to control noise from industries by issuing permits. (See also section 3.3.1)

The Health Act of 1860 may be used to restrict activity that may be hazardous to health. Oslo city has used the law to issue a noise ordinance.

The Worker Protection Law of 1956 contains provisions concerning limitations of noise and vibrations. (See also section 3.3.1)

The law concerning product control of June 11, 1976 is presented in section 3.3.1. The law will make it possible to regulate products that cause health hazards or create disturbances to man or in the environment by emitting noise. Regulations may take the form of performance standards, use regulations or other measures.

4.3.2 The Product Control Situation

Statistical information on exposure and effects of noise is not widely developed, but the two surveys mentioned in section 4.1 involving indoor noise and workers, in addition to certain local investigations, indicate that noise is likely to receive more attention in the following years. The noise situation and the need for control measures are presently under study by the Ministry of Environment.

The only products for which regulations are in effect are motor vehicles.

4.4 Discussion

4.4.1 Legislation

With the amendments to the Federal Aviation Act, the Noise Control Act in 1972 has given the government important, broad powers to attack noise. While much of the power to control noise from the use of products (and ambient noise) rests with the states, the legislation will otherwise be sufficient to control noise from products.

The Noise Control Act is primarily a product control law. Although there is need to control ambient noise from the use of products, and from stationary sources, these have been percieved more as local concerns. This, and the fact that federal engagement in noise is of recent date, may account for the somewhat less ambitious role in local noise control than in other areas of environmental protection.

The act prescribes that standards shall be adequate to protect public health and welfare, due consideration being given to available technology and the cost of compliance. As is the case with laws pertaining to chemicals, the law does not detail further criteria for balancing these factors. This lack of specificity may bring about court action by industry to contest new regulation.

Congress has expressly listed four categories of products to be addressed, one category is electrical and electronic equipment. This means that the law not only applies to products polluting the outdoor environment, but also those that create noise problems indoors. Also other products than those in the four categories may be regulated. This wide scope makes it possible to base regulatory actions on a comprehensive assessment of the noise impacts people are subjected to, and accordingly ensure a reasonably balanced total effort.

As in other modern laws, the Noise Control Act gives any person the right to sue another person to restrain a violation of the Act, or sue EPA or FAA to compel the performance of a mandatory duty under the Act. To ensure timely agency action, time requirements for regulations development are spelled out in the law.

Related to the question of burden of proof, the question of what noise restrictions are necessary to adequately protect health and welfare may be hotly debated as more economically significant regulations are introduced. In requiring EPA to develop information on this subject, Congress has implicitly charged EPA with the burden of proof in the noise field.

The Norwegian product control law contains the possibilities for control found in the U.S. Act, and will further allow in-use control of the products. This will give an even better basis for a balanced approach to regulation and enforcement. The specific obligations of the manufacturer or importer to determine whether products may be hazardous or cause excessive disturbance can become an important aspect in product noise control. For this mechanism to be effective, some consensus on significant noise criteria must probably be spelled out in an official document.

There is no provision in either the U.S. Noise Control Act or the Norwegian Product Control Law to authorize the use of taxes to reduce product noise. The U.S. emphasizes the use of noise labeling as a means towards noise reduction. Similar action may be taken under the Norwegian law.

4.4.2 Actions and Approaches

EPA has started an advanced program that will be significant on a world scale.

In connection with standards presently being developed, high costs or lack of technology has not been much of an issue. The reason is that the requirements appear to be somewhat cautiously set to match easily available, low cost technology. The situation in relation to noise regulations may become considerably more polarized when more requirements are set to attain the recommended exposure levels, more similar to circumstances in the chemical products area.

The "levels document" (section 4.2.3) will probably come under fire when regulations become more restrictive. It is interesting to note that at least it may be possible to describe such levels and use them in practice. (This is presently far less likely for chemicals). The development of the document seems to be a logical first step for methodical control.

As compared to other areas of product control discussed in this study, it is relatively easier to predict the degree of improvement from a given control program in the noise area. EPA attempts to make improvements by a worst-first approach and a general, parallel reduction of noise emitted from all types of products.

