An interpretation and evaluation of the US Environmental Protection Agency ecological risk assessment guidelines

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Abstract

In order to facilitate a common understanding, on-going debate and increasing application of ecological risk assessment (ERA) in South Africa, the ERA process of the US Environmental Protection Agency (EPA) has been summarised and evaluated for South African conditions. Many of the individual steps in the process have been interpreted and reworded in order to improve communication of the concepts. The basic process is unchanged though a few minor changes are recommended as improvements. A comparison is also made with integrated environmental management (IEM). It is noted that ERA addresses many of the key principles underpinning IEM, including consultation with interested and affected parties which provides an opportunity for public and specialist input into the decision-making process. However, there are some differences though more in degree than in principle. Of importance is that the ERA framework provides explicitly for quantification of all aspects of an assessment in an IEM procedure.

Introduction

Many environmental statutes, implemented by the US Environmental Protection Agency (EPA) since the 1970s, regulated and reduced point-source releases to the environment. Risk assessment emerged as a regulatory paradigm in the early 1980s, at a time when regulatory and policy decisions were being influenced by ecological impact measures. The use of ecological information for decision-making expanded slowly through the 1980s. In the mid- to late-1980s, tools and methods for conducting ecological risk assessments began to be standardised (Calow, 1998). The EPA's Science Advisory Board recommended that ERA be the cornerstone for decision-making within environmental management. Their report *"Future Risk: Research Strategies for the 1990s"* (US EPA, 1988) emphasised the need for a fundamental shift in EPA's approach to environmental protection. The move was from conventional approaches to focussing on the resources at risk, their composition within a landscape, multiple stressors and multiple assessment end points. In 1992, the EPA published the *"Ecological Risk Assessment Framework"* as the first statement of principles for ecological risk assessment, and in 1998 published the *"Ecological Risk Assessment Guidelines"*. These documents not only describe single-species, chemical-based risk assessments, but also techniques for assessing risks to ecosystems from multiple stressors and multiple end points. In the rest of the world the value of the process has only recently been considered.

In the UK the Department of the Environment (DOE) generally leads policy to control risk to the environment and published "*A Guide to Risk Assessment and Risk Management for Environmental Protection*" (UK DOE, 1995). This guidance has been followed in reports for instance on dioxin emissions. Legislation in most other EU countries placed a greater emphasis on technological standards to achieve improvement, and risk assessment is more difficult to fit within such a framework. This approach is akin to the precautionary principle, due to its focus on prevention and is not ideally suited for applications where substances are persistent and may build up in the environment.

The draft Australian/New Zealand Standard on Risk Management of 1994 defines risk as follows: *"Risk arises out of uncertainty. It is the exposure to the possibility of such things as economic or financial loss or gain, physical damage, injury or delay, as a consequence of pursuing a particular course of action."* The Management Advisory Board of the Australian Public Service identifies a five-step generic process for managing risk (Australian Academy of Science, 1995). These are: establish the context, identify the risks, analyse the risks, assess and prioritise risks and treat the risks.

Some reasons for risk management in general include the following (Skivington, 1992). The public typically has an unsympathetic attitude towards companies causing adverse environmental impacts. These attitudes have impacts on potential markets. There is also ever-tightening legislation affecting local and international trade. ERA is important for environmental decision-making because of the high cost of eliminating environmental risks associated with human activities and the necessity of making regulatory decisions in the face of uncertainty (US EPA, 1998).

There is a need to establish a common understanding of ERA in South Africa. There is also a need to examine published ERA processes and adapt them, where necessary, to South African conditions. The South African Department of Water Affairs and Forestry (DWAF) is currently collaborating with the CSIR to develop an ERA framework in South Africa. This paper presents a description and examination of the US EPA guidelines for ERA as it is the process used most widely. It is also hoped that the present summary will simplify familiarisation with the original lengthy document (US EPA, 1998).

An interpretation of the US EPA ERA process

The US EPA defines ERA as *"the process that evaluates the likelihood that adverse effects may occur or are occurring as a result of exposure to one or more stressors"* (US EPA, 1998). The process consists of a number of formal phases (Fig. 1).

The interpretation of the US EPA process in this paper distin-

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Received 11 May 1999; accepted in revised form 21 July 1999.

