Environmental Impact of Chemicals: Assessment and Control

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Chapter 16

Risk Assessment and Reality: Recognizing the Limitations

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1 Introduction

Current approaches to pollution control and environmental protection are underpinned by attempts to manage chemicals that enter the environment and to thereby mitigate potential impacts upon ecosystems and human health. At least two frameworks operate in the European Community (EC). One is based upon unified emission standards (UESs) from point sources and is applied by most European regulatory authorities. The second is applied by the UK authorities and is based upon a system of environmental quality objectives (EQOs) and standards (EQSs) for specific chemicals.[1,2] The ultimate object of both approaches is the control of chemicals. The UES approach seeks to regulate at the point of discharge while an EQO/EQS approach regulates levels of chemicals in the wider environment. In practice, however, neither approach can be adopted in isolation. A fixed emission framework still requires monitoring in the wider environment to be carried out while environmental quality standards can only be met through enforcement of conditions imposed upon point source discharges of chemicals. In some cases, such as control of microbiological contaminants for protection of fishery and amenity resources, environmental quality standards are applied throughout the EC.[3]

The selection of chemical contaminants requiring priority control has largely been based upon whether or not they exhibit the combined properties of toxicity, environmental persistence, and a potential to bioaccumulate. Other commonly used defining properties in animal and human models are carcinogenicity, mutagenicity, and teratogenicity. Some form of regulatory prioritization has been inevitable given that most regulatory instruments are permissive in nature and formulated to allow chemicals to be released into the environment. It is estimated that some 63 000 chemicals are in common use worldwide, that about 3000 account for 90% of the total production, and that anywhere between 200 and 1000 new synthetic chemicals enter the market each year.[4] Other figures suggest that in the EC alone, 50 000 substances are in use of which 4500 are

demonstrably toxic, persistent in the environment, and may be bioaccumulative.[5] Prioritization procedures depend upon evaluation of a chemical in relation to defined values of these parameters. One well-known example is the UK 'Red List' system[6] where numerical thresholds for each factor are used in order to establish the necessity of priority regulation and control.

Existing frameworks for chemical regulation and control are, therefore, essentially based upon hazard assessment. This methodology for analysing the environmental effects of chemicals depends upon a comparison of expected concentrations of the chemicals in the environment with the concentrations (usually estimated) at which toxic or other defined environmental effects can be observed. These are not probabilistic techniques: they depend upon simple analyses of data supplemented by expert judgment, application of 'safety factors' to accommodate uncertainty, and a commitment to iterative refinement of the data.[7] In many cases, surrogate values are used to estimate some of these properties, for example predictions based upon chemical structure, known as quantitative structure–activity relationships.[8] On this basis, hazard becomes a property of a given chemical, defined in terms of the parameters selected for its evaluation. The process of assigning hazard ratings can be extremely slow. From the priority candidate list of 129 chemicals selected by the EC from an original subgroup of 500, only 18 have been classified as EC List I chemicals under EC Directive 76/464/EEC.[5]

Risk assessment has been described[7] as an array of methodologies that has developed from actuarial techniques used by the insurance industry. In essence, it holds as a central thesis that it is possible to objectively define the uncertainty attached to undesirable changes taking place in the environment as a result of anthropogenic actions. Simply, it attempts to define the probability of undesirable effects occurring in the environment. This has largely impacted upon the issues concerning human health, where particular health outcomes resulting from a given environmental exposure are reduced to a probabilistic function. This is most often seen in the form of a stated risk of contracting cancer. A one in a million risk is most often used as the delineating probability between acceptable versus unacceptable risk under these circumstances for the US population[9] although risks of some adverse outcomes as high as 10^{-2} and 10^{-3} have been allowed for relatively small, exposed populations. In estimating risk, as opposed to hazard, it is necessary to have information concerning exposure of the studied system to a given chemical.[9]

The rationale that addressing human health concerns will of itself confer protection upon the wider environment has long been suspect as a premise. Indeed the only area where this philosophy overtly persists is in the regulation of radionuclides.[10] In other fields of environmental research it has been recognized that other factors need to be taken into account that may not be immediately obvious from considering the human health aspects alone. These include the greater sensitivity of organisms other than humans to a given exposure, the lack of ecosystem analogues of many human responses, and the converse situation, potentially more intense ecosystem exposures and the greater degree to which non-human organisms are coupled to their environment.[7] Hence, there is a

growing impetus to apply risk assessment techniques to the evaluation of risks to the wider environment and this is generally referred to as ecological risk assessment. In its purest, intended, form this is regarded as a rigorous, scientifically robust, numerical technique that explicitly requires a robust evaluation of exposure as a key element.

