ENVIRONMENTAL REGULATION: AN INTERNATIONAL VIEW*

I Britain

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Environmental regulation, as I see it, is a wide term, far wider than, *e.g.*, the impact of new chemicals introduced to the environment, which I had first thought might be the subject of this symposium. It is a good deal wider even than pollution control, though that is an important part of it. Environmental regulation, as I see it, covers not only that, but also the gathering of information on the environment and what is happening to it and the use of the planning process to avoid environmental damage. In what follows I want to try to relate these various elements together; much of what I will describe will be familiar to many but I hope that it will be useful to set it out, if only as a backcloth for what is to come.

For if the subject is wide, so too is the range of approaches to it which we are to consider here. It was not mere chauvinism which caused this lecture to be placed first, let alone the well-known, probably even well-worn fact that Great Britain, as the earliest country to industrialize, was the first to develop a system and philosophy for controlling the pollution that industrialization produced. The main point, presumably, is to contrast our own system, well-worn perhaps but broadly familiar, with the approaches described in the other lectures: the approach adopted in the United States which differs markedly from ours, not least in having to operate within a federal system; and the approach, quite different again, of the Commission of the European Communities. The Commission, faced with a programme for instant environment, has now to implement it in a way which ensures firm progress towards common goals while at the same time respecting legitimate national differences, not only environmental, but also social, economic, legal and administrative. For differences between systems do not necessarily mean that one is better or another worse. In all cases the development of the organizational structure for control, and the philosophy behind that control, are closely inter-related, and reflect more or less long-standing assumptions both about the relationships between the

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agencies of Government themselves, and between them and those in whose dealings they are administratively involved. Nevertheless there can only be benefit in comparing the philosophies of different governments and organizations and examining their relevance to different situations. Better understanding of different approaches to control should lead to an enlarged awareness of the methods by which that control is achieved and will help us too to deal with problems which go a good deal wider than national boundaries or which call for greater resources than most nations can muster. A case in point is the link concluded recently between the American Chemical Society and this Society —a valuable move for which the Society should be congratulated.

The British philosophy and organization for pollution control has developed slowly and over a long period in response to problems which have become increasingly complex with the progress of technology and invention. As scientific knowledge has advanced, so also has the awareness and sensitivity of those who enjoy the benefits it brings. Recently the average British citizen has become more than ever conscious of his own and everybody else's rights to enjoy a clean and physically safe environment. The public have become aware of the speed at which developments are taking place and the resistance of the environment is being eroded. They demand, rightly, that something is done about these trends. Central government is called on to respond to situations where the scope of the problem appears too great to allow private, independent or local agencies to deal with it by themselves. In situations like that Government must plainly take the initiative, with legislation as necessary. (The obvious example is the Clean Air Act which was passed in the 1950s in response to the excessive death rate due to London smogs.) Rather than seek a new solution for each new problem, Government is obviously concerned to proceed in harness with existing enforcement agencies when possible, and to operate within the framework of existing administrative relationships when these have proved themselves appropriate in the past. This is true not just for obvious crises, like the smogs of the 1950s, where effects are instant and shocking and call for speedy drastic action, but it also applies to the longer-term developments whose cumulative effects may not be obvious to any except specialists in the sciences. Such effects may cause no death that would draw the public's attention to them, but are in the end very significant in a policy of environmental regulation and may even require greater vigilance from central government, its agents and the governed. We are now largely past the time when spectacular improvements in the state of the environment would make the headlines. Present policies for environmental regulation have in most respects to deal with problems less easy to identify. Their success will not be apparent in dramatic ways but thus need the continued co-operation of the traditional enforcement authorities and the industries they are regulating, and a mutual understanding of the constraints under which all are operating in their different ways.

I want now to describe the principles on which we operate today and the broad administrative structure which has grown up to implement them. It is not possible to be comprehensive in the space available, but I hope the illustra-

tions given of the way present practices and relationships operate will help to show how they have evolved and why they have developed in this particular way.

We will begin with the gathering of information needed for environmental regulation. Policies for the management of the environment cannot be formed without knowledge of that environment itself, its physical characteristics and its vulnerability to change; and we need to know also the characteristics of the substances which are being inflicted on the environment and the processes by which they come to affect the natural world and human beings. The accumulation of knowledge upon which policies can be based has two aspects: it involves research into the substances emitted, their effects, particularly their effects on human health, and techniques of controlling them, (*i.e.*, scientific, technological, and medical research) and it also involves the monitoring of the natural environment, the effects of discharges into it and the effectiveness of our controls. The need for such knowledge has long been recognized, but the relationships between the data collected on different fronts and their uses for environmental management have only come to be appreciated fairly recently.

Data on the natural environment have been collected systematically for over a century: the earliest topographic maps of the Ordnance Survey were drawn up just a few years after the first major piece of anti-pollution legislation of the great Victorian administrators (the first Alkali Act in 1863); the Geological Survey covers the solid geology and overlying mantling of glacial debris; the Soil Surveys of England and Wales and of Scotland provide information about the soil; there have been two national Land Use Surveys, in the 1930s and the 1960s; the distribution of wild plants and animals has been mapped, and areas of ecological interest surveyed in detail; historic monuments have been surveyed. All these special surveys together form a series of 'overlays' of information about the country. They are pulled together and incorporated in regional structure plans for the use of the land which each county planning authority has to prepare. Such plans indicate the desired major zones of agriculture, industry, urban residental development, and lines of communication.

These surveys of the natural environment are a basis of our policy-making to which it is important to add surveys of the distribution of pollution. These have come from our national monitoring system: air pollution by smoke and SO_2 is measured at some 1200 sites all over the country, and at 20 sites particulate matter and about 12 airborne metals are continuously monitored. There has been a comprehensive survey of the state of pollution of our inland waters, and we are also monitoring at the tidal limits and major confluences of all our chief rivers.

These and other national surveys are supplemented by information about the detailed picture around major factories or in urban centres, by registers of the location of radioactive wastes, and by other registers now being built up of the location of toxic wastes deposited on land or dumped at sea. There is also a considerable body of information on the location of land rendered derelict by industrial action: we still have some 36 000 hectares of such land, and at least

as much, and probably more, in a thoroughly polluted and run-down state and demanding remedial treatment. But the value of these data is limited unless it can be drawn together and evaluated on a national scale. Much work has been going on in the Department of the Environment to ensure that the data collected by local authorities, other agencies, and the Department itself can be codified on a uniform basis and presented in such a form that lessons of regional or national significance can be drawn from them. The unified monitoring system towards which we are working should enable the Department to determine the most valuable areas for monitoring and the type of monitoring to be done, and thus the control systems that may need to be established to tackle particular types of risk; it will also give pointers to the most efficient methods of allocating resources.

A related system of data collection and research with which you will be familiar is the attempt to provide a data network of environmentally significant chemicals. One of the basic aims of our current research programmes is to know as much as possible about the basic properties of hazardous substances and to predict their environmental significance. The work my Department is doing in conjunction with the Chemical Society, local authorities and other Government Departments to establish a data bank of such substances (to be known as DESCNET) arose from a suggestion made by the Royal Commission on Environmental Pollution, and is a good example of the fundamental work that needs to be done before we can have confidence in our control systems.

On the other sort of knowledge referred to earlier, the basic research without which any survey is hard to mount or interpret, the Department needs and supports a maze of programmes of work geared to explore the factors that determine the ecological pattern—the mosaic of living organisms—and to predict how this pattern will change as land-use practices alter, industry is relocated, new forms of energy generation are adopted, and the nature of our emissions to the environment varies. In the past we have concentrated especially on things that can create acute damage to human health, to agriculture or to structures we build. Now that we have made some impression on the legacy of the industrial past we are also concerned with more subtle effects, including those of chronic exposure over long periods, and, those on species on which our dependence is less direct. This should make us better able to interpret what people need for a creative life and a healthy environment—an environment in which they are not only shielded from acute hazard, but from the stress that such factors as noise and smells, at present well below the thresholds of damage detectable medically, may bring over many years of exposure.

There is a further area of research work I should mention, which is particularly important now when the resources available for pollution control are scarce, and that is research into the costs and benefits of pollution controls. Environmental economics is a relatively young branch of economics, and in the case of pollution control its progress is dependent on the progress of medical research into the long-term health effects of various pollutants. Work is going on in my Department on cost benefit studies into particular pollutants, but in an area

where data on health effects must be painstakingly acquired over a period of years, the process of building a comprehensive picture of costs and the benefits of controls is inevitably slow.

I have dwelt at some length on this first principle, *i.e.*, the need continually and comprehensively to improve our knowledge of pollution effects and control techniques. This is, or should be, the first stage in implementing a philosophy of environmental regulation. The second principle is that the knowledge we obtain and put together should be used to plan our progress in a balanced and integrated way. The relationship between our acquisition of knowledge and our translation of that into a planning strategy is complex and subtle. Essentially, we should look on pollution control or prevention as one aspect of the wise management of natural resources. We believe it is legitimate to use the capacity of the environment to disperse and degrade wastes—so long as we do not over-use it and permit ecological degradation. We need to know how far the environment is already 'saturated' with waste, how wide our safety margin is, and where trouble threatens if we do not improve our management and pollution control. We need to know how environmental and ecological systems will respond to development —to predict the likely consequences of our actions. With information like this we are in a position to assess better the effects of proposed development and can aim more confidently to make planning decisions which protect the environment, while meeting economic and social needs and using our resources sensibly. Expenditure to clean up after the event the mess we have created with careless industrial development is an inefficient approach to environmental management. Advance planning leads to a better balance of economic and environmental interests, more efficient resource utilization, and a higher and more sustainable quality of life. The research workers, the planners and the makers of national policies meet here. The planning principle applies not just in development control policies implemented at local level—with relatively small decisions about the siting of new factories, for example—but at the level of national strategy when decisions are taken about such major policies as energy supply programmes and industrial incentives and regeneration. The protection of the environment should be a positive planning objective weighted in the way that the preservation of employment is weighted; though it cannot exercise the same pull as an objective until we have a more complete picture of the costs of attaining it, in terms of effects on biological and human health, and can set the resources involved more clearly in our overall economic picture than is the case at present.

It has been clear from what I have said so far that we see the centralized planning of our policy of developing knowledge and research on the environment as a key element in the overall framework of regulation. I have mentioned that this knowledge is, and can only be, built up with the co-operation of the other administrative agencies and those, principally industrialists, with whom they work. Similarly, and this is our third principle, we believe the enforcement of environmental policies is best delegated to those authorities who operate at a regional or local level, rather than carried out by central agencies. In Britain

central strategy for pollution control, and the establishment of national environmental objectives, are the particular responsibilities of the Secretary of State heading the Department of the Environment. He has the duty of co-ordinating Government action to combat pollution throughout the United Kingdom, together with responsibility in England for land-use planning, pollution control, transport policy, and public building. In Wales, Scotland, and Northern Ireland these responsibilities are exercised by the respective Secretaries of State. A range of local authorities, on the other hand, is responsible for the implementation of policy in the fields of planning, urban renewal, highway construction and maintenance, management of water supplies and river quality, the maintenance of clean air, and waste disposal. They have acquired these functions over a long period, and their exercise of their fairly considerable powers in the pollution control field is only one aspect of the tradition of strong, independent and responsible local administration which has grown up in Britain. As they have acquired these powers they have developed expertise and the organizational structure to cope with the administration of pollution control and its increasingly complex problems. The recent reorganization of local government aimed in part at rationalizing and strengthening the roles which local authorities have developed over the years so that they can cope with the increasing number of functions which central Government places on them.