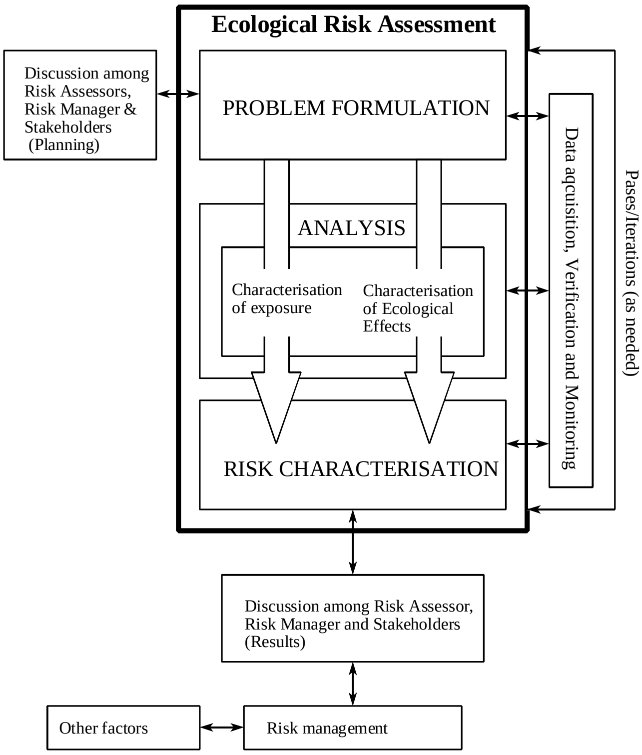


Figure 1
EPA process for ERA (US EPA, 1998)

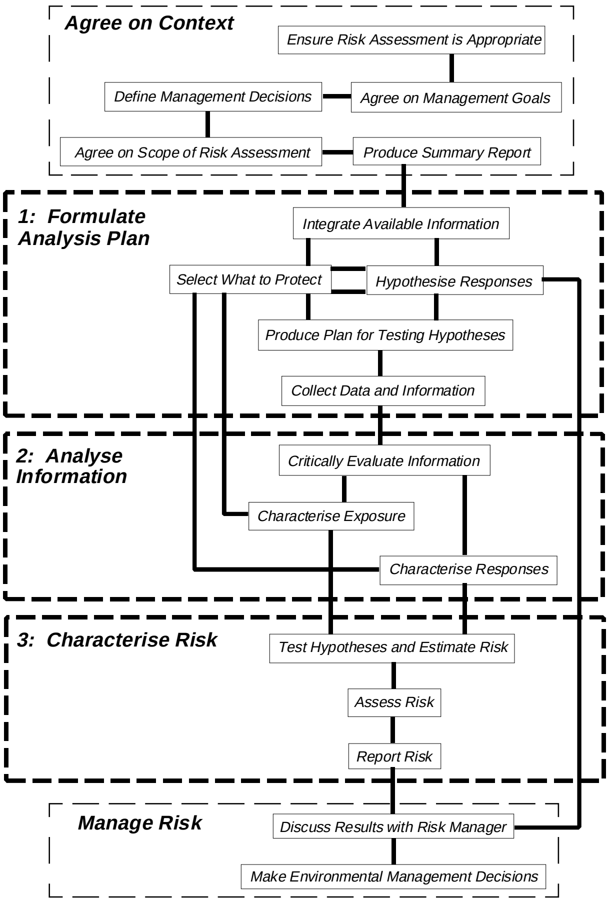
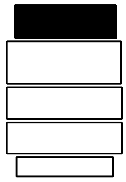


Figure 2
High-level actions in ERA process

guishes between actions in the process (using verbs or phrases that are unambiguously actions) and the issues they are intended to influence. This distinction should clarify communication and hence understanding of the process. Accordingly, tasks have been re-worded (where necessary) specifically as actions. The process is divided into high-level (Fig. 2) and lower-level actions (Figs. 3-5). These are summarised here in text with adjacent pictorials. Each high level task consists of a number of lower-level tasks which, in turn, may comprise even lower-level tasks. The text provides a degree of detail one level below the level depicted in the task diagrams.