The requirements imposed by the law will largely be in the form of product performance standards, limiting the amount or frequency of noise emitted. If carried sufficiently far, this could practically eliminate noise. A number of factors make this impossible or even unnecessary, and products will continue to emit some noise. Hence there will always be a need to control the use of products so that lawn mowers do not needlessly disturb the Sunday morning peace, or so that snowmobiles or dune buggies will not shred the quietness people seek in the outdoors. Successful control of the noise problem in the U.S. depends on the active participation of local governments, and a very active federal program of guidance to states' noise programs is necessary.

In the federal noise control program, regulation of product noise emission has been chosen as the main tool, and this seems to be the best way. The U.S. program plans seem to recognize the importance of self-enforcement by requiring the producer to do the testing, to evaluate his own technological ability to make products which are in compliance with standards, and to keep records, all subject to government audit. Aircraft noise has been a politically significant issue for some time, cost and technology have been important factors to slow down noise

improvement. While new jet engines are significantly better than their precursors, the older engine types will be in operation for quite some time. Consequently, any early improvement in noise impact from planes is contingent upon retrofitting, or modification, of older type engines. It may be very difficult to implement this if the federal government does not decide to foot some of the bill.

The effects of information to the consumer about a product's noise emission characteristics may have good effect particularly when choosing among indoor products that will directly affect the buyer's noise situation. A consumer is somewhat less likely to consider the noise characteristics of an outdoor product as similarly important. Much depends on a person's ability to relate dB-values to annoyance, and how lower dB values will be valued in economic terms.

By statute, EPA is the center of responsibility for federal anti-noise activities. This gives a very good starting point for coordination and a comprehensive approach to noise control.

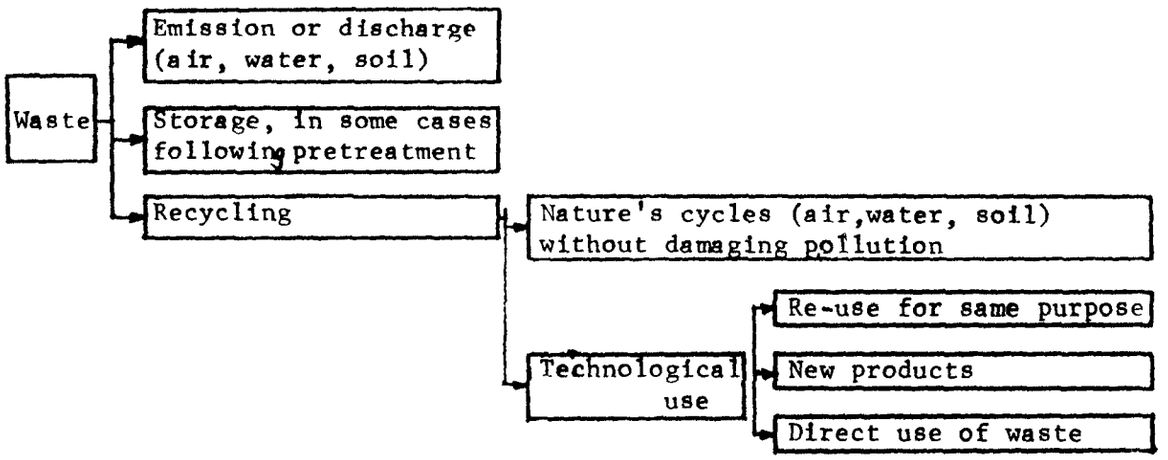
Because of an early start, and considerable scientific capacity, the U.S. noise program will yield very valuable information on effects, control technology, costs and other aspects. This information, and the regulations developed from it, can be put to good use in other countries.

5. WASTE EFFECTS OF PRODUCTS

5.1 The Problem in General

Wastes are essentially superfluous material or energy from production or use of products. Waste is a relative term, since factors such as economics and supply and demand determine what is considered superfluous at any given time. Supply is governed by such factors as availability of natural resources, efficient extraction technology, and politically determine conditions. At this time, many of these factors are generally favorable to the use of virgin materials, rather than to material economy and extensive recycling.