The 1973 Water Act had a similar aim when it created the Regional Water Authorities, the other main agencies to which responsibility for enforcement is delegated. The Water Authorities are regionally based on river basins or groups of basins and managing the whole hydrological cycle in an integrated fashion. Sewerage and sewage disposal, and the prevention of pollution (including the imposition of consent conditions on all discharges of effluent to rivers), are only two of a range of functions; these also include land drainage and flood protection, salmon and freshwater fisheries, the recreation and amenity use of the water space within their regions and, in some cases, navigation. The important feature of the reform was that the ten new Authorities have been created as multi-purpose organizations. At the national level the National Water Council, consisting of the chairmen of the ten Water Authorities and a chairman and other members appointed by Ministers, forms the main source of advice to the Government on national water policy. It aims at providing other Regional Water Authorities with a forum for the discussion of common problems, and develops and disseminates uniform policy and practices for the provision of common services. It is as yet early in the life of the new Water Authorities to say what effects their reorganization has had and will have on their ability to implement pollution controls; the theme behind their creation is that they should be able to manage pollution strategy over the complete natural hydrological formations rather than over segments whose boundaries were determined for administrative convenience. Their creation along these lines is an example of the broader planning policy I talked of earlier.

The third element in the triangle of relationships necessary for the success of our environmental regulation policy is the relationship with industry. Awareness

in industry of its broader responsibilities towards the public it supplies with goods has developed considerably over recent years, and industry has shown its willingness to co-operate with Government in measures to improve the environment, whether these involve legislation or not. The relatively small volume and the character of our recent anti-pollution legislation reflect this. The most significant piece of recent legislation is of course the 1974 Control of Pollution Act, which represents our first attempt to tackle pollution problems on a co-ordinated, comprehensive basis. The provisions in that Act relating to the publication of information about discharges were discussed with the CBI, who recognized the value of such information being publicly available and accepted their inclusion. What is *not* included in the Act is as important as what is included: the Act does not include what tend nowadays to be called 'swingeing' controls on the types, qualities and quantities of substances that may be emitted to air and water and disposed of on land. This reflects our view that Britain, as a manufacturing and exporting nation, must aim at developing prosperous industries while at the same time maintaining a salubrious and even beautiful environment. These are *not* incompatible goals. As one aspect of this approach, we sometimes work towards the pollution control we need through a voluntary agreement between Government and industry. For example, the control of pesticides used in agriculture in Britain is based on such a voluntary scheme, in which industry supplies information about the tests it has carried out on the toxicity and ecological safety of its products, and an independent expert committee scrutinizes the information, approves or disapproves of particular uses of the products, and agrees on special information and guidance to be conveyed on labels or in instruction sheets and handbooks. With the support and even encouragement from the industries concerned the scheme is now being extended to the non-agricultural uses of pesticides. Again the concept of best practicable means which underlies much of our pollution control involves necessarily frank discussion between industry and the control authority before consent conditions for discharges are given.

Describing the relationships between central Government, its enforcement agencies, and industry leads me naturally to a description of our philosophy on standard setting. While central Government lays down the framework for environmental policy, we do not set national environmental quality or emission *standards*. We believe that our response must be flexible from place to place and time to time. Ecological processes and ecological systems are always changing, and the ecological systems we see are in a constant state of dynamic interaction, despite their apparent stability. Likewise our social systems, wants and priorities alter. We have to plan the environment for many decades ahead—if only because a road system or a new town has a life of a century or so—but in some areas it is wise to leave options open for the future where we can. In the more limited field of pollution control this has practical consequences in our approach to environmental standards. We empower the agencies who enforce pollution control to set standards as they see fit in the light of the state of the local environment, the uses to be made of it, the nature of the emissions to it and their effects,

and the technical and economic feasibility of attaining a particular level of control at particular times. So, to take an example, we do not insist that all our rivers are purified to the same degree. We recognize that *some* still unpolluted or important as sources of drinking water, must be maintained at a high standard. *Others*, used as industrial drains in a heavily polluted state, certainly need progressive improvement, but they do not justify the massive expenditure that would for example be needed to restore salmon and trout to their waters. We do of course expect that decisions like these will be taken in the context of an overall plan for water use in the area concerned. Enforcement authorities do not therefore agree standards arbitrarily and without regard to any set of authoritative criteria. That would be to disregard the vast amount of authoritative scientific work which has been done in a national and an international context. One of the rôles of central Government, apart from setting the legislative framework of control, is to give guidance to the enforcement authorities on standards to be adopted or technical controls which experience has shown to be practicable or desirable.

One example of this is the advice now beginning to issue on dangerous wastes to help local authorities with their new responsibilities under the Control of Pollution Act. Another is the help which the Alkali Inspectorate can give to local authorities in dealing with the substances for which they retain responsibility for control under the Public Health Acts, or to planning authorities faced with applications for development involving scheduled processes.

It would be wrong to assume that a flexible system is a chaotic one; wrong to think that if a modern Cobbett went on his Rural Rides today his life would be in more danger in some counties than in others from the air he breathed and the water he drank. But by not requiring absolute uniformity of standards for discharges to air and water, and allowing variation where the natural environment can tolerate it and in response to changes in that natural environment, we believe we can allocate the limited resources available for pollution control more efficiently, concentrating expenditure where it is most needed. Today the problems we face are too great and the resources available too scarce for this not to be an important justification of our approach.

There is another aspect of our environmental regulation policy that is significant for standard setting and for the smooth administration of national policies, and that is the involvement of the public. Government needs to draw on the best brains in the community as a whole, and as a source of authoritative advice it has set up the Royal Commission on Environmental Pollution to act as guardians of the public interest. In the environmental field the scientific and professional communities have a special part to play. In Britain many Departments of Government have specialist Advisory Committees or Councils with independent members. In the environmental field, we have a Clean Air Council, chaired at Ministerial level, with members drawn from Government, the universities, professional bodies, and industry. We have a Noise Advisory Council and a Waste Management Advisory Council with similar composition. These Councils provide advice on priorities for action in their fields. As well as these

formal established bodies there are of course other means of getting advice and help from the scientific and professional community. Occasions such as this symposium are of great value. So too are the links which learned bodies like the Chemical Society have established on a personal basis with scientific and administrative members of the Department. We need a free flow of ideas between experts in different fields, sensitive to different influences and experiencing a wide variety of problems, if we are to develop policies that are both subtle and comprehensive enough to be effective.

But it is not only contact with experts which is important; the awareness and participation of the general public play an important part in environmental management and pollution control. Our planning process allows individuals or bodies whose interests are affected by proposed developments to make objections and in many cases these are explored at inquiries under an inspector appointed by the Secretary of State for the Environment, at which these individuals can state their case. Our wide range of voluntary societies have always been prominent in environmental issues in Britain, and play an important part in bringing the views of the informed public to bear on Government.

There would be little value in outlining and defending the philosophy and organization behind our system for environmental regulation if there were no proof that it has been effective as a means of controlling pollution. It certainly has been successful; progress has been steady on the whole—marked, as progress usually is, by occasional spectacular milestones. Damaging or offensive air pollution from industry in Britain has certainly declined over recent decades. The range of works scheduled for control by the Alkali Inspectorate has been widened progressively. The kind of progress is well illustrated by the trend in emissions from power stations and cement works. In the 14 years 1958—1974 power stations burned 35% more coal, but emitted 82% less grit and dust, and cement production rose by 60% but total emissions in dust were reduced by 85%. Spectacular achievements have been seen in the control (under the Clean Air Acts) of smoke identified in the smogs of the fifties as the most damaging single air pollutant in Britain. Under these Acts, local authorities have established smoke control areas within which it is prohibited to supply or burn smoke-producing fuels. Government grants have assisted in the conversion of houses to burn the new cleaner fuels. The general trend from coal burning to use of gas, oil, and electricity has helped further. Over 69% of all houses in Great Britain in areas identified as 'black' in 1956 and 90% of all houses in Greater London are now covered by such smoke control orders. Total smoke emissions in Britain have fallen from 2.42 million tonnes in 1950 to 0.77 million tonnes in 1970. The effect on winter sunshine in the centre of cities such as London and Manchester is well known.

The rivers of Britain have also shown steady improvement. In 1958 we had 1278 miles of grossly polluted non-tidal rivers; in 1973 only 794 miles were in this category, while the extent of pullution-free waters had increased by nearly 3000 miles. As is well known, new sewage treatment works have prevented the Thames becoming deoxygenated and lifeless in summer, as it was in the 1950s.

On land, our usage of persistent organochlorine pesticides controlled under a voluntary scheme fell from 400 tonnes in 1963 to 300 tonnes in 1967 and has since fallen further. Polychlorinated biphenyls are not supplied for uses that may contaminate the environment.

In quoting these random examples of progress that has been achieved I am not meaning to give the impression that we are complacent, or that we do not recognize that policies must change with the introduction of new techniques in the light of developing knowledge of the way pollution affects the natural environment or in the face of new problems. The capacity of the present system of environmental regulation to match up to increasingly complex and potentially dangerous demands will be severely tested. It is already subject to scrutiny in the European context, in which our traditional control techniques are being contrasted with policies devised within different philosophical and administrative traditions and sometimes faced with vastly different problems. But the more important tests the system faces come from the natural changes in the environment and the processes man is developing to use that environment for his own purpose—to supply him with energy, with material goods and recreational facilities. The flexibility in our control techniques has so far, we reckon, proved an advantage. Is this belief generally shared by informed opinion in this country? How far can our system be adapted in the light of experience elsewhere? What are the implications of membership of the European Community for the process of environmental regulation in this country? These are the kind of questions to which I hope answers will emerge from further papers in this symposium.

II European Economic Community

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1 Introduction

In order to discuss the environment of the present and the future, one must inevitably refer to the past. We probably all remember the publication in the late 1960s of Rachel Carson's book, 'The Silent Spring'. We remember the rising tide of concern with the effects of pollution and the impact of prosperity on the quality of the environment. The Santa Barbara blow-out was followed by the Torrey Canyon affair. 1970 was European Conservation Year and even though some critics unkindly labelled it European Conversation Year, the Conference at Strasbourg in February 1970 was an important step in developing an awareness of environmental problems on a European scale.

The European Commission sent two 'Communications' to the Council on the subject of Environment in 1971 and 1972. The President of the Commission himself, Mr. Mansholt, went to the Stockholm Conference in June 1972 and when the Heads of State or Government met in Paris in October 1972 they gave a specific mandate to the Commission to propose an action programme on the environment.