Agree on objectives



An ecological risk assessment should be a process of sound scientific integrity. It should take account of political, economic and social issues (i.e. those of particular importance to management) though should not be biased or compromised by them. Accordingly, a dialogue between the risk manager and the risk assessor should begin with a planning process preceding the formal assessment. The following are actions that are part of the process of agreeing on the objectives (Fig. 2):

Ensure risk assessment is appropriate. The first important issue is whether a risk assessment will enable managers to make informed environmental decisions, compared to other approaches, such as expert opinion or a precautionary approach. Having decided that this is the case, the two parties need to do the following:

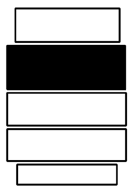
Agree on management goals. Establishing the goals is primarily the task of the risk manager. The risk assessor, however, needs to ensure that the goals can be represented by definitive ecological values, in agreement with the risk manager.

Define management decisions. The more explicitly the management decisions that are to be supported by the risk assessment can be defined, the more well-aligned the risk assessment is likely to be with those decisions.

Agree on scope of risk assessment. Both parties need to be clear on constraints of data availability, scientific knowledge, financial resources and spatial and temporal scales. Of particular importance is the maximum uncertainty that the risk manager will tolerate. The lower the tolerance the more extensive the assessment is likely to be.

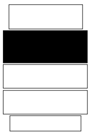
Produce summary report. Ideally a summary report of this dialogue prior to the assessment should be produced that will provide a point of reference for subsequent work.

Formulate analysis plan



This is the first formal stage of an ecological risk assessment (Fig. 3). The prime responsibility now rests with the risk assessor. However, the dialogue between risk assessor and risk manager will need to be maintained to ensure optimum alignment. The risk assessor needs to carry out the following actions:

Integrate available information. Issues including the sources of stressor and stressor characteristics as well as exposure mecha-



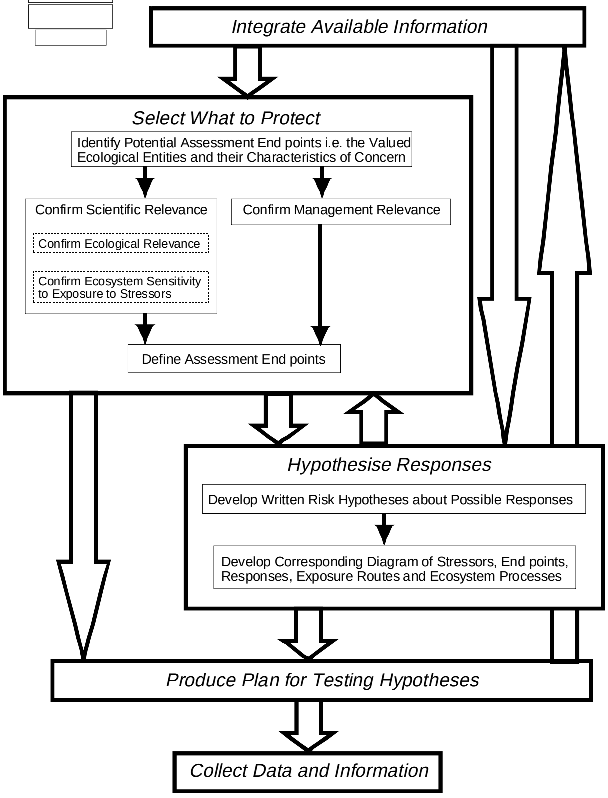


Figure 3
Actions in analysis plan formulation

nisms and time frames must be addressed. Information on the ecosystem potentially at risk needs to be evaluated as well as the likely ecological effects (responses) of the ecosystem to the stressor. If key information is not available it may be necessary to collect data.

Having evaluated what is known about the both the stressor and ecosystem, the risk assessor needs to accomplish the following:

Select what to protect. The risk assessor must identify potential assessment end points. These include both the ecological entity considered to be of value (e.g. a species) and the characteristic of that entity that is potentially at risk (e.g. reproduction success).

In order to confirm scientific relevance the risk assessor must do two things:

First he must confirm ecological relevance. Crucial end points are those that help sustain the natural structure, function and biodiversity of the ecosystem. For example, they could provide a basic food source or habitat. He must also confirm ecosystem sensitivity to exposure to stressors. The end points must be sensitive (i.e. respond significantly) to the stressor under the amount of exposure likely to occur. Scientific rigour in these two areas must be upheld.