Wastes create health and environmental hazards: sanitary problems, pollution of water, air and soil, and in some cases accumulation of toxic substances in plants, animals or man. Increasing amounts of wastes claim more land for new disposal, and there are costs connected with handling and treatment of waste. Wastes may also contribute to deterioration of the quality of life by aesthetic impact. It is usually possible to identify production processes or products, or unsatisfactory waste management, as sources or reasons for waste problems. Improved management practices and increased emphasis on potential waste problems during product development and product use are important ways of avoiding unwanted impacts. The following simplified sketch shows the major alternatives for waste control:



The term "storage" covers land fills, more specialized storage for the purpose of security or later recovery, and any pretreatment applied to the waste to facilitate storage. Recycling (sometimes referred to as resource recovery), includes return of materials to nature in a way that does not cause pollution problems (for example by reducing organic materials to soil improvement components), or direct reuse of the product for its original purpose or as input resource for new materials (including energy), or direct use of the waste for some beneficial purpose.

The manufacturers' emphasis on economical production and distribution, and on marketing-oriented saleability aspects of the products have contributed to increasing waste problems. Little regard has been afforded the products' potential for giving rise to undesirable wastes.

Application of appropriate product control measures will cause industry to apply criteria for product development which will improve the waste situation. Product design can thus be geared to reducing the quantity of wastes. By changing the composition of products, it is possible to remove hazardous or undesirable components from wastes. This can make the wastes more suitable for municipal treatment by avoiding products that decompose slowly, or give rise to polluting leachates or gases. Changes in composition of products can facilitate materials separation and make wastes more easily recyclable. Today, mixed materials use (such as plastic/paper laminates, steel/aluminum combinations in cans) is an obstruction to recycling. Restrictions on the amounts of throwaway or non-returnable products would be effective in reducing wastes and stimulating recovery. Recovery may further be enhanced by standardization of packaging and imposition of deposits or taxes.

Labeling with information concerning environmental effects and correct waste disposal could also diminish some waste problems.

5.2 U.S.A.

5.2.1 Major Legislation

Reference is made to the presentation of the Solid Waste Disposal Act of 1965 as amended by the Resource Recovery Act of 1970 in section 3.2.1. The Act authorizes EPA to issue guidelines, some of which are mandatory for federal facilities. There are no mandatory product control requirements in effect.

The Marine Protection, Research and Sanctuaries Act of 1972 and the Safe Drinking Water Act of 1974 applies to disposal of wastes, but have no provisions directly concerning product control (section 3.2.1).

5.2.2. Proposed Legislation

Several bills concerning wastes have been proposed in the later years. It is presently difficult to predict when a law will be passed, and what provisions it will contain. Two proposals are described below to give an impression of the issues discussed by legislators.

The Senate Bill S.1744 of 1975 proposing the "Resource Recycling and Conservation Act" contains provisions for reducing the quantities of waste. The bill is based on the then recent experience of shortages of food, energy, and other products and materials, and the emphasis is on conservation of virgin natural resoures, promotion of resource recovery and recycling, and reduction of waste through the efficient use of energy and resources short supply. The Act would authorize the use of fees, product mix standards or other means found suitable to encourage the durability, recycleability or reuseability of a product. Only such products which are identified as contributing to the use of unreasonable amounts of energy or virgin materials, either critical for the national welfare or in actual or potential short supply, would qualify for regulation. The main focus of the bill is on conservation, but certain secondary effects of this would have beneficial health and environmental effects.

A House of Representatives staff version of the Solid Waste Utilization bill of December 1975 embodies aspects common to several bills, and some modern approaches to waste control. The bill calls for government demonstration and construction

of solid waste management and resource recovery systems, and provision of technical and financial assistance to state and local governments in planning and developing such systems. National research and development programs would be established for management and organization, and technical methods of collection, separation, recovery, recycling and disposal of solid waste would be developed. There would be incentives for energy and materials recovery. Proper management of hazardous waste would be promoted in various ways. Permits would be required for transport, treatment, storage or disposal of hazardous waste requiring disclosure of information concerning quality and quanity of waste, location of facilities and methods for treatment. Generators of hazardous waste would be required to maintain records of waste and related activities, to follow correct disposal procedures, and to use appropriate labeling and containers.