From the British point of view the timing of all this was important. The Commission in fact sent its formal proposal to the Council in April 1973. This proposal was debated in the Working Groups of the Council between April and July and of course the United Kingdom, which had joined the Community on 1 January 1973, was fully represented in those debates. This was not a case of an already existing Community policy being foisted willy-nilly on a new adherent. The environment policy was and is one to which the United Kingdom has made a full contribution at the level both of conception and of action. On 19 July 1973, the Environment Ministers of the Nine E.E.C. Countries adopted the Programme of Action proposed by the Commission with the amendments that had been applied to it in the course of the discussions in the Council.

This programme, the official text of which was adopted in all the Community languages on 22 November 1973, is the Community's basic mandate. In adopting it, the Council declared that the fundamental aim of Article 2 of the Treaty of Rome, namely to 'promote throughout the Community a harmonious development of economic activities and a continuous and balanced expansion', could not be 'imagined in the absence of an effective campaign to combat pollution and nuisances or of an improvement in the quality of life and the protection of the environment'.

So we must see the E.E.C. Environment Programme as a double-headed affair. On the one hand, we have the fight against pollution and, on the other hand, the efforts to improve the quality of life.

2 The Fight Against Pollution

What are the basic concepts behind the E.E.C. pollution control programme?

A. The Definition of Criteria.—Our first priority is to assess the evidence. What do we know about present levels of pollution? What do we know about the harmfulness of particular pollutants in particular media? When we speak about harmfulness, we are referring not just to harmfulness to man but also to the possible consequences such pollution may have for environment in the wider sense of something which comprises all living things, all fauna and flora, man included, and the complex inter-relationships between them.

Let us take a particular case, that of lead. How much lead is present in the atmosphere? How much lead is absorbed through the lungs into the blood? What is the relationship between the presence of lead in the blood and damage to health?

We have called this aspect of our work the definition of criteria. We have been trying to assess, on the basis of the best scientific and mechanical evidence at our disposal and at the disposal of national governments, what the dose–effect relationship is for certain individual pollutants in particular media, and sometimes, for certain pollutants in combination. So far the Commission has proposed criteria for lead—both atmospheric lead and lead in the blood; we are in the course of finishing our work for sulphur dioxide and for carbon monoxide and will in due course be looking at the effects on health and on ecology, of another twenty or so important pollutants, such as nitrogen oxides, photochemical oxidants, organo-halogen and organophosphorus compounds etc.

Why does the E.E.C. bother with this kind of work? Why not leave it to professional bodies like the World Health Organization? The answer is that, of course, we work very closely indeed with the W.H.O. We draw on their expertise in making our own proposals. The national experts who advise the Commission are often the same as those who advise other bodies.

But there are some important differences between what the Community can do and what W.H.O., for example, can do. The W.H.O. can make recommendations. The Community can, if it chooses, give those recommendations the force of law in the Member States by means of Council decisions, directives or regulations. The Community is, in other words, a political body. If certain normative actions, actions which will certainly have social and economic consequences, are to be taken as a result of the definition of criteria, *i.e.* dose–effect relationships, it is inevitable that the scientific basis for those actions will be validated or revalidated on a Community level.

B. The Definition of Environmental Quality Standards.—Having defined the criteria for certain pollutants, we are now in the process of trying to establish

certain health protection standards or environmental quality standards at a Community level. Somewhere on the curve, you have to draw the line and we believe it makes sense if all the Member States draw the line in more or less the same place.

Let us take another example: How actually can we be sure that a glass of water does not contain a lethal dose of arsenic? Do the water undertakings in Britain, or indeed in other Community countries, undertake not to put arsenic in the water supplies? What about other toxic substances besides arsenic? One can think of plenty.

Now, of course, in Britain the authorities have for generations had a statutory obligation to produce a 'wholesome' water. But this is not necessarily true of all Community countries. The real point is that in this new Europe we are all building it is reasonable to expect that some minimum health protection or environmental quality standards will be observed and enforced. This is not harmonization for harmonization's sake. It is harmonization for the purpose of ensuring that all the citizens of Europe, at least in some fields, attain a certain basic quality of life. If we have time to bother about a common E.E.C. passport we certainly have time to try to ensure that when an Englishman goes on holiday in Italy and asks for 'aqua', he does not get poisoned and *vice-versa*. So we have now proposed some minimum standards for the quality of drinking water. If the Council adopts these standards, they will need to be observed throughout the E.E.C. (to be exact only some of the values we propose will have a mandatory character; others will be treated as guidelines or recommended values).

Similarly, we have made proposals to the Council for basic health protection standards as far as atmospheric pollution by SO_2 and lead are concerned, and we will follow this by proposing standards for other important pollutants, in both air and water.

It may be observed that this is all rather fanciful, that it is all very well in terms of political rhetoric to talk of every European's right to a decent environment but that in the reality it is not one of our most urgent tasks. We would disagree. Even if we leave out of account philosophical considerations, there is a very strong case on *economic grounds* alone for seeking to apply through the Community some common environmental quality standards or objectives.

We are of course fully aware of the traditional British viewpoint that the capacity of the environment to absorb and neutralize waste should be seen in terms of the natural competitive advantage of one country *vis à vis* another. We are aware that the British consider that the environment is a resource to be used but not abused. The British have short fast-flowing rivers and live on an island surrounded by seas and believe it is reasonable, from an economic point of view, to take advantage of that fact in much the same way as, say, Italy takes advantage of the sunshine to grow oranges.

There is a good deal in this argument which we can accept. We would only make three important provisos. First, that the concept of exploiting the carrying capacity of the environment should not lead to the generalized spread of pollution whenever and wherever we still, happily, have some margin for manœuvre.

In other words, the stand-still principle should apply. You do not pollute up to the limit merely because the limit has not yet been reached. (We sometimes feel that the British talk of the ability of the environment to tolerate pollution as one might talk of the ability of the human body to tolerate torture!)

The second proviso is that the scale of the operation can never be purely national. Britain is surrounded by seas but these are not Britain's seas. The English Channel is also La Manche. Britannia may rule the waves within her territorial seas and have jurisdiction in important areas beyond the territorial limits (we are waiting for the results of the United Nations Law of the Sea Conference). But pollution of the sea does not stop at the three-mile limit, or the twelve-mile limit or even the 200-mile limit. One nation's out-tray is another nation's in-tray. In the widest sense, the sea is the last great common resource of all mankind and we have to treat it with respect.

The third proviso is that within the framework of the Common Market important distortions of competition will result if Member States take widely differing views of what it means to 'exploit the carrying capacity of the environment'. Unless we try to apply common environmental quality standards, we may easily have a situation where pollution havens exist within the E.E.C., havens which are created either because a Member State adopts much lower standards of protection than its partners or else, because having adopted satisfactory standards, it fails to enforce them adequately.

Thanks largely to an impulse provided by Britain the Community is now engaged on a major exercise whose object is to define common environmental quality standards for both sea and freshwater in respect of a so-called 'black-list' of pollutants—mercury, cadmium, certain organo-halogen compounds, persistent oils *etc.* At the same time as the Council adopts the values limiting, on a Community-wide basis, the presence of a particular pollutant in the environment, it will adopt a monitoring procedure. The British have proposed, and the Council has agreed, that Member States should demonstrate to the Commission according to this monitoring procedure, that the environmental quality standards are being attained and maintained. If a State cannot do this, it will be obliged to apply certain minimum emission standards at the point of discharge wherever blacklist substances are concerned.

C. Norms—Product and Process.—The third main axis of the 'prevention of pollution' part of the Community's Environment Programme concerns norms: product norms and process norms. In our view it is not enough to define criteria, the dose–effect relationship. It is not enough to define the environmental quality standards or objectives. It is not enough to lay down procedures for monitoring and information exchange. We believe that there are certain cases where it makes sense to lay down on an E.E.C. basis certain norms designed to ensure, or help ensure, that the desired environmental quality is in fact achieved and maintained.

(i) *Product Norms.*—One of the pillars of the Common Market is the free

exchange of goods. The elimination of internal tariff barriers is almost by definition the essential feature of a Customs Union. But what about non-tariff barriers? These can in their way create just as important obstacles to trade as the tariff walls themselves. Many of these non-tariff barriers may originate from the wish to achieve a measure of environmental protection through the specification of product norms.

Let us once more take lead as an example. Assume there is agreement at the E.E.C. Council that lead in the blood can be harmful. Assume there is agreement on the fact that some proportion of lead in the blood derives from lead in the atmosphere. Assume, further, that lead emissions from the exhausts of motor vehicles contribute significantly to atmospheric lead. We then have to ask what actually can be done about reducing lead emissions in the exhausts of motorcars.

There are certainly a number of possibilities. Work is going on with the development of lead traps and other devices of a similar sort. One option is to take the lead out of the petrol itself or, more accurately, not to put it in or at least to put less of it in. Now in Britain there is at present about 0.50 grams of lead in every litre of supergrade petrol. In Germany a law went into effect on 1 January 1976 requiring supergrade petrol not to contain more than 0.15 grams of lead per litre. In other words the Germans intend to impose a standard more than three times as severe as that which prevails in Britain. The Germans take the view that the interests of environmental and health protection require a standard as strict as this, and they are prepared to pay for it in the sense of increased petrol consumption or refinery costs and so forth. The British do not think at the moment it is justified to go so far and they may or may not be right. It is always difficult to judge this kind of thing when what is involved is a trade-off between health and the environment on the one hand and certain social and economic consequences on the other. But the point to be made is that, within the framework of a Common Market or a Customs Union, we have to standardize somewhere. If a man wishes to ski in the New Year in Austria or Switzerland and he decides to drive through Germany to get there, he had better be sure that his car is capable of functioning on low-lead petrol otherwise he may not even reach the Black Forest.

This is why the Commission has proposed a directive designed to achieve a uniform limit to the amount of lead in petrol, namely 0.40 grams per litre. It may not be exactly what the British want. Still less, is it exactly what the Germans want. But that is the nature of compromises. They are never exactly what people want. They do however represent something that people are prepared to live with.

Noise from vehicles is another area where different product norms can create important barriers to trade. Within the E.E.C., standardization of maximum permitted noise levels has already taken place on the basis of an E.E.C. Directive. Given that the E.E.C. itself trades with third countries, such as the U.S. or Japan or Scandinavian countries outside the Common Market, standardization cannot end there. We have to work with bodies like the U.N.'s Economic Commission for Europe and the I.S.O. in Geneva, or the O.E.C.D. in Paris,

to achieve standardization for traded products in the wider international framework.

There are many other cases where environmental protection can in fact lead to protection in the other sense of the word, *i.e.* protection of the economic variety. What we need to do is to pursue the goals of free trade and environmental quality simultaneously. We must standardize, harmonize—it does not matter which word we choose—but we must not do this at the level of the lowest common denominator. Our speed may not be that of the fastest man in the squad, but it should certainly not be that of the slowest either.

The Commission has already proposed, and the Council has already adopted, several directives which have this dual aim of promoting at the same time free trade and environmental quality. Besides the motor-vehicle directive, the Council has similarly adopted directives relating to the biodegradability of detergents, the sulphur content of gas-oil (which is what we call domestic heating oil) and so on. Work will continue in this field.

(ii) *Process Norms.*—There is another kind of norm which is more complex than the product norm and that is the process norm or the process standard which may set levels for pollutants not to be exceeded in emissions from fixed installations or which may fix operating standards for certain fixed installations in order to protect the environment.