There are considerable attractions to the use of risk assessment for regulatory agencies and regulated industries alike. Their use is justified as a way of simplifying and expediting regulatory effort and introducing a quantified predictive element into the equation. In addition, both consider that risk assessment can be used to accommodate uncertainties in the scientific data and that risks can be assigned defined ranges by identifying and manipulating variables whose precise characteristics are uncertain. The techniques, inevitably, have been evolved to accommodate economic variables and this is described as risk–benefit analysis. Management techniques based upon risk–benefit evaluations seek to identify an optimal level of environmental protection. This is when any risks have been reduced to the point where the costs of any further reduction just equal the benefits involved. A risk–benefit analysis cannot ascribe a fiscal value to risk. Where this can be done, however, a cost–benefit analysis results.[11] Hence, risk–benefit analysis is regarded as a component of cost–benefit assessment.

This departure of the techniques of risk assessment from a purely probabilistic calculation into the realms of the commercial and fiscal has raised a number of concerns, particularly since the cost–benefit concept is now incorporated into the definition of the precautionary principle[12] as defined by the UK Government. It can be argued that such profound alterations to the underlying philosophy will force environmental quality towards a series of lowest common denominators rather than promote wholesale improvement. Further, they raise the contentious issue of assigning notional values to both environmental quality and human life. In short, they blur the distinction between the purely numerical evaluation itself and the use of the derived numerical value to formulate policy. While these issues are of considerable societal importance, it is not intended to examine them in any greater detail here. Arguably, however, such contentions might have less significance if the underlying assessment of actual risks in quantitative terms was plausible. In practice this critical element is demonstrably flawed in a number of respects.

This chapter, therefore, outlines the considerable difficulties in attempting to quantitatively define environmental risks arising from chemicals in the environment. These may be conveniently divided into the following categories: analytical and monitoring problems, problems with evaluating the effects of chemical mixtures, and problems in defining appropriate end-points of response to exposure.

2 Analysis and Monitoring

In estimating the potential effects of chemicals using a risk assessment framework, recourse will be made to analytical chemistry techniques. A typical sequence might be to determine the concentration of a chemical in marine food resources

and then subsequently to use this to calculate population exposure via the food chain.[9] In other situations, exposure through air, water, or dermal pathways may be considered. In each case, establishing a plausible exposure value depends upon the quality of the analysis carried out.

The problems in this area may be illustrated by the difficulties encountered in protection of the North Sea over the last decade. These have been brought to the fore by the studies carried out under the auspices of the North Sea Task Force.[13,14] The major control on chemicals entering the system depended upon reducing inputs of selected contaminants by a percentage ranging between 50 and 70%. Various governments supplied data suggesting that these input reduction targets had been met. Scrutiny of the data available upon which to base any evaluation of whether this was the case, however, revealed a number of difficulties. These relate both to the accuracy of the estimates of chemical inputs and to determination of levels of residues in various environmental compartments. This in turn suggested generic limitations which undoubtedly apply to other regional pollution control initiatives and to risk assessment methodologies.

Input Estimates

In theory, input estimates for chemicals may be based upon analysis of point source discharges, or upon measurements taken in the receiving environment. A point source needs to be monitored at least 60 times in a year in order to reliably ensure statistical detection of a fall from 95% compliance on an annual basis. Below this figure, the certainty of ensuring compliance with licence conditions falls off rapidly.[15] Very few effluents are monitored so intensively. Moreover, the licence conditions themselves often regulate only a small proportion of the chemicals routinely discharged.[16]

According to the UK Royal Commission on Environmental Pollution, even licences regulating large industrial discharges may routinely control fewer than 20 physico-chemical determinands.[17] In addition the Commission report also notes the difficulty of evaluating diffuse sources of contaminants. Data generated by the more widely based monitoring programmes do not provide reliable information on inputs. The intensity and frequency of monitoring of even the limited number of chemicals contained in the UK 'Red List'[6] is not regarded as sufficient to detect reductions of inputs of chemicals on a local basis, let alone over the North Sea as a whole.[18,19] As another example, in the case of the Tyne and Tees rivers, metal loadings have been computed for input evaluation on the basis of just four samples a year.[20]

Unsurprisingly, the published input estimates of chemicals into the North Sea are subject to wide uncertainty. In some cases, the maximum and minimum input estimates differ by a factor of 10. In the 1987 quality status report it is noted that all input figures with the possible exception of dumping are subject to considerable uncertainty, the extent of which is variable and difficult to quantify.[13] This has been apparent since at least 1984 when the first estimates of contaminant inputs from the UK became available.[21] There appears to have been no improvement in

this situation to date. The reliability of loading figures is still low and recorded changes in annual loads from rivers are seldom of statistical significance.[20] Certainly, therefore, little justification exists for claiming that, for example, cadmium in the North Sea has reached a steady state.[22]

Atmospheric inputs comprise a further confounding factor. One of the more important results of the recently reported 5 year UK Natural Environment Research Council Project was the possibility that in excess of 50% of some metals entering the North Sea do so from the atmosphere.[23] It seems likely, therefore, that lack of plausible input data exists for the majority of receiving waters on a global basis since the North Sea environment is comparatively intensively monitored. Under these circumstances, protective instruments based upon measured percentage reductions are compromised, while any risk assessment procedure dependent upon such data is inevitably fatally confounded. Much lauded percentage reductions in chemical input, moreover, may well be a complete artefact of the data.

