3 RISK ANALYSIS

3.1 What is Risk Analysis?

McVicar (2004) describes risk analysis as "*a structured approach used to identify and evaluate the likelihood and degree of risk associated with a known hazard. It leads to the implementation of practical management action designed to achieve a desired result regarding protection from the hazard. Actions taken should be proportionate to the level of the risk. This provides a rational and defendable position for any measures taken to allow meaningful use of resources and for the focus to be on the most important areas that can be controlled. Risk management requires that all possible major hazards to the matter of concern should be identified.*"

Risk analysis integrates risk assessment and risk communication, and is structured to support effective risk management. While risk management is not discussed in depth in this document, how the assessment process can link to risk management is illustrated.

Risk analysis has been adopted in a range of international fields affecting aquaculture as a method for integrating risk assessment and risk communication into decision-making. For example, in response to concerns about the transfer and control of diseases of aquatic animals, the World Trade Organisation accepts the risk analysis protocols developed by the Office International des Epizootic (OIE) as the basis for justifying trade restrictions through regulatory actions, including restriction on movements of commercial and non-commercial aquatic animals. The purpose of the OIE protocols was to provide guidelines and principles for conducting transparent, objective and defensible risk analyses in relation to international trade. ICES has embraced this approach in their latest Code of Practice for the Introduction and Transfer of Marine Organisms (hereafter referred to as the ICES Code) (ICES 2005b). One part of the ICES Code is specifically designed to address the "*ecological and environmental impacts of introduced and transferred species that may escape the confines of cultivation and become established in the receiving environment* ".

This document advocates the use of Risk Analysis procedures in assessment of the environmental risk arising from coastal aquaculture developments. Environmental risk assessments are commonly associated with high levels of uncertainty in the probability of outcomes of particular actions, incomplete scientific knowledge, and significant expressions of concern by other stakeholders. Examination of the issues concerned, using a recognized protocol for risk analysis inclusive of good risk communication, is presented as a helpful strategy for developers, regulators and interest groups.

Terms used in fields of human health and environmental risk assessment can have a variety of definitions, depending on their application. These definitions differ subtly and can be a source of confusion.

The definitions for risk and hazard as used in this document are:

Risk: A characteristic of a situation or action wherein two or more outcomes are possible. The particular outcome that will occur is unknown, and at least one of the possibilities is undesired. Risk = Product of the probability of change and severity of change (after Covello and Merkhofer 1993).

Hazard: An agent, medium, process, procedure or site with the potential to cause an adverse effect (EU Commission 2000). A (potential) source of risk that does not necessarily produce risk. A hazard produces risk only if an exposure pathway exists and if exposures create the possibility of adverse consequences (Covello and Merkhofer 1993).

Both the definitions above, of hazard and risk, are linked to what society sees as a negative effect, or an undesirable outcome. In some instances, agents, media, processes or sites may actually result in environmental changes that society considers to be beneficial. For example, increased algal abundance as a result of human release of nutrients into coastal waters is often considered a negative environmental change. In such environments, shellfish culture may lessen the build up of algae. In other, less eutrophic environments, reduction of algal abundance may be seen as threatening the food resources for endemic filter feeding organisms. Thus, in the former case there is no risk of undesirable changes in algal abundance whereas in the latter case such a risk may exist.

3.2 The Structure of Risk Analysis

The risk analysis process is built around the concept that some aspect of the activity under consideration (coastal aquaculture) can lead to the release of a hazard that in turn could lead to an undesirable change in the environment. In the case of coastal finfish aquaculture, an example would be the release of particles of uneaten food and faeces (the hazard) into the environment potentially leading to an unacceptable degree of smothering or alteration of the benthic fauna beneath and around the cages (the endpoint, or undesirable outcome).

Risk analysis can be broken down into four major components:

- Hazard Identification;

- Risk Assessment;
- Risk Management; and
- Risk Communication.

The process and its components are represented in Figure 3.1, in which the relationship between the sequential steps of hazard identification, risk assessment and risk management and the continuous process of risk communication is illustrated. Risk Communication is the most pervasive and important component of risk analysis. It acts to optimise the transparency and openness of the process, as well as maximizing the acquisition of information, and acceptance of the conclusion of the analysis. It has roles to play in the preparation for a risk analysis, during the risk analysis and in some instances as part of the follow-up after completion of the analysis.

Risk analysis provides an objective, repeatable, and documented assessment of risks posed by a particular course of action and answers the following questions:

- What can go wrong? – Hazard Identification;
- How likely is it to go wrong and what would be the consequences of it going wrong? – Risk Assessment;
- What can be done to reduce the likelihood or consequences of it going wrong, or the level of uncertainty in our prediction of the outcome? - Risk Management and;
- How can the analysis process be made understandable, open and transparent to all with an interest in the management of our marine resources? – Risk Communication.

The Risk Assessment component mentioned above is further broken down into four subcomponent steps (Figure 3.2) following the generally accepted protocol proposed by Covello and Merkhofer (1993):

(i) Release Assessment;

(ii) Exposure Assessment;

(iii) Consequence Assessment; and

(iv) Risk Estimation.

3.2.1 Levels of Protection and the Precautionary Approach

The risk assessment phase of a risk analysis provides information on three important aspects of the predicted environmental effect; the severity of change; the probability of it happening, the uncertainty associated with that prediction. The criteria of the desired level of protection are determined by managers, and are compared against the predicted changes. The regulatory response to this information depends on the socio-economic setting in which the decision is made.

Another set of definitions are therefore required prior to initiating a risk analysis. These cover the explicit enunciation of what constitutes an acceptable level of protection for each identified outcome. This will vary from jurisdiction to jurisdiction, as jurisdictions vary in the level of risk they are willing to take depending on their social and economic conditions. In the context of trade restrictions, this is likely to be acceptable as long as restrictions are equally applied to all traders whether the goods and services in trade are created within the jurisdiction, or externally and exported into the jurisdiction. In national or more local regulatory contexts, it implies that regulators can be explicit in the standards that they adopt, and can deliver transparent and consistent decisions from case to case.

Based on the severity and probability of an undesirable outcome being expressed, an explicit table for making decisions can be constructed that illustrates the acceptable level of risk for a jurisdiction. Such a table (*for example*, Table 3.III) could be used to assist resource managers to decide if a licence should be issued (Accept) to operate a farm in a certain location or not (Reject).

This table uses severity and probability to derive consistent and transparent decisions. However, the table does not take account of uncertainty associated with the assigned probabilities. An assessment of a probability as being associated with high uncertainty indicates that the true expression of the risk may differ from the assigned assessment. For example, a risk assessed as of low probability with a high degree of uncertainty may actually be of extremely low or moderate probability. The precautionary principle indicates that such uncertainty should be taken into account in the assessment and decision-making processes. This can be accommodated within the structure described here by considering that if the probability is associated with a high degree of uncertainty, then this should be considered as equivalent to an assessment of a higher probability of occurrence. The decision table above is then modified as shown below (Table 3.IV), which indicates in bold where a higher degree of uncertainty would result in a change of decision from ‘accept’ to ‘reject’.

Risk analysis does not overcome all the shortfalls in the definition and application of the precautionary principle, but it does make the inherent assumptions and value judgments much clearer and explicit. If, however, definitions and the expression of what constitutes an acceptable level of protection are not well made, and made in advance of the assessment, the uncertainties and misuse associated with the use of the precautionary principle also become a threat to the objectivity attainable through risk analysis.