Of course at the local level there often have been established emission standards or operating standards. In Britain, for example, the whole concept of water management is based on the notion of 'consent to discharge' and that consent may lay down specific conditions relating to permitted emissions. The consent may take into account the particular circumstances not only of the environment into which the discharge is made but also of the discharger himself.

The local authorities may work to certain national guidelines in deciding what policy to follow. The Alkali Inspectorate for example have—we are told—a set of 'presumptive limits' which can be alluded to if necessary. But there is not in this country or indeed in many other Community countries a clearly defined national policy of emission control based on the definition of certain common emission or operating standards.

It may be asked then, why try to introduce such a policy on a Community level? The answer to that is that we believe there are certain cases where it makes sense to deal with emissions at the point of discharge without of course prejudicing the policy of environmental management through environmental quality objectives and standards.

Take, for example, the so-called 'black-list' substances. These are substances which, according to the best evidence we have are highly toxic, persistent and bio-accumulative. That is to say, they not only stay in the environment but they are concentrated up the food chain. The small fish eat the plankton and the big fish eat the small fish and so on. We do not believe it makes sense to talk about an absorptive or self-purifying capacity in the environment for this sort of substance. We believe that, as far as possible, the pollution caused by black-list

substances should be reduced to zero. That is why we have proposed (and the Council has accepted) the notion that throughout the Community certain minimum emission norms should be applied to the discharge of these substances, at least up till the point we have managed to define environmental quality standards for such substances and, as already indicated, Member States can demonstrate to the Commission that these minimum environmental quality standards are being achieved and continuously maintained.

This is, if you like, a kind of essential insurance policy. When you do not quite know what you are dealing with, it makes sense to err on the side of caution. Nobody wants a repetition of Minimata.

There are other cases where we believe it is right to try to evolve a common policy towards industrial emissions. The Commission has, for example, made proposals involving, amongst other things, emission norms for the paper–pulp industry and for the titanium dioxide industry. In both cases, we recognize that the environmental circumstances will differ from one discharge to another and we have tried to build into both draft directives a degree of flexibility. Nevertheless, there are cases where the sheer quantity of pollution is important and where the necessary financial investments in pollution-abatement are very considerable. In the long term, we think it may serve to push for certain common standards based on the best available technology. In applying this philosophy, we must certainly differentiate between existing plants, where modification to meet new norms may be difficult and costly, and new installations which may reasonably be expected to observe higher standards from the very beginning.

3 The Quality of Life

In many ways, the 'quality of life' part of the E.E.C. Environment Programme is the most interesting but also the most difficult to realize. Pollution is something you can feel and see and smell. The quality of life—in whatever language you translate it—is a much more nebulous concept. But just because it is difficult to envisage exactly what is meant by 'efforts to improve the quality of life', this does not mean that the Community should flinch from making such efforts. After all the Community has shown itself capable of responding to challenges in the past and we can do so in the future. The entry of the United Kingdom into the Common Market might be considered one of the greatest challenges the Community is ever likely to face. (If it is a challenge, it is of course equally an opportunity.)

A. Environmental Impact Assessment.—Our first priority is to deal with problems of environmental impact as a whole, going beyond those which can be seen in terms of pollution. We need to be able to assess the overall impact of a proposed project, or indeed a policy, on the environment. Different planning procedures exist in different Member States. That is inevitable. Europe has grown up in many different ways and reflects different traditions of public administration. One can nevertheless see the usefulness of treating broadly similar problems in broadly similar ways within the different countries of the Community. If, for

example, two industries sought planning permission to install themselves in virtually identical circumstances in two different countries, or indeed in two different regions of the same country, and it turned out that in one case the application was accepted and in the other case it was refused, real questions would be raised—certainly within the framework of the Common Market—about the fairness of such a decision.

A procedure which has been operating for some years now in the United States is the system of Environmental Impact Assessment which was set up under the National Environmental Protection Act. This Act imposes a requirement on the authorities to prepare an Environmental Impact Assessment for all projects undertaken by Federal Agencies, or which involve Federal Agencies in terms of money or permits *etc.* Effectively, this means that a very substantial proportion of projects, whether private or public, are candidates for the E.I.A. procedure. The filing of a negative or unfavourable E.I.A. does not of itself mean that the project cannot be proceeded with. The document is, however, a public one and it may be used in any public enquiry and before the courts.

We are now considering within the framework of the E.E.C. what kind of E.I.A. procedure it might be appropriate to introduce for the Community, and how such a procedure can be adapted to the systems of planning and local government that exist in the different countries. One can think in terms of specific projects—for example, the siting, construction, and operation of a nuclear power station. Or we can think in terms of *policies* which ought to be evaluated in terms of their environmental impact and possibly modified as a consequence.

Take transport for example. Are more and bigger roads and more and bigger lorries really the best way, in environmental and resource terms, of moving people and goods from A to B? Is the balance between road and rail, private and public modes of transport, the correct one? Does the national transport policy in so far as this exists, fully take into account environmental considerations, starting of course with the most basic environmental consideration of all—the truly horrifying statistics for death and accidents in the Community?

Take agriculture. For twenty years we have witnessed a trend towards the steady intensification of agriculture in Europe. Behind this lie important balance-of-payments questions as well as questions of security. The United Kingdom, which imports as much as half its food, certainly is familiar with these increased pressures on the land.

Yet there may be important environmental consequences, not just in terms of soil fertility and soil structure, from the intensification of agriculture, but also in terms of land-use planning as a whole. The steady erosion of wilderness areas, the draining of wetlands, the replacement of pasture by arable—all these factors may have serious effects on wildlife and on visual amenity and thus, in a very real sense, for the quality of life of every citizen in Europe.

Take the question of the coastline. We all of us know the pressures on the coast. Industry wants to settle there, amongst other things because it wishes to discharge its waste into the sea. People want to build holiday homes there. Power stations are sited on the coast because they need plentiful supplies of

cooling water. Soon, there may be no coast left in Europe—only a clutter of random developments which will effectively deprive succeeding generations of a great natural heritage.

Where does the E.E.C. Environment Programme fit into all this? Well, the first thing to say is that where there are common E.E.C. policies, in fields which have an important impact on the environment, we can try to ensure that these policies adequately reflect the environmental viewpoint.

For example, if the Community is to achieve, as the Council has proposed, 160 GW of installed nuclear capacity by 1985, this should only be done after a thorough-going assessment of environmental factors and under firm environmental constraints, relating not only to the siting of plants but also to their operation and to the disposal of radioactive waste.

A major review is now taking place of the Common Agricultural Policy. Any new model C.A.P. should more fully reflect environmental concerns. We shall certainly work towards this. The Council has already adopted hill farming and forestry directives which can, in one sense, be seen as environmental measures.

We do not yet have a Common Transport Policy but we are moving in that direction. Here too there are important elements, such as E.E.C. tarification and road-user charges, which may in the end have an important place in a coherent environmental strategy designed to minimize the adverse impact of traffic while retaining the undoubted advantages of mobility.

B. Waste.—Within the overall framework of E.E.C. Energy and Resources Policy (though, here too, it is really too early to use such grand expressions), the fight against waste and mismanagement of resources is crucial and can, up to a point, be stimulated and co-ordinated from Brussels. The non-returnable plastic container, for example, poses problems for the environment as we all know—think of the Mediterranean beaches in the summer! And is this, I wonder, a sensible way of using petroleum feedstocks?

We are not overambitious in Brussels about what we can do under the 'quality of life' part of the environment programme. We recognize that the traditional Community instruments of regulations and directives will not be apt in all cases. We know that the complex fabric of society cannot easily be tinkered with.

C. Information and Education.—Above all, quite apart from specific proposals to do with planning, or the conservation of wildlife or the protection of the coastline (all areas where we are at the moment heavily engaged), the E.E.C. Environment Policy and the Environment Programme has to be seen as the catalyst of new concepts and new ideas. The world will only change if people want it to change. And people will only want it to change if they understand in the broadest sense what 'improving the environment and the quality of life' means. That is why one of our major activities at the moment lies in the field of what the French call 'sensibilization et formation' (when the French say 'sensible' the English say 'sensitive'). In fact we need to make people both more sensible

and more sensitive. This can be done at the level of the Consumer. It can also be done through the schools and other educational systems.

Probably the best hope for a decent environment lies with the next generation. We may hope that our children will not make the kind of mistakes we have made or tolerate the kind of damage which, in our quest for so-called 'prosperity', we have inflicted on our surroundings.

4 The International Aspect

The Environmental Policy and the Environment Programme does in fact represent an important new dimension for the E.E.C. People sometimes speak of creating Europe with a 'human face'. But this sounds too much like politicians' gimmickry. What the E.E.C. environment policy ultimately is all about is changing, or at least reorienting fundamentally, the direction Europe is taking. We have to remember that the Common Market was founded at a time when the quest for growth was the dominant economic concept. There is some evidence that the existence of the Common Market has been partly responsible for the unprecedented economic expansion that took place in Europe over the last 15 years. Today, we all look at growth in a different light. It is more elusive, harder to achieve—particularly in the present climate. And in any case we now recognize that increases in Gross National Product are not necessarily an accurate measure of welfare. There are many other factors to be taken into account and these are often difficult or impossible to quantify. We are aiming now, not at a 'no-growth' society but at a 'new-growth' society where expansion takes place in those sectors and services whose *overall* contribution to welfare, measured by the intangible as well as the tangible factors, is highest.

Internationally, that is to say looking beyond the boundaries of the E.E.C., this is a development of immense importance. Europe led the world into the Industrial Revolution and now, like the Grand Old Duke of York, it can lead the world out of it. One of the most interesting aspects of the environment work we are doing is the international aspect. As the Community has developed this new competence internally, so it has developed it externally. The Community as such has become party to international conventions dealing with environmental problems, such as the Paris Convention for the Prevention of Sea Pollution from Land-Based Sources. The Council has instructed the Commission to negotiate the participation of the Community in a convention which is now being prepared under the auspices of the United Nations Environment Programme for the Protection of the Mediterranean. The significance of Community involvement in such a Convention, which embraces European countries, including Greece and Turkey, the Arab States and Israel, must be obvious. Similarly, the problems of the pollution of the Rhine, which have been under study for decades, may prove easier to handle when the Community—as the Council has decided it in principle should—becomes a party to the Convention on the Prevention of the Chemical Pollution of the Rhine which is now being prepared. The fact that the Community has a Common Environment Policy and the fact that the Council has already adopted certain common instruments have

immeasurably strengthened our hand in dealing with third countries. An agreement has recently been signed providing for co-operation with the Swiss on environmental matters. We already have similar agreements with the United States and Canada. It is not without interest that Mr. Brezhnev, speaking in Warsaw last November, singled out the environment as one of the suitable subjects for an East–West Conference. (The Commission played a considerable part in drafting the environmental chapter of the Helsinki agreement which was signed a few months ago.)