Quality of Analytical Data

In turn, the quality of the data derived from analytical programmes needs to be viewed with a great deal of suspicion. The project manager of the latest international Quality Control and Quality Assurance Project (QUASIMEME) notes that it has become quite clear that the measurements made on the same sample by one laboratory often bear no resemblance to the values obtained by another laboratory. More worrying still, this means that the interpretation of the environmental significance of such data sets is no more than an observation on the spread of errors generated by the scientists concerned.[24,25] This is clearly illustrated also by data gathered in a German intercalibration exercise for individual polychlorinated biphenyl (PCB) congeners.[26] The data show a wide range and extreme erroneous values were generated, but not consistently, by any single laboratory. The report concludes that any absolute comparison of the data obtained is only justified if statistical variability is accounted for and that the same PCB congeners are compared. These problems are common both to the North Sea Task Force and to the Joint Monitoring Group of the Oslo and Paris Commissions active in the North East Atlantic region. In 1992 this last group reported a great improvement in the mutual comparability of analysis results. The standard deviations for most PCBs in seal-blubber and sediment extracts had diminished to around 20%.[27] It follows that even if data do stretch back a number of years[28] there has as yet been no comprehensive intercalibration exercise carried out to validate them. Therefore, the use of historical data in resolving trends in contaminant levels and hence in estimating exposures is limited.

Similar problems emerge when considering data sets obtained from long-term monitoring of contaminants present in biota. In this case the analytical imprecision is compounded by others resulting from biological variability. Difficulties in detecting trends are identified in a recent assessment of the ICES Cooperative Monitoring Programme (CMP) of contaminant levels in fish

muscle.[29] It is stated that, accounting for random between-year variation, it would be unrealistic to expect to detect any patterns of change over a 2 to 3 year period. The CMP data sets span no more than 8 years which would give sufficient power to the programme to detect trends in zinc of 10% per year and of copper and mercury of 20% per year, assuming that analytical data are reliable. These are large trends and this has significant implications for exposure estimates. If large-scale pollution incidents are considered, then zinc and copper would need to change by 200% and mercury by 400% to be identified. Only by extending the CMP data to cover 20 years does the power of the programme rise to the extent that trends of 5% can be detected. As pointed out by the authors, the environmental impact of a contaminant over this period, prior to trends emerging, may well prove unacceptable.

Recent serious complications have emerged also in the use of fish as 'sentinel species' for pollution. It has recently been found that for the target species of a US benthic surveillance programme the length of the fish alone accounted for between 19 and 67% of the variability in the data. The study considered only metals and was initiated in response to concerns that size differences alone between fish sampled in different years could obscure the identification of spatial differences or temporal trends.[30] A report from the Netherlands noted that levels of DDT [1,1,1-trichloro-2,2-bis(*p*-chlorophenyl)ethane] and PCBs in cod liver were found to be related to the length or age of the sampled fish. A recalibration of the trends data was necessary since average lengths of the fish have decreased considerably during the last decade.[27]

Implications for Exposure Estimates

Overall, there appears to be little hope of characterizing exposure of organisms or trends in exposure on an ecosystem-wide basis with any great certainty. Under these circumstances, a degree of extreme subjectivity exists in any risk assessment. It is difficult to see how this problem can be fully rectified. Intensification of wide field monitoring regimes is likely to be a cost-intensive procedure. Cost penalties will also accrue from more intense oversight of point source discharges. In the latter case, however, improvement in data resolution is likely to increase to a greater extent for a given unit cost.[31] This is simply because analysis of concentrated discharges poses less technical difficulty than analysis involving samples taken from open waters after considerable dilution has taken place. However, it can be argued that accurate data on contaminants in open waters gives a more reliable indicator of ecosystem exposure. In essence, point source monitoring implies a bias towards control of chemicals, while the monitoring of ecosystem levels draws environmental protection further towards a strategy of management of chemicals in the ecosystem.