Secondly, he must confirm management relevance. It must be ensured that the previously identified management decisions can be supported and hence the goals achieved. In this sense, the assessment end points should ideally be values that people care about.

The final task is to rigorously define assessment end points. These are the definitive measures that scientifically and ecologically represent the broader management concerns. This task may be difficult and require expert judgement. However, the rationale behind the choice should be clear. The assessment end points need not be defined in terms of directly measurable properties using established methods, although this is preferable. Establishing how to evaluate the response of an assessment end point to the stressor needs to be dealt with in some detail in the analysis plan.

Hypothesise responses. An important task is to develop written risk hypotheses about possible responses. Risk hypotheses are predictions of relationships between stressor, exposure and the response of the assessment end points. To facilitate clear communication one should also develop a corresponding diagram of stressors, end points, responses, exposure routes and ecosystem processes. This conceptual diagram should represent the risk hypotheses. In-depth consideration should be given to ensuring all important relationships are included. Not doing so can seriously affect the results of the risk assessment by significantly contributing to uncertainty.

Produce plan for testing hypotheses. The risk assessor should describe how the risk hypotheses will be assessed. What will and will not be done must be explicit.

There are various measures that should be selected at this point. One group consists of measures of effect that evaluate the response of the assessment end point when exposed to a stressor. Another constitutes measures of exposure which establish mechanisms by which exposure occurs. A third group comprises measures of ecosystem and receptor characteristics which affect the assessment end points. The analysis plan should describe these measures in some detail.

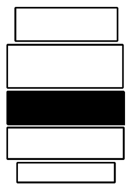
The analysis plan should also include how data will be analysed or modelled and how results will be presented. In particular it should be clear how the data analyses will distinguish between the risk hypotheses.

Finally the analysis plan should be discussed with the risk manager to ensure that the results are indeed those that the manager requires to make sound decisions.

It may be necessary to repeat the steps of this stage a number of times.

Collect data and information. The plan should clearly identify the data that needs to be measured and the information that needs to be collated. This should be done before the next stage is started.

Analyse information



This is the second formal stage of an ecological risk assessment (Fig. 4). It comprises the following actions:

Critically evaluate information. This activity is a more detailed examination of existing information than that carried out as the first step of the first stage of formulating the analysis plan. First the risk assessor must critically evaluate existing studies. The strengths and limitations of data from various sources must be established. These sources include laboratory and field studies, indices, experience from similar situations, structure-activity relationships and models. The purpose and scope of existing studies should be carefully compared with those of the risk assessment. Each study must display due

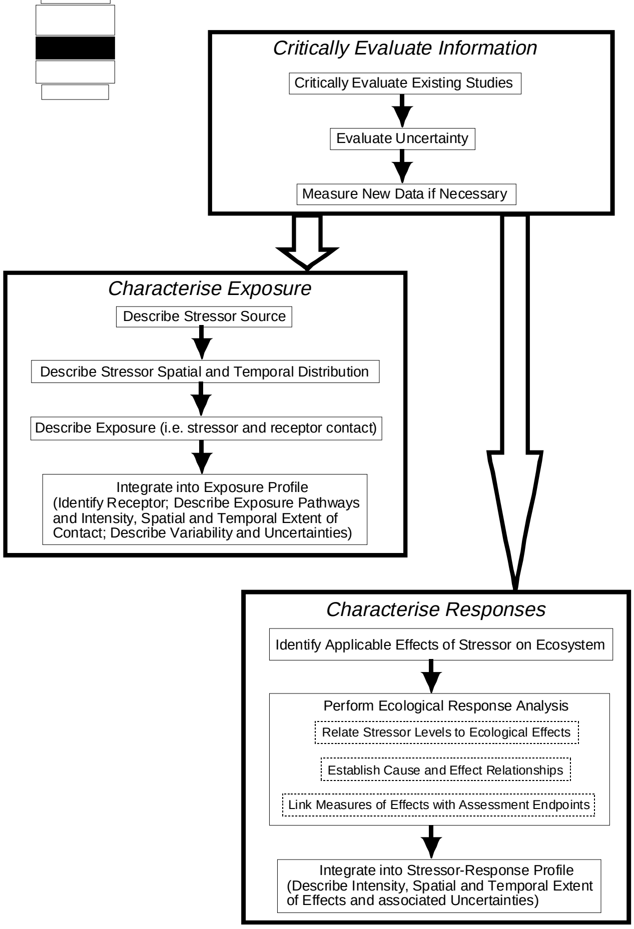


Figure 4
Actions in analysing information

diligence and scientific rigour.