5 Looking Ahead

Today we are in the process of drafting a new edition of the Community's Environment Programme. Already the Council has approved the guidelines: *e.g.* more attention to conservation measures and resource management in the broadest sense; more emphasis to be given to the war on waste; more emphasis on the relationship in this field with the developing countries. Now we are putting flesh on the bones and the Council will shortly have a detailed draft to consider. It will be an ambitious document. It will require the whole-hearted commitment of the Member States, governments and people, if the measures announced in this second programme are to be successfully enacted. Many people will tell us, no doubt, that we are over-ambitious, that we ought to wait until things look a little brighter on the economic scene before presenting proposals that will certainly call for the commitment by Member States and by the Community of substantial resources.

That is not our view. We believe that it is totally illusory to suppose that the 'energy crisis', the 'raw materials crisis', the 'resource crisis' (whatever you wish to call it) is a temporary phenomenon. It is not. The crisis did not happen because in November 1973 Israel went to war with the Arabs or *vice-versa*. The underlying causes were already there, rooted in the patterns of production and consumption which had over the last several decades been developed in the industrialized world.

It is only by changing these patterns that we can attack the fundamentals of the problem. That, in the end, is what the Environmental Policy of the E.E.C. is all about and that is why, so far from being delayed or watered down in the light of present economic difficulties, the E.E.C. Environment Policy and the Environment Programme as it is now evolving deserves still greater support in Britain—and indeed in all the countries of the Community.

III United States

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I am most honoured to have been included in this Symposium to discuss with the international representation here some of the environmental regulations in the United States. Since in some areas our regulations affect people in other countries, I think it is quite important that the rationale for our requirements be understood. As a member of the Environmental Protection Agency team, I have looked forward for some time to meeting people abroad to exchange concepts and ideas of mutual concern. I believe this symposium is being held because all of us, as interested parties, have been working diligently for a number of years to elevate parochial concerns about specific environmental problems to a higher state of universal awareness about man's relationship with his earth. We have heard stringent demands for maximum protection of human and environmental health in the one ear while a consumer outcry against rising costs and further constraints reached the other ear. We have all taken action of some kind and now we are interested in assessing how well we have done and whether in view of what has been done in other countries we should change our course. So we are gathered to exchange viewpoints, and I was indeed most interested in the views of the two previous speakers. Now I hope I can provide you with some insight into the way the U.S. is approaching the problem of regulating chemicals, with emphasis on pesticides. I think it will be easy to discern the usual difference between the deliberative British approach and the more impulsive American approach.

1 The Growth of Pesticide Use

To put this into proper perspective, I believe one should reflect both the time frame and the magnitude of the growth in use of pesticide chemicals. We are all aware that man has struggled throughout history to protect his health and his food supply against pests such as insects, weeds, rodents and diseases. In the past the only tools he could employ to control pest levels were ploughing, planting, burning, and watering schedules and primitive repellents such as smoke. Toward the turn of the century the first pesticides, in the form of sulphur- and arsenic-containing compounds, came into use. Not until World War II did synthetic chemical pesticides replace the earlier methods. Although the use of modern synthetic pesticidal chemicals has resulted in the more abundant, high quality food and fibre production necessary to help meet the needs of a growing world population, *and* are largely responsible for controlling certain insect-transmitted diseases such as typhus and yellow fever, there are

hazards associated with their use, such as toxic exposure and biomagnification. There are also disadvantages such as diminishing effectiveness against pesticide-resistant pests and non-selective harm to natural predators and helpful parasites.

As a result of these disadvantages and hazards, man has found it mandatory to establish some controls over both the use of the pesticides and the amount of residues of these materials allowed to enter the food and feed chain. Although we sometimes think of this type of regulation as being fairly recent, I found out recently that as early as 1450, Scotland enacted one of the first statutes governing product hazard. The Court apothecary then ruled that all persons were forbidden under the pain of treason to bring home poisons for any use by which Christian men or women could take harm.

2 History of Pesticide Regulation

Our first regulation in the U.S. goes back to April 1910 when the first Federal Insecticide Act was enacted. This Act required approval by a U.S. Department of Agriculture Board of insecticides that were to be used on food crops. The principal consideration was entomological tests for efficacy of the product in reducing blight, scale, or crop destruction. Products could be removed from the market if they were found to bear misleading or fraudulent claims. The main concern was that the consumer got what he paid for—that is, that the product did dispel the pest for which it was intended. Pesticide usage was only 50000 pounds per year.

In 1947, when the mass of economic poisons that had been developed during World War II began to cover the nation, the Congress enacted the Federal Insecticide, Fungicide, Rodenticide Act—known as the F.I.F.R.A. At that point, that nation was using about 800000 pounds of pesticides per year.

It may be noted from the title of this Act that it expanded greatly on the pests that were to be controlled. This Act made it mandatory for any pesticide, or 'economic poison'—as this Act termed it, to be registered if it was to be shipped in interstate commerce. Pesticides manufactured and used within any single state did not come under the purview of this Act. In considering Federal registration the examinations also expanded from a consideration only of efficacy to the broader considerations of both efficacy and human hazard. The label on the product became, for the first time, a directive for use with attendant limitations and hazard precautions.

The 1947 Act was the first major step in protecting the public against the potential adverse hazards of pesticide use. The second major step in protecting the consumer against possible harm from pesticidal use was taken in 1954 when the pesticide Amendment to the Federal Food, Drug, and Cosmetic Act was passed. This Amendment provided that a *tolerance*, or allowable residue level, be established for all pesticides to be used on food or feed crops. These tolerance levels are based on data supplied by the manufacturer, demonstrating *that* the product, when used as directed, will result in residues at or below the proposed tolerance level, and that that level is acceptable for human consumption. The determination of an acceptable residue level is based on extrapolation to man of

tests on experimental animals in conjunction with considerations of metabolic data, dietary intake, and probable exposures.

The F.I.F.R.A. served us well for many years. However, the problem with this Act was its all-or-nothing approach to regulation. We registered pesticides and supervised their labelling, but we could not control *use* in any way. We could ban a product outright or leave it entirely alone. As our knowledge about the long term and acute adverse effects of pesticide usage increased, public concern about the build-up of pesticides in the food chain and environment grew. This was only a part of a burgeoning awareness of the interdependence of prosperity, survival, and healthy environs which led Congress and the Administration to create the Environmental Protection Agency. Public fervour regarding environmental abuses reached a peak on 1 May 1970—a day which was termed 'Earth Day'. It was over five years ago, but it is still easy for me to recall the rallies, the clean-up campaigns, the tree plantings. The press and television trumpeted alarm, and called for cleaner cities and a cleaner planet. To many people, the terms 'Environment' and 'Ecology' took on new perspectives, and a new sense of urgency that day. Some called that initial outburst of environmentalism a fad. Clearly, it was, and still is, much more than that. Fads do not endure. Fads do not move the United States Congress, and there can be no doubt that Congress was moved. It was the will and the pressure of at least a large segment of the American people that made it happen. First, came the National Environmental Policy Act. Then the Clean Air Act. Next, the Federal Water Pollution Control Act. Other Acts concerning noise, ocean dumping, *etc.* followed. In the creation of E.P.A., the regulatory function over pesticides was taken from the U.S.D.A., and the tolerance setting function was taken from the Food and Drug Administration; both of these were placed in the newly formed E.P.A.

But coalescing functions into one Agency was not enough. Congress found that there was greater need to revise the existing law to strengthen the regulatory control on use and users of pesticides. As the population had grown with an accompanying need to expand crop yield, agricultural uses, including pest control on stored products, had vastly increased. The pest control arsenal afforded by modern technology had expanded to meet the demand. This same technology gave us certain warnings of adverse effects from these agents—their immediate toxicity, their persistence, their degradation products, their mobility, their accumulation in the food chain. These warnings caused alarm, and continue to do so, both in the scientific community and in the public at large. Regulatory requirements had become somewhat more stringent as the arsenal of products grew and the technology of analysis expanded, but the existing law, even through several amendments, did not seem to provide the mechanism for making and implementing the prudent judgements necessary to avoid irremediable damage to the environment in which we exist. Thus, it was that the F.I.F.R.A. was entirely amended in 1972 by the Federal Environmental Pesticide Control Act, known as the F.E.P.C.A. At this point, consumption of pesticides across the nation had just exceeded one billion pounds per year.

The House Agriculture Committee report summarized quite well E.P.A.'s new responsibilities: (I quote) 'The Committee has found the greatest need for revision of existing laws to be in the area of strengthening regularity control on the use and users of pesticides and speeding up procedures for barring pesticides found to be undesirable. . . .'

The Laws passed since 1970 are by no means the first federal effort to deal with environmental problems. But these laws do represent the sense of urgency, the sense of determination, and the sense of frustration of society's failure to respond to earlier efforts to clean up pollution which was felt throughout the nation. These factors resulted in the incorporation of many highly rigid, extremely stringent statutory requirements into the new laws: automobiles must achieve a 90% reduction in their current emission levels; all industries must install best practicable air control technology by 1977; all municipalities must install secondary water treatment facilities by 1977. The laws require a shake-up in our way of going about our business—that's what they were intended to do.

3 Purposes of the Newest Pesticide Law

Although one of the most persistent facts of life (next to taxes) is change, it seems to be one part of human nature to resist change. Now, because of this resistance, E.P.A. is often considered to be a bad agent for administering the sweeping changes which have been mandated by the Congress. The Act itself has come under vast amount of criticism as being excessively stringent, both to manufacturers and to users. So let's consider the purposes of various parts of this new law and how we are administering it.

In beginning these considerations, three points should be kept in mind. The first is the scope of the law. In the Act a pesticide is defined as '. . . any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant'. That means that we are not only regulating agriculture chemicals but we are regulating substances used to control organisms extending from the minute bacteria in Hygienic Institutions to the large mammalian predators found on open rangeland. The second point is the statutory nature of our regulations. The law is a simply worded act setting forth broad mandates, and the regulations are considered equally as statutory with penalties for violation. The third point is perhaps fundamentally the most important as far as administration of the law. This is a matter of attitude: *i.e.* the use of pesticides demands a different type of control from those used for any other environmental controls. For example, when one considers control of air emission, water effluent, solid waste disposal, noise emission, or radiation, the general practice is to decree some type of elimination or drastic reduction; it is 'do *Not* do something'. On the other hand, in the environmental control of pesticides, we cannot decree overall elimination or drastic reduction. The material must intentionally be released into the environment if it is to achieve its beneficial effects. Once so released, its later movement and effects are extremely difficult to control. This is considerably different from most situations in which

contaminants or pollutants are released because they are by-products of a process and have no residual economic value or are merely being thrown away.

4 The Role of Registration

This circumstance, therefore, makes uniquely important the role of registration in pesticidal control. For it is evident that control of the amount of these chemicals reaching man and his environment may be accomplished only through two mechanisms: first, by reduced use of pesticides in general. This can be accomplished only with full regard for cost:yield relations and/or through development of new technologies of pest management. The second mechanism consists of proper use directions and close control to assure use consistent with such directions in the application of present pesticides.

In order to obtain full benefits we cannot reduce the use of pesticides until new technologies are developed, so we must go to the second mechanism, which is accomplished by registration.