The ultimate purpose of risk analysis is to provide structured and assessed information to underpin a management decision, for example, as to whether or not to permit a particular activity to

Figure 3.1 : The four components of risk analysis and use of levels of protection (L.O.P.) (after OIE 2003).

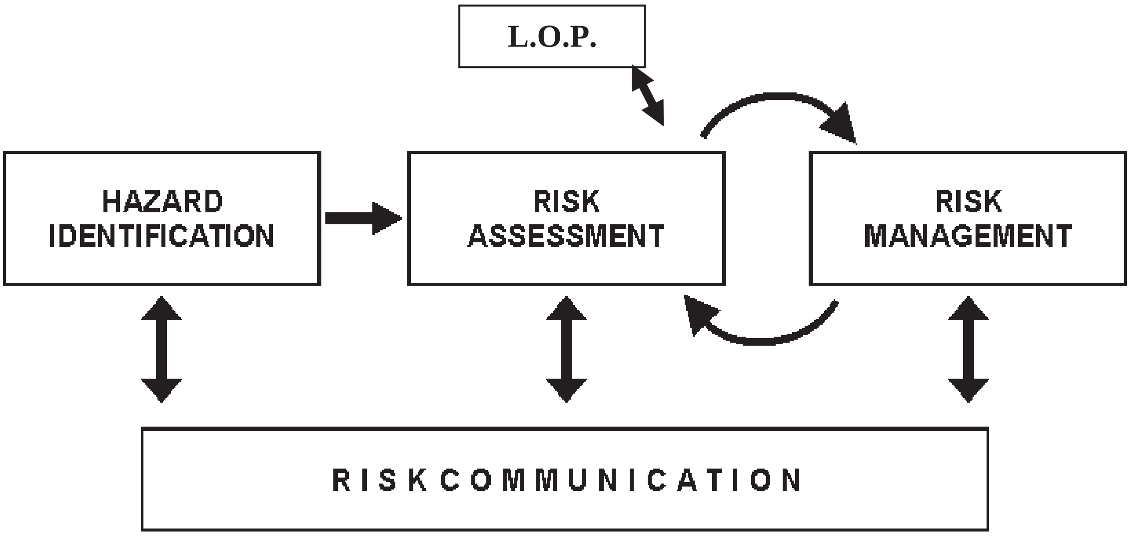


Figure 3.2 : The elements of risk assessment.

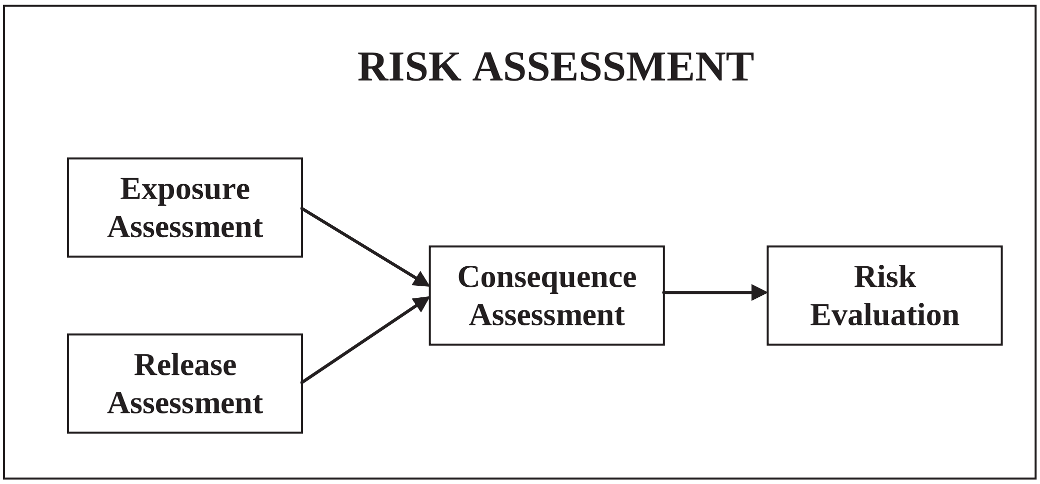


Table 3.1 : Classification of the severity of environmental change. The term 'ecosystems' refers here to water bodies of such size that water quality processes occuring in them largely function independently of the processes in adjoining water bodies. For example, a bay or estuary with relatively short water residence time would not be considered an ecosystem. In contrast, a fjord of an inland sea with a more protracted residence time might be considered an ecosystem for the purposes of these definitions.

Catastrophic:	- irreversible change to ecosystems performance at the faunal-province level or - the extinction of a species or rare habitat.
High:	- high mortality for an affected species or significant changes in the function of an ecosystem. - effects would be expected to occur at the level of a single coastal or oceanic water body. - effects would be felt for a prolonged period after the culture activities stop (greater than the period during which the new species was cultured or three generations of the wild species, whichever is the lesser time period). - changes would not be amenable to control or mitigation.
Moderate:	- changes in ecosystem performance or species performance at a regional or subpopulation level, but they would not be expected to affect whole ecosystems. - changes associated with these risks would be reversible. - change that has a moderately protracted consequence. - changes may be amenable to control or mitigation at a significant cost or their effects may be temporary.
Low:	- changes are expected to affect the environment and species at a local level but would be expected to have a negligible effect at the regional or ecosystem level. - changes that would be amenable to control or mitigation. - effects would be of a temporary nature.
Negligible:	- changes expected to be localised to the production site and to be of a transitory nature. - changes are readily amenable to control or mitigation.

Table 3.II : Definition of assignable qualitative probabilities.

High:	The risk is very likely to occur.
Moderate:	The risk is quite likely to be expressed.
Low:	In most cases, the risk will not be expressed.
Extremely Low:	The risk is likely to be expressed only rarely.
Negligible:	The probability of the risk being expressed is so small that it can be ignored in practical terms

Table 3.III : An example of a table defining the acceptable level of protection

Severity

	C	H	M	L	N
H	Reject	Reject	Reject	**Accept**	Accept
M	Reject	Reject	**Accept**	Accept	Accept
L	Reject	**Accept**	Accept	Accept	Accept
EL	**Accept**	Accept	Accept	Accept	Accept
N	Accept	Accept	Accept	Accept	Accept

Severity = C - Catastrophic, H - high, M - Moderate, L - Low, N - Negligible
Probability = H - High, M - moderate, L - Low, EL - Extremely Low, N - Negligible
Reject = Reject a request for a permit to undertake culture
Accept = Accept the risks associated with permitting the culture to be undertaken

Table 3.IV : Table 3.III adjusted to allow for uncertainty in the probability of change

Severity

	C	H	M	L	N
H	Reject	Reject	Reject	**Reject**	Accept
M	Reject	Reject	**Reject**	Accept	Accept
L	Reject	**Reject**	Accept	Accept	Accept
EL	**Reject**	Accept	Accept	Accept	Accept
N	Accept	Accept	Accept	Accept	Accept

take place. To be able to implement risk analysis effectively and achieve a desired level of protection against an undesired outcome, it is essential that the terminology used is defined and that, prior to the analysis, there is a clear statement of what would constitute an acceptable level of protection from the outcomes of the hazard(s) being examined. If this framework is established at the outset, these attributes determine the nature of the resultant management decisions and actions. Failure to do so potentially compromises the transparency and freedom from bias that can be achieved through the risk analysis process.