It is often supposed that improvement and verification of analytical methods will, in time, partially solve these problems. Nonetheless, there are likely to be surprises. A good example of what can happen is provided by the results of the Total Exposure Assessment Methodology studies conducted by the US

Environmental Protection Agency (EPA).[32] These became possible after the development of suitable personal air samplers. The studies were conducted with two basic guiding principles that firstly all exposure should be measured directly wherever possible and secondly that all participants were to be selected according to robust statistical protocols. The studies focused on around 20 volatile organic compounds. Some long-standing assumptions concerning exposure to these chemicals were overturned. Although the petrochemical industry releases the greatest quantities of benzene, exposures were largely attributable to active and passive smoking. Similarly, the major environmental releases of perchloroethylene are from industry and dry cleaning establishments, yet population exposure is largely attributable to the chemical being introduced into the home on dry-cleaned clothes. Exposures to *p*-dichlorobenzene from domestic products were greatest in the home, as were exposures to certain chlorinated pesticides some of which, like DDT, had been banned a long time previously.

These intriguing results led to the conclusion that exposures must be measured directly, that the amount of a pollutant released by given sources may be subject to considerably different 'delivery efficiencies', and that sources of chemical contaminants in the home must be considered in any exposure assessment and subsequent risk evaluation. In addition, it raises the question of whether personal exposures are adequately controlled by regulation of manufacturing sites or whether the use of certain chemicals in domestic products needs much tighter control. It is likely to be far more difficult to evaluate exposures of organisms other than man in various ecosystems on this basis since such intensive sampling is rarely possible and pollutant dynamics are more complex and less easily evaluated. Overall, of course, a failure to derive credible exposure data means that a risk evaluation cannot be developed beyond a putative hazard assessment.

3 End-points and Markers of Effect

Conceivably, it could be argued that uncertainties in exposure data could be compensated for. Exposure could be manipulated as a variable within the risk assessment framework. This, however, is a departure from the central paradigm of toxicology that dose (exposure) determines effect. In addition, such manipulation actually violates the critical commitment in risk assessment to establishing empirical exposure values.[9,11] An alternative approach is to look for both generalized and specific end-points of response to toxicological stress and monitor these in the environment. In cases where there is a specific response, such as the formation of DNA (deoxyribonucleic acid) adducts upon exposure to benzo[*a*]pyrene or the presence of imposex in a population of marine molluscs exposed to tributyltin this may be a useful approach. This is only useful, however, where causality can be unequivocally assigned, *i.e.* where specific effects result from specific exposures. In practice, such direct relationships are rare, even in workforces occupationally exposed to chemicals, and certainly in natural ecosystems.

The search for suitable end-points in the toxicity test procedures applied in

hazard assessment and subject to iterative verification has provoked much discussion in the literature.[33] Unsurprisingly, this discussion has extended into ecological risk assessment. An excellent overview of the subject of ecotoxicological end-points has recently been published.[34] This distinguishes the substantial differences between end-points derived from toxicity tests [such as LC_{50} (dose that is lethal in 50% of test subjects) values] and assessment end-points. Assessment end-points nearly always refer to effects upon higher levels of ecosystemic organization and over larger spatial and time frames in comparison with the most sophisticated simulated systems used in tests.

The point is made that ecosystem interactions are both subtle and complex. Extrapolation from test end-points to predict ecosystem effects may be valid under certain limited circumstances. Generally, however, constraints exist that limit the predictive power of test end-points. These constraints, or the way in which they operate, may differ markedly in a simulated ecosystem with respect to real-world systems.

The end-points themselves fall into four broad categories. Sub-organismal end-points involve biochemical, physiological, or histological parameters, referred to as biomarkers. Although important, they are not usually of interest to environmental managers in themselves, and moreover there are few predictive models capable of using such data as input. Organismal assessment end-points, which measure death, lifespan, reproductive vigour, or behavioural responses, are most often inferred from standard toxicity test data and cannot, in the vast majority of cases, predict ecosystem effects. Population responses are favoured by environmental managers but toxicity tests are rarely designed to generate population level data. These parameters are relatively chemically non-specific. Nonetheless population level responses are frequently used to assess responses at the next level of organization: whole ecosystems. Assessment at this level is fraught with difficulties since both assessment and test end-points for these systems are problematical and ill-defined. Hence, a general strategy is to select ecosystem end-points on the basis of management goals. Inevitably, it is observed that use of ecosystem end-points in assessment of ecosystems has been simplistic. There is no realistic way of assigning causality by using what can be described as ecological epidemiology.

With each layer of ecosystem organization, therefore, there is a progressive move away from end-points which have utility in the assignment of causality. The problems are equally apparent in human epidemiology.[35] The difficulties of establishing causality in human populations mean that there is a high degree of uncertainty about these relationships. There are relatively few well-defined end-points, and a high dependence upon carcinogenic effect as an index.