Section 3 of our Act, which covers registration and classification of pesticides, therefore, becomes one of the major tools in this control. First, Congress stated that all pesticides must be registered. This means both intrastate and interstate. This is a change from the old law. However, Congress tried to recognize the need for careful judgment in setting the requirements for registration of pesticides, by stating in the law—that in performing its function and in its normal and recognized method of application—the pesticide shall not create unreasonable adverse effects on the environment (and here is the important phrase) taking into account the economic, social and environmental costs and benefits of its use. The imposition of this cost/benefit perspective to pesticide regulation complicates an already difficult problem. What it means to us, however, is that our decisions must be reached by using the 'rule of reason' as a component part of our guidelines, in other words, how can a pesticide be used as a useful tool and be given proper directions for use so that it does not create problems and still does the job it was intended to do. We will continually be called upon to consider carefully the trade-offs between food production, food contamination, human health, disease control, environmental safety, worker safety, and pest elimination. The choice of pesticides and their regulation will, therefore, be based upon our best evaluation of benefit to hazard—not on the basis of toxicity of compounds alone.

5 The Role of Classification

The determination as to whether the *use function* of the pesticide will create any unreasonable adverse effects is arrived at through the thorough examination of data submitted by the registrant in accordance with our registration guidelines. These data, together with information supplied to establish a tolerance—if the pesticide is to be used on a food or feed—provide the basis for ascertaining not only its efficacy and toxicity but its possible genetic effects, its effects on fish and wildlife, its persistence, its translocation in the soil, the likelihood of biomagnification, and its degradation products.

The determination of whether the *application* of the pesticide will create unreasonable adverse effects is arrived at through the Classification Process, in which the product is classified as either *general* or *restricted* use. Simply stated, the Act specifies that *general* products will be those for which label directions and precautions are adequate to protect the general public, and the products may, therefore, be used by anyone, whereas *restricted* products will be those for which additional regulatory controls are needed and the use of the product is *restricted* to competent applicators. Although the classification process is one of the most significant innovations in our history of pesticide legislation, it is also one of the most controversial.

In practice, we intend to have toxic criteria by which we screen those pesticides which might be presumed to exhibit *potentially* unreasonable risk. We will then review the individual product's use history, packaging, formulation, label, and other relevant data to properly evaluate the exposure risk. These assessments must take into account such factors as how the product is to be applied, and how effective the label is in transmitting necessary precautionary information to the user. The 'presumption' that a pesticide should fall into the restricted category as defined by the initial screening step is thus 'rebuttable'. Thus, a pesticide product identified as a candidate for restriction may very well be classified as general if individual label and use history review indicates that the hazard is sufficiently minimized. Conversely, a product that is a candidate for general use may be classified as restricted on the basis of, for example, accident history. The final determination as to the likelihood and unreasonableness of adverse effects thus clearly calls for careful exercise of judgment, and involves special consideration of exposure.

6 Public Participation in Regulation

Since I have just indicated the types of reviews required to determine whether a pesticide is registrable, I might digress to outline the participatory programme followed to establish the requirements. In general, regulatory Acts prescribe in each section broad goals to be achieved. The Acts also set timetables by which regulations for each section should become effective. These regulations delineate in some depth the procedures, processes, or requirements that must be met in order to fulfil the goals set by the act. Because regulatory Acts impinge on some regulatee and also have effects on other pertinent or interested parties, the regulations are developed with fairly constant liaison with and participation by the regulatees and other parties.

In the case of the revised F.I.F.R.A., the Act provided two years after enactment for the promulgation of effective regulations for Section 3 registration and classification. Shortly after enactment a first draft of the regulations was prepared and submitted to registrants, commercial applicators, agricultural organizations, chemical specialty manufacturers, environmentalists and others, for comment. After two or three months of receiving comments, the draft was reworked to accommodate comments that could be included while still maintaining legality of the act. The second draft was resubmitted to interested parties and

an informal meeting was announced to obtain additional comments while permitting parties to voice opinions publicly. Again, the draft was reworked, passed through channels within E.P.A. to assure compatibility with other programmes, and then published as *proposed* regulations in the 'Federal Register', a government document published daily and transmitted throughout the country to inform the public of government actions. Again, a time frame for receipt of comments was allowed, after which the agency again considered the comments and worked toward final regulations. The final draft was submitted to the Administrator together with a lengthy memorandum outlining the issues which had been raised together with the pros and cons of the issues and a rationale for the path selected by the Agency. The final decision on the regulations is that of the Administrator. Thus he may agree with the regulations as written or have parts revised to a position more nearly that of some parties. Upon his signature the regulations are again published in the 'Federal Register' and become effective as designated therein. Recourse against the regulations after that is only through the Courts.

Because we have been wrestling with an unusually large number of issues that these regulatory actions raised, our Section 3 regulations were not issued until early August of this year, almost ten months behind schedule.

7 Applicator Certification

Registration and classification are, of course, a critical keystone to the foundation of F.I.F.R.A. as amended. No less important, however, is the mechanism which the Congress chose to *complement* the classification scheme. Restricted pesticides are of no value unless there are competent individuals to apply them, and the concept of applicator certification is one of the most crucial of the amended Act.

The classification and certification provisions of the law were introduced primarily because it was believed that labelling is not sufficient to prevent the misuse of certain pesticides. Some pesticides were being applied at many times the label concentrations to combat insect resistance. Applicators were being injured by acutely toxic pesticides because they did not use the prescribed safety measures or misunderstood their proper use. Spray tanks which had been filled with pesticides were washed and indiscriminately drained into streams or city sewers. The environment was being unknowingly and unnecessarily exposed to toxic and persistent chemicals. Label regulation simply was not providing the necessary control over pesticides to prevent their improper use.

Congress realized, however, that while labelling directions may not suffice for certain pesticides, even highly toxic pesticides could be used if there were a means to guarantee that the pesticide would be used in a proper manner not entirely conveyable through label instructions. The means adopted by Congress is the certified applicator provision. Section 4 of the Act provides that the Administrator shall set the standards for certifying applicators, and that the States shall accomplish the actual certification in accordance with plans approved by E.P.A. The Agency published final standards for certification on 9 October

1974, and final State plan regulations on 12 March 1975. These regulations specify the basic types of knowledge which the Agency believes are indicators of an applicator's competence to apply restricted pesticides, and the general qualities of State plans which will assure that all applicators certified meet the required standards. As specified in the Act, separate standards for private and commercial applicators have been provided.

We do not envisage farmers having to pass an elaborate academically oriented exam to achieve certification. The purpose of applicator certification is to ensure that users of restricted pesticides have sufficient knowledge to prevent acute injury to human health and environmental effects in or near treatment areas. Toward this end, the standards of competence stress 'practical knowledge', *i.e.*, possession of pertinent facts and the ability to use them in dealing with problems and situations likely to be encountered in an applicator's normal work.

The State plan regulations, too, stress practical implementation. We realize that there is a great diversity among the States in terms of types of pesticides used, numbers of potential certified applicators, agricultural density *etc.* Thus, in developing the proposed standards, we have attempted to deal with the present wide range of capabilities and programmes in the different States. Some States have been exercising fairly tight control in these areas. Other States are just beginning to establish licensing programmes. The State plan regulations, then, provide a State with much flexibility in meeting its own certification needs.

Again, the Section 4 regulations were developed with constant solicitation of input especially from the States and the Extension Service, which will have the primary lead in assisting the States to establish training programmes where desired to facilitate the certification process.

As we learn more about the effects of pesticides, techniques and practices which were acceptable in the past frequently may be judged hazardous by today's standards. The whole applicator certification programme is designed to ensure that applicators' knowledge is commensurate with the state of the art of pesticide handling and application. Certification also offers some degree of assurance that applicators have the knowledge and operational competences properly to use and handle the new types of pesticides which are being introduced and will continue to be introduced in the years ahead.

8 Control of Experimental Uses

I have spent some time on the regulatory Sections concerned with registration, classification, and applicator certification as they are of major importance. Now I should like to touch briefly upon a few other sections of our Act which are of importance, particularly to industry, The first is Section 5 which formalizes the granting of Experimental Use Permits to prospective registrants for the purpose of gathering field data upon which to base a registration. The intent here is to permit some field use of newer compounds or new uses about which little is known, but keeping such use in bounds until registration is attained. This is quite similar to the procedure for 'Trial Clearances' in the United Kingdom.

Proposed regulations to implement this Section were published in March 1974,

but final regulations were not signed by the Administrator, and published in the Federal Register until April 1975. Most of the 13 month interim period was spent discussing the intent and ramifications of the rulemaking with representatives of the Department of Agriculture, Experimental Stations, Land Grant Universities, and other research-oriented organizations. The concern here seemed to focus on the point that E.P.A. was being too restrictive and would, therefore, thwart much needed pesticidal research. It is also possible that there was some reaction to the plain fact that some of these other government agencies were no longer exempt from regulatory controls. Our regulations and the supporting guidelines now define specific examples of situations for field testing which do *not* require a permit, such as less than a total of ten acres, or one acre of surface area for aquatic herbicides.

9 The Use of Public Hearings

I mentioned earlier how we obtain participation in the development of regulations. Through the use of Section 6 of the Act which is called the Rules of Practice, there is provision for public participation in decision making. In trying to determine 'unreasonable adverse effects on the environment', there is a risk/benefit balancing requirement which is complex and often controversial. There are no magic formulas in the risk/benefit balancing act. It is no small task to weigh the known and trusted benefits of a widely used insecticide, for instance, against the probable long-range human or ecological health effects.

How do you measure the potential long term risk to human health against the proven benefit in agricultural production of a pesticide chemical? The answers are never easy. Because they are so complex, the Agency desires to make decisions of this nature based on the fullest possible public record. This is done through legal hearings. The hearing procedure may be initiated by the Administrator in order to determine whether a pesticide chemical should be cancelled or reclassified, or it may be initiated by the registrants if the Agency takes cancellation or reclassification action. Hearings were held in the case of DDT, are currently being held in the case of mercury, mirex, and aldrin/dieldrin, and will be held in the case of chlordance and heptachlor. Comments have been solicited regarding many other pesticide chemicals which have suspected adverse effects. We believe that since it is the public health and welfare at stake in the major pesticide-related decisions of the Agency, the public should have optimum opportunity to participate in the decision-making process.

I will touch upon Section 7 of the Act only because it may involve some manufacturers at this symposium. This section requires registration of establishments, *i.e.*, a number is given to any unit in which a pesticide is to be manufactured, formulated, or packaged. This number must appear on the packages emanating from the establishment so that the source of an item may be traced should this be necessary. These establishment numbers are required even for non-U.S. plants which may have registrations for exporting into the U.S.

10 State Controls

The final Section of interest here is 24(c) with related Section 5(f). As was

previously mentioned, the old F.I.F.R.A. only controlled, through Federal Registration, those products in Interstate Commerce. A State could register, without Federal Control, products manufactured and used solely within the State. Now, under Section 3, all pesticide products must be Federally registered except that a State may be certified under Section 24(c) to register some products for 'Special Local Need' and under 5(f) to issue experimental use permits for such prospective local registrations. However, this means that the States must have a proper registration mechanism, including the necessary scientific personnel, if they want to provide State registrations. This is mandatory because Congress has said that once State registered, the product shall be considered as having been registered under Section 3 in all respects except for use only in the particular State.