3.2.2 The logic model

As indicated above, risk analysis is built around the concept of the release of a hazard that could lead to an undesirable change in the environment. The processes and conditions by which the hazard can result in the undesirable outcome or endpoint should be linked together in a series of sequential steps, forming a logic model for the combination of hazard and endpoint being analysed. This logic model can be written down as a series of steps, and it is usually very helpful to draw the logic model as a flow diagram, distinguishing between inputs of information, processes, decision points, etc., to ensure that the all parties to the discussion have a sound and consistent basis on which to build the risk analysis.

3.2.3 Severity of effects

To continue the example of a hazard arising from the release of particulate organic waste, the degree of smothering of the benthos or alteration of the seabed can differ from site to site, depending on a wide range of factors. It is important that we can describe the severity of this effect. Terms used in the Australian Import Risk Analysis on Non-Viable Salmonids and Non-Salmonid Marine Finfish (AQUIS 1999) are used here to provide a template for these definitions. In that analysis, there are five categories or levels of severity. The definition of each level of severity is determined by three factors:

- The degree of change experienced in the affected ecosystem or species;
- The geographical extent of the change; and
- The temporal duration of the change (from transient to irreversible).

Attributes of the potential change are often characterised by more than one severity class. The overall severity is expressed as the average of the severity categories. For example, if the predicted effect is high mortality of a subpopulation of a species that would be reversed over a couple of generations then,

- High mortality of a species is an attribute associated HIGH severity.
- As only a subpopulation is affected the level is MEDIUM severity.
- The anticipated duration of a couple of generation is a MEDIUM severity characteristic.

The final assessment of the severity of the change would therefore be the ‘average’ of HIGH+MEDIUM+MEDIUM, for example, MEDIUM.

3.2.4 The probability of outcomes

The assignment of probabilities to particular specific outcomes is a critical part of the risk analysis process. In some cases, a fully quantified approach can be taken but, in most cases, knowledge of the probabilities associated with each of the steps between the initial driver and the final expression of the undesirable effect will not be available. Generally, it will be necessary to adopt semi-quantified or qualitative approaches to estimation of the probability. Previous experience, scientific knowledge, and expert judgment, will be the important factors in assessing the probability of the specific undesirable outcome being expressed. However, there will inevitably be a degree of imprecision and uncertainty in the final assigned probability. For example, monitoring data and modelling indicate that the probability of change due to enrichment of the seabed below fish culture units in Scotland is high, but the same degree of change for the same rate of organic carbon release from fish cages in oligotrophic areas of the Aegean Sea may be less probable i.e. moderate to low probability (Cromey *et al.* 2002).

Expression of the probability of a risk being expressed can be achieved in a number of ways. These may be expressed precisely in numerical form or more qualitatively. As numerical quantification is seldom available, the definitions below (Table 3.II) are of a more qualitative nature. The number of categories used to describe severity and probability of a risk may vary. There is nothing dictating that it should be five; it could be more or less. The greater the number used, the more difficult it will be to attribute clearly any particular risk to a specific category. The fewer the number, the more extreme the final evaluation is likely to be.

3.2.5 Uncertainty in estimates of probability

The assignment of qualitative probabilities to particular outcomes or steps in a logic model inevitably involves elements of expert judgement. We do not have the high level of knowledge that is required before we can have a correspondingly high level of accuracy and certainty in estimates of probability. In making predictions, there are two broad sources of error; imprecision and uncertainty. Imprecision is our inability to measure exactly some input or output or relational coefficient. Uncertainty derives from an incomplete understanding of the forcing factors and mechanisms that determine the consequence of a development. That does not mean that all potential sources of inputs or mechanisms need to be known, but account needs to be taken of all the major ones. Many environmental processes are influenced by a great number of factors. However, significant change in the system is usually determined by a much smaller subset of these factors.

For example, we know that there are many potential sources of mortality that affect fish in a wild population. These could include fishing mortality, human destruction of habitat, disease, predation and competition for scarce resources by other species, and others. Within certain limits, and for short term predictions, one or a limited number of these sources of mortality dominate in determining the abundance of the species. Worldwide fishery harvest levels have been set on that basis, with scientists constantly trying to improve their ability to quantify the abundance of stocks and improve their ability to determine more precisely the coefficient describing the relationship between the spawning stock size and composition and the abundance of fish that will ultimately be harvested. That typifies an approach in response to a problem of errors due to imprecision.

Recently it has become clearer that our models to predict the abundance of fish in some populations are missing critical components. Over longer periods, survivorship seems to vary independent of fishing pressure. Work of oceanographers and biologist to resolve the sources of this error have revealed that sudden changes in ocean regimes that typically occur every decade or so can have a greater effect than fishing on the survival of some species (Beamish *et al.* 2004 a, b, c). Other work (*for example*, Frank *et al.* 2005) has shown that excessive harvesting of top predators from an ecosystem can radically affect ecosystem dynamics causing harvest species to experience an entirely new survivorship dynamic. Errors in our prediction of recruitment due to this lack of knowledge of the mechanism giving rise to the change should be attributed then to uncertainty (completeness of our predictive models).

In the context of risk analysis, qualitative (or sometimes quantitative) models are used to estimate the probability of an event occurring. The expert judgments commonly required to express the probabilities come with an inherent degree of underlying confidence or reliability, and this is the origin of the uncertainty in the predictions. High confidence equates to low uncertainty, whereas high uncertainty implies that the experts have low confidence in their estimates of probability.

It is through the adjustment of decisions in relation to the uncertainty that the precautionary principle is implemented in risk analysis.

3.3 Risk Communication

As noted earlier, Risk Communication is the most pervasive and important component of risk analysis. It is central to the preparation for a risk analysis. It should be a clear and strategic activity during the risk analysis and in working out the conclusions from the analysis. In some some instances, such as the implementation of reporting on monitoring results, it can be a part of the follow-up after completion of the analysis. Risk communication has a number of potential audiences including:

- The individual who has information that can be incorporated in the analysis of risk;
- The individual trying to incorporate the outcome of the risk analysis in their personal view of risks;
- Technical peers who will evaluate and contribute to a risk analysis exercise. (Peer-review of risk analyses is an essential component of risk communication. It ensures the best information is incorporated in the analysis and acts as a quality control function for the final product.);
- The resource manager who may incorporate the results of analysis in his decision making; and,
- The public who define what is an acceptable risk and translate that, via political processes, to the manager who makes resource decisions.

Each of these audiences deal with information differently and their best use of information requires that the information is packaged in the manner that they can best use it. As can be imagined, with such a variety of audiences and needs, risk communication is a complex and challenging task. Chapter 5 addresses this topic. At this point, suffice it to say that the pervasiveness of risk communication in any risk analysis requires a good risk communication strategy to be in place at the start of each risk analysis exercise.