An interesting recent natural ecosystem study demonstrates how the sensitivity of an assessment may be influenced by use of more sensitive end-points and more sensitive statistical analysis. Organisms living in the vicinity of oil and gas production platforms in the North Sea are impacted by drilling muds and operational discharges. Early studies suggested that normal baseline biological conditions were attained within 200–1000 m of the 500 m radius primary impact zone. By using more sensitive biological indices and multivariate statistical

techniques, the area of biological impact extends up to at least 3 km from installations.[36] This estimate has been further refined upwards to encompass a 6 km radius around some installations in an elegant demonstration of the fact that assessment of impact upon which future risk assessments depend is highly dependent upon the techniques used to investigate it.[37]

Endocrine Disrupters

Recently, a number of reports have appeared that outline a phenomenon with highly significant implications to natural ecosystems and humans alike.[38–40] It has become apparent that some chemicals released into the environment have the ability to disrupt endocrine systems. This disruption may affect a wide range of organismal functions but has been most readily observed in the form of reproductive disturbance in fish exposed to a range of chemicals in sewage and industrial effluents. Some of the chemicals potentially responsible have been identified. These include various organochlorine pesticides, the PCBs, the dioxins, the phthalate plasticizers, and some phenolic compounds. It is clear that others remain to be identified. Concerns have been voiced that such chemicals may be responsible for observed declines in male fertility in humans and contributors to the aetiology of cancers and reproductive disease.

Endocrine disrupters illustrate the inherent paradoxes in conventional risk assessment procedures. They induce an end-point at the sub-organismal level by interfering with hormonal pathways. Organismal responses have been identified that may affect whole populations. The effect upon ecosystems is largely unknown, although many speculative negative impacts can be inferred. These effects may take place at very low concentrations. The dose–response relationship is unclear and hence the classical assumptions underpinning toxicity are undermined. Exposures, therefore, remain uncharacterized and not amenable to assessment. However, a wide variety of chemicals ranging from herbicides to pharmaceutical preparations are specifically designed to interact with hormonal systems. Until recently, however, the unintended wider spectrum end-points at the sub-organismal level were completely unknown. Most importantly, there is no way that the potential for endocrine disruption can be predicted upon the basis of chemical structure alone. This means in turn that surrogate predictive tools cannot be used. In terms of actually identifying the chemicals responsible, it means that assessment frameworks come into conflict with the issue of chemical diversity.

4 Chemical Diversity

A highly conspicuous feature of toxicological data is that it largely relates to the effects of single chemicals. Very few data have been derived from the testing of combinations of chemicals. Chemicals do not occur singly in the environment and this creates yet further uncertainty in risk assessment procedures. The precision with which causality may be assigned decreases as the level of ecosystem

end-point increases. Equally, precision also decreases when chemicals are present as complex mixtures.

This situation is intensified by the relatively few chemicals monitored in the environment on a routine basis and intercalibrated basis. The QUASIMEME programme, for example, embraces only a limited subset of priority chemicals. As mandatory determinands, the metals Cd, Cu, Hg, Pb, Zn are covered, together with four chlorinated species. Laboratories participating can select voluntarily from a list of 12 other chemical types. Significantly, this voluntary list includes the dioxins, which were scheduled for a 70% reduction under the terms of the 1990 North Sea Ministerial Agreement.[41] This is an extremely limited subset of the number of chemicals routinely discharged into the marine environment. Obviously, a wider variety of other chemicals are monitored in the environment, but not on a systematic basis that allows whole ecosystem impact to be assessed. Indeed in most cases these chemicals are regulated on the basis of surrogate parameters such as those defined in the UK Red List, and this has not allowed evaluation beyond the sub-organismal or organismal levels.

Analysis of effluents from a wide variety of industrial sectors has shown that a substantial proportion of compounds present are difficult to identify even using sophisticated analytical techniques. There are a number of reasons for this, but if it is not possible to identify a chemical being discharged, then it is impossible to ascertain what risk it imposes. It is highly unlikely that even effects at the lowest levels of ecosystem organization can be assessed. In addition, there are often many more chemicals present than are regulated by the licence.[16] This point is illustrated by Figure 1 which consists of three traces obtained by analysis of the solvent extracts of three environmental samples. Table 1 shows that only a relatively small proportion can be identified with a high level of certainty using GC–MS techniques.

The occurrence of complex mixtures of industrial chemicals in open waters was confirmed by research carried out by the UK Ministry of Agriculture Fisheries and Food.[42] Not only did this study identify a wide range of chemical contaminants of clear industrial origin in offshore waters, but also it showed that the exact combination varied between estuaries, presumably reflecting differing industrial activities within each area. A similar finding has been made for the Scheldt estuary. This is regarded as heavily polluted, and studies of organic micropollutants have revealed that a significant component of the chemicals isolated could not be identified.[43] A wide range of organic micropollutants have also been identified in open waters off the Dutch coast.