No direct controls are envisaged to reduce hazardous waste by changing production processes or products, but mandatory labeling instructions for waste disposal may become a positive factor. To discourage the manufacture, distribution and disposal of products using an unreasonable amount of virgin materials, product regulations are proposed. Such regulations may encourage increased durability, recyclability or re-usability of products by mandatory standards or fees. To reduce the volume of waste from packaging, a charge is proposed on the sale of packaging products corresponding to the cost of handling such waste. To further encourage recycling of materials, a time limited subsidy is proposed for products which contain post-consumer secondary material. The funds accrued by charges under the Act would be used to provide grants to states for development of solid waste programs.

5.2.3 The Product Control Situation

The situation concerning hazardous chemical wastes was briefly mentioned in section 3.2.3.

In connection with litter and other types of waste problems, post-consumer product wastes are important. EPA estimates that around 700 kgs of such wastes are created per capita per year, estimated to rise to 1100 kgs per capita per year in 1990. This is a very high figure compared to other nations (in 1972, a largely corresponding figure for Norway is approximately 300 kgs). In the U.S., about 7% is recovered partly as reuseable material, partly as energy.

Rising costs and decreased availability of conventional fossil fuels have tended to make solid waste an attractive energy source. The costs of conventional disposal methods such as sanitary land fill and incineration have continued to rise. The value of recoverable waste materials, particularly scrap metal and paper, has had some upturns in the last years. These factors have increased the interest in the use of municipal solid waste as a source of energy and of recyclable materials, to a limited extend lessening waste disposal problems. In the present economic system there are, of course, no controls of prices on virgin or recovered materials, and prices have fluctuated widely. Resource recovery governed by prices set by supply and demand can hardly be counted on as a stable foundation for reducing environmental waste problems.

Contrary to conservation and accompanying environmental goals, several economic factors now favor virgin production. One is the fact that i.a. virgin timber profits are treated as capital gains for tax purposes, an advantage that is not available for waste paper. There are also certain depletion allowances for processors of virgin materials. Another is the practice of assessing solid waste management costs against municipalities and their general tax funds rather than against those who generate the wastes. This favors the wastemaker and discourages recycling of paper and other materials. In some cases, rail freight rates have been biased against recycled materials.

Littering of natural areas close to cities and suburbs has reached appalling proportions in many areas. The more conspicuous items are car bodies and household appliances, the most numerous are non-returnable glass, metal and plastic containers of various kinds, and automobile tires.

Despite many obvious problems, Congress has been unable to pass legislation to regulate waste management or the quantity or properties of products that create waste problems. As of mid 1975, three states, Oregon, Vermont, and South Dakota had laws restricting beer and soft drink containers and Minnesota had a law affecting all major types of packaging waste. Despite positive experience with, for example, the Oregon law, labor, retailers and industry are still intensely opposed to similar bills. At present, there seems to be little chance for federal product regulations that would be displeasing to manufacturers.

5.3 Norway

5.3.1 Major Legislation

Before passage of the new product control law, the legislative basis for regulating the waste and littering aspects of products was rather limited.

The law concerning authority to ban the use of certain types of non-returnable containers for consumer goods of 1970 has not hitherto been used for regulation.

A temporary law concerning deposit for containers for beer and other soft drinks of 1974 is used to regulate return of glass bottles.

Law on nature conservation of 1970 and the Road Act of 1963 have general provisions prohibiting littering.

Law concerning sanitation tax of 1924 empowers municipalities to enforce mandatory sanitation.

The law on product control of June 11, 1976 (see section 3.3.1) can be used to control waste problems from any type of product. It gives authority to regulate production, importation, sale, labeling, use and other handling of a product. It authorizes mandatory return and deposit schemes, waste source reduction and handling requirements. The design or composition of products may be altered by performance standards or more specific requirements, and products can be banned if necessary.

5.3.3 The Product Control Situation

While the magnitude of waste problems may be somewhat less than in the U.S., a number of specific or local problems need be addressed. Available figures may have a somewhat different basis, but it seems that the quantity of post-consumer waste is about 1/2 of the amount in the U.S.

No adequate information on littering is available, but a subjective judgement indicates that the problem is somewhat more adverse in the United States. The litter situation along the long coast is aggravated by a considerable contribution of waterborne items from shipping activities.

The problems of hazardous waste management are under study. Receiving facilities for hazardous wastes are being planned on a nationwide basis for solvents, pesticides, waste oil, etc. Norway participates in a Nordic waste exchange set up to put wastes to beneficial use in industry, which again reduces contamination from deposited waste. A nationwide system of depositories for heavy metal wastes from industrial metal finishing operations is being set up.