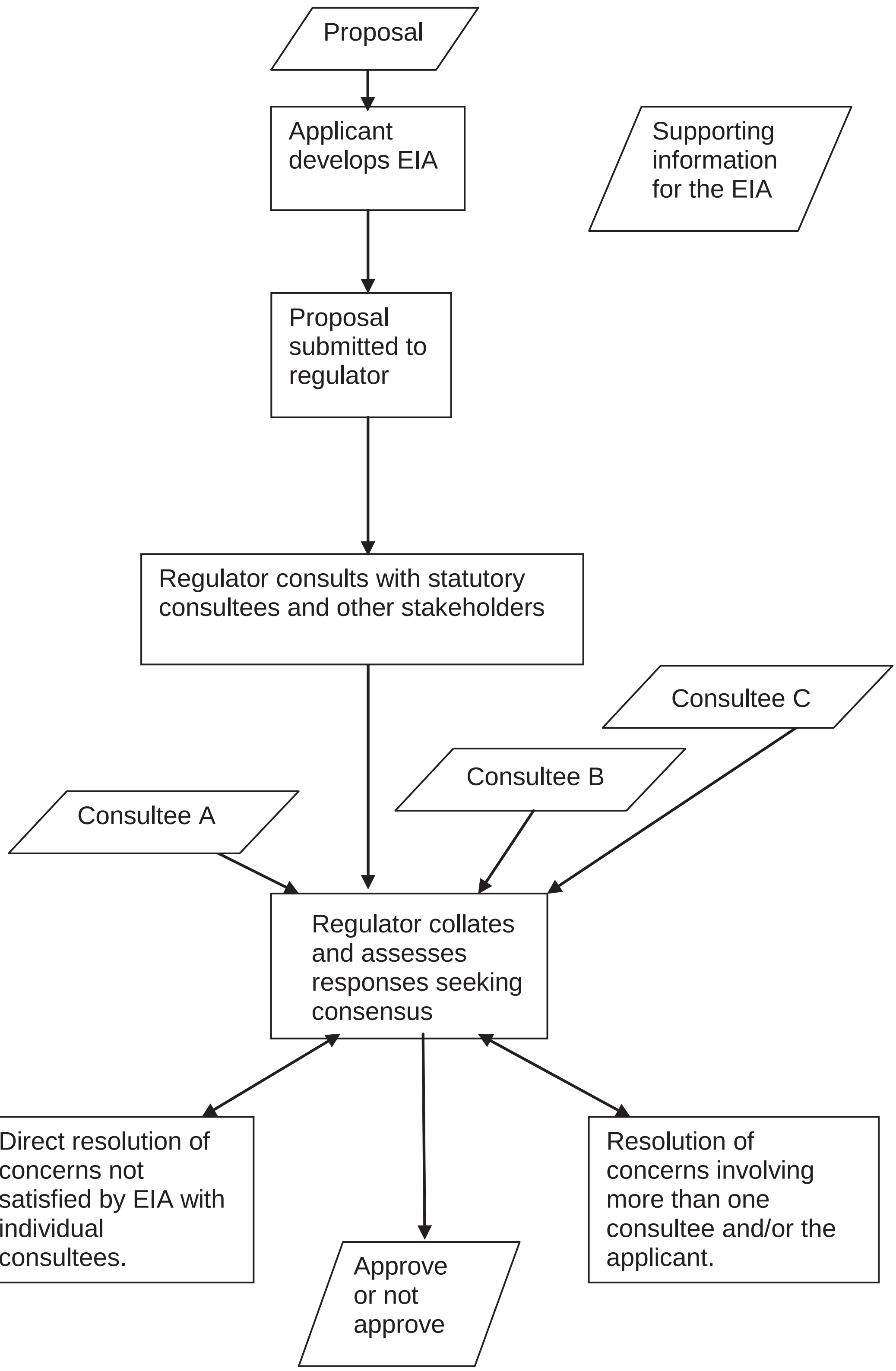
3.4 How can risk analysis contribute to the decision-making process and sustainable development?

3.4.1 *Interaction of Risk Analysis with existing decision-making processes*

The theoretical discussion above presents risk analysis in isolation from existing decision-making processes. In practice, the true potential contribution available through risk analysis will be achieved through integration with existing processes, rather than in competition with them. These processes operate at a wide range of scales. At the smallest scale, Environmental Impact Assessment and the preparation of Environmental Impact Statements are commonly applied at the scale of the single aquaculture unit. The decisions made will therefore refer to a single development proposal, often in isolation from other similar proposals or from other activities taking place in the coastal zone.

On larger scales, integrated coastal management seeks to find the optimum mix of activities in coastal areas, taking account of the full range of existing and

Figure 3.3 : Flow diagram of a regulatory process involving an initital proposal, consultation, and final approval.



potential activities and stakeholders. On a still larger scale, strategic EIA can address the regional potential for particular developments, for example, the potential scale of use of a coastal sea area for the generation of renewable energy.

Risk analysis can be integrated into processes at all these scales. The key initial step is the recognition of the range of hazards involved and the potential undesirable endpoints. At that point, the consequent cause for concern can be expressed in terms that are consistent with the principles of risk analysis.

As an example, Figure 3.3 illustrates typical steps in the process by which a relatively small-scale proposal is ultimately approved or rejected by a regulator. A typical proposal might be for the creation of a new aquaculture site in the coastal zone. The main stages in the process are:

1. The initial formulation of an outline proposal by an aquaculture enterprise. Generally this part of the process will be the responsibility of the applicant and will include a wide range of considerations, including social and economic factors that are outside the scope of this document. It is recognised that EIAs can be prohibitively costly for very small or artisanal developments. Sometimes governments will undertake a group or class assessment based addressing a common practice (for example, British Columbia Environmental Assessment Act, 2002) and requiring applicants to identify how their proposal differs from the 'standard' practice, and what the implications of those differences would be.

2. In order to develop the proposal to a stage where it can be submitted to a regulator that include environmental factors in their consideration, the proposal will commonly need to be developed to include an Environmental Impact Assessment or similar document. This will require the input of information from external sources.

3. The combined proposal and EIA will then be submitted to the regulator for a decision as to whether the proposal will be approved or not.

4. The regulator will then undertake a consultation exercise involving statutory and non-statutory consultees. Each of these will consider the proposal and the information supplied in the EIA in relation to their own sectoral interests and responsibilities and comment to the regulator as to whether their concerns have been adequately discussed and satisfied.

5. In most cases, some concerns will not have been satisfied at that stage, and it will be necessary for the regulator to engage in bilateral or multilateral discussions aimed at resolving outstanding issues.

6. Once this process has been concluded, the regulator will make their decision.

Risk analysis is not explicitly included in the diagram (Figure 3.3) and it is therefore necessary to consider its potential role in the regulatory process. Clearly, the formal structure of a risk analysis can be a useful framework for the resolution processes described at point 5 above. However, for this to be effective, it would be necessary for the information relevant to the concern being addressed to be presented in the form of a risk analysis. The regulator is unlikely to be in a position to undertake major reformatting or analysis of information at either this stage of the decision process, or prior to their consultation after they receive the application. Therefore, the risk analysis format needs to be established and used in the documents supporting the application, for example, in the EIA document.

Guidance on the content of EIAs for fish farm development is available. The guidance normally lists the primary areas of interest of the relevant regulators, i.e. ensures that information is available for assessment against relevant legislation. Guidance, by necessity, tends to be general rather than specific to each proposal. For example, the guidance will indicate that information is required on interactions with protected areas designated for conservation reasons, rather than listing in detail the conservation designations present throughout the possible development area.