Toxicological Effects of Complex Mixtures

Attempts to assess the risks posed by mixtures of chemicals have been confounded by the absence of information on the properties of the individual components. It was found that for 75% of the chemicals isolated and tentatively identified in the Tees area by the sophisticated GC–MS techniques used, no ecotoxicological data could be found.[42] In many cases, due to the lack of ecotoxicological information
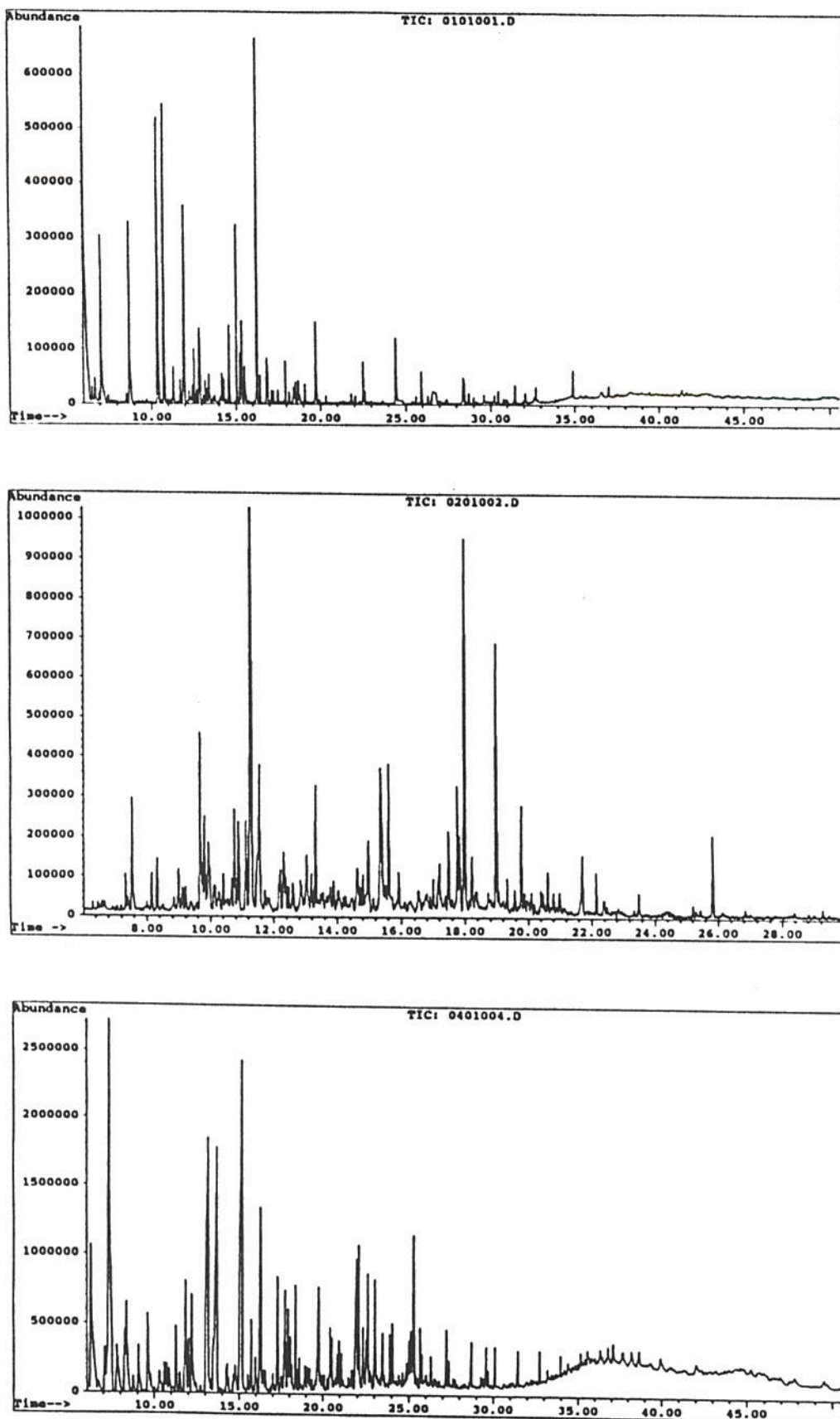
Figure 1 *Traces derived from the GC–MS analyses of solvent extracts of environmental samples. Methods are as outlined in reference 16. The traces were derived (from top to bottom) from a sewage treatment works in the UK, a freshwater sediment from an industrialized area in Israel, and a sediment obtained from a waste water evaporation pond in Spain. Each peak on the trace theoretically represents a single chemical compound. It is clear that there is considerable variability between the effluents with respect to their constituent components*