The next step is to evaluate uncertainty. What is known and not known about exposure and effects should be described and, preferably, quantified. Potential sources of uncertainty include the following: Unclear communication, errors in the information itself (descriptive errors), natural variability in the stressor and ecosystem, gaps in the data, uncertainty about a quantity's true value and model uncertainties. An important aspect is to distinguish between uncertainty due to natural variability and lack of knowledge.

The risk assessor may also need to measure new data if necessary. This would be driven by the data required to reach the specified objectives.

Characterise exposure. To describe the stressor source, the risk assessor must describe the place where it is released or the action that produces it. If the original source no longer exists then the current origin of the stressors is defined as the source (like sediments contaminated by an industrial plant that no longer operates). The intensity and timing of stressor generation must also be addressed.

The next step is to describe the spatial and temporal distribution of the stressor. Pathways that stressors take from the source must be evaluated. Chemical stressors will require an assessment of the media between which they may partition. The attributes of physical stressors, like the size of suspended solids, may influence their fate. Other physical stressors, like filling a wetland or flooding a valley, will not involve pathways but rather evaluation of secondary stressors. Biological stressors may disperse by diffusion or jump-dispersal (erratic spread over time). Ecosystem characteristics will influence all the above. Secondary stressors caused by the primary stressor are important to identify and can significantly influence the result of a risk assessment.

The final step is to describe the exposure (i.e. stressor and receptor contact). This is a critical step because without exposure there can be no risk. It involves describing how, when, where and to what degree the stressor and receptor will occur simultaneously. Both contact and uptake must then be considered. Finally the risk assessor must integrate this information into an exposure profile which is a summary of what has been learned.

Characterise responses. The first task is to clearly identify applicable effects of the stressor on the ecosystem. This may involve further examination of existing studies and should confirm that the effects are consistent with the assessment end points and the conceptual model.

The second task is to perform an ecological response analysis. This stressor-response analysis should relate stressor levels to ecological effects, preferably quantitatively. It should also establish cause-and-effect relationships (causality). Finally it should link measures of effects with assessment end points. Sometimes the latter cannot be monitored directly. In this case, sound and explicit linkages between those effects that can be measured and the assessment end points are needed. These can be based on expert judgement but are preferably based on empirical or process models.

The final task is to develop an integrated stressor-response profile which is a summary of what has been learned.

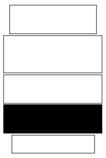
Information gathered at this stage may necessitate returning to an improved formulation of the analysis plan, for example, to modify the end points selected.

Characterise risk

This is the final formal stage of an ecological risk assessment (Fig. 5). It comprises the following actions:

Test hypotheses and estimate risk. The risk assessor must determine the likelihood of adverse effects to assessment end points by integrating exposure and effects data and evaluating any associated uncertainties. The assessor uses the exposure and stressor-response profiles developed in stage two according to the analysis plan produced in stage one. It is at this point that the previously defined hypotheses are tested.

Risk estimates can be obtained in one or more ways. Firstly, they can be expressed qualitatively based on professional judgement (low, medium and high or yes and no). Secondly, they can be expressed as single-point estimate usually as a ratio of two numbers. The exposure concentration divided by an effects concentration is commonly used for chemical stressors. Thirdly, they can incorporate the entire stressor-response relationship. This is appropriate when the stressor level is related to the magnitude of response by a curve. Fourthly, they can incorporate variability in exposure or effects. Variability in exposure can be used to describe risks to moderately or highly exposed members of a population. Variability in effects can be used to describe risks to average or sensitive population members. These provide a convenient means of comparing different risk management options. Fifthly, risk assessors can use process models upon which to base risk estimates. Models are mathematical expressions that represent our understanding of the mechanistic operation of the system. They have the major advantage of allowing "what if" scenarios to be examined. Finally,