In developing the scope for an EIA, applicants therefore need to consider both the general guidance on EIA content, and also make contact with relevant stakeholders and agencies to ensure that they become aware of the specific concerns in the area of the proposed development, and that these are subsequently covered by the EIA document. It is at this stage that the formal risk assessment structure can be introduced, as a process for clarifying the concerns raised, and the hazards and processes involved. Risk assessment is therefore best introduced into this regulatory/approval process as early as possible, i.e. during the scoping and drafting of the EIA document. These actions are the responsibility of the applicant, and therefore it is for the applicant to instigate the use of risk assessment. Regulators (and consultees) can assist by promoting the use of risk assessment in scoping of EIAs.

The example discussed above is structured round a relatively small-scale proposal and hence is addressed through EIA and similar procedures, which are applicable at the individual project level. It has become recognised that such approaches have limitations when dealing with larger scale issues, and consequently Strategic Environmental Assessment (SEA) procedures have been developed as an assessment tool for establishing the suitability or scale of undertaking of a particular plan or programme. The purpose of SEA is to ensure that significant environmental effects arising from policies, plans and programmes are identified, assessed, mitigated, communicated to decision-makers, monitored, and that opportunities for public involvement are provided.

The United Kingdom Department of Trade and Industry describes the SEA as a process that "i*dentifies those areas of environmental concern that may not be obvious by the consideration of impacts resulting from individual projects or operations in isolation*". For example, the undertaking of an SEA of energy policy would facilitate the consideration of continued exploitation of non-renewable mineral resources against the climatic impacts of burning fossil fuels and the development of renewable energy sources. SEA potentially:

- Encourages consideration of environmental and social objectives at all levels, including those of policy development, plans/programmes and specific project objectives;
- Allows effective analysis of cumulative effects and facilitates consideration of synergistic impacts, which are likely to be overlooked or beyond the scope of individual project EIAs;
- Facilitates consultation between various government bodies and stakeholders, and enhances public involvement in the evaluation of environmental and social aspects of policies, plans and projects;
- Encourages consideration of alternatives that are neither obvious nor practical at the project EIA stage.

Perhaps most importantly, in facilitating spatial planning decisions, SEA helps to determine appropriate and inappropriate sites for projects. Individual EIAs may subsequently be undertaken for projects undertaken in areas considered suitable for development.

The considerations undertaken in the SEA process need not necessarily be limited to environmental issues, as the impacts of polices, programmes and plans upon society are also being viewed with considerable concern. The SEA process can also be used to assess the overarching impact a particular policy, plan or programmes might have upon such socioeconomic factors as:

- Population demographic and distribution;
- Economic conditions;
- Employment;
- Cultural values and assets;
- Overall quality of life;
- Social structure; and
- Societal resources.

Through consultation undertaken with communities and interested parties as part of the SEA process, it is possible to identify the:

- Issues
- Needs
- Concerns
- Values
- Ideas

of those communities and sections of society that may be influenced by a particular policy, plan or programme, and integrate these with identified areas of environmental concern.

The SEA concept therefore contains both the environmental science aspects of large scale proposals, matters of policy and principle often on national scales, but also the concerns and needs of those parts of the national community who either may be directly affected by the proposals, or who have an interest in the proposals from other points of view, for example, their values and perceptions of quality of life.

The Risk Analysis process is structured round the formulation and analysis of logic models leading from hazards to undesirable endpoints. In developing these models, and defining the endpoints, many similar aspects of public opinion and sectoral interests/feelings come into play. Aspects of the perception of risk and consequent responses to it are discussed in Chapter 5 on risk communication, where the need to take into account, and benefit from, both the technical, formal approach to risk and the more subjective factors involved in risk feelings is discussed. In summary, the Risk Analysis process is well suited to application in SEAs, as the scale and complexity of the issues involved are not defined at the outset of the process, but can develop and grow as greater integration is achieved of the inputs and concerns of all interested parties.

3.4.2 Risk analysis and sustainable development

Broader considerations of the sustainability of development require that we match human social and economic goals to the ever-changing natural dynamics of our environment and our interactions with that environment. From our experience with traditional fisheries such as salmon and cod, we are now aware that both natural and human forces can induce rapid quantum shifts in the structure and dynamics of marine ecosystems (Beamish *et al.* 2004 a,b,c; Frank *et al.* 2005). The social expectations and values that provide the backdrop to resource management are also subject to change and variation at the international, national and regional level. Various political processes exist to deal with issues around issues of social values and expectations, and these are outside the scope of this document. Similarly change and evolution of economic systems and expectation are also outside the present exercise. While social and economic issues are not dealt with directly herein, it has to be acknowledged that effective tools for managing sustainable resource use for aquaculture must fit in a decision-making context that integrates social, economic and environmental information.

Allocation of natural resources begins when a proponent (either in the private sector or government) requests some sort of licence, permit or exclusive right to use a resource (#1 in Figure 3.4). Although it some circumstances it may just be a formality to get access to the natural resource in a legitimate way, the very act of requesting a permit is normally an acknowledgement that there is some form of existing or potential future competition for the use of that resource.

Resource managers must then consider what they understand of the social values and expectation they are expected to support (#2a in Figure 3.4) and integrate that with the level of use of that resource which can be maintained on an ongoing basis (#2b in Figure 3.4) plus the probable stream of economic benefits that society is likely to gain from this use as opposed to some other use of the same resource (#2c in Figure 3.4). These factors; social, economic and environmental, define the array of uses within the Sustainable Uses of Resources Envelope (S.U.R.E). Planning exercises can be very useful to the resource manager in that they generally try to integrate some of the social and environmental aspects, but can have difficulty in accurately predicting the sequence and timing of multi-use demand for a resource, especially those used by the private sector, and subject to economic forces. The task is further complicated when the manager must decide on the allocation of the next unit of the available recourse. In addition to not knowing what types of resource use might be proposed in future, the manager is also faced with limited ability to predict accurately the outcome of interactions between aquaculture and the environment.

Risk analysis is a particularly attractive tool for helping to decide the allocation of environmental goods and services, in that it can deal explicitly with errors associated with predicting the environmental sustainability of allocating the next portion of the inventory of resources in an area. It also identifies explicitly how social values and expectations influence decision-making for the allocation of environmental goods and services. Risk analysis does this through an explicit statement of what constitutes an acceptable level of protection for the resource. When rigorously implemented, risk analysis can also help identify knowledge gaps and research topics that would most effectively reduce uncertainty associated with our predictions of environmental change.

3.5 The advantages of Risk Analysis over other decision-support frameworks

As previously noted, the purpose of this document is to advocate the adoption of Risk Analysis procedures in assessment and communication of the risks of environmental change arising from coastal aquaculture developments. Existing relevant frameworks relating to risks and environmental change include Environmental Impact Assessment (EIA), Environmental Risk Assessment (ERA). Broader techniques for decision-making drawing on the outputs from such studies include Cost Benefit Analysis (CBA) and Multi-criteria Decision Analysis (MCDA). One of the main objectives of this document is to show how the precautionary approach can be incorporated into decision-making in areas where levels of uncertainty can be high. A precondition for consistent application of the precautionary principle is that there is some standard procedure, framework or checklist for the undertaking the assessment, the characterisation of associated risks and uncertainties, and their communication. The question therefore arises as to why risk analysis offers improvements over these other procedures.

3.5.1 Environmental Impact Assessment (EIA)

EIA is:

"*the systematic, reproducible and interdisciplinary identification, prediction and evaluation, mitigation and management of impacts from a proposed development and its reasonable alternatives.*" (UNEP, 1996)

Guidelines for the application of EIAs to coastal aquaculture have recently been developed (Barg 1992; Hambrey *et al.* 2000; GESAMP 2001, 1997, 1996, 1991) building on widely accepted general frameworks for EIA. It is inappropriate to review the whole process here, but it is informative to examine the conventions for addressing the nature of environmental impacts and associated risks.