Table 1   *Numbers of chemicals identified from the traces shown in Figure 1. Mass spectra for each of the peaks were compared with the 136 000 specimen mass spectra held on the Wiley Spectral Library using probability based matching techniques. A match at 90% probability is regarded as a reliable. At 50–90%, identification is only tentative while below 50% the compound is regarded as unidentified. Relatively few chemicals of those present are routinely identified.*

Sample	Compounds isolated	Match at 90%	Match at 50–90%	Match below 50%
Sewage	77	23	15	39
Sediment	55	15	7	33
Sediment	180	33	21	126

the toxicity of many chemicals had to be inferred by using figures derived from theoretical toxicity models based upon chemical structure.[44] The concentrations of the individual chemicals were not thought to be of concern. Subsequently attempts were made to investigate organismal responses to the mixture using sensitive toxicity tests. These were carried out using oyster embryos placed in the Tees estuary itself. Significant mortalities of the test species took place in the chemical mixture. Indeed, at one point in the upper Tees estuary in 1990, 100% mortality of the test species took place. The study, understandably, concluded by noting that accurate prediction of the joint effects of complex mixtures of substances is not possible at present.

The problems of relating chemical contaminant effects in wider natural communities of organisms are discussed in depth in a recent review.[45] These workers consider that there is a need to determine 'critical body residues' of contaminants in a comprehensive manner as an additional component of ecotoxicological assessments. They suggest that this would greatly assist the evaluation of mixture toxicity. Nonetheless, as pointed out earlier in a submission to the 1990 Ministerial Conference,[46] the lack of information about the environmental behaviour of chemical mixtures in association with other environmental stressors is a continuing and critical deficiency of evaluation procedures applied to marine and other environments.

The acquisition of further information to input into risk assessment processes may be of limited value without a wholesale effort to elucidate toxicodynamics. Mixtures of chemicals in some environmental matrices may exhibit marked departures from behaviour predicted under the assumptions inherent in toxicity tests. Both intuitively and empirically based understandings of the role of dilution may not be valid, a somewhat serious complication. For example, a recent study[47] of the immune capability of shrimp exposed to highly contaminated sediments from Rotterdam Harbour has demonstrated this quite clearly. When exposed to 100% dredge spoil the immune system of the organisms was compromised in relation to control animals living on clean sand. Unpredictably and very surprisingly, shrimp exposed to a mixture of 95% clean sand and only 5% dredge spoil showed a level of immune system compromise greater than those exposed to the 100% dredge spoil. The reasons for this are not clear but neither is

it an isolated observation. This phenomenon has considerable implications for risk assessments carried out in relation to the dumping of contaminated dredge materials at sea.

5 Overview

The foregoing discussion appears at first sight to be unremittingly negative in its view of the sciences of toxicology and ecotoxicology. This is in many ways unfair. Toxicological research and attempts to evaluate ecosystem response have contributed much to our understanding of the effects of polluting chemicals. Indeed such studies, however imperfect, are our only basis for evaluating the effects of chemicals in the environment. Providing that the limitations are understood and respected, then the results from such studies may serve as useful indices in certain applications and contribute much to environmental protection.

Currently, however, risk assessment is not an application that can be considered to be well served by toxicological and ecotoxicological data. As discussed above, inadequacies exist in the data for all but a limited subset of those chemicals emitted to the environment. Exposure estimates are confounded by imprecise estimates of the input of chemicals to ecosystems and lack of direct measurements. The estimation of residue trends is subject to similar imprecision and consequently to an identified and well-recognized utilitarian uncertainty. The end-points targeted by testing procedures do not readily correspond to end-points required by assessment procedures. Assessment frameworks cannot accommodate operative functions that have not been identified, or newly recognized end-points such as endocrine disruption. Existing frameworks cannot assess the behaviour of a single chemical present in a mixture or indeed that of the mixture itself. Finally, risk assessment cannot be applied to chemicals that cannot be readily identified.

A daunting array of inadequacies and uncertainties exist, therefore, each of which on its own could compromise a risk assessment procedure. To put this in perspective, Figure 2 reproduces a conceptual risk assessment structure for human health risks from contaminated marine resources.[9] Considering the potential problems in combination, it is likely that many risk assessment procedures of this kind will be fatally compromised, but with the added danger that the compromises will not be recognized. This may lead in turn to inappropriate environmental management decisions. Even where uncertainties are recognized and can be manipulated as variables within the assessment framework to produce a range of values for risk factors, there is the attendant possibility that manipulation of more than one factor will produce equivocal results. This is not reassuring given that risk assessment and risk–benefit assessment are being widely promoted as managerial tools.