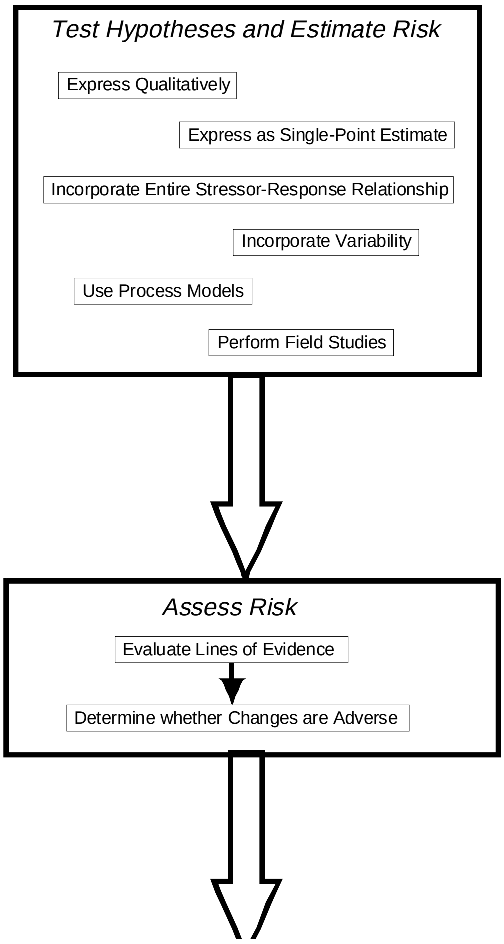


Figure 5
Actions in risk characterisation

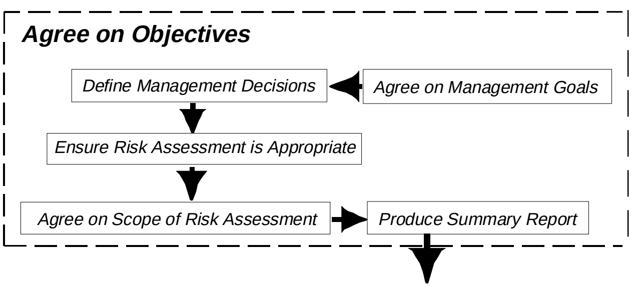


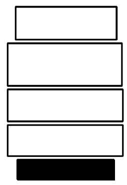
Figure 6
Proposed high-level actions in ERA process

risk assessors can perform field studies and base estimates directly on the results.

Assess risk. It is essential that a technical narrative accompany the estimated risk. Its first task is to evaluate lines of evidence. An attempt should be made to use fundamentally different (i.e. independent) approaches in support of the conclusions, for example, quotients and field studies. The second task is to determine whether changes are adverse. The assessor must evaluate the nature and intensity of the effects, the spatial and temporal scales and the potential for recovery.

Report risk. The results of the risk assessment should be presented clearly and concisely. It should include a degree of detail appropriate to the kinds of management decisions that need to be taken.

Manage risk



Having completed the formal risk assessment process the main task that the risk assessor must perform is the following (see Fig. 2):

Discuss the results with the risk manager. The risk manager needs to ensure that the necessary environmental management decisions can be soundly supported by the results of the risk assessment. If not, then another more detailed risk assessment may be requested and a new analysis plan formulated.

A risk assessment process is iterative by nature. It is possible that the process will be completed first at a rather superficial level. If results are not sufficiently sound to support the required management decisions then, resources permitting, the assessment may be repeated at a more detailed level. Individual stages may also require internal iteration before the required results are obtained.

Once satisfied that the results can be used, the risk manager can proceed with his primary function:

Make environmental management decisions. The risk manager uses the results along with other relevant social, legal, political or economic information to make decisions on how to proceed. This may include invoking mitigation measures, monitoring progress and communicating results to the public.

An evaluation of the process

With regard to the US EPA process guidelines (US EPA, 1998), the following comments can be made.

Firstly, it is suggested here that in the pre-assessment stage of agreeing on objectives (Fig. 2), the first task could perhaps be to confirm the management goals (not ensure that a risk assessment is appropriate). This would be followed by defining the management decisions. Only when clarity is attained in this regard would the risk manager and risk assessor ensure that a risk assessment is appropriate. A re-ordering of tasks, as presented in Fig. 6, is proposed as being more appropriate.