Impact identification in EIA is typically based on the use of checklists, matrices, networks and overlays, including Geographical Information Systems. Environmental specialists in consultation with industry specialists normally formulate these tools. The main types of impact considered include:

- Effects on human health, well-being, environmental media, ecosystems and agriculture;
- Effects on climate and the atmosphere;
- Use of natural resources (regenerative and mineral);
- Use and disposal of residues and wastes; and
- Resettlement, archaeological sites, landscape, monuments and social consequences, as well as upstream, downstream and trans-boundary effects.

Identified impacts are then analysed in three stages:

- Characterisation;
- Quantification and prediction; and
- Assigning significance.

Impact characteristics are described in terms of:

- Nature (positive, negative, direct, indirect, cumulative, synergistic with others);
- Magnitude;
- Extent/location (area/volume covered, distribution; local, regional, global effect);
- Timing (during construction, operation, decom-

Figure 3.4 : A schematic of the decision-making environment for competitive allocation of resources. The numbers and acronym are explained in the text above.

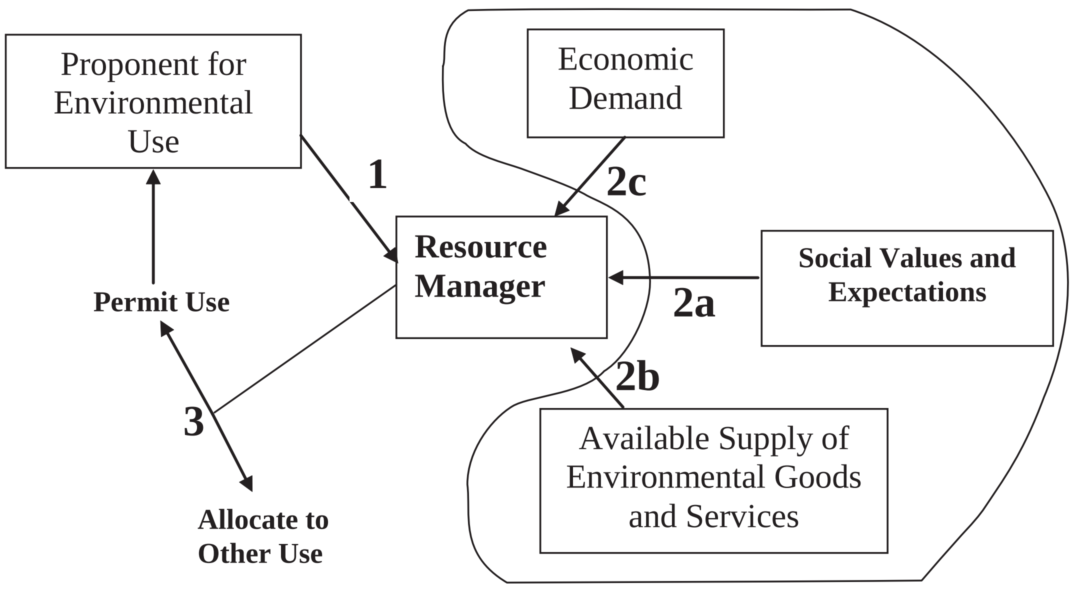
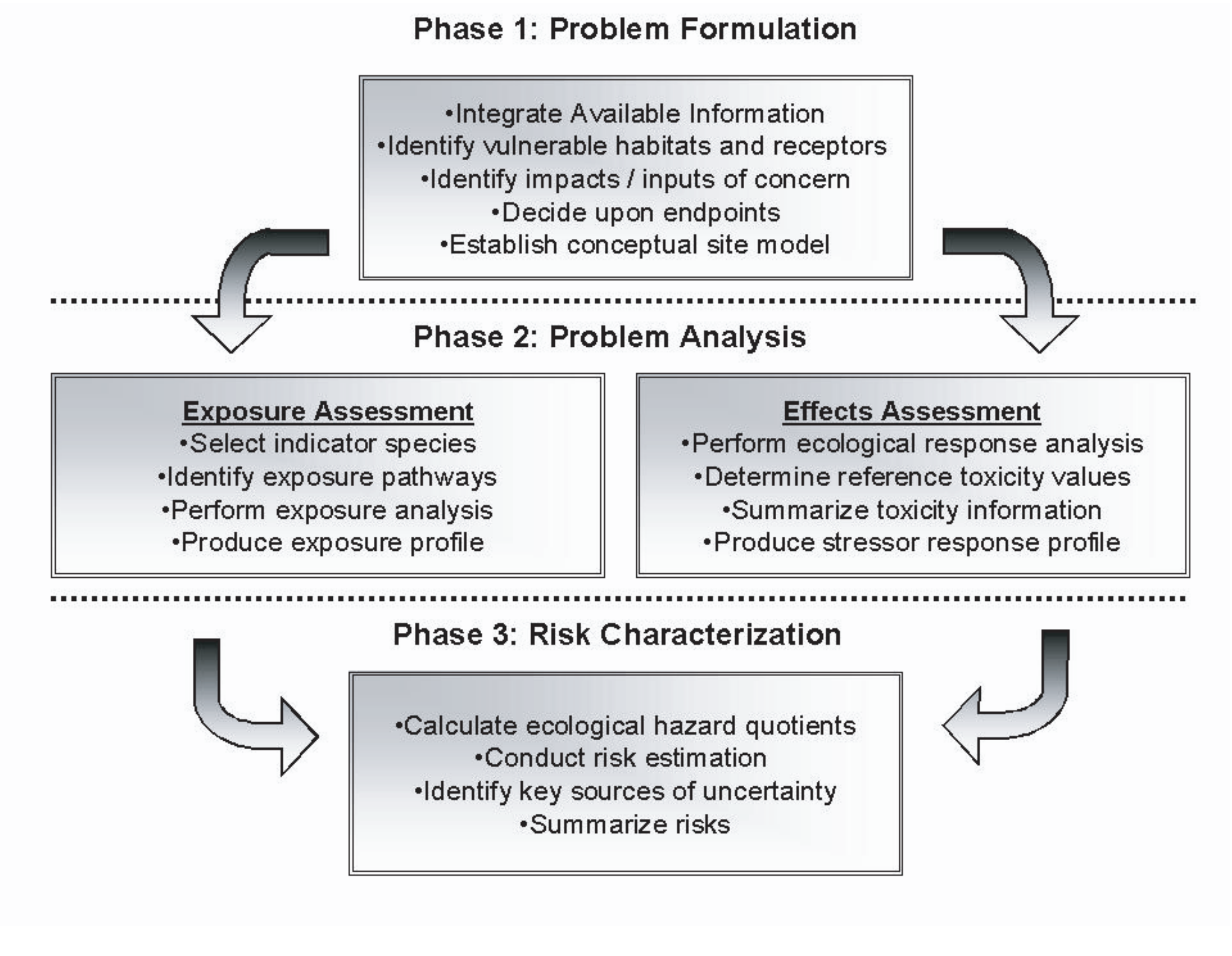


Figure 3.5 : Schematic representation of the ERA process adapted from Asante-Duah (1998).



missioning, immediate, delayed, rate of change);

- Duration (short term, long term, intermittent, continuous);
- Reversibility/irreversibility; and
- Likelihood (risk, uncertainty or confidence in the prediction).