It is particularly important that these limitations are recognized when risk assessment is applied to the formulation of regulations and obliquely to the implementation and enforcement of such controls. Risk assessments should be viewed with deep scepticism unless all of the areas of uncertainty are explicitly
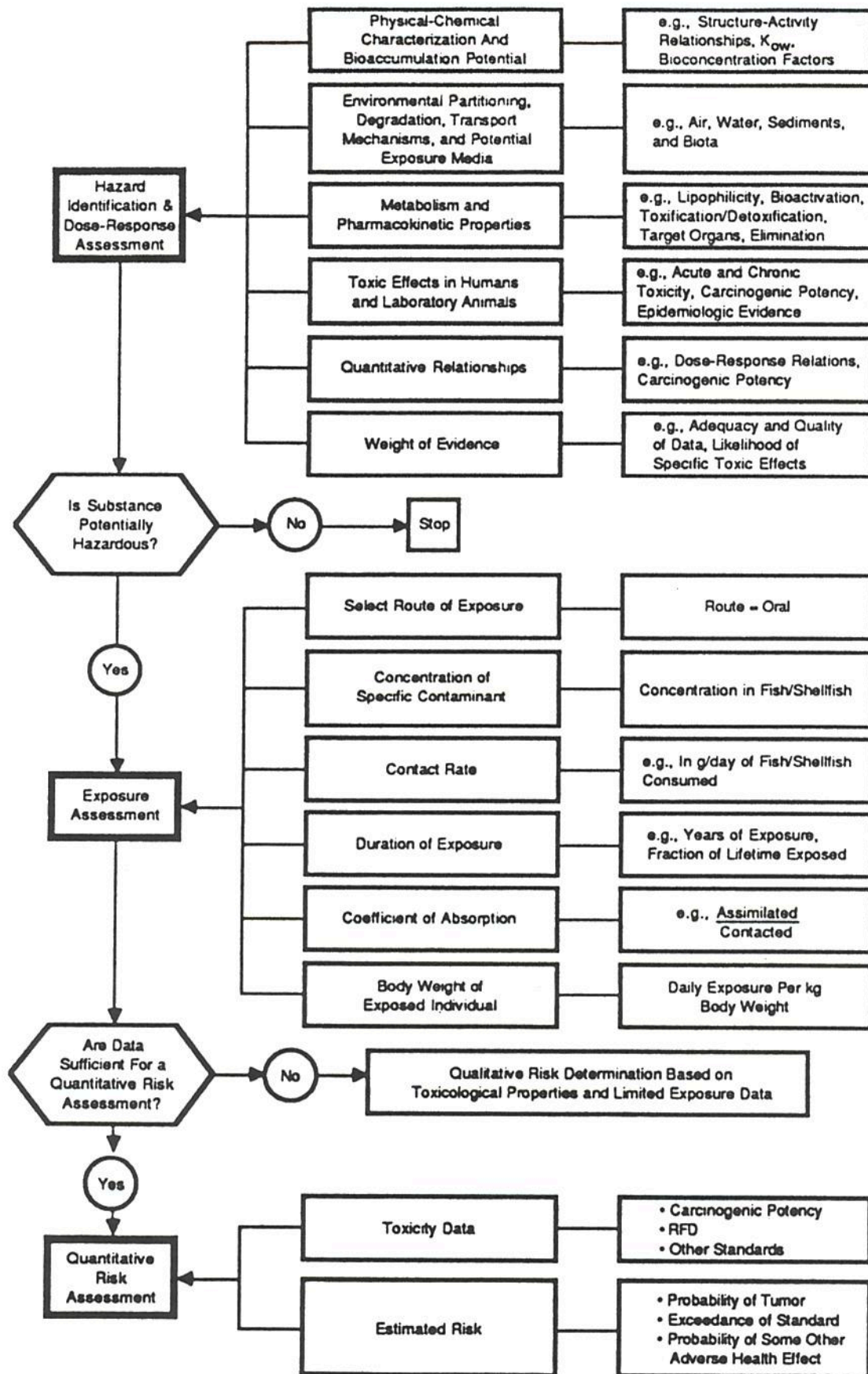
Figure 2   *A conceptual framework produced by the US EPA and reproduced from reference 9. This clearly shows the complex and intricate procedures necessary and the need for good quality analytical data in order to compute exposure factors. In addition, it must be noted that the framework is only capable of accommodating single chemicals for assessment purposes*

defined. In every case, risk assessment must be accompanied by penetrating reality checks at every stage of the process and particularly in the application of assessment results to the formulation of policy. Ultimately, it must be recognized, however,[48] that regulation is at best a compromise between what is achieved at the moment and what is desirable in the future. The best way to remove this element of compromise in the medium to long term is to accept that regulations merely represent resting places on the road to a goal of zero discharge of dangerous chemicals to the environment.

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