Secondly, in stage one (formulating the analysis plan) considerable emphasis is placed on developing risk hypotheses based on an integration of available data. However, in the guidelines document (US EPA, 1998) it is not made explicit in later sections when these hypotheses are tested. It is evident from the tasks performed in stage three (risk characterisation) that this is where the hypothesis testing is done. This is made explicit in the current interpretation of this stage (Fig. 5).

Integrated environmental management

The logical structure of the ERA framework and the integration of probabilities and uncertainties in the ERA evaluation presents a procedure that can be easily and comprehensively understood, documented and communicated. This addresses some of the key principles underpinning integrated environmental management (IEM) such as supporting informed decision-making, enabling consultation with interested and affected parties, permitting mitigation of negative effects and enhancement of positive effects, and providing opportunity for public and specialist input in the decision-making process (DEA, 1992a). The problem formulation stage (referred to as formulating the analysis plan in the current interpretation) of the ERA framework addresses all the issues required for the scoping phase of the EIA, although there is probably insufficient provision for a full consultative process and for revising the outcome of the scoping phase.

The description of the approach to the study as outlined in the IEM guideline documents (DEA, 1992b) is comprehensively addressed in the ERA framework, as are the requirements for assumptions and limitations (by definition of an ERA). The administrative, legal and policy requirements specified in the IEM procedure are not explicit components of the ERA framework, but provide the conditions for problem formulation and determine the framework for risk management. The advantage of this is that the ERA process remains objective and independent, but more feedback from these aspects to the assessment might be required for wide implementation of ERA. The exposure assessment step of ERA addresses all the relevant issues specified in the proposed outline of the IEM project proposal and the ecological components of the affected environment are also adequately covered.

One of the greatest perceived advantages of using the ERA framework in an impact assessment is that it quantifies very explicitly all the requirements of the assessment in the IEM procedure (DEA, 1992a). These requirements include the description of impacts or effects, an account of criteria for determining significance (by design supported in ERA), suggested mitigation options, impacts with mitigation measures (as a scenario-based tool ERA supports these evaluations) and the degree of confidence in the prediction (explicitly determined). The predictive capabilities of the ERA framework, furthermore, strongly support the documentation of the evaluation method, comparisons between alternatives, and the recommendation requirements of the evaluation phase of the IEM procedure. The statement of incomplete and unavailable information called for in the IEM procedure is also required in the ERA process.

The physical, ecological and pollution components of the environmental characteristics check-listed in the IEM procedure (DEA, 1992c) are covered by the issues addressed in the ERA framework. A concern in this regard is that there may not be adequate provision for the integration of physical, ecological and pollution aspects with land use, socio-economic, infrastructural and cultural resource issues.

It is evident that many of the ecological requirements specified in the IEM procedure are dealt with within the ERA framework. A more comprehensive evaluation based on case studies should be conducted to test this hypothesis. An area of concern in the current ERA framework is the limited provision for consultation and feedback during the quantification of effects. Mechanisms for the co-ordination and integration of social, economic, political, ecological and other aspects in the impact evaluation stage also need to be developed and refined.

Glossary

Assessment end point. An explicit expression of the environmental value that is to be protected. An assessment end point includes both an ecological entity and specific attributes of that entity. For example, fish are a valued ecological entity; reproduction and population maintenance of fish form an assessment end point.
Ecosystem. Any unit that includes all of the organisms (i.e. the community) in a given area interacting with the physical environment so that a flow of energy leads to clearly defined trophic structure, biotic diversity and material cycles (i.e. exchange of material between living and non-living parts) with the system (Odum, 1971).
Hazard. A state that may result in an undesired event, the cause of risk. In environmental toxicology, the potential for exposure of organisms to chemicals at potentially toxic concentrations constitutes the hazard.
Receptor: The ecological entity exposed to the stressor.
Risk: The probability of a prescribed undesired effect. Risks result from the existence of a hazard and uncertainty about its expression. The uncertainty may relate to a lack of knowledge or stochastic processes in the environment, whereas variability typically involves spatial and temporal variation.
Stressor: Any physical, chemical or biological entity or process that can induce an adverse response.

Acknowledgements

The authors gratefully acknowledge the comments provided by Mike Hawke (AECI) and Sebastian Jooste (DWA&F), and also the Water Research Commission for supporting the study.

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