There are not many examples of mandatory product control measures aimed at preventing health or environmental hazards by waste or litter. A tax of about $.13 per can was imposed on non-returnable metal beverage cans in 1974. The tax has significantly limited the use of such cans. Plastic shopping bags provided by merchants free of charge on purchase of consumer products have become increasingly conspicuous littering items over the years. In an attempt to reduce proliferation of the plastic bags, a charge of about $.045 was imposed for each bag. For various reasons the measure has not been completely successful.

The state monopoly of wines and liquors buys its own bottles back at about $.075 each (the percentage of returned bottles around 70) and takes foreign bottles back at no compensation. Breweries and soft drink producers charge deposits of $.06 and $.11 per bottle depending on bottle size, and the rate of return of beer bottles is about 98.5%.

One example of likely product control action to be taken under the product control law concerns polychlorinated bicenyls (PCB). Measures will be introduced to limit the use of PCBs and ensure safe disposal of the product itself and of products containing PCBs (such as electrical components).

5.4 Discussion

5.4.1 Legislation

The federal restrictions on air and water pollution limit the discharge of substances and dumping of wastes into water, and the emission of substances into air. The pollution abatement facilities produce increasing quantities of residues from air and water purification processes, creating new pressures on waste disposal. Many bills have been introduced over the past few years to enable the federal government to better cope with this situation. The present federal laws relating to wastes confer little regulatory authority, are not particularly directed at product control, and have virtually no effect in reducing hazards to health or the environment from products.

Enactment of the present laws seems to have been somewhat half-hearted up to about 1974, but efforts have since increased. The present acts are generally regarded as transitional, in anticipation of new legislation.

In Norway, the government has had little authority to regulate products that cause waste problems, but the new product control law is considered to be adequate to protect health and the environment from such products. The law does not call for the use of fees or taxes, although waste control may be one area where such tools could be useful. However, Parliament can prescribe such measures where necessary.

The first draft of the product control bill included a paragraph authorizing control of products which contribute to unreasonable use of energy and material resources. However, it was felt that such controls must be supported by thorough analysis of the resource situation and be based on adopted plans for resource utilization. The provision was defered until such a basis can be developed.

5.4.2 Approaches and Actions

Apart from a number of studies conducted by EPA, no significant actions to control products that create wastes have taken place at the U.S. federal level. Considering the severe problems with hazardous wastes, it is likely that federal action will begin in this area. The legislative development in the area may indicate that measures may be directed more to the urgent needs for handling, disposal and recycling practices for the wastes that are created, than to product control actions to alter design, composition, and other properties of products in an attempt to reduce wastes or alter the quality of wastes to make them more environmentally acceptable.

Considerable interest has been shown in Congress for legislation designed to stimulate conservation and recycling of materials and energy. (Such measures would in turn have positive influence on health and environmental effects of wastes). However, inability to act so far may reflect the political strength of resource-consuming and waste-generating industries. Little change can be expected in this area as long as there is no acute shortage of resources and the market is able to bear the increasing costs. If any breakthrough were to take place, it would probably be in reaction to authoritative predictions of future shortages.

Given more time, Congress could conceivably pass limited legislation to reduce littering by deposit or return schemes and maybe even standardization of packaging. A few states have laws on the books which require recycling of beverage containers and other littering packaging. Considering the apparent needs, and bearing in mind that many of the products in question are traded in interstate commerce, a strong federal role should be justifiable.

In Norway, actions up to now have been largely reactive to immediate problems. To improve the present situation where necessary, a broad effort is required to analyze the product waste situation and identify problem products and suitable control remedies, an effort that will take some time. Meanwhile, ad hoc solutions will be worked out.

For the longer term it will be important to develop product design criteria, generic product standards and standardization schemes to reduce the quantity of wastes, increase re-use and recycling and improve waste separation and treatment properties of products. Information to consumers about product waste hazards and proper disposal is believed to be important, and information programs and labeling must be developed.

Fees may be effective in influencing the design and use of products with waste effects (see, for example, section 5.3.3 on taxation of non-returnable metal beverage cans), but must be studied further to become a truly useful regulatory tool. Local solid waste handling may be entirely user-financed by taxation of products that create unnecessary waste. Such taxation would also contribute to source reduction, and would be in conformance with the polluter pays principle.