This whole concept is a change. As a result, a few State regulatory officials have found difficulty in accepting the superimposition of Federal Control. Generally, these are States which have had fairly close registration control in the past. However, other States have not in the past provided careful examination of the pesticides being given State registrations. Thus, broad regulatory authority of registration at the federal level will provide consistency and uniformity.

11 The Importance of Labels

Now, one last item about the Act. The end product of pesticide registration and classification is the label. Labels, of course, have always been of prime importance. Even children in elementary school know that a product label tells you what you've got and how you're supposed to use it. The necessity to maintain clear, concise labels which provide proper directions and precautions has never been disputed. But with all the emphasis on proper labelling which was placed in the past, there was never any legal compulsion for a *user* to follow a registered label until the F.I.F.R.A. amendments were passed. Now, Section 12 of the new Act, specifies among other things, that it is an unlawful act to 'use any registered pesticide in a manner inconsistent with its labelling . . .' This is one of the most crucial portions of the amended Act, and one which is the source of much controversy today.

The label, indeed, is now not simply informational in nature; it is a regulatory tool to assure proper use of pesticides. Civil and criminal penalties may be imposed for user violations just as they can be for manufacturer misbranding.

The reasons Section 12 was written into the Act are obvious. The best label in the world does the environment or non-target life little good if the product is wantonly misused. I won't dwell on this other than to state that many of our labels have shortcomings. We are working hard to correct these areas during the reregistration process.

We have a tremendous job to do between the effective date of the regulations and October 1976. The task set out in the amended F.I.F.R.A. of registering, reregistering, and classifying all pesticide products used in this country is substantial. There are currently 32500 registered products which must be classified and reregistered, and approximately 10000 State products to be

registered for the first time. This is added to our normal annual workload of approximately 15000 actions, of which 100 are completely new pesticide or major new uses. We must accomplish this task with minimal disruption to agriculture and industry, while at the same time fulfilling our mandate to protect man and the environment.

12 Accomplishing Legislation

I have now covered what I believe to be the essence of the 1972 Act. We in E.P.A. most firmly believe that the statutes we have been commissioned by Congress to administer can bring about very productive and beneficial changes to the environment if all concerned parties will take on the task with reason and plain old common sense. We in the Pesticides Office do not like to think of ourselves as regulator and the rest of the world as regulatee. We believe that fulfilling the statutes can be accomplished only through a joint effort shared by industry, the agricultural community, environmentalists, State governments, the consumer, and the Federal Government. We are also aware that our actions are only part of a larger picture. The public must learn that the environment has to be considered as an entity and in its totality. The environment does require management and this necessitates public support. Attainment of public support is possible if the public can learn why and how environmental control decisions directly and indirectly affect food supplies, employment, and financial stability as well as health, safety, housing, recreation, transportation.

Charles Dickens wrote, 'It was the best of times, it was the worst of times'. In the hardships of employee layoffs, the difficulties of inflation and recession, the squeeze of energy shortages, and the conflicts which require change in our environmental goals—these seem to be the worst of times. But from a longer-term view, we can begin to see the public is making a basic and essential transition, shifting from attitudes of unlimited material growth, consumption, and environmental abuse toward a way of life that seeks to balance man's activities with our natural resources. Only by finding such balance is there hope for the future. Despite the full cost and burdens of seeking that balance, we are moving ahead. In this sense, these are the best of times.

IV An Industry View

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Everyone, I am sure, wishes to avoid causing adverse effects on our environment. As members of the community, responsible members of the chemical industry must and do take all reasonably practical measures to avoid creating unacceptable effects on public health and the environment generally. There is no fundamental disagreement on this broad objective between industry and government. What needs specifically to be achieved, however, and the means of achievement, are matters of considerable debate and discussion. The subject is one in rapid evolution and here I would like to discuss some of the aspects which, in my experience, have caused considerable difficulty in the development of the subject.

My own involvement in the subject has been in the field of pesticides. Experiences with pesticides, in my view, have contributed a great deal to the development of approaches to the more general subject and seem, to some extent, to be contributing to developments now taking place in what I would like to term non-regulated chemicals. I believe it is useful, therefore, to look at some of the issues and experiences in the pesticide area as a background to some of the current thinking in the area of other chemical products.

We should, of course, be wary of taking comparisons too far. From the viewpoint of public health and environmental effects, pesticides are a rather special case. Firstly, pesticide chemicals are purposely developed for specific biological activity, and many are very active indeed. A typical application rate for a modern pesticide is only about 100 mg of active material per square metre of land. Secondly, in that they are applied uniformly over the land, they are, in effect, purposely applied to a large area of our biotic environment. Thirdly, if pesticide residues remain they might be ingested by anyone eating food from treated crops. In fact, the amounts are usually extremely small, and analytical surveys, where they have been carried out, have shown how small these residues are in practice.

Today all developed countries and many developing countries have established legal systems of control over pesticide use. These are nearly all based on the central principle that a product, and usually its recommendations for use, must be approved by a competent authority in the country concerned. Approval rests on the authority being able to satisfy itself that when used as directed the product will provide a useful contribution to the country's agriculture without giving rise to unacceptable secondary effects in the fields of public health and environmental conservation.

It is in the field of judging possible effects on public health and the environment

where such extensive controversy has arisen. We all know that in the public mind there are many aspects of the case where, in effect, proof of absence of residues or of effect is demanded. In so many of these cases it is not, of course, possible. Firstly as an example, I would like to consider residues of pesticides in agricultural crops, these are traces of pesticides or degradation products left in crops after the pesticide has exerted its intended effect. Some 20 years ago, techniques for the analytical examination of these residues were at a comparatively primitive stage. Residues in crops below 0.1 p.p.m. were not capable of determination, and in some countries regulations then in force regarded residue levels below this point as zero. But then the principles of g.l.c. were introduced and straightaway it was often possible to estimate levels of 0.01, even 0.005 p.p.m. It is perhaps worth pointing out that the reproducibility of these tiny figures is often not very good. To those of us brought up as classical analysts the concept of 100% errors is not easy to live with. A lot of time has been wasted in arguing over the difference in the toxicological significance of 0.01 and 0.02 p.p.m. when analytically it is seldom possible to decide which of these two figures is right. At any rate, the trend is always to lower figures as techniques advance. I was intrigued recently to contemplate the significance of data for levels of a chlorinated hydrocarbon insecticide in air expressed as a few parts in 10^{13}; very small, perhaps, but a finite figure. What I am saying is that it is not possible, ever, to demonstrate that something is absent. This has no meaning and even though levels may be very low indeed, in principle they are always finite.

The other negative we have to contend with is non-toxic. Clearly in isolation, this is a meaningless term; we must specify the dose where toxic effects could occur. But even this may not be easy. Some toxicological effects depend for their estimation on the statistical significance of the difference between the incidence of the effect in exposed and treated animals, and the critic can always say that if you had taken more animals you could have got effects at a lower dosage. Some have argued, theoretically, that in such cases as these there is no level one can estimate experimentally that will not give an effect in a more sensitive study. Yet I am sure most of us feel that this is an unacceptable basis on which to make decisions. Again, some compounds produce changes in measured parameters which seem to have no evident relation to health. Plasma cholinesterase levels are typical of this kind of effect. Yet many authorities feel that a demonstrable lowering of plasma cholinesterase is a toxicological effect and not therefore acceptable. I, as a non-toxicologist, cannot say whether they are right or wrong but such instances prompt one to ask what really is health. Speaking at the recent Munich Symposium on Ecological and Toxicological effects of chlorinated hydrocarbons, van Raalte described health as a state where any parameter of physical or relevant laboratory examination lies within the normal range of inter- and intra-individual fluctuations. Thus if I have a serious accident and lose a lot of blood my blood volume has been significantly reduced and my health has been affected. If, on the other hand, I cut myself shaving I lose very little blood and my health is not affected at all. This is a simple concept but of immense importance because it gives us something we

badly need—some concept of the insignificant. We no longer, conceptually, have to prove zero effect. We have to show whether or not the observed effects are of toxicological, or in the case of man, medical significance. Of course, this requires expert judgement but it does make provision for the application of expert judgement and this is what we seek. A great advance is being made in the evolution of regulatory thinking as this concept becomes more widely accepted. It is very far, however, from being universally accepted and still inadmissible as an approach to appraising data in some important countries.

Now we turn to consideration of the environment itself. Here definition is extremely important; the word means different things to different people. Dr. Egan in the recent Jubilee Memorial Lecture discussed this point at some length. As he says environment merely means surroundings; today we mostly use the word in the sense of natural surroundings, taking into account that much of man's everyday life is based on industry, including industrialized farming. In this country, again the Royal Commission on Environmental Pollution has concentrated its attention on what it has termed the external environment—the general outdoor as opposed to local indoor environments. I would like to confine my own consideration to this concept, and mainly to the biotic sector of the outdoor environment.

The problem, then, is what do we consider an adverse effect on the environment? We certainly cannot require zero effect. Indeed many activities and products in my own field are specifically designed to produce effects. We may wish to kill a noxious weed species or the vector of a tropical disease. This is a direct attempt to reduce the population of a species in a locality to a level where it is no longer a menace to man although I can think of no instances where pesticide programmes have been so successful that the undesired species has been eliminated. The pressure is always there for it to return once its ecological niche becomes inhabitable once more.

By and large, we in western Europe live in an environment which is extensively managed by man for his benefit. Few of us are likely to have had much experience of a totally unmanaged environment unless we have been overseas.

Nevertheless we all have a strong feel for what we believe is an unacceptable environmental effect. I am sure none of us would be happy to see a practice which threatened a desirable species. Indeed I believe few of us would wish to see any species seriously damaged unless it posed a direct threat to man. Earlier, I spoke of a country's objectives in environmental conservation. I believe that most countries that place importance on the ecological aspects of their environment have as their objective to minimize interference with ecological systems. Certainly this is the case as far as desired species are concerned, and in many instances—wisely I believe—this is extended to species to which most of us are comparatively indifferent. But here I would like to revert to the medical/toxicological definition of health and draw what I think is a parallel. I do not believe that the death of a comparatively small number of members of any abundant species should be regarded as a serious environmental impact any more than loss of blood from a small scratch should be regarded as impairment of health.

It is interference with the species that should concern us rather than minor effects which do not threaten the species as such.

In this series of examples of where, in my own sphere, much thought has gone into defining objectives, we have, I believe come a long way along the road of not having to be in the position of trying to prove the negative. Nevertheless, the extent to which work is now required for us in industry to satisfy our own internal standards and at the same time to meet those of regulatory authorities has increased enormously. There are three important consequences. Firstly, cost: this varies enormously, of course, with different pesticide products but it is not unusual for at least 50 man-years of effort to be spent on generating the data a manufacturer needs to satisfy himself that the product is in a sound enough position for registrations to be requested. In this estimate I have said nothing of the manpower required by the registration authorities, in what may often be a large number of countries, to satisfy themselves as well. Products with small market prospects or markets confined to a limited geographical area just cannot stand these costs.