In practice, several of these, and particularly the last, overlap with quantification and prediction and are explored in parallel.

Impact prediction draws on a variety of methods including:

- Professional judgement;
- Quantitative mathematical models;
- Experiments, physical models; and
- Case studies.

In all cases, there will be some degree of uncertainty associated with the predictions or extrapolations, and this must be described, measured if possible, and taken into account in assigning significance.

Assigning significance is a largely subjective process, drawing on a synthesis of the above analysis. Logically, significance can only be described in relative terms, and some agreed standard or baseline (based on science, instinct policy or precedence) is required if it is to have any meaning, utility, or consistency. In practice, such a baseline is often absent, and the assessment of significance depends on the knowledge, values and analytical ability of the EIA practitioner, or in some unfortunate cases, the company commissioning the EIA. In order to minimise the chances of bias, the analysis must be presented clearly and simply, and independently reviewed. This is a major challenge when dealing with complex and, in some cases, hypothetical environmental impacts.

Does EIA tend to under-play uncertainty?

It is argued that, in the past, many EIAs have been weak on characterising impacts in terms of their likelihood, and in terms of the uncertainty associated with the predictions. As noted elsewhere, there is typically very high and often unquantifiable uncertainty associated with many environmental and ecological impacts. In practice, it is probable that the true level of uncertainty is rarely emphasised in EIAs for professional reasons. EIA specialists are paid well to make impact predictions. Few developers or decision-makers want to hear a series of “don’t knows” from the experts.

Against this weakness should be set the clear precautionary requirement in best practice EIA. This requires the process to generate an environmental management plan, which, in addition to putting in place measures to minimise possible impacts, also prescribes a monitoring regime and response procedures in respect of possible, but uncertain impacts.

It is clear that more attention needs to be paid to risk and uncertainty within the EIA process. A formal framework for risk assessment is already in wide use – environmental (ecological) risk assessment or ERA. It is arguable that ERA should be an explicit and significant component in EIA.

Other weaknesses

EIA is normally undertaken at farm level, and therefore cannot effectively address cumulative and wider environmental issues, such as nutrient enrichment and interactions with wild species. These need to be addressed at a higher strategic level. While this has been recognised for many years, and strategic, regional or sector level environmental assessment have been recommended, this is rarely undertaken in practice.

3.5.2 Environmental Risk Assessment (ERA)

Environmental Risk Assessment, or Ecological Risk Assessment, is a process for evaluating the likelihood of adverse environmental or ecological effects occurring as a result of one or more environmental stressors, usually of anthropogenic origin (Asante-Duah 1998; Benjamin and Belluck 2001). All available data are collated and, where necessary, more data are assembled to help predict the relationship between stressors and environmental or ecological effects. To date, the process has been applied mainly to the examination of the effects of specific chemicals on soils, aquatic systems and atmospheric systems. It may form a part of an EIA or be undertaken separately in respect of specific chemicals.

The ERA process can be divided into three phases: problem formulation, problem analysis and risk characterisation. The problem analysis stage can be further sub-divided into two distinct sections: characterisation of exposure and characterisation of effect. This means, at least for descriptive purposes, that the risk assessment process has four fundamental elements as illustrated in Figure 3.5.

In spite of this description of the process, the assessment should be iterative. Information that is obtained at a later stage in the process may force a reassessment of an earlier step. In particular, discoveries during the analysis stage may encourage a shift in emphasis in the originally determined endpoints. Rather than being considered a failure of initial planning, this constant reassessment enables environmental risk assessment to be a dynamic process well suited to ecological studies.

A key factor in environmental risk management is determining the scale and nature of potential effects. Although considering all relevant stressors and variables may complicate the process, add increased uncertainty and potentially reduce the confidence in the findings, it adds greatly to the ability of the process to consider and predict for a wide variety of permutations.

Undesirable effects ideally assessed by combining the estimation of exposure with information on the dose-response characteristics (with confidence limits) of key indicator species. The data to generate such curves may be collected experimentally or derived from field survey (ideally both). This then allows for the calculation of a key indicator of negative effects and risk: the hazard quotient or ecological risk quotient. This is calculated as the exposure point concentration, or estimated daily dose, divided by critical ecotoxicity (Asante-Duah 1998).

Determining the nature of unwanted effects can be complicated, as detrimental effects to one aspect of the ecosystem may be beneficial to others. A key attribute of environmental effects to be avoided are those resulting in changes which alter important structural or functional aspects of the ecosystem. The scale, intensity and duration of the impact along with the ecosystem's ability to recover will also be incorporated into the adversity calculation. A well-designed Environmental Risk Assessment should also able to highlight beneficial changes in the ecosystem brought about by anthropogenic interaction.

Environmental Risk Assessments can be sufficiently robust to interpret future potential risks in historically heavily impacted ecosystems. The process can be used as both a prospective and retrospective tool. This enables risk managers to look at likely causal factors of observed effects as well as predicting the outcome of future actions. This aspect is particularly valuable in the natural world where it is almost impossible to begin with a 'fresh canvas' with no prior external impacts. The flexibility of the tool also enables consideration of the chronic and catastrophic effects.

It is widely acknowledged by ERA practitioners that many possible environmental effects cannot be assigned quantitative probabilities to comply with the objectivist ideal. The ERA process therefore allows for qualitative description, which should be highlighted in the conclusion. It has even been argued that the strength of an ERA does not lie in its predominantly objective stance, but instead in the way it treats subjective inputs (Hayes 1998).

The rise in interest in all kinds of risk assessment over recent years is primarily due to its role in informing decision-making. It is particularly useful where there are substantial variables or uncertainties. Cynics, and in particular many environmental groupings, argue that the risk assessment process provides an element of scientific credibility that disguises uncertainty and can be used to add weight to politically motivated decisions. While there is little doubt that the process can be abused, this in no way undermines its strength as a comprehensive framework for assessing effects, quantifying them as far as possible, and describing the risks, uncertainties and probabilities associated with them.

ERA is designed to provide decision-makers and risk managers with comprehensive information relating to the complex consequences of actions in advance of any changes, and the trade-offs between different courses of action.

Potential weaknesses in the ERA approach

Generally, the ERA has been structured to be initiated and applied by experts. It also uses a dose-response type of relationship to describe the interaction between the hazard and the endpoint. As described earlier in Chapter 2 and later in Chapter 5, the public does not formulate its personal valuation of risk in this manner. Consequently, this approach, when used in a participatory regulatory system, starts by expressing the analysis in a format that is more difficult for stakeholders to relate to. When this is done by experts in isolation rather than with the public as part of the formulation of the analysis, this further isolates the public, and leads to possible suggestions of bias in the way the problem is posed. In addition to the public perception of the process, the ERA dose-response model is a poor model for describing many biological systems, particularly where sequential biological interactions may be involved. The phenomenon of multiple thresholds, and rapid quantum shifts in the structure and dynamics of marine ecosystems are described in section 3.4.2.

3.5.3 Cost-Benefit Analysis (CBA)

CBA is a well established tool used in development decision making, principally in relation to large-scale government funded projects. The core of the CBA is the monetary valuation of the costs and benefits associated with a development, so that a benefit/cost ratio can be generated. The assumption is that a ratio greater than one suggests that the project is desirable.