The clause concerning responsibility for anyone who handles a product to take reasonable precautions to avoid health damage, pollution or waste, and the obligation to acquire such knowledge as is necessary to determine whether such effects may arise, applies also to products causing litter and waste. Guidelines will probably have to be written to indicate what the responsibilities are, and how precautions may be taken. It will be possible to require that the producers or importers undertake studies of the waste or littering impacts of their products.

6.0 OTHER TYPES OF HAZARDOUS PRODUCTS

6.1 The Problem in General

This chapter concerns a broad range of products which may give rise to hazards by radiation, inaudible sound, light, heat, etc., or by virture of electrical, explosive, flammable or mechanical properties.

While all such products and their hazardous effects are important in their own right, a detailed treatment of these problems largely falls outside the scope of this report, i.a. because their environmental significance may be relatively limited. However, a brief presentation of laws and the product control situation may be warranted by the fact that some of these products also have properties of environmental significance. For example, a chemical substance may cause both radiation and chemical effects. Or a product could conceivably combine such undesirable properties as electric hazard, fire hazard, heat hazard and excessive noise. Also, the effects of exposure to a product emitting radiation may be additively related to environmental radiation effects. Another reason for including some words on the topic of "other effects" is the fact that many laws, including the new Norwegian product control law, concern such products as well as those that are more environmentally significant. Also, a brief mention of control of "other effects" products will shed some light on the extent of government involvement in product control in general, and give an impression of the scope of environmental product control in the total framework.

X-rays are hazardous to health, and as use of x-rays both for medical and industrial purposes tends to increase, they are cause for growing concern. Following the rapid development of electronic products for research as well as occupational and consumer use, other types of radiation have become increasingly important health hazards. Ionizing radiation (which includes x-rays) may also be emitted from television receivers and electron microscopes. Non-ionizing electro-magnetic radiation is emitted from products such as sunlamps and welding equipment (ultra violet), alarm systems, ovens and heaters (infrared), alarm systems, ovens and heaters and radar devices (microwave). Knowledge of possible harmful effects of radio low-frequency radiation is generally not well developed, and effects of such products as signal generators and power generation and transmission equipment are under study. New applications of laser radiation in products such as cutting and welding devices and communication equipment call for certain safety

precautions. Products such as vibrators (infrasonic), sound amplification equipment (sonic) and cell and tissue disintergraters, cleaners and testing equipment (ultra sonic) also present hazards of various kinds.

Explosives have been subject to control for a long time, and controls are, of course, needed at all steps from production through transportation, storage and use. Relatively new types of consumer products may be prone to explosion (such as spray cans) or implosion (TV tubes). Also, there is a number of chemical substances as well as consumer and building products that may be dangerous because of their flammability properties or because they give off harmful combustion products. Electric fixtures and appliances are responsible for a significant number of injuries due to electrocution and fire hazard.

Finally, there is a vast number of products in the transportation, occupational and consumer sectors that cause a great number of physical injuries each year, as evidenced by accident statistics compiled by the Occupational Safety and Health Administration and the Consumer Products Safety Commission. Some products are inherently hazardous (e.g. power tools), and efforts should be directed at making them safer to use. Some products are unintentionally hazardous (e.g. poorly shielded radiation devices; or bicycles with inadequate brakes), and much of such hazard can be avoided once it is identified. There are also products which purportedly give protection from hazard (e.g. life vests, gonad shields or earbells), and performance failures of such products must be avoided. In some cases, products are subject to uses or treatment for which the product was not intended. Such uses may be either intentional or unintentional, and in some cases it may be necessary to modify or restrict such products.

It is possibly true that most of the damage atributed to these kinds of products are caused by negligence, imprudent or uninformed use. However, there is great opportunity for reducing damage by making products safer.

6.2 U.S.A.

6.2.1 Major Legislation

The Consumer Product Safety Act of 1972 provides a number of options for regulation of consumer products (see section 3.2.1). The Act is used when the Poison Prevention Packaging Act or the two following acts are not applicable.

The Federal Hazardous Substances Act of 1960 (see section 3.2.1) is used to regulate a great number of consumer products for safety from i.a. electrical or mechanical hazard.