Secondly, old pesticides, still very important in agriculture, are continually under study although often enjoying widespread registrations and a long history of safe use. All these products run some risk of failure to measure up to some new criterion as the subject develops, particularly in the field of toxicology. Retrospective appraisal is perhaps an inevitable consequence of the evolutionary nature of the subject, but a price has to be paid in terms of the risk of losing valuable inputs to agriculture.

Thirdly, time is needed to develop data and in any development project a time limitation represents extra risk. It is very unlikely, taking into account that programmes to develop these data must be integrated with the general development programme for the product, that they can be completed in less than four years—often considerably longer before the product has achieved a reasonable registration status.

As well as acting as a constraint on industrial development these requirements may also have the effect of greatly delaying the availability of new products. Of course, it is practically impossible to quantify these effects but I was interested to read a recent article by Professor Alfred Burger on the subject of another important branch of regulated products—pharmaceuticals. The currently long lead times now needed in the U.S.A. for developing data mean a very high price to society, in his view, but the irony of the case is, he says, that the introduction of products considered by the manufacturer to be safer than older products is being greatly delayed in the interests of obtaining sufficient data on safety: an interesting illustration of a case of the application of value judgements.

Thus three important constraints arise from the need to establish acceptance of a product. It is not to say that industry does not see the need for the work to be done but it is to say that a high price has to be paid, and if requirements are increased the price is increased accordingly, be it in terms of money, manpower or denial of new developments.

What position does industry take on these matters? Of course, I cannot speak

for industry as such, but only give my own views although in my experience they do not differ greatly from many others working in my particular field. Firstly, as I said at the outset, industry like any other organization of people is a member of the community. Its aim is and must be to supply what society needs, and society does not want its environment made ugly or dangerous. At the same time it demands an enormous range of benefits made possible only by industrial activity. It needs to be fed, to be protected against epidemics, housed, transported, among many other things—the list is a long one.

The statement issued last year by the International Chamber of Commerce puts the point particularly well when it says 'Industry recognizes that in the environmental context, as in others, it must operate as an integral and responsible member of the Community. It can only prosper to the common benefit if its activities are acceptable. Industry, as any other community member, will be best able to contribute to the community in an atmosphere of understanding and encouragement'. Consequently, a balance has to be struck and we must avoid the trap of a hopeless pursuit of total absolute safety—other more serious dangers will arise if we do. We are in the field of value judgements and the value of the activity or product must be taken into account in assessing the significance of negative values. It is, I believe, in the evolution of our ability to make wise value judgements that society's success or failure in this field will be determined.

Having looked at what I regard as some of the more important features of pesticides in relation to health and environment, I would like now to discuss certain features, as I see them, in the field of pesticide legislation. I would like at this point to say that I am using legislation in the widest sense of the term. In a number of countries, legislative protection of public health and environment is largely *enabling* legislation. What really determines specific outcomes is the ensuing regulations arising from the expert appraisal of data relating to specific cases.

It has been said that legislation is essentially an approach to the handling of conflict. We may argue about this, but where, one asks, is the conflict in this case? In terms of broad objectives most certainly I would not see it as being between industry and governments. Perhaps, some may say, it is between industry and conservationists but again in terms of objectives I do not think so. The basic conflict lies really in the means of achieving the objective, and this derives from the nature of the subject itself. Where there is conflict it is a conflict of the positive and negative values of the product or activity in question, and a conflict over how far towards zero it is necessary to go.

Dr. van Tiel of the Netherlands Plant Protection Service, last year, speaking specifically of pesticide legislation expressed this point by saying that one basic aim common to all pesticide legislation is to provide for a system of legal measures in order to enable responsible authorities to regulate the use of pesticides in such a manner that the need for effective pest control is adequately balanced against the necessity of avoiding side-effects in man, the biotic and abiotic environment and food. In general the two main criteria are: (*a*) efficacy in the use intended; (*b*) the risk of undesirable side-effects. The concept of

balancing positive and negative values is embodied in these features and the scene is set for the necessary value judgements to be made. The law as such in most countries does not direct the thinking of the scientists concerned in detail nor, of course, can it. I do not believe it will ever be more than a serious impediment to arriving at sound value judgements if attempts are made to prescribe rigidly how these ought to be made and on what basis. This is because, as I have already said, there are no absolute values—only relative values. I believe that the central difficulty arising from some extremist views on environmental matters is that they demand absolutes when all competent opinion recognizes that absolutes are inapplicable.

But we have the question of guidelines. Several countries and some international organizations have written guidelines to assist industry in developing and presenting their data. They have a valuable function in that they tend to ensure that registration cases from different organizations are of comparable scope and thoroughness. Indeed, in some cases these guidelines have only been drafted after prolonged and careful consultation with industry, but by no means is this always the case. D. S. Papworth of the U.K. Ministry of Agriculture, Fisheries and Food speaking earlier this year at the Fourth British Pest Control Conference stressed the importance of Government–Industry dialogue in this area. He said 'There should be a stronger requirement for a dialogue between scientists in industry, as in the P.S.P.S. (the U.K. Pesticides Notification system), to clarify the real justification for requesting on every occasion all the wide-ranging tests now mandatory in some countries'.

There are, however, two points I think ought to be guarded against with guidelines. The first is that no matter what they are called they tend to become much more than guidelines. They tend to become a standard that can, if unwisely handled, imprison both industry and government and reduce their ability to design experimental programmes and appraise data with the freedom that an evolving subject requires. Whilst several authorities recognize this potential constraint others have tried to reduce guidelines to the status of a mere checklist, Such an approach, whilst perhaps administratively attractive provides a serious constraint on those who are trying to develop comprehensive and sound cases.

The second point about guidelines is that they have to cover an enormous range of potential cases so that inevitably they tend to be very long and to incorporate extra requirements to cover all eventualities. Here again this danger has often been recognized, but not by any means always, and where it is vital to avoid work that is scientifically of low priority they can result in valuable scientific resources being deployed on work which adds little of value to the subject.

The third feature arising from the current legislative scene I would like to comment upon is the influence that decisions made by technically advanced countries have on decisions by developing countries. These latter often lack enough local expertise to have confidence in their own ability to appraise data and are strongly influenced by conclusions from more advanced countries, even when circumstances may be very different. In this way mistaken value judgements

can be made in a developing country and valuable aids to agriculture and public health may be denied without valid reason. We are all aware of some of the difficulties which have arisen from withdrawal of disease vector control products as a result of such judgements. It would seem of especial importance, when thinking of the world scene, that every effort is taken to avoid outcomes of this sort.

So far I have been talking mainly about pesticides. In many countries somewhat comparable systems of control have been established to cover veterinary, pharmaceutical, food additive, and certain household products. There are differences, of course. As you will readily appreciate a pharmaceutical product taken by a patient to improve his health needs to be assessed in somewhat different terms, toxicologically, from a pesticide residue ingested as a consequence of pesticide use. Nevertheless, in this whole field of regulated chemical products the basic position in most countries is comparable in that legislation requires an authority to appraise the available data and to satsify itself that the product is compatible with the maintenance of public health and environmental conservation. Extensive, formalized, and well-understood legal structures have been established, but here too, there is considerable scope for improvement of appraisal procedures; it is vital that both industry and governments do all in their power to promote the evolution of the subject to a point where the wisest possible value judgements can be made.

There is little doubt in my mind that the greatest advances towards sound systems of appraisal have been made in countries where there is good contact between Government and Industry. It is unfortunate that in some countries the very legislative systems themselves can seriously limit the extent to which exchanges of views between these two bodies are permissible and greatly reduce thereby the effectiveness of communication.

To follow Papworth's point, I believe it is extremely important that a system be developed whereby the immense experience developed by industry in this area could fully be utilized by Governments, on a mutually agreeable basis.

I would like now to turn to the very large field of non-regulated chemical products and the considerable legislative developments now occurring. The specific aspects of this field lie outside my own experience but I find this a particularly interesting subject in that new legislative structures are still in the process of being built.

I would like, therefore, to make some rather general observations in the light of experience already gained in the field of regulated products, although we must clearly be wary of making too many close comparisons.

As many will know, consideration in many quarters both nationally and internationally is being given to introducing more rigid control systems for a very large range of chemical products not currently falling under specific control systems already established. At the present time the ill-effects that these products might produce if irresponsibly used are covered by more general legislation on protection of health and safety and on environmental conservation. Both Industry and Governments, often in close collaboration, have by their existing

systems of control, done an enormous amount of work to avoid serious effects on health and environment. We are not fighting any longer against some of the old environmental problems that once plagued society. In the R.I.C. history of the modern British Chemical Industry can be seen a record of the first alkali act which came into effect in 1864 and required 95% absorption of by-product hydrochloric acid from alkali manufacturers. We have come a long way since that time when legislative objectives seem in our terms to have been so modest. I am merely using this to show that the subject is not a new one. The field has been steadily evolving for many years and has already reached a considerable degree of sophistication particularly as regards health and effluent control. Great successes have been achieved. My medical colleagues tell me that the pattern of disease in our population over the last few decades has not changed in such a way as to support the fear that an epidemic of chemical injury to human health is either present or developing. Nor do I believe that there is evidence of any widespread degeneration of the environment caused by chemical contamination. I do not believe that there are valid scientific reasons for undertaking more than an orderly extension of the knowledge already available.

Coming back to experiences in the regulated field, it would seem essential to avoid, wherever possible, the constraints that rigid regulatory systems inevitably bring unless there is a very well-established argument to the contrary. Obviously in such a vast field the first danger that comes to mind is that of overloading facilities required for generating data, particularly at a time when existing facilities are already heavily committed. The creation of new facilities of course, takes time, money, and above all trained specialized professional scientists, who, of course, are a valuable and scarce commodity in this field. It must be clear to all of us that insistence on too rapid an extension of data could not only threaten existing research facilities, it could result in serious disruption of progress in the chemical industry. In an industry so dependent on development and innovation, any constraint on the introduction of new products could result in the most far-reaching consequences not only in the chemical industry but also for its customers.

Perhaps then, the first step would be for Governments to appraise the order of magnitude of any new requirements they believe should be introduced into this field and carefully assess what effort would be implied by such introduction. Once more objectives need, to my mind, to be particularly closely defined, bearing in mind the capacity of the total community to achieve them. In fact, the problem amounts to how best can available resources be applied.

With such an approach it would be possible for industry and Governments to develop jointly the guidelines needed to decide the requirements for new data, the degree of urgency—an agreement on priorities—and the consequent measures and means of their implementation. In the consideration of manpower and resources, we should bear in mind that it is not only industrial resources but Government resources as well. Of course, for an expert body to be fully effective in appraising data I think the members must, to some degree, be practising scientists in the art so that resources available to Government would seem a

very important factor to consider. As the International Chamber of Commerce stated in their General Principles: 'In order to achieve worthwhile results within reasonable time and at acceptable cost, priority should be given to environmental measures that have the highest ratio of community benefit to cost.'

In this talk I have attempted to draw to your attention some of the very difficult decisions that both Industry and Governments have to make in the protection of man and his environment. It is a field where there are few blacks and whites, where the optimum course is not always the most popular and where public concern is often not very objective. Above all I believe a climate must be established where Industry and Governments can collaborate to achieve the objectives we all seek.