The scope of CBA, in terms of the costs and benefits that it takes into account, is very variable. Increasingly, environmental costs and benefits are included, drawing on the tools associated with environmental economics.

In order to contribute to rational precautionary decision-making, CBA should build on EIA, risk assessment, and financial and economic analyses to provide information to decision-makers on the financial and economic trade-offs between different courses of action. This would allow them to compare these trade-offs with other values and with broader development strategy.

In practice, the emphasis is more usually placed on the generation of simple decision criteria (for example, benefit-cost ratio) to justify a particular course of action. This puts a large portion of the responsibility for the decision in the hands of those conducting the study, since it is typically they who make the subjective assessment of the values of uncertain or non-market costs and benefits. Again, the uncertainty associated with the monetary values generated is rarely emphasised. This uncertainty is typically very high, especially in relation to social and economic costs and benefits.

Cost-benefit analysis is rightly termed analysis rather than assessment, but in practice the criticisms that are levelled at ERA – that it disguises subjectivity in highly questionable numbers, and therefore tends to prejudge what are essentially subjective issues – are also valid. Issues relating to uncertainty need to be given far more emphasis and explained with clarity, so that they can be fully taken into account within an improved precautionary decision-making process.

3.5.4 International Commission on Radiological Protection (ICRP) Principles

Risk is a major issue for human health as it relates to environmental and food safety issues. Much work has been done in this area, and it is worth introducing three interactive concepts or principles used in protecting human health against ionizing radiation (ICRP 1997). These principles are relevant to any assessment and decision-making framework related to environmental risks. They have, for example, been applied to waste management (*see* GESAMP 1991b) :

1. 'Justification' states that no practice should be adopted by society unless it can be shown that the benefits outweigh the detrimental effects;

2. 'Optimisation' states that any 'exposures' (in a broad sense) should be kept as low as reasonably achievable;

3. 'Compliance' requires the setting of exposure limits (or standards) which should not be exceeded. There is no reason why similar concepts should not be applied to the development and management of coastal aquaculture (GESAMP has already applied it to waste management. (GESAMP 1991b).

Justification corresponds to thorough cost benefit analysis as described above. Optimisation is a universal common sense principle applicable to any activity. Compliance is a key element in any environmental management system. The principles however do not offer any guidance as to where or how to set precautionary limits (for example, with regard to compliance standards).

3.5.5 Multi-criteria decision analysis (MCDA)

This approach is specifically designed to explore trade-offs and consider development options against different criteria. It may also be used explicitly to take account of different perspectives relating to subjective issues, risk and uncertainty. It bridges the gap between analysis (which should be a routine technical process) and precautionary decision-making (which is subjective and political).

The core process of MCDA consists of:

1. Establish the decision context;

2. Identify the options to be appraised;

3. Agree objectives and associated criteria;

4. Score the performance of each option against the criteria;

5. Assign weights to each criterion to reflect their relative importance;

6. Combine weights and score to generate an overall value;

7. Examine and discuss the results and adjust as agreed.

MCDA can be undertaken in workshops involving representatives of different interests and technical specialists, or it can be undertaken using questionnaires sent to a representative sample of the population. Relatively sophisticated statistical techniques have been devised to generate weights and assign preferences.

It is used increasingly for environmental planning and management in different parts of the world, but generally on a small scale. For it to work in an informed way, however, it needs the kind of information generated by SEA, EIA, ERA, CBA, etc. to be effectively communicated to all those involved. It also needs to be brought within an agreed strategic framework if it is to generate consistent decisions.

MCDA and its variants have been widely described (UK-DTLR 2000; Rios 1994; Lootsma 1999).

3.5.6 Strengths and Weaknesses of these approaches

EIA and its variants, ERA, and CBA all address important dimensions of decision-making under conditions of uncertainty. They generate information on the nature of the trade-offs associated with development decisions. In some cases, however, they underplay uncertainty and introduce subjective valuation in a manner lacking transparency and accountability. In other words, they go beyond technical analysis into subjective assessment and "pre"-decision making. Since precaution is fundamentally subjective, this is a major weakness.

In order to be more effective, decision-support tools need to place far greater emphasis on risk and uncertainty, and greatly improve the inclusion, presentation and communication of information, so that the various risks and trade-offs can be fully appreciated by decision makers and all stakeholders.

In parallel with this, there is a need to incorporate precautionary approaches into decision-making and environmental management systems, which can also accommodate information on social and environmental effects, associated risks, and costs and benefits. This allows the subjective values associated with precaution to be introduced at a transparent and accountable stage of the process.

Since the emergence of risk assessment as a regulatory tool in the 1980s, the approaches to evaluating environmental risks have been evolving. One of the seminal approaches was put forward by the National Research Council (NRC) of the United States' National Academy of Sciences (NAS) (NAS-NRC) in 1983. This approach was taken up by a number of governmental agencies during the 1990s, including the US Environmental Protection Agency (EPA). Covello and Merkhoffer (1993) reviewed a number of the models (including the NAS-NRC model) in detail. Early applications of risk assessment were in human health, and toxicology. However, by 1992, the EPA (1992) had adapted NAS-NRC protocols for environmental risk assessment, which were designed to be applied to a wide variety of environmental hazards including toxic chemicals.

To date, the application of risk analysis to the environmental interactions of coastal aquaculture has received relatively little attention. In 2005, Nash *et al.* produced a valuable broad overview of many of the hazards and endpoints associated with coastal aquaculture. Nash *et al.* generally followed the EPA NAS-NRC model for risk assessment. Consequently, in many cases, they were not able give detailed guidance on how to link exposure assessment with the characterisation of environmental or ecological effects. This process is important in deriving estimates of the probability of the effect being realised, and of the uncertainty in that estimation. These factors, combined with the predicted severity of the effect are the essential components of the final risk assessment and statement. The report also made little reference to the process of risk communication, or to the affects of uncertainty on the outcome of the analysis.

In 1999, the International Council for the Exploration of the Sea's (ICES) Working Group on the Environmental Interactions of Mariculture started to report on the potential application of risk analysis to environmental interactions of mariculture, and in 2003 joined with a GESAMP initiative to provide guidance on this narrower application of the evaluation risks (Davies *et al.* 2004, 2005). After reviewing potential risk evaluation models, the decision was made to use the Covello-Merkhofer model. A number of attributes made this model more appropriate.

The NAS-NRC model subsumes hazard identification within a problem formulation step rather than as an altogether separate process necessary to justify undertaking a risk assessment. The EPA (1998) model analyses exposure and response in a fashion that is analogous the original dose-response to the NAS-NRC model from which it was derived, rather than clearly indicating the need to define the spatio-temporal relationship (a key component of the public's perception of risk) between the released hazard agent and exposed resource, as described in the Covello-Merkhofer model.

Finally, the sequence of steps in the Covello-Merkhofer model more closely follows the process for the development of effects in nature, in which the evaluation of release and exposure is logically necessary prior to the evaluation of consequences. This also ensures that situations can be identified early where exposure limits, or precludes, strong interactions and a decision can be made to terminate the analysis, and allow the resources required for such an analysis to be directed at more significant threats to the environment.

The Risk Analysis protocol described in this document meets all these requirements and can make a significant contribution to the rigour of debate, the reliability and traceability of development decisions and the receptiveness of the public to decisions based on this process.

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