The Flammable Fabrics Act of 1967 authorized CPSC to set flammability standards, to seize or confiscate products which are not in compliance, and to inspect, test, analyze, etc. Standards apply to imported products, but not to exports.

The Occupational Safety and Health Act of 1970 (see section 3.2.1) is used to set requirements as to safety of products used in the workplace, such as performance requirements, handling and labeling.

The Transporation Safety Act of 1974 (see section 3.2.1) is used to control handling, packaging, labeling, etc. of products. The Act also has provisions concerning transportation of radioactive materials. There is a separate act relating to transportation of explosives.

The Radiation Control for Health and Safety Act of 1968 is used to regulate radiation, sound, light, etc. from all types of electronic products. Regulations take the form of product performance standards and there are certification requirements for products for which standards are applicable. Manufacturers or importers must report any radiation hazard not in compliance with standards, and must alter or replace inadequate products without cost or make a refund for the cost of the product. Imports are subject to the same rules as domestic products, and products must carry labels warning of hazards and proof that they comply with standards.

6.2.2 The Product Control Situation

Control of radiation products in the U.S. is the responsibility of the Food and Drug Administration's Bureau of Radiological Health, which covers both professional and consumer products. Standards for product performance, safety features and labeling exist for diagnostic x-ray equipment and cabinet x-ray machines such as those used in industries, museums, laboratories etc. for various quality control and research applications and for inspecting luggage at airports. Standards are proposed for laser equipment, microwave ovens, ultrasound and photo therapy equipment and sunlamps.

X-rays used for diagnostic purposes account for 90% of all exposure to man-made radiation, and it is the major aim of the program to minimize the exposure by regulating machine performance and to work for safer operators' performance. However, there is no regulation limiting the total exposure each patient or operator may be subjected to over time.

Transportation of radioactive materials is regulated by the Department of Transportation, the FAA, the Postal Service and the Coast Guard through restrictions, handling and packaging requirements.

While authority exists for regulating electrical products, no Federal regulations exist. A regulation concerning extension cords is under preparation by the Consumer Product Safety Commission (CPSC).

Certain explosives and flammable substances and contents of pressurized containers are under regulation by CPSC. The Commission also regulates flammable childrens' sleep ware.

A wide selection of consumer products which give rise to various physical hazards are regulated by CPSC. Most of the regulations concern performance or design features and labeling. Federal control of consumer products is a new effort (CPSC became operational in 1973). It may be too early to assess the impact of the work, but promising advances have been made. The fact that the agency has wide-ranging authority to attack the issues in a methodical way, probably places the U.S. in a uniquely advanced position among countries. (Similar efforts are being planned i.e. in Britain and Scandinavia).

There are also control systems for motor vehicles, aircraft, boats, and products used in the workplace, all regulated by different agencies.

6.3 Norway

6.3.1 Major Legislation

Reference is made to law on worker protection of 1956 (see section 3.3.1).

Law concerning flammable goods of 1971 concerns handling, transportation, storage and sale of flammable goods.

Law concerning explosives of 1974 provides authority to regulate use, storage, trade and other handling of explosives.

The Fire Act of 1970 covers prototype approval of extinguishing equipment and heaters using flammable fuels.

On radiation and electrical equipment there is a law concerning use of x-rays and radium of 1938 and law concerning control of electrical systems of 1929.

The law concerning product control of June 11, 1976 will give a basis for control of any type of product and thereby fill some rather serious gaps in existing legislation. To the largest practical extent, control of various product groups will continue under the applicable special legislation, and the new law will be used beyond this when necessary.

6.3.2 The Product Control Situation

Statistical or other information concerning injury and death related to products are presently not developed sufficiently to permit a quantitative assessment of product hazards. Occupational statistics indicates that there were 6,000 injuries involving various types of machinery and hand tools in 1973. A report on flammable textiles from 1974, estimates that 50 persons die and 1-200 persons are injured per year in cases where clothing has been ignited. Work is now under way to study systems for injury information and to develop strategies for prevention of accidents in the home.

Control activities relating to explosives, flammable substances and radiation have been undertaken. All electrical components are subject to prototype testing and pre-market approval. There are also control systems for transportation of goods, for motor

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